

AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RELATED
AGENCIES APPROPRIATIONS FOR 2023

HEARINGS
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTEENTH CONGRESS
SECOND SESSION

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

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RE- LATED AGENCIES APPROPRIATIONS FOR 2023

TUESDAY, MARCH 29, 2022.

OVERSIGHT HEARING: OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF AGRICULTURE

WITNESSES

**HON. PHYLLIS K. FONG, INSPECTOR GENERAL, U.S. DEPARTMENT OF
AGRICULTURE**

**KEVIN TYRELL, ASSISTANT INSPECTOR GENERAL FOR INVESTIGA-
TIONS**

GIL HARDEN, ASSISTANT INSPECTOR GENERAL FOR AUDIT

ANN COFFEY, DEPUTY INSPECTOR GENERAL

**JENNY BANNER RONE, ASSISTANT INSPECTOR GENERAL, ANALYTICS
AND INNOVATION**

Mr. BISHOP. Good morning. This hearing will now come to order.

As this hearing is fully virtual, we must address a few house-keeping matters. For today's hearing, the chair or staff designated by the chair may mute participants' microphones when they are not under recognition for purposes of eliminating inadvertent background noise.

Members are responsible for muting and unmuting themselves. If I notice that you have not unmuted yourself, I will ask if you would like the staff to unmute you. If you indicate approval by nodding, staff will unmute your microphone.

I remind all members and witnesses that the five-minute clock still applies. If there is a technology issue, we will move to the next member until the issue has been resolved and you will retain the balance of your time.

You will notice a clock on your screen that will show how much time is remaining. At the one-minute remaining mark, the clock will turn yellow. At 30 seconds remaining, I will gently tap the gavel to remind members that their time is almost expired.

When your time has expired, the clock will turn red, and I will begin to recognize the next member.

In terms of speaking order, we will begin with the chair and ranking member. Then members present at the time of the hearing's call to order will be recognized in order of seniority.

Finally, members who are not present at the time that the hearing is called to order will be recognized in the order of arrival.

Finally, House rules require me to remind you that we have set up an email address to which members can send anything that they wish to submit in writing at any of our hearings or markups. That email address has been provided in advance to your staff.

That being said, I would like to welcome everyone to today's hearing, our first of this year.

Before we get underway, I would like to welcome Dr. Harris, as the subcommittee's acting ranking member, as well as to welcome the other members of the subcommittee.

Also, on a somber note, I would like to take a moment to acknowledge and remember our colleague, Representative Don Young, who passed away last week.

Representative Young was the longest serving member of the House, with 49 years of service. He was a strong advocate for the people of Alaska, a great public servant, a gentleman, and a friend.

We will miss him, and we extend our deepest condolences to his family.

I would ask at this time that we observe a moment of silence in honor of Representative Young.

[Pause.]

Mr. BISHOP. Thank you.

I would also like to welcome our witnesses this morning: Ms. Fong, Ms. Coffey, Mr. Harden, Ms. Rone and Ms. Rone—excuse me—Mr. Tyrell from USDA's Office of Inspector. Thank you for appearing before us this morning.

I especially want to express my appreciation of Inspector Fong for your dedicated service over the past eight months managing responsibilities for both USDA and the Federal Housing Finance Agency.

Since the budget was just transmitted yesterday, this hearing will focus more on the OIG's oversight of a wide-ranging department that touches the lives of every single American.

I am pleased to note that the fiscal year 2022 bill fully funded the President's request for the Office of Inspector General, which provided a very generous increase for your office. As I have stated in previous years, I have always been a big supporter of your office. Day in and day out, the OIG staff are truly the unsung heroes in the battle against waste, fraud, and abuse.

Your work through audits, investigations, and reviews helps protect the taxpayers' interest while improving the department's effectiveness and efficiency.

So like previous years, I would like to hear more about your plans to develop adequate oversight of USDA programs and the challenges you face in ensuring agreed upon recommendations are, in fact, implemented and complaints are appropriately addressed.

[The information follows:]

**Opening Statement of
Chairman Sanford D. Bishop, Jr.
Oversight Hearing
USDA Inspector General – Ms. Phyllis Fong
March 29, 2022**

I would like to welcome everyone to today's hearing, our first this year.

Before we get underway, I would like to welcome Dr. Harris as the Subcommittee's Acting Ranking Member, and other members on the Subcommittee.

I would also like to welcome our witnesses, Ms. Fong, Ms. Coffey, Mr. Harden, Ms. Rone, and Mr. Tyrrell, from USDA's Office of Inspector General. Thank you for appearing before us this morning. I especially want to express my appreciation for Inspector Fong for her dedicated service over the past eight months managing responsibilities at both USDA and the Federal Housing Finance Agency.

Since the budget was just transmitted yesterday, this hearing will focus more on OIG's oversight of a wide-ranging department that touches the lives of every American.

I am pleased to note that the final FY 2022 bill fully funded the President's request for OIG, which provided a very generous increase for your office.

As I stated in previous years, I have always been a big supporter of your office. Day in day out, OIG staff are truly the unsung heroes in the battle against waste, fraud, and abuse. Your work through audits, investigations, and reviews helps protect the taxpayers' interests while improving the Department's effectiveness and efficiency.

So, like previous years, I would like to hear more about your plans to conduct adequate oversight of USDA programs and the challenges you face in ensuring agreed-upon recommendations are implemented and complaints are appropriately addressed.

Mr. BISHOP. Now, let me invite our distinguished acting ranking member, Dr. Harris, if he has any opening remarks, and I would like to recognize him at this time.

Dr. Harris, the floor is yours.

Mr. HARRIS. Thank you, Chairman Bishop, and I appreciate your flexibility and everyone's willingness to begin today's hearing earlier so that members can attend the memorial service for Representative Don Young.

Ms. Fong, it is good to see you again, and I want to thank you and your staff for being with us today and for your being flexible with scheduling this morning as well.

We appreciate the critical work your agency is performing. Conducting audits, investigations, and other activities is challenging work even under normal circumstances.

However, over the past two years, programs have been set up or expanded in response to the pandemic, which has only made your work more important. According to the OIG's COVID Funding Dashboard, nearly \$172 billion has been provided to USDA just for pandemic activities, with 78 percent of the funds going toward nutrition programs.

I look forward to hearing more today about how your office monitors the programs and funding, especially when there are headlines like, quote, "FBI Sees Massive Fraud in Group's Food Programs for Needy Children," which was in the New York Times this month on March 9th.

With billions and billions of Federal dollars going out the door, it is very enticing for those who might want to defraud taxpayers. Your office, working with other Federal, State, and local partners, is critical to ensuring program integrity through your audit and investigative functions.

Your testimony also mentions the oversight your office will need to conduct, with respect to the nearly \$3 billion being provided for broadband loans and grants, and watershed and flood prevention operations in the Infrastructure Investment and Jobs Act.

I look forward to hearing what your budgetary needs might be in order to conduct that work.

As we continue to review the fiscal year 2023 budget materials, I remain concerned about the uncontrolled spending though that continues to drive up inflation. The administration continues to show a lack of regard for hard-earned taxpayer dollars in this regard, and we cannot keep adding to our nearly \$30 trillion national debt.

At USDA, we depend upon your agency to provide us with information as to whether the department is effectively implementing the various programs and appropriately using taxpayer dollars.

Again, I appreciate you being with us and look forward to today's hearing.

Mr. Chairman, I yield back.

Mr. BISHOP. Thank you, Dr. Harris.

I am not sure if the full committee chairwoman, Ms. DeLauro, is present. If she is, I would invite her to offer any opening statement she would like.

I know that she is quite busy and has another commitment immediately, and if Ms. DeLauro is not present, I would certainly in-

vite the full committee ranking member if she is present to have any opening remarks.

[No response.]

Mr. BISHOP. Not hearing from either of them, I would at this point like to recognize Ms. Fong.

Ms. Fong, I should let you know that without objection, your entire written testimony will be included in the record, and I will now recognize you for your statement.

And following that, we will proceed with questions.

Ms. Fong, the floor is yours.

Ms. FONG. Thank you, Mr. Chairman, and thank you, Acting Ranking Member Harris, and the distinguished members of the subcommittee.

We truly appreciate your very warm welcoming remarks today and your support of our mission. And we appreciate the invitation to appear to talk about our oversight activities.

And as, Mr. Chairman, you remarked earlier, we especially appreciate the expanded funding for us for fiscal year 2022 and the constructive dialogue that we have with members of the subcommittee all the time on ongoing issues.

As you know, you know our mission. We are here to help the department deliver its programs as effectively as possible, and ultimately you also know that we do not have the authority to implement our own recommendations. We depend on USDA officials to take necessary corrective actions.

For much of the past two years, we have been working in a maximum telework setting, and I have to say I am extremely proud of our dedicated staff. They have demonstrated flexibility and innovation. They have produced outstanding oversight work.

As you all know, we have issued 33 audit products this past year. We obtained 228 convictions in criminal matters, and we reported over 686 million in dollar results for fiscal year 2021, all of which demonstrate the dedication of our staff.

As we move forward in fiscal year 2022, we have a number of challenges in our oversight portfolio. We will continue to finish our work and start other work with respect to several major funding streams that some of you have alluded to. We are finishing our work on all of the disaster assistance programs that were funded in the wake of the hurricanes in 2017.

We have much ongoing work with respect to pandemic funds. Billions and billions of dollars went to the department for pandemic relief, and we have to provide appropriate oversight of that.

And as you also allude to, the infrastructure investment that Congress passed this past November, we do have oversight responsibilities for all of those programs as well. This is in addition to our normal portfolio of statutory mandates, of financial statement audits, improper payments, IT security, and other requirements, as well as our ongoing responsibilities to provide a level of oversight to all of USDA's programs and agencies.

So we believe that our hands are full, and to handle this increased workload we will need all the resources that you have appropriated for us in fiscal year 2022, as well as the increase that has been proposed in the President's fiscal year 2023 request.

We will also have to work smarter. On our own part, we are going to need to develop additional tools and approaches, and to that end we are looking to our data analytics staff as we hone our ability to understand data, develop new approaches and products, and identify potential areas for our audit and investigative work.

This is all in addition to our traditional tools of audit products, criminal investigations, and partnerships with other IG office as we identify and address trends and cross-cutting issues.

As you mentioned, my full statement is in the record. It describes many of the reports we issued last year. So I will just close, again, by thanking all of you and asking for your continued support as we move through the process, the appropriation process, for fiscal year 2023.

The President's request would provide \$112 million for OIG in 2023, which is an increase of about \$5.7 million, which would allow us, in particular, to provide more oversight of the infrastructure investment in NRCS, RUS, and NIFA, among other priorities.

So with that, we would be very happy to address any questions that you might have.

Thank you.

[The information follows:]

**Statement by
Phyllis K. Fong
USDA Inspector General
Submitted to the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives**

Introduction

Good morning, Chairman Bishop, Acting Ranking Member Harris, and Members of the Subcommittee. Thank you for the opportunity to testify about the Office of Inspector General's (OIG) fiscal year (FY) 2021 oversight results and our plans for FY 2022. As you know, OIG's mission is to promote economy, efficiency, effectiveness, and integrity in the delivery of the U.S. Department of Agriculture's (USDA) programs; we conduct audits, inspections, data analytics, and reviews and make recommendations to help improve how USDA's programs operate in order to execute this mission. We also conduct investigations of individuals and entities suspected of engaging in criminal, civil, and/or administrative wrongdoing involving USDA programs and operations. My statement will address OIG's work regarding oversight of USDA's more than \$210 billion in annual appropriations, \$77.5 billion for pandemic response activities, and over \$8.3 billion in infrastructure investments.

It has been more than 2 years since the start of the coronavirus disease 2019 (COVID-19) pandemic. For most of that time, OIG has worked in a maximum telework setting, and our leadership and staff have continued to demonstrate flexibility and innovation. We have recently begun a phased reentry process for those who will be returning to OIG offices. Our results for FY 2021 demonstrate that OIG has continued to achieve substantial and significant results.

In FY 2021, our oversight work resulted in monetary results totaling over \$686 million. We published 33 reports from audit engagements (audits, inspections, etc.) and made 133 recommendations to strengthen and improve USDA programs and operations. Overall, our audit work during this period has identified \$350.4 million in questioned costs and funds that could be put to better use. Our investigative work during the same period led to 228 convictions, with monetary results totaling approximately \$336.5 million.

Our data analytics initiatives empower OIG to leverage data and information proactively in order to promote efficiency and effectiveness and modernize the way OIG does business and conducts its

oversight and operations. In FY 2021, our analytics and innovation staff participated in a total of 46 projects for audits and investigations and issued 2 analytics products.

COVID-19 Oversight

OIG received more than \$3.2 million to oversee the more than \$77.5 billion in USDA funding related to the COVID-19 response. To provide oversight of USDA funding received in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, OIG received \$750,000, almost all of which was expended by the start of calendar year 2021. OIG also received \$2.5 million for oversight of USDA funding associated with the American Rescue Plan of 2021. As of the end of FY 2021, these OIG oversight funds were nearly expended. As we address our oversight portfolio of ongoing USDA programs, our approach is to rely on the best available data to conduct risk assessments of USDA programs and activities to prioritize our resources.

One of our FY 2021 COVID-19 projects was to review the Food and Nutrition Service's (FNS) controls over the Supplemental Nutrition Assistance Program (SNAP) Online Purchasing Pilot in response to the pandemic. Initiated in 2014, the SNAP Online Purchasing pilot allowed households to make online purchases using SNAP electronic benefits transaction (EBT) cards. In response to the COVID-19 pandemic, FNS expanded the pilot from 6 States in March 2020 to 46 States by the end of December 2020. By the end of December 2020, online SNAP purchase transactions increased to more than \$1.5 billion cumulatively. We found that FNS used the same approval criteria it used for the original pilot selections when adding additional States and retailers. We also identified that FNS had not updated its risk assessment of the SNAP Online Purchasing Pilot since creating the pilot in 2014. Lastly, although we found FNS had established criteria and program requirements for retailers to be eligible to participate in the pilot, FNS did not establish controls to effectively monitor, evaluate, or document how participating retailers protect SNAP participants' online personal information. OIG also issued two interim reports in relation to The Emergency Food Assistance Program (TEFAP), which provides supplemental food assistance to persons in need. The first report assessed risks related to TEFAP program operations, including changing conditions that could impact the integrity of the program. We concluded that FNS had not established a formal enterprise risk management process to continuously identify and assess risks related to TEFAP program operations and did not formally evaluate what impact the COVID-19 pandemic could have on the safe and efficient distribution of food assistance to States. The second report reviewed the criteria FNS used to approve States for food and administrative funds provided under the Families First Coronavirus Response (FFCR) and CARES Acts. We concluded that the FFCR and

CARES Acts did not change regulatory requirements to allocate TEFAP food funds and administrative funds. However, FNS implemented an additional eligibility requirement. All states complied with the requirement and we did not find any indication that it negatively impacted the integrity of the program. FNS generally agreed with our recommendations to strengthen SNAP online purchasing and TEFAP, and we reached agreement on the planned corrective actions to address the report's recommendations.

OIG's Office of Analytics and Innovation (OAI) published a USDA COVID-19 Funding Dashboard, which allows stakeholders to track the sources and uses of USDA's COVID-19 funding. This interactive dashboard displays the amounts of USDA COVID-19 funding enacted, budgeted, obligated, and spent, by appropriations act, agency, program area, and use of funds. OAI also published the responses to a survey of Food Safety and Inspection Service (FSIS) inspectors' perceptions of COVID-19 safety in the work environment. OIG's Office of Investigations continues to receive complaints and referrals related to allegations associated with COVID-19 pandemic relief from the public, USDA employees, and agencies. In fact, in coordination with the U.S. Attorney's Office in the Northern District of Georgia and the Internal Revenue Service – Criminal Investigations, OIG had its first successful prosecution of a USDA Coronavirus Food Assistance Program (CFAP) investigation. A Georgia man was sentenced to 30 months in prison and ordered to pay \$248,739 in restitution for submitting false claims related to livestock through the CFAP.

We anticipate completing a number of COVID-19 related projects in FY 2022. One ongoing inspection focuses on AMS' administration of the Farmers to Families Food Box Program. We also expect to conclude a review that examines whether the Farm Service Agency (FSA) provided timely and accurate CFAP direct payments to eligible recipients. In addition, we plan to release a data story, a web based interactive data visualization insight report, about the Farmers to Families Food Box Program and have begun work on a CFAP data story.

Finally, OIG continues to work with the larger Federal oversight community as an active member of the Pandemic Response Accountability Committee, established by the CARES Act, which promotes transparency and coordinated oversight of COVID-19 spending across the Federal Government.

Infrastructure Oversight

The Infrastructure Investment and Jobs Act (IIJA), signed on November 15, 2021, provided USDA more than \$8.3 billion in funding.¹ More than \$2.9 billion is directed toward broadband loans and grants,

¹Pub. L. No. 117-58.

watershed and flood prevention operations, and a new bioproduct pilot program using agricultural commodities. The IIJA provided more than \$5.4 billion for forestry programs designed to reduce wildland fire risk and restore ecosystems. OIG received more than \$27.1 million to provide oversight of the forestry programs funded by the IIJA. In January, we issued our oversight plan and established a multi-disciplinary team to develop a strategic framework that will guide OIG's infrastructure oversight efforts for the next several years.

As part of OIG's oversight responsibilities under the IIJA, one of our first initiatives was to review the results of prior OIG audits that were relevant to funding received by USDA. In February and March 2022, we issued an analysis of the results of our prior work related to the Natural Resources Conservation Service (NRCS), Forest Service, and Rural Utilities Service (RUS). For example, NRCS received \$300 million in funding for the Emergency Watershed Protection (EWP) Program. In February 2022, we highlighted the results of a recent audit of the EWP Program (discussed in Goal 2 below) and explained that while NRCS and OIG have reached agreement on the corrective actions needed to address the concerns identified, the corrective actions have not yet been fully implemented, which heightens risks associated with the use of these funds.

Strategic Goal 1—Safety, Security, and Public Health

OIG's first goal is to help strengthen USDA's ability to protect public health and safety and to secure agricultural and Department resources.

Safety and Security

As part of this goal, OIG works to help ensure safety and security. A recent audit of the Animal and Plant Health Inspection Service's (APHIS) Smuggling Interdiction and Trade Compliance (SITC) Program found that while SITC officials implemented the 13 recommendations from a previous audit, 4 were not fully implemented and 2 were implemented but not followed. Further, we found that the SITC Program needs to enhance its controls for searches of prohibited products purchased through internet sales, and the SITC internet team inconsistently interacted with 22 e-commerce businesses in 2019 and did not request necessary information from 20 of the e-commerce businesses. We found that SITC officers were not consistently inspecting sealed package contents, which may or may not constitute prohibited product, at courier distribution sites. APHIS generally agreed with our recommendations, and we reached agreement on the planned corrective actions to address the report's recommendations.

As required by the Federal Information Security Modernization Act, OIG conducted its FY 2021 review of USDA's ongoing efforts to improve its information technology (IT) security programs and practices. We found that USDA continues to take positive steps to improve its IT security posture, but many weaknesses remain. The Office of Management and Budget (OMB) establishes standards for an effective level of security and considers "Managed and Measurable" as a sufficient level. However, we found the Department's maturity level to be at the lower "Consistently Implemented" level. Based on OMB's criteria, the Department's overall score indicates an ineffective security level. OCIO generally concurred with our recommendations, and we reached agreement on the planned corrective actions to address them.

Animal Fighting

OIG also conducts investigations into allegations of animal fighting. In a recently concluded investigation, conducted jointly with the Bureau of Alcohol, Tobacco, Firearms and Explosives, Federal Bureau of Investigation (FBI), and Michigan State Police, five defendants were sentenced to 749 months of incarceration, over 204 months of supervised release, and fined \$3,000 for animal fighting, drug trafficking, and weapons violations. The investigation determined that five individuals were operating a criminal enterprise associated with animal fighting as well as other activities, including possession and distribution of controlled substances. A total of 67 dogs were rescued and several weapons were seized from convicted felons, as were large quantities of narcotics, including heroin containing fentanyl and Carfentanil. The investigation resulted in the disruption of the criminal enterprise and the successful conviction of all five defendants.

Future Work

We plan to complete work on an audit of FSIS' actions to respond to complaints of workplace misconduct. We also plan to complete two engagements that are assessing different security aspects of USDA IT systems.

Strategic Goal 2—Integrity of Benefits

Our second strategic goal is to strengthen USDA's ability to deliver programs with integrity and effectiveness.

Grant Funds

OIG provides oversight to help ensure or restore integrity in various USDA grant and assistance programs. For example, the Office of Partnerships and Public Engagement (OPPE) accomplishes its mission of improving access to USDA programs and enhancing the viability and profitability of small

farms and ranches, beginning farmers and ranchers, and socially disadvantaged farmers and ranchers through its grant programs, including the Outreach and Assistance for Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program. This program provides eligible organizations with grant funds for outreach, training, education, and technical assistance. A recent audit found that 6 of the 18 applications we reviewed were not eligible to receive grant funds; as a result, OPPE awarded a total of more than \$1.1 million in grant funds to 3 of the 6 ineligible entities. We also determined that the independent review panel did not follow established guidance and did not apply a consistent methodology to score applications; as a result, OPPE cannot ensure it awarded FY 2018 and FY 2019 grants—totaling more than \$25 million—to the worthiest applicants. OPPE officials agreed with our recommendations, and we reached agreement on the planned corrective actions to address them.

Disaster Assistance

OIG also provides oversight of disaster assistance programs relating to emergencies created by natural disasters. One disaster assistance program administered by NRCS, the EWP Program, offers technical and financial assistance to help local communities mitigate imminent hazards to life and property caused by floods, fires, windstorms, and other natural occurrences that impair watersheds. OIG recently evaluated NRCS' controls over the EWP Program relating to hurricane disaster assistance provided for Hurricanes Harvey, Irma, and Maria. We found that NRCS did not establish and maintain a database to accurately track EWP projects at the national level. Additionally, we found that for 15 of 20 sampled Damage Survey Reports (DSR), sponsors did not provide required eligibility documentation and all three States in our sample did not submit 60-day or final reports for our sampled DSRs. As a result, we questioned NRCS' oversight of more than \$239.7 million in EWP project funds. We also found that NRCS had no performance measures specific to EWP; without performance measures, NRCS could not assess and report on the EWP Program's effectiveness. NRCS agreed with our recommendations, and we have reached agreement on the planned corrective actions to address them.

Another assistance program, FSA's Emergency Conservation Program (ECP), assists landowners in restoring land used in agricultural production when damaged by a natural disaster. Congress appropriated \$400 million to ECP to address damage caused by Hurricanes Harvey, Irma, and Maria; wildfires occurring in 2017; and other natural disasters. Our recent audit reviewed the adequacy of FSA's internal controls over approval and payment of ECP applications and found that FSA needs to strengthen the program's internal controls; specifically, we found that FSA issued more than \$700,000 in ECP payments for 15 of 40 applications in our sample without properly documenting FSA's concurrence, or when FSA

should not have concurred, with waiving the prior approval rule. We also found, in all four counties we reviewed, that district directors did not sufficiently document or timely review ECP applications. Lastly, FSA processed cost-share payments for 14 of 40 applications using insufficient documentation, included ineligible costs, or calculated cost-share reimbursements incorrectly. FSA agreed with our recommendations and we have reached agreement on the planned corrective actions to address them.

Food Assistance

A significant portion of OIG's investigative resources are dedicated to ensuring the integrity of SNAP by combating the unlawful practice of exchanging benefits for currency or other ineligible items. One such investigation resulted in an Iowa food market owner first signing a plea agreement in February 2021 for one count of conspiracy to commit wire fraud. The market owner also agreed to pay \$550,000 in restitution to USDA's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and entered into forfeiture agreements for the cash seized at the owner's properties (\$226,928), bank accounts (\$111,928), and three residences. In July 2021 the market owner was then sentenced to 15 months in prison, followed by 3 years of supervised release. The owner was also ordered, at sentencing, to pay \$1,445,460 in restitution to WIC and SNAP (\$945,631 for WIC and \$499,829 for SNAP). The higher amount was the result of a successful argument for more restitution by the United States Attorney. The cash, bank account balances, and proceeds from the sale of homes forfeited by the market owner will be applied to the restitution. The case was referred to OIG by the FBI and the State of Iowa.

Fraud in the Organics Program

In another recent investigation, an OIG Investigations team and subject matter experts dismantled a multi-state organic fraud scheme that involved over a dozen known victims and countless consumers while simultaneously strengthening the integrity of the USDA Agricultural Marketing Service—National Organic Program (AMS-NOP). This investigation was initiated based on information provided in a referral from AMS-NOP that outlined multiple complaints against a farming entity and a grain broker, both of which were owned by the same defendant. OIG agents in multiple States worked together to identify the true origin of "organic" grain that was in abundance but originated from only two organic certified producers. There were ultimately six individuals involved in this fraudulent activity and one defendant admitted the scheme involved at least \$142.4 million in misrepresented "organic" grain sales, the vast majority of which were fraudulent. At sentencing, each defendant was sentenced to a term of imprisonment and ordered to pay fines and restitution. They also agreed to forfeit a collective amount of

\$128.1 million in illegally derived proceeds. Additionally, results included six indictments, six arrests, five convictions, \$100,000 in fines, and \$205,600 in restitution.

Future Work

We are completing an audit of the Foreign Agricultural Service's oversight of the Agricultural Trade Promotion Program. We are also reviewing the Rural Utility Service's Rural E-Connectivity Pilot Program. This work will also support and inform OIG's oversight of the \$2 billion in broadband funding provided by the IJA.

Strategic Goal 3—Management Improvement Initiatives

Our third strategic goal is to strengthen USDA's ability to achieve results-oriented performance. By conducting audits and investigations focused on areas such as financial management, IT, procurement, and employee integrity, we help USDA better manage its assets.

Civil Rights Complaints Process

USDA's Office of the Assistant Secretary for Civil Rights (OASCR) is responsible for making final determinations on complaints of discrimination filed by any persons who believe they have been subjected to prohibited discrimination in a USDA program. We evaluated OASCR's oversight of the civil rights program complaints process and concluded that OASCR needs to develop a stronger internal control environment over its program complaints processing to ensure that complaints are timely and appropriately handled, and that OASCR achieves established goals and objectives. The agency agreed with our recommendations, and we have reached agreement on the planned corrective actions to address them.

Improper Payments

We found that USDA was not compliant with the Payment Integrity and Information Act of 2019 (PIIA). USDA reported mandatory improper payment information for 15 high-risk programs for FY 2020. We found that 6 of the 15 high-risk programs either did not meet annual reduction targets or reported gross improper payment rates that exceeded 10 percent. This occurred because some programs' policies and procedures were not followed by staff, and the corrective actions have not yielded the desired results. Furthermore, we identified an incorrect improper payment rate, erroneous statements, and unsupported statements in the payment integrity section of USDA's Agency Financial Report. These errors reduced the quality of USDA's improper payment reporting and prevented stakeholders from using the report to

make informed decisions. USDA agencies agreed with our recommendations, and we have reached agreement on the corrective actions to address them.

Financial Management

OIG completed its review of the financial statements for FY 2021 for USDA and component agencies to express opinions about the fair presentation of those statements. Our consideration of USDA's internal control over financial reporting identified deficiencies related to financial management, information technology, and unliquidated obligations. Additionally, we identified noncompliance with certain laws. Based on our audit of USDA's consolidated financial statements, 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 2021 financial statements received an unmodified opinion.

The Digital Accountability and Transparency Act

The Digital Accountability and Transparency Act of 2014 (DATA Act) requires USDA to submit to the United States Department of the Treasury (Treasury) Federal contract, loan, and grant spending information for Federal programs so that taxpayers and policy makers can more effectively track Federal spending. We reviewed the FY 2020 fourth quarter financial and award data that USDA submitted for publication on USAspending.gov and found that, although USDA transmitted its FY 2020 fourth quarter submission to the Treasury's DATA Act Broker, its submission was not complete and contained records that were not accurate or timely, according to DATA Act reporting standards. We also found that USDA component agencies and offices did not consistently implement and use Governmentwide financial data standards established by OMB and the Treasury. Without the consistent use of standards, USDA cannot attest to the reporting of reliable, transparent, and consistent Federal spending data for public use. Departmental and agency officials agreed with all of the report's recommendations, and we have reached agreement on the corrective actions to address them.

Employee Misconduct

As part of this goal, OIG investigates allegations related to employee integrity. One such investigation resulted in a former NRCS employee's sentencing of 4 months in prison for conspiracy to restrain trade and conspiracy to commit wire fraud. The investigation began when the FBI Guam Office requested assistance from USDA OIG into a bid-rigging conspiracy involving a college professor, the former NRCS employee, and the former employee's family member. The professor conspired with the former USDA employee and family member to rig bids for Federally funded project work pursuant to cooperative

agreements between the Federal Government and a local university. During this time, the professor also served as the university's Principal Investigator for certain Federally funded cooperative agreements. In this latter role, the professor was responsible for bidding out and awarding project work in compliance with the university's procurement process. However, instead of soliciting bids from the Guam community, the professor produced fictitious bids in order to make the procurement process appear legitimate and awarded a total of 41 contracts to their own business and the former NRCS employee's business. The defendants fraudulently obtained over \$200,000 in project work. In total, the three defendants were sentenced to 16 months in prison, 36 months of supervised release, 12 months of probation, and 50 hours of community service. They also were fined \$24,000 for charges related to money laundering, conspiracy to restrain trade, and wire fraud involving Federally funded environmental work projects.

Future Work

At present, OIG is evaluating whether NIFA designed and implemented adequate internal controls to properly select Agriculture Food and Research Initiative (AFRI) grant recipients and to monitor AFRI projects' compliance with grant agreement terms and conditions, and fulfillment of their stated objectives. OIG is also assessing whether USDA Government purchase card transactions complied with laws and regulations. In addition, OIG will audit the FY 2022 financial statements of USDA and designated component agencies.

Conclusion

In closing, we would like to thank the Subcommittee for your continued 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.

For FYs 2017–2021, OIG's appropriations totaled approximately \$492.7 million. During this period, the potential dollar impact of OIG's audits and investigations was \$4.3 billion, resulting in cost savings and recoveries of \$8.72 for every dollar invested. During this same period, OIG made 992 audit recommendations to improve USDA programs. Furthermore, OIG investigations resulted in 2,083 successful convictions in that same 5-year period.

We appreciate your support in continuing to provide the funding necessary to perform effective oversight and make recommendations to Congress and USDA decision-makers to improve program effectiveness.

This concludes my testimony. I would be pleased to answer any questions you may have.

Mr. BISHOP. Thank you very much, Ms. Fong.

We will now proceed with questions. As I mentioned earlier, we will begin with the chair and ranking member, then alternating majority and minority with members present at the time of the hearing start in the order of seniority. After that, I will recognize members not present at the time that the hearing was called to order in order of their arrival.

Each member will have five minutes in each round. So please be mindful of your time.

Ms. Fong, I have two questions for your opening related to civil rights. First, you and I discussed that a recent agriculture authorizing committee hearing, the \$6 million increase for the Office of Civil Rights in the House fiscal year 2022 bill.

I am extremely happy to report to you that we retained the full House level for OCR in conference, and the conference report specifically says that the increase is for addressing program deficiencies identified by the Office of Inspector General.

For my colleagues on this subcommittee, would you discuss what you see is the benefit of these funds?

And, second, at that same hearing with the Agriculture Committee, you and Chairwoman Hayes discussed the impact of the 2018 reorganization of civil rights functions at USDA. You indicated that their strategic plan was no longer effective, as stated in a recent report on USDA's oversight of the civil rights complaints process.

I want to cut to the chase. Did the reorganization under the previous administration do more harm than good?

If so, how can we fix it?

Ms. FONG. Thank you for your questions.

And I remember our dialog at that hearing. It was very productive, and I appreciate knowing that the funds have been appropriated for the Office of Civil Rights. That is great information.

As members of this committee may know, we did an audit report last year that looked at the Assistant Secretary for Civil Rights Office's ability to handle program complaints of inequitable treatment, and we have some very significant findings that the handling of complaints was much longer than set forth in all the timelines that would apply.

And while we did our work, the staff of that office made it very clear to us that they felt they needed additional resources both for staffing as well as for information technology systems to track their work and the progress and their outcomes.

And I think it is in relation to that that this committee was able and recognized the need to provide additional resources.

My sense is that it will be very important to see how that office takes those funds, how they use it. Are they able to get the resources to where they need to get them so that they can make progress in terms of addressing those delays and implementing an effective IT system?

In terms of your question, Mr. Chairman, on whether the reorganization was effective or not, I think our report indicates that the approach to processing complaints which had been to decentralize it and put more responsibility in the agencies with less oversight

centrally, that that approach was not effective as borne out by our recommendations.

And so we will watch with great interest to see how that office moves forward in the future, and at some future appropriate time, we will undoubtedly do additional work.

Mr. BISHOP. Thank you very much, Ms. Fong, for that.

I think I have about a minute left. So let me go to another question.

I want two questions related to animal fighting. Your testimony discussed the recent dog fighting case in Michigan that OIG and other law enforcement agencies brought to conclusion.

Do you wait for evidence that non-USDA criminal activities are involved before taking action on cases of dog or animal fighting?

If you proceed alone, how many cases have you sued alone and how many with law enforcement?

Second, the fiscal year 2021 bill included an increase of \$500,000 earmarked for animal fighting, and that funding is in the base for fiscal year 2022.

How have you used those funds? And are your resources constrained in terms of your work for animal fighting?

And you have got about 34 seconds from my time.

Ms. FONG. We will be happy to provide additional detail in a QFR, but very briefly, we get involved in these cases. We have about 67 open investigations currently. We definitely spent all of the \$500,000 last year and more.

And we get involved in many different ways, through hotline allegations, through referrals from the FBI, referrals from APHIS and the program officials, referrals from State and local law enforcement. Any number of ways that you can think of, we do initiate cases based on that, and we work very closely with our State and local law enforcement partners on these cases.

Mr. BISHOP. Thank you very much, Ms. Fong. My time has expired.

And at this time I am happy to yield to our acting ranking member, Dr. Andy Harris.

Dr. Harris, you are recognized for five minutes.

Mr. HARRIS. I thank you very much.

Let me first just ask broadly. With the increase in funding for COVID and, again, you know, just tens of billions of dollars have increased, as well as the increase, the ongoing increase, I think, in the SNAP Program through the updated Thrifty Food Plan, I mean, the enticement for fraud appears to be greater.

So you dealt with the SNAP Program in your testimony and with COVID funding to some extent, but where do you think the largest fraud potentially could have occurred with the COVID funding to USDA?

And what are you doing to try to search that out?

Ms. FONG. With respect to the COVID response funds, and thank you for your question on that, we have been looking at potential fraud in all the programs because we know that there is always a potential whenever there is a large amount of money.

We also, as you know, have a hotline, and so we receive any number of allegations pertaining to all of USDA programs.

We have been working very closely with the Farm Service Administration on the CFAP Program in a proactive way to try and identify potential indicators of fraud, and we did that with FSA very early on.

We issued a number of bulletins to their staff to say take a look at this. If you have got situations coming up where you might see this indicator, please contact us because it is really important to get involved at the front end on these kinds of issues.

We have also received allegations in the Food Box Program. We have had a number of cases that have looked at those allegations, and as well, you know, in the SNAP Program, the feeding programs we receive allegations and run those down as well.

Mr. HARRIS. Thank you.

Yes, with regard to the infrastructure oversight, and I know I have asked you about this last year. A grave concern to me is that, you know, we are spending billions of dollars for broadband extension, for instance, but is your office conducting oversight into whether or not those funds are used appropriately and grants given to providers who actually can deliver on their promise?

I mean, it is one thing to send the money to them. Another one whether or not they can actually deliver. And you do not mention that in your testimony.

Ms. FONG. Yes. We actually have been following the broadband programs over a number of years. It's a matter that we regularly audit on a periodic basis.

We do have an ongoing audit right now of the Reconnect Program which looks precisely at the issues you are talking about, eligibility of recipients, making sure that recipients are appropriately selected.

And through that audit we hope to also evaluate whether RUS has addressed concerns that we have raised in prior audits over the years.

And, of course, as you mentioned, under the Infrastructure Act, we do have oversight responsibility of those funds, and we are at this time evaluating how best to move forward with that.

Mr. HARRIS. Well, thank you very much.

You know, I will tell you one of the fascinating parts of this job is that I learn a lot of new things, and in reading your testimony, I came across the term "data story." I am sorry. I am just not familiar with what a data story is.

So I did what everyone else would do and Googled it, and I am curious if what I understand is true. Why would the OIG's Office be doing data stories about programs?

Why would, for instance, the Farm Service Agency not do the data story about CFAP payments?

I mean, why would it fall to the OIG's Office?

Ms. FONG. And that is a really interesting question. We view it as part of our role to bring transparency to government spending and how funds are being used, and we also view it as an opportunity for us when we do these data stories to generate our own thinking about potential audits, inspection, and investigative work.

So we do it for, you know, a range of reasons.

In terms of explaining it, I would be happy to ask Jenny Rone to offer some comments if you would like more detail on that.

We have a data story coming out soon, which I think is very exciting.

Mr. HARRIS. Yes, Ms. Fong, maybe just send me a copy of the data story.

Thank you very much.

I yield back.

Mr. BISHOP. Thank you very much, Dr. Harris.

At this time I am delighted to yield to the gentleman from Wisconsin, Mr. Pocan.

Mr. Pocan, you are now recognized for five minutes.

Mr. POCAN. Thank you very much, Mr. Chairman. I appreciate it.

And thanks for our guests being with us.

I would like to try to get to two different areas if possible, one being animal welfare and the other being meat packing plants.

So first on animal welfare, I just want to thank you for honoring my request for an audit around the enforcement of the Animal Welfare Act with respect for dog breeders. I know it got abbreviated because of COVID, but I am looking forward to seeing it, and also the fact that you are going to continue that audit in fiscal year 2023.

I was just curious if you could share a little more detailed timeline on what I can expect and what will be considered in that.

The second part of the animal welfare question is, as you know, the inadequate Animal Welfare Act enforcement has been a long-standing issue for APHIS. Your office found in a 2010 audit that the agency chose to take little or no enforcement action against serious or repeat violators, which weakened the agency's ability to protect animals.

A decade later we are still seeing puppy mills with hundreds of violations of Federal law and they get to keep their licenses while the animals in the cages are the ones who are suffering.

I appreciate that your office had conducted repeated audits of the agency and made many recommendations for how they can improve, but I am disappointed that more progress has not been made. I worry that we are still going to be asking the same question ten years from now if something does not change.

So what plans do you have to ensure that APHIS actually fulfills its statutory obligation to enforce the Animal Welfare Act going forward?

Ms. FONG. Yes, and thank you for your interest in all of that work that we do and have done and will be doing.

I am going to offer the mike to Gil Harden who has probably more detail on the audit that we are going to do in 2023.

Mr. HARDEN. Yes, thank you.

And, Congressman, we do plan to do that work in 2023. As you know and as Phyllis has said, we are starting our movement back into the offices and thinking about doing work onsite. So that is why it was pushed to next year.

But it will get into looking more deeply at the recommendations we made in the past in terms of enforcement, which we need to do the work on the ground at the site to know how well that is being enforced or overseen.

We did continue to see, you know, problems with oversight and what we could look at this time around, and so we will just continue that look in the future.

Mr. POCAN. And to the second part of the question about ensuring APHIS actually fulfills its statutory obligation enforcing the Animal Welfare Act?

Mr. HARDEN. I think it will be part of looking at how they dealt with those recommendations as to whether we can ask questions about how well or how they can better enforce the Act.

Mr. POCAN. Okay. Thank you.

And then as a second area, and I noticed Madam Chairman has joined us, and I know this is important to her, too, is the COVID outbreak and the meat packing plants.

You know, last year we talked about your investigation into food safety and inspection services' response to outbreaks of COVID at meat packing plants. I see that your fiscal year 2022 annual plan includes continuing to evaluate this COVID response at meat slaughter/processing establishments.

I was wondering, again, what the scope is on here and when we can expect to see that report, especially with concern on when your office's pulse survey found that 48 percent of front-line inspectors agreed that FSIS was responsive to safety concerns during the pandemic.

Ms. FONG. Yes. That audit is very close to completion. I think it is safe to say—Gil, correct me if I am wrong—that it should be out in the next few months.

Mr. HARDEN. Yes.

Ms. FONG. And the scope of it is as you explained or discussed just now. It is what FSIS did with its COVID funds, how it ensured that inspections continued, the steps it took to ensure the safety of its inspectors, and whether it had sufficient resources for PPE and other kinds of equipment.

So I think you will see that very shortly.

Mr. POCAN. Great. Also, in poultry I think in your fiscal year 2022 annual plan, they are looking at an audit on the new poultry inspection system. Can you tell us a little bit about that timeline and that report?

Ms. FONG. Gil, I turn it to you.

Mr. HARDEN. Thank you.

That is one that we did include in the plan that we published in October. Because of delays in terms of getting back in the office and actually doing work in the field, we have not started that work as of yet. We will be looking to see if we can start that later this fiscal year or early in 2023.

Mr. POCAN. Okay. Thank you very much, Mr. Chairman. I have got 16 seconds. So I yield.

Mr. BISHOP. Thank you very much, Mr. Pocan.

At this time I would like to recognize the gentleman from Washington, Mr. Newhouse, who will be followed by the chair of the full committee, Ms. DeLauro, who has joined us, and at that time she can give an opening statement, and she can also ask her questions.

But I now recognize Mr. Newhouse. The floor is yours.

Mr. NEWHOUSE. Well, thank you, Mr. Chairman.

I am going to write this date down, one of the few times that I get to go before Madam Chair.

So thank you very much, Mr. Chairman and Dr. Harris, as well.

I just want to thank Ms. Fong and your team for being with us today. Thank you for all of the things that you do at USDA to ensure that those precious Federal taxpayer dollars are being used, spent properly and everything that you do in support of the USDA mission.

You know, combatting waste and abuse is a huge job, and something that we have to be ever vigilant on. I think some of the numbers in your statement, I think, bear repeating.

In fiscal year 2021, oversight work resulted in monetary results totaling over \$686 million. I appreciate that.

That led to 228 convictions. Your investigative work is just a tremendous record there, and I appreciate your diligence in these results.

Unfortunately, you know, people are taking advantage of some of these things that are meant to assist American citizens. That one example of a Georgia man who was sentenced to 30 months in prison, had to pay in restitution almost \$250,000.

These things happen, and we need to have a strong oversight. So I appreciate the work that you and your team do.

Mr. Chairman, I will submit questions for the record in anticipation of attending the memorial service for the Dean of the House, Mr. Young. I will be leaving shortly, and so I wanted to recognize that that is going on today.

But I do fully appreciate the work that USDA and the OIG Office do on behalf of the American taxpayer, and I appreciate you being with us this morning.

Mr. BISHOP. Okay. Thank you, Mr. Newhouse.

And at this time, I recognize the chair of the full Appropriations Committee, Representative DeLauro, the gentlelady from Connecticut.

The CHAIRMAN. Thank you so much, Mr. Chairman. I am delighted to be with you, and thank you for recognizing me. And thank you to Dr. Harris as well.

It is great to see you, Inspector Fong, and welcome back to the Appropriations Committee. We are always so grateful for your testimony.

I want to ask about an issue that you and I have discussed before. That is the hundreds of millions of dollars that have flowed to what I view as corrupt Brazilian meat packer, JBS, the procurement contract awarded by the Department's Agricultural Marketing Service.

As I have said to you before, I am concerned by that because, as you know, the Federal Acquisition Regulations and the related USDA policies require that government contractors have, quote, "present responsibility," and accordingly, present responsibility can be impacted by fraud, bribery, and other violations of Federal laws.

You also know that in recent years, I have repeatedly urged the department to open its suspension and debarment investigation into JBS to determine whether the company meets its legal requirement of, quote, "present responsibility."

They have refused.

In the past, I have also urged you to conduct an investigation using your independent authority and responsibility under the Inspector General Act of 1978, to ensure that taxpayers' dollars do not continue to flow to a company engaged in criminal activity.

At the time, you suggested to me and similarly your staff suggested to my staff that you would not investigate because the Department of Justice had an ongoing investigation.

Well, Inspector General, the DOJ has concluded their investigation. It ended with the Batista brothers pleading guilty, guilty, conspiring to violate the Foreign Corrupt Practices Act.

So, Chairman, I would like to submit the guilty plea into the record.

Stunning charges by the DOJ, showing more than a decade of criminal activity, a massive bribery scheme by the Batista brothers to obtain illicit loans from Brazil's National Bank.

These ill-begotten loans were then used by JBS to illegally enter and consolidated the meat packing industry in the United States to the detriment, to the detriment of America's farmers and ranchers, as well as consumers and their families.

I could go on about JBS' illegal activity. They have a history of manipulating cattle markets, price fixing in beef and poultry. Recently President Biden's National Economic Council released data showing that they are price gouging consumers at the grocery store. They have an abhorrent track record of exploiting their workers and failing to ensure a safe workplace.

And since 2019, JBS—and this does not count the preceding years—JBS has received \$171.5 million, and they are receiving subsidies today from the Federal Government.

My question is simple. How with the guilty plea, why have you not opened an investigation?

Why is the Federal Government subsidizing what is likely the most corrupt corporation on the face of the earth?

Ms. Fong.

Ms. FONG. Yes, thank you very much for your concerns.

I know we have had dialogue over the years on this issue, but I appreciate the information you provided for the record on the guilty plea, and I think you have raised an interesting question about whether or not suspension and debarment is an appropriate remedy at this time, given that there has been a guilty plea and a conviction.

I think our staff will go back and see if there is anything additional that we can do now that the Justice Department is completed with its process.

The CHAIRMAN. You can open up an investigation. Will you open up an investigation now that the guilty plea is there?

That is the question. Now that we have a guilty plea, why is there not immediately an investigation into all of this.

And—anyway, why can we not move that? What is the timing? Are you going to proceed to do that?

And we are continuing to subsidize JBS. Today we subsidize JBS, and to the detriment of our farmers and ranchers in this country.

Ms. FONG. I will say to you that we will go back and evaluate the situation to see if there is anything appropriate for us to inves-

tigate or whether there are other remedies, and we will get back to you on that.

The CHAIRMAN. I would hope you would.

They have been found guilty. They have been found guilty. We know what happens when someone is found guilty, and that we cannot even have an investigation to deal with suspension and disbarment seems to be an abdication of responsibility and the abdication of the independent authority that you have to move forward on this.

There would appear to be no going back and looking at what is there. You have got a fait accompli. They are guilty of violating the Foreign Corrupt Practices Act. There is so much documentation about they are manipulating the market, about price gouging, about a workplace where we had six people who died who they did not take care of their workers.

And yet it just seems that we cannot move. I need to know why, and I want to know how soon we will have an investigation.

Thank you, Mr. Chairman.

Mr. BISHOP. Thank you very, Madam Chairman.

And the documents are submitted and received and made a part of the record of this hearing.

The CHAIRMAN. Thank you. Thank you very much.

[The information follows:]

The Honorable Grace Meng
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and
Related Agencies
Questions for the Record
Fiscal Year 2023 Oversight: Office of Inspector General, U.S. Department of Agriculture

At a House Agriculture Subcommittee on Nutrition, Oversight, and Department Operations, Inspector General Fong emphasized how USDA “is continually challenged to find effective ways to encourage and support all.” Given the Department’s history of civil rights issues, including thousands of filed claims of denial of equal services to farmers of color, earning the trust of communities of color could be a challenge as the Department administers programs designed to support these farmers and ranchers.

As the 2017 Census of Agriculture noted, Asian American producers and farmers had grown 7% from the 2012 census. I am interested in the participation of Asian American, Native Hawaiian, and Pacific Islander farmers in programs like the Socially Disadvantaged Farmers and Ranchers program and how effective the Department’s outreach is in these communities when it comes to programs like this, or the loan forgiveness program that was established under the American Rescue Plan.

- **How can USDA improve the trust from and outreach to socially disadvantaged groups, including AANHPI farmers and ranchers?**

OIG provides oversight of USDA programs and operations, including those established to serve socially disadvantaged groups. In January 2020, OIG initiated an audit of USDA’s Office of Partnerships and Public Engagement (OPPE). OPPE was established to improve access to USDA programs and to enhance the viability and profitability of socially disadvantaged farmers and ranchers. OPPE accomplishes its mission through its grant programs, including the Outreach and Assistance for Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program, also known as the 2501 Program. Based on our review of the 2501 Program, we determined that OPPE did not establish a performance plan and set performance goals and indicators to measure and assess its progress towards achieving the 2501 Program’s purpose. In November 2021, we recommended that OPPE establish performance goals and performance indicators so that grantees could report performance information back to OPPE. OPPE agreed with OIG’s recommendations and proposed corrective action to address the weaknesses noted. By establishing goals and indicators, OPPE should be able to better evaluate the 2501 Program’s success and determine if its outreach efforts increased the participation of socially disadvantaged groups, such as Asian American, Native Hawaiian, and Pacific Islander (AANHPI) farmers and ranchers. OIG does not have any current audit work planned regarding participation rates in relation to programs under the American Rescue Plan. However, we will consider participation rates along with other topical areas as potential areas for review in future audit planning.

Furthermore, OIG’s Office of Investigations is responsible for addressing allegations of wrongdoing in USDA’s programs and operations, including those involving socially

disadvantaged groups. The Office of Investigations' efforts are aimed at addressing violations regarding such programs. This investigative work is focused on the integrity of the respective USDA programs to ensure that relevant funding is provided to those whom the programs are intended to benefit.

Vacant Nomination Positions

Inspector Fong, will you commit to investigating what actions USDA has taken to advance agricultural trade given its lack of political leadership (i.e., Under Secretary of Trade and Foreign Agricultural Affairs) and lack of trade-related missions?

Response: In planning our oversight work each year, OIG strives to provide audit and investigative oversight to all key mission areas of the Department. In Fiscal Year (FY) 22, OIG is conducting an ongoing audit to determine whether effective policies and procedures have been implemented in Foreign Agricultural Service's (FAS) Market Access Program to evaluate participant eligibility, select proposals, and allocate funding.¹ We anticipate issuing this report in the first half of FY 23. OIG's plan for FY 2023 also includes an audit to evaluate FAS' controls over grant funding for the McGovern-Dole International Food for Education and Child Nutrition Program. OIG's Office of Audit does not have any project work specific to the area of trade within FAS planned for FY 23 but will consider it in our future planning.

Food Box Program

1. In your testimony, you mention the ongoing inspection of the Farmers to Families Food Box Program. I have constituents who would like to see an updated version of this program be put back in to place. Please share the information you have collected so far with the committee and when you expect to have your review completed.

Response: Since OIG's testimony on March 29, 2022, we issued an inspection report regarding the Agricultural Marketing Service (AMS) Farmers to Families Food Box Program (Food Box Program).² Our review assessed how, for Round 1, AMS designed the Food Box Program solicitation, what methodology AMS used to allocate funding, and whether AMS awarded the contracts in accordance with requirements. We found that AMS designed the solicitation according to the requirements of the Federal Acquisition Regulation and the U.S. Department of Agriculture's Departmental guidance, and AMS substantially adhered to the funding allocation decisions described in the solicitation. However, while AMS established a panel to evaluate Round 1 Food Box Program proposals, the agency did not always award contracts in accordance with the specified requirements of the solicitation. As a result, some proposals were accepted and awarded contracts despite not meeting the specified requirements of the solicitation. We

¹ Audit Report 07601-0001-21, *Controls Over the Market Access Program*.

² Inspection Report 01801-0001-22(1), *COVID-19 - Farmers to Families Food Box Program Administration - Interim Report*, June 2022.

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recommended that AMS develop policies and procedures for performing expedited award processes during Federal emergencies and upload all relevant Food Box Program supporting documentation for Round 1 to the agency's system of record. AMS agreed with our finding and recommendations. Our final report, planned for release in FY? 2023, will address what controls AMS developed and implemented to ensure Round 1 Food Box Program awardees fulfilled the obligations of their contracts.

CFAP

1. Regarding the CFAP payments, I have heard from my constituents that payments were far too slow to arrive and sometimes did not end up processed at all. What information have you collected so far that you can share with the committee as it relates to CFAP payment timing?

Response: OIG is conducting an inspection for which the objective is to determine whether the Farm Service Agency (FSA) provided timely and accurate Coronavirus Food Assistance Program (CFAP) direct payments to eligible recipients.³ This inspection covers program payments made under CFAP-1, which had an application period ending September 11, 2020.

In our inspection, we are evaluating FSA's compliance with its general rule that payments must be made within 30 days of the receipt of complete documentation⁴ to avoid an interest penalty. While we cannot provide specific results of our ongoing work, we are assessing whether payments for twenty-nine (29) types of agricultural commodities made to a random sample of ninety-nine (99) producers selected for our review met this standard. OIG will share a copy of the inspection report once results are published. We anticipate issuing this report in the first half of FY23.

2. Depending on the results of the review, are you willing to recommend additional CFAP payments to eligible recipients?

Response: As stated above, the objective of our inspection is to determine whether FSA provided timely and accurate CFAP direct payments to eligible recipients. OIG may include monetary recommendations upon issuance of the inspection report if the evidence provides a basis for any such recommendations. It is OIG's practice to recommend that USDA agencies address any payment errors identified through our review work, including to address errors that result

³ Inspection 03801-0001-31, *COVID-19 Coronavirus Food Assistance Program Direct Support*.

⁴ USDA FSA, *Handling Prompt Payment Interest Penalties Handbook*, ¶5(A), "Determining Payment Due Date," 61-FI (Rev. 2) (June 5, 2017).

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in either overpayments or underpayments made to producers. OIG will share a
copy of the inspection report once results are published.

REP. MARK POCAN

MARCH 29, 2022

QFRS FOR USDA OIG HEARING

Animal Fighting

1. In 2019, the federal prohibition on animal fighting in the states was extended to the U.S. territories. In light of this expanded enforcement authority, what additional resources does the USDA OIG need to shrink the scale of this illegal enterprise nationwide?

Response: OIG conducts investigations into allegations of violations of the Animal Welfare Act, including allegations of animal fighting. Many examples of our success in this arena involve collaboration between various Federal, State and local law enforcement and prosecutorial entities wherein investigative operations involve the identification of other associated criminal enterprises and their activities, such as narcotics trafficking, gambling and weapons violations. Our results often reflect arrests and convictions of offenders, rescue of abused animals, and the seizure or confiscation of narcotics, weapons and illicit profits. The below data reflects some of our efforts for the period spanning FY2020 through FY2022 year-to-date (YTD).

In FY2020, FY2021 and FY2022 (YTD), respectively, 10.24%, 12.28% and 15.38% of our direct investigations time was spent on animal fighting investigations. This was expended annually on a total of 30, 32 and 24, investigations, respectively that utilized dedicated labor, regardless of the year the investigation was initiated.

OIG Region	Total Number	Dog Fighting	Cock Fighting
Southeast	42	27	15
Midwest	12	6	6
Northeast	11	6	5
Southwest	12	5	7
Western	9	2	7
Total	86	46	40

There is not a set standard for the amount of OIG resources used for each investigation. It is situationally dependent. In FY2021, OIG was directed to utilize \$500,000 from its appropriated budget to address concerns with, and combat crimes related to, animal fighting. OIG did expend, through the conduct of several investigations, the designated \$500,000 in addition to over \$380,000 in

appropriated funding. There is a primary agent assigned to conduct each investigation who may request additional staff resources, as needed. OIG identified several animal fighting enterprises organized on a national scale, resulting in the simultaneous execution of several search warrants requiring a significant number of OIG personnel to assist. To explain this in monetary terms, for these 86 investigations above, OIG used an average of 12.63% of our direct investigations time for animal fighting investigations in FY2020, FY2021 and FY2022 (YTD). These investigations cost approximately \$2,487,239 including labor, staff, equipment, specific training, digital forensic examinations, and related expenses.

Animal Welfare Act Enforcement

1. Late in 2021, the Department of Justice took action against a USDA licensed dog breeder, Daniel Gingerich, who ultimately surrendered over 500 dogs in his care. The USDA's handling of the Gingerich matter has been pointed to as an example of the agency's failure to take timely enforcement action, promptly confiscate animals found suffering, or otherwise ensure the humane care and treatment of dogs afforded protection under the AWA. Will the OIG ensure that the new audit includes an assessment of the USDA's handling of the Gingerich matter?

Response: OIG's Annual Plan for fiscal year (FY) 2023 includes an audit entitled "Animal Care Program Oversight of Dog Breeders—Site Visits." It is OIG Audit's practice to coordinate with OIG Investigations in order to avoid potential interference with any investigations or legal proceedings. At the start of this audit, OIG Audit will discuss with OIG Investigations whether it is appropriate to include or exclude this case from a potential audit sample. Regardless of whether or not this specific case is included in the audit sample, OIG will consider whether there are indications of potential internal control areas to assess within the scope of this planned audit.

2. The OIG represented that they will be visiting USDA facilities to know how well the AWA is being enforced. Can you provide some examples of what the OIG will be looking for and evaluating when they visit these facilities and explain what role facility visits play in evaluating agency enforcement overall? Can you also explain how the OIG determine which facilities to visit?

Response: OIG's Annual Plan for FY 2023 includes an audit entitled "Animal Care Program Oversight of Dog Breeders—Site Visits." The planned objective of this audit is to review the adequacy of the Animal and Plant Health Inspection Service's (APHIS) oversight of dog breeders through site visits. Specifically, we will: (1) evaluate the adequacy of agency controls to ensure dog breeder compliance with the Animal Welfare Act, and (2) ensure previously identified deficiencies have been effectively mitigated. This audit will focus on conducting site visits that were canceled due to health and safety concerns related to the

COVID-19 pandemic, as a part of a previous audit report.¹ Please note that planned site visits will take place at dog breeder facilities, which are not USDA facilities. OIG will make determinations regarding the specific scope of OIG review work at facilities and the methodology for selecting which facilities to visit when developing the audit plan at the beginning of the project.

3. In addition to site visits, evaluating existing USDA inspection records and observations against USDA enforcement actions should provide insight into how well the AWA is being enforced. Does the OIG plan to review past inspection reports and written observations that show which dog dealers have violated the AWA, which violations were recorded on inspection reports, and what action, if any, was taken by the agency in response to those violations? For example, the total number of violations recorded in inspection reports has drastically declined since 2014 with nearly 2,000 violations recorded in 2014 and fewer than 200 recorded in 2019 and 2020. Will the OIG be evaluating this steep decline? And will the OIG be reviewing inspection reports that do reflect violations to evaluate the Agency's enforcement response to those violations?

Response: As previously mentioned, OIG's plan for FY 2023 includes an audit entitled "Animal Care Program Oversight of Dog Breeders—Site Visits." The planned objective of this audit is discussed in response to question 2. We will consider the information mentioned above during our planning phase.

4. How will the OIG be evaluating the impact of APHIS compliance policies and guidelines on animal welfare?

Response: OIG's plan for FY 2023 includes an audit entitled "Animal Care Program Oversight of Dog Breeders—Site Visits." The planned objective of this audit is discussed in response to question 2. As part of that audit, we plan to evaluate the adequacy of APHIS' controls to ensure dog breeder compliance with the Animal Welfare Act and assess compliance based on policies and regulations.

5. Will the OIG be evaluating the Agency's process for investigating and seeking penalty assessment against violators?

Response: OIG's plan for FY 2023 includes an audit entitled "Animal Care Program Oversight of Dog Breeders—Site Visits." The planned objective of this audit is discussed in response to question 2. Our current objectives do not include evaluating whether the Agency is appropriately exercising its authority to seek/impose penalties.

¹ Audit Report 33601-0002-31, *Animal Care Program Oversight of Dog Breeders*, June 2021.

6. The OIG said it would be evaluating whether the USDA has implemented its recommendations from the 2010 audit to ascertain whether the USDA is meeting its obligation to ensure humane care and treatment. Over 12 years has passed since the last OIG audit, even if USDA followed the OIG's 2010 recommendation, would it be fair to say those recommendations may not have anticipated the regulatory landscape as it exists today? Does the OIG plan to assess USDA's enforcement beyond its initial recommendations and offer new recommendations where necessary to achieve animal welfare?

Response: As discussed with your staff in August 2022, OIG has recently updated the wording of the Animal Care Program Oversight of Dog Breeders Site Visits audit objective to focus on previously identified areas of weakness and examine whether they are being effectively mitigated. The revised objective, which is discussed in response to question 2, allows OIG to assess the current state of such areas and the adequacy of APHIS' oversight of dog breeders. OIG will provide recommendations for corrective action if findings are significant within the context of the audit objectives.

7. Will the OIG be evaluating whether the Agency is appropriately exercising its confiscation authority?

Response: As discussed above, we plan to evaluate the adequacy of APHIS' controls to ensure dog breeder compliance with the Animal Welfare Act and assess the Agency's compliance based on policies and regulations. The planned objective of the audit is discussed in response to question 2. Our current objectives do not include evaluating whether the Agency is appropriately exercising its confiscation authority.

8. Will the OIG be evaluating whether the Agency is appropriately exercising its authority to suspend a license?

Response: OIG's plan for FY 2023 includes an audit entitled "Animal Care Program Oversight of Dog Breeders—Site Visits." The planned objective of the audit is discussed in response to question 2. Our current objectives do not include evaluating whether the Agency is appropriately exercising its authority to suspend a license.

Mr. BISHOP. At this time I would like to recognize the gentlelady from Illinois, Ms. Underwood.

You have five minutes for questions.

Ms. UNDERWOOD. Thank you, Mr. Chairman.

And thank you to our witnesses for being here and for the important work that you do.

Cybersecurity needs to be front of mind for every industry in America right now, including agriculture. The cyber threat proposed by Putin's unprovoked war in Ukraine and the solar wind attack last year underscores just how vulnerable our Federal agencies and critical infrastructure can be.

Weak cybersecurity at our Federal agencies exposes Americans to privacy and security threats while putting our national security at risk, and at USDA, attacks or disruption to agency operations threatens our food supply, our economy, and our scientific achievement.

So today I would like to learn more about your assessment of the cybersecurity vulnerabilities at USDA and your plans in the space moving forward.

Your office's fiscal year 2021 Information Security Modernization Act audit reported that USDA's IT security program for fiscal year 2021 was, quote, "not effective." This clearly is cause for some concerns.

Ms. Fong, without going into sensitive detail on this public setting, can you tell us broadly what areas of USDA's IT security program warrant the greatest or most urgent attention for fiscal year 2022?

Ms. FONG. I will be happy to comment on that and then, Gil, I think you may have some additional details to offer.

The department's IT security posture has been a significant issue for any number of years. We have not yet at the department made it to an adequate level of IT security, and that is something that just continually needs attention.

What we see, generally speaking, is that at the department level there are good policies that are put into place, but then each individual USDA agency has to implement that with regard to all of its IT systems, and that is where we see a number of challenges over the years.

So there needs to be concerted effort throughout the department to bring every agency into a secure environment. That being said, we do that FISMA review every year to provide an overall picture.

We also have a number of ongoing and planned audits focused on specific aspects of cybersecurity that are especially vulnerable.

And I will turn the mike over to Gil to offer some additional comments on that.

Mr. HARDEN. Thank you, Phyllis.

With respect to some of the key areas for them to focus on this year in response to the FISMA review we did, they need to focus on areas of risk management, data protection, and privacy, some security training, and configuration management type issues.

We also do look just for awareness on IT security as part of our financial statement of work. So it is covered in other areas annually as part of those reviews.

Other work that we have ongoing, two to highlight, one deals with some penetration testing that we are doing around security at this point in time.

Another area is configuration of USDA virtualization platforms.

We can be happy to schedule time with you and your staff to discuss all that and maybe some detail as well as some other work that we are doing in this IT security arena.

But it is one that we do have as a matter of focus because of the sensitivities that you mentioned, as well as it being a longstanding security weakness for the department.

Ms. UNDERWOOD. Good. I am looking forward to that conversation.

The audit noted that USDA has at least 22 open recommendations for actions to improve IT security. Only four were completed last year, while 16 new ones were added. Can you tell us more about why it is important that the agency implement these recommendations in a timely manner?

Mr. HARDEN. Implementing those in a timely manner will help put the policies in place so that they can be assessed, which is one of the areas that the department needs to take the next steps to be at a higher security posture.

They do have policies and procedures in place that are consistently implemented. They need to implement some other ones, but they need to take the next step of assessing how well they were implemented and revising where appropriate.

Ms. UNDERWOOD. And only about a third of USDA systems were reviewed by your office in the fiscal year 2021 audit. What budget would your agency need to complete a full IT security review that included all systems each year?

Mr. HARDEN. I would have to get back to you on that, but I would offer that we do a sampling of systems in any IT work or any audit or inspection work that we do. So the systems that are sampled each year are different.

And so like three agencies in OCIO were part of the review last year. There will be different agencies and systems that are reviewed this year. And other systems are also covered in other reviews.

Ms. UNDERWOOD. Well, given the heightened threat environment, I think this is an area that we would like to continue to explore and work with you to ensure the protection, again, of not just the critical Federal system, but the data and information so that we can continue to have a robust and reliable food supply chain in this country.

Thank you.

And I yield back.

Mr. BISHOP. Thank you, Ms. Underwood.

And at this time I am delighted to yield to the chair of the Military Construction, Veterans Affairs, and Related Agencies Subcommittee of the full Appropriations Committee, Ms. Debbie Wasserman Schultz, the gentlelady from Florida.

You are now recognized.

Ms. WASSERMAN SCHULTZ. Thank you so much, Mr. Chairman, and I appreciate the opportunity to talk with the IG and her team.

I want to return to the issue of animal fighting. I know a couple members have asked about this and animal welfare in general, but the USDA does play a major role in animal welfare because you are in charge of enforcing the Animal Welfare Act.

And animal fighting is not only cruel and unethical. It can also spread disease, and your role is, in particular, critical to bringing to justice those engaged in this horrendous act.

My question is of Mr. Tyrell.

Mr. Tyrell, my fellow animal lovers on this committee—as you can see there are many—joined me in working hard to increase your budget so that you have the resources needed to successfully locate and identify perpetrators.

Can you provide this committee with any details on what your office is doing with the increased funding Congress provided in recent fiscal years?

And what are you doing to coordinate efforts with State and local officials to leverage those resources provided to combat animal fighting?

Mr. TYRELL. Thank you, Congresswoman Schultz.

So we work very closely with both APHIS and our Federal, State, and local counterparts in looking at the Animal Welfare Act and conducting these investigations.

You know, every allegation we receive we have to assess carefully to look at the overall impact that each of these allegations may have on a criminal investigation or whether we should open a criminal investigation.

You know, these are very complex investigations, obviously, and we consider a number of factors before we open them, but any allegations of health and safety are really one of our highest priorities.

The monies that we received last year went a long way in helping us tackle this problem and put more resources into it. So any additional resources will obviously help us put more focus on this issue and try to, you know, bring it under control as best we can.

Ms. WASSERMAN SCHULTZ. And coordinating with State and local officials so you can leverage those resources?

Mr. TYRELL. We actively coordinate with State and local officials already. So you know, a lot of the allegations that we get concerning animal fighting actually come from our State and local counterparts.

And when they reach out to us, you know, we partner up with them and work very closely on trying to combat this problem.

Ms. WASSERMAN SCHULTZ. Have you been able to step up enforcement and increase investigations as a result of the funding?

Do you have more reach specifically?

Mr. TYRELL. We have. So last year, as an example, you know, we nearly saw probably about a 50 percent increase in the number of investigations that we are able to conduct from the previous year, and you know, a lot of that can be attributed to the additional funding that we received.

Ms. WASSERMAN SCHULTZ. Great. I want to turn to issues surrounding Florida citrus. In 2018, Congress provided more than \$2 billion for disaster assistance to help offset agricultural producers' losses related to hurricanes and wildfires.

Within that funding, we allocated \$340 million specifically to the Florida Citrus Block Grant Program, which is a joint venture between USDA and the Florida Department of Agriculture.

These were funds that were a lifeline for many citrus producers in Florida that have been on the frontlines of experiencing the damaging effects of climate change.

Mr. Harden, last June your office finalized a report evaluating this program. Can you provide us with a summary of your findings?

Mr. HARDEN. Yes, ma'am. A problem with the microphone.

Yes, we did take a look at that program, and one of the key things that we found was that a significant number of those participants, 31 of the participants we looked at, had not also applied for the Wildlife and Hurricanes Indemnity Program, which was a prerequisite for the block grant.

We did not make any additional recommendations regarding that matter in the report just because we had mentioned or we had already made recommendations in another report related to the hurricane funding.

Ms. WASSERMAN SCHULTZ. So I am sorry. If they made a mistake, does that means that there needs to be and better guidance from the department so that they include enough information to be eligible to receive the assistance?

Mr. TYRELL. Yes, I think that would be part of the answer. I mean, by the time—

Ms. WASSERMAN SCHULTZ. I am not sure why you would not have made any recommendations if that was an issue.

Mr. TYRELL. To explain that a little clearer, I am sorry. We had made recommendations to clarify that in another separate report. So we did not need to make the recommendations again.

Ms. WASSERMAN SCHULTZ. Okay. I would like a little bit more information from you on this than my time is allowing. So if you would follow up with me I would appreciate it.

Mr. TYRELL. I would be happy to follow up.

Ms. WASSERMAN SCHULTZ. Thank you, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you, Chair Wasserman Schultz.

At this time I am delighted to yield to the gentlelady from New York, Ms. Meng, for five minutes for your questions.

Ms. Meng, you have the floor.

Ms. MENG. Thank you, Mr. Chairman.

And thank you to Inspector Fong and your team for being here today.

I wanted to ask about a report that your office had released last August regarding the SNAP online purchasing pilot. As you know, this 2014 initiative was dramatically expanded from five to 47 States, including Washington, D.C., last year due to the coronavirus pandemic.

I have strongly advocated for expanding this pilot, including working in a letter with 94 New York elected officials from all levels of government to the previous administration.

But as we consider expanding, I want to make sure that this program is functioning with the utmost integrity to reach as many re-

cipients as possible. And that integrity has to include protecting participants' personal identifiable information.

The report noted that FNS had not updated its risk assessment since 2014, and we know it is problematic because many people have to submit really sensitive information like a Social Security number or their date of birth.

The report also stated that FNS can do a better job of monitoring, evaluating, and documenting retailers' compliance with safeguarding this personal information of SNAP participants, to which FNS agreed to.

I wanted to ask how frequently should FNS be updating its risk assessment to protect privacy and data.

And also, given that the total value of online SNAP purchase transactions increased from 18.9 million to more than 1.5 billion from March to December of 2020, are there any recommendations for FNS to ensure the program's integrity?

Ms. FONG. I will just offer a few comments and Gil may have more specifics.

And thank you for raising that audit. I think it really highlighted significant issues that you mentioned about protecting privacy information. That was really one of our significant findings there.

And the point that we were making on the risk assessment was that with the tremendous increase in the number of States and the dollars, the volume, that it clearly called out for a new risk assessment because the risk had theoretically just been magnified.

I think in terms of moving forward, we would recommend that FNS update risk assessments as appropriate when there is a change in the risk environment, if some other factor comes into being that would, you know, militate towards updating the risk assessment. That would be the time to do it.

Gil, I am going to turn it to you for some comment.

Mr. HARDEN. Yes, thanks, Phyllis.

And I will just echo kind of what you were saying in response to your question, Congresswoman, in terms of how often to update it.

IT is really driven by what is going on in the program and no way what the changes are. Clearly, with the increase in volume in the program, they needed to update that risk assessment.

Now that they know that there is the potential weakness with personal and private information, they need to make sure that risk is addressed as well.

Most all of the work that we have done at FNS with regard to COVID, as well as other agencies as well, has asked the question about risk. How do you assess that risk? What risk are you willing to accept? And why are you willing to accept those?

And for the ones that you are not willing to accept, what measures are you putting in place to address those risks?

So that is a very standard question that we are asking as part of that in most of the work.

Ms. MENG. Thank you.

I am sorry just to switch really quickly. I wanted to ask about another report that OIG had released about the Emergency Food Assistance Program, which was really helpful to us here in New

York and around the country when our local pantries experienced a dramatic increase in requests for their services.

But we know that there are many challenges that FNS faced in implementing TEFAP during the pandemic: cancelled food orders, inability to conduct oversight of State agencies because of travel restrictions.

From OIG's perspective, what lessons should FNS learn from the pandemic to ensure that they are better prepared to combat ongoing supply chain and food distribution issues?

Mr. HARDEN. In response to that, we are actually in the process of completing our work on TEFAP. We have issued two interim reports.

So there again, the one area that we saw that they needed to take better action on was looking at a risk assessment for TEFAP and the changes that were happening traditionally versus going on with COVID.

But the team is also working on the final questions that we were looking at now and we may have some additional insights into your questions with that report that will be forthcoming.

Ms. MENG. Great. I would love to see that.

Thank you, Mr. Chairman, and I yield back.

Mr. BISHOP. Thank you, Ms. Meng.

At this time, I am delighted to recognize the gentleman from Texas, Mr. Cuellar. You have five minutes, and you are now recognized.

Mr. CUELLAR. Thank you, Mr. Chairman.

And, again, to the witnesses, thank you so much.

The committee is a big supporter of the USDA's Reconnect Program to help the rural and the underserved communities to make sure they can access the digital tools so they can improve their health, educational, economic outcomes.

As you know, the committee added an additional \$450 million, and I want to thank the chairman for his leadership on this Reconnect Program in the fiscal year 2022 appropriations, and that is on top of the \$2 billion that got provided in the Infrastructure Investment and Jobs Act.

My question, and I think we all have got different communities that have high poverty. Along the U.S.-Mexico border we have what we call the Border Colonias, basically no water, no sewage, and I think a lot of us members have similar types of communities.

My question is: do you all have any metrics or performance measures that have been established to ensure that the Reconnect Program is effectively serving those communities that are impacted by high and persistent poverty?

It is a great program, but I keep hearing from constituents in my area, and I do not know about other members, about not having enough funding for this program so we can connect them.

I would appreciate any ideas on performance measures and how you measure the impact of the Reconnect Program.

Ms. FONG. That is a really interesting question. As you know, we have talked earlier in the hearing about the fact that we have got an ongoing audit or inspection of the Reconnect Program focused on eligibility, which is, you know, an important question to ask.

But your question goes even further, which is to assess the impact of the program and are the funds getting to the communities that have a great need for them.

And as I am sitting here thinking about it, the data stories that we talked about earlier in the hearing, which is a product that we will be issuing shortly for the Food Box Program, which takes data that shows where the program monies went, who touched it, who received the benefit of it; it could be that this could be an interesting project for us to think about from a data analysis standpoint, to see is their data shows; does RUS keep the data that shows the communities it is going to?

What does that look like with an overlay of, say, census data?

And what can we learn from that?

So I think that is a really interesting question, and we will go back and give some thought to that.

Gil and Jenny might have comments as well.

Mr. HARDEN. Yes. I was just going to add from the rollout of the infrastructure money and starting to listen at how the department is dealing with all four buckets of money, one of the things that they talk about is the equity action plans, and which is getting to those underserved or less served.

And so we will be monitoring and following how they are going to measure that, and if they are not measuring that, asking questions as to how or why that is not being addressed.

Mr. CUELLAR. Well, thank you.

My time is up but I appreciate any way the committee can work with you. Thank you so much.

Thank you, Mr. Chairman.

Mr. BISHOP. Thank you, Mr. Cuellar.

I think we have completed the first round, and we will move on to a second round, but during the second round, given the fact that we have got some other activities, particularly the memorial for Mr. Young, we are going to reduce the time for the second round to two minutes.

At this time I yield to myself to continue to question Ms. Fong.

The OIG's latest semiannual report to Congress was issued in November of 2021, and it shows significant decreases in the number of open audit recommendations, OIG recommendations of which agencies have not completed corrective actions.

Since OIG started reporting these open recommendations in 2014, the average numbers about 420 at the end of a fiscal year. As of September 30th, 2021, the number of open recommendations was down to 260.

Can you explain what that means? Is it because you are issuing fewer recommendations or the agency is putting more effort into implementing your recommendations or is it something else?

Or is this cause for celebration?

Ms. FONG. Thank you for the question.

We issue recommendations where we think recommendations are warranted. So it is not that we are trying to issue fewer recommendations.

I think the change that we are seeing comes from the tone at the top at USDA where the Secretary has made it very clear to all of us that he wants to see these recommendations addressed where

appropriate; take action if circumstances have changed. We get into dialogue with that.

We have, our office has worked very closely in partnership with the Office of the Chief Financial Officer and the program agencies to really identify the issues that need to be addressed and to pursue them.

And I think what we are seeing here is the result of that concerted effort on the part of the whole department to address these issues.

Mr. BISHOP. Thank you, Ms. Fong.

Dr. Harris, you are recognized.

Mr. HARRIS. Thank you very much.

Just a brief question. You know, I have seen some memos from March 23rd from the U.S. Department of Agriculture instructing the WIC Program, the SNAP Program, and the School Lunch Program to help conduct voter registration.

And what is of concern to me in the memos, and I read it verbatim, the first memo says, "The NVRA requires SNAP State agencies to offer voter registration opportunities to any person who applies or renews for an application."

But it does not say that an instruction has to be provided as to whether or not someone is actually eligible to vote.

So, for instance, we know that under WIC and under School Lunch Program, people are in the country illegally, can get the program, but obviously are not eligible to vote. They do not even have a green card much less eligible to vote citizenship.

Why is that instruction? I mean, would that not be an important thing to emphasize that part of the education of the people who are giving these voter registration forms should be to inform them of who actually can vote and who cannot?

Ms. FONG. That is a very interesting issue. I personally am not aware and have not seen the memos. I think I do understand your question and will have to go back and take a look at that and perhaps reach out to your staff, you and your staff, to see if there is anything that is appropriate for us to do at this point.

Mr. HARRIS. All right. And if I can, Mr. Chairman, I will be more than happy to enter the three memos into the record and provide them to the OIG.

I just, you know, wonder whether this is the best use of nutrition program money because my understanding is administration money can be used for this.

And if we are going to do it, whether or not we should also be providing a clear guidance on who can and cannot register to vote or who can or is not eligible to vote.

Anyway, thank you very much, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you, Dr. Harris.

Ms. Underwood, you are now recognized.

Ms. UNDERWOOD. Thank you.

Last year constituents reached out to my office regarding a USDA licensed tiger exhibitor with a facility in my district. These constituents were horrified to find publicly available inspection reports from the Animal and Plant Health Inspection Service, APHIS, showing repeated violations of the Animal Welfare Act.

Some of these violations affected the welfare of the animals, like a lack of veterinary care. Others endangered the community, like insufficient fencing for tigers at another facility in Kansas.

The idea of a local Tiger King was scary enough, but APHIS' response added to our angst. We tried for months to get answers from the agency, and we were eventually able to get a staff level briefing, but at that briefing, we were informed that the exhibitor's license had just been canceled.

But then we learned last week that APHIS has reversed course and issued a new license to a repeated offender for a facility in Kansas.

In a March 2021 report, your office assessed that, quote, "APHIS cannot fully ensure the safety of the animals exhibited or the safety of the public who view those animals."

In light of this disturbing example, I am concerned that this is still the case. Ms. Fong, does your office plan to conduct any kind of follow-up to the March 2021 report to evaluate whether APHIS is now able to ensure the safety of animals and the public?

Ms. FONG. Just thank you for bringing that to our attention. I had not heard of that situation.

As you mentioned, we issued that report about a year ago. We do not normally do a follow-up audit a year later. We try to give the agency time to, you know, address our recommendations.

That being said, we can go back and take a look to see what the status of our recommendations are, where the agency is with it, and see if there is anything appropriate for us to do at this point.

Ms. UNDERWOOD. Yes, ma'am. I think that that would be an appropriate course of action. It is clear to me that APHIS has a lot of room for improvement, and OIG's review and recommendations are welcome first steps, but these wild animals in our communities is upsetting.

I yield back.

Mr. BISHOP. Thank you, Ms. Underwood.

Ms. Fong, we talked about major management challenges last year and how some require persistent efforts year after year just to even make progress. I am particularly concerned about improper payments.

It appears that USDA has not been compliant with various improper payment statutes for each of the last ten years. Earlier this month, your office reported that the previous administration may have overpaid over \$57 million to over 150,000 producers through the Market Facilitation Program.

Would you tell us what went wrong and what corrective actions has USDA taken?

And are they able or can they recoup the money?

Ms. FONG. Thank you.

You are referring to a report that we recently issued on the Market Facilitation Program, which was based on a statistical sample, a review of a number of producers and the payments that were made to them.

And we found, you know, as you mentioned, that a number of payments were improperly made.

The recommendations that we issued to the department were that FSA needs to strengthen its controls to make sure that they

have the right documents to support the payments that they are making.

And we also recommended that FSA go back with respect to the 2021 payments that we thought were not supported and talk to the producers and take any appropriate action to get repayment of the overpayment, if appropriate.

So I think moving forward, you know, we have made those recommendations to improve the program and to try and recoup some of the funds.

Mr. BISHOP. Thank you.

Mr. Harris.

Mr. HARRIS. I have no other questions, Mr. Chairman.

Mr. BISHOP. Okay. Well, I have one other question.

Your annual plan for fiscal year 2022 indicates that you expect to use about a third of your resources dedicated to the investigation side of OIG on the Farm Production and Conservation Programs. This is almost 50 percent higher than anticipated for last year.

Can you tell us the reason you are expecting to need more investigative resources for the Farm Production and Conservation Program this year?

And are there trends of specific issues or concerns that you are expecting or that you are seeing?

Ms. FONG. Thank you for that question.

I think either Kevin or Ann would offer some thoughts on that.

Ms. COFFEY. Okay. Just in terms of the program, each year we assess where we are in terms of what percentage of resources that we use and that is based on sort of what our current work is.

So for fiscal year 2021, we are looking at the number of cases we had with respect to the farm servicing and conservation services, and so from that perspective, that sort of serves as a basis for us to determine what our next year's work is going to do, especially in light of the fact that we have cases that go multiple years. We do not necessarily conclude a case in one year.

And obviously with COVID there has been a number of programs that are out there which are responsive and fall under the farm service agency, where we have seen an uptick in investigative work.

And so that really would account for the increase that we have seen or that we anticipate seeing for fiscal year 2022.

Mr. BISHOP. Thank you, Ms. Coffey.

Ms. Fong, Ms. Coffey, Mr. Harden, Ms. Rone, and Mr. Tyrell, thank you for your testimony and for spending time with us today.

Along with what we have discussed, we will also forward additional questions for the record, and we appreciate your diligence in getting responses to us in a timely manner.

Dr. Harris, do you have any closing remarks?

Mr. HARRIS. No, I do not. I just want to thank the Office of the Inspector General for the wonderful work the Inspector Generals do across the government agencies and look forward to working with you and working on your budget request.

Thank you. I yield back.

Mr. BISHOP. Thank you, Dr. Harris and all of the members of the committee for attending.

Thank you also to our staff who put this hearing together.

And, again, thank you, Ms. Fong and your staff for your participation and the excellent work that you do year after year.

With that, I believe that this subcommittee has completed its work for the day, and the subcommittee is now adjourned.

[Questions submitted for the record follow:]

The Honorable Grace Meng
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and
Related Agencies
Questions for the Record
Fiscal Year 2023 Oversight: Office of Inspector General, U.S. Department of Agriculture

At a House Agriculture Subcommittee on Nutrition, Oversight, and Department Operations, Inspector General Fong emphasized how USDA “is continually challenged to find effective ways to encourage and support all.” Given the Department’s history of civil rights issues, including thousands of filed claims of denial of equal services to farmers of color, earning the trust of communities of color could be a challenge as the Department administers programs designed to support these farmers and ranchers.

As the 2017 Census of Agriculture noted, Asian American producers and farmers had grown 7% from the 2012 census. I am interested in the participation of Asian American, Native Hawaiian, and Pacific Islander farmers in programs like the Socially Disadvantaged Farmers and Ranchers program and how effective the Department’s outreach is in these communities when it comes to programs like this, or the loan forgiveness program that was established under the American Rescue Plan.

- **How can USDA improve the trust from and outreach to socially disadvantaged groups, including AANHPI farmers and ranchers?**

THURSDAY, APRIL 28, 2022.

U.S. DEPARTMENT OF AGRICULTURE

WITNESSES

HON. TOM VILSACK, SECRETARY OF AGRICULTURE, U.S. DEPARTMENT OF AGRICULTURE

JOHN RAPP, DIRECTOR, OFFICE OF BUDGET AND PROGRAM ANALYSIS

Mr. BISHOP. Good morning. This hearing will now come to order.

As this hearing is fully virtual, we must address a few house-keeping matters.

For today's hearing, the chair or staff designated by the chair may mute participants' microphones when they are not under recognition for the purposes of eliminating inadvertent background noise.

Members are responsible for muting and unmuting themselves. If I notice that you have not unmuted yourself, I will ask if you would like staff to unmute you. If you indicate approval by nodding, staff will unmute your microphone.

I remind all members and witnesses that the five-minute clock still applies.

If there is a technology issue, we will move to the next member until the issue is resolved and you will retain the balance of your time.

You'll notice a clock on your screen that will show how much time is remaining. At one minute remaining, the clock will turn yellow. At 30 seconds remaining I will gently tap the gavel to remind members that their time is almost expired.

When your time has expired, the clock will turn red, and I will begin to recognize the next member.

In terms of speaking order, we will begin with the chair and the ranking member. Then members present at the time the hearing is called to order will be recognized in order of seniority and, finally, members not present at the time the hearing is called to order, in the order of their arrival.

Finally, House rules require me to remind you that we have set up an email address to which members may send anything they wish to submit in writing at any of our hearings or markups. That email address has been provided in advance to your staff.

Well, good morning, and welcome to today's budget hearing. Today we are examining the Department of Agriculture's fiscal year 2023 budget request.

I am pleased to introduce our distinguished witness today, Secretary Tom Vilsack.

Thank you for being here, sir. It was good having you in Albany, Georgia last week to announce USDA's investment in radium screens and to highlight the impact of Infrastructure Investment

and Jobs Act and what it will have and how it will impact rural communities across our country.

Now, this budget comes to Congress at a very important moment in time. For the past two years, USDA has played a major part in the government's response to COVID-19. Through six coronavirus relief bills, including the American Rescue Plan Act, Congress entrusted USDA with tens of billions of dollars and additional flexibilities.

For those funds and authorities, USDA is helping to put food on the table both at home and at school by expanding access to food programs.

USDA is strengthening the food supply chain by investing in infrastructure and support for food processors and local food systems to build resiliency in the food supply.

And USDA is doubling down on its efforts in rural America, including investments to support rural hospitals, local communities, rental assistance for low-income and borrowers, and further investments in broadband expansion.

But even as some aspects of the pandemic response wind down, there are issues such as addressing climate change, securing the food supply chain, ensuring more of our rural communities have access to the same high-speed Internet as our suburban and urban communities. That will keep USDA at the forefront of American policy priorities for the foreseeable future.

With all that as the backdrop, USDA's fiscal year 2023 request for this subcommittee is \$23.6 billion, an increase of 2.2 billion, or 10 percent, over fiscal year 2022.

Overall, I am pleased that this budget continues to build on agency-wide priorities that were funded in fiscal year 2022, including investments to ensure equitable participation in USDA programs, address the impacts of climate change, and support staff and leadership officers at USDA.

Notable investments include a \$200 million increase for the Re-Connect Program; a \$119 million increase for the Agriculture and Food Research Initiative; \$50 million to expand Conservation Assistance for beginning, historically underserved, or veteran farmers; fully funding the SNAP, Child Nutrition, and WIC Programs to meet expected participation in fiscal year 2023.

So today I will be interested to hear about how USDA can improve the quality of life in our communities, how its work affects the lives of every American on a daily basis.

Secretary Vilsack, thank you, again, for being here. I appreciate all of the work that you have done in a little over a year, and I look forward to working with you as the fiscal year 2023 process moves forward.

[The information follows:]

Opening Statement of
Chairman Sanford D. Bishop, Jr.
FY 2023 USDA Budget Request with Secretary Vilsack
April 28, 2022

Good morning and welcome to today's budget hearing.

Today we are examining the Department of Agriculture's Fiscal Year 2023 budget request.

I am pleased to introduce our witness, Secretary Vilsack – thank you for being here. It was good having you in Albany, Georgia last week to announce USDA's investment in Radium Springs, and to highlight the impact the Infrastructure Investment and Jobs Act will have in rural communities across the country.

Now, this budget comes to Congress at an important moment in time. For the past two years, USDA has played a major part in the government's response to COVID-19. Through six coronavirus relief bills, including the American Rescue Plan Act, Congress entrusted USDA with tens of billions of dollars and additional flexibilities.

With those funds and authorities, USDA is helping to put food on the table both at home and at school by expanding access to food programs. USDA is strengthening the food supply chain by investing in infrastructure and support for food processors, and local food systems, to build resiliency in the food supply. And USDA is doubling down on its efforts in rural America, including investments to support rural hospitals and local communities, rental assistance for low-income and elderly borrowers, and further investments in broadband expansion.

But even as some aspects of the pandemic response wind down, there are issues, such as addressing climate change, securing the food supply chain, and ensuring more of our rural communities have access to the same high-speed internet as our suburban and urban communities, that will keep USDA at the forefront of American policy priorities for the foreseeable future.

With all that as the backdrop, USDA's FY 2023 request for this Subcommittee is \$23.6 billion, an increase of \$2.2 billion or 10% over FY 2022. Overall, I am pleased this budget continues to build on agency-wide priorities funded in FY 2022, including investments to ensure equitable participation in USDA programs, address the impacts of climate change, and support staff and leadership offices at USDA.

Notable investments include:

- A \$200 million increase for the ReConnect Program.
- A \$119 million increase for the Agriculture and Food Research Initiative.
- \$50 million to expand conservation assistance to beginning, historically underserved, or veteran farmers.
- Fully funding the SNAP, Child Nutrition, and WIC programs to meet expected participation in FY 2023.

So today, I'll be interested to hear about how USDA can improve the quality of life in our communities and how its work affects the lives of every American on a daily basis.

Secretary Vilsack, thank you again for being here. I appreciate all the work you have done in a little over a year, and I look forward to working with you as the FY 2023 process moves forward.

Mr. BISHOP. Now, let me ask our distinguished ranking member, Dr. Harris, if he has any opening remarks, and if so, I would like to recognize him at this time.

Dr. Harris.

Mr. HARRIS. Thank you, Chairman Bishop.

Thank you, Secretary Vilsack. I also want to welcome you to today's hearing. I look forward to discussing the U.S. Department of Agriculture's fiscal year 2023 budget request and some other topics of importance.

Now, the USDA's budget request for the Agriculture Subcommittee, as the chair has just indicated, is an increase of ten percent over last year's level, which is a large increase.

Yet this request does not address the immediate concerns on the minds of consumers, farmers, and ranchers, such as inflation, which is at a 40-year high at 8.5 percent and began skyrocketing well before the war in Ukraine.

Supply chain issues continue to affect the agriculture industry, from bottlenecks at shipping terminals, labor shortages in the trucking and rail industries, and farm equipment and parts in short supplies.

It is unfortunate the President's budget includes provisions threatening the stepped-up basis and imposing capital gains taxes on hardworking farm families to pay for his climate agenda and other big government spending.

These ideas have been rejected by Congress before when the administration tried to sell the American people on the Build Back Better plan which included those provisions, and I expect these proposals will meet the same fate again.

Now, with the war in Ukraine, we are on the brink of a global food crisis. America's producers are the most innovative, efficient, and capable in the world and are ready to step in to fill the needs.

But when fertilizer costs are up more than 300 percent in some areas, there are significant concerns among producers about the future. Rising energy and input costs in agriculture are taking away from the momentum of higher commodity prices that might help producers break even or be just above the bottom line.

USDA needs to be communicating the department's plan to address this global food crisis and support producers in meeting the increased global demand.

While this subcommittee is responsible for discretionary funding, I think it is important that we maintain close oversight of the mandatory spending as well. USDA has proven itself quite capable of single-handedly increasing mandatory spending without a blink from the Office of Management and Budget or approval from Congress.

Last year, USDA unilaterally increased spending \$20 billion a year on the SNAP Program by reevaluating the Thrifty Food Plan, which is a market basket of foods a household should purchase for a healthy diet and is used to establish SNAP benefit levels.

As stewards of taxpayer dollars, we have an obligation to scrutinize mandatory funding when it goes beyond what Congress has authorized or intended, and that was one example. My Republican colleagues at the House and Senate Agriculture Committee have

asked the GAO to review USDA's methodology for reevaluating the Thrift Food Plan, and I look forward to results of that review.

Mr. Secretary, we had a chance to visit a few months ago. So you know that I have a large poultry district, and I am closely watching the highly pathogenic avian influenza outbreak.

I appreciate the recent meeting I had with the Animal and Plant Health Inspection Service Administrator, Kevin Shea, and want to continue working with USDA on addressing this very destructive disease.

I am also monitoring the Packers and Stockyards Act rulemaking process with great concern to my constituents. Greater transparency and competition in the livestock and poultry markets is well intentioned, but there could be unintended consequence.

So I will be closely watching as the department moves forward with an analysis of the economic effect of any changes.

Again, Mr. Secretary, I appreciate you being with us and look forward to today's hearing.

I yield back, Mr. Chairman.

Mr. BISHOP. Thank you, Dr. Harris.

I am not sure if the chair of the full committee, Ms. DeLauro, is on the line. Is she?

If so, I would recognize her.

[No response.]

Mr. BISHOP. If not, I would also recognize the ranking member of the full committee, Ms. Granger, if she is on the line, if she is available.

[No response.]

Mr. BISHOP. Hearing from neither at this time, I would like to recognize Secretary Vilsack, and without objection, sir, your entire written testimony will be included in the record, and I will recognize you now for your opening statement, and then we will proceed with questions.

Secretary VILSACK. Mr. Chairman and Ranking Member and members of the committee, thank you very much for the opportunity to be with you this morning.

You know, I do not think this committee needs to be reminded. Perhaps those who are watching this hearing need to remember the importance and significance of the food and agriculture industry in our country. It is a critical part of our infrastructure.

Our food independence is critical to our national security. It contributes nearly 20 percent for our Nation's economic activity; plays an important role in ten critical infrastructure sectors, everything from food and health and water to manufacturing and finance and transportation; and is responsible for employing nearly 29 million Americans.

Our national security interests are intimately tied to the strategic investment in the Department of Agriculture in this sector and to rural American. This sector's assets and supply chain systems and networks provide vital services to our Nation and are essential to our security, our economic vitality, and our way of life.

I want to spend the remaining minutes of my time this morning talking about three specific areas that often do not get the kind of attention that I think they deserve.

Let me begin with the fact that as of today, the Department of Agriculture has 5,300 fewer people working at it than it did when I left office in January of 2017. This is despite the fact that both the discretionary and mandatory budgets have increased. The discretionary budget has been increased by 18 percent, and the programmatic spending has increased by several billion dollars.

The reality is that effective management of the resources that you all provide does, in fact, require staffing. We have critical shortages in rural development and food and nutrition in the consumer service area, and in our NRCS area or conservation.

As you look at this budget, you are going to see requests for additional staffing, and it is a response to the fact that we are down by 5,300 folks. Now, what is that?

I think there are two fundamental reasons, and I appreciate the fact that this committee last year for the first time in quite a while not only approved pay increases for workers, but also provided the resources for those pay increases.

In the past that has not been the case, and the result is that oftentimes we would have to reduce staff in order to cover the cost pay increases.

At the same time, while non-discretionary spending grew from 2014 to 2021 by 27.4 percent, USDA's discretionary budget grew by only 14 percent, roughly one-half of other agencies.

During the course of the last four or five years, we have seen non-defense spending by Congress increase by 21 percent, while USDA's increase was less than six percent.

I would suggest to you that as you look at this budget, please bear in mind the relative position that USDA bears to other non-defense administrations and the important work that we do at USDA.

The second area I would like to talk about briefly is research. You know, it is interesting. Over the last 24 years, health care research has increased by over 400 percent. R&D research at the USDA, however, over the last ten years, if you take inflation into consideration, has essentially been flatlined.

I would suggest to you that it's important and necessary for us to pay attention to agricultural research, as I'm often reminded while health care research can cure diseases, USDA research can prevent disease, both in terms of people and in terms of animals.

Our agricultural share of the total Federal investment in non-defense R&D over the last 20 years or so has declined from 4.3 percent of the overall non-defense R&D to now 2.3 percent.

So I would encourage this committee to take a look at the important role that research can play and the necessity of having adequate resources. We are falling behind in agriculture research to our friends in China, and that is an area that I do not think we want to essentially be second place in.

And I think it ultimately has negative implications for agricultural productivity and our ability to deal with the pests and diseases that we that we are currently dealing with and those that may occur as a result of climate change.

The last item I want to visit with in the remaining time that I have is just to remind the committee of the importance of our rental housing portfolio at USDA. We have over 403,000 units that we

essentially provide resources to that enable to have families have access to affordable rental housing.

Unfortunately, many of the mortgages on those properties are going to be paid off in the very near future, and as they are, those units are going to come out of the Rental Assistance Program, which is going to create some challenges for families.

In addition, we have not over a period of time invested in revitalizing and rehabbing many of those units. In fact, we are going to begin to see a loss of thousands of units as a result.

So we are requesting additional resources to allow us to upgrade the rental housing stock in rural America so that we can continue to provide decent housing for those who want to live, work, and raise their families in rural communities.

Mr. Chairman, I know there are a variety of issues that you all want to discuss, and so I will stop there and look forward to the questions of the committee.

[The information follows:]

**Statement by
Thomas J. Vilsack
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 28, 2022**

Thank you, Chairman Bishop, Ranking Member Harris, and members of this Subcommittee, for inviting me here today to discuss the Administration's priorities and to provide you an overview of the President's Fiscal Year (FY) 2023 Budget for USDA.

Under the President's leadership, America is building back better. We have begun to turn the tide on the pandemic and our country has made historic progress in the face of unprecedented challenges. With Putin's price hike affecting American families at the pump and at the grocery store, we are pulling out all stops to tackle inflation. At the same time, economic indicators are overwhelmingly positive. We created more than 6.5 million jobs in 2021, the most our country has ever recorded in a single year. Our economy grew at 5.7%, the strongest growth in nearly 40 years. The unemployment rate has fallen to 3.8%, the fastest decline in recorded history. This progress was not an accident. It is a direct result of President Biden's strategy to combat the pandemic and grow our economy from the bottom up and the middle out.

The FY 2023 Budget details the President's vision to expand on this Administration's progress and commitments to the American people and recognizes the historic investments that Congress has made through the American Rescue Plan and the Infrastructure Investment and Jobs Act. This Budget begins to reinvest in USDA's long overlooked workforce through investments in staff and technology, as well as the foundations of our country's strength: education, research, food security, safe and affordable housing, and productive lands. These are all areas that for far too long their funding has been stagnant or nearly level. The work proposed by this budget will spur new job creation and opportunities in rural America; help build resilience in the food supply chain and restore America's advantage in agriculture; leverage all of USDA's expertise to address climate change; and support a stronger nutrition safety net.

The President's Budget for 2023 for USDA programs within this Subcommittee is \$189 billion, of which approximately \$165 billion is mandatory funding and \$24 billion is net discretionary funding. It gives USDA a new set of tools and builds on our existing capabilities to address the urgent challenges of our time—responding to the nutrition insecurity crisis, investing

in research, rebuilding the rural economy, strengthening and building markets for farmers and producers, and addressing the impacts of climate change. This Budget is not a wish list, it is a to do list. The challenges of our time and our ability to address those, require serious investments in USDA agencies and operations, non-action or continued underinvestment has significant and immediate implications for the United States of America.

Rebuilding Rural America

It is no surprise when I say the United States' prosperity and well-being are intrinsically tied to rural America's ability to thrive in the new global economy. The President's Budget proposal enables USDA to work closely with rural America and empower communities to take the reins as they rebuild their economies, workforces, and infrastructure to create more opportunities for a circular economy where wealth is created and stays in rural areas.

It has been said that Rural Development can build a town from the ground up. The essence of that statement is that USDA Rural Development, when well-resourced and well-staffed, provides support that is critical to improving quality of life in rural America – whether it is through increased access to broadband service, affordable housing in underserved communities, or resilient wastewater infrastructure. Beyond improvements to the quality of life, these investments attract new businesses, create a greater sense of pride in the community, and allow rural America to prosper.

To bring these outcomes to reality, the Budget proposal increases funding for Rural Development by \$935 million, including critical increases for combatting climate change. Funding includes \$1.773 billion for USDA multifamily housing programs, an increase of \$256 million over the 2022 enacted level. This significant investment would start to reverse chronic defunding of these programs and help address housing insecurity and rent burdens in rural communities. This funding will be prioritized for projects that improve energy or water efficiency or facilitate climate resilience. Additionally, the Budget proposes \$1.5 billion in loan level for low-income single family housing loans, an increase of \$250 million, and proposes a critical increase of \$204 million for Rural Development to revitalize its staffing and technological capacity. The Budget also increases USDA's investment in expanding rural broadband service to put rural America on a long-term path to economic success. The Budget includes \$600 million for ReConnect, an increase of \$200 million in new competitive funding

over the 2022 enacted level, to provide flexible loans and grants to deploy broadband to unserved areas. This investment also builds on the \$2 billion of funding provided by Congress in the Infrastructure Investment and Jobs Act.

The President's Budget proposes \$727 million in budget authority and \$1.5 billion in loan level for USDA's Water and Wastewater Grant and Loan Program. This includes a new \$100 million in set aside funding for lead pipe replacement in rural households, and \$140 million in loan level for the most economically distressed communities with borrower interest rates offered at one and zero percent. This is an increase of \$73 million over the 2022 enacted level and is a key investment in safe drinking water and sanitary waste disposal systems, which are vital to achieving a high quality of life and are essential to rural residents. The proposed increase would create good-paying jobs and help thousands of communities across rural America gain much needed access to clean drinking water.

Supporting Nutrition for the Nation

USDA's core nutrition programs are the most far-reaching, powerful tools available to ensure that all Americans, regardless of race, ethnicity, or background, have access to healthy, affordable food. Building on these programs, the Budget makes strategic investments to ensure that those in need can access nutrition programs that are run efficiently and effectively; to advance nutrition security through education and evidence-based interventions; and to support the purchase of nutritious and local foods. I want to highlight just a few priorities.

We know that the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) drives better health for infants and more nutritious diets for children, and it is a key tool to address disparities in maternal and child health outcomes. Continuing the bipartisan commitment to full funding, the Budget requests \$6 billion for WIC to serve an estimated 6.25 million moms, infants, and young children per month in FY23. It also proposes to continue the enhanced Cash Value Benefits (CVB) through 2023 to provide participants with increased benefits to buy fresh fruits and vegetables. This ensures that all participating women and children have access to the scientific-based recommended level of fruits and vegetables.

SNAP is the primary source of nutrition assistance for many low-income people and research has shown that participation in SNAP reduces food insecurity and allows families to have healthier diets. Healthier diets are known to lead to better health outcomes and, in the long-

run, lower health care costs. In 2023, participation is estimated to increase to an average level of 43.5 million participants per month from 42.3 million in 2022. While participation is expected to increase, the overall cost of the program is actually expected to decrease by more than \$29 billion. The decrease is primarily due to the expected expiration of emergency allotment (EA) payments that have been provided during fiscal years 2020 through 2022. Those EA payments and other program waivers are anticipated to continue for the length of the Public Health Emergency, likely through the majority of FY 2022.

Child nutrition programs, such as the National School Lunch Program, School Breakfast Program, Summer Food Service Program, and Fresh Fruit and Vegetable Program, play a crucial role in ensuring that children receive nutritious meals and snacks that promote health and, educational readiness. When students participate in school meals programs, their behavior, comprehension, and attendance improve. The meals children receive prepare them for learning and shape their food choices and health outcomes as adults. Providing healthy, nutritious, and appropriate food choices can decrease obesity rates, and will reduce food insecurity and result in better health outcomes. To better support this work this Budget funds the Child Nutrition Programs, through new appropriations and prior year balances, at a level that will allow for the anticipated increases in participation and food cost inflation. The Budget projects serving 5.6 billion lunches and snacks (an increase of about 350 million over the current estimate for 2022) and 2.7 billion breakfasts in schools, 2.2 billion meals in child and adult care programs, and 145 million meals through the Summer Food Service Program.

Mounting evidence supports the effectiveness of USDA nutrition education and promotion efforts to improve knowledge and catalyze healthier behaviors. Still, USDA faces multiple challenges in our efforts to deliver effective and cohesive nutrition education across programs. The Budget seeks funding for a new initiative to build and broaden Food and Nutrition Service' (FNS) capacity to deliver effective nutrition education and promotion to all Americans within existing program structures by supporting research and evaluation of effective strategies; leveraging partnerships with States, local, and nongovernmental organizations; targeting underserved communities with culturally appropriate resources and interventions; and improving public access to USDA's nutrition education resources.

The Budget also invests in the vital functions of FNS to deliver on this ambitious agenda. While federal funds managed by FNS have increased dramatically, as much as 70 percent in

recent years, the staffing levels have decreased. The Budget proposes significant investments in FNS to ensure the agency can provide the appropriate level of oversight and stewardship, pursue its crucial mission to address food and nutrition security, and innovate and modernize to best serve those in need.

Supporting Research

USDA research influences every program that we implement, and it is incredibly important to deepen our support for the organizations that conduct and synthesize USDA studies and information. The share of total food and agriculture research conducted by the U.S. government was relatively stable at around 50 percent from 1970 to 2008. But, by 2013, that share had fallen to under 30 percent. That's a significant difference since private R&D tends to focus on commercial applications (and only a few major crops and livestock markets) while the public sector is still responsible for much of the fundamental research that creates the building blocks for major agricultural innovations. Fundamental work conducted by public R&D, in areas like food safety, animal health, specialty crops, water quality and human health, benefit society more broadly but may offer potentially lower monetary returns or nonmarket benefits.

Between 1948 and 2019, total agricultural output in the United States grew by 142 percent. This rise was not due to increases in agricultural land or labor—in fact, both inputs declined over the period. The productivity stemmed from the adoption of a whole suite of innovations and technology transfer in crop and livestock breeding, nutrient use, pest management, farm practices, and farm equipment and structures. These innovations are the fruits of publicly funded agricultural R&D.

That is why this Budget proposes an increase of over \$355 million for a total of \$4.05 billion for USDA's research, education, and economics programs. This investment is critical to addressing the mounting hunger and nutrition insecurity crises, strengthening and building markets for farmers and producers, and addressing the impacts of climate change. This Budget includes increasing the National Institute of Food and Agriculture's (NIFA) Agriculture Food Research Initiative (AFRI) to \$564 million, an increase of \$119 million over 2022 enacted to include broad emphasis on rural circular economies through clean energy technologies and climate-smart agriculture and forestry. These investments complement proposed increases for the Agricultural Research Service (ARS) to expand research to fully understand the myriad aspects

of climate change drivers and impacts, and to strategically develop approaches that can help mediate climate change and its impacts on agriculture, our rural economy, ecosystem services, and the quality of our natural resources.

Finally, the Budget proposes investments in USDA's research agencies to rebuild both capacity and credibility after years of staff losses. In FY 2021, the Research, Education, and Economics Mission Area was successful in hiring above their FY 2020 staffing levels, but they are still significantly understaffed to address the current and emerging challenges noted above.

Combating Climate Change

Climate change presents real threats to U.S. agricultural production, forest resources, and rural economies. Producers and land managers across the country are experiencing climate impacts on their operations through shifting weather patterns and increasingly frequent and severe storms, floods, drought, and wildfire. This Budget underscores the Biden-Harris Administration's commitment to address the impacts of climate change with a comprehensive approach that's inclusive of science and on-the-ground investments to support our producers and land managers across the country.

Farmers, ranchers, and foresters can lead the way with tackling the climate crisis through the adoption of voluntary and farmer friendly incentive-based climate-smart agricultural and forestry practices. That is why this Budget proposes \$1 billion for Conservation Operations to support producers and landowners in undertaking voluntary conservation and climate-smart practices on agricultural lands that will improve the profitability and resilience of producers and reduce emissions.

The Budget proposes \$20 million for the Healthy Forests Reserve Program to enroll private lands and acreage owned by Indian Tribes for the purpose of restoring, enhancing, and protecting forestland to enhance carbon sequestration, improve plant and animal biodiversity, and promote recovery of endangered and threatened species under the Endangered Species Act.

The Budget proposes to enhance the Equity Conservation Cooperative Agreements, begun in 2021, with an additional \$50 million, bringing total funding for this initiative to \$100 million. The Agreements are two-year projects that expand the delivery of conservation assistance for climate-smart agriculture and forestry to farmers and ranchers who are beginning, limited resource, historically underserved and/or veterans. This will allow for important outreach

and promotion of inclusive outcomes in a collaborative approach. Another critical investment in the Budget is \$21 million to support and expand NRCS's greenhouse gas measure, monitor, report, and verify efforts as well as efforts to increase internal capacity related to climate change science. The budget also includes additional funds for the Natural Resources Conservation Service (NRCS), to increase the delivery of science-based conservation planning and technical assistance that supports the needs of producers seeking to implement voluntary conservation practices that can have technical, climate, financial, and economic benefits for their farms.

The Budget also provides \$300 million in new funding to support de-carbonization of the electric grid to meet the Administration's goal of zero carbon electricity by 2035. Specifically, grants and loan modifications will be used to encourage rural carbon pollution free electricity, with the greatest benefit going to the optimal combination of carbon reductions and need.

Increasing annual funding for the Rural Energy for America grant program will assist agricultural producers and rural small businesses to purchase or install renewable energy systems or make energy efficiency improvements, as well as funding to State, Tribal, or local governments, institutions of higher education, rural electric cooperatives, and public power entities or councils for energy audits or renewable energy development assistance to rural small businesses or agricultural producers.

In addition to combatting climate change, this Budget also helps us react to the implications of a changing climate as we respond to the prevalence and spread of chronic wasting disease (CWD) as well as the spread of invasive plants, pests, and other diseases which are moving at an unprecedented speed. The Budget calls for an investment of \$6 million for the Civilian Climate Corps within our Animal Plant Health Inspection Service (APHIS) to address issues related to invasive species control and climate change and an increase of \$3 million to research the implications of climate change on the pervasiveness of CWD.

Focus on Diversity, Equity, and Inclusion

Building a better America means bringing people of all backgrounds and lived experiences to be a part of a healthy, safe and inclusive workplace – from ensuring we are recruiting the best and the brightest across our great country to investing in our employees through recognition, wellness programs, and support to our employees, including LGBTQ+, veterans, employees with disabilities and employees from historically underserved communities,

ensuring they have the equipment they need, and access to promotions, learning and development and retirement with a great sense of achievement. And building a better America is about ensuring all people have equal access to USDA opportunities, which demands that we design and implement our policies and programs with our diverse customers at the center. The FY 2023 Budget focuses on building a USDA that is a model employer and a great place to work, proposes investments that remove barriers to accessing USDA programs, and addresses historic gaps with respect to who benefits from USDA programming.

One long-standing barrier preventing farmers from benefitting from USDA programs is heirs' property, which refers to when family land is inherited without a will or legal documentation of ownership. Heirs' property has historically been challenging to heirs because of their belief that they cannot get a farm number without proof of ownership or control of land. Though those affected are in all geographic and cultural areas, many Black farmers and other groups who have experienced historic discrimination, have heir's property. This Budget requests \$62 million for the Heirs Property Relending Program to assist heirs in resolving ownership and succession issues on farmland with multiple owners. Examining barriers to heirs' property owners is a part of a broad USDA effort to revising policies to be more equitable.

To better use the research and development capacity at Minority Serving Institutions (MSIs), this Budget proposes nearly \$315 million with almost \$227 million going toward Historically Black Colleges and Universities, which includes the 1890 Land Grant Institutions. The Budget also supports preparing more Hispanic Americans for careers in agricultural science and agribusiness through important investments in the Hispanic Serving Institutions Education Partnerships Grants Program. The Budget includes a 120 percent increase above 2022 enacted levels for Federally Recognized Tribes Extension Program, to allow the program to serve the demand from 1994 Land-grant Institutions more fully and effectively.

Ensuring that all rural communities are made aware of and encouraged to participate in USDA programs, this Budget proposes \$39 million to sustain and expand the Rural Partners Network (previously known as StrikeForce) authority. The Rural Partners Network will provide targeted training, technical assistance, and outreach to distressed communities including energy communities in rural America through an all-of-government approach and support more strategic community engagement, facilitate regional coordination among federal agencies to share best practices, braid federal resources, and foster collaboration with local and State partners. This

work follows through a commitment the President made when he came to office – we must invest in America’s heartland in a meaningful way.

Making USDA a Strong, Modern Organization and a Best Place to Work

Nearly 100,000 strong and with a budget of more than 200 billion, you would expect—and hope—that USDA has a robust operational core: An operational core that has top notch human capital and administrative staff and offices that can support and provide critical guidance given the anticipated retirements, need to hire and hire in a vastly competitive climate, and focus on having cultures and workplaces that demonstrate a commitment to the employees. I have made it a priority to make USDA a Best Place to Work. We have prioritized creating a diverse, inclusive, equitable and accessible workplace; engaging and supporting our employees in meaningful ways; recruiting the next generation of USDA staff and leaders. However, we are challenged because more often than not USDA’s ‘staff offices’ operate on shoe-string budgets and with staffing levels that dwarf the responsibility USDA offices bear.

An analysis of staffing levels since 2008 indicates that the communications shop, for example, has been whittled down from 85 to fewer than 50 people today – and the work as well as the importance to message to the American people about services, benefits and programs as well as to rebuild trust in our federal institutions is more important than ever. Our Office of Contracting and Procurement is a fraction of the size it needs to be to oversee the contracting offices throughout the Department. USDA obligates \$10 billion on contracts annually, and this Budget requests funds to ensure a larger staff and sound succession plan are in place to provide strong leadership over contracting and procurement throughout USDA. You might expect an agency of the size and scale of USDA to have a robust training division – a team focused on workplace wellness, employee engagement and recruiting the next generation of USDA staff and leaders in rural America. But you’d be wrong. Our Budget proposes to increase USDA’s Office of Human Resource Management by 31, compared to the current staff of just 87 staff. These increases will help us leverage the HR work that we do with the Mission Areas and build a best-in-class operation for our nearly 30 agencies and offices that employ about 100,000 people. Year after year, USDA staff have taken on more and more work to meet our complex mission and new directives from Congress. But without commensurate increases in staff support, it positions us for greater risk and creates a culture of siloes where we must find ways internally to

fund these necessary functions. While our mission areas, agencies, and specific programs have often drawn greater interest and funding increases from Congress, the FY23 budget proposes an initial set of steps to build back a robust operational core within USDA. Doing this right will take time and focus over the course of multiple years, but it couldn't be more important. In addition to the programs that the public relies on and Subcommittee and Congress generously fund, I implore you to also concentrate on the critical needs of organizational abilities and operations management that ensure our staff are properly supported and our programs are delivered efficiently, effectively, and with integrity.

The FY 2023 Budget lays out a plan for USDA to build on the early progress and commitments of this Administration, build back our workforce, and implement the historic legislation passed in the past year while tackling critical issues within the food supply chain, the impacts of climate change, and the pressures on our public and private lands. As I stated at the beginning of my testimony, the Budget is not a wish list, it is a to do list and USDA needs the support of this Subcommittee and of Congress to make the much-needed investments called for in the President's FY 2023 Budget. I look forward to working with this Subcommittee and to answering any questions you may have about our Budget proposals.

Mr. BISHOP. Thank you, Mr. Secretary.

We will now proceed with questions.

As I mentioned earlier, we will begin with the chair and ranking member, then alternating majority and minority, those members present at the time the hearing started in order of seniority.

After that I will recognize members not present at the time the hearing was called to order in their order of arrival.

Each member will have five minutes in each round. So please be mindful of your time.

I will now recognize myself for questions.

Mr. Secretary, I was interested in your comment because in February during the Agriculture Committee hearing on foreign policy, I asked Under Secretary Bonnie about staffing concerns in the Farm Production and Conservation Mission area, and I recognized the increased workload over the past few years, especially at FSA, due to ad hoc programs like the Market Limitation Program, the Coronavirus School Assistance Program, the Wildfire and Hurricane Indemnity Program.

We are all glad that USDA has the flexibility of creating and administering these programs in support of our producers, but ensuring FSA is fully staffed is key to their effective and timely delivery, and I am happy that you have recognized that and brought that to the forefront in your budget request.

You request an additional 64 employees for FSA, an additional 535 for Conservation Technical Assistants at NRCS, noting expanded staffing capacities needed to keep pace with increased mandatory financial assistance authorities that will exceed \$3 billion in 2023.

And I am happy that you are asking for additional resources for staffing.

My question is will these requests meet the needs to do the core work, especially at FSA, and I am concerned that those 64 employees may not be able to keep pace with retirements and attrition.

And while we are discussing FSA staffing levels and workload, can you provide the committee an update of the timing for the WHIP disaster limitation and sign-up for the 2020 and 2021 property process.

Secretary VILSACK. Mr. Chairman, I am confident that our request will allow us to continue to do the good work at FSA offices across the United States.

NRCS is a different story. The reality is we have to have people working individually with producers, particularly for those who have been historically underserved so that they fully understand and appreciate the programs that are available to them.

We also have, as you know, an expanded urban agricultural presence which is going to require as well additional resources for NRCS.

So between the two I think we have made a request that will allow us to continue to do the work that is incredibly important. And I will tell you that this is an organization that last year, last fiscal year, basically provided over 53,000 farm loans to farmers in need and also provided nearly 43,000 NRCS contract conservation contracts which were approved, in addition to all of the pandemic assistance and all of the additional expenses that were forthcoming

as a result of a variety of programs that you all have funded recently.

Mr. BISHOP. The administration has rightfully made ensuring equitable participation in USDA program a top priority. And two weeks ago you released the USDA's Equity Action Plan.

And two findings stood out to me in particular. First, that USDA farm programs are tailored to the needs of larger agriculture producers and, second, that FSA and RMA have had very few programs and avenues providing technical assistance and support to organizations that help underserved farmers and ranchers.

So I have been concerned the majority of financial and technical assistance goes to larger farmers, and I am glad that this is being recognized.

As we discuss the unique challenges that our small farmers face, is there anything that we need to do in our fiscal year 2023 bill to address these identified gaps in service?

Secretary VILSACK. Well, fortunately, Mr. Chairman, you passed the American Rescue Plan, which provided us the resources to begin a process of creating relationships between USDA and a series of community building organizations that can provide technical assistance, trusted organizations in communities to reach out to historically underserved producers, and to provide the one-on-one information and contact that is necessary for those producers to understand (a) what is available and (b) how to basically qualify for it.

In addition, you also provided resources for us to adequately fund the Heirs' Property Relending Program, which is going to allow us to enable those fractionated interests and the owners of that land to be able to consolidate land ownership so that they are able to participate fully in programs.

Our risk management folks have found \$2 million to provide additional outreach, and they have begun to craft a series of programs and risk management tools that are directly connected to and speak to this issue of small and midsize producers.

They recently announced a micro crop insurance program that is providing crop insurance protection for facilities that have less than \$100,000 in sales.

So there is a tremendous opportunity here and a tremendous outreach effort that is undertaken in order to ensure they will be able to get the access to programs they need.

Mr. BISHOP. Thank you, Mr. Secretary.

My time is up, and we will now go to Dr. Harris.

And, Dr. Harris, you are now recognized for your questions for five minutes.

Mr. HARRIS. Thank you very much, Mr. Chairman.

Again, thank you, Mr. Secretary.

Now, I have read your written remarks to the committee, and the second paragraph talks about economic indicators that are overwhelmingly positive. So I am not sure when this was written, but I am sure you are aware that the GDP actually contracted 1.4 percent last quarter. That is not economically positive.

We have inflation at historic highs. That is not economically positive.

We have interest rate increases that are being planned that will likely result, and most economists feel most likely result, in recession. That is not economically positive.

And a majority of Americans simply disagree that they think the economy is in good shape.

So I am not sure. You know, if we start from an unrealistic predicate, then we are going to make bad decisions.

So, for instance, you talked about 5,000 fewer employees, but in an organization that has nearly 100,000 employees, that is just doing a little more with a little less, and I think that is what Americans expect from us, as our trillion-dollar deficits fuel inflation. And the American people have figured it out.

I think we have to look at ways of doing more with less in the government, not doing the same with more, which I think is what you suggest when we have to add employees, for instance, in then FNS program which should be winding down because of, again, the wind down in some of the COVID funds. We should actually require fewer employees than we have now as these funds wind down.

So that leads into my question about the SNAP Program. If the administration is doing so well with the economy, why do you estimate SNAP participation will actually increase 1.2 million people next year because the SNAP Program is usually a reverse indicator of the economy?

The economy gets better, SNAP participation goes down because fewer people qualify. But you project an increase. So do you believe the economy is getting better or not?

Secretary VILSACK. Well, I think the response is a balanced view here. You have mentioned some of the challenges that we have with inflation, and that is true.

But you did not mention the fact that we have had significant job growth recently, and while that is good news, we still have a challenge in many areas of the country in terms of unemployment rates that continue to be high, particularly in persistently poor areas.

I was recently in Mississippi and communities where the poverty rate has been in excess of 20 percent for over 20 years.

So there are still challenges, number one.

Number two, I think it is important to recognize that we need to continue to look for ways in which those who are eligible for programs actually participate in the programs.

One of the areas in SNAP that we want to continue to focus on are senior citizens, folks who have retired, who are on fixed incomes, perhaps it is a Social Security check, who actually qualify for SNAP but currently are not receiving the benefit of SNAP.

Obviously, it is in our best interest to make sure folks have access to these programs.

The same thing is true with our WIC Program. Fifty percent of those who are eligible for that program do not participate in that program, Congressman, and so therefore, it is important for us to continue to look for ways in which we can make sure that the programs that you all have created are available and utilized by the people that they are designed for.

Mr. HARRIS. Well, thank you. I appreciate the answer, but I hope that is weighed, again, in a time when you paint this incredibly rosy picture of the economy with millions of people getting more jobs.

That should actually take millions of people off of being eligible for SNAP benefits.

Now, you know that GIPSA is a concern of mine. My Republican counterparts in the House and Senate Ag. Committee sent you a letter about the importance of doing an updated comprehensive economic analysis.

You know, your reply was a little vague. Again, I look forward to seeing that economic analysis. Will you still commit to ensuring that a proper updated economic analysis is going to be performed on that?

Secretary VILSACK. Yes.

Mr. HARRIS. Okay. Great.

The ReConnect Broadband Program, you know, again, the rural areas do need broadband. That was so clearly exemplified during the COVID crisis, and I am glad that we have more resources.

But is the USDA coordinated? Because now we have several agencies involved, are you coordinating with the National Telecommunications and Information Administration to ensure that we are not duplicating?

We are sending all of this money out there, that we are actually spending efficiently, wisely and not duplicating government effort.

Secretary VILSACK. We are sharing data through an MOU that was recently signed. We have weekly meetings. We are basically coordinating our mapping, as well.

So, yes, that coordination is taking place, and the goal, obviously, is to avoid duplicating and providing double coverage and not being able to provide coverage throughout the entire country.

That is the goal here, is to get everyone access to high-speed Internet.

Mr. HARRIS. Well, thank you so much because, again, we have the resources now. Let's go and get it done.

Thank you very much. I yield back, Mr. Chairman.

Mr. BISHOP. Thank you, Dr. Harris.

At this time I am delighted to recognize the gentleman from Wisconsin, Mr. Pocan.

Mr. POCAN. Thank you very much, Mr. Chairman, and thank you, Mr. Secretary, for being with us.

One of the things I wanted to lead with is to thank you for that additional money for SNAP and the outreach defined, making sure that everyone who needs that program has access to that program.

Perhaps in a body made up of half millionaires, we do not quite understand the need for SNAP like people in my district do, and even though we are coming out of COVID, there are some industries that have not and some populations that have not.

So thank you for that increase in the budget.

I would like to get to three subject areas, and I think the first two you can probably answer fairly quickly and maybe leave a little bit more time for the third.

Just kind of giving you a little up-front.

ARS buildings and facilities, you know, those Agricultural Research buildings are so important. We recently in the omnibus got money to replace a World War II era building that we had in Wisconsin in my district. I appreciate that.

So we also know that with increased cost, some of those building costs are going to be more than people anticipated. These buildings across the country, I am hearing estimates of price increases that are approaching \$200 million.

So my question is are we able to support meeting these needs in the fiscal year 2023 appropriations bill?

And how can we make sure that, you know, with these increases when people have budgeted for something that there may be additional support for these buildings to still be able to get off the ground?

Secretary VILSACK. It is a great question, and I will be honest with you. It is a challenge. We have got 23 or so projects that we were adequately and fully funded by Congress in previous budgets. We now are very concerned about the increased cost and the impact on those 23.

We have several that are partially funded, which obviously will impact. We are going to continue to look for ways in which we can stretch those dollars.

These facilities are incredibly important to our research priorities, and so we are going to continue to look for ways to make sure we do as much as we can with the resources that we have.

Mr. POCAN. I appreciate that. Thank you.

Community facility loans, you know, we have had a couple of communities in my district last year that, through some of your department's critical functions, you are providing financing for infrastructure in rural communities. We are grateful that they approved these community facility loans for projects in Baraboo and Lafayette in my district.

However, both of these communities ran into the same issue in dealing with real development and ultimately had to have their loan underwritten twice, once by the State office and then once by the Federal office. That put both projects in jeopardy because of the length of time it took, and honestly, I ran out of excuses in talking to them along the way.

Can you speak to why there is this process that is now taking twice to have some of these loans underwritten and what we could do to maybe streamline that timeline?

Secretary VILSACK. You know, Congressman, that is a question that I do not have a very good answer to, but it is a concerning question that you ask, and what I will do is I will go back to our team and ask the question why we have made it more difficult.

The goal here should be to making it easier instead of more difficult.

Mr. POCAN. Yes, and I know that is your goal. So that right, but maybe this is more raising awareness, but in two communities we had this problem, and one, it was a little embarrassing. Every time I went up there I did not have an answer for them.

At least, you know, everything is taken care of now, but it is an issue.

Finally, I want to thank you for the additional money that you have in antitrust enforcement you asked for, specifically what I would call the meatpacking cartel in this country.

As we know, we have very few companies that are doing this, and yet at a hearing this week, you know, again, they deny any price fixing and everything else, but we are hearing from the actual cattle ranchers that they get some of the lowest prices and they are barely getting by.

As you look at this money, how can some of this go to trying to address the cost increases that people right now are experiencing?

Because I truly believe this is one where price gouging is at the center of why we have some of these increases around me.

Secretary VILSACK. I think there are three things. First of all, it is important and necessary for us to have continued competition and expanded competition, which is why we have announced a series of programs to help existing processing facilities that are small and midsize stay in business and be able to expand, while we have also addressed and will be addressing this summer the expansion of new facilities to provide competition.

Secondly, I think it is about transparency. We are, in fact, looking at the packers and stockyard rules and making sure that they are strong enough to be able to send a clear message that it is not appropriate to take advantage of producer.

And then finally, it is, in fact, once you have strengthened packers and stockyards' capacity basically having the resources to be able to call people and hold people accountable.

And that is the intent of what we expect to be able to do at USDA.

Mr. POCAN. Well, with my time left I am going to make sure I am respectful of the chairman's request, but thank you very much on this front, and I really look forward to what we are able to do.

So thanks so much. I appreciate it.

I yield back, Mr. Chairman.

Mr. BISHOP. Thank you, Mr. Pocan.

At this time I am delighted to recognize the gentleman from California, Mr. Valadao.

Mr. Valadao, you are recognized.

Mr. VALADAO. I appreciate that. Thank you very much, Chairman.

Secretary Vilsack, thank you for coming today to testify in front of the subcommittee.

The jurisdiction of your department includes one of the most important issues of agriculture producers in rural communities, members throughout my district and in the Central Valley of California.

And personally, I would like to thank you for taking some time to personally come out and visit the district a few months back. I really appreciate that.

Since you last testified the water conditions have unfortunately not improved throughout the West, particularly in Central Valley. Despite the adoption of more modern and efficient technologies, including drift, farmland in my district continues to be fallow. Wells are going dry.

And your testimony highlights the importance of all Americans to, as you say, have access to healthy, affordable food. And I could not agree more.

But it is the situations like the one we are currently facing in the West, along with supply chain issue and workforce shortages, that are proving to make this task a much more difficult task than it should be.

Last spring President Biden established the Drought Relief Working Group, of which you are a part. Please update us on what you and the other task force members are doing to assist agriculture producers and rural communities as it relates to the horrible effects of the ongoing drought.

Secretary VILSACK. Well, there are several things, Congressman. First of all, we are in the process of providing the resources that you all provided with the WHIP-Plus program. We just recently put out about \$550 million to livestock producers that were impacted by a series of weather-related issues.

We have basically simplified that process. We anticipated and expect that we will begin to get the payments to crop producers out in May and early June, and that process is going to result in resources getting to farmers relatively quickly.

We also are obviously making sure that folks take full advantage of the Livestock Indemnity Program. Crop insurance and the NAP Program are available.

We recently made sure that folks were aware of the Emergency Assistance for Livestock, Honeybee and Farm-Raised Fish, and expanded that opportunity not only to cover indemnity, but also to cover transportation expenses.

So we have looked for ways in which we can make it a little bit easier. We continue to work on our modeling. We continue to work on providing information to producers so they can make the most informed decisions concerning what they can do and where they can do it.

We continue to focus on our climate hubs to provide additional ways of mitigating and adaptation strategies. So there is, I think, a series of things that we have done, and we will continue to look for ways in which we can provide assistance and help.

Mr. VALADAO. I appreciate that, and hopefully we can work together on that because that situation is going to get more dire as the weather warms up.

So, Secretary Vilsack, the next issue for me is farmers in my district have had nearly four years of market turmoil overseas and here at home. At this very moment, the industry faces millions in losses every day simply because they cannot get their goods onto ships out of port.

We have seen government purchasing sprees for feeding programs' support payment, but these actions miss the mark in significantly connecting our farmers' and ranchers' abundance of food with our growing population.

Simply put, USDA must do more and must be more aggressive to promote our homegrown agriculture goods and encourage U.S. consumers to support our local farmers.

How does the USDA plan to address the ongoing challenge, especially with the port situation, and take action to ramp up domestic consumption and promotion of U.S. products?

Secretary VILSACK. Well, we have had an opportunity to work with the Port of Oakland and the Port of Seattle to create essentially a pop-up location, which hopefully will increase the utilization of empty containers that have been leaving our ports without agricultural products to be essentially with agricultural products.

We had a record year in exports last year. We anticipate and expect a record year as well this year, but there is obviously continued work.

We continue to reach out to shippers, have had communications and contact with the shippers to encourage them to do a better job.

We are obviously taking a look at what you all and Congress can do in terms of the legislation that is being proposed to essentially provide some additional tools.

We continue to work with the Maritime Commission to encourage them to use the tools that are available.

We recently talked to the National Surface Transportation Board to deal with the rail issues that have been problematic.

We continue to work with our sister agencies to encourage an acceleration of CDLs so we get folks behind the wheels of trucks to be able to move product in the market both domestically and internationally.

We are going to continue to look for creative ways. We are open to ideas and thoughts, and, Congressman, if you have ideas and thoughts about what we need to be doing that we are not doing, I am more than happy to hear from you and to be able to direct some of the resources that we have available for that purpose.

Mr. VALADAO. I appreciate that.

With the five-minute time limit, it is hard to get into those types of details here, but I do look forward to that opportunity to have a continued dialogue because a lot of the ideas that you mentioned are helpful.

The Ocean Shipping Reform Act, if we can get that out of Congress over to the President's desk, I think that would be helpful.

But the reality is farmers are seeing lower prices. I mean, almonds are low. Pistachios, still not very well. I met with my walnut guys, and these guys are all truly struggling because they cannot get product on the ships.

So I appreciate the efforts, and I yield back.

Mr. BISHOP. Thank you, Mr. Valadao.

I now recognize the gentlelady from Illinois, Ms. Underwood. You are now recognized for five minutes for your questions.

Ms. UNDERWOOD. Well, thank you, Mr. Chairman.

And thank you, Secretary Vilsack and Mr. Rapp, for joining us for this hearing today.

I have been hearing from farmers in my district who are facing increased input cost, including the cost of fertilizer, and I am hearing that it is cutting into their bottom line.

Pandemic-related supply chain disruptions and Putin's unprovoked war against Ukraine have undoubtedly contributed to this problem.

But we also know that a longstanding, significant factor has been the trends of market consolidation and anticompetitive practices in the agriculture industry.

We also understand that the vast majority of our fertilizer supply is controlled by a small number of large corporations, which is similar to what is happening with our meat processing system.

And so, you know, farmers and producers are absorbing high cost and accepting unfair contracts because huge corporations know that they do not have a choice.

It is also threatening the sustainability of smaller farms. It is destabilizing our food supply and harming consumers.

We know that the Biden administration and USDA are taking action, including a recent announcement that USDA is setting up a \$250 million grant program to support independent and sustainable American fertilizer production.

Can you give us an update on the status of this grant program, including when this funding will become available and whether it will continue for fiscal year 2023?

Secretary VILSACK. Well, I appreciate the question.

Our intent and goal are to try to solicit information which we are doing at this point in time on ideas about how best to use those resources.

I would expect and anticipate that we will close that information gathering process sometime this summer and begin to make decisions in terms of how best to allocate those resources and perhaps even add to those resources.

I would also say that we have taken additional action. We are working with State Attorney Generals who are currently doing a market study of the very issue that we talked about in terms of consolidation and whether or not these price increases that the farmers have seen are justified.

We continue to do research on ways in which we potentially could use less fertilizer. We continue to look for ways in which we can encourage farmers to use conservation practices and crop decisions that may result in the need for less fertilizer.

And we have recently provided a new risk management tool to encourage farmers, particularly in the Midwest, to consider only a single application of nitrogen fertilizer, and then if they suffer product loss as a result or productivity loss, we would have an opportunity to provide some additional resource to sort of offset that loss.

So there is a variety of ways in which we are currently trying to address this issue in a very aggressive way.

Ms. UNDERWOOD. I appreciate that, but for the grant do you have any estimation for fiscal year 2023?

Secretary VILSACK. Well, our goal is to obviously make decisions before the end of this fiscal year. We have utilized these resources from CCC. So it is an opportunity for us to basically figure out what is it that farmers and what is it that the market believes needs to be done.

It is not an easy issue. It is a relatively complicated issue, and we may find that need to put more resources behind this initiative, and that is one of the reasons why we are collecting information.

Ms. UNDERWOOD. I am also very pleased that USDA and the Department of Justice are working together to increase enforcement of Federal antitrust laws in the Packers and Stockyards Act, including setting up a joint online portal for producers to report potential violations.

Can you provide an update on the progress of this joint USDA-DOJ effort so far?

And does this scope extend beyond the meat processing sector, for example, into fertilizers, seed, and other industries?

Secretary VILSACK. We continue to monitor the portal for information that would allow the Department of Justice to make decisions about whether or not cases should be pursued.

In the meantime, what we are doing at USDA is the process of strengthening the Packers and Stockyards Act to make sure that we have an Act that, in fact, provides a balanced and level playing field for producers.

You will probably see in the very near future our efforts in terms of the poultry tournament system, providing greater transparency and fairness in that system. That will be followed by a focus on discrimination and retaliation to basically provide some relief in circumstances where folks are being discriminated against or retaliated against.

And then we will have a rule at some point in time this year on our preferences. So there is an effort to try to strengthen our capacity to take action.

Ms. UNDERWOOD. In addition to unfair and anticompetitive forces in agricultural input industries in the markets for agricultural goods, our small and midsize farmers are up against farm unconsolidation. For decades Federal policy has consistently favored large farm operations, and start-up farms and small farms have struggled to access USDA resources.

What efforts are you all taking to reverse those trends?

Secretary VILSACK. Well, the first thing we did is to establish the rule that was in the 2018 farm bill for heirs' property, to basically allow the consolidated or fractionated interest into a single owner so that individuals could qualify for programs that would allow them potentially to purchase land.

Secondly, as you may know, under the American Rescue Plan, Section 1006, there are resources for us to figure out ways in which we can provide access to land.

You know, this is a complicated issue. We are looking at ways in which, for example, Federal lands could potentially be made more readily available to historically underserved producers.

We are working with our outreach partners. We have recently provided \$75 million in resources at 20 different organizations and groups to help us understand how we can best provide not only land access, but also market access. You can have land, but if you don't have markets, you need both, and we are in the process of trying to figure out ways in which we can expand both land access and market access.

Ms. UNDERWOOD. I yield back.

Mr. BISHOP. Thank you, Mr. Secretary and thank you Ms. Underwood, for your very insightful questions.

And at this time I would like to recognize the gentleman from Washington, Mr. Newhouse.

Mr. NEWHOUSE. Thank you, Mr. Bishop. Mr. Chairman, I appreciate that.

It is good to see you, Secretary Vilsack. Thanks for being with us today.

Let me associate myself with some of the remarks you have already heard. As one of the farmers that is serving in Congress, as you well know, there is a lot of anxiety in ag. country these days. There are a lot of challenges that we face, and we certainly appreciate your efforts in recognizing those facts and all of the hard work the agency is doing to assist the industry.

First of all, something that is very important to me, I want to thank you for your support of the Farm Workforce Modernization Act, particularly your testimony. I think it was last fall, last year anyway, in front of the Senate Judiciary Committee.

I am sure in your travels around the country you are hearing just like I am that labor is one of the biggest issues facing our farmers and our ranchers, and it goes without saying that our immigration laws are broken. We need to fix them. We need meaningful immigration reform.

We have got to have a legal workforce and an available workforce, and I appreciate your efforts on that.

I am hopeful still and I would appreciate if you could continue to put some urgency in the Senate as much as you can with your strong voice that we can get something done this year to pass that legislation into law.

Kind of an unrelated topic though, I wanted to touch on the dietary guidelines for Americans just issued. As you are well aware, the last few rewrites of the DGA have been criticized, gosh, from several different sectors.

Congress has repeatedly urged the USDA and HHS I should say to improve the transparency, the process, the objectivity, and to rely on the preponderance of scientific evidence to make any changes.

You are well aware that Congress at least twice over the last several years has mandated that NASEM, or the National Academies of Sciences, Engineering, and Medicine, review the DJ process and report back to us, as well as other relevant agencies with recommendations.

We have also weighed in as part of the fiscal year 2022 Appropriations Act, directing NASEM to further review the 2020 process and advise the agencies on how the next rewrite could be improved.

So, Mr. Secretary, it is my understanding these recommendations from NASEM are still not out. Admittedly, there have been some starts and stops, but to complicate things, your agency as well as HHS issued in April a Federal Register notice that the process to write the new 2025 to 2030 dietary guidelines has begun, including the release of the proposed research questions to be considered by the next committee.

So a couple of things, and maybe I will ask several questions here and in your response, you can touch on some of them.

Can you help us feel assured that the work of NASEM is not being ignored?

And how will the department plan to incorporate the findings and recommendations of NASEM's review?

And could you inform me why the committee's work at the NASEM was put on hold for two months earlier this year? Essentially why the start and stop that we are seeing?

And will you assure that the department will incorporate the findings and recommendations of any NASEM review into the development of the new guidelines?

And then particularly, was a decision not to have the next DGA Committee focus on any alcohol research questions a result of recommendations from the NASEM or was that a recommendation from another Federal agency?

I know there is a lot there, but if you could respond, I would appreciate that.

Secretary VILSACK. Well, I think the key take-away to your question, Congressman, about the DGA is the amount of time it takes to actually get this done in an orderly and proper fashion. So it is important for us to have started this process now by basically putting together a set of questions which we are asking people to respond to and react to.

It may very well be that the set of questions that we propose are not, in fact, the set of questions that we actually present to the researchers for consideration because we may get push-back. We may get, "Hey, you left out this or you should not have included that."

That is the whole purpose here. The whole purpose is to give people an opportunity to weigh in on whether we are hitting the mark or missing the mark, and I would expect and anticipate to the extent that the research and review of the DGAs comes up with proposals to strengthen the effort to make sure that we are, in fact, following the science, there would be no reason why we would not be interested in adopting those.

Obviously, we have got a partner in this in HHS, and they have a say in it as well. In fact, they are the lead agency for this ground.

But we will continue to work hard to try to make sure these dietary guidelines are appropriate and supported by the science.

Mr. BISHOP. Thank you very much, Mr. Newhouse and Secretary Vilsack.

Mr. NEWHOUSE. Thank you.

Mr. BISHOP. At this time, we have been joined by the distinguished chair of the full committee, the gentlelady from Connecticut, Ms. DeLauro.

At this time recognizing her busy schedule and conflicting hearings today, I would like to recognize her for five minutes for whatever purpose she may deem appropriate.

The CHAIR. Thank you so much. Thank you very, very much. I want to thank my colleagues on the committee as well for allowing me to move forward.

And it is wonderful to see you, Mr. Secretary, again and thank you for your testimony, but thank you for your many years of dedication and hard work always in this area.

I have questions that I will submit for the record, but I wanted to speak about an extremely disturbing report that I recently ac-

quired from a whistleblower who worked at the Abbott facility, which produces instant formula recalled by the FDA in February.

Chairman Bishop, I really appreciate you giving me the opportunity to share this during this hearing.

Mr. Secretary, to my knowledge you have not seen this report, and I bring it to your attention because I know of your deep commitment to child nutrition and the WIC Program is important to maternal and child health outcomes.

Abbott Nutrition is the exclusive supplier for the majority of State WIC agencies, and this has a serious impact on families served by WIC. Over 1.2 million infants serviced by WIC are limited to specific grants of contract formula, like Similac.

I believe you will be as outraged as I am by what this report means for the health of those infants.

In September 2021, FDA learned of a potential link between a rare and deadly food-borne pathogen in powered infant formula manufactured by Abbott Laboratories in a facility in Sturgis, Michigan.

This week, I received a 34-page report from a whistleblower, a former employee at the plant which produced the contaminated formula, which led to at least four hospitalizations and the deaths of at least two babies.

The whistleblower report lays out a damning list of allegations of wrongdoing at this factory, including falsification of records relating to testing of seals, signing verifications without adequate knowledge, failure to maintain accurate maintenance records, shipping packages with fill rates lower than what was on the label, and more; releasing untested infant formula; hiding information during the 2019 FDA audit; lax practices associated with clean, in-place procedures; lack of traceability of the product; failure to take corrective measures once the company knew their testing procedures were deficient; an atmosphere of retaliation against any employee who raised concerns about company practices.

And these are just a few of the allegations laid out in the report.

I want to remind everyone we are talking about infant formula. Parents trust that formula will be safe and healthy for their newborn babies. It should be the most regulated of any product.

I am deeply concerned about the practices at this Abbott facility and their apparent failure to implement and enforce internal controls at this facility. We need to know exactly who in the company was aware of this failure and the alleged attempts to hide this information from the FDA.

I am equally concerned that the FDA reacted far too slowly to this report. The report was submitted to the FDA on October 19, 2021. The FDA did not interview the whistleblower until late December 2021.

According to news reports FDA did not inspect the plant in person until January 31st, 2022, and the recall was not issued until February 17th, 2022.

Why did the FDA not spring into action? Why did it take four months to pull this formula off store shelves?

How many infants received contaminated formula during this time by parents who trusted that formula they were buying was safe?

How many additional illnesses and deaths were there due to the FDA's slow response?

I have already requested the HHS Inspector General to look into this. I can assure that this committee will also carry out its oversight role to find answers into how this happened and how we can prevent it from ever happening again.

I want to say thank you to the brave whistleblower for coming forward with this critical information. Mr. Secretary, we look to you and the USDA for leadership on issues of child nutrition. I strongly encourage you to investigate USDA's contracts with Abbott Nutrition. If Abbott cannot guarantee the safety of infant formula purchased through the WIC Program, the federal government should not be in business with them. I look forward to working with you on this.

And Mr. Chairman, I ask unanimous consent to submit this report to the committee record for this hearing.

Mr. BISHOP. Without objection, it is so ordered.

The CHAIR. And I want to once again thank you, Mr. Chairman. I know of your interest in the issues of child nutrition and of children being safe with the food that their parents believe that they are eating and, in this particular case, what infants are being fed, so, again, thank you very, very much. And I want to thank, again, my colleagues on the committee for allowing me to move forward.

Mr. BISHOP. Thank you, Madam Chair. Thank you very much. At this time, I am delighted to recognize the gentleman from Michigan, Mr. Moolenaar. Is Mr. Moolenaar—I'd like to recognize you for five minutes for your questions. You are now recognized, sir.

Mr. MOOLENAAR. Thank you, Mr. Chairman. And Mr. Secretary, thank you for appearing today. And just a few things I wanted to touch base with you on. First of all, just want to reemphasize the importance of rural broadband. And I know that is something very high on your radar screen. And just want to continue encouraging movement forward in that.

Also, I wanted to talk with you about the avian influenza and just get your thoughts on that going forward and how we are addressing it and what we need to do going forward. And, you know, obviously the African swine fever also is a concern as well. But wanted to talk with you briefly about the influenza.

Secretary VILSACK. Congressman, as of today, there are roughly 29 states that have dealt with and are dealing with AI, the roughly 200—almost 240 blocks have been impacted and affected. In 21 states, it's both commercial and backyard blocks. In eight states, it's just simply backyard. We have 585 folks between the federal and state efforts here focused on this on a daily basis.

We are concerned, obviously, about rapid spread, and that is why we have encouraged producers to be very cautious and very careful about biosecurity. I would say that we, I think, have seen improvements in that respect. We more rapidly identify AI. We more rapidly respond and more rapidly quarantine. We more rapidly depopulate and dispose. And that's—and compared to where things were in 2014 and 2015, we've sequenced about 1100 genomes of this virus so that we have a sense of where its headed. About \$146 million, which has been paid in indemnities to this point, we just recently received approval for another 263 million.

To put this in proper perspective, that is about half of where we were in 2014/2015 with the last outbreak. We are going to continue to focus on rapid detection, quick quarantine and disposal—depopulation and disposal. And hopefully with the warming temperatures, we will see an abatement of this—of this virus. Not much you can do in terms of wild fox. So that is why it is important for producers to be very careful in biosecurity.

On African swine fever, obviously the goal here is to make sure it doesn't hit the mainland. We have created a protective zone in Puerto Rico. We are working with the Dominican Republic and Haitian officials to begin the process of trying to get it under control in those countries. We are working with other partners, Mexico, to basically encourage a real focus in the Dominican Republic and Haiti on this issue. We provided resources. We provided staff. We provided lab operations, and we have also bulked up our own security, working with Customs folks. We are making sure that the right questions are being asked. And the last thing I would say is we have got a very aggressive advertising and marketing program in airports basically encouraging folks not to bring into the United States anything that could potentially compromise our pork industry.

Mr. MOOLENAAR. Okay. Thank you very much, Mr. Secretary. I'm kind of between two hearings this morning, so I appreciate your response and look forward to working with you in the year ahead.

Thank you, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you, Mr. Moolenaar.

And at this time, I am pleased to recognize the gentlelady from New York, Ms. Meng. You are now recognized for five minutes.

Ms. MENG. Thank you, Mr. Chairman, and Secretary Vilsack. It is good to see you again. Thank you so much for being with us today. I wanted to ask about the availability of foods that are certified kosher and halal in the Emergency Food Assistance Program. As you know, there has been a tremendous increase in demand for food assistance nationwide. But unfortunately, there are still very few items that are certified kosher on the TEFAP available foods list that is critical for helping pantries and banks meet this increased demand.

Last year, I secured language in the House report urging your department to work with both Jewish and Muslim community leaders on expanding this list to ensure TEFAP was accessible for those with culturally or religiously sensitive diets. In September, we then sent a letter signed by 47 of my colleagues requesting an update on USDA's plan.

I am aware that USDA is gathering information. But while I appreciate that a comprehensive strategy will take time, I would like to know what can be done now to address so many of the unmet needs of individuals with religious or cultural dietary needs and TEFAP food boxes. And also, are there particular challenges that USDA is facing in expanding the number of processed or shelf-stabled foods that are certified kosher or halal that are listed on the TEFAP available foods list? And does USDA need additional funding to expand kosher and halal options on the list?

Secretary VILSACK. Well, one of the things we have done, Congresswoman, is we have begun to try to develop a more robust local

and regional connection to the TEFAP program. So we have provided resources that will go through states to be able to establish and provide hundreds of millions of dollars of purchasing at the local and regional level. And this is one way of addressing the issue as we are formulating a much more longer-term and more comprehensive strategy.

It gives the ability to use those resources at the local level to purchase those culturally appropriate foods. We are also doing this, I might add, not only for TEFAP, but we are also doing it in relationship to School Nutrition Program as well, providing additional resources to schools and encouraging them to utilize this for the purchases at the local level.

We also have been working and provided a program called the Region Resiliency Program with food banks where we are offering resources to be able to allow them to deal with culturally sensitive foods. And this is also remote and rural areas as well as the infrastructure. The first wave of those grants should be forthcoming in the very near future. So there is an effort here to provide the resources while we are putting together the plan.

I think we have sufficient personnel to put the plan together. Obviously, it somewhat depends on the input that we get in terms of whether or not we have sufficient resources. And once we have a sense of that, we will certainly let you know.

Mr. BISHOP. Congresswoman, I think you are on mute.

Ms. MENG. Sorry. Thank you for that. And then I wanted to also ask quickly about hot foods exemption and SNAP. We discussed this last year when you came before this committee. I am grateful to see your review of the Thrifty Food Plan include an increase to the SNAP benefit to reflect current food prices beneficiaries are facing but also want to know of any additional efforts to modernize the SNAP program, specifically a permanent repeal of the hot foods provision.

Secretary VILSACK. Our focus—to be candid, our focus initially on SNAP was to take a look at the Thrifty Food Plan, not only to take a look at what families are, in fact, purchasing from the grocery store but looking at food costs, looking at the dietary guidelines and looking at what the nutrition science tells us. You know, I will tell you that we—you know, we continue to look for ways in which we can create greater convenience with reference to SNAP. And we are also doing this as well on the WIC Program, basically providing online opportunities, online capacity. I think there is still some—some policy issues that we have to work through in terms of online access, but we are continuing to focus on trying to make it as convenient as possible.

Ms. MENG. Thank you. And we are working on SNAP PLUS Act legislation, bipartisan effort with Congress members Bobby Rush and Brian Fitzpatrick, which would permanently repeal this exemption in SNAP. And in light of the upcoming Farm Bill reauthorization, would love to work with you and your team to ensure that we are making key nutrition programs accessible to the needs of our current world. Thank you, and I yield back.

Mr. BISHOP. Thank you, Ms. Meng. At this time, I am delighted to recognize my friend, the gentleman from Alabama and the

former chair of the subcommittee, Mr. Aderholt. Mr. Aderholt, you are now recognized for five minutes.

Mr. ADERHOLT. Thank you, Mr. Chair. It is great to be on the virtual call today with the Secretary and Mr. Rapp. Thank you both for being available today. Of course, it is—as we all know, agriculture is a core pillar of American history since the foundation of this country. And it is critical that we ensure that your department is well-supported to continue that legacy. And certainly we want to do what we can to make sure that we—from a congressional standpoint and appropriations standpoint do what we can. Of course, I want to just mention the broadband issue that is something that resonates with so many of us on this subcommittee and all through Congress and across the United States, whether it be rural districts whether it be urban districts, whether it be conservative districts, whether it be liberal districts. It is something that really is—everybody can agree on it.

So it is good. Occasionally, they have those issues that everyone can agree on and we feel like is important to—for the benefit of the entire nation, especially what we have seen after the situation with COVID over the last several—or actually the last couple of years. But I want to pivot a little bit to more on international side of agriculture.

Of course, Russia's unprovoked war on Ukraine has had a ripple effect across the global markets, including the trade of key items like wheat and fertilizers. My question, Mr. Secretary, would be does the USDA's budget for fiscal year 2023 address any of the concerns that are emanating from the war in Ukraine and its impact on the global food supply chain.

Secretary VILSACK. I'm kind of used to calling you Mr. Chairman. Congressman—

Mr. ADERHOLT. I get—chairman.

Secretary VILSACK. Appreciate the question. Our budget basically provides the resources to do what we think is necessary. I would say that we just recently today announced the ability of us to tap in the Bill Emerson Trust to fully utilize all of the resources in that trust to provide food assistance. And we are also utilizing some resources from CCC to reduce the transportation costs associated with getting those products to folks in need. There may very well need to be the need to rebill, if you will, the Emerson Trust. And I think there is a provision in perhaps a supplemental bill that would potentially address that issue.

So that is a new development and obviously could not take into consideration at the time the budget was put together, which was pre-invasion. But I would say we want to keep an eye on that issue in terms of our ability to provide additional assistance in the future.

Mr. ADERHOLT. Okay. Good to know that that is on your radar screen and will be addressed. And then one last thing. If we look beyond the crisis in Ukraine and towards an additional efforts to reassure our supply chain, especially in regards to China, how does USDA's fiscal year 2023 budget request address our reliance on Chinese exports?

Secretary VILSACK. Well, I would say that the concern we have about Chinese exports, Congressman, is the need for us to continue

to look for ways in which we can diversify so that we are not as overly reliant on a single market. We know what happened when that market was disrupted during the trade war. We saw the devastation to producers. So we are continually—look for ways in which we can expand new market opportunities. The Indo-Pacific framework that was announced by the USTR is one way of focusing on ways in which we can knock down barriers. Recently, additional beef sales in Japan, additional corn sales, frozen pork sales in Vietnam, potatoes in Mexico. We are breaking down barriers, so that we can expand access to additional markets.

I think there are opportunities in Southeast Asia. I think there are opportunities in Africa. So the budget basically provides us the opportunity to continue to look for ways in which we can expand presence.

At the end of the day, expanding market opportunity is about presence. It is about having people in place, which we have. It is about the resources that MAPP and FMD provide to basically have promotions and the opportunity for us to do additional trade missions. So you are going to see a very aggressive effort in trade missions this year.

We had one in the Middle East. We have got one scheduled in Spain. We have got one scheduled in Kenya. We have got one scheduled in the Philippines. So there is going to be a continued focused effort on increasing and expanding our presence in these foreign markets, so that we diversify and we are not as reliant on China as we have been in the past.

Mr. BISHOP. Thank you, Mr. Aderholt, and thank you, Mr. Secretary.

At this time, I am happy to recognize my friend from Texas, Mr. Cuellar. Mr. Cuellar, you are now recognized for 5 minutes.

Mr. CUELLAR. Thank you, Mr. Chairman, and, Mr. Secretary, it is a pleasure seeing you again. I want to first of all say—I want to thank you for the work that you all are doing in the Rural Partners Network. I think it is a great idea getting the whole of government together, getting all of the I believe about 16 agencies working together. So I certainly want to say thank you so much.

I do understand you have a first cohort that went out, and I think there is a second one. But I am still looking for the State of Texas where we have got more colonias than any other place in the rural areas that we have.

Just want to see if there is anything we can help you in building capacity, because I know that could be an issue. But we certainly want to work with you on that issue. That is one question on when you think the U.S.–Mexico border can come in. I think New Mexico has been covered, but we have the largest amount of colonias.

And then you and I had talked about the colonias coordinators and about appointed—you didn't want to have an office, but you said we will look at a coordinator. So I want to see if there is an update on that.

And, finally, I want to ask you about the cattle fever ticks effort. Since 2008 when we had that farm bill, we have been adding monies and appropriations. Through the help of Chairman Bishop and other folks, the Farm Bureau, we have been adding monies. But in the areas of South Texas along the border, we have the Rio Grande

Valley, and that causes issues because we might do our work on the U.S. side, but then you have wildlife that will cross the river. So we are trying to set up a buffer state with the governors of Mexico that border Texas.

So I want to see how we can work with you on fever ticks because even though we have added millions of dollars, the containment has not shrunk. It actually has grown, and that affects our cattle industry.

So those are the questions that I have. And, Mr. Secretary, I really want to thank you for the great work that you are all doing. We want to be helpful to you in this Appropriations Committee.

Secretary VILSACK. Congressman, we established the Rural Partners Network with the \$5 million that was appropriated, and we have asked in this budget for an increase to \$39 million. And so our ability to expand this program to other states and to other areas of the country is obviously dependent on the ability to provide the resources for the staff.

What this is is basically putting people in specific communities, so they are there 365 days a year working with folks at the local level to identify programs, and then working with the rural desk officers in the 13 federal agencies and 3 commissions to basically remove whatever barriers may exist to developing successful projects.

We are hopeful that this pilot basically gives us a very clear idea of how we need to do business in the future in terms of whole of government approach. So, obviously, the additional resources would be helpful.

We haven't forgotten about Texas and the colonias. I can tell you that we have our rural development folks very much focused on making sure that resources are getting into and providing the technical assistance and support for projects in that area.

And I am certainly happy to work with you to encourage Secretary Villalobos and others in the Mexican government to work collaboratively with you to make sure that we are containing the cattle fever tick issue in a way that is more satisfactory than we have in the past. Obviously, what we want to do is constrain this. We don't want to see it expanded.

Mr. CUELLAR. And, again, before my time is over, I want to say thank you. And I want to say thank you on the avocado issue. People talk about border crisis, but I think our crisis would have been if we would have not got those avocados from down there to cross the border.

But I do want to say thank you because of your good relationship with the Mexican government that can help us diffuse some of those difficult issues that sometimes arise.

So, Mr. Secretary, just for the record—and it will depend on the generosity of this chairman—but we did—we are making a request to increase the funding for the rural network program that you talked about. So we will work with the chairman and the generosity of the full committee. Hopefully, we can expand that to other states also because it is a good approach.

With that, thank you so much, Mr. Secretary.

Thank you, Mr. Chairman.

Mr. BISHOP. Thank you, Mr. Cuellar and Mr. Secretary.

At this time, I am pleased to recognize the gentlelady from Minnesota, the chair of the Defense Subcommittee. Ms. McCollum, you are now recognized for 5 minutes for your questions.

Ms. MCCOLLUM. Thank you, Mr. Chair. Mr. Vilsack, good to see you. As you know, we are struggling with Avian Flu in Minnesota, and we in the metropolitan area are even trying to do our fair share in ceasing the spread of this by asking people to remove their bird feeders. It might sound like a small thing to do, but we are trying to do everything we can to help you and help the Minnesota folks with Avian Flu.

I was pleased to see that there was an increase of more than \$350 million to USDA's research programs. They have been dealing with COVID-19, climate change, conflict, economic downturns. They have all contributed to the rise in hunger, and then Russia's unlawful invasion into Ukraine and the effects that that has had on global food supply.

So we are all aware that costs are up, yields are going to be down, and I believe, from what I have read, we are at the greatest risk with our global food supply since World War II.

These impacts are being felt at home. They are also being felt around the world. Africa imports a huge percentage of its food from Russia and Ukraine, and it is being hit especially hard. Wheat prices are up by 20—excuse me, 60 percent. Fertilizer shortages could cut food production by almost 20 percent.

So, and that continent which already is facing severe food and malnutrition, security concerns before the conflict, they could lose up to \$11 billion worth of food, and then, as I have said, we have got the conflict—the war in Ukraine.

This feeds into a national security crisis for the United States when there is so much civil strife going on, especially for access to food. So I am going to acknowledge the work—I have been reading while the hearing has been going on the supplemental request.

Thank you for all the work the Department of Agriculture is doing in that to address this. But I want to take just a few minutes to ask you about research. U.S. producers and consumers, you know, they need help with improving resistance to pest, disease, and droughts, and scaling up climate resilience.

So what can you tell us about the role that you hope these new investments in agriculture research will play in helping to meet not only our food here in the United States and prices families can afford, but also the global challenges and demands that you are seeing happen?

Secretary VILSACK. If population projections are accurate, we would need as a global community to increase food production by 50 percent by the year 2050 in order to feed all of the people in the world.

That is a tremendous increase in productivity, and it is not going to happen unless we have the research that allows us not only to be more productive but to be more productive in the context of a changing climate where we may have less available water resources in some parts of the world to be able to continue productivity as we know it today.

So it is incredibly important, from gene editing to adaptation and mitigation strategies for climate, that we have a robust effort on the research side.

I am part of the President's Cancer Moonshot. And when I say "I," I mean the Department of Agriculture is. I am on the Moonshot cabinet. And the reason I am on that cabinet is because we have the capacity through research potentially to prevent cancer, not to cure it but to prevent it, through proper nutrition.

Specifically, precision nutrition, the ability to really focus on specific dietary needs of individuals based on their health condition in which food and the food that they consume may very well be helpful in either preventing or mitigating the consequences of a disease that they may be prone to have. So that research is incredibly important.

We are dealing with an obesity issue in this country. That, obviously, speaks to the need for research.

We have talked about Avian Influenza. We have talked about African Swine Fever. We need vaccines. The good news is, on African Swine Fever, that we seem to be making some progress, fairly accelerated progress, in terms of the development of a vaccine that would absolutely cause a sigh of relief on the part of pork producers, not just in this country but around the world.

You know, I could go—I mean, there are unlimited opportunities. We have aviation biofuel. There is a necessity of understanding precisely how to produce a low carbon fuel for our transportation system. The airlines are begging for this fuel. They need it. We need to do more research on precisely what feedstock actually works and how we develop logistically the supply chain for that feedstock. There are issues relative to the health of our forests that we can talk about. I could go on and on and on.

The point of this is that we haven't funded research. We haven't funded it anywhere near the level of importance and significance that it has, and that was the reason why I opened today with focusing in part on research. If we don't get serious about this and continue to nickel and dime it, we are just not going to be able to make good progress, and others are researching. Our Chinese friends are definitely researching.

We don't want to be second rate or second class when it comes to agriculture research. We need to continue to be a leader in this world—in this area.

Ms. MCCOLLUM. Thank you, Mr. Chair, and thank you, Mr. Secretary. Mr. Chair, you are muted. You are muted, Mr. Chair.

Mr. BISHOP. I am so sorry. Thank you, Ms. McCollum, and thank you, Mr. Secretary.

And at this time, I would like to recognize the gentlelady from Maine, the chair of our subcommittee of interior. Ms. Pingree, you are now recognized for 5 minutes for your questions.

Ms. PINGREE. Well, thank you so much, Mr. Chair. Thank you for holding this hearing today. And, Secretary Vilsack, it is always wonderful to see you, and I appreciate your spending time with our committee and talking to us about the budget for the next year.

I have a couple of questions I will submit for the record. I have some things I often talk to you about about the organic rules and about climate change. But I really want to just spend my time talk-

ing about one thing that is a relatively new issue in my State, but really a devastating issue, and that is the challenge that our farmers are finding in having their land contaminated by PFAS.

I know I have communicated with the Department about this a little bit, and it may be an issue that some of my colleagues haven't thought about much, but treat this as a cautionary tale because I think that Maine has done a lot of investigation into this, our farmers are very actively engaged in trying to understand the impact this has on their farms.

But because much of the contaminated land is due to the spreading of sewage sludge on the land, much of it back in the 1970s and 1980s, it is likely to be appearing in states all over the country. And as I say, it is just devastating. I have participated in some roundtables with farmers in our State who already know they have contaminated land.

I have met extensively with our commissioner of agriculture and our head of the environment, and I am really proud of my State for investing in the funds to help farmers test their land and to do everything they can to support these farmers. But when you listen to a young family—and I know we are all anxious to have more young farmers and we have been really proud in our State at how many young people have gotten engaged in farming—many of them are certified organic, so they are particularly cautious about that land.

But once they find out that they have gotten that diagnosis of PFAS contamination, it is just—it is a dead stop. You know, all of a sudden, the products that you have been cultivating in the greenhouse, the things you are about to plant in the land this spring, you just have nowhere to turn.

Your land is contaminated, and very likely you have produce that will be unsaleable. Perhaps you have a dairy herd which has been eating contaminated feed. Perhaps you don't have contaminated land, but you brought hay from somebody else who had contaminated land and didn't know about it. And we have just really seen the tip of the iceberg.

But like I said, it is heartbreaking to talk to the farmers. Many of them are concerned about their own health. Because we have a lot of young farmers, a lot of them have young children who have been, you know, outside playing in the yard or drinking the water that is also contaminated.

Our State is doing a wonderful job investing in testing, but it takes a long time. It takes a long time to discover which lands had sewage sludge spread on them, and there is a lot because it was a conventional practice and probably for many years we assumed it was a good idea, and adding fertility to the land. We didn't know that there were these permanent chemicals—PFAS—in some of that sewage sludge, and we are finding it all over our State.

Some of the farmers, because they don't have time to wait for the State, are paying for their own testing. They are testing themselves and finding extremely high level of contamination in their own bodies, in their children's bodies.

So I just can't say enough about how hard it is to witness this going on and to realize we just don't have the resources. We don't have the science. We can't tell a farmer right now what to do to

mitigate the problem, to remediate the problem, and we are still trying to figure out what are safe levels in produce, in other products. And our own CDC in the State of Maine is doing that kind of research.

So I know I am kind of going on here, but I just can't say enough about it and the importance of the USDA stepping in to help. Funds are being set up in our State to support those farmers who may be devastated economically, to do more research, to do more testing, to support the testing, but I guess—and I have contacted the USDA, and I know that you are working cooperatively with us, but what else do you need to be able to take a bigger leadership role? What kind of funding do you think you need to face this problem going into the future?

And, as always, I certainly invite you to come to the State of Maine, because I would love nothing more than having you sit down with some of the farmers and hearing their story firsthand and hearing, with our own Department of Agriculture, about how they are dealing with this.

Secretary VILSACK. Well, you have correctly identified the need for more information. I think we need a national standard, so that there is a better understanding of precisely what is acceptable. I think we also need to get away from the ad hoc commodity-by-commodity assistance program that we currently have to create more of an overall program that basically covers all of the commodities.

We have something for the dairy industry, but we don't necessarily have something today for produce. And so this is a significant funding issue and one that I suspect you are going to take up in the farm bill.

And I would use this opportunity that you have raised just simply to make this pitch. We always go into the farm bill discussions with the notion that we have to do it within the existing budget. I think that is a mistake, and I think there needs to be some real thought about this, and we need to maybe suggest that on at least this occasion there may be a need for additional resources in that farm bill to address these kinds of emerging issues that you have just identified.

Ms. PINGREE. Well, thank you for that, and I wholeheartedly support you in that endeavor and will look forward to working with the Department about all of the things that you needed—the criteria, the support, and, really, the change in the way that we look at supporting farmers because, as you said, we may have some ideas about how to go about it in the dairy industry, but beyond that, we haven't given it enough thought, and we certainly don't have the program.

So thank you for your consideration. Thank you very much, Mr. Chair. I look forward to working with you on this challenging issue.

Mr. BISHOP. Thank you, Ms. Pingree, and thank you, Mr. Secretary.

We have completed the first round of questions, and we will now begin the second round. And in that light, I recognize myself for 5 minutes.

Mr. Secretary, I was pleased to see a strong focus on minority serving institutions in your fiscal year 2023 budget request. And, in particular, I was pleased to see that it included requested in-

creases for the Cooperative Extension Service and the programs focused on 1890 and 1994 land grant institutions.

Extension programs are notable in their ability to rapidly get new agricultural knowledge to end users. 1890 and 1994 land grant partners are critical to ensuring that those research gains are felt equitably for all of our stakeholders across the country.

As a federal partner of the Nation's extension system, NIFA plays a key role in funding, organizing, and strategizing extension initiatives. What is your goal for increasing extension efforts and building up our minority serving institutions?

Secretary VILSACK. Mr. Chairman, when states began to undercut and underfund extension services at the state level, extension at the 1862 land grant universities began to transition away from providing individual farmer assistance to a method of basically working with consultants who in turn are working with individual farmers.

The problem is that many farmers, particularly those who have been historically underserved, don't necessarily have those crop consultants. They may not be large enough to have the crop consultants to be able to provide the assistance and technical advice. So it is essential and necessary for us to understand the necessity of providing that level of technical—individual technical assistance to those producers.

And one way to do that, obviously, is through minority serving institutions. It isn't the only way, but it is an important way, because they are a trusted source in those communities for information. And so that's why we have encouraged an increase—proposed an increase in the budget, to basically provide those resources to be able to do more of that.

In addition, we have also, as I mentioned earlier, utilizing the Section 1006 money from the American Rescue Plan, to also create multiyear commitments to provide additional technical assistance and access.

This is really, really important. You can have a program, but if people don't know about it and don't know how to go through the process for applying for it, you essentially don't have a program. So this is incredibly important, and we hope that you find the wisdom in providing additional resources in this area.

Mr. BISHOP. Thank you, Mr. Secretary. At last month's hearing with the inspector general, we talked about the impact of the previous Administration's reorganization of civil rights functions at USDA. The OIG recently issued a report that indicated that the departmental civil rights strategic plan was no longer effective, especially in terms of handling complaints. During the hearing, the inspector general stated that this was due to the decentralized nature of the approach that put more responsibility on the agencies with less oversight centrally.

What is your opinion of the OIG's assessments? And do you have plans to undo that reorganization and how you are addressing the issues identified in the IG's report?

Secretary VILSACK. I have a great amount of respect for the OIG and its function, and I have a good relationship with Phyllis Fong and her team. We meet on a monthly basis to basically go over investigations and audits, and so forth, and so we are very serious

about following the recommendations that are made in OIG reports. And that is also true of GAO reports as well.

I will say that our civil rights effort has improved. We were at 69 percent EEO rating, and we are now at 79 percent, and our hope is that by the end of this fiscal year we are closer to 100 percent. We have clearly focused on providing information concerning the level of complaints and the handling in a timely way of those complaints.

I get a monthly report on that as well, and I have seen progress to the point where now 90—more than 90 percent of all EEOC complaints are being handled in a timely way through all aspects—acceptance, denial, review, investigation, and so forth. So I think we are seeing progress. We have got more to do, and we are committed as part of our effort, at creating a great place to work and our equity commitment at USDA. We are committed to making sure we do everything we can to follow the recommendations of the OIG.

Mr. BISHOP. Thank you, Mr. Secretary.

And, at this time, I will yield and recognize our ranking member, Mr. Harris, for additional questions.

Mr. HARRIS. Thank you very much, Mr. Chairman. And, again, thanks, Mr. Secretary, for being here. Obviously, very important Department you run for my district.

Just to follow up a little bit on the reconnect broadband, just to, you know, express a little concern that the infrastructure law changed the threshold for underserved area, you know, from 90 percent to only 50 percent. You know, if you could just keep an eye on it, make sure that doesn't cut out some of our rural areas or delay the buildout into our rural areas, you know, I would greatly appreciate that.

Let me talk—just ask one question about the SNAP program. You know, the SNAP employment and training programs are great ideas. Obviously, you know, a hand up is just as important as a handout. In Maryland, we have a couple of great providers, one in Annapolis that takes homeless individuals on the program and teaches them culinary skills, so they can get employed in the food industry.

How many new SNAP employment and training programs have you brought into the program while you have been secretary?

Secretary VILSACK. Well, we don't bring the—it is not the Department's responsibility to bring those programs in. It is essentially we provide resources to the state, and then states basically provide employment and training.

When I was secretary before, we basically did a pilot project to identify best practices. For example, I can tell you the State of Washington has got a very, very good employment and training program.

The one benefit that I have seen between this time and last time, we did see historically states not spending, not investing all of the employment and training money. That is no longer—I am told that is no longer the case, that states are in fact utilizing those resources. They are taking resources in an innovative way.

You mentioned Maryland's two programs. I think you would find that that is true in many states across the country.

Mr. HARRIS. Well, that is great. If you can get back to me just with the total numbers that are being funded, I realize you are not responsible for getting them in, but, you know, what is happening down—

Secretary VILSACK. Oh, okay.

Mr. HARRIS [continuing]. At the state—

Secretary VILSACK. Yeah.

Mr. BISHOP [continuing]. That would be great. You know, just going back to the global food crisis, you know, I understand the announcement made today, over \$600 billion, I guess \$670 billion, going to be spent with some—with the drawdown on the Bill Emerson Humanitarian Trust for the commodity purchase, which is only \$282 million of that. That is the amount that is going to go to American farmers.

\$388 million from the Commodity Credit Corporation is for necessary costs and transportation expenses. Now, I have a little heartburn over that because, you know, that seems like the tail is wagging the dog. I mean, we have way more costs of delivering the item than actually the food product itself, which obviously benefits our American farmers.

And, you know, I understand that, for instance, we could save \$20 million by not having the requirement for a U.S. shipper to deliver these products. Now, again, the Food for Peace program, we have that requirement. The shippers have to be U.S. shippers.

But this is an emergency situation, and our choice is between spending that 20 million in an already congested market for shipping or buying more product from our farmers. So if you can address that. You know, is the goal of the USDA to get as much product as possible there, realizing that of course these administrative costs look very, very high?

Secretary VILSACK. I had the same reaction you had. In fact, the first time I saw the number it was actually higher than the 300 million number that you mentioned. We were able to essentially ask questions about that high number, got it down to the number where it is today.

There are two components to this. You have mentioned one component—well, actually two components. You have mentioned one component. There is a cargo preference component, which is roughly about \$89 million of that number. The balance of that number is basically the cost of transportation in the countries that we are sending the food to.

So this is an issue of how difficult it is to get product, once you make the decision to provide product to Ethiopia, for example, how much does it cost to actually get it to people in Ethiopia? That is a pretty expensive proposition, apparently.

So we ought—we raise these issues. I don't think I—I am not sure that I have the authority, as secretary, to waive those provisions. I think there are others in the Administration that have that authority and would raise that issue, and that is a decision that will be made, obviously, by those who have the authority to do so. But we have at least put it on the table and basically made sure people were aware of the fact that we could save those resources.

Mr. HARRIS. Thank you.

Secretary VILSACK. We are obviously looking for ways in which we can provide help and assistance. And I might add that we are also looking for ways in which we can increase productivity here at home, which is why you will see in this proposal additional resources to increase the marketing assistance loan program and also to incent double cropping in the areas where that may make sense for producers, providing them incentives and—

Mr. HARRIS. Thank you very much. Our time is out. I would just ask you to—you know, if we could get that strategic plan for Ag ARDA that would be great, you know, get that off the ground. But I understand we don't have the plan yet.

Anyway, I yield back, Mr. Chairman.

Mr. BISHOP. Thank you, Mr. Harris, Dr. Harris, and Secretary Vilsack.

At this time, I am happy to yield for a second round to the gentlelady from Illinois. Ms. Underwood, you are now—

Ms. UNDERWOOD. Thank you, Mr. Chairman. Farmers on the front lines of climate change both bury the brunt of its impacts but also central to delivering climate solutions on the path to net zero by 2050, but they cannot do it alone. Advances in research, technical assistance, and investments in climate smart agricultural practices through USDA will be vital to this mission.

USDA's fiscal year 2023 budget request increased funding for the conservation technical assistance to address the Administration's priority of addressing climate change.

Secretary Vilsack, can you explain on how the agency plans to use this funding to improve assistance to producers to implement climate smart practices?

Secretary VILSACK. Yes. Basically, what we want to be able to do is to continue to provide resources to contract with trusted community-building organizations and entities that have access to and are connected, if you will, to producers, particularly historically underserved producers, to basically make sure that they are receiving information about conservation programs and receiving information about how to apply for and qualify for those conservation programs, helping guide them through the process to make sure that they actually get the assistance and help.

Chief Cosby is very interested in and very committed to this. We established an appropriation or a set of resources this year. We obviously want to make sure that that continues, that technical assistance continues. I would also point out that we are also providing a billion-dollar initiative on climate-smart commodity in forest products. We look forward to receiving applications. The deadline for applications is about ready to expire. We anticipate and expect a very good interest in that program that will also provide support. And we have structured that program in a way that ensures that historically underserved producers can participate in. We will certainly make sure that happens.

Ms. UNDERWOOD. Great. I am encouraged by the Administration's request to extend, enhance WIC of cash value benefits for fruits and vegetables which reach over 4.75 million moms and kids across the country, including many in my district. These enhanced benefits align with science-based recommendations to build on WIC's demonstrated record of improving maternal and child health.

Improved maternal nutrition, in particular, is a key step in preemptively addressing risk factors for pregnancy as we seek to reduce instances of maternal mortality and morbidity.

In your view, Mr. Secretary, how do enhanced WIC benefits strengthen WIC's public health impact?

Secretary VILSACK. Well, by providing greater access to fruits and vegetables, the belief is that that is obviously going to make a difference in terms of the health and well-being of pregnant women as well as their children.

It is one of the reasons why yesterday, I had the opportunity to speak to the Black Mayors Association conference that is being held in Washington, D.C., and I used that opportunity to encourage the mayors who were in attendance at that reception to expand access to WIC and to take full advantage of the WIC program.

I am concerned, and I know you are personally, about the fact that 50 percent of those who qualify for the program are currently not engaged and involved in the program. And unfortunately many of those who are qualified that are involved are people of color, women of color. And so it is important and necessary for us to continue to do a better job of outreach.

It is one of the reasons why we are allocating some of the resources from the American Rescue Plan to basically look at ways in which we can improve outreach to get more participation in that program. So it is not only increasing the bonus, it is also making sure that people are actually available for the regular benefits of the program.

Ms. UNDERWOOD. Well, we would certainly be interested in hearing more details about that kind of ARP-funded outreach effort, if you can have your team follow up with my office.

Additionally, when we can expect USDA to comprehensively evaluate the WIC food package to better align it with science-based nutrition recommendations, which would strengthen WIC's positive impact on maternal and child health?

Secretary VILSACK. That is forthcoming in the very, very near future. I think we are very close to getting that done.

Ms. UNDERWOOD. Okay, but you are committed to doing it?

Secretary VILSACK. Yes, well, yes, absolutely.

Ms. UNDERWOOD. Okay, great. Thank you so much.

I yield back.

Mr. BISHOP. Thank you, Ms. Underwood.

At this time I recognize for a second round of questions. Mr. Valadao from California, you are now recognized. Mr. Valadao.

Mr. VALADAO. Thank you, Mr. Chairman.

Mr. Secretary, again, thank you for this opportunity. Secretary, the Administrator had a nominee at the USTR for the position of Chief Agricultural Negotiator, but that nomination was recently pulled and this position remains vacant. Although this position is not within your department—I know you understand just how important this role is to the people your department serves—this role needs to be filled as soon as possible, and I am concerned the Administration is not taking this position, and to be honest with you, trade as a whole as seriously as it should be.

How do you plan to work with the President, with President Biden and USTR Representative, or Ambassador Tai, to support filling this role with the most appropriate candidate?

Secretary VILSACK. I am aware of the fact that the Trade Representative just recently concluded three interviews for that position. I know two of the three people that she interviewed, and I can assure you that both of those individuals are highly qualified for that job and they are taking that position extremely seriously. And we are in the process of hopefully in the final stages of getting a nominee to the Undersecretary position here on Trade.

I would, with all due respect Congressman, I would take a little bit of exception to the notion that we are not taking trade seriously. I can tell you that I have had more conversations on trade, more conversations with ag ministers across the—in fact yesterday it was Ireland and the U.K.—we are doing more trade missions, we are seeing more barriers being broken and taken down in terms of additional product and we have a record amount of exports now.

I understand that there are some commodities that you are interested in where we have work to do, but on balance we are seeing a significant increase in trade activity. So I think in fairness, I wanted to make those points.

Mr. VALADAO. I appreciate that and, obviously, my district represents, I want to say somewhere around three, four hundred different commodities, and so yes, there have been some where exports have increased, but there are some that are truly struggling and it is a tough time for a lot of farmers across the country. But I just have such a wide variety that I hear, especially the ones who are having the toughest time, we hear from the most, and so this is something that we are watching closely, and I appreciate the efforts that are being made and hopefully we get to a conclusion soon and have someone in that position.

The second one comes up a lot as well, the sign-up for the second round of the Coronavirus Food Assistance Program, or CFAP, closed last October. A lot of my constituents have since reached out to my office asking if additional CFAP rounds will become available in the future. Our agriculture producers across the U.S., especially in my district in Central Valley, are still hurting as a result of the pandemic and other issues.

Do you plan on opening up CFAP again for another round?

Secretary VILSACK. Well, I think it is dependent on whether or not there are resources. There are other steps that we intend to take to improve the safety net, which we expect and anticipate to be able to roll out during the spring and summer. I do not know if it is “CFAP” but I think there are additional programs that will be made available to producers.

Mr. VALADAO. All right. Mr. Secretary, I appreciate you taking some time for us. That is really all the other questions I had. Anything else, if I have more, I will submit for the record. So thank you for your time today and the opportunity.

I yield back.

Mr. BISHOP. Thank you very much, Mr. Valadao, and Secretary Vilsack.

At this time for a second round, I am delighted to recognize Mr. Newhouse from Washington. You are now recognized for five minutes for additional questions.

Mr. NEWHOUSE. Thank you very much, Mr. Chairman. I appreciate that.

Mr. Secretary, I know you are aware that the Federal Columbia River System in the Pacific Northwest comprises 31 hydroelectric projects in the Columbia River Basin. In fact, I would say it is crucial to the ag industry, not only in my state but the entire nation, literally 50 percent of our domestic exported wheat of the United States goes through this system. And that is just one example of really how important this is to the agricultural industry.

I sent you, along with several of my colleagues, a letter, I think it was dated March 15th, citing several questions about the CEQ's engagement process, the stakeholder engagement process, and the focus that breaching the Lower Snake River dams would have on our agricultural sector, and if I could, I would like to follow up on that letter.

My questions are this: Has the CEQ included USDA in the current stakeholder engagement process examining the species recovery in the Columbia River Basin; and if so, what is the USDA's role in that process?

And then has the USDA been consulted on the impact removing the Lower Snake River dams would have on wheat producers, and specifically and how removing the producer's method of transportation to the West Coast would affect U.S. wheat and other domestic markets?

Secretary VILSACK. Congressman, I would say that our responsibility both with CEQ and also I would say also with EPA is to make sure that we are engaging with them to make sure they have all the information necessary on the impact that a particular course of action being considered would have on producers. That is the first thing.

The second thing is to make sure that we advocate, obviously, on behalf of producers, and depending upon what the decisions are made, that we then take a look at how we at USDA can utilize the resources we have to mitigate the consequences or impact of any decision. I mean I don't want to tell CEQ necessarily or EPA exactly what to do because I don't frankly want them telling me exactly what to do, but we have an advisory role. And then based on what they decide to do within their jurisdiction, we can figure out ways in which we can potentially help farmers implement, help farmers mitigate the consequences of actions.

Mr. NEWHOUSE. So can I take from that, then, that USDA has been engaged with CEQ through this process? Or—

Secretary VILSACK. I believe it has, Congressman. I could be mistaken about this, and if I am we will let you know, but I believe we have been engaged because that is our job and it is our responsibility.

Mr. NEWHOUSE. Okay. Okay, well, just to underscore the importance of that entire system, too, like I said, the nation's agricultural industry, but in particularly the Pacific Northwest and the seven neighboring states, it is a critical piece of infrastructure would—the breaching dams would significantly, negatively, and ad-

versely impact the industry, and I appreciate your input and your communication with the CEQ as they consider options here.

Thank you very much, Mr. Secretary. It is always a pleasure to see you in front of our committee.

With that, Mr. Bishop, I will yield back.

Mr. BISHOP. Thank you very much. And Secretary Vilsack, thank you so very much for your testimony here today. Mr. Rapp, thank you for your attendance and support of Secretary Vilsack. We all understand how incredibly busy you are these days, so thank you, thank you, thank you for your time. Thank you also for the hard work that you and the department are doing to help lift up rural America. I look forward to working with you as we continue the fiscal year 2023 appropriations process.

Along with what we have discussed, we will also forward additional questions for the record and we will appreciate your diligence in getting your responses to us in a timely manner.

I would recognize Dr. Harris, but I believe he had to excuse himself for another hearing, and so he will not be giving a closing statement.

So let me just say in his absence, thank you to Dr. Harris and to all of the members in attendance, and thank you for the staff who work so hard to pull this hearing together. With that, this subcommittee is now adjourned.

[Questions and answers submitted for the record follow:]

**The Honorable Grace Meng
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and
Related Agencies
Questions for the Record
Fiscal Year 2023 Budget Request for the Department of Agriculture**

New York is among the leading producers of dairy in our country, with nearly 3,600 small, medium, and large-sized dairy farms. The dairy industry is New York's largest agricultural sector and fluid milk sales are critically important for its success. Access to milk, including flavored milk, in school meals is also important for meeting the nutritional needs of children. USDA recently announced its transitional nutrition standards for the coming two years, which allows for schools to offer flavored and unflavored low-fat and nonfat milk.

- **Are there other steps USDA is taking to promote access to flavored and unflavored milk in schools and increase access to dairy products?**
- **Has USDA supplied information to schools regarding the nutritional benefits of serving flavored milk and promoting access to flavored milk as part of school meals?**

THE U.S. DEPARTMENT OF AGRICULTURE
WITH SECRETARY TOM VILSACK
QUESTIONS FOR THE RECORD
FISCAL YEAR 2023 BUDGET REQUEST FOR THE DEPARTMENT OF AGRICULTURE
HOUSE AGRICULTURE APPROPRIATIONS SUBCOMMITTEE HEARING
APRIL 28, 2022

QUESTIONS SUBMITTED BY ACTING RANKING MEMBER ANDY HARRIS

Reconnect Broadband Program

Mr. Harris: Over the past couple of years, Congress has provided nearly \$4 billion for the Reconnect program through the appropriations process and the Infrastructure Investment and Jobs Act. I support this program and know how important it is for rural businesses, households, and communities to have access to broadband. But I am concerned about the changes made in the Infrastructure law to lower the unserved area threshold from 90 percent to only 50 percent of households lacking access to broadband. These changes will likely shift dollars away from the rural areas most in need of broadband and can result in overbuilding and redundancy in areas that may already be served. I would also note that there are broadband programs at other Federal agencies, like the National Telecommunications and Information Administration (NTIA) and the Federal Communications Commission (FCC).

How is USDA making sure unserved communities that are in need of broadband access is being made a priority through the Infrastructure funding?

Response: Congress passed, and President Biden signed the Infrastructure Investment and Jobs Act (IIJA) into law (P.L. 117-58) on November 15, 2021. In recognizing that the digital divide disproportionately affects communities of color, lower-income areas, and rural areas, and that the benefits of broadband should be broadly enjoyed by all, the IIJA invests in broadband (high-speed internet) infrastructure, including in rural areas where households have historically had lower access to broadband compared with households in urban and suburban areas. The IIJA includes funding for two USDA broadband programs that serve rural communities: the ReConnect Program and the Rural Broadband Program. The IIJA provides \$2 billion for USDA broadband programs; this includes \$1.926 billion for ReConnect grants and loans and \$74 million for Rural Broadband Program.

USDA Rural Development is committed to the deployment of broadband in unserved areas. Prior to the enactment of IIJA, Congress provided a more restrictive definition of eligible service area for the ReConnect Program; where at least 90% of households lack sufficient access to broadband. Sufficient broadband access is defined as speeds of at least 100 Megabytes per second (Mbps) download and 20 Mbps upload (i.e. 100/20). Congress redefined eligible service areas for the IIJA funds to be where at least 50% of households do not have sufficient broadband access of speeds at least 25/3 Mbps.

USDA is currently in the process of sending out announcements for ReConnect Round 4. We have made it our highest priority to ensure that unserved and underserved communities benefit

from the ReConnect Program. The Round 4 Funding Opportunity Announcement (FOA) scoring system is heavily weighted toward the rurality of the proposed funded service area (PFSA); the lack of existing service in the PFSA; the economic need of the community, and affordability for the community.

The IIJA includes a set-aside that requires 10% of the funding for the ReConnect Program be reserved for service areas where at least 90% of households are in rural areas without sufficient broadband access of speeds of at least 25/3 Mbps.

The IIJA includes a rural in character exception which uses the definition of eligible rural area codified in the Rural Electrification Act: cities or towns with 20,000 or fewer inhabitants and not in an urbanized area contiguous and adjacent to a town that has a population of greater than 50,000. The exception allows the Secretary of Agriculture to allocate up to \$50 million of ReConnect Program funds to projects in areas that are rural in character. The ReConnect funding announcements, application review and awarding process ensures that projects in underserved communities are prioritized.

Mr. Harris: How is USDA coordinating with the NTIA and FCC to ensure there is not duplication of service?

Response: USDA approaches federal broadband coordination in three ways; interagency agreements, ongoing information sharing and open communications. In May, the USDA, the Federal Communications Commission (FCC), National Telecommunications and Information Administration (NTIA), and the Department of Treasury announced an interagency agreement to share information about and collaborate regarding collection and reporting of certain data and metrics related to broadband deployment. Most importantly, this Memorandum of Understanding (MOU) brought the Department of Treasury into a data sharing agreement. USDA shares our broadband mapping data with the FCC and NTIA and we maintain open and frequently used lines of communications with sister Federal agencies to ensure timely collaboration. This shared information prevents use of Federal funds that would duplicate service in an area.

Mr. Harris: During Round 1 of the ReConnect Program, USDA executed and Interagency Agreement with NTIA to leverage their staff and expertise to assist with USDA's outreach efforts. USDA and NTIA have hosted several state roundtables to engage community leaders and federal partners.

Is USDA providing Reconnect funds in areas that have already been designated to receive NTIA or FCC funds? Is there any prohibition on redundant funding? If not, are there any guardrails on funds going to areas already covered by other programs? If so, please explain those parameters.

Response: USDA has established a policy whereby we are working to ensure that our ReConnect projects complement and do not duplicate awards being made by NTIA and the FCC. For our 3rd round of ReConnect funding, we are taking steps to de-conflict the geographic boundaries of any of our potential awards with the Rural Digital Opportunity Fund (RDOF) and are ready to Authorize Awards that have been made, or awards made by NTIA.

Mr. Harris: On a related note, if there is a prohibition or effort to avoid duplicative funding, concerns have been raised that some of the FCC recipients may never in fact build. How will USDA work with those agencies to ensure that service is ultimately provided to the areas that may not be eligible for Reconnect funding?

Response: USDA is working closely with our Federal Partners to ensure our funding works to complement their efforts, so that we can get service out to all areas of the country. And we are communicating regularly regarding any changes to funding. For instance, the FCC informed USDA when they made the decision to “reject” Rural Digital Opportunity Fund (RDOF) applications submitted by a few winning bidders whose long form applications were not accepted by the commission. As a result, USDA allowed Round 3 applicants to apply for funding in those areas. An application would be eligible for ReConnect as long as they can pass all of our eligibility requirements.

Dietary Guidelines for Americans

Mr. Harris: USDA and HHS recently started the 2025 Dietary Guidelines for Americans (DGA) process by publishing the proposed scientific questions that will inform the process. On the DGA website, it states, “There are two topics not on the list of questions to be examined by the 2025 Dietary Guidelines Advisory Committee (DGAC) that will be addressed in separate processes.” One topic is alcoholic beverages and the other is sustainability.

Mr. Secretary, you were the Secretary of Agriculture last time sustainability crept into the 2015 dietary guidelines process, and most of the food and agriculture industry was adamantly opposed to its inclusion. While it sounds like a positive development that sustainability is not on the list of questions to be addressed by the DGAC, the statement about a “separate process” creates some confusion and skepticism. What does it mean specifically that sustainability, and alcoholic beverages, will be addressed in “separate processes?”

Will the processes for alcoholic beverages and sustainability be distinct from each other or generally the same structure?

Response: We appreciate your question and interest in the process to develop the next edition of the Dietary Guidelines for Americans. USDA and the U.S. Department of Health and Human Services (HHS) are working together to determine the approaches that will be employed on alcoholic beverages and sustainability. It’s premature to discuss the plans, but once they are in place, information will be posted publicly at DietaryGuidelines.gov. We would be happy to share this information once it is available.

Food and Nutrition Service Anti-Discrimination Policy

Mr. Harris: USDA issued a press release on May 5, 2022, that it will interpret the prohibition on discrimination based on sex found in Title IX of the Education Amendments of 1972, and in the Food and Nutrition Act of 2008, to include discrimination based on sexual orientation and gender identity. It also states that state and local agencies, program operators and

sponsors that receive funds from FNS must investigate allegations of discrimination based on gender identity or sexual orientation.

Mr. Secretary, I agree that there is no room for discrimination in accessing USDA's nutrition programs, and anyone who meets the eligibility requirements should receive assistance. How prevalent is discrimination based on sexual orientation and gender identity across all of USDA's nutrition assistance program? I want to understand the scope of the problem this announcement is trying to address. Please provide examples and how many complaints have been filed in this regard and how FNS and state agencies have addressed this issue. Please also clarify the specific authorities FNS has to combat discrimination and the authority FNS has to include discrimination based on sexual orientation and gender identity.

Response: Each of the Food and Nutrition Service (FNS) programs also has enabling regulations that include certain civil rights components. The Supplemental Nutrition Assistance Program (SNAP) regulations at 7 CFR 272.6 describe procedures for Supplemental Nutrition Assistance Program (SNAP) complaint handling, and specifically authorize State SNAP agencies with an approved complaint processing procedure to opt to directly process program civil rights complaints. States must process discrimination complaints based on sexual orientation and gender identity just as they would process discrimination complaints based on sex.

Generally, State agencies must "timely" forward all complaints of prohibited discrimination to FNS, unless they have an approved complaint processing procedure in place. In addition, State agencies must maintain records of complaints and submit records to FNS. State agencies with approved complaint processing plans must follow those plans in handling complaints, including submitting decisions to FNS for review before they are issued, and ensuring decisions include appeal rights to USDA's Office of the Assistant Secretary for Civil Rights.

Before 2016, FNS complaint databases were not set up to track complaints of discrimination in SNAP programs that raised issues based on gender identity or sexual orientation separately from other sex discrimination complaints. Beginning in 2016, FNS Civil Rights tracked complaints based on gender identity or sexual orientation manually. Between February, 2016, and August, 2022, FNS received 36 complaints of discrimination in the SNAP program based on sexual orientation or gender identity.

FNS reached out to all 36 complainants. In 33 cases, FNS received no response from the complainant. FNS closed one case because the complainant filed in court on substantially the same issues, received one request to withdraw the complaint, and issued one final agency decision finding no discrimination.

State partners have always effectively processed complaints based on sex discrimination, and FNS civil rights staff are available to answer questions and ensure that our State partners can efficiently deliver the SNAP program.

Wild Caught Catfish Inspections

Mr. Harris: In both the fiscal year 2021 and 2022 omnibus appropriation laws, \$1 million was provided to FSIS for the inspection of wild caught catfish. Please provide a breakout of how the \$1 million is being spent in both fiscal years. How is FSIS working with catfish processors to educate them about the availability of these funds?

Response: On March 22, 2021, the Food Safety and Inspection Service (FSIS) issued Notice 11-21 to its inspection workforce which stated FSIS would no longer bill establishments that process invasive wild-caught catfish for inspections that occur outside of scheduled hours (i.e., overtime and holiday time). In addition, FSIS would reimburse establishments for any overtime or holiday hours previously billed going back to October 1, 2020. Inspection program personnel (IPP) assigned to establishments that process wild-caught catfish were directed to share this information with establishment management at their next weekly meeting. FSIS shared this Notice in its March 26, 2021, FSIS Constituent Update, which is distributed to over 46,000 stakeholders.

Later this spring I also anticipate FSIS to issue a directive to its inspection workforce. The IPP will assign to establishments that process wild-caught catfish shared with establishment management that FSIS will not bill establishments that process invasive wild-caught catfish for inspections that occur outside of scheduled hours (i.e., overtime and holiday time). FSIS will ensure these establishments were not charged or will be refunded for any overtime or holiday hours that were billed and collected for reimbursable services provided on or after October 1, 2020. The FSIS fiscal year (FY) 21 and 22 appropriations bills included up to \$1 million each to defray the costs of inspection of invasive wild caught catfish. FSIS defrayed a total of \$33,953 in FY 21 and an additional \$60,653 through April of FY 2022.

CCC Funds

Mr. Harris: Mr. Secretary, a lot of liberty has been taken in spending billions of CCC funds on the Biden Administration priorities, in particular for climate smart ag. How are you able to make transfers in FY 22 under Section 5 of the CCC Charter Act if such transfers were not included and approved by Congress as part of the CCC FY22 budget? Please provide your legal authority for these transfers.

Response: Section 5 of the CCC Charter Act (15 U.S.C. § 714c), which is supporting our highly popular work to create new markets for climate smart commodities, permits CCC funds to be used (1) in the fulfillment of its purposes, or (2) in carrying out its annual budget programs submitted to and approved by the Congress pursuant to chapter 91 of title 31. The use of Section 5 authorities is thus not conditioned on inclusion in the annual budget programs of CCC submitted to Congress, and therefore it is not conditioned upon approval by Congress.

Mr. Harris: In September 2021, USDA issued a press release stating that it would use \$3 billion to carry out several initiatives, and this funding came from CCC funds. These funds were not used in fiscal year (FY) 21 but appear to have been transferred at that time solely to increase the net realized losses of CCC for that fiscal year so that the replenishment of CCC's borrowing

authority in FY 22 would be increased by that amount. Please explain how these funds were transferred from CCC to other USDA agencies without the requisite Congressional approval as provided in the opening sentence in section 5 of the CCC Charter Act.

Response: The authority for CCC to transfer the \$3 billion to other USDA components is found at 15 U.S.C. § 714b(j) & (l) and 7 U.S.C. § 8316.

“[A]pproved by the Congress” is a phrase that appears in one of two provisions contained in a prefatory clause in Section 5 of the CCC Charter Act (15 U.S.C. § 714c). This prefatory clause describes two types of actions under the Charter Act for which Congress has limited the CCC’s use of its general powers: when the CCC is fulfilling its purposes, and when it is carrying out a budget program. As discussed below, with respect to the second type of activity, Congress did not bind itself to evidence its approval in any particular means, but historically has done so by continuing appropriations and by declining to take action to disapprove a budget program (or amendment thereto).

Section 5 provides that “[i]n the fulfillment of its purposes and in carrying out its annual budget programs submitted to and approved by the Congress pursuant to chapter 91 of title 31, the [CCC] is authorized to use its general powers only” for the purposes set out in that section.

As a matter of statutory construction, the “and” must be disjunctive because to read it otherwise improperly would render superfluous the “and in” text separating the first and second clauses of this provision. Put another way, the CCC

- (1) in the fulfillment of its purposes; and
- (2) in carrying out its annual budget programs submitted to and approved by the Congress pursuant to chapter 91 of title 31

is, in either of cases numbered 1 or 2, authorized to use its general powers only for the specific purposes set out in Section 5.

The text of Section 5 thus does not provide that the use of Section 5 authorities is conditioned upon inclusion in the annual budget programs of CCC submitted to Congress, and therefore it is not conditioned upon any approval by Congress. That Congress would allow for such flexibility follows naturally from the Government’s need to deal with and address unexpected and urgent agricultural issues within the scope of the CCC’s purposes under the CCC Charter Act that arise throughout the year, separate from CCC’s annual budget programs.

This interpretation of Section 5’s prefatory and descriptive, not prescriptive, second clause containing the “approved by the Congress” phrase is corroborated by the decades-long practices of Congress and the CCC in fulfilling the CCC’s purposes. To illustrate, USDA has not amended the CCC’s annual budget to reflect Congressionally-mandated uses of CCC funds or CCC funds, facilities, and authorities under Section 5, such as the uses specified under section 5(h), which represent the bulk of CCC spending.

Alternatively, for the sake of argument, even if the “and” is read conjunctively, what is meant by the phrase “approved by the Congress” is governed by chapter 91 of title 31, the Government Corporation Control Act (GCCA).

The CCC is a “wholly owned Government corporation” under the GCCA. 31 U.S.C. § 9101(3)(A). Section 9103 of the GCCA provides in part that:

§ 9103. Budgets of wholly owned Government corporations

....

(c) The President shall submit the budget programs submitted by wholly owned Government corporations (as changed by the President) as part of the budget submitted to Congress under section 1105 of this title. The President thereafter may submit changes in a budget program of a corporation at any time.

In short, Congress provided that changes in a CCC budget program may be submitted “at any time.”

The GCCA also contains provisions concerning Congressional action on budgets of wholly owned Government corporations. 31 U.S.C. § 9104. Section 9104(a) of the GCCA provides that Congress shall “consider budget programs for wholly owned Government corporations the President submits” but does not compel or anticipate a particular manifestation of congressional approval of the Government corporation’s budget, which, for example, may be indicated by the appropriation of funds in response to a submitted budget under 31 U.S.C. § 9104(a)(2) or through the absence of express disapproval of a particular program.

The CCC has historically chosen to use the budget amendment process under the GCCA as a means of informing Congress of new activities and uses of funds for purposes authorized under Section 5. The CCC intends to continue this tradition, not because it is statutorily required, but because it has proven a useful means for Administrations and the Congress to coordinate and monitor their respective activities relating to the CCC.

Read together, the GCCA and Section 5 provisions inserted by Congress provide considerable flexibility to submit, adjust and consider CCC budgets.¹

In sum, Section 5 authorizes the CCC to use its specific powers in Sections 5(a) through (h) to fulfill its purposes, and to carry out its annual budget programs. Neither Section 5 of the CCC Charter Act nor the GCCA restrict what “approved by the Congress” means for CCC purposes. Nor do they dictate the particular means by which Congress’ approval of changes to CCC annual budget programs may be evidenced.

¹ Further, Congress also specified that:

(b) This section does not—

(1) prevent a wholly owned Government corporation from carrying out or financing its activities as authorized under another law; . . . or

(3) affect the authority of a wholly owned Government corporation to make a commitment without fiscal year limitation.

31 U.S.C. § 910(b).

Mr. Harris: In the Appendix to the Budget of the U.S. Government for FY23, under CCC, it notes a series of proposed transfers from CCC to unidentified receiving accounts. For each proposed transfer, please provide a description of the intended use and the Treasury account symbol for the receiving account.

Response: Please see the table displayed below, which provides a description of the intended use and Treasury account symbol for the receiving accounts.

USDA CCC Transfers FY 2023 (Dollars in Thousands)			FY 2023 Amount
Agency	Treasury Symbol	CCC Transfers	
AMS	12A2501	Specialty Crop Block Grants	85,000
AMS	12X2500	Milk Donation Program	5,000
AMS	12X2500	Local Agriculture Market Program - AMS - 57% plus 62% of 8% Admin	30,978
AMS	12A0215	Sheep Production and Marketing Grant Program	2,000
APHIS	12A1600	Plant Pest & Disease Management Disaster Prevention	75,000
APHIS	12X1600	Animal Disease Prevention and Management	30,000
FNS	12M3507	Seniors Farmers' Market Nutrition Program	20,600
NASS	12X1801	Organic Production and Market Data Initiatives - NASS	1,000
NIFA	12A0520	The Gus Schumacher Nutrition Incentive Program	50,000
NIFA	12A0520	Organic agriculture research and extension initiative	50,000
NIFA	12A0520	Specialty Crop Research Initiative	80,000
NIFA	12A0502	Farming Opportunities Training and Outreach	25,000
NRCS	12A1072	Watershed protection and flood prevention	50,000
NRCS	12X1004	Environmental Quality Incentives Program (EQIP)	2,025,000
NRCS	12X1004	Conservation Stewardship Program	1,000,000
NRCS	12X1004	FSRIP Technical Assistance	238,000
NRCS	12X1004	Regional Conservation Partnership Program	300,000
NRCS	12A1004	Education and Risk Management Assistance Agriculture Management Assistance Program (AMAP)	3,000
NRCS	12X1004	Agricultural Conservation Easement Program (ACEP)	450,000
OSEC	12A0115	Transparency and accountability for socially disadvantaged farmers and ranchers	20,000
RBS	12X1908	Rural Energy for America Program	50,000
RBS	12X3105	Rural Economic Development Grants	5,000
RBS	12X2073	Bioenergy Programs for Advanced Biofuels	7,000
RBS	12X1900	Local Agriculture Market Program - RBS - 35% plus 38% of 8% Admin	19,022
RD	12A0403	Biobased Markets Program	3,000
RMA	12X4085	Education and Risk Management Assistance	4,000
FSA	12X5635	Pima Agriculture Cotton Trust Fund	16,000
FSA	12X5636	Agriculture Wool Apparel Manufacturers Trust Fund	30,000
			4,678,600

Mr. Harris: Do you agree that if Congress approves the CCC budget for FY 23 as submitted in March to Congress that it may not use its discretionary authority under any other statute that is not identified in its budget submission?

Response: We understand your question to be that to the extent the CCC budget may identify a particular authority for its prospective activities, would that preclude the use of its discretionary authority with respect to such activities. The CCC may use its discretionary authority as authorized in the CCC Charter Act, unless specifically prohibited by law to the contrary. The use of discretionary authority is not conditioned on inclusion in the annual budget programs of CCC submitted to Congress.

Highly Pathogenic Avian Influenza

Mr. Harris: Mr. Secretary, as you know, I am closely monitoring the outbreak of Highly Pathogenic Avian Influenza as it's top of mind for my poultry constituents. As USDA identifies poultry and egg producers affected by the virus, I understand farm locations are to remain confidential. However, I'm hearing concerns that perhaps the locations of affected operations are being leaked to the public. Are you aware of this concern? Have you looked into this situation or even asked the Inspector General to investigate whether the locations of poultry and egg operations are being leaked?

Response: We take the privacy and confidentiality of producers seriously and work to ensure specific details about any impacted location are not made publicly available for business confidentiality and security reasons. Early in the course of the outbreak, the Animal and Plant Health Inspection Service (APHIS) was notified of a Google map created by a private individual that appeared to provide specific locations of Highly Pathogenic Avian Influenza cases. Upon investigation, we confirmed that the map only provided approximate locations and all information included was available in the public domain. APHIS has no evidence to believe that any APHIS employee leaked information to the map creator or that there was a data system breach based on our internal investigation.

Emerging Animal Diseases

Mr. Harris: Food safety, quality and availability are paramount concerns for both producers and consumers. Preventing the spread of infectious diseases in the animal population is crucial to these concerns. The USDA plays a vital role in not only addressing disease outbreaks when they occur, but also actively working to prevent outbreaks. With the increasing number of infectious diseases threatening animal agriculture, such as Highly Pathogenic Avian Influenza (HPAI) and African Swine Fever, what steps are being taken to address emerging animal diseases? How does the USDA plan to partner with private industry to develop vaccinations for emerging diseases?

Response: Protecting the health of domestic livestock herds from emerging animal diseases is a high priority for the Department. USDA is currently responding to HPAI domestically and working to prevent the introduction of African Swine Fever into the United States. At the same time, we are bolstering our preparedness efforts. Using funding provided by the 2018 Farm Bill as well as annual appropriations, USDA has partnered with States and industry to conduct tabletop exercises, create stockpiles of emergency program response tools and laboratory supplies, and vaccines where available: for example, for foot and mouth disease. We have worked closely with our Customs and Border Protection partners to improve port of entry inspection to detect and seize prohibited materials. The National Bio and Agro-Defense Facility (NBAF) is nearing completion. NBAF will be the first laboratory facility in the U.S. to provide biosafety level-4 laboratories capable of housing cattle and other large livestock. NBAF will also feature a Biologics Development Module (BDM) for the pilot scale development of vaccines and other countermeasures, augmenting laboratory research and accelerating technology transfer to industry partners.

QUESTIONS SUBMITTED BY CONGRESSWOMAN BARBARA LEE

Agricultural Exporters

Rep. Lee: Secretary Vilsack, I know you are well aware and engaged in the ongoing export situation at Port of Oakland in my district. This port is consequential for Asia-bound farm products, particularly tree nuts, meat products, and dairy. The exporters that rely on this port – both within California and elsewhere in the country – have incurred severe financial losses from this, and stand to lose more in the coming months.

Can you provide an update on the engagement USDA is specifically having with the ocean carriers to urge a resumption of service?

Response: As agricultural producers and companies deal with the continued impacts of the COVID-19 pandemic, ocean carriers' poor service and refusal to serve customers, including refusing to provide and ship containers, have exacerbated existing challenges. Specifically, ocean carriers have made fewer shipping containers available for U.S. agricultural commodities, repeatedly changed return dates, and charged unjust fees. These same ocean carriers have short-circuited the pathways typically used to make shipping containers available to be filled with agricultural and other goods, and they have subsequently rushed these containers back to foreign ports empty. These trends have and continue to be seen at several U.S. ports, including but not limited to the Port of Oakland, the Port of Seattle, and the Port of Tacoma, where many ocean carriers have partially or completely suspended their services. I myself have engaged with many of these carriers to convey the impacts and disruptions of this poor service. While I hope that these carriers take steps to make more shipping containers available, I don't have control over their actions. That's why I have been focused on making sure USDA leverages the authorities we have available to us to support agricultural commodity owners in moving their products to market. Through our Commodity Container Assistance Program, which is fully operational at the Port of Oakland along with the ports encompassed by the Northwest Seaport Alliance in Washington State, I believe we are doing just that.

Rep. Lee: What type of support is USDA providing to agricultural exporters as they attempt to navigate these conditions?

Response: USDA is implementing the Commodity Container Assistance Program, funded through the Commodity Credit Corporation, to increase capacity for exporting agricultural commodities through the Port of Oakland, along with other ports. Additional details are available at www.farmers.gov/ccap website and I expect a Notice of Funding Availability to be posted on the Federal Register later this spring.

Research Infrastructure

Rep. Lee: Secretary Vilsack, thank you for your commitment to NIFA and for your continued support for agriculture research. Recent reports indicate there is a serious need for investments in agricultural research infrastructure. Many agriculture research facilities were built in the 50s and have outlived their useful lives. Improving the infrastructure for agriculture

research facilities, such as at our nation's land-grant universities, would help ensure the U.S. can continue to be competitive globally and be positioned to address food insecurity issues.

Would providing additional funding for grants through the Agriculture Research Facilities Act be something that the USDA could utilize to help to address research infrastructure needs facing agriculture research facilities?

Response: Yes, if the Committee were to include funds in the FY 2023 Appropriations bill to support the Research Facilities Act authorization, USDA's National Institute of Food and Agriculture (NIFA) would be able to make competitive grants to assist in the construction, alteration, acquisition, modernization, renovation, or remodeling of agricultural research facilities, depending on the funding level provided, to help address research infrastructure needs.

Rep. Lee I know that we have a number of aging agriculture research facilities in California and throughout the nation, and improvements to agriculture research infrastructure facilities would help ensure that the U.S. can stay at the cutting edge of research to ensure that our nation can meet food supply needs, and that critical research can be done to address issues such as improving techniques for drought resistance crops; addressing the need for pesticide alternatives; promoting sustainable agriculture practices; and addressing emerging crop and plant diseases.

How could the USDA better support the needs for agriculture research infrastructure improvements to be made?

Response: Infrastructure investments would ensure America's global preeminence and competitiveness in agriculture research and have a direct impact on the quality of science, ensure safety in the classroom and experiment stations, and recruit the best and brightest scientists to address ongoing and emerging agricultural challenges. Projects to improve infrastructure can immediately create local jobs and realize savings over time in lower capital cost, improve energy conservation, and lead to operational and maintenance solutions. Failing infrastructure keeps the agricultural colleges from taking advantage of opportunities offered by modern advances in technology and computational science, much of which require modern facilities for research. Failing infrastructure also makes it difficult for our agriculture colleges and land grant universities to attract top quality researchers to their campuses. One possible barrier to participation by colleges is the matching requirement: smaller schools would be at a disadvantage if they need to provide 100% match. A smaller match requirement or no match requirement might eliminate this barrier. Additionally, a portion of the program could be set-aside to address needs of underrepresented communities. This would allow a more equitable distribution of the infrastructure investment funds.

Cooperative Extension Support

Rep. Lee: Secretary Vilsack, NIFA's capacity fund programs such as Hatch, Smith-Lever, and McIntire-Stennis play a critical role in supporting cooperative Extension, research and education services in communities throughout the United States. Providing funding for capacity grant programs is critical to ensure that there are services that can be provided in communities,

such as 4-H programs for youth; including STEM programs; agriculture experiment stations to assist with agriculture producer needs; cooperative Extension programs; master gardener programs; and other activities. These programs funded through capacity grant funds play a critical role in addressing community needs. Yet, there isn't much attention or understanding given to the important role capacity grant funding plays in supporting our rural and urban communities.

I understand from the University of California's Agriculture and Natural Resources, which carries out cooperative Extension programs in counties throughout California, that in 2020 alone over 2,500 research and Extension projects were conducted, leading to advancements that help to address agriculture industry needs, as well as local community needs, such as through outreach to local communities.

How can the USDA better support telling the story of what is accomplished by capacity driven programs in serving our local communities?

Response: USDA National Institute of Food and Agriculture (NIFA) is diligently in communication with the Land-grant university community to continuously monitor progress, accomplishments, and impacts derived from capacity driven and competitive programs. The NIFA Communications Office works closely with the Land-grant partners to continuously improve how we highlight compelling examples on the impacts of investments from capacity driven programs. NIFA and our Land-grant partners disseminates this information through digital and social media means as well as articles in traditional media. To review Impacts please see the University Impacts page that is searchable by capacity programs at: https://www.nifa.usda.gov/news?f%5B0%5D=post_type%3A1922

Rep. Lee I also am concerned that funding for capacity funded programs is not keeping pace and funding needs to be increased. Do you agree that the cooperative Extension programs carried out through Smith-Lever and Hatch, McIntire-Stennis and other programs should be provided with greater funding levels to support the critical role carried out in our local communities?

Response: Extension programs carried out through Smith-Lever and the Renewable Resources Extension Act provide on the ground non-formal education activities and objective science-based information to people throughout the country directly to farmers, foresters, and other residents of rural communities as well as to people living in urban areas. Extension emphasizes delivering research and education taking directly to the people to create positive change and solutions to contemporary problems. Through Extension, land-grant colleges and universities bring vital, practical information to agricultural producers, small business owners, consumers, families, and young people. National, regional, and local, changes in the food and agricultural system and declining real-dollar resources have forced state Cooperative Extension programs to prioritize their resource investments and change information delivery models. This prioritization is driven by state and local stakeholders to address contemporary issues. Continued investments in Extension would expand our ability to reach people and communities, make a real difference in these areas, and support a system that has historically assisted people and communities across the nation for 100 years.

Research programs such as Hatch Act, Evans-Allen, McIntire-Stennis and other programs provide support for National, regional, and local challenges to support the food and agriculture and related systems. For example, the innovations supported by Hatch funds have demonstrably helped increase farm incomes, improved nutrition security, and enhanced the quality of life in America. Hatch funding provides critical support of science and data-driven long-term research on local and regional agricultural systems that are carbon-neutral, climate-smart and maintain profitability and productivity for U.S. farmers and ranchers. Hatch and McIntire-Stennis capacity funds are matched by non-Federal funds to support continuing agricultural research at approved schools of forestry, land-grant institutions, as well as State Agricultural Experiment Stations (SAES) in the 50 states, the District of Columbia, and the Insular Areas. Most of the 1890 Land-grant institutions that receive Evans-Allen capacity funds also receive matching non-Federal funds. Appropriated funds that Congress provides are used to conduct original research, investigations, and experiments bearing directly on and contributing to the establishment and maintenance of a permanent and effective agricultural industry of the States, including research basic to the problems of agriculture in its broadest aspects, and such investigations as have for their purpose the development and improvement of the rural home and rural life and the maximum contribution by agriculture to the welfare of the consumer, as may be deemed advisable, having due regard to the varying conditions and needs of the respective States.

Finally, 25% of Hatch funds must be used for cooperative research employing multidisciplinary approaches in which a State agricultural experiment station, working with another State agricultural experiment station, the Agricultural Research Service, or a college or university, cooperates to solve problems that concern more than one State. Much of the research supported with Hatch funds at the state level is not amenable to support due to the time restrictions found within competitive grants or funding from private or corporate interests. Understanding and mitigating the impacts of climate change on food and agricultural production, for example, requires continuous support that is not sustainable by individual 3 to 5-year competitive grant awards. In many cases, Hatch funds provide seed money that enable researchers to become competitive for other sources of funding and supportive of land-grant universities competitiveness in the food, agricultural, natural resource, and human sciences. Continued investments in Hatch funding will ensure that rural communities remain competitive and produce and deliver new knowledge focused on the food, water, energy, and climate nexus to achieve healthy environments and ecosystems, plants and animals, humans and communities, and economies and trade, both domestically and internationally.

Expanded Food, Nutrition, and Education Program

Rep. Lee: Secretary Vilsack, NIFA provides critical support for nutrition education programs including through the EFNEP (Expanded Food, Nutrition and Education Program) and SNAP-Education programs to assist with nutrition services in local communities.

If there were greater investments made in nutrition education programs such as EFNEP and SNAP-Ed, would this allow these programs to provide greater nutrition education support in local communities?

Response: The Expanded Food and Nutrition Education Program (EFNEP) is the nation's first nutrition education program for low-income populations and remains at the forefront of nutrition education efforts to reduce nutrition insecurity of low-income families and youth today. Despite the fact that nutrition education and promotion plays an invaluable role in USDA's ability to not just provide all Americans access to safe, nutritious, affordable food but also to help them understand how to prepare it on a limited budget and facilitate consumption across a range of life stages and food preferences, EFNEP's funding has remained nearly level for the last 13 years. Fostering meaningful partnerships with local communities has been a fundamental element of so many of EFNEP's activities. NIFA continues to strengthen and prioritize opportunities for program design and would stand ready to create or enhance additional promising opportunities that greater investments would provide to local communities.

As USDA's first Federal nutrition education program, for more than 5 decades (since 1969), EFNEP has used community-based, relationship-driven, hands-on educational approaches across this country to positively impact economic, obesity, and food insecurity challenges, helping to further USDA's goals on promoting and elevating nutrition security. In FY22, NIFA received \$70 million for land-grant university Cooperative Extension partners to conduct EFNEP in all 50 states, six U.S. territories, and the District of Columbia. Results from FY21 report located here <https://www.nifa.usda.gov/efnep-2021-national-impact-report> included:

- EFNEP employed 1,363 educators who are members of the communities they serve.
- EFNEP educators worked directly with 38,852 adults and 136,296 youth.
- EFNEP graduates reported a collective food cost savings of \$469,698.80; and
- 95% of adults participating in EFNEP improved their diet, including consuming additional fruits and vegetables.

Specialty Crop Research Initiative

Rep. Lee: Secretary Vilsack, there are many significant research challenges facing the agriculture industry and crops. The Specialty Crop Research Initiative (SCRI) provides critical funding support to address research challenges, such as emerging diseases including citrus greening.

Are there ways that the role of SCRI could be bolstered through additional investments?

Response: Since passage of the 2014 Farm Bill, SCRI has been competed in a 2-stage process. Pre-applications are reviewed by industry representatives for relevancy to industry needs and challenges. Industry reviewers decide which pre-application teams are invited to submit full applications, thus ensuring that all projects considered for funding are important to some sector of the specialty crop industry. Full applications are reviewed for scientific merit. Funding recommendations are developed by combining results of the relevancy review with results from the scientific merit review. From fiscal year 2018 through fiscal year 2022, projects considered to be fundable requested \$1,311,427,125. Unfortunately, though, the funds available to support those projects during those same years were \$336,211,367 which is slightly more than 25% of what was requested so the vast majority of project requests went unfunded.

Rep. Lee: Can you provide us with some highlights about how the SCRI program is serving the needs of our nation's agriculture producers and how additional investments could help to achieve greater investments in addressing challenges, such as to address sustainable agriculture needs, such as the need for more drought resistant crops?

Response: An underlying philosophical tenet of the SCRI program is that all funded projects need to address the long-term sustainability of specialty crop production by addressing immediate challenges at the speed of business. Four current projects highlight broad areas that have been supported across many specialty crop production systems.

- Biology, management, and reducing the impact of the spotted lanternfly in specialty crops in the eastern USA. The spotted lanternfly is an invasive insect pest that has the potential to impact specialty crops nationally with a farm gate value of \$18 billion. This project is investigating immediate strategies to protect specialty crops in areas where the pest is known to occur while simultaneously investigating the basic biology of the pest in order to prevent spread to other areas. SCRI has also supported projects for other invasive insects, such as spotted-wing drosophila and brown marmorated stinkbug, but there are projects on other invasive pests and diseases that have not been funded due to unavailability of funds.
- Optimizing blueberry pollination to ensure future yields. This current project builds on the success of an earlier project that compared pollination with native pollinators with that of the honeybee nationally across many crops. Pollination is essential for the production of many specialty crops, including tree fruit, tree nuts, berries, and many vegetable crops. Climate change and invasive pests and diseases of honeybees cause major challenges for specialty crop producers who need to hire pollination services from beekeepers. Having tools to optimize pollinator availability and use will be essential to continued economically viable production of specialty crops.
- Enhancing resource utilization for sustainable lettuce production in changing climates. The focus of this project is to evaluate genomic resources in lettuce for the development of traits that will lead to new lettuce cultivars that are more resilient in the face of climate change. The project will focus on the genetic basis of nutrient and water use efficiencies, tolerance to abiotic stresses, and root architecture. The project team will make these resources available to both public and private lettuce breeders to ensure that improved cultivars are available to growers. As drought and excessive heat continue to plague the western United States, efforts like these are needed in essentially all specialty crops.
- An integrated approach to address the labor shortage on mushroom farms through smart agriculture. Mushroom production is a very labor-intensive process that relies almost exclusively on an immigrant work force to accomplish all aspects of growing. Many other specialty crops also rely on an immigrant workforce, especially at harvest time and there is high competition across the nation for access to the needed labor. SCRI has been at the forefront of USDA efforts in automation, sensor technology, robotics and artificial intelligence in the development of tools and strategies that

reduce the amount of manual labor required to successfully and economically produce specialty crops. Continued and increased investment in labor saving technology and training of a new workforce skilled in the use of this new technology is essential to the long-term sustainability of specialty crop production.

I would also share that the Current Research Information System (CRIS) web site that NIFA maintains is a great resource to learn more about the projects that have been funded by USDA's various research programs. That site can be reached here: <https://cris.nifa.usda.gov/>.

Underrepresented Farmers

Rep. Lee: Secretary Vilsack, farmers from underrepresented communities often face numerous challenges on the pathway to growing crops and securing entry to the marketplace.

Are there ways that the USDA can make improvements to the circumstances faced by farmers from underrepresented communities to achieve success through cooperative Extension activities?

Response: USDA is well positioned to improve the circumstances faced by farmers and ranchers from underrepresented communities to achieve success through cooperative Extension activities. At the state and local level, cooperative Extension works with producers and their families in underrepresented communities to enhance their social and economic wellbeing. Outreach activities include: increasing access to USDA programs and services; enhancing market access, including meat markets and small local processing plants, accessing loans and grants; promoting research and making it understandable for farmers in underserved communities; assisting young farmers with land access, land retention, access to capital; microloans; translating educational materials for language and low literacy; ensuring that farmers have access to improving profitability and sustainability; assisting with risk management, including whole farm planning skills like recordkeeping and financial management; and promoting positive youth development through 4-H. The Extension Disaster Education Network (EDEN), with support from NIFA, provides assistance to cooperative Extension systems to assist EDEN during disaster recovery, mitigation, and recovery.

Training for cooperative Extension professionals around the demographics and conditions which contribute to underrepresented / underserved farmers is another step that can be taken to understand scope and scale of this issue nationally and regionally. Education is needed for cooperative Extension professionals to understand factors that cause stress and prohibit success, including the daily 'lived experience' of underserved farming families. This could include ensuring that qualitative and quantitative data and case studies are being shared among educators.

Rep. Lee: Could greater investments be made by the USDA to bolster cooperative Extension programs that could focus on assisting underrepresented farmers?

Response: Investments can be made to bolster cooperative Extension programs that focus on assisting underrepresented farmers including expanding broadband access to these communities to increase internet access; help to disseminate and integrate agricultural research

findings into these communities (e.g., breeding, local processing, local markets, increased value-added opportunities to enhance food preservation in areas lacking refrigeration). Providing adequate federal grants to land grant colleges and universities to hire additional Extension staff and paraprofessionals to provide one-on-one training to farmers in underserved communities to ensure that farmers are not left out. Expand block grants, competitive and non-competitive grants that are available in underserved communities through the cooperative Extension Services. These additional investments would increase the opportunities to expand the creation of cooperatives to enhance market access, provide access to healthy food, nutritious meals for K-12, housing availability, safe drinking water, family health and vaccination. Increased investment in trainings for cooperative Extension professionals would sharpen the focus on the challenges and critical issues of underrepresented farmers, and target outreach and programming that reduces barriers for stress and success of underrepresented farmers.

Urban Agriculture

Rep. Lee: Secretary Vilsack, ensuring food security needs are met in local communities, such as in urban communities, is an issue I am very interested in given the nature of my district. Many people in my district are interested in growing food, such as fruits and vegetables in local settings.

Are there ways that the USDA can further foster urban agriculture needs through cooperative Extension and other programs to support local growing activities, provide information about best practices, and support urban agriculture growing activities in local communities?

Response: NIFA is uniquely positioned to provide leadership on fostering urban agriculture needs through partnerships with the Land-Grant University System and government, private, and non-profit organizations. Our research, education, and Extension programs provide solutions to those who need them. One of the ways NIFA is supporting urban communities in growing food is through the Urban, Indoor, and other Emerging Agricultural Production Research, Education and Extension Initiative (UIE). This program provides \$10 million in grants for research, education, and Extension work to solve key problems of urban, indoor, and emerging agricultural systems. The priorities for this program engaged stakeholders through a public input solicitation process and consults with the Federal Advisory Committee (FAC) for Urban Agriculture. The outcomes of the UIE program will strengthen urban, indoor, or other emerging agricultural and food-production systems by providing critical knowledge and information transfer to ensure adoption at a local, regional, and national level.

There are other NIFA programs such as the Community Food Project, which bring together stakeholders from distinct parts of the food system to foster understanding of national food security trends and how they might improve local food systems, including support for projects benefitting urban audiences. Another NIFA program, the Food and Agriculture Service-Learning Program, funds projects that increase the knowledge of agricultural science and improve the nutritional health of children in elementary and secondary schools. The program's goal is to increase the capacity for food, garden, and nutrition education within host organizations, such as school cafeterias and classrooms. The program fosters higher levels of community engagement between farms and school systems by bringing together stakeholders from distinct parts of the

food system. Furthermore, Extension Master Gardener, Junior Master Gardener, Master Food Preserver programs and the National Center for Home Food Preservation all support individuals of all abilities and geographic regions to plant, grow, and harvest a garden, as well as safely preserve food.

In addition, our new People's Garden Initiative that is run by the Natural Resources Conservation Service (NRCS) is helping empower local communities and urban residents to build a more diverse and resilient local food system, and address issues like nutrition access and climate change.

Agriculture in Energy, National Security, and Health

Rep. Lee: Secretary Vilsack, more and more federal agencies are recognizing the importance of agriculture in energy, national security, and health. What is USDA doing to work with research and education leadership at other federal agencies to leverage resources to take on our country's greatest challenges?

Response: The Agricultural Research Service (ARS), USDA's chief scientific research agency, prides itself on its many research collaborations with federal partners.

The National Bio and Agro-Defense Facility (NBAF), which is in its final stages of development in Manhattan, Kansas, is a unique national security asset that will establish critical relationships between federal agencies, universities, stakeholders, and international partners for surveying and addressing existing and emerging biological threats against animal agriculture. Since USDA's Animal and Plant Health Inspection Service (APHIS) and ARS are cohoused in the NBAF facility, task forces around disease threats involving the two agencies will be formed to coordinate research, diagnostic activities, and information sharing.

ARS scientists at the Southeast Poultry Research Laboratory in Athens, Georgia, and the National Animal Disease Center in Ames, Iowa, also work closely with APHIS on animal diseases. ARS scientists at the Foreign Disease-Weed Science Research Unit in Fort Detrick, Maryland, work with the intelligence community, Department of Defense (DOD), universities, and international consortia on existing and emerging biological threats against plants.

ARS partners with DOD, National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), and Centers for Disease Control to prepare against biological threats to food supplies and human health. ARS researchers in Crop Production and Protection National Programs ensure a stable food supply to feed the United States and the world and work closely with APHIS and other federal agencies to provide safe products for export and to enhance economic benefits and stability for growers and producers. For instance, ARS laboratories in Beltsville, Maryland, provide diagnostic development and support to APHIS for early and accurate detection of plant pathogens and pests.

In accordance with the Executive Order (EO) on Biotechnology and Biomanufacturing (September 12, 2022), ARS will work with colleagues at the National Science Foundation (NSF), Department of Energy (DOE), and National Institutes of Standards and Technology on

the USDA contribution to the EO Implementation Plan. ARS works with counterparts at USDA's National Institute for Food and Agriculture (NIFA), NIH, and the Office of Science and Technology Policy to coordinate research investments and translation of basic discoveries to the non-specialist audiences for energy crops, industrial feedstock crops, microbiomes, and human nutrition.

The ARS Food Safety Program has a collaborative Interagency Agreement (IAA) with the USDA Food Safety and Inspection Service (FSIS) to conduct research and develop technologies FSIS needs to modernize processes, develop and implement policies, and manage and facilitate their regulatory activities. APHIS and the ARS Food Safety National Program are currently conducting an ambitious collaborative national survey to determine whether *Trichinella* parasites, a roundworm that can be ingested with undercooked meat, still pose a risk to the safety of pork produced within the United States.

Previously, the FDA's Center for Food Safety and Nutrition provided funds to ARS National Food Safety scientists at the Western Regional Research Center to conduct a collaborative 5-year study on the levels and types of pathogens found within California's agricultural regions for fresh produce, particularly the Salinas Valley.

Researchers in the ARS Human Nutrition National Program cooperate with and maintain communication with a number of other agencies, including NIFA, NIH, the Interagency Committee on Human Nutrition Research that coordinates human nutrition research across agencies, FDA (Closer to Zero) the Dietary Guidelines Coordinating Committee; and DOD (selected nutrition research topics). The USDA National Nutrient Database is regularly used by many government agencies and programs such as school lunch programs.

In the fall of 2022, the White House will hold a conference on Hunger, Nutrition, and Health, the first White House conference on hunger and nutrition since the Nixon administration, over 50 years ago. Before the conference, the Biden-Harris Administration plans to release the national strategy for ending hunger and healthier eating. The national strategy will comprise five pillars addressing food insecurity, diet-related diseases, and health disparities. The fifth pillar "Enhancing nutrition and food security research, including by bolstering funding to improve metrics, data collection, and research to inform nutrition and food security policy, particularly on issues of equity and access; and implementing a vision for advancing nutrition science" will highlight the impact of Land-Grant Universities in working with federal agencies to leverage resources to tackle food and nutrition security.

In fiscal year (FY) 2021, the Center for Disease Control and Prevention (CDC) in collaboration with the USDA and NIFA entered into \$9.5 million Interagency Agreement to engage Land-grant Universities (LGUs) and the Cooperative Extension System (CES) to improve COVID vaccination coverage in rural and other medically underserved communities in large agricultural production regions of the nation. Subsequently, a cooperative agreement was established with the Extension Foundation to lead a nationwide local response entitled Extension Collaboration for Immunization, Teaching, and Engagement (EXCITE). In Phase I of EXCITE, 96 projects representing 73 LGUs across the United States were funded. Phase I resulted in 291,636 local engagement activities and 26,517 shots in arms. Planning for Phase II is currently underway.

USDA is working to finalize a Memorandum of Understanding (MOU) between USDA Rural Development, U.S. Forest Service and NIFA to establish to support recreation economy development in rural gateway communities, with an estimated completion date in the fall of FY 2022. Each of these agencies make financial investments and deliver technical assistance through programs such as Recreation Economies for Rural Communities (RERC) funded by U.S. Forest Service and U.S. Environmental Protection Agency (EPA) and the Regional Rural Development Centers (RRDCs) funded by NIFA. The inter-agency work that will occur under this MOU will formalize and strengthen existing inter-agency collaboration and will promote greater coordination to expand support for the enhanced development of recreation economies in rural gateway communities and of the recreation economy industry nationwide.

The purpose of the National Plant Diagnostic Network (NPDN) is to reduce the vulnerability of the U.S. food and agricultural system to chemical or biological attack. The network coordinates the development, implementation, and enhancement of diverse capabilities for addressing threats to the Nation's agricultural economy and food supply. To attain these purposes, the overarching goals of the NPDN are to: produce educated and capable first responders (detection), provide accurate, reliable, and timely diagnostics and surveillance (diagnosis), and supply useful, real-time data from innovative information and communication systems reporting).

The National Nanotechnology Initiative (NNI) is a U.S. Government research and development (R&D) initiative. Twenty Federal departments, independent agencies, and commissions work together toward the shared vision of a future in which the ability to understand and control matter at the nanoscale leads to ongoing revolutions in technology and industry that benefit society. The NNI supports a shared infrastructure and establishes shared goals, priorities, and strategies to enhance interagency coordination of nanotechnology R&D that builds on agency-specific missions and activities, and leverages resources while avoiding unnecessary duplication. NIFA participates in the NNI, and supports applied research on nanotechnology-enabled applications, devices, and systems for a wide range of agriculture, food, and environmental priorities. The scope of this infrastructure includes rapid detection and effective intervention technologies for precision agricultural production; effective and efficient delivery of agricultural production inputs; ensuring food safety and biosecurity; developing effective treatments to improve animal health and novel value-added bionanomaterial products; and enhanced use and protection of natural resources, the environment, and agricultural production ecosystems.

NIFA has a Memorandum of Understanding with the National Science Foundation under which programs in Robotics and Cyber-Physical Systems are implemented. The five-year funding allocation for Cyber-Physical Systems (CPS) ended in 2020, but NIFA has been able to extend that funding on a limited basis towards NSF's Smart and Connected Communities (S&CC) program. This program is a subset of CPS and supports use-inspired research; addressing communities' social, economic, and environmental challenges by working with community stakeholders. An effort is underway to extend this support into NSF's CIVIC Innovation Challenge program, in which the research and action competition is driven by community priorities. We anticipate that future funding for the activities described above would be under the same model as S&CC. NIFA is also working with the USDA APHIS to create surveillance and diagnostic approaches that may be used to identify mutations of SARS-CoV-2 (the virus

responsible for COVID-19) that may be infective in livestock in the future. Various aspects of this work are supported in several program area priorities of the Agriculture and Food Research Initiative (AFRI), including the interagency program with NSF and NIH, Ecology and Evolution of Infectious Disease. Finally, NIFA is working to finalize a Memorandum of Understanding with the NIH to renew the program titled “Dual Purpose with Dual Benefit: Research in Biomedicine and Agriculture using Agriculturally Important Domestic Animal Species.”

Finally, we are working to finalize a government-wide MOU in support of the Sustainable Aviation Fuel (SAF) Grand Challenge to reduce the cost, enhance the sustainability, and expand production of SAF. Goals for the SAF Grand Challenge will include achieving a 50% reduction in life cycle greenhouse gas emissions compared to conventional fuels and supplying sufficient SAF to meet 100% of aviation fuel demand by 2050. This SAF Grand Challenge will be the culmination of years of interagency cooperation on shared energy challenges in working groups such as the interagency Biomass Research and Development Board (BRDB). The USDA is an active participant in the BRDB, which provides a forum for leadership across Federal agencies to discuss opportunities for biomass, and related product development and supply chains, to address national needs for bioenergy and biobased products.

Agriculture and Climate

Rep. Lee: The connection between agriculture and climate is undeniable and we also know that climate-smart agriculture can be a key driver of reducing emissions and a tool in our fight against worsening climate change. What investments does USDA plan to make in the future to ensure that there is solid research to develop new agricultural practices and evidence-based policies and a pipeline for those new tools and changes to reach farmers in practice?

Response: The Agricultural Research Service (ARS) works within and among almost all its National Programs to address the many challenges and opportunities that climate change presents to U.S. agriculture. While this is not a comprehensive list of ARS research on climate change mitigation, adaptation, and resilience, significant work includes the following.

For the past two decades, ARS scientists have been collecting standardized greenhouse gas (GHG) emissions and soil carbon storage data across our GRACEnet research network. This effort has driven improvements in the performance and accuracy of modeling, inventory, and decision support for greenhouse gas emissions.

The Long-Term Agroecosystem Research network, which has 18 locations across the U.S., studies, improves, and disseminates agricultural best practices that help ensure U.S. production systems are adaptive, resilient, and part of the climate solution.

ARS co-leads the USDA Climate Hub initiative, which is an integral partner in translating ARS science into regionally relevant practice and technology transfer information. To guide strategic research directions, we prioritize obtaining stakeholder input about productivity, resilience, viability, adaptive capacity, and potential for GHG mitigation. An appropriated budget increase in fiscal year (FY) 2022 is helping enhance the capacity of the Climate Hubs to synthesize and translate our science for customers and partners.

ARS climate change mitigation and adaptation priorities in the fiscal year 2023 President's budget request include a Climate Science Center of Excellence that would target regional and national data integration and synthesis. This would leverage data from across ARS and integrate datasets from the National Oceanic and Atmospheric Administration (NOAA), the National Aeronautics and Space Administration (NASA), and other partners across the Federal government to provide tools needed for agricultural mitigation and adaptation.

ARS is also proposing a new project with a focus on innovation, engineering design, development, and deployment of high-tech Internet of Things (IoT) sensors and instruments that will enhance our ability to inform, model, understand, and predict the interactions and outcomes between climate and agricultural systems.

ARS research leadership works closely with the Climate Hubs, Natural Resources Conservation Service (NRCS), Farm Service Agency (FSA), National Institute of Food and Agriculture (NIFA), and others to ensure the innovations, technologies, tools, and products resulting from our research are integrated into conservation and commodity programs, Extension, and training and outreach materials. Almost all ARS research locations have local stakeholder groups and field days for sharing their findings with local and regional producers.

ARS houses four Regional Biomass Research Centers that work closely with research partners in the U.S. Forest Service (USFS), Department of Energy (DOE), and others to coordinate priorities for biomass feedstocks and bioenergy.

ARS coordinated closely with USDA's Office of the Chief Economist and others in partnering with the U.S. Environmental Protection Agency (EPA) on the Enhanced Efficiency Fertilizer challenge. This challenge will catalyze the development and marketing of innovative fertilizer technologies that mitigate the challenges that fertilizers pose for water resources and air emissions. ARS researchers are working closely with other USDA agencies, Federal partners, and global collaborators on other aspects of optimizing fertilizer application and management and mitigating their environmental impacts. These collaborations occur through efforts like FRST (the Fertilizer Recommendation Support Tool, which was led by ARS and included hundreds of Federal, State, and University partners), Manuresheds (helping match available manure nutrient supply with the regional croplands that need nutrients), and the Legacy Phosphorous project.

Many of the programs managed by NIFA now emphasize climate change. Adjustments have been made to the Agriculture and Food Research Initiative (AFRI), which is NIFA's flagship competitive program, and NIFA partners with state experiment stations and Extension leaders to identify and address climate-related critical issues in their states. Through AFRI and the family of capacity programs, NIFA will continue to make substantial investments in climate-smart agriculture and climate-smart forestry practices, greenhouse gas mitigation, clean energy, soil health, bioproducts, new generation fertilizers, and other topics of national importance. The NIFA-funded work is most often developed to integrate with Extension so that synergies develop between the functions.

All six of the Farm Bill priority areas in AFRI include specific investments that support research, Extension, and workforce development to respond to climate change. For example, in the AFRI Sustainable Agricultural Systems (AFRI SAS) program, NIFA supports development of new agricultural practices and outreach to farming and rural communities through new focus areas on climate-smart Agriculture and climate-smart Forestry, the Bioeconomy, and Nutrition Security, all with an emphasis on climate. AFRI SAS requires integration of research, Extension, and education, to benefit people across communities and to make information accessible to farmers. Additionally, NIFA will continue to invest in partnerships between state Extension programs and USDA Climate Hubs to leverage public assets and develop additional synergies. A new and upcoming investment through AFRI will include establishment of a Climate-Smart Extension Coordinated Agriculture Project that will strengthen connections between Extension and all climate-related public research activities. Agricultural, rangeland, aquaculture, and forestry systems are increasingly threatened by climate change and extreme weather events. Investments through AFRI are an effective means to address climate driven social, economic, and environmental challenges as well as derive benefits in underserved communities, reduce loss of natural habitats and biodiversity, support sustainable agricultural intensification, and meet accelerating demands for food, ecosystem services, and bioproducts.

The Evans-Allen Capacity Program supports agricultural research activities at 1890 Land-Grant Institutions. The legislative authority specifies that funds appropriated under this section include expenses of conducting agricultural research, disseminating the results of such research, and purchase and rental of land and the construction, acquisition, alteration, or repair of buildings necessary for conducting agricultural research. This program supports state-identified critical areas, which include Agroclimate Science, one of NIFA's current Science Emphasis Areas. Evans-Allen Capacity Program support extends beyond main campuses and experiment stations throughout the states and regions of the respective 1890 institutions. In addition to serving as critically important agricultural research institutions, NIFA invests through the Evans-Allen program to deliver opportunities to many underserved communities.

Through the Hatch Act of 1887 NIFA will continue to invest in climate-related research conducted at State Agricultural Experiment Stations (SAES) that are units' of 1862 Land-Grant institutions. Hatch Program funds are a major part of NIFA's research investment portfolio in climate change and will continue to be provided for research on all aspects of agriculture, including all issues related to climate change adaptation and mitigation. Research conducted through SAES catalyzes the institution's academic programs as well as state Extension programs. Additionally, SEAS is leveraged with state funds, including investments from producers, such as "check-off funds".

In addition to investments through Evan-Allen and Hatch, NIFA will continue to invest in climate change research through the McIntire-Stennis Program. This capacity program funds research on forest management emphasizing private forests, wood products, and forest-related rangeland ecosystems. The nation's private and public forests are a critical resource for addressing climate change.

The USDA investments in research generate objective information for a variety of Extension programs throughout the nation and NIFA makes further investments through Extension capacity

funds to support the unique outreach mission for Land-grant institutions. The primary capacity programs that support Extension include: 1) Smith-Lever Act Program that funds cooperative Extension work at 1862 Land Grant Institutions, 2) the Agricultural Extension Programs at 1890 Institutions Program that funds Extension work to address the needs of 1890 stakeholders, such as for small and medium-sized farms and woodlands, and 3) The Renewable Resources Extension Act Program that funds Extension work to assist forest and rangeland stakeholders. All of these Extension capacity programs are a major part of NIFA's investment portfolio in climate.

NIFA is committed to supporting the Land-grant community through ongoing and increasing investments to address climate change and support adoption of essential practices in order to change the course of the global climate threat. As the world's foremost public agricultural science agency, NIFA will carry out the USDA strategic goal to: Combat Climate Change to Support America's Working Lands, Natural Resources and Communities and Expand Opportunities for Economic Development and Improve Quality of Life in Rural and Tribal Communities.

In addition to the work in our research institutions, through the Partnerships for Climate-Smart Commodities that I announced in February, USDA will be directly supporting new efforts for producers to create new markets for climate smart commodities. This new Partnerships work also has a research and data sharing component and will help farmers develop new agricultural practices and be more profitable in the long run as they use these new tools and change their farming practices, while also finding ways to support early adopters.

Student Eligibility for Supplemental Nutrition Assistance Program (SNAP)

Rep. Lee: Secretary Vilsack, in general, students enrolled at least half-time in an institution of higher education (e.g., college, university, trade/technical school) are not eligible for SNAP unless they meet certain exemptions. The Consolidated Appropriations Act, 2021 temporarily expanded student eligibility to new groups from January 16, 2021, through the end of the public health emergency.

Beginning January 16, 2021, two new types are now exempt. These are students who:

- Are *eligible* to participate in state or federally financed work study during the regular school year. The institution of higher education (i.e., the college or university) determines if a student is considered *eligible* for work study.
- Have an Expected Family Contribution (EFC) of 0 in the current academic year. Students receive an EFC after applying for financial aid.
- Across UC, for example, nearly 40% of students are food insecure. The correlation between nutrition and academic performance is strong and clear.

Rep. Lee: As we are moving out of the public health emergency, what is USDA's sense about the impact of the expansion in eligibility?

How does USDA plan to address the nutrition deficit on college campuses and ensure those neediest college students are able to excel academically and provide for our future workforce?

Response: The USDA Food and Nutrition Service (FNS) highly encourages States agencies to prepare for the expiration of the Federal Public Health Emergency and expiration of the temporary student exemptions provided by the Consolidated Appropriations Act. This preparation should include any necessary system changes, outreach strategies with key stakeholders, and additional training for eligibility workers.

FNS is also encouraging State agencies to thoroughly screen students for all currently allowable exemptions as students who were previously certified under the temporary exemptions may continue to be eligible under a different exemption. State agencies that implement effective screening procedures during the Supplemental Nutrition Assistance Program (SNAP) application process can better identify students that meet exemptions and are eligible for benefits. However, SNAP student eligibility policy is complex, and FNS has learned that some State agencies apply some components of student policy differently. To ensure that State agencies know how to properly screen students for exemptions and determine student SNAP eligibility, FNS is drafting several policy memos to clarify several areas of confusion and FNS expects to publish the first such memo, focused on eligibility of individuals with partial meal plans, this summer.

FNS is collecting best practices for SNAP student outreach from State agencies and higher education stakeholders through regular engagements and plans to share these broadly. FNS hosted targeted webinars in Spring 2022 for State agencies on the sunset of the temporary student exemptions provided by the Consolidated Appropriations Act. Finally, FNS included student outreach as a priority area in both the fiscal year 2022 and 2023 SNAP Outreach Priorities memo, which identifies areas that State agencies should consider targeting in their SNAP outreach plans.

Child Food Insecurity

Rep. Lee: Secretary Vilsack, California and Maine have made school meals available to all children because we recognize the healthfulness and social benefits. In most states, however, large proportions of children from income-eligible homes do not get the healthy meal to which they are entitled, also contributing to rates of food insecurity.

Making school meals available to all children during the pandemic laid the groundwork for Universal school meals -- 'school meals for all' -- but this flexibility ends this summer. The Community Eligibility Provision (CEP) is a measure that helps by qualifying all children in high need schools for free meals, but that program is complicated to apply for, limited to the very highest need schools, and significantly under-used.

What funding does USDA need to help all eligible school districts participate? Have there been projections about the costs? What would be the costs be if the income threshold for schools was lowered from the current 40% of enrolled students to 25%?

Response: The CEP allows eligible school districts and schools in high poverty areas to offer all students school meals at no charge, which increases children's access to healthy school meals. Unlike the COVID-19 waivers that allowed universal free school meals and reimbursed all meals at the Federal free rate, CEP schools are reimbursed based on the percent of students directly certified for free school meals multiplied by 1.6 (the CEP "multiplier"). This means unless schools have at least 62.5% of students directly certified for free meals, they will receive less than the Federal free rate for each meal served. School districts must use non-Federal funds to cover any additional costs. At lower eligibility levels, more meals are reimbursed at the lower paid rate, and schools must consider sources of non-Federal funds to make CEP financially viable.

- As part of the American Families Plan, the Biden-Harris Administration supported expanding CEP by:
- Increasing the CEP multiplier to 2.5 for a 4-year period;
- Lowering the eligibility threshold to 25 percent for elementary schools for a 4-year period; and
- Creating a state-wide CEP option.
- Targeting expansion to elementary schools aims to drive better long-term health outcomes by ensuring low-income children are receiving nutritious meals at an early age.
- Because CEP is a cost sharing model between the Federal government and school districts, school districts must explore election options and decide whether CEP is financially viable to operate.

QUESTIONS SUBMITTED BY CONGRESSWOMAN GRACE MENG

Access to Milk and Flavored Milk

Ms. Meng: New York is among the leading producers of dairy in our country, with nearly 3,600 small, medium, and large-sized dairy farms. The dairy industry is New York's largest agricultural sector and fluid milk sales are critically important for its success. Access to milk, including flavored milk, in school meals is also important for meeting the nutritional needs of children. USDA recently announced its transitional nutrition standards for the coming two years, which allows for schools to offer flavored and unflavored low-fat and nonfat milk.

Are there other steps USDA is taking to promote access to flavored and unflavored milk in schools and increase access to dairy products?

Response: USDA supports the inclusion of fluid milk and other dairy products in the school meals programs as part of a healthy meal pattern established by the Dietary Guidelines for Americans (DGA). Fluid milk is a required meal component in both breakfast and lunch, and other dairy products may be offered to satisfy the Meat/Meat Alternates component of meal pattern requirements, as detailed in USDA's Food Buying Guide for Child Nutrition Programs.

USDA Food and Nutrition Service (FNS) is in the process of developing a Crediting Tip Sheet for Milk to add to a series of three existing Crediting Tip Sheets. This tip sheet will be a useful reference for program operators to learn additional strategies for crediting milk in child nutrition programs. Offering Smoothies as Part of Reimbursable Meals, currently available in English and Spanish, provides guidance on crediting milk and yogurt toward meal pattern requirements when used in smoothies.

USDA is actively engaged with dairy industry partners (e.g., the International Dairy Foods Association) to assist school districts that are having trouble procuring milk for school meals due to supply chain challenges. When USDA learns of school districts experiencing challenges sourcing the milk necessary to meet meal pattern requirements, for example, as a result of several dairy closures in the Mid-Atlantic and southern U.S. we share that information with dairy industry partners. Through their networks, partners help identify regional and local milk producers and vendors that can step in to ensure that schools can procure fluid milk for school meals.

Ms. Meng: Has USDA supplied information to schools regarding the nutritional benefits of serving flavored milk and promoting access to flavored milk as part of school meals?

Response: Fluid milk requirements are mandated by the Richard B. Russell National School Lunch Act (NSLA), which requires that a variety of milk types are offered to students and are consistent with the most recent Dietary Guidelines for Americans (DGA). Under current meal pattern requirements and nutrition standards, all fluid milk must be fat-free (skim) or low-fat (1 percent fat or less). Milk may be unflavored or flavored, provided that unflavored milk is offered at each meal service.

USDA recognizes that for some children, flavored milk is a palatable option that improves consumption of important nutrients provided in milk. However, flavored milk also includes added sugars. While there is currently no standard for total sugars or added sugars in meals served through the school meal programs, the Dietary Guidelines for Americans, 2020-2025 recommends limiting added sugar to less than 10 percent of calories per day. USDA will continue to support a variety of fluid milk types that are consistent with recommendations from the DGA.

QUESTIONS SUBMITTED BY CONGRESSWOMAN CHELLIE PINGREE

Strengthening Organic Enforcement (SOE) Final Rule

Ms. Pingree: The strengthening organic enforcement (SOE) rule is the most significant revision to organic standards since the publication of the original organic rule in 2001. The 2018 Farm Bill required a rulemaking to be completed by December of 2019. The comment period ended on the proposed SOE rule in October of 2020. Can you provide an update on this status of the final rule, and give me your commitment to prioritize its implementation?

Response: USDA staff are working diligently to prepare the Strengthening Organic Enforcement Final Rule. At this time, we are expecting publication in Fall 2022.

National Organic Certification Cost Share Program

Ms. Pingree: The cost of organic certification can be a burden to many farmers, particularly smaller-scale organic farmers. In the 2018 Farm Bill, Congress funded the National Organic Certification Cost Share Program (NOCCSP) to provide a 75 percent reimbursement for organic certification costs, up to \$750 annually per certification scope per operation. The funding was based on input from the Farm Service Agency (FSA) regarding funds needed to run the program, once available program carryover balances were factored in. As a result of inaccurate data from FSA, reimbursement rates were slashed for Fiscal Years 2020-2022. It is critical to get NOCCSP fully restored as soon as possible. Between the new funding provided in the 2018 Farm Bill and the carryover balances, is there enough funding available to restore the full authorized reimbursement rates for the NOCCSP for FY 2023? If not, how much is needed to meet that goal?

Response: The 2018 Farm Bill (FB) authorized \$2 million from the Commodity Credit Corporation (CCC) to be used for National OCCSP for each of fiscal year (FY) 2019 and 2020, \$4 million for FY 2021, and \$8 million for each of FY 2022 and 2023. The Farm Service Agency (FSA) will not have final numbers for the available carryover funding to utilize for FY 2023 until spring 2023.

In FY 2019, which was the most recent year we paid at a 75% cost share with a \$750 maximum payment cap, we obligated \$12,048,560. Comparing that to the total estimated resources available for FY 2023, FSA would be \$571,135 short in being able to fund all claims, which does not account for increased participation. To provide a safe estimate and fully pay all contracts at the 75% cost share with a maximum payment cap of \$750, FSA anticipates the agency would need an additional \$5 million which should give sufficient funding to account for increased participation numbers, which is expected as a result of a change in the Agricultural Marketing Service rule on Organics. However, it is important to note these are estimates based on past performance and the Agency will have a better understanding of funds available for FY 2023 by the early spring 2023.

Displayed below is a table that provides the borrowing authority from CCC, carryover from previous years, total expenditures for the past four fiscal years, and estimates for FY 2023. The

table shows that if the cost share of 50% with a \$500 payment cap is applied in FY 2023, based on the 3 prior year's total expenditures, adequate funds would be available. However, if Congress sought to return the cost share and payment cap for FY 2023 back to 75%/\$750 beginning with FY 2023, the total resources in FY 2023 of \$11,477,424 would be less than the total expenditures issued in FY 2019, \$12,048,560, the last year 75%/\$750 was applied, a deficit of \$571,136.

Please note that the FSA obligates funds to State Departments of Agriculture upon completion of a grant, however the expenditures and potential carryover is not determined and finalized until the spring of the following year when State Departments of Agriculture provide total expenditures. The total expenditure for FY 2022 (\$5,649,764) and carryover shown in FY 2023 (\$3,933,424) are only estimates based on State obligations and will not be finalized until the spring of 2023. Although we only reflect a short fall of \$571,135 in FY 2023 when applying the 75%/\$750 maximum payment cap, FSA expects it would need \$5 million to safely cover any actual outcome expenditures for FY 2022 and take into consideration the recent AMS Organic rule change which is expected to increase participation in NOCCSP.

Fiscal Year	2019*	2020**	2021**	2022**	2023
New Borrowing Authority from CCC	\$2,000,000	\$2,000,000	\$4,000,000	\$8,000,000	\$8,000,000
Sequestration	124,000	118,000	228,000	456,000	456,000
Carryover from Previous Year	15,700,055	5,527,495	3,737,960	2,039,189	3,933,424
Total Resources	17,576,055	7,409,495	7,509,960	9,583,189	11,477,424
Total Expenditures	12,048,560	3,671,534	5,470,771	5,649,765	TBD

*Payments issued at a 75% cost share rate and maximum \$750 payment cap.

**Payments issued at a 50% cost share rate and maximum \$500 payment cap.

Healthy Food Financing Initiative

Ms. Pingree: Healthy Food Financing Initiative (HFFI) invests in projects to increase supply of and demand for healthy foods in underserved communities, through loans, grants, and by providing technical assistance. USDA's third request for proposals this year drew over \$90 million in requests from every state in the country. Presently the program is only able to fund \$4 million in requests. How can USDA support this great demand for the HFFI, and the on-going need to build a more resilient food system that increases access to fresh food in rural and small towns across the country?

Response: I am committed to creating local and regional food systems that benefit all Americans, from farmers and ranchers to small businesses and families who currently have to travel a long way from home to find fresh, healthy food. That is why, in early 2022, I intend to use resources provided to USDA in the American Rescue Plan to increase funding to the Healthy Foods Financing Initiative (HFFI) by \$155 million. This additional funding will provide USDA

Rural Development with new investment opportunities to significantly increase funding for HFFI and help meet the program demand. The additional investments will address the need to build a more resilient food system that will increase food and nutrition security in underserved areas.

QUESTIONS SUBMITTED BY CONGRESSMAN MARK POCAN

Institute for Rural Partnerships

Mr. Pocan: Rural communities across the country are facing significant challenges, ranging from transportation to economic development. The Institutes For Rural Partnerships have a significant opportunity to help address and overcome these challenges. I know UW-Madison is excited about the opportunity to fund research and community building efforts happening on campus and around the state. Has USDA decided where this important program will be housed at the agency?

Response: USDA's National Institute of Food and Agriculture (NIFA) is implementing this new program authorized and funded in the Consolidated Appropriations Act, 2022 (P.L. 117-103). NIFA has been and will continue to be in contact with the University of Wisconsin at Madison and the other institutions involved with the Institute for Rural Partnerships to implement this program.

Animal Welfare Act Enforcement

Mr. Pocan: Alarming and of great concern to members of this subcommittee, this is still happening under the current administration's watch. At a puppy mill in Iowa, USDA inspectors repeatedly found AWA violations and witnessed animal suffering—such as starving and dead dogs—but failed to confiscate a single dog. Months went by and not until intervention by the Department of Justice did USDA move to revoke the breeder's license. The agency did not impose any financial or other penalties against the facility for any of the documented 200 violations of the AWA. Instead, they relied on nonprofit organizations to conduct the rescue, rehabilitation, and rehoming of over 500 dogs. This could have been avoided if the USDA had properly used appropriated funds and exercised its authority to intervene earlier. This could have happened at many stages – when the licensee failed to give access to inspectors, or learned dogs were being hidden at undisclosed locations, or the first time they saw a dog suffering. But the agency failed to act at all. How will the USDA reform this program to protect animal welfare and punish repeat violators of the law?

Response: The health and welfare of vulnerable animals is important to the USDA and is important to me personally. We work closely with State Officials, the Department of Justice, and others to use all our authorities to go after those who violate the law and put the health and welfare of animals at risk.

USDA works continuously to strengthen its Animal Welfare Act (AWA) enforcement efforts. Total AWA enforcement actions, including official warning notices and requests for enforcement investigations, have increased from 17 in FY 2019 to 128 in the first half of FY 2022. In addition, the Animal and Plant Health Inspection Service (APHIS) recently hired four additional employees to its Animal Care enforcement unit. USDA has also made a number of changes to strengthen its enforcement efforts in response to recent USDA Office of Inspector General audits. For example, APHIS now provides automatic weekly updates to the appropriate state animal health official whenever a direct noncompliance issue is identified in that state. In

response to a separate OIG audit on animal exhibitors, APHIS completed a study of all the barriers between the public and dangerous exhibited animals, which helped identify noncompliant barriers and is informing possible regulatory improvements.

Disaster Planning for Farm Animals

Mr. Pocan: In recognition of the fact that extreme weather can have devastating impacts on our agricultural communities, during the past several appropriations cycles, the Committee has directed the USDA to work with producers to develop disaster preparedness plans to help mitigate losses. How has the agency responded to this directive?

Response: The Farm Service Agency (FSA), Natural Resources Conservation Service (NRCS), and Risk Management Agency (RMA) are committed to ensuring that producers have tools to be proactive and resilient in the face of natural disasters. This occurs with risk management tools, conservation planning, and through working with producers to provide education and technical assistance on our many standing disaster assistance programs, along with recent ad-hoc disaster assistance programs.

FSA has a network of over 2,100 state and county offices across the country that are fully prepared to support producers in the wake of disasters. After a disaster strikes, FSA focuses on helping producers recover through its standing disaster programs, including the Emergency Conservation Program, the Emergency Forest Restoration Program, the Livestock Forage Disaster Program (LFP), the Livestock Indemnity Program, the Emergency Loan Program, the Disaster Set-Aside Program, the Noninsured Crop Disaster Assistance Program (NAP), the Tree Assistance Program, and the Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program. It is important to note that, under FSA's current workforce and structure, the agency has the ability to administer programs from neighboring or different locations in the event that a major event impacts one of its service centers. FSA offices have the flexibility to take applications from any service center nationwide.

When it comes to FSA's efforts to help producers prepare for and mitigate the effects of natural disasters, FSA has also been very focused on helping producers become more climate resilient. FSA recently released its agency-wide Climate Adaptation Plan, which outlines several actions to support producers in both adapting to and mitigating the impacts of climate change, including climate-induced disasters.

Through conservation planning, NRCS works with agricultural producers and others to make producers' agriculture operations more resilient to extreme weather events by identifying and addressing natural resource concerns. Through a variety of programs, NRCS works at the individual farm level by providing one-on-one technical and financial assistance, as well as on a broader landscape scale, working with partners who have shared interests in ensuring that agricultural producers and associated communities are well-prepared in the face of disasters.

Through the conservation planning process NRCS assists producers with both adapting to and mitigating the effects of climate change. Examples of agency actions that improve agriculture resiliency to natural disasters include, implementing conservation measures aimed at improving

soil health, improving water use efficiency, transitioning to less water intensive crops, establishing rotational grazing systems to make better use of available forage, and other actions.

When disasters occur, NRCS programs can be extremely effective in implementing natural resource recovery efforts. For example, the Environmental Quality Incentives Program (EQIP) can play a vital role in assisting producers recover from and build resilience to natural disasters like floods, hurricanes, wildfires, and drought. Through EQIP, NRCS provides financial assistance to address and prevent the excessive soil erosion caused or impacted by natural disasters. The Emergency Watershed Protection (EWP) Program allows communities to quickly address serious and long-lasting damages to infrastructure and to the land, via partnerships with sponsors. The EWP Program policy requires that each NRCS State Conservationist develop and maintain an emergency recovery plan (ERP) that contains specific state procedures for implementing emergency recovery measures if a disaster occurs. The State Conservationist must review and update the ERP annually. The ERP must comply with laws, regulations, executive orders, other requirements applicable to the EWP Program, and at a minimum should include:

- State specific emergency recovery process and flow chart
- Contact information for local, State, and Federal emergency managers
- Interagency coordination and contacts for emergency consultations and permits
- Descriptions of typical recovery measures and implementation examples for the State

Over the last several years, RMA has strived to improve options for all of agriculture. RMA implemented the Quality Loss Option to reduce the impact quality losses have on a producer's future crop insurance coverage. To respond to more severe and frequent hurricanes, RMA recently introduced Hurricane Insurance Protection; Wind Index (HIP-WI) for the Gulf Coast, Eastern Seaboard, and Hawaii that provides prompt payment to producers when a hurricane hits. For those facing historic drought, the Pasture, Rangeland, and Forage (PRF) insurance program, which provides coverage for producers who hay and graze livestock, now has almost 250 million acres insured compared to under 100 million in 2018. It should also be noted that coverage for livestock is broadened by the authority provided in the 2015 Agriculture Appropriations Bill that specifically stated losses under LFP are not considered the same loss for the purposes of NAP or PRF. For specialty crops, RMA developed a new nursery policy that is easier for producers to access and for insurance companies to sell insurance for; and we service and are implementing a new policy for strawberries in Florida and California. To build upon this work, in 2021, RMA implemented a new Micro Farm Policy targeted at providing a crop insurance policy for smaller producers who sell locally, such as for farmer's markets along with other enhancements to Whole Farm Revenue Protection.

Further RMA remains committed to promoting climate smart agriculture while adhering to vigorous program standards. For instance, RMA now provides coverage for rice growers who use innovative irrigation practices such as alternative wet-dry and furrow irrigation. Early this year, RMA implemented the Post Application Coverage Endorsement that provides coverage to producers in select counties in the Midwest who "split apply" nitrogen, which built upon RMA's actions last year to add flexibility for producers to hay, graze, or chop cover crops and still receive 100% of the prevented planting payment, and the 2021 and 2022 Pandemic Cover Crop Program which provided a \$5 per acre premium benefit for producers who planted cover crops.

Mr. Pocan: Has there been an expanded effort to ensure farmers and ranchers are adequately prepared for disasters, especially considering President Biden's proposed budget for USDA anticipates there will be a greater need for funding under current disaster assistance programs, including the Livestock Indemnity Program?

Response: The USDA Farm Service Agency (FSA) remains committed to administering all of its standing and ad-hoc disaster assistance programs and supporting our nation's farmers and ranchers who are on the frontlines of climate change and are experiencing firsthand the impacts of climate-induced disasters on rural communities. FSA's Livestock Indemnity Program (LIP) is part of a suite of standing disaster programs and provides critical assistance in the wake of disasters. In particular, LIP provides benefits to eligible livestock owners or contract growers for livestock deaths in excess of normal mortality caused by eligible loss conditions, including eligible adverse weather, eligible disease and attacks by animals reintroduced into the wild by the Federal government or protected by federal law, including wolves and avian predators. In addition, LIP provides assistance to eligible livestock owners that must sell livestock at a reduced price because of an injury from an eligible loss condition.

The Natural Resource Conservation Service (NRCS) has expanded efforts to ensure farmers and ranchers are adequately prepared for disasters resulting from climate change. Through the implementation of the NRCS Climate Change Adaptation Plan several steps are being taken to integrate climate change information into NRCS tools and processes. Actions are also being taken to improve climate change literacy of both NRCS staff and customers. These efforts include providing information, tools, resources, and opportunities for producers to understand and address climate change impacts, such as increased frequency and intensity of certain natural disasters. Among other activities, these actions include integrating climate change information, such as drought or excessive moisture data, into the agency's processes for resource allocation and prioritization, as well as into the conservation planning process and tools used when working directly with producers.

Animal Depopulation via Ventilation Shutdown

Mr. Pocan: As avian influenza continues to spread across states, I appreciate the work APHIS is doing to quickly respond to outbreaks and prevent further spread of the disease. While I understand this is a very difficult situation that requires the depopulation of animals to protect the well-being of themselves and others, it is important to ensure methods of depopulation that are of great concern to both Members of Congress and the general public are avoided to the extent practicable. This includes ventilation shutdown, which has been criticized for causing prolonged distress and suffering and has not been approved by the World Organisation for Animal Health due to its negative welfare implications. Under USDA's January 2022 Ventilation Shutdown Plus (+) Policy, six criteria must be met in order for the USDA to grant the use of ventilation shutdown; the first criteria is that other methods are not available or will not be available in a timely manner. However, we are seeing various media articles that suggest the use of ventilation shutdown is increasing. Can you speak to USDA's efforts to ensure ventilation shutdown is used as a method of last resort, rather than the default, particularly for large commercial operations?

Response: When responding to animal pest and disease emergencies such as highly pathogenic avian influenza, the Animal and Plant Health Inspection Service (APHIS) uses depopulation methods in accordance with the 2019 American Veterinary Medical Association (AVMA) Guidelines for Depopulation of Animals. APHIS prioritizes use of depopulation methods that are both efficient and humane, and only uses ventilation shutdown plus (+) in limited, specifically described circumstances. APHIS assesses each premises to determine the best approach given site-specific conditions. Ventilation shutdown plus (+) is the last option that is considered when selecting a depopulation method. APHIS continually seeks to improve methods used to depopulate Highly Pathogenic Avian Influenza (HPAI) infected poultry quickly, dispose of carcasses, and decontaminate premises using new research and results from prior HPAI stamp out programs.

Mr. Pocan: Are APHIS officials strictly adhering to the agency's ventilation shutdown policy and documenting the rationale for its use?

Response: APHIS officials strictly adhere to the agency's ventilation shutdown plus (+) policy and document the rationale for its use in each circumstance. Ventilation shutdown plus is only used in constrained circumstances and after the following criteria have been met: 1) other methods are not available or will not be available in a timely manner; 2) the amplification of the virus on the premises poses a significant threat for further transmission and ongoing spread of HPAI; 3) the ventilation shutdown plus policy has been reviewed and discussed by APHIS officials, State or tribal officials, and the incident management team; and 4) State officials and the premises owner approve of the method. APHIS requires written and/or electronic documentation of these criteria for each request to use ventilation shutdown plus.

Rural Energy for America Program

Mr. Pocan: Within the REAP program, ensuring the program serves applicants who want to invest in a broad range of renewable energy technologies through a Reserve Fund is broadly supported. A recent letter supporting REAP funding for FY23 from more than 100 stakeholders including the Farm Bureau, Ag AC, supports this step. Can USDA implement a reserve administratively for underutilized renewable technologies?

Response: Rural Development (RD) has determined that USDA cannot administratively implement a reserve for underutilized renewable technologies. However, the program statute authorizes the Secretary of Agriculture to consider the type of renewable energy system to be purchased in determining grant awards. RD uses this authority to give additional priority to applications proposing to purchase underutilized technologies. Additionally, the pending legislation would create and fund a program that prioritizes underutilized technologies.

Mr. Pocan: REAP applications remain cumbersome and challenging even for smaller projects. It doesn't need to be this way. Are there steps USDA can take now to streamline the applications process so that smaller farms and businesses seeking to leverage REAP for projects can do so more easily while still ensuring the goals of the program are met?

Response: Reducing the complexity of the Rural Energy for America (REAP) program and all of our Rural Development programs for both applicants and USDA staff is a major priority for USDA. RD is required to follow the guidelines established by the President's Office of Management and Budget to administer Federal grants.

RD has made some streamlining improvements in regulation updates that were published in 2021, including:

- We removed a burden by allowing the applicant to certify to their eligibility as a rural small business or agriculture producer. The previous regulation required submittal of evidence/documentation.
- A full technical report is no longer required for every type of technology.
- The feasibility study is no longer based on total project cost threshold, rather it is now based on the calculated risk of the project.
- In the coming months, we will continue to pursue the resources necessary to simplify and modernize the REAP application process, keeping in mind the statutory limitations.

USDA also looks forward to working with Congress as you develop the next Farm Bill to seek out opportunities to streamline and make updates to our program authorizations that will make it easier for farmers and rural communities to apply for these critically important programs.

QUESTIONS SUBMITTED BY CONGRESSMAN DAVID VALADAO

Chlorpyrifos

Mr. Valadao: As you are aware, in August of 2021, EPA banned a critical pesticide, Chlorpyrifos on food, of which has historically treated 80 variations of food crops for pests. This was devastating news to U.S. farmers and ranchers, already struggling with input costs.

It's my understanding that prior to EPA's decision to ban it, USDA staff pointed out to EPA is very own science as recent as 2020 supported continues, safe and limited uses of Chlorpyrifos on: alfalfa, apples, asparagus, cherries, citrus, cotton, peaches, soybean, strawberries, sugarbeets and wheat. Unfortunately, EPA chose to ignore USDA's recommendation to follow the science and continue limited use of Chlorpyrifos on these crops.

Do you believe that EPA should have stood by its science, and allowed for the 11 continues uses of Chlorpyrifos this growing season and beyond?

Response: The U.S. Department of Agriculture Office of Pest Management Policy (OPMP) understands that EPA's 2021 decision to cancel all food tolerances was based on their view that the aggregated risk of all chlorpyrifos uses combined does not meet the safety standard. Prior to that decision, in March 2021, OPMP provided comments to EPA in response to the 2020 chlorpyrifos proposed interim decision (PID), which included a rationale for retaining multiple uses. These comments reflected input from numerous agricultural stakeholders. Our comments can be found on the internet at the following address:
<https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1101>

Mr. Valadao: In the aftermath of PEA's Chlorpyrifos decision, have you and Administrator Eagan spoken about how to preserve Chlorpyrifos use for this growing season, per EPA 2020 science, and beyond?

Response: OPMP has been in regular contact with EPA to discuss the importance of chlorpyrifos. We have and will continue to provide information to help inform EPA's decisions across the board, including information on the key uses of crop protectants that meet safety standards and that help ensure continuity of the food supply chain. As with any chemical, we encourage EPA and registrants to maintain safe uses and refine existing uses to allow continued access to pest control tools

Mr. Valadao: Will you urge EPA Administrator Regan to allow for continued, limited use of Chlorpyrifos in 2022 and beyond, according to EPA's own 2020 science?

Response: The decision to re-visit or potentially re-register labels with chlorpyrifos uses rests with EPA and the chlorpyrifos registrants. We have and will, however, provide information to help inform EPA's decision, including information on the benefits of chlorpyrifos to growers. As with any chemical, we encourage EPA and registrants to maintain safe uses and refine existing uses to allow continued access to pest control tools.

THURSDAY, MAY 19, 2022.

U.S. FOOD AND DRUG ADMINISTRATION

WITNESS

**DR. ROBERT M. CALIFF, MACC COMMISSIONER OF FOOD AND DRUGS,
U.S. FOOD AND DRUG ADMINISTRATION**

Mr. BISHOP. This meeting of the Agriculture Subcommittee of the Appropriations Committee will now come to order.

At this hearing, it is fully virtual. We must address a few house-keeping matters.

At today's hearing, the chair or staff designated by the chair may mute participants' microphones when they are not under recognition for purposes of eliminating inadvertent background noise.

Members are responsible for muting and unmuting themselves. If I notice that you have not unmuted yourself, I will ask if you would like the staff to unmute you. If you indicate approval by nodding, staff will unmute your microphone.

I remind all members and witnesses that the five-minute clock still applies. If there is a technology issue, we will move to the next member until the issue is resolved. You will retain the balance of your time.

You will notice a clock on your screen that will show how much time is remaining. At one minute remaining, the clock will turn yellow. At 30 seconds remaining I will gently tap the gavel to remind members that their time is almost expired.

When your time has expired, the clock will turn red and I will begin to recognize the next member.

In terms of speaking order, we will begin with the chair and ranking member. Then members present at the time the hearing is called to order will be recognized in the order of seniority, and finally, members not present at the time the hearing is called to order are in the order of their arrival.

Finally, House rules require me to remind you that we have set up an email address which members can send anything they wish to submit in writing at any of our hearings or markups. That email address has been provided in advance to your staff.

That being said, we will begin.

And let me just say good morning. I want to welcome all of you to today's hearing. The hearing this morning is review the Food and Drug Administration's fiscal year 2023 budget request.

Our witness is the Commissioner of the Federal Drug Administration, Dr. Robert Califf.

Before we begin with hearing proceedings, I would like to welcome a new member to our subcommittee. Ms. Julie Letlow representing the Fifth District of Louisiana was recently selected to join us.

Welcome, Ms. Letlow, to the wonderful world of Agriculture Appropriations.

Dr. Califf, we would first like to congratulate you on your recent confirmation as Commissioner. It has been over a year since the FDA had a permanent leader during a time when the agency continues to have vast and ever-growing responsibilities.

FDA continues to play a vital role in ensuring the safety and efficacy of vaccines and drugs designed to address the coronavirus. However, there are countless other ways that your work matters to all Americans, and we need to ensure those critical responses get the attention that they need.

I expect much of our conversation today to discuss the overall safety and effectiveness of the products under FDA's purview, and improvements can be made on both the food and medical sides.

Aside from COVID-19, a myriad of other public health challenges, including combatting the opioid crisis, youth tobacco use, and new tobacco product standards on flavors. All have real world impact on Americans and their health.

At the forefront of many minds right now is the critically low supply of infant formula affecting so many American families. The American people rely on FDA to protect infant health by ensuring they have access to safe formula.

I would like to later discuss what FDA is doing to mitigate shortages and what changes can be made to improve the inspection process of manufacturers. This includes harmful delays and inaction on warnings at the Sturgis, Michigan facility. The agency received reports as early as September of 2021, but did not inspect the associated facility until January of 2022, which is, indeed, unconscionable.

I would also like to hear plans to address the backlog of foreign inspections and plans to conduct foreign inspections moving forward, admitting that all too well that over 75 percent of active drug ingredients are provided by foreign countries, including some with very poor safety profiles.

Given concerns about drug manufacturing in foreign countries, these facilities must be held accountable and treated equitably with U.S. manufacturers.

Unfortunately, food-related illness stemming from outbreaks of E. coli and salmonella or toxic levels of heavy metals in baby foods and food-related health concerns continue to be of monumental concern.

Citizens put their trust in FDA's regulation and oversight every time they sit down for a meal or take a pill, and they deserve an FDA that is at the top of its game.

We want to work with you to help modernize FDA so that you can carry out your mission of protecting the health and safety of all Americans.

I want to thank you for being with us today, and I look forward to our discussion.

Lastly, I wish to commend the commitment and talent at the agency. While certain issues may exist, we recognize the commitment of those that work so hard at the agency to keep our food, our medical devices, and our prescription drugs safe.

In that vein, a special shout-out to the leadership and staff at the Center for Biologics and the Center for Devices for their monumental effort to get us vaccines and tests for COVID-19.

[The information follows:]

**Opening Statement of
Chairman Sanford D. Bishop, Jr.
Fiscal Year 2023 Budget Hearing
Food and Drug Administration
Commissioner Dr. Robert Califf
May 19, 2022**

Good Morning.

I want to welcome all of you to today's hearing. The hearing this morning is to review the Food and Drug Administration's fiscal year 2023 budget request. Our witness is the Commissioner of FDA, Dr. Robert Califf.

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I would also like to hear plans to address the backlog of foreign inspections and plans to conduct foreign inspections moving forward. Many know all too well that over 75% of active drug ingredients are provided by foreign countries, including some with poor safety profiles. Given concerns about drug manufacturing in foreign countries, these facilities must be held accountable and treated equitably with U.S. manufacturers.

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In that vein, a special shout-out to the leadership and staff at the Center for Biologics and the Center for Devices for their monumental effort to get us vaccines and tests for COVID-19.

Mr. BISHOP. Now, let me ask our distinguished Acting Ranking Member, Dr. Harris, to give any opening remarks that he might have, and I certainly would like to recognize him at this time for that purpose.

Dr. Harris, you are now recognized.

Mr. HARRIS. Thank you, Chairman Bishop.

And I also want to welcome Ms. Letlow to the committee and congratulate her on being our new subcommittee member.

We all look forward to working with you this year.

Dr. Califf, I want to welcome you to today's hearing. I look forward to the discussion on FDA's budget request and other topics of importance.

I will say that FDA's total request of \$8.4 billion, which is a 25 percent increase above the fiscal year 2022 enacted level, is quite steep. I recognize that \$1.6 billion in mandatory funding is requested to support FDA's part of the administration's pandemic preparedness plan.

But setting that aside, FDA is still seeking an overall increase of \$509 million, more than half a billion dollars above fiscal year 2022, with \$153 million coming from new user fees.

Now, without a doubt FDA does critical work that touches the lives of all Americans. However, this budget request does not acknowledge the economic reality that our Nation faces. In times like these, as stewards of taxpayer dollars, we must make tough decisions in the greater interest of the American people.

Growing the size of government programs and the Federal workforce is generally not in the best interest of our Nation's economy and future.

Further, I believe that many of the problems facing your agency can be solved through strong leadership rather than more money.

For example, as I am sure you are aware, last month Politico ran an article titled "The FDA's Food Failure." There were some repeated concerns that stood out, such as the lack of leadership at FDA, the slow decision-making processes, and the lack of transparency and accountability to Congress.

Too often we as appropriators hear how problems will be solved if there was only more money or only more staff, but I disagree. Leadership is needed to be good stewards of the resources at your disposal and to make sure FDA is fulfilling its core critical mission.

Nothing makes that point clearer than the recall and shortage of infant formula that is causing almost unimaginable stress and anxiety for countless parents and caretakers across the country. Nationwide there are reports that 40 percent of formula is out of stock. Yet one of the largest formula manufacturers in the U.S. has had one-third of its production halted since February.

We need to make sure this plant is re-safe to open, but it is hard to see any evidence that FDA has made it a priority to get this plant clean and cleared and back online.

In light of this issue and many other highlights in the political water, FDA's budget request for an additional \$11.6 million increase for the Center for Food Safety and Applied Nutrition, CFSAN, for health equity through nutrition gives me great concern.

Do not get me wrong. I want all populations to have access to healthy foods and the nutritional information they need to make healthy decisions. But other agencies within the Department of Health and Human Services, along with the U.S. Department of Agriculture and their collaboration on the dietary guidelines are already doing this type of work.

Rather than engage in duplicative efforts, I would urge the FDA to focus on its core responsibilities.

It is clear upon the infant formula recall and examples in the Politico article that CFSAN does not need to take on new initiatives. It needs to focus on its mission-critical functions first, such as ensuring a safe and abundant food supply for babies and all Americans, and let the other agencies tasked with promoting nutrition information do their job.

Dr. Califf, after you were confirmed, we had the chance to talk, and I mentioned my concerns about FDA's EUA standard, health care supply chain vulnerabilities, and some other topics that I look forward to discussing today.

Specifically, I would like to see the FDA do more to utilize its emergency authorities to more quickly and effectively respond in times of crises. I am sure all of us are eager to hear how you will bring leadership, accountability, and transparency to FDA in light of the recent challenges the agency has faced.

I look forward to working with you, and I appreciate you being with us for today's hearing.

Thank you, Mr. Chairman, and I yield back.

Mr. BISHOP. Thank you very much.

And at this time I see that we are fortunate to have the full committee chair with us, and I would like to now yield to Chairwoman Rose DeLauro, the gentlelady from Connecticut, for any opening remarks that she may have.

Ms. DeLauro, you are now recognized. The floor is yours.

The CHAIR. Thank you so much, and thank you very, very much, Mr. Chairman, and thank you to Acting Ranking Member Harris, for holding what is a very important hearing.

And I want to say a thank you to you, Commissioner Califf, for testifying this morning.

We are dealing with an infant formula emergency in this Nation, a crisis of both safety and supply. I sounded the alarm on this crisis and have been working on this issue since news of the recall growth in February.

I am glad that you are testifying before us today because we need to get to the bottom of the disgraceful lack of oversight and a terrible safety issue from an Abbott Nutrition manufacturing plant that led to at least two babies dying and several others being hospitalized after consuming Abbott's infant formula.

We need also to get to the bottom of FDA's full response which contributed to product staying on the shelves and in the homes of families the country over, potentially putting babies at risk and forcing parents to play a game of Russian roulette that they did not know they were playing.

I want to say thank you to Chairman Bishop for holding this hearing and for your long-time leadership on this subcommittee.

In September 2021, FDA inspectors conducted a routine inspection of the Abbott laboratory's facility in Sturgis, Michigan, where suspicions of wrongdoing were already present, as noted in a Bloomberg article published May 12th from a reporter who obtained the FDA report through a Freedom of Information Act request.

On October 20th, 2021, a whistleblower, who worked at that Abbott facility, submitted a report to the FDA unveiling a damning list of allegations of wrongdoing at the hands of Abbott.

Recalls happened, but if the allegations are true, the company has lied, cut corners, falsified records to cover up their misdoings at the risk of infant health, and retaliated against employees who tried to correct the problems they were seeing.

They knowingly put a contaminated product on the market. That is plain wrong.

The FDA knew about what Abbott was doing in October, but it was not until late December that the FDA interviewed the whistleblower and then not until a month after that in late January was the plant inspected in person.

Abbott then issued the recall in February, some four months later.

In March, I requested an HHS Office of the Inspector General to start looking into the tragedy, and then I got hold and submitted for the record the whistleblower report, with a truly awful allegation against Abbott.

Their wrongdoing includes the falsification of records, the testing seals on empty cans, releasing untested infant formula, just to name a few.

It all begs the question: why did the FDA not spring into action? Why did it take four months to pull this formula off the stores' shelves? How many more illnesses and deaths were caused due to the FDA's slow response?

Who received the report at the FDA? What did they do with the report? Who in the leadership had access to that report? Who did not have access to that report? And why was there no reaction?

It makes me question which side the FDA is on. Are they on the side of Abbott and industry or on the side of the American consumers, in this case babies and their moms and dads?

We must get to the bottom of this whole safety issue, but today we are dealing with a serious infant formula shortage in this country, where parents, many of whom are struggling, are now scrambling to find a formula to feed their babies.

The shortage was caused in large part by the lack of action by the FDA and by corporate greed and consolidation, in this case, Abbott putting profits and production over people.

This should not happen in the wealthiest Nation in the world, and there are two parts of this shortage: safety and supply. And we cannot and should not have to choose between the two, and I reject there is danger in this false dichotomy.

President Biden just announced that he will be invoking the Defense Protection Act to increase domestic production of infancy formula and launching Operation Fly Formula to use Federal planes to fly formula in from abroad.

I have been calling for the swift importation of safe infant formula from FDA approved facilities overseas. That is the direction we need to go in. That is what I hope is being planned.

These steps can help us to achieve the goals, and I applaud the first steps this week, and we passed last evening a bill to deal with a portion of this effort, and last night we voted on a bill to provide \$28 million in new funding for the FDA to address the shortage, to prevent fraudulent products from entering the marketplace, and to help acquire better data on the situation in the marketplace.

To prevent shortages from happening again, we will work to strengthen the workforce focused on formula issues and increase FDA's inspection staff.

But as the ranking member has pointed out, funding is not the only answer. This issue goes beyond funding, and that has to do with a structural problem.

For another time I would want to discuss the need for a Deputy Commissioner for Food, with accountability to the Commissioner and have direct line authority over the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and food related components and operations of the Office of Regulatory Affairs.

This should happen immediately, and the person who is appointed needs to have relevant and appropriate food credentials, someone with that background who understands this issue.

I understand the FDA has begun to take action to address the shortage, which is encouraging. I remain concerned about the safety of the formulas that end up on our shelves, and as I have said, we cannot be forced to make a false choice between safety and supply.

I am disappointed that the FDA's recently released guidance does not go far enough to ensure formula is safe for our babies because the food we feed our babies must be the safest product on the market, which is why I want to focus on FDA-approved facilities, because we have a standard that may not have been applied to Abbott, but we have a standard when people grab a container of infant formula from the shelf. I want them to know that they do not have to play a guessing game. I want them to know that they can have confidence that it is safe.

Commissioner Califf, I hope that you have been able to reflect on what went wrong, and with that, come with answers because we are all waiting for them. We need to get to the bottom of this terrible tragedy to prevent anything like this from ever happening again.

And I thank you so much, Chairman Bishop and Acting Ranking Member Harris.

And I yield back.

Mr. BISHOP. Thank you, Ms. DeLauro, and thank you for your passion and compassion on this issue.

It appears that Ranking Member Granger has not yet entered the meeting, and so with that, Dr. Califf, without objection, we will recognize you for your testimony.

Your entire written testimony will be included in the record, but I hope that you will give a somewhat abbreviated statement so that we can proceed with questions.

I am sure that members have a number of questions for you and we would like to expedite the hearing as much as possible.

So at this time, Dr. Califf, you are recognized for your opening remarks.

Dr. CALIFF. Thank you, Mr. Chairman.

And I will go quickly here because I certainly understand your request.

Chairman Bishop, Ranking Member Harris, and members of the subcommittee, thank you for the opportunity to appear before you today.

First, let me thank the subcommittee for your continued support of FDA, particularly over the last two years, as the agency has worked tirelessly to respond to the COVID-19 pandemic and other challenges facing the agency, including the recent stress on the infant formula supply chain.

Before discussing FDA's fiscal year 2023 budget request, I want to discuss the current events around infant formula and reiterate FDA's firm commitment to ensuring the parents and caregivers have access to safe and nutritious infant formula.

As a parent and grandparent, I recognize that many parents and caregivers have been unable to access the infant formula and critical medical foods that they need, and they are understandably frustrated and anxious.

My daughter spent a month in an intensive care unit as an infant, and the memories are certainly still with me.

The United States was facing infant formula supply chain stress even before the Abbott nutrition recall that began in February. The pandemic, the war in Ukraine, and labor supply issues have all had an impact, and I can assure you FDA has been working tirelessly to address this issue.

This week we have set up a mechanism that streamlines the ability for companies that do not normally sell infant formula in this country to do so and provides other flexibilities to domestic distributors who can help increase availability.

I want to be clear. Under this process, an infant formula would only be imported after the agency reviews the product and determines the product is safe and provides adequate nutrition. Safety is paramount.

In addition, a consent decree, a permanent injunction was entered between the FDA and Abbott Nutrition. Under the consent decree, Abbott has agreed to take actions overseen by FDA and independent experts that will result in an increase of infant formula products and ensure safe powdered infant formula is produced at the facility.

As you also know, yesterday the President invoked the Defense Production Act to ensure that manufacturers have the necessary ingredients to make safe, healthy infant formula here at home and announced Operation Fly Formula to speed up the import of infant formula to stores as soon as possible.

Again, we know many parents and caregivers are feeling frustrated. With these three recent actions, we anticipate that additional products can quickly hit U.S. stores.

We have a critical opportunity here to invest in FDA's ability to work with partners to ensure a safe and adequate supply of infant

formula and metabolic formulas for the millions of infants who rely on them for their sole source of nutrition.

Approximately three and a half million infants are born annually in the United States, and yet CFSAN has funding for only 13 staff members to ensure the safety and adequate nutrition of these products.

We also have no authority or dedicated resources to monitor and respond to supply chain disruption. This crisis has shown us the impact of having a single manufacturer cease production for a brief period, and unless we strengthen the resilience of our supply chain, we could be one natural disaster, quality mishap, or cyberattack from being here again.

I hope I can with this committee ensure we have the tools and resources we need moving forward. While expressions of empathy are important, I know that parents want formula on the shelves for healthy infants and in the hands of pediatricians for infants with special metabolic problems.

Since the American public is our customer, I urge when considering the budget to give our public funding for technology and experts at least as good as businesses we regulate. No modern company or health system would make such major decisions without a robust data and analytical system and dedicated expert analysts to do the work.

Our budget request will help build a foundation for FDA to ultimately enable the agency to meet the growing needs and mandates upon which the public depends.

While there are many critical priorities in our budget proposal, I would like to mention three specific funding needs that do not get enough public attention: data and technology modernization; people; and infrastructure.

The technology and data systems that we have are not of the quality we need for us to fully facilitate innovation in the rapidly moving industry which we regulate in order to protect the public from well-meaning or intentionally harmful products.

A final thought here. When we review the infant formula situation, we will certainly find specific issues where we could have done better, and we will, of course, take accountability for any shortcomings. But unless we make the right investments in our infrastructure, including technology data, people, and a modernized supply chain system, we will continue to see shortages and problems across the industries we regulate.

Thank you for inviting me, and I look forward to answering your questions.

[The information follows:]

Statement by
Robert M. Califf, M.D.
Commissioner of Food and Drugs, Food and Drug Administration
Fiscal Year 2023 Budget Hearing
Food and Drug Administration
May 19, 2022

Chairman Bishop, Ranking Member Harris, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the President's Fiscal Year 2023 Budget Request for the Food and Drug Administration (FDA or the Agency).

I would like to start by thanking the Subcommittee for your continued support of FDA. The Agency appreciates the funding increases provided by the Subcommittee in the FY 2022 Omnibus and your ongoing partnership is much appreciated as we execute our mission to protect and promote the public health, including our ongoing response work related to the COVID-19 pandemic. As we collectively work together as a nation to try and turn the corner of the COVID-19 pandemic, the Agency is using the lessons learned over the past two years and optimistically looking forward. FDA's talented and dedicated workforce has worked night and day for the past two-plus years to respond to the pandemic and this work has been deeply consequential for strengthening our nation's response and protecting public health. At the same time, one of the biggest lessons learned from our COVID-19 response was the overwhelming need identified by FDA leadership to modernize the Agency, including through improved data processes, IT infrastructure, and facilities, to name just a few priorities. As a private citizen who was involved in the pandemic response alongside many in industry and academia, I can attest to the fact that this sentiment was also observed by many outside the Agency as well. This effort will require significant additional funding and we look forward to providing you with the rationale for our plans to meet these needs, delineating the benefits to the public health that will accrue, and working with you to make sure the FDA remains the gold standard around the world.

FDA's FY 2023 Budget Request builds upon our FY 2022 request while also acknowledging additional future needs and challenges. Our program level request totals \$8.4 billion, which represents an overall increase of approximately \$2.1 billion above the FY 2022 Enacted level. Of this total, \$3.0 billion is for user fees, which is an increase of approximately

\$153 million above the FY 2022 Enacted level. Further, the Budget requests a total of \$3.7 billion in discretionary budget authority, which is an increase of approximately \$356 million above the FY 2022 Enacted level, and \$1.63 billion in mandatory funding to support the Administration's plan to transform U.S. capabilities to prepare for and respond rapidly and effectively to future pandemics and other high consequence biological threats. These increases are organized into six critical areas that advance the Agency's critical activities in support of protecting and promoting the public health: (1) enhancing food safety and nutrition; (2) advancing medical product safety; (3) investing in core operations; (4) modernizing infrastructure, buildings and facilities; (5) tobacco user fees; (6) supporting Cancer Moonshot goals; and (7) pandemic preparedness.

I. Enhancing Food Safety and Nutrition

FDA's Budget requests an increase of approximately \$76 million above the FY 2022 Enacted level, to support our continuing efforts to enhance human and animal food safety and human nutrition. Every American deserves access to safe and nutritious food, and our foods program staff at FDA work countless hours in partnership with federal, state, local, tribal, and territorial partners to ensure that our nation's food supply is safe. To deliver on this promise, the Budget requests funding to address health equity issues related to access to healthy and safe food. The Budget also seeks to address the rapid changes occurring in the way foods are produced, delivered, and handled. We must have modern tools and technologies to ensure the Agency's capabilities do not lag behind these sweeping changes. As a regulatory agency, if FDA cannot keep up with industry, our oversight will struggle to be effective. Modernization of our systems will enable us to prevent significant harm to the public from unsafe food.

New Era of Smarter Food Safety

The Budget requests approximately \$59 million, an increase of \$43 million above the FY 2022 Enacted level, for our New Era of Smarter Food Safety initiatives. The goal of these initiatives is to bend the curve of foodborne illness in this country by reducing the number of illnesses attributed to FDA-regulated human and animal foods and to protect consumers from other unsafe foods. This approach builds on the modernized food safety regulatory framework created by the Food Safety Modernization Act (FSMA), including investments in animal food safety oversight. The requested funding would support the use of new technologies and data analytics to strengthen prevention activities, including the use of artificial intelligence, improve

the ability of the Agency to rapidly trace food contamination back to the source and address the cause, and improve the efficiency and effectiveness of FDA's oversight activities.

Healthy and Safe Food for All

As a nation, we continue to need to improve not only the healthfulness of food that we put into our bodies, but also the safety of this food, including steps to reduce the presence of toxic metals and chemicals, especially in the food consumed by our most vulnerable and underserved citizens.

As a cardiologist, I have seen the effect of poor nutrition on the human body, often beginning in childhood. Additionally, I am acutely concerned with the safety and availability of infant formula as a sole source of nutrition for many infants in our country today. To make progress on these issues, the Budget requests an additional \$33 million above the FY 2022 Enacted level across several initiatives that would seek to improve health equity through nutrition; to research, detect, and reduce exposure to harmful chemicals and toxins in food; and to complete additional nutrition work specific to infants, toddlers, and pregnant and lactating people.

II. Advancing Medical Product Safety

The increasing sophistication, complexity, and digitization of medical products will benefit the public greatly, but these trends also require more sophisticated regulation to facilitate innovation and prevent unintended harm. In addition to our important work on food safety and nutrition, FDA also continues to face record levels of submissions for new medical products. Despite the pandemic, in the last few years, the Agency has continued to approve a record number of safe, reliable, effective, and innovative products that will improve the length and quality of life of patients and their families. In order to maintain this essential work and uphold the high standards upon which Americans rely when reviewing these products, the Budget requests an increase of approximately \$95 million above the FY 2022 Enacted level. These additional funds will help address some of the Agency's highest priorities, including post-market monitoring for the continued performance, safety, and effectiveness of approved products and addressing public health issues such as the opioid epidemic. The U.S. faces significant challenges, including diseases and conditions, both rare and common, for which there are few or no therapies, current and future medical product shortages, and ongoing efforts to enhance patient safety. Investments in FDA medical product programs will assist on these fronts and

ensure that FDA can continue to be an able, dynamic, and trusted partner to patients, physicians, and other health care professionals.

Cancer Moonshot

FDA is committed to supporting efforts to deliver safe and effective new therapies to patients, including through working to advance critical disease research, including on cancer. The Budget requests \$20 million for the Oncology Center of Excellence to support the Administration's goal of reducing cancer-based death and illness as part of the Cancer Moonshot initiative. These elements of FDA's contributions to the Cancer Moonshot would include the advancement of research, external collaborations, educational outreach programs, and programs that expedite the development of oncology and malignant hematology products using an integrated clinical evaluation approach. Among other activities, resources will also enable FDA to expand efforts that facilitate approval of important cancer treatments by international regulatory authorities at the time of FDA approval and will foster harmonization of cancer treatments in other countries with the U.S. standard of care.

Supply Chain

By the time a public health emergency is declared, it is often too late to effectively prevent or mitigate shortages, and our goal as an Agency and as a nation should be to proactively intervene to assure patients and our health care providers on the front lines maintain access to the devices they need. That is why I strongly support efforts to fully fund the Budget's approximately \$17 million request in additional resources for the Resilient Supply Chain and Shortages Prevention Program. Funding will complement foundational work supported with our COVID-19 supplemental dollars and will continue to build capabilities for a permanent program for U.S. supply chain resilience for medical devices. This program will help ensure that U.S. patients and the clinicians who care for them have access to the critical devices they need and help reduce U.S. dependence on devices from other nations, including masks, gowns, and other forms of PPE. The program will enhance FDA's capacity to rapidly intervene to prevent and mitigate device supply chain interruptions by developing and applying data analytics for predictive modeling, improving early signal detection and monitoring, and investing in preventive measures to avert shortages. This funding will ultimately promote enhanced resiliency in the medical device supply chain, and in addition to helping FDA be prepared for the next pandemic, it will also allow the U.S. to be better prepared for future events that don't rise to

the level of a public health emergency, such as during hurricanes and other natural disasters, as well as during steady state operations.

Complimentary to our initiative on devices, FDA is also seeking over \$6 million across both the human and animal drug product areas in order to enhance supply chain surveillance in these industries as well. Investing in these key product areas at FDA will allow us to build both more technologically advanced supply chain surveillance systems beyond just devices and promote a regulatory environment that is more responsive to notifications from stakeholders and health care professionals, allowing for a nimbler and more responsive FDA.

Cybersecurity

Further, the Budget requests approximately \$5 million above the FY 2022 Enacted level to address medical device cybersecurity, along with a request for new related authorities, as we continue to see cybersecurity threats to medical devices increase. Cybersecurity exploits are one of the most substantial threats faced by this nation, and the impact could be particularly harmful for our health care system, where vulnerabilities could compromise entire hospital systems or disrupt manufacturing of countless devices. Funds for our device cybersecurity initiative will be used to help address risks associated with legacy devices, such as automated insulin pumps and implantable cardiac pacemakers, and rapidly address new medical device vulnerabilities.

Opioids

I remain deeply concerned about the devastating impact of the opioid crisis on families across our country. FDA's Budget includes a requested increase of \$30 million above the FY 2022 Enacted level to support the Administration's Advancing the Goal of Ending the Opioid Crisis. FDA is taking steps to address four priority areas of this epidemic: (1) decreasing exposure and preventing new addiction; (2) supporting the treatment of those with opioid use disorder; (3) fostering the development of novel pain treatment therapies; and (4) improving enforcement and assessing benefit-risk. Among other planned activities, these funds will address these priorities by supporting development of opioid overdose reversal treatments and treatments for opioid use disorder, assessing feasibility to integrate opioid Risk Evaluation and Mitigation Strategies (REMS) education into IT health systems/Electronic Health Records, expand current initiatives to interdict shipments of opioids, unapproved foreign drugs, counterfeit pharmaceuticals, and fraudulent products, and advance the development, evaluation, and marketing authorization of digital health medical devices that help address opioid use disorder.

III. Investing in Core Operations

The Budget requests an additional \$158 million above the FY 2022 Enacted level to support Agency-wide crosscutting initiatives that support both food safety and medical product safety and are complimentary to funding initiatives described earlier in this testimony. While the Agency has a number of critical needs in this area, including the ongoing need to support lab safety, address employee pay costs, and reduce animal testing using alternative methods, I would like to draw your attention to two especially critical topics— data and technology modernization and inspectional activities.

Data Modernization and Enhanced Technologies

To fulfill our ongoing and evolving public health mission, FDA requires the ability to continuously access, aggregate, visualize, and analyze multiple sources of information. Improving FDA's data processes and infrastructure is not only a good investment, but a necessary one in order to keep up with today's modern regulatory landscape. These investments are also important not just for FDA, but for our partners. FDA shares data both internally and externally and requires the ability to quickly and reliably extrapolate information to inform emergency response, as well as for standard oversight activities. FDA is requesting approximately \$42 million above the FY 2022 Enacted level for Agency-wide investments in centralized data modernization.

Without additional funds to modernize our data systems, FDA will be forced to continue to use outmoded, legacy systems that do not integrate with more current systems, test reviewers will not be able to reliably keep up with expected growth in product submissions over the upcoming years, and Agency-wide efforts to leverage new data-rich capabilities like machine learning and artificial intelligence will be delayed. This translates into a slower and less effective FDA. We must make these investments now to ensure the Agency remains the gold standard for product standards and reviews.

Optimizing Inspectorial Activities

The Budget also includes a request for an increase of \$24 million to optimize our inspections work Agency-wide. As you know, our ability to execute our inspections was disrupted due to the evolving COVID-19 pandemic. The requested funding will help to bring our program back on track and to improve its operational readiness. As we do this, the requested funding would support capacity building to improve data analysis, increase efficiency and

productivity, and ultimately streamline and optimize end-to-end inspections across both foods and medical product areas. I am aware of this Subcommittee's interest in our inspectional work and our Budget request will help to ensure the Agency can modernize and execute our inspectional programs effectively.

IV. Modernizing Infrastructure, Buildings & Facilities

FDA's FY 2023 Budget also requests approximately \$40 million above the FY 2022 Enacted level, for a total of \$353 million, to ensure that FDA's offices and labs across the country are optimally functioning to enable FDA to carry out its mission. This funding is critically needed to complete projects that will improve the condition of FDA's owned buildings and site infrastructure. Of the total \$40 million request, \$31 million is specifically for Buildings and Facilities, an increase of \$18 million above the FY 2022 Enacted level, to improve the condition of FDA's mission-critical, owned site infrastructure and buildings. Currently, the poor overall condition of FDA's owned buildings and facilities, especially its labs, directly affects FDA's ability to foster the scientific innovation necessary to improve health care, expand access to medical products, and advance public health goals.

V. Tobacco User-Fees

Additionally, the Budget request includes \$812 million in user fees to support FDA tobacco's program. Included within this total is an additional \$100 million in tobacco user fees and updated authorities to include manufacturers and importers of all deemed products (i.e., to include those not already subject to user fees such as e-cigarettes) among the tobacco product classes for which FDA assesses user fees. FDA is also requesting an inflation adjustment for all tobacco user fees to ensure that the resources can keep up with the Agency's public health mandate and with the evolving marketplace of tobacco products. Without additional user fees, FDA will be forced to continue to spread out the flat budget available for tobacco regulation, which has remained stagnant for the past three years, limiting our ability to protect the over 2 million young people who reported using e-cigarettes and other tobacco products in the last year.

I must also note that in addition to presenting a heavy resource challenge, a lack of new tobacco user fees also represents a fundamental parity issue across tobacco-related industry. Prior to the court-ordered deadline of September 9, 2020, FDA received timely premarket tobacco product applications for approximately 6.7 million products. Thanks to the tireless efforts of the over 1,100 staffers at FDA's Center for Tobacco Products, together with the

support of over 200 employees from across other parts of the Agency, we have met this challenge and have acted on over 99% of these applications thus far, and the remaining product reviews will be completed expeditiously. However, I must emphasize that this tremendous effort was undertaken with no additional resources – without e-cigarette manufacturers having to pay a single cent despite their products taking up a significant amount of our tobacco workload. I would strongly urge this Subcommittee to work with authorizers in this fiscal year to provide the requested authority and new resources so that we may more expeditiously and comprehensively take the actions necessary to prevent new youth initiation of tobacco products, and to support those of all ages who are seeking to reduce smoking of tobacco products and quit these products.

VI. Pandemic Preparedness

Finally, the Budget includes a request for \$1.63 billion in new mandatory resources over a five-year period to implement the HHS Pandemic Preparedness Plan. Of this total figure, the request includes \$1.1 billion to expand and modernize FDA's regulatory capacity, IT, and laboratory infrastructure in order to facilitate development and expedite evaluation of vaccines and therapeutics that target high-profile viral families. The request also includes \$355 million to speed development of diagnostics, as well as \$175 million to strengthen foreign inspections, harmonize premarket product reviews, and reduce zoonotic pathogen spillover.

The funds would support biodefense preparedness, expediting overall vaccine design, testing, and authorization capacity by bolstering FDA's cadre of reviewers, increasing resources for inspections, and investing in electronic information exchange among stakeholders. It would increase the Agency's readiness to facilitate the development of new vaccines, including those based increasingly on mRNA technology and other rapidly modifiable or novel platforms, and enhance FDA's active and passive vaccine safety and effectiveness surveillance programs. This request would also support the development of a training center for inspection of advanced medical products.

Along with these initiatives, the pandemic preparedness request would also be used to establish a cross-agency One Health Center of Excellence, allowing FDA to strengthen its interdisciplinary approach to solving multifaceted health challenges, like COVID-19, where the health of humans, animals, and their shared environment are intrinsically linked. This effort will also build internal capacity to address ongoing public health challenges that are exacerbated during pandemics like the COVID-19 public health emergency, such as human and animal food

contamination, diabetes, heart disease, and cancer. The resources requested for vaccine activities, One Health, and other integral parts of the broader HHS Pandemic Preparedness Plan, are critical to ensure the United States is properly prepared for the next pandemic and to increasing our chances of preventing future pandemics. As a nation, we cannot afford to play catch up with the next threat to our national wellness and readiness.

VII. Conclusion

I would like to close by thanking the Subcommittee again for your continued support of the Agency, and again thank you for inviting me to testify today. I look forward to working with you and I am happy to answer your questions.

Mr. BISHOP. Thank you very much, Commissioner.

At this time we will begin our questions, and I will begin.

Commissioner, there will be a lot of questions about the infant formula crisis today, but I wanted to lead with the most basic questions, and the subcommittee wants a real answer.

It is unconscionable that it took four months from the time the first infant illness was reported before FDA sent an inspector to the plant. Why was that?

Can you walk us through the process going forward on how you get the Abbott plant in Sturgis, Michigan back online?

The President has invoked the Defense Production Act to address the formula shortage, and we will purchase formula under that from other countries and have them flown into the U.S. to restock our shelves, and that we expect to be done quickly.

But this is temporary action. What is the FDA going to be doing to assure that this product is safe? As the chairlady has pointed out, not only do we need supply, but we need safety.

Would you address that?

Dr. CALIFF. Chairman, first of all, the question of what happened. I think Chairman DeLauro, I think, correctly stated the time frames. The dates are well known. The information is in the public.

We have an ongoing investigation about the details of exactly what happened, you know, from Point A to Point B along the way, and since it is ongoing, I cannot give extensively more details on that part of it.

I will comment directly on the issue of bringing the Sturgis plant back up, and I think the issues that you all have raised in your opening comments really exemplify the problem that we face when we have a concentrated industry where taking down one plant had such an enormous impact.

This creates a situation where we have a delicate balance. If conditions are unsafe, how do we get the plant back up and operating without interrupting the supply, remembering that this plant not only makes general infant formula but is the largest supplier of the special metabolic formula for about 3,000 infants in our country who are totally dependent on very specialized formula that no one else makes?

And so we had to really wrestle this to the ground with Abbott, ending up in a consent decree with the Justice Department, to make sure that as we bring the plant up, both the FDA Inspectorate and external experts are watching every step of the way.

I am pleased to say today we have already made significant progress, and I think we are on track to get open within the next week to two weeks, most likely at the out bounds, two weeks, but we are monitoring it every—

Mr. BISHOP. Thank you, Commissioner.

I hate to interrupt you, but I wanted to get to another question quickly, and my time is going to expire. We have moved to four minutes.

Of course, you have heard reference to Politico's story indicating a quote that current and former officials used the term "ridiculous," "impossible," "broken," "Byzantine," and "a joke" to describe the

state of food regulation at FDA, and there are questions about the leadership problem.

What can we expect to see?

You announced last night that you plan to leverage the Principal Deputy Commissioner expertise to provide strategic counsel, including the Center for Food Safety and Applied Nutrition and Office of Regulatory Affairs.

What can we expect from this action to improve the operations?

And what is your reaction to Chair DeLauro's suggestion for restructuring the center?

Dr. CALIFF. Thank you for raising those questions.

I learned in 2016 that the food side of the FDA was under resourced consistently, very much so compared to the medical product side of the FDA. You know, we will make sure you are supplied with the comparative information.

It is very important that we have the proper hiring authority and are able to pay the salaries of scientists, but you are also raising the question of leadership.

You know, I will mention that many of the most critical people were in position of leadership in the past, and so they are certainly in a place to know. This is not a surprise.

As I was considering coming back to the FDA, many of them called me. So I was very well aware coming in that we need to do major improvements on the food side of the FDA, not because the people are bad, but there is a need for consistent leadership and the right resources for people to get their work done.

What Dr. Woodcock brings—

Mr. BISHOP. Mr. Commissioner, you will have an opportunity, I think, to elaborate on that.

Dr. CALIFF. I understand.

Mr. BISHOP. My time has expired, and I want to give the opportunity to the other committee members to engage in questions because we are pushed for time this morning.

So I would like to yield to Dr. Harris as the distinguished ranking member for his questions.

And we have reduced the question time to four minutes because of the exigencies of our time this morning.

You are now recognized, Dr. Harris, for your questions.

Mr. HARRIS. Thank you very much, Mr. Chairman.

Dr. Califf, on Monday the FDA issued enforcement discretion guidance to help increase the supply of formula, including formula that is being imported. Under that guidance, could we be importing infant formula from China?

Dr. CALIFF. It is not our primary intent to be bringing in formula from China, and it is not our first call. That is not excluded under the guidance, but we know a number of the facilities around the world that we can use where we have experience already, as Chairman DeLauro already pointed out.

Mr. HARRIS. Okay. Thank you.

No, my concern is just that, you know, during COVID we have not done as many inspections overseas, and now we are going to be bringing in things from overseas where perhaps the inspections over the past few years have not been as rigorous.

Now, a lot has been said, you know, that the Cronobacter cases came from the Abbott plant, but am I correct that the CDC concluded its investigation with no findings of a definitive link between the Abbott formulas and the four cases based on their genetic analysis of the Cronobacter?

Dr. CALIFF. I do appreciate your question, and this is very complicated. So we will have to get back to you about the details, but the short side of it is using genotyping we could not connect the cases directly to the Abbott plant. That is correct.

But the investigation is not over because Cronobacter is a very difficult organism to culture, and we do have five cultures that are positive for different types of Cronobacter from the Abbott plant. They just do not match up.

And so the plant definitely needed to be dealt with. Saying that cases came directly from that plant is something that we cannot say until the investigation is entirely completed.

Mr. HARRIS. Well, thank you.

That was my concern because I think Ms. Psaki and the White House actually said that infants died from that plant, and just to correct the science, that link has not been definitively made.

And we should stick with the science on that. I mean, it may well have happened, but not scientifically proven.

Finally, you and I have discussed emergency use authorization, and the administration has said we could have 100 million cases of COVID this fall. It could be a new variant.

I am still concerned that there is no end stage treatment. Those are for individuals who have gone to the ICU, have been put on a ventilator, have pneumonia. We know that there is not a good treatment available for that under emergency use authorization.

And I would just urge and ask, you know, is this of concern to the FDA because I know, as we have talked about this, the regulation is pretty clear and the statute is clear. "May be effective" should be the guideline for when the EUA can be issued when nothing else is available.

And as you know, there are studies being done, Phase 3 trials on late-stage therapies. Obviously, they may be effective. They are in phase three trials, and there is no other treatment.

So could you briefly address what the FDA is doing to make sure that this fall, if we get a resurgence of COVID, we actually have an emergency use authorized or approved drug for treatment?

Dr. CALIFF. Two quick comments on that. Number one, we do have treatments that are effective. They are not curative for that stage, that have a benefit. Steroids now, being two in particular, but we will get you more details on those.

We are always looking for more effective treatments and welcome anyone who can bring data indicating they have an effective treatment, and we will act on it as quickly as we possibly can, which I think has been very quickly in the past and will continue to do that.

Mr. HARRIS. Thank you very much.

Mr. Chair, I yield back.

Mr. BISHOP. Thank you, Dr. Harris.

At this time, I am delighted to yield to the chairlady of the full committee, the gentlelady from Connecticut who has been so vigilant in monitoring this issue and bringing it to public attention.

So at this time I yield to Chairwoman Rosa DeLauro for your questions.

The CHAIR. Thank you very, very much, Mr. Chairman.

Just a couple of very quick facts. The fact is at the FDA food safety is not a priority. That is a fact. It just is not. There needs to be a restructuring of the food safety with people who know food safety.

I also might add that Dr. Woodcock was the Acting Commissioner when this October whistleblower report reached the agency.

A fact about bacteria. It changes. I am not a doctor. It mutates over time. It thrives in the kind of dry powder that formula is made up of, and it could have changed over time.

My question is the following. Dr. Califf, have you read the whistleblower report?

Dr. CALIFF. I have, yes. I have looked at it, yes.

The CHAIR. Okay. Let me just say what was the allegation that concerns you the most?

Dr. CALIFF. I would say the most concerning—let me just point out that in my career, I have frequently been in the position of being the person in charge when whistleblower complaints are raised in an organization.

The most concerning charge is that the integrity of the organization was compromised. So once that integrity is compromised, then the question is how can you trust any of the systems that are in place.

The CHAIR. Well, in fact, yes. Whoever looked at that report felt that there was no need to respond at all from October to February, until there was a recall. That is a dereliction of duty, in my view.

And in addition to which you have a person who, as an Acting Commissioner, should have done that. Now it would appear that that person is going to oversee this effort. That is the fox in the henhouse.

If I can, let me ask you this issue. In the guidance that you put forward, you list recommended, recommended but not required information for the manufacturers, and the manufacturers are most likely not FDA approved.

You have seven FDA approved facilities which you could go to immediately, but what you are talking about in the guidance is that you list recommendations, recommendations that are not required to be followed, and so, in fact, they do not even have to include your recommendations in their application for certification and for review.

Will you commit to not exercising enforcement discretion with respect to critical statutory and regulatory safety requirements?

Dr. CALIFF. Yes, with an emphasis on those critical requirements. We will not let infant formula into the U.S. that is not safe.

The CHAIR. Well, but these folks do not have to abide by your recommendations. It is a guidance. Nothing is required of these potential manufacturers, nothing.

Dr. CALIFF. With due respect, Madam Chairwoman, you are correct in what you say, except that we have the authority to either let the product in or not. So we have control over there.

The CHAIR. Well, if you have got somebody who certifies and you also talk in your guidance that people and efforts can self-certify or have a third party certify so that you, in fact, do not have the tangible evidence from these facilities that, in fact, their product is safe to be imported, that baby formula is safe.

I just want you to commit to the safety portion of this effort, and you do not have in place a mechanism that would guarantee the safety right now. You just do not. That guidance does not allow you to determine and to define the safety of the products that may be coming from facilities that are not FDA approved.

And why are we not going to facilities that are FDA approved and not allowing all of these other potential manufacturers to enter into our system with the potential of creating another crisis?

Guidance is not standardized. You have no guidance standardized across applications. You pick and you choose. If you do not have standards and they go across the board, you do not have a standard application process and which you can judge upon.

I apologize to you, Mr. Chairman, for going over.

Mr. BISHOP. Thank you, Ms. DeLauro. Hopefully we will be able to come back and follow up.

At this time I would like to recognize the gentleman from California, Mr. Valadao, for your questions.

Mr. VALADAO. Thank you, Mr. Chairman.

Commissioner Califf, thank you for coming to testify in front of the subcommittee today.

This hearing is obviously very timely at this shortage that is an emergency and has been for way too long.

I believe all of us here on the committee are hearing from our constituents about the dire infant formula situation. Between the infant formula recall, subsequent plant shutdown, ongoing supply chain disruption, and people panic buying out of fear that they will not be able to feed their babies, this has become a dangerous and unacceptable situation.

Low income and disadvantaged communities like many in my district are suffering from consequences of the recall that started three months ago or closer to four months ago. These families have been suffering through the COVID-19 pandemic, ongoing supply chain issues, inflation, and more, and they need a break.

This administration appears interested in alleviating the issue, but it has taken too long to get to this point. We must ensure the shortage is fixed immediately.

As you well know, especially on this committee, recalls of products in our country is not a new thing, and when it comes to something as vital as the children's food supply, it seems the FDA just did not take this one as seriously as they should.

This is not about purchasing a popular, trendy type of infant formula. This is about a critical access to specific formulas parents and caregivers need for their babies.

Even one of my own children was relying on a very specific type of formula. So as a father who has had the opportunity or been in a situation where I had to drive all over town to chase specific for-

mulas, and this was far before any shortage, I can only imagine the stress these parents are experiencing.

Did the FDA treat this just like every other or any other recall that they have had to deal with or did they understand the gravity of the situation from the beginning?

More importantly, do they now fully grasp how devastating this entire situation has been and continues to be?

Dr. CALIFF. Well, first of all, I thank you for raising the specific issues of concern.

From day one when we saw the problems with the Abbott plant, we knew that this was a critical plant for the supply chain, and the team was meeting on a very regular basis, trying to figure out how to manage the situation, hoping to keep the plant open with better quality measures, and then it became clear that was not going to work, and we had a period of time of having to reach a consent decree, which is a complicated legal proceeding.

But as I have indicated, we are all very aware. Many of us are parents or grandparents. Many of us have relatives that are in the same situation. We are hearing from everyone. So we are very focused.

Mr. VALADAO. All right. I appreciate that, and so I am limited on time obviously. So I hope you understand this is something that is having a huge effect, and obviously people all over the country are struggling with this.

We are hearing two weeks, and I know that the chairwoman had mentioned that we want to see this open. I would like to know what the FDA is doing on the ground at the Abbott plant in Michigan to help the situation as much as they possibly can.

Are they working with them? Are folks on the ground as we speak right now making sure that we can get this facility up and running?

Dr. CALIFF. We are working with Abbott every day, and I am getting a report twice a day, in the morning and the evening, about the progress that is being made.

I mean, recognize we are just on day three now, but it looks like it is going well; that Abbott has remediated a number of the issues; and we are going to make sure it gets done as quickly as it possibly can.

Mr. VALADAO. All right. I understand that you have announced a Principal Deputy Commissioner. I think you had mentioned it earlier in one of the statements. Dr. Woodcock will have a greater role in the strategic counsel over the food side of the FDA. I know she has tremendous expertise on the drug side, but I am hearing some concern about whether this decision will lead to a change that is needed on the food side, especially when she has been in the FDA for decades.

Can you help me understand the rationale of this decision?

Dr. CALIFF. Sure. I would say this is just a start of a change. As I mentioned earlier, I knew coming in that we are going to need to make major fortification of the food side of the FDA with a focus on the things that you all have all brought up.

Dr. Woodcock knows every nook and cranny of the FDA. She knows how the operations work. She already had information technology redesign underway, which is critically needed.

If you think about our inspectors out there, comparing the technology they have compared to what I saw in my previous job at Alphabet, it is night and day, and we have to fix that so that they can be efficient.

This is just the start of a change. She is not going to be permanently in the job. It still reports to me, and we will make further changes that you will hear about over the next period of time.

Mr. VALADAO. All right. I appreciate.

My time is up. I yield back.

Mr. BISHOP. Thank you, Mr. Valadao.

At this time I am delighted to recognize the gentlelady from Maine, Ms. Pingree. You are now recognized for your questions.

Ms. PINGREE. Thank you so much, Mr. Chair, and thank you so much for having this critical hearing at this moment in time.

And thank you, Mr. Commissioner, for being with us today and answering our questions.

I just want to associate myself with questions that have already been asked by Chair Bishop, Chair DeLauro, Mr. Valadao, really on both sides of the aisle. Obviously, this is a very troubling, troubling situation.

And I am not going to repeat all of the same questions. I just want to say that I am concerned, Mr. Commissioner, that you are not providing us with more detailed information. I think we have to dig deeper into this troubling pattern of leadership challenges and structural issues on food safety at the FDA.

This is not new, and we have to work on this. And this is a huge crisis for America, and I am very, very concerned about where we are.

I am just going to pivot because, like I said, I feel really grateful that my colleagues have been asking good questions, and I know others will be asking more as well.

I just want to talk a little bit about vaccine access for children. You know, I really appreciate that the FDA has done some challenging, essential work over the last two years on COVID, particularly in the vaccine space. One key group with no authorized COVID vaccines are children five and under.

I totally understand and appreciate how important it is to evaluate safety and efficacy. That is a huge concern in America, but I am hearing all the time from parents and caregivers in Maine and also around the country who are just really frustrated and feel left behind.

Any further delays that continue, these children will enter yet another school year unvaccinated. Can you commit to us that reviewing any potential authorization for a vaccine covering children under five will happen as quickly as possible?

And what timeline can we reasonably expect and tell people you will follow once an application is received?

Dr. CALIFF. I will answer quickly. You know, I have been involved in children's therapeutics my whole career, and one of the major lessons is that children are not just small adults. And so you have to do specific studies for the biology and the size and mechanics of how children dispose of therapeutic interventions.

Having said that, we now have the Moderna application in hand, as you know. As soon as we are ready, which is imminent, we have

a number of dates reserved for the Advisory Committee meetings. So as soon as we are ready, we will have that meeting and have the Advisory Committee weigh in on whether the safety and efficacy are adequate.

And there are others. The Pfizer application should be coming in sometime soon also.

So I am definitely committed as quickly as possible. I have two grandchildren under age five. So I am very much in the same boat that is being described.

Ms. PINGREE. So there was some talk for a while that the FDA would wait until the Pfizer application was in, which seems really unthinkable not to move forward as quickly as possible, but just for some level of efficiency or I do not know what the rationale was.

Can you commit that that is not going to happen?

Dr. CALIFF. There is no delay in the Moderna application because of another application. Each one will be considered on its own.

And I do not need to tell you that sometimes discussions that are held as you are developing a strategy get touted as if that is a decision that has actually been made. That was never the case, and I want to refute that from the beginning.

Ms. PINGREE. Well, thank you for setting that straight and for moving with all appropriate speed.

Obviously, that is a critical age group, and you know, they have different bodies and, you know, needs. So I do want to be as safe as possible, but you know, congratulations to you on having two grandchildren under five. I have four grandchildren under five and, you know, again, we hear this from mothers and caregivers all the time.

So thank you for the work that you have been doing, and really please continue this conversation about food safety and the huge difficulties that people are having today. That is really very important to the oversight of this committee.

Mr. Chair, I yield back.

Mr. BISHOP. Thank you, Ms. Pingree.

I now recognize Mr. Moolenaar of Michigan. You are now recognized for your questions, Mr. Moolenaar.

[No response.]

Mr. BISHOP. Please unmute, Mr. Moolenaar.

[No response.]

Mr. BISHOP. Mr. Moolenaar, I believe that you are still muted. We will move to Mr. Newhouse and see if we cannot get you some technology and come back to you.

At this time I recognize Mr. Newhouse, and we will come back to Mr. Moolenaar at the earliest convenience.

Mr. NEWHOUSE. Thank you, Mr. Chairman. Hopefully the clock will reset.

I appreciate the opportunity. Dr. Califf, thank you for being here with us.

I will not repeat what others have said but just associate myself with much of the concern that has been expressed.

I would like to ask you about the money that was just appropriated. I would like to know how in your estimation an additional \$28 million assures parents that imported formula will be safe for

their children, how it is going to help replenish the inventory in grocery stores in a timely manner.

Did you request this additional funding, especially in light of the fact that just a couple of months ago we increased the FDA budget by over \$100 million, \$11 million of that specifically for maternal and infant health and nutrition activities?

So could you shed some light on some of the money situation for us?

Dr. CALIFF. Sure. I appreciate the question.

I think Chairwoman DeLauro made the case very strongly that safety has to be paramount. So the bulk of that money would go for inspectors to make sure that material is not being put on the shelves which is unsafe, which is a very laborious effort right now, particularly given our information technology deficits that I have mentioned.

We also need the in-house expertise to evaluate these applications as we try to diversify the supply chain, and overseeing the Abbott plant takes up a whole number of people to make sure every single aspect of that is being done correctly.

And then as I have already mentioned, the underlying information technology is critical here. American business or health care systems would not depend on the kind of information technology we have to make these kinds of decisions, and we need to do something about it, in my opinion.

And let me just also mention. You mentioned the other maternal-fetal issues. This is not the only one. We have toxins in infant and baby food. We just had a guidance on apple juice, for example. This takes very high-quality scientists to do the analyses, collect the data to figure out how quickly we can bring these levels closer to zero, just as one example.

And then many members have been concerned about recommendations on seafood. I could go on and on. These things are all critical to our most vulnerable people, our children and their mothers. So they all need to be a priority.

Mr. NEWHOUSE. No doubt. I totally agree.

Did you request the additional funding?

Dr. CALIFF. Yes.

Mr. NEWHOUSE. Well, like I said, I associate myself with a lot of the comments made.

I would like to shift gears, if I could, to another topic. Since the legalization of hemp and hemp products was made several years ago, I believe we are still waiting on FDA for some action to be taken, and currently the industry is in a state of uncertainty because of no direction.

Could you provide an update on FDA's comprehensive sampling of CBD products that was discussed in July of 2020, a report on this labeling, and specifically the long-term plan that you may have and what you have found to date?

Dr. CALIFF. I really appreciate that question, and the amazing plethora of derivatives of the cannabis plant is really quite profound and astounding and already in widespread use for a variety of means, as you know.

Most of the FDA efforts so far have been spent on research to figure out what the risks, if any, are of various uses of this material in its different forms.

We are committed. I just want to tell you 2016 I worked on this. Coming back in 2022, it looks pretty much the same in terms of where we are. We just know more now because we have done more research.

I am very committed to taking a path on this and just to put a marker down, I do not think the current authorities we have on the food side and the drug side necessarily give us what we need to have to get the right pathways forward. We are going to have to come up with something new, and I am very committed to do that.

Mr. NEWHOUSE. Well, I appreciate hearing that.

Mr. BISHOP. Thank you, Commissioner.

I am afraid the gentleman's time has expired.

Let me recognize Mr. Pocan, and following Mr. Pocan we will go back to Mr. Moolenaar.

Mr. POCAN. Okay. Thank you, Mr. Chair.

And thank you, Commissioner Califf. I really have appreciated the previous conversations we have had.

Please take this in the proper vein, but I think, you know, there was frustration when you were asked what happened and the answer you gave back is we are investigating and I cannot talk about it.

You can talk about it. Honestly, you should talk about it.

One problem that I have seen over and over with the FDA in my ten years here is you guys are not good at communicating, and you know, this is something that parents are asking us about. They want to know what happened. You all have got to get that down to explaining in a way that real people can understand.

I understand there is science behind it. But it is not acceptable to say that you cannot comment on it.

I am just putting that out there. The public wants to know more. We have got to do that.

I also share in all of the questions that people have asked in this area, as well as Representative Pingree's questions around the vaccine. We are getting that for children under five. When is that going to be available?

Let me go to a couple of different subjects. CBD, while CBD is widely used in a number of products, as you just had the conversation with Mr. Newhouse, technically CBDs fail in the eyes of the FDA as illegal.

What is FDA's plan to clarify that CBD could not possibly be regulated as a food or food additive, and is there any timeline?

Dr. CALIFF. The research so far has shown that there are some risks with CBD, and so we are going to need a different pathway than just the standard food pathway.

I have told you and I really mean it. I am committed to do something about this, and it is going to take some work. I hope that you will work with me on that because it is going to take some creativity.

You know, when you come back six years later to the job you had before and nothing has really changed, that is telling you that you cannot just keep trying to do the same thing over and over.

Mr. POCAN. Yes, this is the frustration. I will be honest. I have had it with FDA also on Kratom. You and I have had that conversation where, you know, as you may know, Senator Lee and I sent a letter to actually Secretary Becerra in March of this year, bipartisan letter. The Secretary acknowledged that there is emerging science that contradicts the previous positions of the FDA on Kratom's safety profile.

And yet you have recently put more alerts, import alerts, on companies that are going a legal, proper way of handling Kratom coming into the country versus the companies that are not.

And the real question is is there a way to try to lift that import restriction on those companies that followed all the rules. I believe the technical language is a structure function claim versus the others because right now it is kind of hitting everyone with one FDA order, which I think is an extremely antiquated position that the FDA has on Kratom.

As you know, you and I have talked about it. NIDA is in a very different place than you are on Kratom.

Dr. CALIFF. Well, I do look forward to coming back to you hopefully in a couple of months with very specific suggestions on what to do. There are millions of people using Kratom. We do have real adverse events though, I mean, real negative things that had happened to people, and it does interact with multiple neurotransmitters.

NIDA is doing a lot of research. I am very good friends with Nora Volkow, the head of NIDA. We will continue to work with NIDA, and we will go where the science tells us to go.

But like I said with regard to cannabis products, we need something different for these kinds of products that are not traditional foods, not traditional drugs.

Mr. POCAN. If I can just reclaim just because I have 28 seconds, also you recently updated the fact sheet on Kratom on April 27th with only minor modifications, and honestly, there is not only arguable conclusions, but you are linking to outdated, incomplete, and inaccurate information.

Again, in this letter, Secretary Becerra seems to have a bit of a different position. If you could just look at that, that update was not much of an update, and I think it is being very unfair to the consumers who are legally using Kratom in this country.

And I will yield back.

Dr. CALIFF. I will definitely look at it. Thank you.

Mr. POCAN. Thank you.

Mr. BISHOP. Can you hear me?

Okay. Mr. Moolenaar, you are now recognized. I hope your technical difficulties have been resolved.

[No response.]

Mr. BISHOP. I am afraid we cannot hear you, Mr. Moolenaar. Okay. With that, we will try to come back to you, Mr. Moolenaar.

Ms. Letlow, you are now recognized. Welcome to the committee. And the floor is yours.

Ms. LETLOW. Thank you, Chairman Bishop, Dr. Harris, and members of the subcommittee.

I am honored to join this distinguished and to have the opportunity to represent the priorities of the Fifth Congressional District of Louisiana and the communities throughout the Delta region.

As the newest member of this subcommittee, I am particularly eager to work with my colleagues in advocating on behalf of our farmers, ranchers, and forest landowners.

Agriculture is the backbone of my district, and it is one of the largest economic forces in the area.

Dr. Califf, as a mother of a four and a two-year-old, it was not long ago that I was completely dependent on infant formula to fulfill my children's nutritional needs. I can only imagine the terror of parents across this country are feeling as they desperately search for formula to keep their children alive, quite literally, with some parents forced to admit their children to the hospital when no formula can be found.

This shortage impacts parents and health care providers nationwide. It is at the forefront of everyone's mind today, but for my district it is incredibly important that we work in an expeditious fashion to increase access to safe formula options because I represent a heavily rural district and makes up close to 20 percent of the Louisiana population and covers the largest geographic area with a diverse economic base.

I say all of this to paint a picture of what families face in urban areas is likely exasperated in rural America where proximity to retailers and availability of certain goods could be a 30-minute drive to the nearest retailer.

Dr. Califf, as I am sure you are aware, there are specialty metabolic formulas that only Abbott produces, which are necessary formulas for many families. With the forced closure of the Abbott facilities, did FDA consider there was no one else that could step in to provide those specialty formulas?

And at any point did FDA become concerned about a lack of supply in the days prior or following the closure of this plant?

Dr. CALIFF. Let me just say for everyone concerned, I do think it is useful to divide the formula into the general formula, as you all have astutely done in your questions, and the specialty metabolic formula which deals with a much smaller but really critical group of infants who are totally dependent not just on formula, but on the very exact makeup of the formula.

So from the first day, we had a team of people, and we were in connection with the American Academy of Pediatrics to try and do everything we could to keep the formula coming from that Abbott plant, from their stores and releasing it on a lot-by-lot basis as needed, carefully weighing the safety and the critical needs that these infants have.

This system is not perfect, but the network of communication is still very much in play with the pediatric community, the hospital community, and our team at the FDA working together.

It will not get better until we can rev up that plant again and also diversify, but I hope you also appreciate that because this special metabolic formula is very complicated, you cannot just start up a plant and do it. It takes a lot of work to get a plant able to do it.

So we have gone to work with Abbott to make this work while we are also diversifying this line.

Ms. LETLOW. Thank you, Dr. Califf. I want to get one more question in.

Given the FDA's recent announcement on the new enforcement discussion guidance, how much formula do you expect will be imported?

And what is the real timeline of seeing those products on our store shelves?

Dr. CALIFF. Well, the way we are thinking about it is we are pulling a bunch of levers at the same time. The other formula manufacturers in the U.S. have revved up their supply to 24-by-seven. It has increased considerably.

We are going to start up the Sturgis plant. We have the importation that you are referring to, and I think with a combination of all three, we should begin to see improvement within days.

And I do want to point out that right now in the last week, we have had more infant formula bought, by between 11 and 19 percent, than what was bought in the month before the closure of the plant.

So we are actually have—

Ms. LETLOW. So I can tell my constituents that within a matter of days they will be able to find formula on the shelves?

Dr. CALIFF. It will gradually get better. You know, the big problem we have right now is distribution, and I think your question very important, what you called attention to. The worst problems are in the rural areas because they are not the major areas that are purchasing these goods, and we are going to have to pay very special attention to that.

So within days it will get better, but it will be a few weeks before we are back to normal.

Ms. LETLOW. Thank you so much for your time.

Mr. Chairman, I yield back.

Mr. BISHOP. Thank you, Ms. Letlow.

At this time I recognize the gentlelady from Illinois, Ms. Underwood. You are now recognized for four minutes.

Ms. UNDERWOOD. Well, thank you, Mr. Chairman.

Hi, Dr. Califf.

FDA has recently announced several steps to get more formula onto shelves, including permitting Abbott Nutrition to release products from the Sturgis facility to people needing urgent supplies for certain specialty and metabolic formulas on a case-by-case basis.

Dr. Califf, can you describe how your agency is communicating with health care professionals and with families about the risks and benefits of using specialty and metabolic formula products from the Sturgis facility so that parents can make informed decisions about safely accessing the products their infants need?

Dr. CALIFF. Thank you.

And I know that you have a nursing background. So you have a very special feel for what is at stake here.

As I just described, the specialty formula—general formula is hard enough, 30 constituents have to be there in just the right amount or we have a history in this country of disasters that have

occurred when that does not happen. And so it does take very much hands-on evaluation step by step.

There is a committee of the American Academy of Pediatrics, and in fact, a physician that was featured in the New York Times yesterday, I talked with him on the phone. He is the chair of the committee on this subject at the American Academy of Pediatrics.

So we are working through the professional society on this, and case by case, if families are having problems, we need to hear from them.

Ms. UNDERWOOD. Okay. As we take action to immediately address infant formula shortages, we also need to comprehensively assess the causes of the current shortages so that this never happens again.

A whistleblower report included numerous disturbing allegations about wrongdoing at the Sturgis plant, and it was especially troubling to learn that the report was submitted to FDA on October 20th of 2021, but FDA did not inspect the plant in person for more than three months.

But in this time frame, on December 29th, 2021, FDA temporarily postponed some inspections due to the Omicron surge, but continued to conduct, quote, mission critical work.

According to your agency's resiliency roadmap for FDA inspectional oversight, there are four factors for determining if a product meets a threshold for mission critical inspections: if it receives breakthrough designation; if it is used to treat a serious medical condition; if it is related to the agency's COVID-19 response; or if there is evidence of serious adverse events.

So based on these criteria, would powdered infant formula at the Sturgis facility be considered a product that meets the threshold for mission critical inspections?

Dr. CALIFF. As I said in my opening statement, we will find specific issues where we could have done better. You have just done a very good job of enumerating several of those, including this one.

So I cannot disagree with your statement.

Ms. UNDERWOOD. Yes, it is not optional for families. This is essential. So what steps will FDA take to ensure that inspections of infant formula manufacturing facilities continue to be carried out on a safe and timely basis during public health emergencies or any other period where the inspections are postponed?

Dr. CALIFF. Well, I have already assured you all that no matter what, we will be on top of this issue until we are back to normal, you know, working around the clock day and night.

It would surely help if we had a larger number of people because, as we diversify the facilities and we bring in we sources, as the chairwoman has already made the point quite succinctly, we are going to need people who can actually evaluate whether the formula is safe; not only that, whether it is effective, especially in these metabolic formulas.

There are only a handful of people that even understand the illnesses that these children have.

Ms. UNDERWOOD. Right. Okay. Thank you.

I yield back.

Mr. BISHOP. Thank you, Ms. Underwood.

We will try Mr. Moolenaar again. You are now recognized, and hopefully we have got the technical difficulties resolved.

You are now recognized, Mr. Moolenaar.

Mr. MOOLENAAR. Mr. Chairman, thank you for continuing to call on me. I am hoping I am coming through.

Mr. BISHOP. You are.

Mr. MOOLENAAR. All right. Dr. Califf, thank you for your testimony today. I know you have been getting a lot of questions on baby formula shortage. I just wanted to share with you.

I have been hearing from hundreds of Michigan families about how this formula shortage is affecting them or someone they know, and I just wanted to share a couple of stories with you and ask how you as an agency can respond to them.

A father in Manton, Michigan wrote, "My child has an allergy to milk. So she has to have a very specific formula. Now that that formula is short, other babies that do not need this type of formula that is necessary for my daughter are allowed to purchase it through the WIC program, making her formula even more scarce. I have had to resort to getting formula from out of state and Canada at times. The shipping costs are a huge burden on my family and it requires hours of research that I could be spending with my family."

And a mother in Macomb County wrote, "I have had issues finding my son's formula since October of 2021. So I bought in bulk. Then everything I had on hand was recalled. I could get it at Target for a few weeks. Then they stopped having it. Even Amazon stopped getting it. Back in March of this year I had to switch to a different kind of formula. I am fortunate enough to be able to afford and buy multiple cans at a time. So when I found it at Costco, my mom, me, and my sister bought what I needed to get through six weeks. Now the kind my son is on is not even in stock at Costco. I pray I have enough to get him to his first birthday. My friends have to search multiple stores to find the kind the baby is on. Another ends up changing formula each time she runs out because it is all she can find. We just cannot breastfeed. Our babies rely on formula. It is scary being a mother right now."

I will also add a local grocery store owner also wrote me saying, "It is heart wrenching to have to tell our customers that we have no baby formulas to offer them. We are concerned that our local babies are not getting the nutrition they need. Nutrition in general is a very challenging problem in our rural area."

Dr. Califf, what would you like to tell these parents who are concerned about just simply finding food for their babies?

Dr. CALIFF. I will tell them that we are very concerned and feel badly that they are going through this, and we are doing everything we can to fix it.

And if I could make a couple of quick points about things that you brought up, you know, as I mentioned, the sales are actually higher than they were. People are buying more formula now than before the recall, and so we have a problem of distribution.

The FDA has no access right now into the supply chain data from the companies that manufacture and sell the formula. So a good bit of my week this week is getting on the phone with CEOs

using an old-fashioned method called the telephone to try to get the right product to the right place in an organized way.

We are requesting, again, that we have more authority to look at the supply chains, much like the banks did years ago, so that we can task and preempt these kinds of problems rather than having to react to them.

Mr. MOOLENAAR. Well, thank you, Dr. Califf.

Just a quick question, also changing gears a bit on standards of identity. The lack of enforcement of dairy standards is something I have raised with you and several of your predecessors. I am hoping that the forthcoming guidance will move beyond the current practice of nonenforcement and require everyone to simply follow the law.

A related issue I wanted to raise with you is the standard of identity for yogurt, and it is my understanding that the FDA recently updated this in June of 2021, but the industry actually does not support that.

Mr. BISHOP. Mr. Moolenaar, I am so sorry, but your time has expired.

Mr. MOOLENAAR. Okay.

Mr. BISHOP. And I want to get to Ms. Wasserman Schultz of Florida, and following Ms. Wasserman Schultz, I will declare the subcommittee in recess subject to the call of the chair, immediately following votes.

But Ms. Wasserman Schultz will not be able to return. So you are now recognized, Ms. Wasserman Schultz, for your questions.

Ms. WASSERMAN SCHULTZ. Thank you, Mr. Chairman. I appreciate your indulgence.

And I really want to say that everyone knows that the world's best oranges are grown in the great State of Florida. My good friends on this committee from California might disagree, but the truth is that Florida's climate has a distinct impact on how oranges are grown, making them comparatively sweeter and juicier than growers from other states.

Unfortunately though pests, diseases, and more violent hurricanes are having a devastating impact on Florida's citrus growers and processors. These circumstances have resulted in a natural decline in the Brix level for Florida's mature oranges.

In fact, for most of the last citrus season, Florida's oranges did not meet the Federal minimum standard of 10.5 degrees Brix.

The Brix standard was adopted nearly 60 years ago in 1963 at a time when our understanding of climate change was minimal. And despite these natural changes to Brix levels, there are no known adverse health consequences for consumers.

We need FDA to work directly with Florida citrus growers and processors to find a solution, which should include providing additional flexibility by modernizing requirements to account for the naturally occurring Brix variation.

Failure to do so will result in the industry losing out on imports from Brazil and Mexico and worsening our trade deficit.

Commissioner, what is FDA's current engagement on this issue?

And are you committed to finding a solution to this problem in the immediate future?

Dr. CALIFF. I am definitely committed to finding a solution, and your point, I think, exemplifies something we have been talking about, changes in the climate, changes in the crops, human health. This is high science, and we need the people who can actually do the work to make the best judgments based on the data.

It is not something you just make up. You actually need the data, and you need analysis. So very much appreciate your interest in this.

Ms. WASSERMAN SCHULTZ. Thank you. I appreciate you as well.

And the other thing I wanted to focus on is something that I know you and I have talked about several times before. In Florida, for example, more than 25 percent of high school students use e-cigarettes, and more than 29,000 kids under 18 try cigarettes for the time each year.

Tobacco kills 32,300 people in my State every year, costing Florida about \$8.64 billion in annual health care expenses, and the proportion of cancer deaths in Florida attributable to smoking is 29 percent.

These are not just numbers. These are our friends and family and devastatingly our children. I lost my own mother to lung cancer just a year ago.

The FDA has the authority to address this serious public health problem, and I have been advocating for several years for FDA to consider rulemaking to prohibit menthol cigarettes and flavored cigars, and I am thrilled that FDA initiated this process just a few weeks ago with proposed product standards.

Can you provide the committee with an update on these proposed standards and the impact this would have on preventing children from falling victim to big tobacco?

Dr. CALIFF. Sure. And I am a cardiologist. I have spent many years, three and a half decades caring for people who are critically ill, many of them in the State of North Carolina due to tobacco-related illness. So I am very sensitive to this topic.

These standards are now out for public comment, and we are going to have several public meetings, and then we will answer the comments, and then they will be put into effect, with modifications based on the comments that we do get.

So we are encouraging people to come to the table, particularly the sensitive issue of, as the standards come into play, what do we do about local enforcement if there is illicit trade, where this might be applied differentially.

So I am very sensitive to that issue. The FDA is not involved in local enforcement, but we want to make sure through community engagement that people understand that we are going after the people manufacturing these products, not local citizens, but also make sure that local law enforcement in communities understand that.

Ms. WASSERMAN SCHULTZ. Thank you so much.

I only have a little bit of time left, not enough to ask another question. So I appreciate your indulgence, Mr. Chairman, and I yield back.

Mr. BISHOP. Thank you, Ms. Wasserman Schultz.

The committee will now stand in recess, subject to the call of the chair, immediately following the vote and we will reconvene.

[Recess.]

Mr. BISHOP. All right. The subcommittee is now called to order. We will resume, and I believe when we went into recess I was about to recognize the gentlelady from New York, Ms. Meng.

So at this time, I'm delighted to recognize for questions Ms. Meng. You now have the floor.

Ms. MENG. Thank you, Mr. Chairman, and thank you, Ranking Member Harris. It is good to be with all of you and thank you for this opportunity.

Dr. Califf, as you know, there are concerning reports about the presence of hazardous chemicals that are known by the EPA to be likely cancer-causing substances as well as undisclosed fragrance chemicals that contain potential allergens in menstrual products. And given that these products are frequently used in highly absorptive parts of the body, the risk that fragrance ingredients could pose to health is grave. And just because an ingredient is not on the list of fragrance allergens does not mean that it will not have an impact on a woman's health.

I wanted to ask what the FDA process looks like for fragrance ingredients to be listed as an allergen, and are there additional resources necessary for your scientists to continue advancing this research?

Dr. CALIFF. Thank you for your interest in this topic, which is complex. And I would say the first principle is we—I think all of us at FDA believe that whatever is in something that's sold to the public, it should be listed so that people know it's there, which, as you know, has been—just that in itself has been a big challenge to get the authority to require that that is the case.

Beyond that, in order to deal with this scientifically, we need to do an evaluation of the level of the constituent, what its effects are on the health of individuals and others who may come in contact with it. And we are therefore supportive of working towards having the correct labeling and understanding the risks with all the factors involved.

I think we have already heard quite a bit this morning about the resource issues that we have on this side of the FDA, and I just want to emphasize this is not a simple matter of someone sort of guessing about what the levels are and what the risks are. This is a huge scientific issue requiring big data and computational skills to get the answer, and federal agencies working together.

So, appreciate your interest. We look forward to working with you on it.

Ms. MENG. Thank you. Definitely. And I also wanted to ask about your Closer to Zero Action Plan to reduce exposure to metals in foods for babies and young children. I know that FDA missed its first deadline. It wasn't until mid-April that the FDA submitted its proposal to OMB for review.

I wanted to ask what the FDA's revised schedule for the Closer to Zero Action Plan is and what are plans for coordination with OMB?

Dr. CALIFF. Yes. First, just to acknowledge that we'd all like these levels to be zero, so that is why it is Closer to Zero. We have to bring these levels down at a rate which will enable the industry to adapt and get there. I think you are aware that the apple juice

levels just came out, and for the kids who drink a lot of apple juice this will be, like, over a 40 percent reduction in exposure for those kids.

We do have several others that are in OMB. I met with the head of OMB last week to urge that we move as quickly as possible, and we are going to stay in touch and shepherd these through as quickly as we possibly can.

Again, just like what I said about the fragrance issue, exactly where the level should be over time as we bring it down is a matter of scientific discussion and measurement about which there are several opinions, and we need to get that resolved.

Ms. MENG. Thank you very much. And I will yield back, but I just wanted to also associate myself with the comments of our chairman and many of our colleagues today about the infant formula shortage. I had one of my babies had to use EleCare, one of the special formulas only produced by Abbott, and that was hard to find even during good times. So I really want to associate myself with the comments of my colleagues and ask that you please communicate with us and our families across America so that we can be responsive with our efforts.

Dr. CALIFF. Okay, if I may, Mr. Chairman, just quickly mention EleCare is our main focus right now in the plant in Michigan, and I hope we—I think we are going to be moving very quickly on that. It is the number one priority because it is essential. It is the largest population of—it is essential infant formula.

Mr. BISHOP. Thank you, Ms. Meng, and thank you, Mr. Commissioner. We have completed our first round of questions and we will now begin the second round.

But I continue to be disturbed by the length of time that it took for FDA to really start to address this problem, and secondly, of the nonspecific and the vague way that the implementation of a plan to solve it with the supply chain, with the inspections, with the safety. That is really a concern, and I hope that before we close that you can be a little bit more specific in terms of how that is going to happen.

Let me go to the question of the foreign drug inspections. Over the last two years we provided funding specifically for FDA to increase unannounced foreign drug inspections in certain countries to ensure the safety of the drug supply, and the FDA's practice of announcing foreign inspections weeks in advance brings up the issue of parity with how we treat our domestic manufacturers and what kinds of issues could be covered up during a waiting period.

Unfortunately, FDA used our 2021 funding to set up a test of announced versus unannounced inspections and not to restart the unannounced inspections, which was our intent.

You know well the perils of drug manufacturing in certain countries. Can you give us your commitment that you will direct FDA to restart unannounced inspections as directed by Congress?

Dr. CALIFF. Yes, sir. Let me assure you that I have been the subject of inspection in universities and companies I worked for for clinical trials, biologics and technology development, and I am very well aware of the importance of having a certain amount of unannounced inspections. We appreciate the money that was allocated the first time around, I think about 8.5 million, and today I can

say that we have started the unannounced inspection program in India. China will follow behind, but as you know, because of the COVID outbreak, it is difficult to get started in China.

So the plan is to have hundreds of unannounced or short-notice inspections that we will be able to report back to you about.

Mr. BISHOP. All right. The infant formula crisis has focused attention on the fact that the infant formula office has a staff of only nine people. The budget acknowledges that funding in our fiscal year 2022 bill will add four people to the office, which is great, but I worry about how many other drastically understaffed offices there are at FDA that we don't know about.

It seems we only learn about those staffing shortages when there is a crisis. This has been a concern for many years and over a number of administrations. So speaking for the subcommittee, we want to help ensure that all of FDA's operational units are properly staffed. What are the other understaffed parts of FDA that we should be concerned about that are not addressed in your budget request?

Dr. CALIFF. I would just say the entire food side of the FDA is understaffed in every category. That is why in the budget we have asked for money to staff up, and also to improve the authority for hiring and salaries just like we have on the medical products side. This is absolutely essential.

I certainly want to notice that I don't disagree with your statement that money alone won't fix it. But basically, I think you can see with infant formula, I mean, nine people for something this important is just not enough. And we got money for four more, but in the current federal hiring authority it takes months to bring someone on board. And we don't see that with the authority that we got with 21st Century Cures on the drug and device side.

So I really want to implore you to help us get staffed up, and I take seriously your other part of it that the money and people alone will not solve the problem; we also have to have leadership and structure.

Mr. BISHOP. My time has expired. Hopefully the Senate will pass the supplemental quickly.

Let me yield to Dr. Harris for a second round of questions. My ranking member, you are now recognized.

Mr. HARRIS. Thank you very much, Mr. Chairman.

Dr. Califf, I know that last fall the FDA released its final guidance on short-term sodium—voluntary short-term sodium reduction. Look, I understand that for some people sodium is not a good thing and reducing dietary intake is probably warranted. For others it may not make a difference. We don't know how to differentiate between those two right now. So I worry about a one-size-fits-all plan.

But will the FDA conduct a study on the impact of the short-term targets to understand consumer acceptability and what impacts those reductions might have on public health?

Dr. CALIFF. Dr. Harris, I know you are an anesthesiologist and know a good bit about the topic of autoregulation, and so for sure one size fits all is not the solution to the problem. But I also know you are aware that in the voluntary levels, we are talking about super-high levels that are built into food, just bringing it down to

a level that would be more like what the average intake is for most people. And I think the data are very clear that super-high levels are not good for anyone unless you have one of the strange diseases—by the way, post-COVID is part of dysautonomia where you don't have enough constriction of your blood vessels to keep a blood pressure when you stand up.

And so we will be evaluating the impact and the progress towards reduction, and I am very excited a focus of the administration across NIH and FDA and Department of Agriculture is going to be diet, what we eat. There is a big summit coming up at the White House, and I am sure sodium will be a key part of it.

Many people will weigh in on where we are and where other societies are with regard to sodium. So we need to keep an open mind about the right policy.

Mr. HARRIS. Okay. Thank you very much. It has been touched on with regards to the infant formula, this—the problem of domestic manufacturing versus overseas manufacturing. But writ large, I think COVID has made us aware that we don't have enough domestic manufacturing of both pharmaceuticals and active pharmaceutical ingredients.

How is your agency and specifically this budget request supporting more domestic manufacturing of pharmaceuticals and medical products so that we don't have this issue of do we have to depend upon foreign nations, sometimes unfriendly?

Dr. CALIFF. Well, I would like to spend an hour talking with you about this, but in brief, because this is a big focus of ours and I am going to write a lot about it, you are going to see more about it. The two cases we have in front of us now are examples of why the two extremes are wrong. The infant formula crisis is happening in the face of complete domestic production. And you know about contrast media, if one of you were to—we have had some prominent politicians have strokes recently—one of the major suppliers of contrast media only had one factory in Shanghai that was making contrast media, and when that shut down because of COVID, now when people roll in with a stroke or heart attack they may not be able to get an angiogram because you need contrast media.

So we have got these two extremes. What we need is a versatile supply chain built on a digital backbone so that we can keep track of where the products are and to stress test that supply chain.

Now, in the budget is manufacturing in place, which I think is the most exciting technology part of it, and also platform manufacturing. It is in the budget. I know we have limited time, but I could talk a long time about this, as you can tell. We have to do something about this. The answer is not just onshoring. The answer is having a diversified system where we can prevent shortages occurring preemptively instead of waiting for them to happen.

Mr. HARRIS. Okay, thank you very much. Mr. Chair, I yield back.

Mr. BISHOP. Thank you, Dr. Harris. At this time I yield for a second round to the chair of the Committee, the gentlelady from Connecticut, Ms. DeLauro.

The CHAIR. Thank you very, very much, Mr. Bishop. And just a quick follow-on to I think what Dr. Harris was speaking about. And also, Dr. Califf, our biggest problem here is the consolidation of the industry. We only have four sources in the United States that are

manufacturing this product, and quite frankly, Abbott has cornered the market, 43 percent of it. So when they go out of sync—so underlying all of this, and not for today's conversation because it is a lengthy one, is just we have to get out of the sole-source contracting business and we need to do this not only here but in the meatpacking industry as well.

It has been said by Chairman Bishop, and I associate myself with his comments and also with the Ranking Member's comments. I understand you need resources, and I have worked to increase resources to the FDA, but your problems are structural. You have serious structural leadership issues. Someone in this agency needs to have serious, relevant and food credentials, who understands it, because otherwise food safety will be a second-class citizen—continue to be a second-class citizen at the FDA.

I want to just mention to you a colleague earlier on—you can't hide behind an investigation. We need answers and we need them now. Who received this report? What did they do with it? Who was heading the FDA at that time? My understanding is that the acting commissioner was Janet Woodcock. What did she know about this?

So who was handling all of this and when this report went through the FDA and investigating all of this?

Dr. CALIFF. Well, as I have said, you have got the timeline down and you have got the key issues. I know we have an oversight hearing next week, and we will be prepared to go into much more detail at that point. And as I have said, we could do better than we did and—

The CHAIR. You have an Oversight Committee next week. You are before the Committee that funds what you do.

Dr. CALIFF. Yes.

The CHAIR. So this information is relevant to this subcommittee of Appropriations.

Dr. CALIFF. Well, I appreciate what you are saying, but it is the investigation is not completed yet and so I am not in a position to answer specifics like that.

The CHAIR. So you have no idea who received the documents at the agency?

Dr. CALIFF. Well, we do know—well—

The CHAIR. So who physically received the document? Where did it go? Who read it? What was the chain of command? You apparently don't have any answers to that question. That is indicative of, again, not responding to the seriousness of this issue. That says it all, Dr. Califf. It says it all.

One last point I want to make. I only learned this in the last 48 hours. 2014, Abbott deliberately and successfully tried to weaken bacteria-testing safety standards. And I will credit FDA here. FDA issued a proposed rule that would have increased regular safety inspections of infant formula manufacturing facilities and in the effort to prevent the contamination of infant formula.

I believe it was Abbott, I think it might have been Gerber, and there may have been others who led—they led the charge to weaken the inspection regime. Now, this is a company and a manufacturing entity that has a sole-source contract. And that is what—

Dr. CALIFF. Well, but—

The CHAIR. But I want—my question to you, I want you to address that, but do you have a plan to increase inspections and testing at these facilities, and what is that plan?

Dr. CALIFF. As we—first of all, thank you again for the additional funding, but the plan is to increase the inspections with the workforce that we have in a very orderly way, particularly in the Sturgis facility. Essentially it's like a daily inspection. We are there with the Abbott people overseeing what they are doing, so we are in the plant.

And as for the other U.S. facilities, we'll have to get back to you on the specific number of times we will inspect, but we will have a very orderly specific inspection system.

I would like to add the supply chain issues that we have all been talking about, we need to have access to the supply chain data, which we don't have. In other words, each company has its own supply chain. They handle it very carefully for their own needs. But if you ask the question, how do they all fit together? We don't have that information. And they can give it to us if they want, but we need to have the authority to get that.

And let me just also—

The CHAIR. I have to ask—

Dr. CALIFF [continuing]. Acknowledge, I think you said it says it all: I am committed to get back to you with specifics about what happened. I am just not prepared today to do it. I apologize for that.

The CHAIR. Well, we have to change underlying—and I will end here because my colleagues have been indulgent with me here this morning. The fact that you are the regulatory agency and you do not—first of all, you do not have mandatory recall, and you do not have, you just said, access to data. Well, you ought to be up here demanding that we provide you with that kind of authority to get the information that you need in order to be able to do your job as a regulatory agency.

Thank you, Mr. Chairman; thank you to the Ranking Member and to my colleagues.

Mr. BISHOP. Thank you, Ms. DeLauro.

And at this time I'd like to recognize Mr. Valadao for a second round.

Mr. VALADAO. Thank you, Mr. Chairman.

Mr. Califf, I'd like to discuss the issue of feed additive approvals. As you know, new animal feed additives can offer meaningful environmental benefits in dairy and other ag production. Reducing intrinsic methane emissions by as much as 30 percent, but FDA's current approval process treats these items as drugs even though they move entirely through the animal's digestive tract.

We included language in the fiscal year 2022 report to direct FDA to look at reviewing ingredient claims on environmental and other issues as foods, as we provided 1 million in new funding approvals in the final bill. Can you provide us an update with the work your agency is doing on this?

Dr. CALIFF. Yes, we are moving along well with that, and I am fully aware that. This is a big issue for the farming community both on the animal side and also on the agriculture side. So we want to come to a resolution.

So we are getting a good bit of research done about the safety and benefits of addition to food, and in not too long a period of time we will get back to you with specifics about that. It is something that we are working on.

Mr. VALADAO. No, it is something that honestly is important to a lot of folks and it has come up quite a bit in especially my district. I have got one of the largest dairy districts in the country, and it is important. So I look forward to hearing from you and talking to you more about this.

And Mr. Chairman, I have asked all the questions I have got for the record right now. I think I will submit anything else we have got through the—for the record on the side. So, appreciate the time. Thank you very much. Thank you, Commissioner.

Mr. BISHOP. Thank you, Mr. Valadao.

Ms. Underwood, you are now recognized for a second round.

Ms. UNDERWOOD. Thank you, Mr. Chairman.

As a registered nurse, another priority that I am focused on is protecting our nation's young people from the health risks of e-cigarette products. According to a 2021 survey data from CDC and FDA, more than one in three high school students and more than one in 10 middle school students reported that they have used tobacco products, and e-cigarettes were the most commonly used product.

CDC and FDA researchers concluded that factors that might continue to promote tobacco product use among U.S. youth, such as the availability of flavors and access to tobacco products, remained prevalent in 2021.

Let's be clear. The reason why flavored e-cigarettes have been and continue to be so accessible for young people is because of the FDA's unacceptable delays in reviewing pre-market tobacco product applications and the failure by your predecessor to meet the court-ordered review deadline of September 9th, 2021.

While I have been pleased to see the marketing denial orders that you have announced since being confirmed, some of the most popular products among young people remain on the market and just last week FDA filed a status report in the U.S. District Court for the District of Maryland in which the agency provided an estimation that application reviews will not be completed until June 30th, 2023.

Dr. Califf, with more kids getting addicted to nicotine every day, can you provide an explanation of why FDA is projecting that reviews will not be completed until next June, nearly two years after the court-ordered review deadline?

Dr. CALIFF. Thanks for bringing attention to this issue. And as a cardiologist and someone very involved in medicine, et cetera, the addiction to nicotine is a very difficult problem and there is no question that there is an industry that develops specifically to get teenagers addicted to nicotine, in which case the old statement that was uncovered in the tobacco industry, customers for life. Because stopping vaping is extremely difficult to do.

There is nothing I would like more than to move these things along more quickly, but what we gave the court was an honest assessment giving the number of people we have and the legal requirements we have to consider these applications. And I also want

to emphasize this is an industry that has amazing capabilities on the legal front. If we make one single error in process, we could be set back for years in these applications.

Ms. UNDERWOOD. Yes, sir.

Dr. CALIFF. And then finally, I just want to add we have consistently for the last I don't know how many years asked for user fees from the vaping industry. Right now, all of this work is entirely unfunded. We are doing it borrowing people from other parts of the FDA, and we have a request in for what I think is, for such a prosperous industry, a very reasonable user fee arrangement and I hope Congress will act on this.

Ms. UNDERWOOD. Thank you. We know that tobacco products must have an FDA marketing order before coming to market, meaning that e-cigarette products without marketing orders are currently on the market illegally and FDA has the authority to initiate enforcement actions to remove these products from the market. Will you commit to using this authority while FDA completes its review of the remaining pre-market tobacco product applications?

Dr. CALIFF. Well, I appreciate the sentiment, which I share to a great degree. But I know you are also aware that if we take action like that, we will end up with a lot of our legal force tied up in court. And so we are going to have to be very judicious the way we use that authority, because we want to reserve our abilities on the legal front to take care of the problems that we know will be lasting.

So I want to come back to you and discuss that specifically to make sure that we at least have an understanding of what our capabilities are in that regard.

Ms. UNDERWOOD. Right, but Dr. Califf, I mean, to say that we are going to wait another several months, over a year, to be able to take enforcement action is something that is just unconscionable given what we know is happening in the communities that we serve across this country.

Thank you, I yield back.

Mr. BISHOP. Thank you very much, Ms. Underwood. Thank you, Commissioner. I believe that we have exhausted the questions from the members, and I appreciate very much your availability, Commissioner Califf.

We all understand how incredibly busy you are these days, and we appreciate your time. These issues are very, very, very important, though. And as I mentioned at the outset, FDA's work is vitally important to every American in order to keep them safe and healthy. And the challenges that we discussed today show just how crucial it is for the agency to be at peak performance with all hands on deck every single day.

We want to help you in any way that we can to surmount these challenges, and with respect to the infant formula issue that we have been dealing with today, I want to just make sure that people know that we are not finished with this. We are going to dig down deep and on May 25th, next week, we are going to be dealing with the infant formula stakeholders that we will hear from to get their perspective on what this crisis means and how we need to deal with it.

But along with all that we have discussed, we will also forward additional questions to you for the record and we look forward to your diligent and timely responses.

Dr. Harris, do you have any closing remarks? If so, I will yield to you for that purpose.

Mr. HARRIS. Thank you. Thank you, Mr. Chair. Dr. Califf, again, thanks for coming before the subcommittee. As we talked about I think when we first met, you have got a tough job. I mean, the FDA is an agency with very broad regulatory authority in areas that are, because of COVID and now because of the infant formula, quite controversial.

So good luck in doing it. Let us know in any ways we can help. And again, I just want to thank you for being willing to step up, being willing to head the agency, and good luck in the future.

I yield back, Mr. Chairman.

Mr. BISHOP. Thank you, Dr. Harris, and thank you to all of the members of the subcommittee in attendance, and thank you to our staff who put this hearing together.

With that, this subcommittee hearing is adjourned.

[Questions and answers submitted for the record follows:]

ACTING RANKING MEMBER ANDY HARRIS, M.D.

MAY 19, 2022

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Infant Formula

Is the Abbott Sturgis, MI facility in cGMP compliance? If yes, then why did you shut them down? If not, then will they be in cGMP compliance when they resume manufacturing? If yes, then why will FDA require that they do additional batch testing before releasing product? If no, then is it FDA's policy that additional sample testing from pharmaceutical manufactured batches compensates for non-cGMP compliance?

Was *Cronobacter Sakazakii* found in the retention samples of the implicated batches in the Sturgis facility? Was it found in unopened containers of the implicated batches in the homes of the infected children whose illness reports were the impetus for your shutting down the Sturgis facility thereby causing a nationwide crisis?

Are FDA District Office inspectors or investigators incentivized in any way to write Observations on FDA Form-483 reports from inspections of pharmaceutical manufacturing facilities? Is there any consequence to these inspectors or investigators for writing inaccurate or false Observations?

Is Abbott's response to the most recent FDA Form-483 Observations available to the public? If not, then when will they be available to the public?

Digital Health Innovation

One of the ongoing challenges for small tech start-ups that innovate in the digital health space is working with federal agencies, like the FDA, to approve their products in a timely and transparent manner. I've heard from innovative small businesses in Maryland that have challenges working through the FDA process.

- Will you work with me to ensure FDA provides more open and transparent engagement with digital health companies, ensuring the FDA review team meets deadlines, provides substantive feedback and responds to requests for information in a timely manner?
- Additionally, I would request that the FDA provide reliable guidance about how the agency determines which products qualify as consumer wellness products, especially in the wearables space. Would you be willing to work with me on this?

Rare Diseases

Commissioner Califf, as you know, conducting clinical trials for the development of prescription drugs to treat rare disease is especially challenging. Patient recruitment and retention is particularly difficult. The Covid-19 pandemic has exacerbated these challenges and resulted in

significant delays and disruptions. In order to understand the full impacts of the pandemic on clinical trials and address them, the House Agriculture Appropriations Subcommittee included report language in FY 2021 directing FDA to submit a report to Congress on this important issue with recommendations to address them within 90 days. Given that the Agency failed to produce that report, the Subcommittee included the same report language in the FY 2022 Appropriations bill.

- Can you please provide me a status update on the Agency's work to provide this critically important study?

Future COVID-19 Variants

COVID-19 variants like Delta and Omicron, and subvariants like Omicron BA.1 and Omicron BA.2, have rapidly emerged, and new variants likely will continue to emerge. Unfortunately, these variants have rendered some therapeutics ineffective, so we have limited options in our medicine cabinet to fight the currently circulating strains of COVID-19. This is especially concerning for vulnerable populations, such as nursing home and long-term care residents, immunocompromised patients, and racial and ethnic minority populations, who have been disproportionately impacted by COVID-19. Due to the uncertainty of the nature of future variants, a broad spectrum of products for both treatment and prevention should be available for deployment proactively. Requiring new countermeasures to meet ad hoc criteria for each new variant leaves patients without effective tools and harms these vulnerable populations.

- What is FDA doing to streamline the authorization and approval process for products addressing new COVID-19 variants in order to ensure we have effective vaccines, therapeutics, and diagnostics to prevent and treat COVID-19 variants BEFORE they spread?
- Does FDA have a plan to clarify the standards for determining the efficacy of products against emerging variants prior to the variant becoming the predominant strain in circulation?

Ophthalmic Drugs

FDA recently released a direct-to-final guidance document changing the regulatory standard for ophthalmic drugs packaged with eye cups, eye droppers, or other dispensers to treat them as combination products. These products were previously regulated pursuant to 21 CFR 200.50, which stated that the eye cups, eye droppers, or other dispensers were part of the drug product and not device components. FDA stated in its guidance that it was implemented with immediate force and effect –and no opportunity for notice and comment – “given the urgency of these issues following the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Genus Medical Technologies LLC v. U.S. Food and Drug Administration* [Genus Decision].” Even though the Genus Decision pertained only to medical imaging products, FDA appears to have conveniently expanded that opinion to other types of medical products. In doing so, FDA revoked a regulation that has been in place since 1975 with the infrequently used mechanism of direct-to-final guidance, depriving the public of the notice and comment process.

- Please explain why FDA felt that the Agency had the authority to revoke a regulation through guidance, which is non-binding and does not have the force and effect of law, rather than revising or revoking its regulations through notice and comment rulemaking.
- Further, please explain why FDA concluded that the Genus Decision applied to 21 CFR 200.50 and why the Agency felt it was impossible to allow for notice and comment on the guidance document issued.

T-Cell Response

With each new variant that emerges, there is a lack of population-level data on how our immune systems respond - not just antibodies but also T-cells. This is limiting our ability to inform public health policy decisions. Last week a letter was sent to you by a number of experts in the field of cellular immunity urging the FDA in its guidance to vaccine developers to include a recommendation for T-cell assessment in COVID-19 vaccine clinical trials to more comprehensively measure immune response.

- Given the need to understand the efficacy of COVID-19 vaccines and boosters that can only be answered by understanding both T-cells AND antibodies, can you share what steps FDA is taking to guide manufacturers to generate this data?
- How can on-going and new cellular immunity research with respect to COVID-19 being conducted at the NIH support efforts to integrate T-cell data into vaccine, booster, and other public health decisions at FDA and the federal government at large?

A recent paper in *Science Immunology* [*Understanding T-cell responses to COVID-19 is essential for informing public health strategies*] discusses the need to understand the complete immune response to COVID-19 to inform public health policies and interventions.

- How can immune response data, including both Abs and cellular immunity, be used by the FDA or other public health entities to measure the U.S.' progress towards herd immunity and inform future public health guidance as additional variants emerge?
- How has technology to measure T-cells changed in the last decade? Can you explain recent advances that might enable vaccine manufacturers to provide this information at scale?

Congress included language in the FY 2022 appropriations bill encouraging NIH to conduct additional research around cellular immunity for COVID-19 and requesting an HHS-wide assessment of the department's efforts to incorporate cell-mediated immunity measures.

- How might this kind of data assist FDA in assessing the effectiveness of vaccines, boosters, and therapeutics?
- How can FDA work with CDC and outside stakeholders to make this sort of data collection a reality?

Tobacco Products

In 2017, FDA announced its Comprehensive Plan for Tobacco and Nicotine Regulation. At the center of the comprehensive plan is the role of nicotine and that, while addictive, it is delivered through products on a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes. FDA also has recognized that certain electronic nicotine delivery system (ENDS) products may provide a net public-health benefit by transitioning and completely switching addicted smokers from combustible cigarettes to a less harmful, noncombustible form of nicotine delivery. The Tobacco Control Act's PMTA pathway allows FDA to authorize new products, including ENDS, to enter the market if FDA determines the products are appropriate for the protection of public health, and the Agency has granted marketing orders for several ENDS products. Will FDA and the Center for Tobacco Products continue to embrace its comprehensive plan for tobacco and nicotine products and the continuum of risk to advance public-health objectives?

The Tobacco Control Act provides FDA with annual user fees for activities relating to tobacco regulation. Currently, the Center for Tobacco Products (CTP) receives \$712 million in annual user fees from certain classes of tobacco product manufacturers. According to previous Tobacco Product User Fee Reports to Congress, the user fee structure currently allocates funds and personnel across tobacco-regulatory programs and activities regardless of the product category. In FY 2020, FDA expenditures included over \$150 million on public education campaigns aimed to prevent youth from tobacco initiation and use and nearly \$285 million on scientific research and infrastructure. For FY 2023, FDA has requested an additional \$100 million in annual tobacco user fees to include other classes of tobacco products not currently subject to user fees under the Tobacco Control Act, including ENDS products. Is FDA, in fact, limited in allocating resources to certain programs, such as PMTA review for ENDS products and compliance and enforcement, without additional user fees? Will FDA provide more details and better transparency on how current user fees are allocated, particularly with respect to PMTA review and enforcement actions against illegally-marketed products?

Based on 2020 and 2021 data from the CDC and FDA's National Youth Tobacco Survey (NYTS), we have seen significant declines in underage use of tobacco products, particularly ENDS products. Although data collection methods have differed in recent years, according to the 2021 NYTS, just over 2 million high- and middle-school students currently use ENDS products, down from over 5 million in 2019. In 2021, current use was 11.3% among high-school students and 2.8% among middle-school students, compared to 27.5% and 10.5%, respectively, in 2019. Similarly, frequent use (use on 20 days or more) of ENDS products also has declined, with such use at 4.9% among high-school students and 0.5% among middle-school students in 2021 compared to 9.4% and 1.9%, respectively, in 2019. Meanwhile, youth use of traditional cigarettes continues to decline to historical lows. We believe legislation like Tobacco 21, which Congress passed in 2019, has had a significant impact on restricting underage access to tobacco products and reducing underage use. Do you believe that evidence-based interventions, like restricting access to legal, regulated tobacco and nicotine products to adults, can accelerate the declines in underage use?

Under the Tobacco Control Act, FDA evaluates premarket tobacco product applications (PMTAs) to determine whether the marketing of a new product is “appropriate for the protection of public health.” Under this public-health standard, FDA assesses whether the benefits of marketing the product for adult tobacco users outweigh the risks to nonusers, including those underage, based on the science and evidence. In fact, FDA, via the PMTA pathway, has issued marketing authorizations for 21 ENDS products, finding that the data demonstrated the authorized products “could benefit addicted smokers who switch to these products – either completely or with a significant reduction in cigarette consumption – by reducing their exposure to harmful chemicals.” Will FDA and the Center for Tobacco Products continue to advance tobacco harm reduction through the Tobacco Control Act’s science- and evidence-based premarket review and authorization process?

ACTING RANKING MEMBER ANDY HARRIS, M.D.

MAY 19, 2022

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Infant Formula

- 1) Is the Abbott Sturgis, MI facility in cGMP compliance? If yes, then why did you shut them down? If not, then will they be in cGMP compliance when they resume manufacturing? If yes, then why will FDA require that they do additional batch testing before releasing product? If no, then is it FDA's policy that additional sample testing from pharmaceutical manufactured batches compensates for non-cGMP compliance?

Response:

The FDA inspection team observed significant operational deficiencies in Abbott Nutrition's Sturgis facility during the January – March 2022 inspection. While the totality of evidence obtained during our inspection caused FDA to conclude that infant formulas produced at this plant were produced under insanitary conditions and may be contaminated with *Cronobacter*, Abbott voluntarily made the decision in February 2022 to temporarily cease production. This was prior to the completion of FDA's inspection.

Although the decision to temporarily cease production was Abbott's, FDA based its conclusion of insanitary conditions on the following evidence:

- 1) The firm did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms;
- 2) The firm did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source;
- 3) The firm's investigation file on a complaint did not include the determination as to whether a hazard to health exists; and
- 4) Personnel working directly with infant formula did not wear necessary protective apparel.

On May 16, 2022, the U.S. District Court for the Western District of Michigan entered a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott Nutrition principals. Under the consent decree, Abbott Nutrition agreed to take corrective actions following FDA's 2022 inspection of the firm's Sturgis, Michigan, facility. The consent decree obligates Abbott Nutrition to take actions that are expected to ultimately result in an increase of infant formula products, while ensuring that the company undertakes certain actions to ensure that safe powdered infant formula is produced at the facility. When the company restarted production at this facility, on June 4, 2022, it did so in conformity with the applicable provisions of the consent decree and meeting applicable food safety standards. As a part of the consent decree, Abbott Nutrition agreed to perform enhanced finished product testing.

- 2) Was *Cronobacter Sakazakii* found in the retention samples of the implicated batches in the Sturgis facility? Was it found in unopened containers of the implicated batches in the homes of the infected children whose illness reports were the impetus for your shutting down the Sturgis facility thereby causing a nationwide crisis?

Response:

As noted above, Abbott voluntarily made the decision in February 2022 to temporarily cease production and recall some of its products. However, even prior to that, the United States was facing infant formula supply chains stressed by the COVID-19 pandemic which contributed to the current crisis.

FDA investigators collected numerous product and environmental samples during the inspection of Abbott Nutrition's Sturgis facility. Product samples FDA collected at Sturgis during FDA's inspection from January to March analyzed for *Cronobacter* tested negative. Additional samples taken from unopened containers of the implicated batches collected from the homes of infected infants also tested negative. It is well-documented in the scientific literature, however, that such end-product testing is unlikely to detect low levels of contamination. In contrast, six environmental subsample surface swabs collected from the facility during that inspection tested positive for *Cronobacter sakazakii*. The positive *Cronobacter sakazakii* environmental samples collected at Abbott Nutrition's Sturgis facility have been analyzed using whole genome sequencing, revealing five different strains of *Cronobacter sakazakii*. These findings remain a serious concern, as environmental sources of *Cronobacter* in infant formula manufacturing plants have been identified as one of the most likely sources of contamination.

- 3) Are FDA District Office inspectors or investigators incentivized in any way to write Observations on FDA Form-483 reports from inspections of pharmaceutical manufacturing facilities? Is there any consequence to these inspectors or investigators for writing inaccurate or false Observations?

Response:

FDA investigators are not incentivized to write observations on FDA Form-483s; they are trained to ensure that, if an FDA Form-483 is to be issued, each observation noted on the 483 is clear, specific, and significant. The observations are cited when, in an investigator's judgment, the conditions or practices observed indicate that an FDA-regulated product is in violation of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and related Acts, including current good manufacturing practice requirements.

The investigators' draft Establishment Inspection Report (EIR), which includes the FDA Form-483 observations, is reviewed by a Supervisory Investigator prior to it being finalized. In addition, these work products are subject to assessments for certain quality

factors as part of the quality management program in the Office of Regulatory Affairs (ORA).

The FDA Form-483 observations are considered along with the EIR, which is prepared following the inspection and includes evidence that support each FDA Form-483 observation. FDA considers the FDA Form-483, the EIR, all evidence or documentation collected on-site, and, if available, any responses made by the company, and then determines what further action, if any, is needed.

- 4) Is Abbott's response to the most recent FDA Form-483 Observations available to the public? If not, then when will they be available to the public?

Response:

Public availability of certain FDA records, including company responses to FDA Form-483s, is subject to information disclosure regulations found in Part 20 of Title 21 of the Code of Federal Regulations, as well as the Freedom of Information Act and other pertinent federal statutes.

Digital Health Innovation

- 5) One of the ongoing challenges for small tech start-ups that innovate in the digital health space is working with federal agencies, like the FDA, to approve their products in a timely and transparent manner. I've heard from innovative small businesses in Maryland that have challenges working through the FDA process.
- a) Will you work with me to ensure FDA provides more open and transparent engagement with digital health companies, ensuring the FDA review team meets deadlines, provides substantive feedback and responds to requests for information in a timely manner?

Response:

Yes, FDA is committed to continuing to work with Congress, patients, industry, academic institutions, health care providers, and others to ensure a clear, predictable path to market for innovative new devices, including those digital health products that patients, consumers, and others increasingly rely on to monitor and improve their health. FDA's device program has worked for years to prioritize timely patient access to new and innovative digital health technologies, starting with issuance of guidances in 2013, to working with Congress to help further clarify the path to market for certain software functions through the software provisions in the 21st Century Cures Act, to implementation of the Cures provisions and issuance of our Digital Health Innovation Action Plan and subsequent guidance to help tailor FDA's oversight to where it provides the most value.

Most recently, FDA established the Digital Health Center of Excellence (DHCoE) – to accelerate digital health advancements, increase awareness and understanding, and – importantly – to provide efficient and least burdensome oversight while meeting FDA’s standards. The DHCoE works to provide regulatory clarity to stakeholders. Since FY 2018, DHCoE has put out draft or final guidances on 14 topics related to digital health policy, including the “Content of Premarket Submissions for Device Software Functions” draft guidance in November 2021. FDA appreciates the opportunity to work with all sponsors of new and innovative digital health and other technologies, and looks forward to continuing to help support development of these products so U.S. patients have as many safe and effective options as possible. In addition, we encourage stakeholders to reach out to digitalhealth@fda.hhs.gov if assistance is needed. In FY 2022, we fielded over 700 inquiries through this mechanism, resolving more than 90% within two weeks.

Please note that FDA would be pleased to talk with any businesses in your district that believe they have encountered challenges working through the Agency’s process.

b) Additionally, I would request that the FDA provide reliable guidance about how the agency determines which products qualify as consumer wellness products, especially in the wearables space. Would you be willing to work with me on this?

Response:

Yes, FDA looks forward to the opportunity to work with you to ensure clarity for these important products. FDA recently updated its guidance, Policy for Device Software Functions and Mobile Medical Applications Guidance¹, which describes the Agency’s policy for device software functions and mobile medical apps that meet the device definition, including some that are the focus of FDA’s regulatory oversight and some for which FDA does not intend to enforce requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance also provides information on some software functions that do not meet the device definition, and as such, are software functions that are not subject to applicable FDA regulatory requirements. The update is intended to provide clarity and predictability for software manufacturers on this topic.

Section 520(o)(1)(B) of the FD&C Act, which was added by the 21st Century Cures Act, states that software that is intended “for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition” is not a device under section 201(h) of the FD&C Act. FDA also recently launched our Digital Health Policy Navigator² to assist developers in determining whether their product is, or is not, a medical device (such as general wellness products).

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>

² <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator>

Rare Diseases

- 6) Commissioner Califf, as you know, conducting clinical trials for the development of prescription drugs to treat rare disease is especially challenging. Patient recruitment and retention is particularly difficult. The Covid-19 pandemic has exacerbated these challenges and resulted in significant delays and disruptions. In order to understand the full impacts of the pandemic on clinical trials and address them, the House Agriculture Appropriations Subcommittee included report language in FY 2021 directing FDA to submit a report to Congress on this important issue with recommendations to address them within 90 days. Given that the Agency failed to produce that report, the Subcommittee included the same report language in the FY 2022 Appropriations bill.

Can you please provide me a status update on the Agency's work to provide this critically important study?

Response:

Detailed data on delayed or cancelled trials due to the effects of COVID-19 are not available, but we are aware that the pandemic resulted in disruptions to clinical trials in general and that impacts may be felt acutely by patients with rare diseases where there are often no available therapies. The most comprehensive source of information would likely come from stakeholders sponsoring or conducting these clinical trials. However, given that clinical trials can be conducted over the span of years, we also recognize that there might be some lag in capturing and documenting the impact of COVID-19 on the clinical trial enterprise. FDA is committed to mitigating the negative impact of COVID-19 on clinical trials.

To help sponsors of ongoing trials during the COVID-19 public health emergency, FDA published a final guidance titled *Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency*,³ with recommendations to assist in maintaining the continuity of clinical trials, as appropriate, during the public health emergency while helping to ensure the safety of trial participants and protecting the quality and integrity of the data. The guidance incorporates lessons from and examples informed by experience with previous public health emergencies, including recommendations for leveraging existing health care infrastructure, conducting remote assessment and monitoring, identifying and prioritizing critical processes, leveraging technology and innovations, and helping to ensure effective communication and documentation. The guidance can be found on FDA's website and has periodically been updated with additional answers to questions FDA has received from stakeholders. FDA also published a guidance titled *Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency*,⁴ which includes recommendations for addressing the impact of COVID-19

³ <https://www.fda.gov/media/136238/download>

⁴ <https://www.fda.gov/media/139145/download>

on meeting trial objectives. FDA has received positive feedback from stakeholders on these two guidance documents as to their utility in helping to minimize or avoid delays or cancellations in clinical trials, including for rare diseases.

Despite the challenges of COVID-19, FDA's work to advance treatments for rare diseases and to help ensure continuity of care for people with rare diseases remains a top priority.⁵ Working with sponsors and patients, FDA remains focused on facilitating development and approval of products for serious conditions where there is unmet need. For example, in Calendar Year (CY) 2021, CDER and CBER approved 30 new molecular entities with orphan drug designations for rare diseases. This represented 50% of all new drug and biological product approvals. In CY 2019, the year before the COVID-19 public health emergency, CDER and CBER approved 22 new molecular entities with orphan drug designations for rare diseases. CY 2021's approvals of new molecular entities with orphan drug designations for rare diseases is consistent with the average number of new molecular entities with orphan drug designations for rare diseases from 2017-2020 (27 per year). Currently, using the metric of approvals of new molecular entities with orphan drug designations for rare diseases, the Agency has not seen a decrease in approvals due to COVID-19.

Future COVID-19 Variants

- 7) COVID-19 variants like Delta and Omicron, and subvariants like Omicron BA.1 and Omicron BA.2, have rapidly emerged, and new variants likely will continue to emerge. Unfortunately, these variants have rendered some therapeutics ineffective, so we have limited options in our medicine cabinet to fight the currently circulating strains of COVID-19. This is especially concerning for vulnerable populations, such as nursing home and long-term care residents, immunocompromised patients, and racial and ethnic minority populations, who have been disproportionately impacted by COVID-19. Due to the uncertainty of the nature of future variants, a broad spectrum of products for both treatment and prevention should be available for deployment proactively. Requiring new countermeasures to meet ad hoc criteria for each new variant leaves patients without effective tools and harms these vulnerable populations.
- a) What is FDA doing to streamline the authorization and approval process for products addressing new COVID-19 variants in order to ensure we have effective vaccines, therapeutics, and diagnostics to prevent and treat COVID-19 variants BEFORE they spread?

⁵ <https://www.fda.gov/news-events/fda-voices/rare-disease-therapy-development-and-access-remain-top-fda-priorities-during-covid-19>

Response:Vaccines

Ever since the first SARS-CoV-2 variants of concern, FDA has planned for the possibility that the COVID-19 vaccines would need to be changed and has previously provided guidance to vaccine manufacturers on how to do so efficiently. In June 2022, FDA convened its Vaccines and Related Biological Products Advisory Committee to publicly discuss whether a change to the vaccine strain composition of COVID-19 vaccines for booster doses would be necessary for the 2022 fall and winter seasons. The committee voted overwhelmingly to include an Omicron component in COVID-19 vaccines for use as a booster dose. On August 31, 2022, FDA issued emergency use authorizations (EUAs) for the Moderna COVID-19 Vaccine, Bivalent for use as a single booster dose in individuals 18 years of age and older and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for use as a single booster dose in individuals 12 years of age and older. On October 12, 2022, FDA authorized Pfizer-BioNTech COVID-19 Vaccine, Bivalent and Moderna COVID-19 Vaccine, Bivalent for use as a single booster dose for children ages 5 through 11 years, and 6 years through 17 years, respectively. Both vaccines are authorized for use as a single booster dose at least two months following completion of primary or booster vaccination. These bivalent COVID-19 vaccines include an mRNA component corresponding to the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component corresponding to the Omicron BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the Omicron variant.

FDA authorized the bivalent (Original and Omicron BA.4/BA.5) mRNA COVID-19 vaccines based on the totality of available evidence, including immune response data from investigational vaccines developed to address prior variants (e.g., Beta). To address variants that may emerge in the future, experience with the currently available bivalent COVID-19 vaccines could potentially support the inference of effectiveness for strain composition changes targeting those variants and could potentially allow for use of further adapted vaccines before the variant becomes predominant.

Therapeutics

FDA's understanding of the impact of circulating variants on available COVID-19 therapeutics is essential to the U.S. Government's response to the COVID-19 public health emergency. For this reason, the Agency's EUAs for COVID-19 therapeutics that may be impacted by changes to SARS-CoV-2 are intentionally proactive, facilitating the prompt assessment of the authorized product's activity against variants of concern as they are identified. Specifically, these EUAs include requirements for the EUA sponsor to monitor genomic databases for the emergence of new variants with submission of monthly reports to FDA and to promptly test the activity of the authorized product against global variants of interest. These conditions, among others, are essential to our understanding of the therapeutics for their authorized uses, and importantly, these conditions enable FDA to promptly update the authorization, including the authorized

labeling, when appropriate so providers have the most current information for clinical decision-making.

COVID-19 product development remains an Agency priority. As part of the Coronavirus Treatment Acceleration Program, the Center for Drug Evaluation and Research continues to work closely with sponsors to accelerate the study of potentially beneficial drugs for the prevention or treatment of COVID-19. As part of these efforts, FDA has published a number of guidance documents to which sponsors may refer when considering their drug development program. For example, FDA's guidance document titled *Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants*, During the COVID-19 Public Health Emergency provides the Agency's recommendations for the development of monoclonal antibody products targeting SARS-CoV-2, including recommendations on how sponsors can address emerging variants. As stated in this guidance, FDA will streamline the data necessary, when scientifically justified, to support the development of monoclonal antibody products targeting SARS-CoV-2 and will expedite the review of these data. Given the serious concerns raised by the emergence of SARS-CoV-2 variants, FDA intends to leverage its emergency authorities under section 564 of the Federal Food, Drug and Cosmetic Act, when appropriate, to foster the development and availability of therapeutics for use during the COVID-19 public health emergency.

Diagnostics

Since the start of the pandemic, FDA has adapted its regulatory approach to address the public's testing needs and has worked closely with test developers to adjust as those needs have changed. These efforts have helped increase testing capacity and broaden public access to rapid tests, including those purchased over-the-counter (OTC). The Agency is also focusing our review on diagnostic tests that are likely to fulfill an unmet need (such as diagnosing infection with a new variant or subvariant), among other categories of tests, to help assure U.S. patients maintain access to the tests that they need.

FDA has collaborated with stakeholders to better understand the public health impact of new SARS-CoV-2 variants and their impact on test performance, has been routinely monitoring publicly available databases, and has coordinated efforts to evaluate the impact of new virus variants on tests that have received EUAs.

In February 2021, FDA issued the *Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests* to provide a policy and recommendations for evaluating the potential impact of emerging and future viral mutations of SARS-CoV-2 on COVID-19 tests for the duration of the COVID-19 public health emergency, including considerations for test designs to minimize the impact of viral mutations and recommendations for ongoing monitoring.

On September 23, 2021, FDA revised the EUAs of certain authorized molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. These conditions are now

included in all other EUAs for COVID-19 molecular, antigen, and serology tests, and they continue to be included in new EUAs. These conditions require test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance, among other requirements.

To date, more than 430 distinct COVID-19 tests have been issued EUAs. FDA will continue to offer support and expertise to assist with the development of accurate and reliable tests, including those that target new variants.

- b) Does FDA have a plan to clarify the standards for determining the efficacy of products against emerging variants prior to the variant becoming the predominant strain in circulation?

Response:

Please see FDA's response to the prior question.

Ophthalmic Drugs

- 8) FDA recently released a direct-to-final guidance document changing the regulatory standard for ophthalmic drugs packaged with eye cups, eye droppers, or other dispensers to treat them as combination products. These products were previously regulated pursuant to 21 CFR 200.50, which stated that the eye cups, eye droppers, or other dispensers were part of the drug product and not device components. FDA stated in its guidance that it was implemented with immediate force and effect –and no opportunity for notice and comment – “given the urgency of these issues following the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Genus Medical Technologies LLC v. U.S. Food and Drug Administration* [Genus Decision].” Even though the Genus Decision pertained only to medical imaging products, FDA appears to have conveniently expanded that opinion to other types of medical products. In doing so, FDA revoked a regulation that has been in place since 1975 with the infrequently used mechanism of direct-to-final guidance, depriving the public of the notice and comment process.
- a) Please explain why FDA felt that the Agency had the authority to revoke a regulation through guidance, which is non-binding and does not have the force and effect of law, rather than revising or revoking its regulations through notice and comment rulemaking.

Response:

Although the product at issue in *Genus* involved a medical imaging product, the court in the *Genus* decision stated “[e]xcepting combination products, ... devices must be regulated as devices and drugs—if they do not also satisfy the device definition—must be regulated as drugs.” In implementing the *Genus* decision, FDA determined that the language in 21 CFR §200.50(c) indicating that eye cups, eye droppers, and other dispensers intended for ophthalmic use are regulated as drugs when packaged with ophthalmic drugs was made obsolete, because these articles meet the device definition in section 201(h) of the Federal Food, Drug, and Cosmetic Act. Therefore, in our March 2022 Guidance entitled *Certain Ophthalmic Products: Policy Requiring Compliance with 21 CFR Part 4*, we explained that ophthalmic products, consisting of an ophthalmic dispenser packaged with the ophthalmic drug with which it is intended to be used, would be subject to 21 CFR Part 4, as drug-led combination products.

In addition, we do not believe the change to regulating certain ophthalmic products as drug-led combination products rather than drugs is likely to have a significant impact on these products.

As we explained in our March 2022 Guidance, we made the determination that prior public participation for this guidance document was not feasible or appropriate because FDA needed to communicate its compliance policy for certain ophthalmic products in a timely manner given the urgency of these issues following the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Genus*. However, even though we did not provide an opportunity for prior public participation, the guidance remains subject to comment in accordance with FDA’s good guidance practices (GGP) regulation, and FDA will consider all comments received and determine whether revisions to the guidance document are appropriate. To date, we have not received any comments on the guidance in the docket.

- b) Further, please explain why FDA concluded that the *Genus* Decision applied to 21 CFR 200.50 and why the Agency felt it was impossible to allow for notice and comment on the guidance document issued.

Response:

Please see FDA’s response to the prior question.

T-Cell Response

- 9) With each new variant that emerges, there is a lack of population-level data on how our immune systems respond - not just antibodies but also T-cells. This is limiting our ability to inform public health policy decisions. Last week a letter was sent to you by a number of experts in the field of cellular immunity urging the FDA in its guidance to vaccine developers to include a recommendation for T-cell assessment in COVID-19 vaccine clinical trials to more comprehensively measure immune response.
- a) Given the need to understand the efficacy of COVID-19 vaccines and boosters that can only be answered by understanding both T-cells AND antibodies, can you share what steps FDA is taking to guide manufacturers to generate this data?

Response:

FDA agrees that greater understanding of the role of T-cell response in protection against COVID-19 could be useful to the scientific and public health community. As noted in FDA's guidance document Development and Licensure of Vaccines to Prevent COVID-19 (<https://www.fda.gov/media/139638/download>), understanding of SARS-CoV2 immunology and vaccine immune responses that might predict protection is limited and evolving. The guidance also states that once "additional understanding of... vaccine immune responses that might be reasonably likely to predict protection ... is acquired," it may be possible to approve a COVID-19 vaccine under accelerated approval, if an applicant provides sufficient data and information to satisfy the applicable requirements. In addition, one of the references that the authors of the letter cite, an article published in Science Immunology, states that "a comprehensive understanding of the adaptive immune response to SARS-CoV-2 infection is imperative." The article also notes that "[d]efining what constitutes a protective versus harmful T-cell response [to SARS-CoV-2] warrants further investigation." Basic scientific research is necessary to assess the contribution of T-cell responses to protection.

- b) How can on-going and new cellular immunity research with respect to COVID-19 being conducted at the NIH support efforts to integrate T-cell data into vaccine, booster, and other public health decisions at FDA and the federal government at large?

Response:

The mission of the FDA is to protect and promote the public health, in part by ensuring the safety and effectiveness of the medical products we regulate. In keeping with that mission, FDA uses every tool available to help patients access promising medical

products while facilitating research to evaluate their safety and effectiveness as well as manufacturing efforts. Research that yields informative and practical means to measure relevant immune responses will be very helpful in both developing COVID-19 vaccines and informing FDA's evaluation of vaccine safety and effectiveness.

Throughout the pandemic, as the virus that causes COVID-19 has continuously evolved, the need for FDA to quickly adapt has meant using the best available science to make informed decisions with the health and safety of the American public in mind.

FDA defers to NIH regarding its research efforts.

- 10) A recent paper in *Science Immunology* [*Understanding T-cell responses to COVID-19 is essential for informing public health strategies*] discusses the need to understand the complete immune response to COVID-19 to inform public health policies and interventions.
- a) How can immune response data, including both Abs and cellular immunity, be used by the FDA or other public health entities to measure the U.S.' progress towards herd immunity and inform future public health guidance as additional variants emerge?

Response:

More research is needed to understand the role of SARS-CoV-2 T-cell testing and serology testing in evaluating a person's immunity or protection against COVID-19. Antibody levels associated with protection against SARS-CoV-2, known as a correlate of protection, have not been established. Furthermore, at present there is an incomplete understanding by the scientific community of the nature of COVID-19 herd immunity or how measurements might be useful. In certain cases, FDA considers neutralizing antibody titers (a functional measure of the vaccine immune response against SARS-CoV-2) to be clinically relevant to infer effectiveness of COVID-19 vaccines. Because no specific neutralizing antibody titer has been established to predict protection against COVID-19, two immunogenicity endpoints (Geometric Mean Titer and Seroresponse rate) are considered appropriate for comparing the range of neutralizing antibody responses elicited by the vaccine.

- b) How has technology to measure T-cells changed in the last decade? Can you explain recent advances that might enable vaccine manufacturers to provide this information at scale?

Response:

Technologies for measuring T-cells have improved considerably in the last decade with better reagents, advanced instrumentation, and a greater understanding of the key parameters that should be analyzed. The use of T-cell tests to evaluate immunity is an ongoing area of research for COVID-19 and other infectious diseases as well. FDA is committed to following the latest research in the field to facilitate the development and availability of safe and effective vaccines for the United States. Unlike B cells, whose primary job is to make antibodies, T-cells perform many different functions. The main advances in the last decade relate to expanding the types of T-cell functions that can be measured in a laboratory, as well as increasing the sensitivity of measurements. However, for researchers and for vaccine manufacturers alike, reliable T-cell measurement options are limited by the difficulties in obtaining human samples during clinical studies. Obtaining T-cells from patients' blood for such tests is very time consuming, requires very large blood volumes (much more than that needed for antibody studies), requires a high level of expertise, and requires specialized equipment to freeze and store the resulting T-cells. Similarly, obtaining measurements in T-cell assays is quite complex. To date, these considerations have constrained large scale studies involving measurement of T-cell-mediated immunity, but there are technologies on the horizon using molecular methods that may facilitate such investigation.

11) Congress included language in the FY 2022 appropriations bill encouraging NIH to conduct additional research around cellular immunity for COVID-19 and requesting an HHS-wide assessment of the department's efforts to incorporate cell-mediated immunity measures.

- a) How might this kind of data assist FDA in assessing the effectiveness of vaccines, boosters, and therapeutics?

Response:

The mission of the FDA is to protect and promote the public health, in part by ensuring the safety and effectiveness of the medical products we regulate. In keeping with that mission, FDA uses every tool available to help patients access promising medical products while facilitating research to evaluate their safety and effectiveness as well as manufacturing efforts. Research that yields informative and practical means to measure relevant immune responses will be very helpful in both developing COVID-19 vaccines and informing FDA's evaluation of vaccine safety and effectiveness.

Throughout the pandemic, as the virus that causes COVID-19 has continuously evolved, the need for FDA to quickly adapt has meant using the best available science to make informed decisions with the health and safety of the American public in mind.

- b) How can FDA work with CDC and outside stakeholders to make this sort of data collection a reality?

Response:

All of the Agency's COVID-19 response efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the federal government, to help ensure the development and availability of critical, safe, and effective medical products to address the COVID-19 public health emergency.

Tobacco Products

- 12) In 2017, FDA announced its Comprehensive Plan for Tobacco and Nicotine Regulation. At the center of the comprehensive plan is the role of nicotine and that, while addictive, it is delivered through products on a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes. FDA also has recognized that certain electronic nicotine delivery system (ENDS) products may provide a net public-health benefit by transitioning and completely switching addicted smokers from combustible cigarettes to a less harmful, noncombustible form of nicotine delivery. The Tobacco Control Act's PMTA pathway allows FDA to authorize new products, including ENDS, to enter the market if FDA determines the products are appropriate for the protection of public health, and the Agency has granted marketing orders for several ENDS products. Will FDA and the Center for Tobacco Products continue to embrace its comprehensive plan for tobacco and nicotine products and the continuum of risk to advance public-health objectives?

Response:

Yes, FDA's comprehensive plan for tobacco and nicotine regulation, which the Agency continues to make progress on implementing, serves as a multi-year roadmap to protect youth and significantly reduce tobacco-related disease and death. The goal is to ensure that FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Tobacco Control Act.

Key features of the comprehensive plan include:

- Regulatory policies on addiction, appeal, and cessation;
- FDA's Youth Tobacco Prevention Plan: to prevent access to – and use of – tobacco products, particularly e-cigarettes by children and teens; and
- Science-based review of tobacco products.

Tobacco products are inherently dangerous. FDA reviews new tobacco products to determine if their marketing is appropriate for the protection of the public health, if they are substantially equivalent to an eligible predicate tobacco product, or if they are exempt from the requirements of substantial equivalence. The Agency remains committed to its responsibility to review new tobacco products to determine if they meet the appropriate statutory standard for marketing.

- 13) The Tobacco Control Act provides FDA with annual user fees for activities relating to tobacco regulation. Currently, the Center for Tobacco Products (CTP) receives \$712 million in annual user fees from certain classes of tobacco product manufacturers. According to previous Tobacco Product User Fee Reports to Congress, the user fee structure currently allocates funds and personnel across tobacco-regulatory programs and activities regardless of the product category. In FY 2020, FDA expenditures included over \$150 million on public education campaigns aimed to prevent youth from tobacco initiation and use and nearly \$285 million on scientific research and infrastructure. For FY 2023, FDA has requested an additional \$100 million in annual tobacco user fees to include other classes of tobacco products not currently subject to user fees under the Tobacco Control Act, including ENDS products. Is FDA, in fact, limited in allocating resources to certain programs, such as PMTA review for ENDS products and compliance and enforcement, without additional user fees? Will FDA provide more details and better transparency on how current user fees are allocated, particularly with respect to PMTA review and enforcement actions against illegally-marketed products?

Response:

Per statute, FDA's tobacco user fees are available only for the purpose of paying the costs of FDA activities related to the regulation of tobacco products. FDA is not limited in allocating resources to certain programs, such as premarket tobacco product application (PMTA) review for electronic nicotine delivery systems (ENDS) products and compliance and enforcement.

That said, section 919 of the Federal Food, Drug, and Cosmetic Act does not currently provide FDA with the authority to assess and collect user fees for ENDS products—which include e-cigarettes—and certain other deemed products. While much of CTP's current workload (including, for example, application review and compliance and enforcement) is related to ENDS products, manufacturers and importers of ENDS products do not pay tobacco user fees for regulatory oversight of such products. FDA has had to reallocate a significant portion of the \$712 million in user fees it collects annually

from the existing six product classes to regulate certain deemed products, especially ENDS products, which are a high priority due to their popularity among youth.

FDA is committed to being transparent in how tobacco user fees are allocated. For example, in response to the Consolidated Appropriations Act, 2021, FDA submitted a Tobacco Product User Fees Report to the House Committee on Appropriations.⁶ CTP budgets and tracks spending by program area, such as Scientific Research, Compliance and Enforcement, and Public Education Campaigns. However, most of FDA's tobacco regulatory activities cut across multiple product classes and programs so we do not track spending by tobacco product class, nor do we breakout spending for program areas into subcategories, such as spending specifically just for PMTA review or enforcement against illegally marketed products. For example, the review of product applications for various classes of tobacco products is done by staff in CTP's Office of Science (OS) and Office of Compliance and Enforcement (OCE), and many of the same staff conduct both scientific research (including research to inform product review) and compliance and enforcement efforts.

However, the Center can report that for tobacco product application reviews, the majority of CTP's 550 OS staff spend most of their time on one or more aspects of product review. In addition, about 50 OCE staff spend at least some of their time on product reviews. CTP also invests significant resources toward a range of other compliance and enforcement activities, including contracting with the states and U.S. territories and tribes to conduct compliance inspections of tobacco retailers, performing inspections of registered tobacco manufacturers, and surveilling websites, social media, and print publications that promote and sell tobacco products.

- 14) Based on 2020 and 2021 data from the CDC and FDA's National Youth Tobacco Survey (NYTS), we have seen significant declines in underage use of tobacco products, particularly ENDS products. Although data collection methods have differed in recent years, according to the 2021 NYTS, just over 2 million high- and middle-school students currently use ENDS products, down from over 5 million in 2019. In 2021, current use was 11.3% among high-school students and 2.8% among middle-school students, compared to 27.5% and 10.5%, respectively, in 2019. Similarly, frequent use (use on 20 days or more) of ENDS products also has declined, with such use at 4.9% among high-school students and 0.5% among middle-school students in 2021 compared to 9.4% and 1.9%, respectively, in 2019. Meanwhile, youth use of traditional cigarettes continues to decline to historical lows. We believe legislation like Tobacco 21, which Congress passed in 2019, has had a significant impact on restricting underage access to tobacco products and reducing underage use. Do you believe that evidence-based interventions, like

⁶ <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/reports-congress>

restricting access to legal, regulated tobacco and nicotine products to adults, can accelerate the declines in underage use?

Response:

Yes, FDA agrees that sales access restrictions are an important component of comprehensive efforts to prevent underage access to and use of tobacco products.

- 15) Under the Tobacco Control Act, FDA evaluates premarket tobacco product applications (PMTAs) to determine whether the marketing of a new product is “appropriate for the protection of public health.” Under this public-health standard, FDA assesses whether the benefits of marketing the product for adult tobacco users outweigh the risks to nonusers, including those underage, based on the science and evidence. In fact, FDA, via the PMTA pathway, has issued marketing authorizations for 21 ENDS products, finding that the data demonstrated the authorized products “could benefit addicted smokers who switch to these products – either completely or with a significant reduction in cigarette consumption – by reducing their exposure to harmful chemicals.” Will FDA and the Center for Tobacco Products continue to advance tobacco harm reduction through the Tobacco Control Act’s science- and evidence-based premarket review and authorization process?

Response:

Ensuring new tobacco products undergo premarket evaluation is a critical part of FDA’s mission to protect public health. FDA will continue to use an evidence-based approach to make marketing authorization decisions, as well as take other scientifically-supported regulatory actions, in a way that can reduce the public health burden of tobacco products across the entire population of our country.

FDA will continue to apply the statutory standard of “appropriate for the protection of the public health” when reviewing PMTAs to determine if they should receive marketing authorization. Per the statute, FDA will make this determination with respect to risks and benefits to the population as a whole, including users and nonusers of tobacco products, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

FDA evaluates the risks and potential benefits of permitting the marketing of a new tobacco product on a case-by-case basis depending on the available evidence pertaining to the specific tobacco product that is the subject of the application. The onus is on applicants to provide the most robust scientific evidence available to support their application.

CONGRESSMAN ROBERT B. ADERHOLT

MAY 19, 2022

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Illicit Drugs

Question 1: Commissioner Califf, in your written statement you emphasize your concerns with the opioid crisis impacting the country. Specifically, you list out four priority areas, one of which includes “improving enforcement and assessing benefit-risk.” Could you discuss more on this priority and what the FDA is exactly doing?

Response:

The effects of the drug overdose crisis and claims on human life are staggering, including enormous individual and societal costs as people and families grapple with substance use disorder (SUD). FDA has identified specific Overdose Prevention Priorities in our Overdose Prevention Framework (Framework) to provide a focus for the Agency’s actions to address the crisis and sustain long-term recovery outcomes.

The FDA’s four priorities are:

1. Supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing;
2. Encouraging harm reduction through innovation and education;
3. Advancing development of evidence-based treatments for substance use disorders; and
4. Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.

Specific to improving enforcement under the Framework, we commit to further develop our surveillance, enforcement, and interdiction work targeting illegal, unapproved, counterfeit, and potentially dangerous products at international mail facilities, express courier hubs, and ports of entry across the U.S. We will build on our surveillance, compliance, and enforcement actions, including to address health fraud including SUD treatment claims. This includes joint interdiction operations with other federal agencies such as Customs and Border Protection. FDA has also been aggressively working to address controlled substances illegally sold online, including through high-impact partnerships. In April 2022, we partnered with the Drug Enforcement Administration to issue first-of-their-kind joint warning letters to operators of two websites illegally selling Schedule II stimulants, including amphetamine drug products marketed as Adderall. More information about our Framework and our activities related to this priority are available on our website.¹

Regarding benefit-risk assessment, our benefit-risk assessment for opioids also considers whether characteristics of a particular new drug product could impact the broader public health.

¹ <https://www.fda.gov/news-events/fda-voices/fdas-overdose-prevention-framework-aims-prevent-drug-overdoses-and-reduce-death>

This involves consideration of the risks related to misuse, abuse, opioid use disorder, accidental exposure, and overdose for both patients and others. Drug approval and withdrawal decisions involve this benefit-risk framework. However, we have learned that even the evolution of our framework is not suited to address all of the risks posed by opioids. Therefore, FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for all opioid analgesics intended for outpatient use to help ensure that the benefits of these drugs continue to outweigh the risks. REMS are drug safety programs that the FDA can require for certain medications, such as opioids, that have serious safety concerns to help ensure the benefits of the medication outweigh its risks.

The FDA does not have the statutory authority to require that drug developers seeking approval of opioids demonstrate that their products offer material safety advantages (e.g., a reduction in respiratory depression or a reduction in abuse liability) over existing approved opioids; we are exploring the need for potential new authorities to address this. More information about our approach to benefit-risk assessment is available on our website.²

Question 2: What countries in particular do we see the most concern stemming from when it comes to unapproved foreign drugs? Additionally, of those most concerning countries, is the FDA taking any concentrated action to address those specific nations?

Response:

Over the past three years, the top countries for which FDA took action with respect to unapproved drug products were India, El Salvador, and Mexico, based on data regarding imported products at both commercial ports of entry, as well as products intercepted at International Mail Facilities (IMFs). Over this period of time, FDA refused entry to over 100,000 lines³ of such products from these countries and had over 80,000 of those lines destroyed. The below table breaks this down by country:

Country	Lines Refused	Lines Refused that were Destroyed
India	74,944	66,878
El Salvador	16,787	10,406
Mexico	8,368	3,291

In FY 2022, FDA conducted operations to further target unapproved drugs from countries of concern, including these three. During just a single one-week period, FDA identified 22 lines of unapproved drug product coming from Mexico and El Salvador consisting of products such as antibiotics (e.g. amoxicillin and penicillin), anti-inflammatories, sexual dysfunction drugs (sildenafil), and asthma medications. These products were all refused entry and destroyed.

² <https://www.fda.gov/news-events/fda-voices/fda-continues-important-work-substance-use-and-overdose-prevention-efforts>

³ A line is a distinct product within a shipment. A single shipment may include multiple lines. A line is not a measurement of volume of product, which can vary or fluctuate.

To combat future importation of such violative unapproved drug products, FDA uses historical information such as manufacturing information, import history and country of origin to target and detain future shipments using our risk-based analytics tool, PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting). In addition, FDA uses Import Alerts, which help prevent the importation of products that appear to be in violation of FDA's laws and regulations. For example, in FY 2022, FDA added 11 firm/product combinations from India and 11 firm/product combinations from Mexico to an Import Alert. As a result, future entries of such products from these firms may be subject to Detention Without Physical Examination. In the IMFs, local FDA staff continue to work with their U.S. Postal Service and U.S. Customs and Border Protection counterparts to identify mail shipments from these three countries of concern for greater scrutiny as well.

Supply Chain

Question 3: Commissioner Califf, the supply chain disruptions impacting our economy are not new to anyone and the closures behind the baby formula factory serves as an unfortunate case study.. How is the agency working to ensure that other manufacturers across the industry don't suffer from similar situations?

Response:

The current supply chain disruption is largely because of the nature of the infant formula industry in the U.S. As of May 2022, there were 12 domestic facilities and nine international facilities that produced powdered infant formulas for the U.S. market, all owned by five firms. The Sturgis facility was both one of the largest producers of formula for the U.S. Department of Agriculture's Special Supplementation Nutrition Program for Women, Infants, and Children (WIC), and a sole or significant producer of unique specialty and metabolic formulas that serve as the sole nutritional option for populations of infants and others with rare medical conditions. The U.S. market is unique since about half of formula sold is through WIC and states have single-source contracts for these products. In addition, powdered infant formula firms rely on many of the same ingredient suppliers and, in our experience, do not have robust back-up plans for unforeseen manufacturing interruptions or supply chain perturbation.

FDA does not have authorities and dedicated resources to predict, detect, and respond to food supply chain issues. Nevertheless, FDA has taken numerous actions that contribute to addressing the domestic infant formula supply. The Agency instituted regularly scheduled meetings with major infant formula manufacturers to facilitate sharing of infant formula production and projection data, discuss and identify emergent issues with raw materials, discuss questions or concerns with products being marketed under enforcement discretion, and highlight additional supply chain issues as they arise (i.e., potential disruptions from severe weather). FDA issued a guidance document regarding the exercise of enforcement discretion for infant formula to help increase product supply in the U.S. As of October 12, 2022, infant formula manufacturers marketing products under enforcement discretion have made estimated contributions of 18.9 million cans (403 million 8oz bottles) of formula to the U.S. market. In addition, FDA has begun the process of developing a prevention strategy to reduce the likelihood of contamination of powdered infant formula products moving forward. This plan will leverage

information gained through investigation findings, stakeholder engagement, and research to prevent or minimize future illnesses caused by *Cronobacter* in all powdered infant formula products and help to build a more robust domestic supply chain for infant formula products. Further, the Agency has already begun taking steps toward implementing the recommendations contained in an internal report which evaluated FDA's response efforts.

Strengthening data and technology tools at FDA and other agencies is also critical to enhancing infant formula supply chain resiliency. A dynamic, interconnected supply chain monitoring platform and robust data sets are necessary to enable the Agency to be most effective in monitoring infant formula and medical food supply chains, managing risks, and identifying and quickly addressing supply chain disruptions to reduce impacts on consumers. FDA continues to monitor the status of the infant formula supply using the Agency's 21 Forward food supply continuity system, combined with external data. Although 21 Forward was originally designed to address the broader food supply during the pandemic, FDA has adapted the system to monitor and support infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Further support and development of this technology will allow the Agency to integrate, analyze, and monitor multiple data sets in real time to inform our response and help us focus on the areas of greatest need.

Current funding for this tool and associated data sets has been extended through the end of February 2023. Long-term resources and additional authorities would allow FDA to integrate additional internal and external data sources into the 21 Forward food supply chain continuity system, including data on the availability of raw materials, packaging, transportation, and imports, further strengthening FDA's real-time response efforts. In the President's FY 2023 budget request, we have identified legislative proposals that would enhance FDA's ability to prevent or mitigate shortages of infant formula and medical foods, requiring manufacturers to notify FDA when they become aware of a circumstance that could lead to a shortage and sharing information that could help promote regulatory compliance.

Cybersecurity

Question 4: While the FDA budget requests \$5 million above the FY 2022 enacted level for cybersecurity, do you believe this increase is sufficient enough given the array of threats we face?

Response:

The Agency appreciates your consideration of the funding request for \$5 million in FY 2023, as well as the \$500,000 in recurring funds for medical device cybersecurity that Congress has provided to FDA since FY 2019. FDA cannot deny that additional funds could be helpful for this work, particularly given the dynamic environment, but we commit to keeping you and the Committee apprised if our needs in this space change.

Cyber incidents are continuing to increase in the U.S. Between 2016 and 2020, there was a 17-fold increase in the number of alerts released by the Cybersecurity and Infrastructure Security Agency regarding medical device vulnerabilities. Patients, industry, other federal agencies, and all segments of the ecosystem – including health care delivery organizations and researchers – depend on FDA to help assess the scope of threat and harm to patients, coordinate mitigations, and support our entire health care system to help prevent harm to patients. Without adequate cybersecurity maintained throughout the lifecycle of medical devices, there will continue to be incidents as a result of insecure devices. Legacy devices are one of the biggest threats to our health care system, as recently highlighted by the FBI.⁴ These devices remain in use for years, and present cybersecurity risks that are significantly difficult—if not impossible—to fully mitigate. This is in addition to mounting threats from other nations – including China and Russia – to U.S. infrastructure and our health care delivery organizations. The only way to stave off these threats is to ensure cybersecurity is designed into devices from development and maintained throughout the device lifecycle, which FDA is responsible for overseeing. As cybersecurity threats and other incidents continue to increase, we must also increase our vigilance and adopt a stronger posture – and we need dedicated funds to do this.

In summary, there are too many cyber incidents for FDA to currently respond to as thoroughly as we would prefer, if at all, and resources would open a wide variety of opportunities where FDA could help protect patients while supporting the U.S. government in its response to a host of situations.

Question 5: How is the FDA working with other cybersecurity offices across the US Government to ensure maximum cohesion?

Response:

FDA works closely with several federal government agencies including the U.S. Department of Homeland Security (DHS) and its Cybersecurity and Infrastructure Security Agency (CISA), members of the private sector, medical device manufacturers, health care delivery organizations, security researchers, and end users to increase the security of the U.S. critical cyber infrastructure. As noted in our response to the prior question, other federal agencies, and all segments of the ecosystem depend on FDA to help assess the scope of threat and harm to patients, coordinate mitigations, and support our entire health care system to help prevent harm from coming to patients. Working collaboratively with industry and other federal government agencies, FDA continues its efforts to ensure the safety and effectiveness of medical devices, at all stages in their lifecycle, in the face of potential cyber threats.

For instance, FDA serves as a co-chair of the Government Coordinating Council (GCC) for the Healthcare and Public Health (HPH) critical infrastructure sector. The GCC works closely with the HPH Health Sector Coordinating Council (HSCC), which together form a public-private partnership among industry leaders and the government to address the most pressing security and resiliency challenges to the health care sector as a whole including cybersecurity. Additionally, as co-chairs of several task groups within the HSCC Cybersecurity Working Group, FDA is

⁴ <https://www.ic3.gov/Media/News/2022/220912.pdf>

helping lead efforts to address cybersecurity policy issues such as legacy devices, vulnerability communications, and secure device design.

With respect to secure device design, FDA participated in the development of the Medical Device and Health IT Joint Security Plan (JSP). The JSP is a total product lifecycle reference guide to developing, deploying, and supporting cybersecure technology solutions in the health care environment. FDA also serves as a co-chair of the IMDRF working group tasked with drafting a global medical device cybersecurity guide. The purpose of the guide is to promote a globally harmonized approach to medical device cybersecurity that at a fundamental level ensures the safety and performance of medical devices while encouraging innovation. As you can see, some of the Committee's previous investments in cybersecurity at CDRH, as well as the funds we are requesting for FY 2023, support not only FDA's efforts, but they support the U.S. Government's vigilance as a whole, our health care system, and our national security. Moreover, CDRH is the only place in the government that provides this support due to our role reviewing medical devices for safety and effectiveness. For example, CISA relies on CDRH to help them quickly and effectively assess risks and potential responses to medical device cybersecurity issues. Without CDRH's specialized expertise, CISA, other parts of DHS, NSC, the FBI, and state and local governments risk missing or misunderstanding the unique patient safety risks that medical device cybersecurity issues present. HHS and other federal agencies rely on CDRH for the same reason. There is a demonstrated track record and need for FDA's expertise and its unique role to support our government's overall vigilance, and funding FDA receives to support cybersecurity of medical devices will have a good return on investment.

Tobacco

Question 6: Commissioner Califf, at the request of the FDA, the National Academies of Science, Engineering, and Medicine recently completed a year-long expert review of premium cigars consumption. The 520 page report found that the patterns of use of premium cigars are distinct from other tobacco products, the products are not marketed to children and that smoking one cigar per data dies not significantly increase the risk of mortality. Additionally, Judge Amit Mehta of the District Court for the District of Columbia also rendered a decision which provides a definitional framework for premium cigars so as not to subject these artisan, hand-made products to the regulatory framework designed for mass produces, machine made products like cigarettes. With these determinations in mind as well as FDA's own determination that premium cigars are the "lowest enforcement priority," how do you intend to ensure FDA's limited resources in this space are focused on the core mission of the Family Smoking Prevention & Tobacco Control Act, namely preventing youth access to tobacco products and the negative health effects of cigarette smoking addiction?

Response:

FDA's Center for Tobacco Products (CTP) is committed to its mission of implementing the Tobacco Control Act to protect Americans from tobacco-related disease and death by regulating

the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

CTP takes a comprehensive approach to reduce the negative health effects of tobacco use. The Center develops policy, issues regulations, conducts research, educates Americans on tobacco products, and makes decisions on whether new tobacco products can be marketed. The Center's goals are:

- Preventing people from starting to use tobacco products;
- Encouraging tobacco users to quit; and
- Reducing the harm caused by tobacco use.

FDA prioritizes its work to make the best use of resources. Preventing youth from using all tobacco products and significantly reducing disease and death from combusted tobacco product use, the leading cause of preventable death in the United States, are two of FDA's highest priorities. For example, FDA has issued proposed product standards to prohibit menthol as a characterizing flavor in cigarettes, and to prohibit all characterizing flavors (other than tobacco) in cigars. FDA is also working on a proposed product standard that would require cigarettes and other combusted tobacco products to be minimally or non-addictive. These actions have the potential to significantly reduce disease and death from combusted tobacco product use by reducing youth experimentation and addiction and increasing the number of adult smokers who quit.

Sunscreen

Question 7: Commissioner Califf, as you may know recently actions at the state and local levels, such as those in Hawaii, have resulted in, at minimum, a requirement that consumers obtain a prescription to use FDA-approved OTC sunscreen products. These actions hinder access to these products and harm consumer education initiatives related to safe and effective sunscreen products that are proven skin cancer prevention tools. These bans were fueled by very limited scientific studies related to the perceived environmental impact of sunscreens. While states have taken certain actions to limit access to OTC products due to misuse or abuse, these actions have not extended to perceived environmental impact. Work is currently being undertaken by the National Academy of Sciences to determine the extent of the environmental impact of sunscreens as well as the human impact of limiting access to these products as proven skin cancer prevention tools. However, access issues to these important products remain. FDA remains the sole agency with jurisdiction over the regulatory status of these products, including their prescription status and whether they remain on store shelves, and FDA has exerted its jurisdiction over the regulation of OTC products in the past when states and localities have taken actions to modify these products. However, FDA has taken no action to assert their jurisdiction with respect to sunscreens. As Commissioner of Food and Drugs, which oversees the regulation

of sunscreen ingredients and other OTC products, how will you ensure the FDA asserts its regulatory jurisdiction over OTC sunscreen products to ensure Americans have access to these important products? Will you commit to coordinating with relevant stakeholders on this issue?

Response:

FDA remains committed to ensuring that the sunscreens available to American consumers are safe and effective, including those sunscreens marketed under the new paradigm for OTC monograph drugs laid out by the CARES Act. As described in a 2019 proposed rule for sunscreens⁵ and subsequent 2021 proposed order⁶ under the new paradigm for OTC monograph drugs, FDA conducted an extensive review of the available data on sunscreen monograph active ingredients. Among other things, FDA's proposals indicated that data was insufficient to support positive GRASE determinations for sunscreens that include twelve of the current sunscreen monograph active ingredients and identified the specific types of safety data needed to address these gaps. The Agency is committed to working with industry to advance development of this needed data. While this data is being gathered, FDA has also undertaken a robust communication plan emphasizing that consumers should continue to use broad spectrum sunscreens of SPF 15 or greater and other sun-protection measures to help protect themselves from skin cancer and other harms associated with sun exposure.

Alzheimer's

Question 8: Dr. Califf, just three weeks about, the Centers for Medicare and Medicaid Services finalized their coverage policy – the policy that determines what expenses the agency is willing to pay for on behalf of Medicare patients – for an Alzheimer drug approved by FDA under the accelerated approval process. This new CMS policy seems to establish new requirements for FDA approved drugs. Is it accurate to say that Alzheimer's patients will have to join government-approved studies, such as patient registries or clinical trials, to gain access to FDA-approved treatments?

Response:

The Agency is committed to using expedited programs to bring medicines to underserved populations with serious conditions and unmet medical need when the science supports the decision within the statutory authorities given to FDA by Congress. Our decision regarding Aduhelm exemplifies that commitment. It is important to distinguish between FDA's role and CMS' role. The standard for Medicare coverage is not the same as the standards for FDA approval of a drug. Our role is to determine if a drug is safe and effective for its intended use. The Agency cannot speak for CMS. That said, we continue to see sponsors pursue accelerated approval.

⁵ <https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use>

⁶ <https://www.federalregister.gov/documents/2021/09/27/2021-20780/amending-over-the-counter-monograph-m020-sunscreen-drug-products-for-over-the-counter-human-use-over>

Question 9: Do you support policies that, effectively, tell seniors they must agree to give the government their health data, and be part of an experiment, in order to gain access to a treatment the FDA has deemed safe and effective?

Response:

Please see FDA's response to Question 8.

Question 10: Decisions about whether or not drugs are safe and effective have historically been left of the FDA, which is the gold standard in terms of science-based, rigorous drug review. In both the proposed decision and the final coverage decision for an Alzheimer drug, the Centers for Medicare and Medicaid Services appear to question the FDA's judgement regarding whether these drugs are safe and effective. Are you concerned how this National Coverage Determination could undermine the FDA in the eyes of the public?

Response:

Please see FDA's response to Question 8.

Question 11: Medicines approved under the accelerated approval pathway must meet the same standard of safety and efficacy for approval as medicines awarded traditional approval, yet the Centers for Medicare and Medicaid Service's National Coverage Determination indicates that CMS believes that without a direct measure of clinical benefit, drugs approved under the accelerated approval process do not meet the reasonable and necessary standard for Medicare coverage. Aren't you concerned that this would have a significant chilling effect on other companies seeking accelerated approval for their medicines to the detriment of patients with other serious an life-threatening diseases such as – to treat rare cancers or neurological disorders such as Alzheimer's?

Response:

Please see FDA's response to Question 8.

CONGRESSMAN ROBERT B. ADERHOLT

MAY 19, 2022

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Illicit Drugs

Question 1: Commissioner Califf, in your written statement you emphasize your concerns with the opioid crisis impacting the country. Specifically, you list out four priority areas, one of which includes “improving enforcement and assessing benefit-risk.” Could you discuss more on this priority and what the FDA is exactly doing?

Question 2: What countries in particular do we see the most concern stemming from when it comes to unapproved foreign drugs? Additionally, of those most concerning countries, is the FDA taking any concentrated action to address those specific nations?

Supply Chain

Question 3: Commissioner Califf, the supply chain disruptions impacting our economy are not new to anyone and the closures behind the baby formula factory serves as an unfortunate case study. How is the agency working to ensure that other manufacturers across the industry don't suffer from similar situations?

Cybersecurity

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products to the regulatory framework designed for mass produces, machine made products like cigarettes. With these determinations in mind as well as FDA's own determination that premium cigars are the "lowest enforcement priority," how do you intend to ensure FDA's limited resources in this space are focused on the core mission of the Family Smoking Prevention & Tobacco Control Act, namely preventing youth access to tobacco products and the negative health effects of cigarette smoking addiction?

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Alzheimer's

Question 8: Dr. Califf, just three weeks about, the Centers for Medicare and Medicaid Services finalized their coverage policy – the policy that determines what expenses the agency is willing to pay for on behalf of Medicare patients – for an Alzheimer drug approved by FDA under the accelerated approval process. This new CMS policy seems to establish new requirements for FDA approved drugs. Is it accurate to say that Alzheimer's patients will have to join government-approved studies, such as patient registries or clinical trials, to gain access to FDA-approved treatments?

Question 9: Do you support policies that, effectively, tell seniors they must agree to give the government their health data, and be part of an experiment, in order to gain access to a treatment the FDA has deemed safe and effective?

Question 10: Decisions about whether or not drugs are safe and effective have historically been left of the FDA, which is the gold standard in terms of science-based, rigorous drug review. In both the proposed decision and the final coverage decision for an Alzheimer drug, the Centers for Medicare and Medicaid Services appear to question the FDA's judgement regarding whether these drugs are safe and effective. Are you concerned how this National Coverage Determination could undermine the FDA in the eyes of the public?

Question 11: Medicines approved under the accelerated approval pathway must meet the same standard of safety and efficacy for approval as medicines awarded traditional approval, yet the Centers for Medicare and Medicaid Service's National Coverage Determination indicates that CMS believes that without a direct measure of clinical benefit, drugs approved under the accelerated approval process do not meet the reasonable and necessary standard for Medicare coverage. Aren't you concerned that this would have a significant chilling effect on other companies seeking accelerated approval for their medicines to the detriment of patients with other serious an life-threatening diseases such as – to treat rare cancers or neurological disorders such as Alzheimer's?

REP. BETTY MCCOLLUM
MAY 19, 2022

BUDGET HEARING: FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Question 1: Over-the-Counter Hearing Aids

I appreciate FDA's work in drafting the proposed over-the-counter (OTC) hearing aid rules and increasing access to hearing loss solutions. I, along with several of my colleagues, submitted a letter outlining our concerns with the rule as proposed. Those concerns included appropriate amplification levels, known as output and gain, as well as the importance of ensuring adequate consumer protections -- many of which are currently contained within state licensing laws and at risk of being preempted under this draft rule.

OTC hearing devices are intended only for those over the age of eighteen with "perceived mild-to-moderate hearing loss." However, the proposed rule allows OTC devices to be amplified up to 120 decibels (dB) without imposing any hearing gain limit. This threshold allows those with hearing loss greater than the intended mild-to-moderate level to access OTC hearing devices.

This hurts consumers and patients in two ways. First, individuals suffering from greater levels of hearing loss could put off a needed visit with a licensed hearing professional, which could lead to worsening their existing symptoms, delaying an accurate diagnosis and treatment, and even creating irreparable damage to their hearing. Secondly, those with perceived mild-to-moderate hearing loss could be exposed to harmful levels of noise that could result in further damage to their long-term hearing.

Ninety-one stakeholders ranging from patient advocacy organizations to trusted hearing providers submitted formal comments to the FDA expressing concern that the proposed 120 dB maximum output limit and omission of a gain requirement will put patient safety at risk. These stakeholders include the American Academy of Otolaryngology - Head and Neck Surgery, American Society on Aging, the American Speech-Language-Hearing Association, the American Academy of Audiology, and more.

Concerns have also been shared by 43 states attorneys general, who submitted comments to FDA urging the agency to preserve the authority of states in regulating professionals and consumer protections -- including Minnesota's Attorney General. This is in addition to the efforts of over 17 other states' attorneys general to issue warnings to consumers about companies advertising OTC hearing aids when the category does not yet exist.

Can you tell me what is being done to ensure OTC hearing aids will not cause greater hearing loss for individuals?

Does FDA intend to work with the states to harmonize the federal and state hearing aid requirements and ensure continued consumer protections apply prior to implementation?

Question 2: Skin-Lightening Cosmetic Safety

For the past few years, I have worked in this Committee on the issue of skin-lightening cosmetics, and we've successfully secured increased funding for FDA to help educate the public about the dangers of these products, and to combat their illegal sales.

Skin-lightening cosmetics are disproportionately targeted towards and used by women of color, and many of these products contain dangerous or illegal levels of ingredients like mercury—which, as you know, can lead to serious and long-term risks to human health.

I was pleased to see FDA issued warning letters last month to twelve companies for selling skin-lightening products illegally marketed as over-the-counter (OTC) drugs—and making clear to consumers there are no FDA-approved, or otherwise legally marketed OTC skin lightening products.

The BeautyWell Project is an organization in my district that has worked for years on ending the use of skin-lightening products, and successfully petitioned Amazon to have more than a dozen products with dangerous levels of mercury removed from its site.

I know it means a lot to the BeautyWell Project, and other groups like it, for the FDA to be shining a light on this important issue, so I wanted to thank you for the agency's commitment to continuing its work in this space.

Are there any updates to FDA's work, or thoughts on the dangers of skin-lightening products in general you would like to share? Thank you.

REP. BETTY MCCOLLUM

MAY 19, 2022

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- a) Can you tell me what is being done to ensure OTC hearing aids will not cause greater hearing loss for individuals?

Response:

On August 17, 2022, FDA issued its final rule on hearing aids. This action, among other things, establishes a new category of over-the-counter (OTC) hearing aids and the requirements for these devices to provide for reasonable assurance of safety and effectiveness. It improves access to these devices by enabling consumers who are 18 years and older with perceived mild to

moderate hearing impairment to purchase these hearing aids directly from stores or online retailers without the need for a medical exam, prescription, or a fitting adjustment by an audiologist. Concurrently with issuing the final rule, the FDA also issued the final guidance, Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs), to clarify the differences between hearing aids, which are medical devices, and PSAPs, consumer products that help people with normal hearing amplify sounds in certain environments. FDA finalized the rule after receiving and reviewing more than 1,000 public comments on the proposed rule issued on October 20, 2021. Comments submitted by consumers, professional associations, hearing aid manufacturers, public health organizations and advocacy groups, Members of Congress, state agencies, and other stakeholders are summarized in the preamble of the final rule, along with the FDA's respective responses. In response to public comments and to provide a reasonable assurance of the safety and effectiveness of OTC hearing aids, the final rule incorporates several changes from the proposed rule, including lowering the maximum sound output to reduce the risk to hearing from over-amplification of sound, revising the insertion depth limit in the ear canal, requiring that all OTC hearing aids have a user-adjustable volume control, and simplifying the phrasing throughout the required device labeling to ensure it is easily understood. The final rule also includes performance specifications and device design requirements specific to OTC hearing aids.

- b) Does FDA intend to work with the states to harmonize the federal and state hearing aid requirements and ensure continued consumer protections apply prior to implementation?

Response:

States will generally be able to enforce reasonable consumer protections for OTC hearing aids. Although the FDA Reauthorization Act of 2017 (FDARA) preempts certain kinds of state and local requirements that are specifically related to hearing products and that restrict or interfere with commercial activity involving OTC hearing aids, not all state or local requirements fall within the scope of the FDARA preemption provision.

For example, FDA believes that state or local requirements that provide for reasonable warranty or return periods for hearing aids are generally likely to promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids. Additionally, requirements that provide for the reasonable disclosure of the terms of sale in a receipt are generally likely to promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids.

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Are there any updates to FDA's work, or thoughts on the dangers of skin-lightening products in general you would like to share? Thank you.

Response:

The Agency continues to take a number of actions in this space. Regarding public education, the Office of Cosmetics and Colors (OCAC) within the Center for Food Safety and Nutrition and the Center for Drug Evaluation and Research (CDER) have been engaging with the Office of Minority Health and Health Equity (OMHHE) on the *Skin Facts!*¹ Initiative to educate the public about the dangers of skin lightening products containing hydroquinone or mercury. To build a foundation for the development of the educational initiative, OMHHE, OCAC, and CDER also collaborated with the Reagan-Udall Foundation for the FDA to conduct formative research among diverse stakeholders for their perspectives, attitudes, knowledge, and motivations on the use of and potential risks from skin lightening products containing hydroquinone or mercury. FDA also announced two "Educational Funding Opportunities: Expanding education on skin lightening products" to expand and advance work with stakeholders and partners for education, outreach, and public awareness activities on the use of and potential risks from skin lightening products. The first funding opportunity was announced in March 2022, with awards announced in August 2022. The second funding opportunity was announced in October 2022, with an application deadline of December 5, 2022.

As you noted, CDER recently issued warning letters to companies illegally marketing skin lightening products containing hydroquinone. FDA has also issued a consumer update, cautioning consumers to avoid skin creams, beauty and antiseptic soaps, and lotions that contain mercury. In addition, OCAC continues to maintain a webpage informing consumers about the risks of mercury in skin products.

¹ <https://www.fda.gov/consumers/skin-facts-what-you-need-know-about-skin-lightening-products/about-skin-facts#:~:text=that%20contain%20mercury,The%20Skin%20Facts!,products%20containing%20hydroquinone%20or%20mercury>.

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Alzheimer's Treatment

- 1) The Centers for Medicare and Medicaid Services (CMS) finalized their national coverage determination (NCD) for the first FDA-approved Alzheimer's treatment in two decades, Aduhelm, restricting access to only those lucky enough to enroll in a randomized controlled trial. I am deeply concerned this will have a disproportionate impact on rural, low-income, and minority patients who are less likely to access clinical trials.

Question: Please elaborate on efforts taken by the FDA during this process to protect access for these Alzheimer's patient populations.

Response:

The Agency is committed to using expedited programs to bring medicines to underserved populations with serious conditions and unmet medical need when the science supports the decision within the statutory authorities given to FDA by Congress. Our decision regarding Aduhelm exemplifies that commitment. It is important to distinguish between FDA's role and CMS' role. The standard for Medicare coverage is not the same as the standards for FDA approval of a drug. Our role is to determine if a drug is safe and effective for its intended use. The Agency cannot speak for CMS.

Certificate for Device Not Exported from the U.S.

After congressional direction on the FDA's existing Certificate to Foreign Government mechanism included the FDA Reauthorization Act of 2017 (FDARA; Public Law 115-52) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136), the Agency established a new Certificate for Device Not Exported for the United States (CDNE) for FDA approved or cleared medical devices exported from FDA-inspected facilities outside the United States. Since then, concerns have been raised that the CDNE and its content is causing confusion among manufacturers and regulators in foreign countries.

- 2) **Question:** Are you aware of these concerns and do you commit to examining and addressing them?

Response:

FDA appreciates the Committee's interest in this issue. We have heard from stakeholders that these new certificates (CDNEs) are not being understood to provide the same

assurances as Certificates to Foreign Governments (CFGs) for devices exported from the United States, and that is because these are not devices for which FDA has the same jurisdiction or information. FDA is working on a draft guidance to try to clarify this issue. It will also be an opportunity for stakeholders to provide feedback on the contents of the form and certificate.

In addition, FDA remains open to working with Congress to clarify the objective of this statutory provision given the challenges with certifying a device that is made in one foreign country and shipped to another foreign country without ever entering U.S. commerce. FDA believes that section 905 of the Food and Drug Administration Safety and Landmark Advancements Act, as passed by the Senate HELP Committee, would provide a workable approach, as it provides clarity that the devices that are the subject of these certificates must be imported or offered for import into the U.S. Registration and listing with FDA are not alone sufficient to provide these assurances, but if a manufacturer attests that it currently imports its device into the United States, this would enable FDA to provide the assurances that manufacturers and foreign regulators appear to be looking for FDA to certify.

With or without further revisions to the statute, FDA is committed to working with stakeholders to provide appropriate certifications for devices and addressing any confusion about what our certificates do and do not convey.

FDA's Food Program

- 3) Structural changes in recent years have impaired many aspects of the FDA's food program. The New Era of Smarter Food Safety blueprint and implementation of the Food Safety Modernization Act have perhaps been hit the hardest. These key initiatives depend on all three major food program units – CFSAN, CVM, and ORA – working together along with their state partners with a common strategic mission and internal accountability.

Question: Will you correct structural imbalance and unify the food program under a deputy commissioner for food and nutrition, someone with direct authority over the major food program units, with accountability to the commissioner?

Response:

The foods that Americans consume have never been safer, in part because of the great work of our employees. Over the past decade, our Foods Program has achieved a great deal, including the adoption of Whole Genome Sequencing of pathogens, enabling faster outbreak identification and response; the implementation of the FDA Food Safety Modernization Act (FSMA), publishing over fifty FSMA-related guidances; the launch of our New Era of Smarter Food Safety initiative, which builds on the work of FSMA while

taking a modernized approach to food safety that leverages technology and other tools; and making significant progress on the nutritional quality of the foods we eat, including empowering consumers through major changes to product and menu labeling, and the reduction of *trans fats* and sodium—each of which are estimated to save thousands of lives. That said, we can always find ways to do our jobs better.

In February, I rejoined FDA as Commissioner of Food and Drugs, having served in the role five years earlier. During my confirmation I heard many concerns about the status of the foods program. Since my return, the Agency has continued to take many significant actions that benefit the public health. Yet at the same time, FDA has confronted a series of challenges that have tested our regulatory frameworks and stressed the Agency's operations, prompting me to take a closer look at how we do business.

As part of this effort, I have commissioned an external review of the Human Foods Program to assess fundamental questions, including structure, function, funding, authorities, and leadership. This review is being led by Dr. Jane Henney, who served as Commissioner from 1999-2001, along with an independent panel of experts, through the Reagan-Udall Foundation, an independent partner organization for the Agency. The independent panel will report its findings to the Agency on December 6. The report will also be made public. I am looking forward to receiving and reviewing this report as it will help inform any potential changes to FDA's foods program. I expect to make decisions about the structure and leadership of the foods program after full consideration of this important report.

Most important to me is making a decision that will set the FDA Foods Program on the best course to face the next decade of food policy opportunities and challenges. Although optimizing the organizational structure and leadership of the Foods Program will be critical, I expect that in order to put the food program on the best course we will also need to ensure that it is properly resourced and has the authorities it needs to best oversee the safety of our food supply chain. If we do not also address these issues, we likely will not be able to solve some of the underlying issues and challenges the Foods Program has faced. I would be happy to speak further with you about this following completion of the RUF evaluation.

Animal Drug Inequalities

- 4) At a recent FDA public meeting on the current Animal Drug User Fee Act negotiations, a representative of the sheep industry explained that U.S. sheep producers have few products available to maintain the health of their animals. In fact, their competitors in other markets have access to approved drug products that are not available to U.S. producers, meaning when Americans consumer imported lamb, they are consuming meat raised with medicines not available to our own domestic producers. Other farm commodity organizations have also raised concerns about a lack of approved medicines.

- a) **Question:** What can FDA do differently to ensure a more robust supply of medicines needed to address unmet medical needs in animals?

Response:

FDA's Center for Veterinary Medicine (CVM) is committed to implementing strategies that encourage industry to develop and seek FDA approval for products that can address unmet medical needs across all species, including minor species like sheep.

The Minor Use and Minor Species (MUMS) Act was passed by Congress in 2004 with the intent to increase the availability of animal drugs for minor species. Since it was passed, few new animal drugs have been approved for minor species and approvals are especially limited for food-producing minor species such as sheep.

There are many reasons why sponsors may choose not to submit applications for minor species, and CVM regularly engages in dialogue with organizations representing many facets of the animal industry to better understand what additional actions the Agency can take to incentivize and support development of these drugs.

The economics of developing drugs for smaller populations of animals is one of the most significant and persistent barriers to this sector's growth. We would be happy to further discuss this issue with Congress.

- b) **Question:** Can we expect some solutions when Congress considers ADUFA next year?

Response:

While MUMS is outside the scope of the ADUFA negotiations, we continue to interact with new animal drug stakeholders, outside of negotiations, to learn more about the challenges associated with MUMS approvals. Our intent is to develop ideas for new incentives that may facilitate more MUMS drug development based on the feedback received. We would be happy to further discuss this topic with Congress.

CONGRESSWOMAN CHELLIE PINGREE

MAY 19, 2022

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

1. Prescription Drug Access from Canada

For decades, Americans have been buying prescription drugs from Canada for personal use. Recent surveys estimate that approximately 4 million Americans import medicine for personal use and 20 million say they, or someone in their household, has done so because prices are much lower in other countries. Do you agree that medicines approved by Health Canada and purchased from licensed Canadian pharmacies are safe? Do you agree that many of these prescription drugs are more affordable in Canada? In a time of increasing costs across all sectors, shouldn't we encourage all avenues to lower drug prices - including personal importation of drugs from Canada - to help Americans afford their life-saving medicines?

2. COVID-19 Vaccine Access for Children

Children under five are currently the only age group still without access to a COVID-19 vaccine. Will the FDA prioritize review of Moderna's application for the under 6 age group so that these children have some protection available? Do you anticipate that a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting will be held earlier than June 14th and 15th if the review is completed early?

3. Impacts of COVID-19 on Clinical Trials for Prescription Drugs to Treat Rare Diseases

Conducting clinical trials for the development of prescription drugs to treat rare disease is especially challenging. Patient recruitment and retention is particularly difficult. The COVID-19 pandemic has exacerbated these challenges and resulted in significant delays and disruptions. In order to understand the full impacts of the pandemic on clinical trials and address them, the Subcommittee requested a report in FY2021 and FY2022 requesting recommendations to address them within 90 days. Can you please provide a status update on the Agency's work to provide this critically important study?

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FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

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Response:

FDA understands the importance of Americans having access to high-quality medicines they can afford. We also take very seriously our responsibility to ensure that the drugs Americans take are safe and effective, and that our actions live up to our reputation as the world's "gold standard."

In October 2020, FDA and the Department of Health and Human Services finalized a rule to implement parts of section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow FDA-authorized programs to import certain prescription drugs from Canada under specific conditions that ensure the importation poses no additional risk to the public's health and safety while achieving a significant reduction in the cost of covered products to the American consumer. The rule includes a number of key features to address risk to public health and safety, including important provisions to ensure quality and safety of imported drugs, and awareness and oversight of entities in the supply chain. These important provisions will help the Agency identify issues and take action to ensure that proposed section 804 importation programs will not introduce suspect or potentially harmful products into the U.S. marketplace. FDA is committed to working with States and Indian Tribes that propose to develop section 804 importation programs, consistent with the President's Executive Order on Promoting Competition in the American Economy. FDA also issued final guidance describing the procedures drug manufacturers can follow to facilitate importation of prescription drugs, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country.

In most circumstances, it is illegal for individuals to import drugs into the United States for personal use. This is because drugs from other countries that are available for purchase by individuals often have not been approved by FDA for use and sale in the United States. FDA cannot ensure the safety and effectiveness of drugs that it has not approved that are not imported through the legitimate U.S. drug supply chain.

FDA's personal importation policy provides guidance regarding situations where FDA does not intend to prevent the importation of an unapproved drug for personal use. You can learn more about this on our Personal Importation webpage.¹

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Response:

On June 17, 2022, the U.S. Food and Drug Administration authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age. For the Moderna COVID-19 Vaccine, FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 17 years of age. For the Pfizer-BioNTech COVID-19 Vaccine, the FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had been authorized for use in individuals 5 years of age and older.

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Response:

Detailed data on delayed or cancelled trials due to the effects of COVID-19 are not available, but we are aware that the pandemic resulted in disruptions to clinical trials in general and that impacts may be felt acutely by patients with rare diseases where there are often no available therapies. The most comprehensive source of information would likely come from stakeholders sponsoring or conducting these clinical trials. However, given that clinical trials can be conducted over the span of years, we also recognize that there might be some lag in capturing and documenting the impact of COVID-19 on the clinical trial enterprise. FDA also recognizes that the COVID-19 public health emergency may have impacted the conduct of clinical trials of medical products in general, and that this impact would be felt acutely by patients with rare diseases where

¹ <https://www.fda.gov/industry/import-basics/personal-importation#UScitizen>

there are often no available therapies. FDA is committed to mitigating the negative impact of COVID-19 on clinical trials.

To help sponsors of ongoing trials during the COVID-19 public health emergency, FDA published a final guidance titled *Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency*,² with recommendations to assist in maintaining the continuity of clinical trials, as appropriate, during the public health emergency while helping to ensure the safety of trial participants and protecting the quality and integrity of the data. The guidance incorporates lessons from and examples informed by experience with previous public health emergencies, including recommendations for leveraging existing health care infrastructure, conducting remote assessment and monitoring, identifying and prioritizing critical processes, leveraging technology and innovations, and helping to ensure effective communication and documentation. The guidance can be found on FDA's website and has periodically been updated with additional answers to questions FDA has received from stakeholders. FDA also published a guidance titled *Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency*,³ which includes recommendations for addressing the impact of COVID-19 on meeting trial objectives. FDA has received positive feedback from stakeholders on these two guidance documents as to their utility in helping to minimize or avoid delays or cancellations in clinical trials, including for rare diseases.

Despite the challenges of COVID-19, FDA's work to advance treatments for rare diseases and to help ensure continuity of care for people with rare diseases remains a top priority.⁴ Working with sponsors and patients, FDA remains focused on facilitating development and approval of products for serious conditions where there is unmet need. For example, in Calendar Year (CY) 2021, CDER and CBER approved 30 new molecular entities with orphan drug designations for rare diseases. This represented 50% of all new drug and biological product approvals. In CY 2019, the year before the COVID-19 public health emergency, CDER and CBER approved 22 new molecular entities with orphan drug designations for rare diseases. CY 2021's approvals of new molecular entities with orphan drug designations for rare diseases is consistent with the average number of new molecular entities with orphan drug designations for rare diseases from 2017-2020 (27 per year). Currently, using the metric of approvals of new molecular entities with orphan drug designations for rare diseases, the Agency has not seen a decrease in approvals due to COVID-19.

² <https://www.fda.gov/media/136238/download>

³ <https://www.fda.gov/media/139145/download>

⁴ <https://www.fda.gov/news-events/fda-voices/rare-disease-therapy-development-and-access-remain-top-fda-priorities-during-covid-19>

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Alzheimer's Treatment

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- 2) **Question:** Are you aware of these concerns and do you commit to examining and addressing them?

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assurances as Certificates to Foreign Governments (CFGs) for devices exported from the United States, and that is because these are not devices for which FDA has the same jurisdiction or information. FDA is working on a draft guidance to try to clarify this issue. It will also be an opportunity for stakeholders to provide feedback on the contents of the form and certificate.

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- 3) Structural changes in recent years have impaired many aspects of the FDA's food program. The New Era of Smarter Food Safety blueprint and implementation of the Food Safety Modernization Act have perhaps been hit the hardest. These key initiatives depend on all three major food program units – CFSAN, CVM, and ORA – working together along with their state partners with a common strategic mission and internal accountability.

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Response:

The foods that Americans consume have never been safer, in part because of the great work of our employees. Over the past decade, our Foods Program has achieved a great deal, including the adoption of Whole Genome Sequencing of pathogens, enabling faster outbreak identification and response; the implementation of the FDA Food Safety Modernization Act (FSMA), publishing over fifty FSMA-related guidances; the launch of our New Era of Smarter Food Safety initiative, which builds on the work of FSMA while

taking a modernized approach to food safety that leverages technology and other tools; and making significant progress on the nutritional quality of the foods we eat, including empowering consumers through major changes to product and menu labeling, and the reduction of *trans fats* and sodium—each of which are estimated to save thousands of lives. That said, we can always find ways to do our jobs better.

In February, I rejoined FDA as Commissioner of Food and Drugs, having served in the role five years earlier. During my confirmation I heard many concerns about the status of the foods program. Since my return, the Agency has continued to take many significant actions that benefit the public health. Yet at the same time, FDA has confronted a series of challenges that have tested our regulatory frameworks and stressed the Agency's operations, prompting me to take a closer look at how we do business.

As part of this effort, I have commissioned an external review of the Human Foods Program to assess fundamental questions, including structure, function, funding, authorities, and leadership. This review is being led by Dr. Jane Henney, who served as Commissioner from 1999-2001, along with an independent panel of experts, through the Reagan-Udall Foundation, an independent partner organization for the Agency. The independent panel will report its findings to the Agency on December 6. The report will also be made public. I am looking forward to receiving and reviewing this report as it will help inform any potential changes to FDA's foods program. I expect to make decisions about the structure and leadership of the foods program after full consideration of this important report.

Most important to me is making a decision that will set the FDA Foods Program on the best course to face the next decade of food policy opportunities and challenges.

Although optimizing the organizational structure and leadership of the Foods Program will be critical, I expect that in order to put the food program on the best course we will also need to ensure that it is properly resourced and has the authorities it needs to best oversee the safety of our food supply chain. If we do not also address these issues, we likely will not be able to solve some of the underlying issues and challenges the Foods Program has faced. I would be happy to speak further with you about this following completion of the RUF evaluation.

Animal Drug Inequalities

- 4) At a recent FDA public meeting on the current Animal Drug User Fee Act negotiations, a representative of the sheep industry explained that U.S. sheep producers have few products available to maintain the health of their animals. In fact, their competitors in other markets have access to approved drug products that are not available to U.S. producers, meaning when Americans consumer imported lamb, they are consuming meat raised with medicines not available to our own domestic producers. Other farm commodity organizations have also raised concerns about a lack of approved medicines.

- a) **Question:** What can FDA do differently to ensure a more robust supply of medicines needed to address unmet medical needs in animals?

Response:

FDA's Center for Veterinary Medicine (CVM) is committed to implementing strategies that encourage industry to develop and seek FDA approval for products that can address unmet medical needs across all species, including minor species like sheep.

The Minor Use and Minor Species (MUMS) Act was passed by Congress in 2004 with the intent to increase the availability of animal drugs for minor species. Since it was passed, few new animal drugs have been approved for minor species and approvals are especially limited for food-producing minor species such as sheep.

There are many reasons why sponsors may choose not to submit applications for minor species, and CVM regularly engages in dialogue with organizations representing many facets of the animal industry to better understand what additional actions the Agency can take to incentivize and support development of these drugs.

The economics of developing drugs for smaller populations of animals is one of the most significant and persistent barriers to this sector's growth. We would be happy to further discuss this issue with Congress.

- b) **Question:** Can we expect some solutions when Congress considers ADUFA next year?

Response:

While MUMS is outside the scope of the ADUFA negotiations, we continue to interact with new animal drug stakeholders, outside of negotiations, to learn more about the challenges associated with MUMS approvals. Our intent is to develop ideas for new incentives that may facilitate more MUMS drug development based on the feedback received. We would be happy to further discuss this topic with Congress.

CONGRESSMAN DAVID VALADAO

MAY 19, 2022

FISCAL YEAR 2023 BUDGET REQUEST FOR THE FOOD AND DRUG ADMINISTRATION

Alzheimer's Treatment

The Centers for Medicare and Medicaid Services (CMS) finalized their national coverage determination (NCD) for the first FDA-approved Alzheimer's treatment in two decades, Aduhelm, restricting access to only those lucky enough to enroll in a randomized controlled trial. I am deeply concerned this will have a disproportionate impact on rural, low-income, and minority patients who are less likely to access clinical trials.

Question: Please elaborate on efforts taken by the FDA during this process to protect access for these Alzheimer's patient populations.

Certificate for Device Not Exported from the U.S.

After congressional direction on the FDA's existing Certificate to Foreign Government mechanism included the FDA Reauthorization Act of 2017 (FDARA; Public Law 115-52) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136), the Agency established a new Certificate for Device Not Exported for the United States (CDNE) for FDA approved or cleared medical devices exported from FDA-inspected facilities outside the United States. Since then, concerns have been raised that the CDNE and its content is causing confusion among manufacturers and regulators in foreign countries.

Question: Are you aware of these concerns and do you commit to examining and addressing them?

FDA's Food Program

Structural changes in recent years have impaired many aspects of the FDA's food program. The New Era of Smarter Food Safety blueprint and implementation of the Food Safety Modernization Act have perhaps been hit the hardest. These key initiatives depend on all three major food program units – CFSAN, CVM, and ORA – working together along with their state partners with a common strategic mission and internal accountability.

Question: Will you correct structural imbalance and unify the food program under a deputy commissioner for food and nutrition, someone with direct authority over the major food program units, with accountability to the commissioner?

Animal Drug Inequalities

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Question: What can FDA do differently to ensure a more robust supply of medicines needed to address unmet medical needs in animals?

Question: Can we expect some solutions when Congress considers ADUFA next year?

The Honorable Grace Meng
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and
Related Agencies
Questions for the Record
Fiscal Year 2023 Budget Request for the Food and Drug Administration

1. The FY22 House Report included language directing the Food and Drug Administration to update its 510(k) guidance to include labeling for menstrual products and report back to the committee on the plan to update this guidance.

- **Where in the process is the Agency with the requested update on the 510(k) guidance and when we should expect to see the recommendations regarding labeling for menstrual products?**

Response:

FDA appreciates the Committee's concerns about the safety of menstrual products and ensuring that consumers and health care providers have transparency regarding the ingredients that compose these products. The Agency will continue working to update its existing menstrual products guidance to include recommendations that intentionally added ingredients, including fragrances, be disclosed on the label. FDA intends to also provide additional clarity on tampon testing, including the impact of product use on the body and microbiomes through testing methods recommended by the Agency. FDA looks forward to engaging with patients, health care providers, and others during a public comment period when those guidance updates are proposed. While the Agency is currently unable to provide a timeline for completion of the guidance update as our work on this issue is still early in development, we commit to providing another update on this issue when available.

2. The FDA announced on April 13th steps they would take to increase racial and ethnic diversity in clinical trials. Incremental changes to address this problem have taken decades and are contributing to continued safety and efficacy issues for non-white populations, particularly the Asian American, Pacific Islander, and Native Hawaiian community.

- a. **As travel costs are a major barrier to clinical trial participation, how much money is the FDA putting toward travel costs to ensure diversity of participants?**

Response:

FDA remains committed to increasing enrollment of diverse populations in medical product and drug development and will continue to engage with federal partners, medical product manufacturers, healthcare professionals and health advocates to reach this important goal. FDA does not fund or financially support the vast majority of clinical trials involving medical products, which are generally sponsored by organizations, other Federal offices and agencies, or individuals. In limited cases, FDA may financially support certain clinical trials through grant awards.

For all clinical trials of FDA-regulated medical products, FDA's 2018 guidance titled *Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators*¹ notes that reimbursement for reasonable travel expenses such as airfare, parking, and lodging may be provided. This guidance also notes that consideration may be given to paying the participants in exchange for their participation in research. FDA recognizes that payment for participation may raise difficult questions that should be addressed by the institutional review board (IRB). For example, the IRB should address how much money research subjects should receive, and for what purposes subjects should receive payment, such as their time, inconvenience, discomfort, or some other consideration. Payments for participation in research should be just and fair.

- b. Does the FDA plan to put out guidance about clinical trials in other languages beyond English and Spanish, particularly regarding the location of such trials? If not, can you describe what the FDA is doing to reach minority communities whose primary language is not English or Spanish?**

Response:

FDA is committed to encouraging diverse participation in research used to support marketing applications for regulated medical products. FDA has continued to promote diverse participation in clinical trials through hosting public meetings, developing resources and tools, and issuing guidance documents. While FDA guidance documents for industry, FDA staff, and other stakeholders are available on the FDA website in English, FDA also provides a variety of resources and tools for diverse communities through education and outreach campaigns in multiple languages.

In support of these efforts, the FDA Office of Minority Health and Health Equity developed the Diversity in Clinical Trials Initiative, which includes an ongoing multi-media, public education and outreach campaign to help address some of the barriers preventing diverse groups from participating in clinical trials through a variety of culturally and linguistically tailored strategies, tools, and resources. The campaign aims

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

to combat myths, educate consumers about key issues, provide positive messaging reflecting diverse spokespersons who are representative of diverse communities, stimulate dialogue among peers and peer-to-provider groups, and provide culturally and linguistically appropriate resources available in multiple languages.²

The FDA's Office of Women's Health also conducts outreach on this important topic through the Diverse Women in Clinical Trials Initiative. This initiative was developed in collaboration with the National Institutes of Health's Office of Research on Women's Health to raise awareness about clinical trial participation by diverse women of different ages, races, ethnic backgrounds, disabilities, chronic illnesses, and health conditions and to share best practices. The initiative includes a consumer awareness campaign, resources in multiple languages and workshops for health professionals and researchers.

² <https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity>

The Honorable Grace Meng
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and
Related Agencies
Questions for the Record
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1. The FY22 House Report included language directing the Food and Drug Administration to update its 510(k) guidance to include labeling for menstrual products and report back to the committee on the plan to update this guidance.

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- **As travel costs are a major barrier to clinical trial participation, how much money is the FDA putting toward travel costs to ensure diversity of participants?**
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WEDNESDAY, MAY 25, 2022.

THE INFANT FORMULA CRISIS

WITNESSES

**GINGER CARNEY, DIRECTOR OF CLINICAL NUTRITION, ST. JUDE'S
CHILDREN'S RESEARCH HOSPITAL**

SARAH CHAMBERLIN, EXECUTIVE DIRECTOR, NATIONAL PKU NEWS

MICHAEL GAY, OWNER AND MANAGER, FOOD FRESH

BRIAN RONHOLM, DIRECTOR OF FOOD POLICY, CONSUMER REPORTS

Mr. BISHOP. Three, two, one. Good morning for those in western time zones. Good afternoon for those of us in central and eastern time zones. This hearing will now come to order.

As this hearing is fully virtual, we must address a few house-keeping matters. For today's hearing, the chair or staff designated by the chair may mute participants' microphones when they are not under recognition for purposes of eliminating inadvertent background noise. Members are responsible for muting and unmuting themselves. If I notice that you've not unmuted yourself, I would ask you if you would like for staff to unmute you. If you indicate approval by nodding, staff will unmute your microphone. I remind all members and witnesses that the five minute clock still applies. If there is a technology issue, we will move to the next member until the issue is resolved, and you will retain the balance of your time.

You will notice a clock on your screen that will show how much time is remaining. At one minute remaining, the clock will turn yellow. At 30 seconds remaining, I will gently tap the gavel to remind members that their time has almost expired.

When your time has expired, the clock will turn red, and I will begin to recognize the next member. In terms of the speaking order, we will begin with the chair and ranking member, then members present at the time the hearing was called to order will be recognized in the order of seniority, and finally, members not present at the time the hearing was called to order in their order of arrival.

Finally, House rules require me to remind you that we have set up an email address to which members can send anything they wish to submit in writing at any time during our hearings and mark ups. That email address has been provided in advance to your staff.

Good afternoon, and welcome to today's hearing. Following last week's hearing with FDA Commissioner Dr. Robert Califf, we are again looking at the infant formula recall, the nationwide formula shortage, and the impact it is having on infants, kids, and families.

In the past week, both Congress and the administration have moved swiftly to address the formula shortage crisis. Last week, Congress passed two bills which would expedite the return of safe

formula to store shelves and expand the options that our most vulnerable families have when purchasing formula through the supplemental nutrition program for women, infants, and children.

We must continue to press forward with oversight of the FDA, as well as get the FDA the much-needed resources to meet the needs of the crisis, and allow them to increase the capacity to inspect and ensure the safety of the formula supply, both in the U.S. and as we bring in emergency supplies from abroad. We need the funds to get this done.

The Administration also moved quickly by invoking the Defense Production Act to streamline the supply lines for existing, safe formula to get to American shelves, even from overseas supplies. The administration is also using the Defense Production Act to make sure that our domestic manufacturers have access to the ingredients they need to ramp up production of the formula.

Today's hearing is important, because we need to fully understand the impact of a shortage of formula supply on our country. As we will hear from today's witnesses, formula supply does not just impact infants. It strains our grocery chains, and families in different communities face different challenges. Without information, worry takes over and leads to counterproductive behavior, like hoarding, and it creates fertile ground for bad actors creating fake formulas, and sellers, and price gougers.

With that, I am pleased to introduce and welcome our panel of witnesses, Sarah Chamberlin, executive director of the National PKU News. Michael Gay, owner and manager of FoodFresh in Paxton, Georgia, representing the National Grocer's Association. Ginger Carney, director of clinical nutrition at St. Jude's Children's Research Hospital, and Brian Ronholm, director of food policy at Consumer Reports. Thank you all so much for being here.

Our first witness is Sarah Chamberlin, a mother whose eight-year-old daughter relies on special formula for about 70 percent of her nutrition. It is a reminder that formula is not just for infants, and that specialty formula is life sustaining, and can be needed for lifelong nutrition as a medical treatment for certain conditions. Simply put, there are no alternatives.

And also glad we will hear from Michael Gay, representing the National Grocer's Association. Grocers are very much on the frontlines. They are on the ground, and can see a community's needs in real time. I'm very concerned about our rural communities that often have only one grocery store, leaving people with little choice but to travel significant distances for formula.

I'm also looking forward to hearing from our other witnesses, Ginger Carney, who is the director of clinical nutrition at St. Jude's Children's Research Hospital. Carney and Brian Ronholm, director of food policy at Consumer Reporters, to gain insight from their expert knowledge and their decades of experience.

Both Abbott and FDA share in the blame for the situation we are in right now. Whereas Abbott failed the public by not maintaining a safe manufacturing site to produce this vital nutritional resource, the FDA did not live up to expectations, inspecting and responding to concerns about the manufacturing process and safety.

Because of these circumstances, we find ourselves climbing out of a crisis, which has harmed children and understandably worried

families. I'm glad this committee will give voice to those stories today.

I again want to thank our witnesses for being here. We know how busy you are, and on behalf of the committee, we are grateful that you've taken the time to speak with us today.

[The information follows:]

**Opening Statement of
Chairman Sanford D. Bishop, Jr.
The Infant Formula Crisis
May 25, 2022**

Good afternoon and welcome to today's hearing.

Following last week's hearing with FDA Commissioner, Dr. Robert Califf, we are again looking at the infant formula recall, the nation-wide formula shortage, and the impact it is having on infants, kids, and families.

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Last week, Congress passed two bills which would expedite the return of safe formula to store shelves and expand the options that our most vulnerable families have when purchasing formula through the supplemental nutrition program for Women, Infants, and Children.

We must continue to press forward with oversight of the FDA as well as get the FDA much needed resources to rise to this occasion. The FDA increase its capacity to inspect and ensure the safety of the formula supply both in the U.S. and as we bring in emergency supplies from abroad. We need the funds to get this done.

The Biden Administration also moved quickly – invoking the Defense Production Act – to streamline the supply lines for existing, safe formula to get to American shelves, even from overseas suppliers. The Administration also is using the Defense Production Act to make sure that our domestic manufacturers have access to the ingredients they need to ramp up production of formula.

Today's hearing is important because we need to fully understand the impact of a shortage of formula supply on our country. As we will hear from today's witnesses, formula supply does not just impact infants, it strains our grocery chains, and families in different communities face different challenges. Without information, worry takes over and leads to counterproductive behavior like hoarding and creates fertile ground for bad actors like fake formula sellers and price gougers.

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1. Sarah Chamberlin – Executive Director, National PKU News;
2. Michael Gay – Owner and Manager of Food Fresh in Claxton, Georgia representing the National Grocers Association;
3. Ginger Carney – Director of Clinical Nutrition at St. Jude Children's Research Hospital; and
4. Brian Ronholm – Director of Food Policy at Consumer Reports.

Thank you all so much for being here.

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Because of these circumstances we find ourselves climbing out of a crisis which has harmed children and understandably worried families. I am glad this committee will give a voice to those stories today.

I again want to thank our witnesses for being here. We know how busy you all are. On behalf of the committee, we are grateful you have taken the time to speak with us today.

Mr. BISHOP. Now, I'd like to ask our distinguished ranking member, Dr. Harris, if he has any opening remarks, and if so, I would like to recognize him at this time for those remarks. Mr. Harris, you are now recognized.

Mr. HARRIS. Thank you, Chairman Bishop, and I'd like to welcome our witnesses to the hearing today. I appreciate you all sharing your experiences with us as our country remains in the middle of an infant formula supply crisis.

Like parents across America, I'm frustrated by the Biden Administration's lack of urgency prior to last week to address this issue. Supply challenges started last fall. On November 12th, 2021, WSOC in Concord, North Carolina reported that Dr. Margaret Quinlan, a UNC Charlotte professor, said, "Our Country is failing us if they are not seeing this as something that needs to be a priority."

CNN also had a headline a few days later, "baby formula is getting harder to find," but rather than tackle this looming crisis, the Biden Administration chose to work on the holiday gift supply chain instead.

The formula shortages cited in national and state media outlets last fall have been exacerbated with the Abbott recall of infant formula, and the facility closing in February.

Again, CNN had a headline in February, baby formula shortage has some families scrambling, and when did the administration finally decide to take action? Last week. The administration should have made it a priority to address supply chain shortages long before now. Instead, parents and caregivers are facing unimaginable stress and anxiety as they search for formula to feed their babies.

After one of the largest formula manufacturing facilities in the U.S. closed, the administration should have been working around the clock to get this plant safely back online as quickly as possible. Three months have passed, the facility remains idle. I believe this crisis could have been averted if the administration had acted on supply chain issues last fall.

Existing funding and authorities were at their disposal, and could have been utilized to address this predictable situation much more quickly, just as Republicans suggested, and just as the administration did this past weekend by having formula flown in from overseas. None of these actions needed more money or more authority from Congress. It would have just taken leadership and initiative from the administration. It's disappointing we find ourselves in this situation when the alarms were sounding months ago.

But again, I want to thank our witnesses for joining us today to share their experience and the impacts they have seen from this crisis. I look forward to today's discussion. Thank you, Mr. Chairman, and I yield back.

Mr. BISHOP. Thank you, Dr. Harris. We are fortunate to have the full committee chair with us, and I would now yield to Chairwoman DeLauro for any opening remarks that she may have. Chairwoman DeLauro, who has been very, very passionate on this issue, and we certainly look forward to hearing your remarks.

The CHAIR. Thank you very, very much, Mr. Chairman, and let me just congratulate you on yesterday's election. It's great to see

you, and as we try to move forward, I want to say thank you both to you and to the acting ranking member, Mr. Harris, for holding what is an important hearing.

And I would particularly thank our witnesses this afternoon for testifying on the infant formula crisis in our country. We are all absolutely shocked by the crisis that's facing America's babies, and for moms and dads, a crisis about safety and supply.

At least two babies died and several others were hospitalized after consuming Abbott's infant formula, and for the past several months, parents all over the country have been struggling to find safe formula to feed their babies. On Monday, I held a roundtable in my district and heard heartbreaking stories of already vulnerable parents scrambling to feed their babies. They reiterated a formula that has been historically difficult to find is now nearly non-existent on shelves. Moms and their advocates fear that babies may become undernourished and develop enduring health problems.

One 19-year-old mother told me that that despite relying on formula to feed her three-month-old baby, she was denied WIC, and was told she should just breastfeed. Like far too many others, she is unable to produce nourishing breastmilk and relies on community support to feed her baby, and now she is struggling to find any baby formula at all.

Also heard from grandmothers who were taking care of their grandchildren and having to take them to the emergency room with vomiting and with diarrhea, and linked directly to the formula that they were taking, Abbott's formula.

Another was a mom of a baby who after eating Abbott's contaminated formula, which was later on the recall list, was sick for eight days in and out of the hospital, and told—and told that her son merely had a virus.

This formula stayed on shelves much longer than it should have. The stories I have heard were absolutely unacceptable, and these same stories are happening in big cities, small towns, rural communities all over our nation. Parents need more help.

As you know, in September 2021, FDA inspectors conducted a routine inspection of an Abbott nutrition facility, where suspicions of wrongdoing were already present. On October 20th, someone working at the facility submitted a whistleblower report to the FDA unveiling a damning list of allegations, asserting that the company lied, cut corners, falsified records to cover up their misdoings.

Not until late December did the FDA interview the whistleblower, and then not until late January was the plant inspected in person. Abbott then issued the recall in February some four months later.

In March, I requested an HHS Office of Inspector General report to look into the tragedy, and then I got ahold of a whistleblower report and submitted it for the record to make it public. Last week, I introduced and the House passed a \$28 million supplemental appropriations bill to give the FDA the resources it needs to address the coming shortage. It is mostly personnel to be able to deal with inspecting facilities, and also to review the infant formula applications that are coming in. They do not have the personnel.

I have no problem faulting the FDA for what they have done, but we cannot compound the problem by not providing resources at this moment for much needed inspection personnel and infant application submission reviewers in order that we know that the products that are coming in are safe, and are—not wanting to move forward on that \$28 million really says a lot about people and their care about what is going on in this—in this space.

At a hearing last week, the subcommittee questioned the FDA Commissioner Califf on FDA's incredibly slow response, which led to Abbott products staying on the shelves longer than they should have and potentially putting even more babies at risk.

In the long term, the FDA must address its longstanding structural issues. I believe we must establish a deputy commissioner for food safety within the FDA. Someone with extensive knowledge, background, and credentials in food safety.

This week I will introduce the Keep Infant Formulate Safe and on the Shelves Act, which addresses the root cause of the crisis, including product safety and supply infrastructure, and I'm moving to deal with the issue of consolidation in the industry, which only allows for four major suppliers, thereby if one is gone, we have this shortage that's been created—that's been created.

Because unfortunately then none of this is new. We recently learned that in 2014, the formula industry deliberately and successfully tried to weaken bacteria testing safety standards. The FDA had proposed rules, a protocol that year to increase the regular safety inspections of infant formula manufacturing facilities to prevent the contamination—the specific contamination that we are discussing today. This very crisis is now facing our nation's babies.

And while the FDA was slow to respond, and I'm going to make a distinction between the FDA and the Biden Administration, because the Biden Administration moved quickly, as did USDA when dealing with waivers for WIC recipients to be able to purchase another product other than the Abbott product.

But the administration put Operation Fly Formula, and the invocation of the Defense Production Act has secured infant formula from FDA regulated facilities to be flown in and imported quickly to meet this urgent need. I will follow up to make sure that they are FDA related—approved facilities.

I am concerned about FDA guidelines, which say that we can entertain other facilities that do not meet the FDA standards. The first batch of that formula arrived quickly. It arrived this week in Indianapolis. More is coming. There's a shipment that arrives at Dulles today. We are—the administration is addressing the critical supply issue while ensuring that the product being manufactured is safe and healthy for our babies.

In the wealthiest nation in the world, babies should not be at risk of going hungry. Parents should not have to play a guessing game and wonder if they are feeding their babies something that is safe. Unfortunately, that is where corporate greed, consolidation of formula production into just four major companies, and a lack of proper oversight have led us.

I hope that our witnesses can help us further understand the impact that this shortage has had on babies and their parents, and what else we can do to prevent this from happening again. I want

to say a thank you to the chairman, who really has moved—speaking about moving quickly, moved very quickly on addressing this issue and calling hearings in order to address it, and also thank the acting ranking member. I yield back.

Mr. BISHOP. Thank you very much, Ms. DeLauro. I don't believe the full committee ranking member is present with us, or I would ordinarily recognize her at this time, but in her absence, I will now recognize our distinguished guest for five minutes for brief oral statements, and then we will proceed with questions.

Without objection, each of your entire written testimonies will be included in the record. So, if you could summarize your testimony within the five minutes, we would most appreciate that. Ms. Chamberlin, welcome, and you are now recognized. Please proceed.

Ms. CHAMBERLIN. Good afternoon, Madam Chairwoman, Chairman Bishop, ranking members Granger and Harris, and members of the subcommittee. Thank you for inviting me to testify.

My name is Sarah Chamberlin, and my younger daughter has the genetic metabolic disorder phenylketonuria, better known as PKU. I am here to share the profound effects of the formula crisis on our family and those like us.

There are very few exactly like us. Of the three and a half million babies born in the U.S. each year, only about 275 are diagnosed with PKU, but let me be clear: this crisis is not limited to infants. There are many others who rely on formula as their lifeline from infancy to adulthood, including thousands with inborn errors of metabolism, GI and allergic disorders. I hope my testimony will amplify their voices.

People with PKU can't metabolize one of the amino acids in protein, which then builds up and acts as a neurotoxin. Babies with PKU are born healthy, and within months if untreated become irreversibly brain damaged. Newborn screening now allows us to detect and begin to treat PKU almost immediately after birth, ensuring normal or near normal health outcomes for these individuals, provided they have lifelong access to medical formula.

My daughter Izzy was diagnosed at six days old, and she'll be nine in August. She is limited to a diet of five grams of protein from food per day, which is the equivalent of about one slice of American cheese. The rest of her nutrition is provided by an Abbott amino acid formula, so it was not part of the recall.

To Izzy, her milk, as she calls it, is her life. It has sustained her since she was an infant, and she knows it. Her health all comes down to the formula. It's essential. It's expensive. It's inconvenient. It tastes awful, but it's what allows her to live a full life, playing softball, learning fractions, and taking jazz dance every Friday. She's relied on it her entire life, and suddenly she can't rely on it.

That's why I'm here today. When the Abbott plant was closed in February, we knew we couldn't risk running out of formula, and that we'd have to transition her to a new brand slowly. Every formula has very distinct tastes. To me, Izzy's tastes like nickels dissolved in sugar, with a fair dash of salt, and the only reason they are tolerable, is because they are necessary, and because patients get used to them over years.

By earlier April, we were at half-new, half-old formula, which was right about when we heard that the new formula we were

transitioning her to was on back order. So, what are we supposed to do now?

We are not alone in our distress. A friend in Louisiana had to ration the formula her daughter gets for a similar disorder. The video she sent me of her usually vibrant, active 12-year-old curled in the fetal position, crying, is heartbreaking.

Last week, two children with short bowel syndrome were hospitalized because without the specialty formula, the only way to keep them alive is IV nutrition. A friend in her 40s with PKU who was without formula wrote, I am a wife and mother.

I am exhausted and having constant migraine headaches and memory issues. I am overwhelmed and emotionally fragile. I am malnourished. The message from our community in short is this, "we are not okay". Chairwoman DeLauro has said that, "parents should not have to choose between the supply of products and food safety. That is unconscionable."

I could not agree more, but in mid-March, the FDA said that patients considering using Abbott metabolic products manufactured at Sturgis between January and March should consult with their healthcare provider in considering whether the benefit of consuming such products outweighs the potential risks of bacterial infection.

The consequences of inadequate medical nutrition are so grave that we really have no choice. My daughter Izzy does not have a choice. Going without her formula would mean temporary disability. It would mean missing the end of her softball season, not mastering fractions, and never perfecting her jazz dance routine for her performance next month. Long term, it would mean permanent brain damage. For people with other similar disorders, it could mean coma and death.

I deeply appreciate the work of the committee to increase immediate supply, and demand accountability from the FDA to avoid a future crisis. As the immediate shortage recedes thanks to this work and the work of your Congressional colleagues in the administration, we must remember that supply is not the same thing as access. In the US today, thousands face huge bills for medical nutrition, the very formula we're discussing today, but their insurance refuses to cover, and this has disastrous consequences for their health.

The Medical Nutrition Equity Act, HR-3783, and S-2013 provides for insurance coverage for these formulas as essential medical treatment. It is critical that you pass the MNEA this year to ensure that everyone has access to the formulas that you are all working so hard to resupply. We need your help. We are not okay. Thank you for your time and consideration today.

[The information follows:]

**Testimony of
Sarah Chamberlin, Executive Director, National PKU News*
The Infant Formula Crisis
May 25, 2022**

* National PKU News is the nation's oldest support and advocacy organization for individuals with Phenylketonuria (PKU) and allied disorders. Before the internet, there were things printed on paper, called newsletters, and this is the source of the organization's name. For 27 years, the organization published a newsletter three times per year to disseminate research, build connections, engage, and educate those with inborn errors of metabolism. The newsletter was discontinued in 2015; the organization continues to provide support and advocacy for the community.

Good morning, Madam Chairwoman, Chairman Bishop, Ranking Members Granger and Harris, and Members of the Subcommittee. Thank you for inviting me to testify. My name is Sarah Chamberlin, and I am the parent of two daughters, one whom I was fortunate to be able to breastfeed for 15 months, and one for whom breast was definitely not best. My younger daughter Isabel is 8 years old and has the genetic metabolic disorder Phenylketonuria, better known as PKU, and I am here to share the profound and severe effects of the formula crisis on our family, and those like us.

To start, there are very few like Isabel: of the 3.5 million babies born in the United States each year, only about 275 are diagnosed with PKU. The fact that we are so rare is another reason I would like to thank you for this invitation: voices from the PKU community are rarely heard on the national stage, and May happens to be PKU Awareness Month. My testimony here will hopefully amplify the voices of tens of thousands of other parents, and patients, who are in desperate need of formula: neonates and newborns; adoptive parents like my dear friends who realized their dream of adoption just over a week ago and were confronted with the formula crisis as they left the hospital with their newborn daughter Annie; and thousands of others with inborn errors of metabolism, GI, and allergic disorders who rely on specialty formula as their lifeline from infancy through adulthood.

People with PKU are unable to metabolize one of the amino acids in protein: phenylalanine or "phe." In unaffected bodies, phe is metabolized into tyrosine, and from there, into key neurotransmitters that regulate mood, executive function, and more. In those with PKU, unmetabolized phe builds up and acts as a neurotoxin, and those key neurotransmitters down the metabolic pathway are never created. Babies with PKU are born healthy, and within months, if untreated, become catastrophically and irreversibly brain-damaged. Before early detection and treatment, thousands were institutionalized, and while they lived typical lifespans, their intellectual development rarely exceeded that of a toddler. The primary treatment for PKU was developed in the 1950s and consists of a diet low in protein (and therefore phenylalanine) and a metabolic formula to provide complete nutrition minus the offending amino acid. It wasn't until the launch of the National Newborn Screening Program in the 1960s, one of this nation's most successful public health programs, that PKU could be detected and treated in a timely enough manner to prevent devastating disability. The core of this treatment remains a lifelong diet of metabolic formula, following this diet *for life* provides normal or near-normal health outcomes individuals with PKU.

This is a photo of Izzy and I in 2013, just after we were woken from a nap by a call from Mt. Sinai hospital, on the sixth day of her life. The next morning, we learned that her diagnosis meant she'd be on a protein-restricted diet for life. My first thought was "thank goodness for newborn

screening.” My second thought was “how does a person live on a low-protein diet? Isn’t protein essential to life?” And I was right: protein is essential for life, but our kid can’t have it—at least not intact protein found in the foods you buy at the grocery store. And you immediately learn that almost *everything* has protein. Izzy’s dietary prescription is about 5 grams of protein from food per day, which is approximately the amount of protein in a handful of Cheddar Goldfish. The only way she gets enough calories & nutrients to thrive is to consume an amino acid formula that contains all the protein she needs, minus the amino acid that is toxic to her body. Isabel actually requires *more* protein than a typical child her age and weight because her body doesn’t absorb protein from formula the same way it would absorb intact protein from food. So we return to the formula: it’s essential for life. It’s expensive. It tastes awful (she can’t drink it from an open cup without retching and still uses a sippy cup at age 8). But it’s available: breakfast, lunch, and dinner, and it keeps her alive, playing softball, learning fractions, and taking jazz dance classes every Friday. It’s available, until it’s not.

And that’s why I’m here today. When the Abbott Nutrition plant in Sturgis, Michigan was closed on February 17th of this year, we knew two things: we couldn’t risk running out of formula, and we couldn’t risk Izzy rejecting a new brand. Izzy has been on Abbott formula practically her entire life, and would probably survive solely on it, and Skittles, if we let her. To Izzy, her “milk” is her life: it is 70% of her nutrition; it has sustained her since she was an infant; and is what she asks for when she needs to recharge physically, emotionally, and psychologically. There are three other major manufacturers of PKU formula, but switching to a new product isn’t like getting a new brand of milk at the store: these formulas have very distinct, often overpowering tastes—to me, Izzy’s tastes like nickels dissolved in sugar, with a fair dash of salt—and the only reason they are tolerable is because they are necessary and patients have become habituated to them over years.

In early March, we started mixing a new brand of formula into Izzy’s daily allotment of 154g of powder (she goes through a can in about 3 days). On the first day, we mixed in 5g, and then waited a few days to see if she would reject it. When she didn’t, we increased the amount every few days. By early April, we were at half new/half old formula. Which is right about when we heard that the new formula we were transitioning her to was on backorder: strained supply lines and an influx of new patients has meant additional pressure on other formula companies, who have yet to catch up. Now we’re stuck in the middle: we can’t rely on an ongoing supply of her old formula, and, at this point, we can’t get any more of her new formula either. We’re making do, counting the cans in the pantry and the days on the calendar, and hoping that at some point something will change. And that is not a comfortable place to be. While I realize there are legal and regulatory considerations, it’s been more than three months, and neither Abbott nor the FDA can give a clear indication when the factory will resume production, and how soon we can count on a steady supply of metabolic and specialty formula. I’m not asking for a magical solution; I’m asking for help in understanding how we got to this point, and how we can prevent a similar crisis in the future, because lives are at stake.

We’re not alone in our distress: a friend in Louisiana was forced to ration the amount of formula her daughter gets to treat Tyrosinemia, a similar disorder, after spending weeks trying to transition her to another formula; the video she sent me of her usually vibrant, active, 12-year-old curled in the fetal position, crying, refusing the new formula, is heartbreaking. Last week, two children with Short Bowel Syndrome were hospitalized because without their specialty formula, the only way to

keep them alive is IV nutrition. And it's not just children. A friend in her 40s with PKU whose formula is unavailable because of the shortages wrote: "I am a wife & mother. Right now I am exhausted, I'm having almost constant migraine headaches. I am having memory issues. I am overwhelmed and emotionally fragile. I am malnourished!" The message from our community in short is this: this is not OK. We are not OK.

Congresswoman DeLauro has said "parents should not have to choose between the supply of the product and food safety. That is unconscionable." And I completely agree. Yet, that is exactly the choice we are faced with. In mid-March, the FDA addressed the particular risk to individuals on specialty and metabolic formulas with the following statement regarding consuming Abbott specialty products that were already in circulation, or that might be released:

Those seeking access should consult with their healthcare provider in considering whether the benefit of consuming such product outweighs the potential risk of bacterial infection in the user's particular circumstances.

This is an impossible choice for a parent to have to make for their child, or an adult to make for themselves. These disorders are difficult enough to manage, and the consequences of inadequate treatment so grave, that we really have no choice: thousands of us assumed the potential risk of consuming these products, because the risk of going without medical nutrition is so much worse. For Izzy, not having formula would mean that within days she'd begin to break down emotionally, psychologically, and physically. Imagine getting only 30% of your nutrition and calories day after day, and having your brain chemistry upended by dangerous imbalances in the neurotransmitters that regulate every aspect of your functioning. For Izzy, this would mean temporary disability. It would mean missing the end of her softball season, not mastering fractions, and never perfecting that jazz dance routine for her performance in mid-June. For people with other similar disorders, it could mean coma and death.

And so we return to the formula. In recent weeks, we've all been talking a lot about the supply of formula. And in the short term, that's the most important thing: making sure that there is sufficient supply for everyone who needs it. **But supply and access aren't the same thing, and I don't want to lose sight of that.** Of the approximately 17,500 people diagnosed with PKU since Newborn Screening began, 40% of them (~8,000 people) are lost to care. This means they are untreated, not seen by specialists, without formula or medical foods, and suffering the effects of their disorder, getting worse every day. The reasons for this are myriad: standards of care for PKU were revised in the 1990s and the dietary restrictions are difficult, time-consuming, and almost untenable for an adults. However, the largest percentage of this group is likely lost to care because of one simple reason: they cannot afford that care. My daughter weighs 62 pounds and is just over four feet tall. Her insurance is billed \$1,674.16 per month for her formula, an amount that will increase with age and weight. We're lucky that as of today, our health plan covers most of it, but there is no guarantee that this will continue. The state-based laws that govern medical nutrition coverage are at best inadequate, at worst, discriminatory, and leave behind so many: even when states do require coverage, there are exceptions based on age, gender, insurance type, income, formula type, and diagnosis. In some states, formula is covered only until the age of one, or, in my least favorite example, until "child-bearing age," defined as 34 (both of my children were born after I turned 34). Speaking of children, women with PKU are at risk of Maternal PKU Syndrome

when they don't get enough medical nutrition. Effects on the fetus can include intrauterine growth restriction, microcephaly, heart defects, and increased risk of miscarriage. No matter where you live, self-insured plans aren't bound by state insurance mandates, and all these loopholes mean that tens of thousands who require medical nutrition—the very formula we're discussing today—don't get coverage for it. The entire premise of the Newborn Screening Program is that we only screen for disorders we can treat. Babies born with PKU can and should be treated throughout their lives, but when we fail to provide access to medical nutrition to those who need it, we undermine the life-saving promise of the Newborn Screening Program. That is why I am asking that you not only continue to address the formula shortage, but that you also pass the Medical Nutrition Equity Act (HR3783/S2013) this year. This legislation will provide a Federal floor of coverage for medical nutrition administered under the care of a physician for disorders which often have no other treatment.

I deeply appreciate the work of this Committee to respond to the current crisis with efforts to increase immediate supply and impose reporting requirements on the FDA so that such a situation never reoccurs. **As the immediate shortage recedes thanks to this work, and the work of Congress and the Administration, we must keep in mind the crisis of access will not end for our community when supply resumes.** Thousands of Americans with inherited metabolic disorders, and allergic and gastric conditions who rely on specialty formulas have been in crisis for a very long time. **They need your help. It is critical that you pass the Medical Nutrition Equity Act this year to ensure there is long-term access to these specialty formulas that you are working so hard to restore to the shelves.** Thank you for your time and consideration today.

Mr. BISHOP. Thank you, Ms. Chamberlin. Mr. Gay, you are now recognized for five minutes.

Mr. GAY. Thank you.

Mr. BISHOP. You may begin.

Mr. GAY. Good afternoon, Chairman Bishop, ranking member Harris, and members of the Agricultural Appropriations Subcommittee. My name is Michael Gay, and I currently manage Food Fresh, and independent, locally owned grocery store in Claxton, Georgia.

It's an honor and privilege to speak with you today. I am testifying on behalf of the National Grocer's Association, the trade association representing the independent grocery stores. My store, Food Fresh, is the only grocery store in Evans County. We work very hard every day to make our community better and our store conditions wonderful.

The formula shortage has hit our community hard. Moms and families are worried about where their child's next meal will come from. I've had to put limits on formula that customers can purchase in my store. This is heartbreaking to do, and so many families are in such great need. My managers have had to personally manage formula stock in my stores because demand has been so great. I had seven phone calls just yesterday asking if we had a specific type of formula in the store.

When I told most of the moms that the formula they were asking for was not available, but I did have it in a different brand, they were very scared to switch, because they didn't understand that the formulas are very, very similar.

These are examples of what I've seen happening in my store. I would like to share a little bit about what the members of NGA are experiencing. In a survey of its members, NGA found that most stores are dealing with significant formula shortages. The vast majority are unable to access specialty formula. They are receiving inconsistent information from state WIC agencies, and customers are panic buying.

These stories are all very important context for what I believe is critical to recognize, the role that WIC is playing in this shortage. WIC purchases account for more than half of the formula sold in the United States. Therefore, WIC is ever present in the infant formula discussions for retailers.

WIC is an essential program for families in my community. It provides supplemental nutrition to moms, babies, kids, and we are honored to be able to provide this program. WIC is not a money maker for retailers. In fact, it's the opposite. Many stores actually lose money as WIC vendors, but it is an important community service that we participate in to ensure that our families get the resources that they need to raise healthy kids and future leaders.

Independent community grocers play an essential role as the private partners in the public/private partnership of WIC. But as it exists today, WIC is very burdensome for retailers to offer this program. I'm going to share a few opportunities for improvement to consider avoiding future disruptions of WIC products like infant formula.

First, WIC's rigid rules have made it difficult for the program to be responsive to critical shortages throughout the pandemic and

now during the formula crisis. Substitutions may be easily available when situations like this arise. The emergency waivers instituted by the USDA during the pandemic have provided flexibility in some states, but those waivers were only available because of the pandemic.

To prevent this issue from happening in the—happening in the future, Congress should allow WIC vendors operating during severe supply shortages, disasters, or public health emergencies, areas to automatically substitute limited WIC approved products impacted by supply chain disruptions.

The USDA should direct states to include product substitutions for WIC in their emergency preparedness plans. These changes would have allowed families to immediately switch to another formula in states with shortages, allowing for a smoother continuation of feeding infants.

Secondly, there is a significant need for USDA to examine the long-term effects of cost containment, competitiveness, and peer grouping formula for WIC vendors. States operate a peer group system to monitor vendor prices and determine reimbursements are cost competitive. These cost containment measures have led to reduced retail imbursement, and reduced retailer participation in a program leading to fewer locations for families to access formula.

Additionally, the WIC infant formula cost containment measures have led to extreme consolidation in the formula marketplace, leaving it highly vulnerable to supply disruptions like we are experiencing now.

These contracting policies must be reviewed to ensure future food security of the nation's babies and families. Finally, the FTC announced they are launching an inquiry into the ongoing shortage of infant formula. NGA supports getting to the bottom of this issue to ensure that it never happens again.

In conclusion, we want to work to maintain our strong existing public/private partnership with the WIC program, and continue to serve our rural and urban families. We all know that infant formula is a necessity for babies to grow and thrive. Let's all work together to get these babies fed and ensure that this never happens again. Thank you all for the opportunity to discuss this important issue today, and I look forward to any questions you might have.

[The information follows:]

Testimony of Michael Gay
Owner and Manager, Food Fresh, Claxton, Georgia
On Behalf of The National Grocers Association
The Infant Formula Crisis
May 25, 2022

Good afternoon, Chairman Bishop, Ranking Member Harris, and Members of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Subcommittee. My name is Michael Gay, and I currently manage Food Fresh, an independent, locally-owned grocery store in Claxton, Georgia. It is an honor and a privilege to speak with you today.

I am testifying on behalf of the National Grocers Association, the trade association representing the independent supermarket industry. NGA represents the 21,000 independent community grocers and the wholesalers that service them. Independent community grocers account for 33 percent of all grocery sales, exceeding \$250 billion, and more than 1 million American jobs. We are inherently tied to the strength and vitality of the markets we serve – at the heart of local communities and the U.S. economy. Independents provide jobs and boost local tax revenues while bringing choice, convenience, and value to hard-working Americans.

My store, Food Fresh, is the only grocery store in Evans County, Georgia. We work hard every day to make our community better, including accepting both SNAP and WIC programs in our store. We often serve customers working overtime or two jobs to make ends meet. For these customers, every minute they spend with their children is precious, whether it's helping them with homework or discussing their day. The shortage of infant formula has been playing out in my store for weeks. Moms and families are worried about where their child's next meal will come from and with infants, formula is often the only food they can eat. This shortage is causing families to spend less time with their kids and more of their limited time and resources searching for infant formula.

I have had to put limits on the number of formula canisters customers can purchase in my store. This is heartbreaking to do and enforce when so many families are in such great need. My manager has to personally manage the formula in my store because the demand is so great. I had seven phone calls yesterday asking if I had a specific brand formula in store. When I told moms that I had the same type of formula in a different brand, they were scared to switch because they did not understand that the formulas are very similar.

These are examples of what I have seen happening in my store. I would like to share a little bit about what the members of the NGA are experiencing. In a survey of its members, NGA found that most stores are dealing with formula shortages, the vast majority are unable to access specialty formulas, they are receiving inconsistent information from state WIC agencies, and consumers are panic buying at their stores. Scared families are stocking up on formula for their own children or grandchildren, driving long distances to purchase formula, or having family members in other cities purchase formula for them and ship it to them. All these purchases, which are often larger than normal, are contributing to making the situation worse.

These stories are all important context for what I believe is critical to recognize, the role that WIC is playing in this shortage. WIC purchases account for more than half of the formula sold in the United States, therefore, WIC is ever present in infant formula discussions for retailers.

WIC is an essential program for families in my community and communities around the country. It provides supplemental nutrition to moms, babies, and kids and we are honored to be able to provide this program for the families in our community. WIC is not a money maker for retailers – in fact, it's the opposite. Many stores actually lose money as WIC vendors. But it is an important community service, and we participate to ensure our families get the resources they need to grow healthy kids and future leaders.

Independent community grocers play an essential role as the private partners in the public-private partnership of WIC. Without independent grocers' involvement in WIC, the program would simply not operate effectively and many families in need would be left behind. But as it exists today, WIC is very burdensome for participating vendors and is dominated by red tape and regulations that make it difficult for retailers to offer the program. I'm going to share a few opportunities for improvement that we believe would be important consider for the long-term to help avoid future disruptions to the availability of WIC products like infant formula.

First, WIC's rigid rules have made it difficult for the program to be responsive to critical shortages throughout the pandemic and, now during this formula crisis. Recently, I often have not had enough formula for a mom to fill her prescription when she comes into the store. While Georgia will be implementing electronic WIC in the coming months, currently, families are still using paper vouchers to access their WIC benefits in stores. If a mom comes to my store with a prescription for four cans of formula, and I only have two cans on the shelf, she can only get two cans for the month because she must turn in her prescription voucher with her purchase. She cannot return later to purchase the other two cans.

The lack of e-WIC is also leading to the inequitable distribution of formula to families. Because I'm trying to make sure everyone has access to at least some formula, I have limited how much families can purchase at one time. We cannot limit WIC moms because they can only purchase one time per month, which has led to WIC moms being able to purchase more formula than non-WIC moms. Since Georgia is a Mead Johnson state, the formula shortage has taken longer to materialize but we are seeing this issue getting worse quickly. It took until this week to approve substitutions. We are hoping that the manufacturers will support these changes and allow for substitutions moving forward.

Substitutions must be made easily available when situations like this arise. The emergency waivers instituted by the USDA during the pandemic have provided flexibility in some states, but those waivers are only available because of the pandemic. And in states like Georgia, the flexibilities have taken way too long to be applied.

Retailers have experienced difficulties keeping WIC-approved foods and formula in stock after natural disasters due to infrastructure and transportation issues, and during the onset of the COVID-19 pandemic due to high demand. This created situations in which WIC participants were unable to purchase certain products on their prescription lists until a waiver request has been submitted by the state WIC agency and approved by the U.S. Department of Agriculture

(USDA), which takes time. Unfortunately, this often leads to WIC participants walking away from the store without their prescribed products in hand.

To prevent this issue from happening in the future and to create a more efficient product substitution process, Congress should allow WIC vendors operating during severe supply shortages, disasters, or public health emergency areas be provided flexibility by permitting substitution for certain WIC-authorized items that are unavailable. The flexibility should be automatic and limited to WIC-approved items impacted by supply chain disruptions. The USDA should direct states to include product substitutions for WIC in their emergency preparedness plans. These changes would have allowed families to immediately switch to another formula in states with shortages contracts allowing for the smooth continuation of feeding for infants.

Second, there is also a significant need for USDA to examine the long-term effects of cost containment, competitiveness and peer grouping formulations for WIC vendors. States operate a peer group system in which retailers participating in WIC are grouped together to monitor vendor prices, to determine that reimbursements to stores reflect prices in like stores, and to ensure that prices are cost competitive. When these groups are not updated in a timely manner, they lead to reduced reimbursements for retailers even if their situation has changed. There have also been situations where states have not been transparent about their peer groupings and technical definitions that determine the peer groups leading to misaligned prices and losses for stores. For these reasons, more clarification and direction from states is needed on the formulation of WIC peer groups. USDA should direct states to notify retailers which peer group they are in, and the criteria used to determine it. States should also be directed to publicize the methodology used to determine peer groups. These cost-containment measures have led to reduced retailer reimbursement and reduced retailer participation in the program leading to fewer locations for families to access formula.

Additionally, the WIC infant formula cost containment measures have led to extreme consolidation in the formula marketplace, leaving it highly vulnerable to supply disruptions like we are experiencing now. These contracting practices must be reviewed to ensure the future food security of the nation's babies and families.

Yesterday, the FTC announced they are launching an inquiry into the ongoing shortage of infant formula. It is important that we get to the bottom of this issue to ensure that it never happens again. NGA is supportive of this inquiry and is willing to support the FTC efforts however possible.

Finally, retailers participating in WIC programs that have not transitioned to e-WIC often take a loss when wholesale prices increase in infant formula because the increase in cost to the store goes into effect immediately, while the increase in reimbursement to the retailer may be reflected several months to over a year later. A timelier reflection of formula price increases in the reimbursements to stores is needed to ensure small rural stores can afford to continue participating in the WIC program.

In conclusion, we want to work to maintain our strong existing public-private partnership with the WIC program and continue to serve our rural and urban families and babies. We hope to work with you to improve the WIC program and increase access to infant formula for both families and retailers.

We commend Congress for recent efforts to support a White House Conference on Food, Nutrition, Hunger, and Health. NGA plans to participate in this conference and we expect to support these WIC reform proposals as part of our recommendations for the conference.

We all know that infant formula is a necessity for babies to grow and thrive. Let's all work together to get these babies fed and ensure that this never happens again. Thank you for the opportunity to discuss this important issue today. I look forward to your questions.

Mr. BISHOP. Thank you very much, Mr. Gay. Ms. Carney, you are now recognized.

Ms. CARNEY. Thank you, good afternoon Chairs DeLauro and Bishop, and ranking member Harris. Committee members, and my fellow distinguished panelists, I am honored to have the opportunity to speak before you today.

My name is Ginger Carney. I am a registered dietician nutritionist, and international board certified lactation consultant, and director of clinical nutrition and lactation services for St. Jude's Children's Research Hospital in Memphis, Tennessee.

I'm here today on behalf of the Academy of Nutrition and Dietetics, which represents more than 112,000 nutritional professionals. As the immediate past president of the Tennessee Academy of Nutrition and Dietetics, I'm prepared to give you a sense of how this crisis is impacting families across the country.

No child should face hunger because of safety and supply shortages. Since February 2022, dieticians have been working around the clock to determine appropriate and safe formula alternatives for patients impacted by the current shortage. I have experienced the devastation the formula supply chain disruptions has placed on so many families, even in my own home town.

In my role in a pediatric research hospital, we have experienced shortages in our interval feeding formulas, or formulas provided through a tube for those children who cannot or will not eat enough to sustain them.

Many of our patients are children with cancer, who cannot tolerate certain foods because their digestive systems have been compromised by chemotherapy and radiation, causing them to rely on specialized formula for their nutrition needs.

The clinical dieticians on my staff have had to draw on their extensive expertise to recommend the appropriate tube feeding formulas to provide optimal nutrition support while monitoring tolerance in these children that we serve here at St. Jude.

Dieticians around the country can spend hours on the phone every day speaking with vendors to try to find formula for their patients. One colleague of mine in Miami, Florida, reported that parents will file prescriptions to pharmacies, but it may take up to one month before a shipment is received, and then there is no guarantee that an ongoing supply of formula will be there.

Recently in Memphis, two children were admitted to our local pediatric hospital with dehydration caused by intolerance to a formula which had been substituted for their regular, specialized formula. Caregivers are at their wit's end, and feel that they must find something to feed their children.

When an infant is hungry, or a child is dependent on a specialized feeding, it can be life threatening when these needed formulas are not available. In February of 2022, a colleague in Florida met with first time parents of a set of premature 10-month-old twins in her clinic. At the time of this visit, she observed that the babies were behind developmentally, and not yet able to eat solid foods. So, it was recommended that they continue their hypoallergenic formula to meet a hundred percent of their nutritional needs.

When the formula became unavailable, the parents began giving the babies almond milk, thinking this was an appropriate substi-

tution. The switch to almond milk caused a reduction in the babies' calorie intake by nearly 60 percent. The babies eventually became lethargic and malnourished, leading to an emergency hospital admission.

Imagine having to worry that you might not be able to keep your baby fed as your last can of formula is almost empty. Parents are driving for hours to nearby towns to find formula, and many families are not even able to do this given financial or geographic limitations.

So this crisis is disproportionately impacting low income and rural families. My WIC colleagues in Louisiana and Tennessee have similar experiences fielding phone calls from panicked caregivers. Some WIC dietitians are even riding around their cities to take pictures of store shelves to advise their clients which store has the formula that they need in stock.

One mother remarked that she was petrified that any formula she found could be contaminated. We appreciate that members of Congress are taking action, but more needs to be done. Our Government needs to do more to help new moms establish and maintain breastfeeding, even if they return to work or school. But when that is not possible, there has to be systems set up so that we never experience this kind of formula crisis ever again.

Our recommendations include first, we know the importance of the first 1,000 days of life for long term health outcomes. We must track the cohort of children experiencing this crisis and determine the short and long term impact on their medical outcomes and nutrition security. To date, we are not aware of any efforts to formally document this.

Second, other developed countries seem to have managed any shortages without significant issues. We must learn from others and revisit the laws and regulations to ensure a stable supply in our country in the future. This includes a thorough examination from production and oversight to access and affordability.

And third, insurance companies must reduce the burden required for treatment authorization for non-formulary infant formulas. I want to thank everyone for your time and consideration today, and I'm happy to answer any follow up questions. Thank you so much.

[The information follows:]

**Statement for the Record of
Ginger Carney, MPH, RDN, LDN, IBCLC, RLC, FILCA, FAND
Immediate Past President, Tennessee Academy of Nutrition and Dietetics
The Infant Formula Crisis
May 25, 2022**

Chairs DeLauro and Bishop, Ranking Members Granger and Harris, committee members and my fellow distinguished panelists: I am honored to have the opportunity to speak before you today.

My name is Ginger Carney, I am a registered dietitian nutritionist, an International Board-Certified Lactation Consultant, and director of Clinical Nutrition and Lactation Services for St. Jude Children's Research Hospital in Memphis, Tennessee.

I am here today on behalf of the Academy of Nutrition and Dietetics, which represents more than 112,000 registered dietitian nutritionists; nutrition and dietetics technicians, registered; and advanced-degree nutritionists. As the current infant formula supply shortage continues, Academy members are on the frontlines to serve communities across the country. As the Immediate Past President of the Tennessee Academy of Nutrition and Dietetics and a current member of several Dietetic Practice Groups focusing on key areas of nutrition care, including the Pediatric Nutrition Dietetic Practice Group and the Women's Health Nutrition Dietetic Practice Group, I am prepared to give you a sense of how this crisis is impacting infants, young children and families including some of our most vulnerable populations like WIC recipients and those with metabolic disorders – where we know the first 1,000 days of life are critical for setting them up for long term health. We need to do more to address this crisis and to prevent it from happening in the future.

No infant should face hunger and food insecurity because of safety or supply shortages. Since February 2022, dietitians have been working around the clock to determine appropriate and safe formula alternatives for patients impacted by the current shortage. I have experienced the devastation the formula supply chain disruption has placed on so many families in my hometown of Memphis, Tennessee.

This crisis is not only impacting infants – there are many children who require special feedings and rely on therapeutic formulas meet their nutritional needs to thrive and for adequate growth. In my role in a pediatric research hospital, we have experienced shortages in our enteral feeding formulas, or formulas provided through a tube for those children who cannot or will not eat enough to sustain them. Many of our patients are children with cancer who cannot tolerate certain foods because their digestive systems have been compromised from chemotherapy and radiation causing them to rely on specialized formula for their nutrition needs. The clinical dietitians on my staff have had to draw on their extensive expertise to recommend the appropriate tube feeding formulas to provide optimal nutrition support while monitoring tolerance for the children we serve at St. Jude.

Dietitians may spend hours on the phone every day, speaking with representatives to try to find formula for their patients. One colleague in Miami, Florida, reported that parents will file prescriptions to pharmacies and it may take up to one month before a shipment is received and

there is no guarantee when the formulas will be back in stock. Another dietitian from Kansas shared that babies with intolerances have been significantly impacted with the shortage and at risk of poor growth, gastrointestinal problems, and even severe dehydration, a pediatric emergency, if parents modify recipes or attempt to make their own formula.

In fact, this exact event happened in Memphis just recently when two children were admitted to our local pediatric hospital with dehydration caused by intolerance to a formula which had been substituted for their regular specialized formula because of unavailability. Parents and caregivers are at their wits' end and feel that they must find something to feed them – when an infant is hungry or child is dependent on a specialized feeding, it can be life-threatening when needed formulas are not available.

Many times, with an abrupt formula change, patients may experience intolerance which can cause gastrointestinal upset, dehydration and electrolyte imbalance. Long-term complications like this can lead to poor growth and even serious metabolic issues.

A fellow Academy member who works in a children's hospital shared this story of a family she met with in February 2022, three weeks before the formula recall. First-time parents to a set of premature, 10-month-old twins came into her clinic for a routine follow-up.

At the time of this visit, the babies were behind developmentally in eating solid foods, so 100% of their nutrition was still coming from a formula that was recalled as a potentially contaminated formula. When they learned they could no longer use this formula, they switched to almond milk – they thought that almond milk would be a good alternative because the formula they were on previously was hypoallergenic. Unfortunately, this is not the case.

The switch to almond milk reduced the babies' calorie intake by nearly 60%. The babies were immediately admitted as high-risk patients to the hospital during their follow-up visit – they were incredibly lethargic and severely malnourished after receiving almond milk at a 60% calorie deficit for three weeks.

I'm sure many of you understand just how stressful it is to be a parent. Imagine having to worry that you might not be able to keep your baby fed as your last can of formula is almost empty. Parents are driving for hours to nearby towns to see if even one or two cans of their baby's formula is on store shelves. As you can imagine, many families are not able to do this given financial or geographic limitations, so this crisis is once again disproportionately impacting low income and rural families.

My colleague in Louisiana who works for WIC shared that she is spending all day fielding phone calls from panicked and desperate parents looking for infant formula.

A dietitian with the WIC program in Nashville told me that now her job now entails riding around the city on a daily basis to take pictures of store shelves so that she and her staff can advise their clients which store has the formula they need in stock. One of the mothers she serves told her that she was petrified that any formula she gave her baby could be contaminated.

My Tennessee colleague also told me that she is seeing an increase in an interest with expectant mothers to seriously consider breastfeeding considering the formula crisis. To assure nutrition for their infants, some mothers are re-lactating which is no easy task. My own niece delivered a baby earlier this month and her desire to breastfeed was confirmed because of the shortage of formula. Fortunately, she refused formula discharge gift bags that were brought to her upon discharge which could have interfered with the establishment of successful breastfeeding. Traditionally formula gift packs are given to all new moms, whether breastfeeding or not.

The health, growth and development of America's youngest citizens are at risk due to the formula shortage. We appreciate that members of Congress are acting now to ramp up production and increase the supply by providing flexibilities and increasing funding. However, we are concerned about the impact of this crisis and how we will measure that as well as prepare appropriately to prevent this from happening in the future.

First, we know the importance of the first 1,000 days of life for long term health outcomes. We must track the cohort of infants experiencing this crisis and determine the short- and long-term impact on their medical outcomes and nutrition security. To date, we are not aware of any efforts to formally document this.

Second, we have not heard that this has happened anywhere other than in the United States. Other developed countries seemed to have managed any kinds of shortages without significant issues. We must learn from others and revisit the laws and regulations to ensure a stable supply in the future. This includes a thorough examination from production and oversight to access and affordability. We cannot let this happen again.

And third, insurance companies must reduce the burden required for treatment authorization for non-formulary infant formulas.

Thank you, once again, Chairs DeLauro and Bishop, Ranking Members Granger and Harris, and all committee members for your time and consideration. I would be happy to respond to any questions that you may have.

Mr. BISHOP. Thank you very much, Ms. Carney. Mr. Ronholm, you are now recognized for five minutes. You may proceed.

Mr. RONHOLM. Thank you, Chairman Bishop, and Chairwoman DeLauro, Dr. Harris, subcommittee members. Thank you for the opportunity to testify today. When a root cause analysis of this crisis is conducted, there will be several issues that will be examined to determine the contributing factors.

First and foremost, the actions of Abbott will need to be thoroughly reviewed, especially given the allegations contained in the whistleblower report. Another factor is what impact did market concentration have in causing this problem?

However, I would like to focus my testimony on how the structure, governance, and performance of the FDA approved program impacted the infant formula problem. A timeline of FDA's actions throughout the infant formula situation is attached as part of my testimony. As you will see, there are numerous questions that many of you in Congress have, and many consumers have about whether FDA performed its regulatory role effectively.

The evidence suggests that the agency was too slow to act, failed to take this issue seriously, and was not forthcoming with information to parents and caregivers. The infant formula crisis exposed a greater structure and culture problem that has long existed at FDA.

This was merely one symptom of the overall problem, and it is clear that confidence in the food program at FDA is eroding. A big reason for this is the food program has second class status within FDA, and it's resulted in serious problems.

The FDA also lacks a single, full time, fully empowered expert leader of all aspects of the food program. As you know in recent decades, most FDA commissioners have been medical specialists who naturally focus on the programs impacting medical products. This is certainly warranted considering the impact these programs have on public health, and the pandemic as a perfect example of this.

However, this usually results in intense competition for the commissioner's time and support, and focus on the food program is typically what has suffered under this dynamic. It has become impossible for an FDA commissioner to possess the bandwidth to provide leadership and accountability to a set of offices that regulate 80 percent of our food supply.

It is this fragmented structure that led an unprecedented coalition of consumer groups, industry trade associations, and state and local regulators to join together recently to call on FDA to unify the food program under a deputy commission for food.

This position would have accountability to the commissioner, and direct line authority over CFSAN, VCM, and the food related operations of ORA. This will bring focused leadership and accountability to the food program.

The current fragmented structure of the food program results in delays in making compliance decisions, including recalls. Congress and the HHS Inspector General should investigate how this fragmented structure in leadership affected its response to the Abbott infant formula problem.

Perhaps sensing this frustration, Dr. Califf recently announced the appointment of Dr. Janet Woodcock, FDA's principal deputy commissioner, to oversee several parts of the FDA, including the major food program offices. This is another issue where consumer groups and industry agree, this move is disappointing and needs reconsideration.

Dr. Woodcock's extensive FDA career has focused on policies impacting medical products, but she has no notable food policy credentials. Plus, this new arrangement provides no integration or accountability, and no expert leader. It virtually ensures that the food program will continue to have second class status.

Another area where there are serious questions is how funding is allocated within the FDA food program. This is an issue that Chairwoman DeLauro and Chairman Bishop have led in seeking these answers. ORA, which is responsible for inspections and compliance, receives approximately 70 percent of all FDA food program funding, and despite the funding increases Congress has provided, ORA's domestic food inspections have declined in the years following the enactment of the Food Safety Modernization Act, and before the pandemic shutdown.

So the question this subcommittee needs to be asking about ORA, or, how does ORA allocate food program funding, and is ORA making the best use of these resources? We are fortunate to have a person with immense expertise and abilities like Dr. Califf serving as FDA commissioner. His recent testimony about investing in technology to leverage oversight activities certainly makes sense. However, investing in technologies and implementing structural changes for better governance are not mutually exclusive opportunities. We are not going to algorithm our way out of the existing problems in the FDA approved program, and we also need structural changes and stronger leadership that places a great emphasis on food policy. Thank you for the opportunity to testify today, and I look forward to your questions.

[The information follows:]

**Statement For the Record of
Brian Ronholm, Director of Food Policy, Consumer Reports
The Infant Formula Crisis
May 25, 2022**

Chairman Bishop, Dr. Harris, and Subcommittee members, thank you for the opportunity to appear before you today to discuss the factors that contributed to the current shortage of infant formula products in the U.S. and the impact it is having on American families and consumers.

Founded in 1936, Consumer Reports is an independent, non-profit and non-partisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, Consumer Reports advocates for laws and company practices that put consumers first. We are dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

FDA Governance and Performance

When a root cause analysis of the infant formula shortage is conducted, there will be several issues that will be scrutinized to determine what may have contributed to it. First and foremost, the actions of Abbott will need to be thoroughly reviewed, especially given the allegations outlined in the whistleblower report. Another factor to be studied is what impact did market concentration have in causing and exacerbating the infant formula crisis.

However, I would like to focus my testimony on the issue that is most relevant to this subcommittee's jurisdiction, and that is how the organizational structure, governance, and performance of the FDA food program impacted the infant formula recall.

A timeline of FDA's actions throughout the infant formula situation is attached as part of my testimony. As you will see, there are numerous questions that many of you in Congress have – and many consumers have – about whether FDA performed its regulatory role effectively throughout this process. The evidence seems to suggest that the agency was too slow to act, failed to take this issue seriously, and was not forthcoming with information to parents and caregivers.

There are many stakeholder groups in the food policy community who believe that the infant formula crisis exposed a greater organizational structure and culture problem that has long existed at FDA. The infant formula crisis is merely one symptom of the overall problem and it is becoming increasingly clear that confidence in the FDA food program is eroding among consumers, industry, states and other stakeholder groups.

Fragmented Structure and Poor Governance

A significant reason for the diminished confidence is that the FDA food program has second class status within the agency and it has resulted in serious problems relating to its structure, governance and performance. Another primary reason is the FDA lacks a single, full-time, fully empowered expert leader of all aspects of the food program.

As you know, in recent decades, most FDA commissioners have been medical specialists who naturally focus on the programs impacting medical products. This leadership focus is certainly warranted considering the significant impact these programs have on public health, and the pandemic provides an example of this.

However, this usually results in intense competition for the commissioner's time and support, and focus on the food program is typically what has suffered under this dynamic. It has become virtually impossible for an FDA commissioner to possess the bandwidth to provide strategic leadership and management accountability to a large set of offices that regulate 80 percent of our food supply.

The lack of a single full-time leader affects all aspects of FDA's food program. In addition to the infant formula recall situation, the most significant is the effect of these issues on the implementation of the Food Safety Modernization Act (FSMA).

The success of FSMA depends on all major food program units – Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) – working together with state partners and with a common strategic direction, clear priorities, sound resource management, and internal accountability.

Success also requires transparency and robust engagement with consumers, industry, states, and other stakeholders. This is an element that is currently lacking with the FDA food program.

It is this fragmented structure and dynamic in the FDA food program that led an unprecedented coalition of consumer groups, industry trade associations and state and local regulators to join together recently to call on FDA to unify the food program under a deputy commissioner for foods. This position would have accountability to the commissioner and direct line authority over CFSAN, CVM, and the food-related components and operations of ORA. The coalition letter urged Commissioner Califf to immediately appoint someone with relevant and appropriate food credentials.

In addition to bringing focused leadership and accountability to the FDA's food program internally, a unified structure and a full-time senior expert leader would strengthen the program's standing externally and its ability to be in effective dialogue with its many stakeholders.

While typically many of the organizations that sent the letter may not agree on a number of issues, we do agree that there are serious problems within FDA's food program as it relates to organizational structure, governance and performance. We are aligned on the importance of the food program for protecting consumers and the ability of the food industry to operate effectively.

The fragmented structure and framework of the food program results in delays in making compliance decisions, including recalls. **Congress and the HHS Inspector General should investigate how FDA's fragmented structure and leadership affected its response to the Abbott infant formula problem.** The duplicative multiple compliance and recall groups within each part of the food program and the lack of unifying leadership often result in these delays and an overall lack of urgency.

FDA's Recent Appointment of a Food Program Overseer

Perhaps sensing this frustration, Dr. Califf recently announced the appointment of Dr. Janet Woodcock, FDA's principal deputy commissioner, to oversee and provide strategic counsel to seven parts of the FDA, including the major food program offices – CFSAN, CVM, and ORA.

This is another issue where consumer groups, industry and state and local regulators agree – this move is disappointing and needs reconsideration. Dr. Woodcock's extensive FDA career has focused on policies impacting medical products but she has no significant food policy credentials or standing in the food policy community. Appointing someone with a medical products background to oversee the food program is a solution that demonstrates the insular and dismissive approach that FDA too often takes toward the food program; it virtually ensures that the food program will continue to have second class status at FDA.

From an operational perspective, this new arrangement does not provide any food program integration, no full-time food expert leader, and no more genuine accountability for ORA, CFSAN and CVM than what exists now. Dr. Woodcock's new role goes far beyond the food program, including leadership of the commissioner's signature digital transformation initiative and oversight of all of FDA's budget and administrative program. It is not plausible that she or anyone would have the capacity to provide meaningful operational accountability or provide the sustained leadership required for the culture change that is needed in the food program.

FDA Resource Management and Food Program Funding Transparency

Another area of broad general agreement among stakeholder groups is the need for increased funding for the FDA food program to fulfill its mission. This subcommittee, and Congress in general, has provided considerable funding for the food program, especially for the implementation of the Food Safety Modernization Act (FSMA).

However, the current fragmentation of the food program and the lack of a single, empowered full-time expert leader has caused delays in the implementation of FSMA and questions about how funding is allocated within the FDA food program. This is an issue that Chairwoman DeLauro and Chairman Bishop have led in seeking these answers.

The essence of FSMA was calling for a shift in FDA's culture from one that reacted to food safety situations to one that focused on prevention. This is most critically needed in ORA, which is responsible for inspection and compliance, and receives approximately 70 percent of all FDA food program funding.

ORA is viewed historically as an insular organization that resists change, does not transparently share food resource and program data with food policy leaders in CFSAN and CVM. Under the current governance structure, ORA makes unilateral, unaccountable resource allocation decisions that have resulted in a large overhead structure. Only about a third of its resources are allocated to its food safety and compliance activity.

Despite the funding increases Congress has provided, ORA's domestic food inspections declined by 30 percent in the years following the enactment of FSMA and before the pandemic shutdown in March 2020. ORA also significantly reduced FDA-funded state inspections, which can be conducted at a lower cost.

ORA also has taken a dismissive approach to the inspection mandates under FSMA, viewing the mandates as the maximum number of domestic inspections and has used the mandates as an excuse to reduce inspection work by the states. An inspection task force led by Dr. Woodcock issued a report last year recommending that Congress consider repealing the FSMA inspection mandates. This would be a significant step backward.

The questions this subcommittee needs to be asking about ORA are: How does ORA allocate food program funding? and Is ORA making the best use of these resources?

The success of FSMA, and the FDA food program overall, requires a full-time, empowered, expert leader who can lead culture change and ensure accountability for resource management across ORA, CFSAN, and CVM.

We are fortunate to have a person with immense expertise and abilities like Dr. Califf serving as FDA Commissioner. His recent testimony about investing in technology to leverage oversight activities certainly make sense, especially given his recent background at Google.

However, investing in technologies, and implementing structural changes for improved governance are not mutually exclusive opportunities. We are not going to be able to algorithm our way out of the existing problems in the FDA food program. We also need structural and governance changes, stronger leadership and a higher priority that puts food in the FDA's front seat, along with drugs, devices, biologics, and tobacco.

Recommendations

Below are recommended actions that the subcommittee can take to address the systemic problems at FDA that exacerbated the infant formula recall situation.

- Investigate how FDA's fragmented structure and leadership affected its response to the Abbott infant formula problem.
- Urge Dr. Califf to reconsider the appointment of Dr. Woodcock to oversee seven parts of the FDA, including the major food program offices. Dr. Woodcock has no significant food policy credentials and no standing in the food stakeholder community. In addition, Dr. Woodcock was acting commissioner and overseeing the agency's actions when the Abbott infant formula situation developed into a crisis.
- Urge Dr. Califf to unify the food program under a deputy commissioner for foods that would have accountability to the commissioner and direct line authority over CFSAN, CVM, and the food-related operations of ORA. This unified structure and a full-time senior expert leader with relevant and appropriate food credentials would strengthen the program's standing externally.
- Continue the investigation initiated by Chairwoman DeLauro and Chairman Bishop seeking detailed answers on how ORA allocates food program funding to determine whether ORA is making the best use of these resources.

Thank you for the opportunity to testify today. I look forward to any questions.

Timeline of FDA Actions on Infant Formula Situation

- **September 2019:** FDA detects *Cronobacter* in Abbott's Sturgis facility, and also found it had failed to test a representative sample for Salmonella at the final stage of production cycle.
- **September 2021:** FDA learns that a Minnesota infant had been hospitalized for three weeks with *Cronobacter sakazakii*, and that the infant had consumed powdered infant formula manufactured by Abbott.
- **September 2021:** The same week that the FDA learned about the Minnesota case, the agency conducts an inspection of Abbott's Sturgis facility. However, it is not conclusive whether this was a routine inspection or a response to the Minnesota case.
- **October 2021:** FDA receives a report from a whistleblower that outlines allegations of wrongdoing at the Sturgis facility, including: falsification of records; releasing untested infant formula; hiding information from the FDA; and lax sanitation practices. The report was sent to principal deputy commissioner Dr. Janet Woodcock, CFSAN director Dr. Susan Mayne, ORA associate commissioner Judith McMeekin, and Office of Criminal Investigations associate commissioner Catherine Hermesen; it was not sent to deputy commissioner for food policy and response Frank Yiannas.
- **December 1, 2021:** FDA reportedly receives a second complaint about a case in Ohio that resulted in a death.
- **December 2021:** FDA interviews whistleblower – two months after receiving it.
- **January 11, 2022:** FDA reportedly receives a third complaint about a cronobacter case.
- **January 31, 2022:** FDA begins an extensive inspection of the Sturgis facility – over three years after first encountering cronobacter at the facility; almost five months after learning of the Minnesota case; almost four months after receiving the whistleblower report.
- **February 1, 2022:** FDA confirms presence of *Cronobacter* at Sturgis facility.
- **February 2022:** The whistleblower report is shared with FDA's deputy commissioner for food policy and response Yiannas, four months after FDA received it and two months after FDA interviewed the whistleblower.
- **February 17, 2022:** FDA issues warning to consumers not to use certain powdered infant formula manufactured at Sturgis facility. Abbott announces its voluntary recall of these products. These actions occur two years and five months after FDA first detected cronobacter at the Sturgis facility; and over four months after learning of the Minnesota case.
- **March 2022:** FDA principal deputy commissioner Dr. Woodcock announces that her office will lead the internal investigation into FDA's actions and response to the infant formula situation involving the Sturgis facility. Dr. Woodcock served as FDA Acting Commissioner during this time, creating an inherent conflict of interest.

- **March 4, 2022:** Chairwoman DeLauro requests that the HHS IG investigate FDA's handling of the Abbott infant formula recall.
- **April 1, 2022:** FDA establishes an Incident Management Group to work on issues surrounding the infant formula recall and shortage.
- **April 8, 2022:** FDA receives Abbott's corrective action plan to address the problems outlined in the investigation that began January 31, 2022.
- **April 29, 2022:** FDA allows Abbott Nutrition to release recalled products to individuals needing urgent, life-sustaining supplies of specialty formulas on a case-by-case basis.
- **May 10, 2022:** In announcing the actions it is taking to improve supply, FDA challenges the notion that there is a shortage, noting that more infant formula was purchased in April than in the month prior to the recall.
- **May 16, 2022:** A proposed consent decree between FDA and Abbott is announced in which Abbott agreed to take corrective actions following FDA's inspection of the Sturgis facility.
- **May 16, 2022:** FDA announces a guidance that outlines increased flexibilities regarding importation of certain infant formula products in an effort to increase supply.
- **May 19, 2022:** Dr. Califf testifies before the House Agriculture-FDA Appropriations Subcommittee that it will take another two weeks for the Sturgis facility to open. He estimates that it will take another eight weeks after the plant's opening for supply to reach store shelves.
- **May 19, 2022:** During the same hearing, Dr. Califf confirms the appointment of Dr. Woodcock as an overseer of the food program at the FDA. As FDA Acting Commissioner, Dr. Woodcock oversaw much of the agency's response to the infant formula crisis.

Stories submitted to Consumer Reports

- **Out of time.** *I breastfed my son for 6 months. After much thought and consideration we successfully transitioned him to formula for his next 6 months before switching to milk. Now, with only a couple months before his first birthday, they've turned into the most stressful time in his life. In my husband and my lives. I do not have the option to go back to breastfeeding, and now I don't have a means of giving my son what he needs -which should be a basic physiological need. I pray no mother goes through the stress of when or how her child will get what they need. This shortage is the new pandemic and must come to an end. — Meghan, IL*
- **Twins.** *My daughter has twin boys and they were born 6 weeks premature. We watch them during the day. She was using Aldi formula. Now you can not find anything. Everyday my husband and I visit the 3 Aldis within a 10 mile radius to see if they have had a shipment. Since she has 2 babies it is very scary when we go 2x a day to check to see if they got a shipment and the shelves are empty. So far she has had to change their type just to feed them. Hopefully they do not have a reaction. They had stomach issues due to being premature. This is ridiculous. — Kathleen, NY*
- **Frustration Mode.** *My story begins back in mid November just before Thanksgiving, I had only 1 week supply of Similac ready to feed sensitive formula for my 4 month old grandson Aidan. I drove for over 2 hours going from King Kullen to Stop and Shop and several CVS stores only to find they did not receive any shipment of formula. I spoke to a CVS store Manager in Wantagh and recommended that I contact the manufacturer directly. So the following morning I called Abbott directly and was able to order formula online with them. For a while that was working out and Target and Walmart supply was hit and miss. They were more times out of stock than had a supply and limited how many bottles you could order. I needed one 32 oz bottle for each day a month's supply costs close to \$300.00. In mid January again stores were out of stock even Abbott. I texted Abbott on January 11th asking when they expected Similac Pro sensitive to be available to order. They answered that they had no timeline because shipping delays and issues with staff shortages. But assured they were making every effort to make improvement with their distribution center. Well things got worse we had to have friends from out of state purchase for us as many as they could get. About that time in February there was a recall in Similac powder formula which we had on hand. So that could not be used so everyday I was on the computer checking Target Walmart and Abbott several times a day. Last month I called the American Pediatrics Society spoke in length of this crisis the lady said there was nothing they could do. I suggested maybe I should contact The NY Times or my Congressman. She agreed. The following week a story came out on ABC news but didn't get much attention. But then more and more states were being hit but this crisis. This was a health crisis but no body seemed to want to do anything to resolve it. I felt so frustrated and feeling how could this be allowed to happen. In 2 months my grandson can turn to milk but I worry about all those families raising little babies. It is a disgrace that our Government is so slow to act. Congress should why it's costs \$9.00 for a 32 oz bottle of liquid formula — Patricia, NY*

- **Low supply needs formula to supplement.** Unfortunately, I am a mother that would like to breastfeed exclusively, but I have low supply and make about 1/3 milk production of what my baby needs. I use formula to supplement the additional nutrition my 4 week old baby needs. We didn't have a huge supply of formula as she was just born and didn't know how she would react to different brands. It is incredibly stressful to be tied to a pump 9x a day, breastfeeding, doing/eating all the things to increase supply, and not be able to produce enough. Then add the extra stress of the formula shortage on top, just makes my low supply dip even more. It has been a scramble to find formula and most shelves are bare near where I live. Online retailers are all sold out. I have had to call on friends and family to search in their neighborhood to send what they can find to help us get about a month supply. We have had to just use what we can get, versus the ones most appropriate for her and what we would want to buy. Hearing that this could go on for another 8 weeks at least is incredibly frustrating considering my baby's intake of formula is rising as she grows. So many families are worse off than we are and that devastates me to hear as a mother. — **Mollie, CO**
- **Fear my baby will go hungry.** My son had an issue gaining weight because I was not producing enough breast milk. My son was in the 3rd percentile in weight at 3 months, before I introduced formula. On formula, my son thrived and jumped to the 24th percentile by 6 months. But now, the formula I have been feeding him is gone (Similac Advance Pro) and I am struggling to find formula of any kind. My son NEEDS this formula or he will not make it. I have had to ask parents, friends, co-workers to look for formula and buy it for me. This has been incredibly stressful and my son should not be at risk of going hungry, because there is NOTHING else I can feed him. Please fix this!!! — **Chantel, CA**
- **Military mom.** I'm a mom who combo feeds, I breastfeed and use formula. My daughter needs formula for weight gain, it's so stressful. There are days when I don't pump enough milk and have to rely on formula. My daughter also need a special kind, this is really stressful — **Kieyesa, VA**
- **Special needs.** Our twins have developmental delays due to prematurity. We rely on Alimentum as our main source of calories. In February our twins had profuse diarrhea for a week straight. I suspected the formula, as the diarrhea smelled like spoiled milk. We stopped the formula immediately. Luckily we were able to supplement with pureed fruit and almond yogurt. They will eat nothing else, and have lost so much weight as a result. Our littles have a milk allergy, and there is nothing else on the market they will drink. We've tried everything. We pray this shortage is resolved for the countless families that depend on these formulas as a food source. — **Mirtha, CA**

Resource for Consumers

- **What to Do If You Can't Find Baby Formula.** For parents who need to find baby formula now, experts offer advice for tracking it down. Read the advice [here](#).

Mr. BISHOP. Thank you, Mr. Ronholm. We will now proceed with questions. As I mentioned earlier, we will begin with the Chair and Ranking Member then alternating Majority and Minority with members present at the time the hearing started in order of seniority. Following that I will recognize members not present at the time the hearing was called to order in their order of arrival. Each member will have five minutes in each round, so please be mindful of your time. I will now recognize myself for questions.

Let me start with you, Mr. Ronholm. In your testimony, you indicated a successful foods program at FDA requires transparency and engagement from the agency, and you mentioned the recent announcement that Dr. Woodcock would be providing strategic counsel that seeks to improve coordination and transparency of food operations at FDA. However, this move does not reinstate the position—reinstitute the position of Deputy Commissioner of Foods which provided a direct line of authority over the food and regulatory activities at FDA. You suggest that part of the solution to improve the foods inside of FDA is to reinstate the position of Deputy Commissioner of Foods, and we will certainly look into doing that.

In the interim, given your expertise and familiarity with FDA are there other changes that could be made to improve transparency and accountability to help rebuild confidence following the recent criticism of FDA?

Mr. RONHOLM. Thank you, Mr. Chairman. Reinstating—I would just note that reinstating the Deputy Commissioner for Foods position would not require congressional action. Dr. Califf could certainly make that announcement at any time of making this move. But setting that point aside, I would just say that because ORA's human food inspection operations reports directly to the commissioner instead of a food policy leader that means there's no single FDA official whose job it is to lead the Food Mission area and provide effective oversight to the program as a whole.

So if this fragmented structure is meant to succeed, information on budget, planning and program information must be widely shared to managers across the program, and decision roles must be clear. Also, accountability for how resources are used must be in place. So this means CFSAN and the Office of Food Policy and Response should have full access to all ORA budget planning and budget implementation data related to the Human Food Program. It also means that CFSAN and the Office of Food Policy and Response should have full access to all ORA operational data related to inspection, lab analysis and state partnerships.

So again as a result of this fragmented structure there needs to be that increased coordination and accountability to make it more effective.

Mr. BISHOP. Thank you. Ms. Chamberlin, thank you so much for your testimony. It was very moving. I am glad we were able to highlight your family story. Of those with rare medical conditions, formula is life sustaining. I know you have been an advocate for many years, and I imagine it felt difficult to say everything in just five minutes. So is there anything additional that you would like to add?

Mr. RONHOLM. Thank you, Chairman Bishop, and thank you for your co-sponsorship of MNEA. I have two quick things. Since the onset there has been sort of an in joke in people who advocate for rare disease that COVID taught the rest of the world what it was like to have a rare disease. So many people were sick. We had no idea what was going on for a while. We had no diagnosis. We had no treatments. We still have no cure, and we were confined to our homes and isolated, but that crisis spurred good things.

There was remarkable support from our government and innovation in our scientific community, and I feel much the same about the formula crisis. So many people now understand how vital the white powder in these cans is to so many, and I'm hopeful that those of us who rely on this lifelong will have the attention and the support of both the public and our government in supporting the MNEA. Now that people understand us we need them to take action.

Mr. BISHOP. Thank you very much. Mr. Carney, I thank you for your testimony. Can you talk about some of the possible short-term concerns? You mentioned hospitalizations and that there are perhaps a number of short- and long-term impacts with medical outcomes and nutrition security. Can you talk about some of the short-term concerns and long-term and the risk of making formula—diluting formula to try to make it last longer? My time is almost expired.

Ms. CARNEY. Okay. I will be quick. Yes, we need to make sure that parents know that this—as we have said today this crisis will be going on for several more weeks, so we need to be prepared. I would want to warn parents not to make homemade formulas—the American Academy of Pediatrics warns against that—as well as they should not dilute the formula as both of these situations can lead to disastrous results and lead possibly to hospital admissions. They should check with their pediatricians or even a registered dietitian that specializes in pediatric for guidance on proper substitutions.

Mr. BISHOP. Thank you. My time has expired, and at this time I will yield to the distinguished Ranking Member, Dr. Harris, for your questions. Dr. Harris, you are recognized for five minutes.

Mr. HARRIS. Thank you very much, Mr. Chairman. I want to thank all the experts here today. Ms. Carney, let me ask I am hearing that some hospitals are having admissions through the emergency rooms. Parents can't find formula or, I don't know, maybe even some infants are getting ill because they don't have the formula they need. Is this happening nationwide? Or how would we know if that is happening and the extent to which that is happening?

Ms. CARNEY. Certainly we have heard of infants and older children, too, being admitted to the hospital when they try to substitute formulas or they make their own formula. As I referred to in my testimony here in Memphis we had two children, I believe they were older children, with Short Bowel Syndrome that were admitted to the hospital because of intolerance to the formula. They needed an elemental formula, and they went to something that they could—just anything they could find. And since they were not

able to absorb it they had severe diarrhea and got severely dehydrated.

Mr. HARRIS. So there is obviously some risk from this formula shortage that doesn't have to do with contamination. It has to do with the result of not having formula.

Mr. Ronholm, let me ask you specifically because in your timeline you don't mention the CDC and state agencies looking at the Cronobacter cases—because Cronobacter is ubiquitous. I mean, it is all over—that CDC could not find a link between the Cronobacter that was found in the Abbott plant and the Cronobacter that infected children. In fact, one of the cases it was found in the distilled water that was used to mix the—Cronobacter found in distilled water used to mix the formula.

So given that, is there some concern that this should have been resolved a lot earlier? I mean, they could have investigated this a lot earlier and started reopening the plant earlier when there was no direct linkage between the Cronobacter at the Abbott plant, again something that is ubiquitous, and the Cronobacter that caused these tragic infections two of which of course led to death but none of them genetically the Cronobacter that was in the Abbott plant.

Mr. RONHOLM. Thank you, Dr. Harris. So the timeline that we put together was focused exclusively on FDA action, so we didn't incorporate the CDC and state actions. Just in terms of making that link with the Abbott plant I think we probably need to be a little careful just in terms of the small sample size I think that was taken during that testing process and trying to make that link with the Abbott facility.

You are absolutely correct that at this point there is no direct link, but I would just say that if you are taking a small sample size I think it makes it more difficult to make that link. So if you were to imagine a barrel full of Lego pieces and you grab one handful, but it doesn't include a red piece. So you conclude that the tub must not contain a red one. I mean, it is highly unlikely that would be the case, but that is just an example that we have to be careful about making that definitive conclusion that there is no link because I think a lot of it has to do with what happened with the testing at the Sturgis facility.

Mr. HARRIS. Sure. So let me just follow up. One thing you mentioned in your testimony and goes a little beyond your testimony actually, look, when the FDA was set up we were in a much different world. The drug industry and the need to have a high level of expertise in drugs kind of distracts the FDA I think from the food aspect of it. Is it time to split the two apart and not to split the two within the FDA but to split them into two separate agencies one of which deals with pharmaceuticals and one of which deals with food safety?

Mr. RONHOLM. I think that idea, Dr. Harris, deserves a lot of attention and merit. I know it is something that Chairwoman DeLauro has been focused on for years and that splitting out the food safety functions of the agency as it exists now and creating a separate agency while still remaining under the HHS umbrella that certainly would be I think an effective approach that would

get to the issues that I think everyone has become aware of during this crisis. Absolutely.

Mr. HARRIS. Yeah. Of course that will take statutory action. I mean, we have to do that. In the meanwhile, what qualifications should the person at the FDA who will now be put in charge of food, what qualifications should they have?

Mr. RONHOLM. Yeah. So right now I think as an interim step before we can get to that point where you are taking food safety out of FDA I think what we need is an empowered deputy commissioner position that holds food programs accountable, has oversight authority, and I think that person needs to have strong, deep food policy credentials, decades of experience in food policy whether it is industry consumer groups, et cetera. There needs to be somebody who is steeped in food policy that can understand the intricacies, the nuance to be able to develop policies to react, to focus on illness prevention and react to a crisis like this.

I mean, I think today what happened at the other committee hearing they couldn't decide whether three or four people should testify on this crisis. If you have one person leading the whole program, all Congress has to worry about is inviting one person to testify and hold that person accountable.

Mr. HARRIS. Thank you very much. I yield back, Mr. Chairman.

The CHAIR. Mr. Chairman, you are on mute.

Mr. BISHOP. I am sorry. Thank you. Dr. Harris, thank you for your questions. At this time, I would like to yield to the Chairwoman, Ms. DeLauro, who has been very tenacious, aggressive and unyielding in getting to the bottom of this crisis.

Chairwoman DeLauro, you are now recognized for your questions for 5 minutes.

The CHAIR. Thank you so much, Mr. Chairman. I was just very interested in the exchange between Dr. Harris and Mr. Ronholm because, in fact, I recommended and Senator Durbin has as well for many years an independent food safety agency because when we get into these crises not unlike what happened today at the prior committee meeting no one is in charge. No one individual is in charge of food safety where the responsibility lies.

In the interim, I think that Mr. Ronholm has laid out a structure because we know that it takes a while to get to where we want to go, but eventually single food safety agency. We now have 15 agencies at the federal level who deal with some form of food safety. The principal ones are USDA and FDA. It should be one single agency.

Mr. Ronholm, the FDA received a report from a worker from the Abbott manufacturing facility in Michigan unveiling a damning list of allegations—falsification of records, testing scales on empty cans, releasing untested infant formula to name a few. Have you read the whistleblower report? And then as a food safety—

Mr. RONHOLM. Yes, I have.

The CHAIR. Thank you. As a food safety expert what was the allegation that you found alarming?

Mr. RONHOLM. The most alarming allegation in the report that I found would be the falsification of records. Now, falsifying records doesn't necessarily represent an immediate food safety threat in and of itself, but what it does reflect is the lack of a strong food

safety culture at the facility, and that points to a much deeper problem that exists both at the facility and within the corporation. So when you have that level of a food safety culture problem, it results in things like gloating about hiding information from the FDA and other more immediate food safety threats like releasing the untested products, the unsanitary conditions at the plant and failure to take corrective actions.

And you think of the other things that falsifying information can lead to such as making it difficult to recall bad products. It would be difficult to trace where and what communities were affected by a particular recall if the records have been falsified or not available. There would be no way to look back at fixing problems that have been identified in the past. So you have all of this—you have all of these activities, all of these important actions that plants take tied to falsifying records, so that to me is the major red flag of how a bad food safety culture can permeate an organization.

The CHAIR. Quite frankly, I wish Dr. Taylor when I asked him that question had a similar answer or at least had an answer to that issue.

Dr. Carney, my opening remarks on Monday I did a roundtable event with community organizations, Mothers on Infant Formula. I mentioned a grandmother brought two of her grandchildren to the emergency room experiencing vomiting and diarrhea. Later the grandmother realized that the formula she was giving her grandchildren were part of the recall. A couple of quick questions. Currently, Cronobacter is not a reportable disease. Does that contribute to the issue of tracking?

Ms. CARNEY. Thank you so much, Ms. DeLauro. I don't know if that is an issue of tracking. I think it is—yeah, because it is not a diagnosed disease, and the only way we would know is if somebody was admitted for those different symptoms that you have just described is to look at their condition, look at what they had consumed and knowing what formula or feeding had been recommended for them.

So we have to know if formula is contaminated before it gets to the children. We cannot let that happen and then try to diagnose that in the emergency room or in the hospital somewhere so that it can be—so we don't ever give it to them and make sure that they are getting clean, safe formulaic feeding.

The CHAIR. Okay. I am going to run out of time, Dr. Carney. Should it be a reportable disease? Let me just ask you for a yes or no. Should it be a reportable disease?

Ms. CARNEY. I think we have to report it so that we can track it and we can—

The CHAIR. I have legislation, by the way, that I talked about which would make it a reportable disease. The other thing is because of this trying to track the cases which you mentioned before we had two infants that died, four hospitalized, do you think there is any underreporting of this because we don't have a tracking system? And you have got to be brief because I have ten seconds.

Mr. RONHOLM. I'm sorry, Rosa. Was that directed at me?

The CHAIR. It was going to go to Dr. Carney, but let me—Mr. Ronholm. Somebody.

Ms. CARNEY. I am sorry. I missed the question.

Mr. BISHOP. All right. We will perhaps come back to it, Ms. DeLauro. Your time has expired.

I will now recognize the gentleman from California, Mr. Valadao, for five minutes.

You are now recognized, Mr. Valadao.

Mr. VALADAO. Thank you, Mr. Chairman.

Thank you to all of our witnesses for your willingness to testify in front of the subcommittee today and share your perspectives of the ongoing infant crisis.

Less than one week ago, the Food and Drug Administration Commissioner testified in front of this committee as well. There is still much that is unknown.

It was more than discouraging to see that he was unable to answer questions related to timing, causes, accountability, and more. It is unacceptable. We need formula on our shelves yesterday, and we need real answers from our officials so that we can ensure this never happens again.

Just yesterday I was in a grocery store in my district and noticed the lack of formula on the shelves. Instead there were pieces of paper with a picture of the formula and a note instructing the customer to take the paper to the cashier to purchase.

I am not sure what their exact inventory is, but it did not look promising, unfortunately.

It is almost June now. The recall was in February, and how are families in rural communities supposed to provide food for their babies that rely on this product, especially those who participate in the WIC Program or do not have the means to drive all over the region looking for a specific type of formula.

Thank you all again for your participation and continuing the conversation as we wait for the FDA and Abbott Nutrition to get the Sturgis facility back up in production.

The FDA provided a response yesterday to a letter I sent earlier this month along with my colleagues related to the infant formula shortage. In this letter, they claim that the FDA began alerting Federal partners and stakeholders about the potential supply disruption even before Abbott voluntarily recalled the product.

It seems an advanced alert like this could have better prepared stakeholders for the formula shortage disruption. Mr. Gay, were you notified about the forthcoming formula shortage by the FDA, USDA, a manufacturer?

If so, when?

Mr. GAY. Thanks for the great question.

We were, but it was very late, probably just a few weeks before it really hit the news. Our warehouse tried to procure, obviously, different things, but the bigger issue for our store particularly is that in a rural area such as ours, probably 85, 90 percent of my formula is WIC formula, which is just down to one type of formula.

So even like today, for example, on my truck Monday, I got about 20 cases of Gerber formula in different varieties, but that is not approved on WIC, and the Georgia WIC Office just approved some substitutions for formulas that were, you know, subscribed by the doctor with the contract formula.

So therein lies the problem, is there is no easy way to substitute that for the customer, and so even if you had advanced knowledge

of it, there is no way to go around whatever your customers, particularly in our area, would have been able to buy.

Mr. VALADAO. So you were given about a two-week heads-up, it sounds like. And then in your testimony, you provide recommendation for the WIC Program that you feel would improve the process for both WIC retailers and participants.

Have you expressed these concerns to the WIC Program officials?

And if so, how have those concerns and recommendations been received and what kind of feedback have you heard?

Mr. GAY. Unfortunately for us, Georgia will be probably the last remaining State to not be eWIC approved. So we are still actually taking paper vouchers, which has made the process doubly hard because it is not a matter of just substituting UPC. You have to physically go back to the WIC office and have your WIC exchanged.

We have, you know, obviously addressed those before even in our area. Hurricanes are things with similar things, and we very rarely get any real guidance or any help, so to speak, from the WIC Offices here. It falls basically to us to handle it the best we can with our customers.

Mr. VALADAO. The paper prescription one in your testimony is the one that blew my mind. I was totally surprised by that one, but I appreciate you expressing that one. That is something we do need to look into more.

And then, Ms. Carney, as of last week's FDA hearing, I expressed concerns with the Commissioner about Dr. Janet Woodcock becoming Principal Deputy Commissioner due to her lack of expertise in food policy. I was not reassured with the response I received and still have those concerns.

In his testimony, Mr. Ronholm expressed a similar concern with this action and potential consequences this decision will have on food policy under her leadership.

Ms. Carney, given your expertise and line of work, I am curious about your opinion on this decision. Do you agree with the concerns that Dr. Woodcock is not the best suited for this position and that the FDA should have someone with adequate expertise on food policy in this role?

Ms. CARNEY. I do not know if I can speak directly to that. I am not really familiar with the person in charge, but I will say that we do have to have somebody that is competent and understands the repercussions of getting babies and children unsafe formula and food.

Mr. VALADAO. All right. Thank you.

And my time has expired. So I yield back.

Mr. BISHOP. Thank you, Mr. Valadao.

And at this time I am delighted to recognize the gentlelady from Maine, Ms. Pingree.

Ms. Pingree, you are now recognized for five minutes for your questions.

Ms. PINGREE. Thank you so much, Mr. Chair, and thank you for holding this hearing and to my colleagues for their questions and the panel for all that you are talking to us about.

Mr. Ronholm, you have already provided us with such great information, and I appreciate the work you have done on this and the

role Consumer Reports plays in making sure consumers have this important information.

You have already talked a lot about how changing the agency, maybe a single agency could make all the difference and a different leadership structure.

Is there anything else you want to add on information sharing, leadership structure that we should consider as we think about how restructuring would work?

Mr. RONHOLM. Yeah, I mean, I think the leadership component of this is the key. I mean, I think we really need to have that one single person in charge of the Food Program to be able to have that expertise, to have that oversight authority of the Food Programs to be able to respond to these types of situations.

I think one thing that I also mentioned was that if this fragmented structure is going to go forward, you must have information sharing between ORA, the Office of Regulatory Affairs, which is in charge of the inspection compliance piece for FDA, and allow them to share that information and work plans with CFSAN, CVM, and the Office of Group Policy and Response.

Without this type of information sharing, without this type of collaboration, you know, I think we are going to continue to see what we are seeing now, just this kind of fragmented structure and how it leads to these types of crises.

You know, there is a running joke. If the Group Policy would alter the F is silent in FDA and the F only roars when there's a crisis like this, and I think you need that type of collaboration.

Ms. PINGREE. Yes, I totally agree. And thank you for that. I think it is something we have all been talking about for a long time, and I think there could be bipartisan agreement on how to go about doing that.

I want to take up a slightly different topic other than just how the agency worked, and, Ms. Chamberlin, you actually mentioned this, about how the pandemic really got us thinking about a whole variety of different things, and now this has really helped people to understand formula, particularly those formulas that are medically necessary.

I am always interested in nutrition, diet, and health, and this fits right into that, and I have been a cosponsor of the Medical Nutrition Equity Act, which would ensure a baseline of insurance coverage.

So between you and Ms. Carney, could you talk a little bit about it? I think people really do not understand the insurance challenges, the cost, and the lack of availability to those people who need this.

Ms. CHAMBERLIN. Yes, thank you.

And thank you for your co-sponsorship. It is very important to so many.

So my daughter is just over four feet tall, and she weighs about 62 pounds, and her formula is billed out at almost \$1,600 a month to her insurance, and that is an amount that will increase, you know, with weight and age, and she will be on that her entire life.

The way that insurance reimbursement for medical nutrition is structured is State-based, and so one State may cover a child up to age one. One State may cover up to age five.

You may only get coverage for PKU but not tyrosinemia just because that wasn't written into the law. You know, it is age, disorder, gender, type of insurance, income, and then anyone who is on a self-insured plan will not be bound by any State law. So that plan will not be bound by any requirements to cover medical foods. They can do it, but they do not have to, and so you will be——

Ms. PINGREE. Thank you.

Go ahead, yes.

Ms. CHAMBERLIN. I was just going to say you have a huge number of people who slipped through all of those loopholes, and what the MNEA does is for those people we will provide that Federal floor. This is their medical treatment for life, and it guarantees that they can continue to thrive.

Ms. PINGREE. Yes, and thank you.

And thank you for using your personal knowledge of your daughter's challenges and informing us of all of that.

And, Ms. Carney, I do not have a lot of time left, but you know, we can see how important it is to have a Federal standard here, but you must experience this all the time when families are challenged by insurance rules.

You are muted, I think.

Ms. CARNEY. Thank you so much.

Yes, absolutely, and registered dietitians are so important in working with families like Ms. Chamberlin is describing all kinds of children that need different formulas, different diets.

Another Medical Nutrition Therapy Act is up for discussion that would allow dietitians to provide specialized nutrition to the families and patients that are in need of these special formulas.

Ms. PINGREE. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you.

At this time I am delighted to yield to the gentlelady from Louisiana, Ms. Letlow.

Ms. Letlow, you are now recognized for five minutes for your questions.

Ms. LETLOW. Thank you, Chairman Bishop and Dr. Harris.

I join my colleagues on the subcommittee in expressing my sincere gratitude to all our witnesses with us today.

Just last week, the Food and Drug Administration Commissioner, Dr. Califf, testified before this subcommittee as one of his first official visits to Congress since the start of this crisis, and while it was past time for answers and a solution, we were still left with grave uncertainty, with no clear end to this shortage in sight.

As a mother of a four-year-old and two-year-old, I cannot imagine the sheer terror families must be experiencing as they desperately search to find the most basic, life sustaining nourishment for their children. I stated in my remarks to Dr. Califf it was not too long ago that I myself was completely dependent on formula to fulfill my children's nutritional needs.

In many cases not all formulas are the same. Families know the specific brands and types of formula that work best for their children, and access to these essential goods simply should never be compromised.

In part of my questioning, I asked Dr. Califf how much formula FDA expects will be imported under the new enforcement discussion guidance, and what is the real timeline of seeing those products on our store shelves.

His answer was it will gradually get better. Unfortunately, many of our constituents have encountered empty shelves for three weeks now, and it is time we seek solutions to address this shortage expeditiously and establish safeguards should our domestic supply ever be threatened again.

Ms. Carney, as heartbreaking as it is to hear the personal stories you have shared, thank you for shedding some light on the true crisis families are facing and for your dedicated work as a nutritionist to provide care to your most critical patients during this time.

As you and Ms. Chamberlin both mentioned in your testimony, families and health care providers took it upon themselves soon after the closure of the Abbott facility to introduce new formula mixes to sustain their children's daily nutritional needs. Maybe at the time it was for precautionary reasons, but it is now a reality.

Through this committee's work in funding our Federal agencies, the FDA just received a \$102 million budget increase, including an \$11 million increase specifically for maternal and infant health and nutrition for fiscal year 2022.

Having provided the necessary resources, how could the FDA work more collaboratively with manufacturers and health care providers to address disruption in the supply chain and avoid this unprecedented shortage?

Ms. CARNEY. Sure. Thank you so much for that question.

I think that we have to stay on top of the supply chain. I am in a hospital. When our supplies get low, we scramble to find the right substitute or not even substitute, but a good alternative to feed our patients and keep them nutritionally sound.

We need communication. We need accountability, and we need to know what is available that we can give to our patients so that they do not suffer some of these things that I described in my testimony.

Ms. LETLOW. Sure. Thank you.

And to follow up to that, given that Abbott is the only producer of some specialty metabolic formulas, from a health care perspective, do you believe there is a role providers could play in working with the industry and FDA to ensure additional options for therapeutic formulas remain available when the main source is at risk?

Ms. CARNEY. For sure we need alternative sources, and we need to look to other places that might produce this formula, manufacture some formulas. I do not think there needs to be a monopoly by one company in these specialty formulas because, as Ms. Chamberlin has described her daughter, when they are out of that formula, that is the only thing she can take.

So with the help of dieticians, we can help figure out some other dietary things that she can do to keep her daughter thriving and growing, but it causes a lot of distress, of course, and so we need other options and other sources besides one company. It just should not be that way.

Ms. LETLOW. Sure. Mr. Gay, I represent a heavily rural district where the proximity and availability of retailers for certain goods

as limited, and given your background as a rural retailer, I am sure you understand how important these stores are to our local communities.

Can you share with the subcommittee how the shortages not only affected your store, but most importantly, your customers?

And secondly, I believe retailers can play a vital role in the distribution of essential products. What additional steps have you taken to overcome these supply challenges to make sure infant formula is restocked, especially in our rural communities?

Mr. GAY. Thanks for the question.

Yes, the nearest big box retailer, so to speak, from any direction of my store is probably 25 to 30 minutes, and like I said, a lot of our formula, you know, 90 percent of it is probably sold just on WIC.

So it becomes a big problem that people cannot leave to go get anything else.

And as far as this specific formula thing, it has been much different than any of the other pandemic stuff. There were times when some of the bigger box retailers were getting items that I could not get or were not getting my fair allocation of.

I have talked to some warehouses, and this is not one of those situations. Everyone is getting their fair share of formula now.

So I say that to say this. If there were times when my customers needed something and I could get it from somewhere else, I go get it whether we sell it at what we paid for it or are not making any money on it just so they do not have to leave the community.

This is one of those times where I do not have the ability to go get it from anywhere else. This solely falls back to a shortage with the oversight is not getting the plant back open fast enough.

Ms. LETLOW. All right. Thank you so much.

Mr. BISHOP. Thank you, Mr. Gay.

Thank you, Ms. Letlow. I believe your time has expired.

And at this time I am pleased to recognize the gentleman from Wisconsin, Mr. Pocan.

Mr. Pocan, you are now recognized for five minutes for your questions.

Mr. POCAN. Thank you very much, Mr. Chairman.

And thanks for having in many ways the second hearing on this subject in two weeks, which is showing again, I think, Congress responding quickly like we did in the House, passed a bill to the President, the Defense Production Act.

Clearly, there were problems at the FDA, and we have had a great conversation about that this morning, but I think there may be some other concerns we should also talk about a little bit.

I just want to start with Ms. Chamberlin. I just want to let you know your advocacy, today you have just got a new sponsor on that bill. I was texting my office, and we called up Jim McGovern's office, and we are on it.

So I just want to let you know your time has been well spent, and thank you for informing me, and as other members may ask the question, I will also refer them to that bill. So thank you for your time today.

I do want to ask a question of Mr. Ronholm. What you started to say and I will not start with the monopoly problems. I will talk about the FDA, and I think we have talked a lot about the FDA.

I think though we do have to fix the FDA situation on this, and I think we can do it in a bipartisan way. There is still a problem when four companies are producing 90 percent of the product, right? And we know what that means.

Often consumers are going to get a raw deal, perhaps on paying out for it from things like right now when someone goes down who has got these exclusivity contracts through WIC.

So I guess my questions are: one, how has sole-sourced WIC contracts impacted parents during the infant formula shortage, trying to get to this monopoly issue?

Second, should we be considering any changes in Congress either in the appropriations process or the next farm bill to adjust this?

And then third, should we be allowing this monopoly structure that States are using our WIC Federal dollars to then have these monopoly relationships?

Because to me that may be part of the problem.

Mr. RONHOLM. Yes, those are all very critical questions, Mr. Pocan, and I think your point is certainly well taken in terms of, you know, four companies that control 90 percent of the market, and only three of them actually bid with rebate contracts, and Abbott is by far the largest one, and I believe they have contracts in 30 or 31 States, I think was the latest figure.

So, you know, when those contracts come up, these companies submit based on their ability to meet the demand in a particular State, and Abbott is usually the only one that is big enough to do that.

And I think, you know, we mentioned that they have a large part of the market. I think when it comes to the WIC market, they have approximately 55 to 60 percent of the WIC market. So that is a significant size of the market that really needs to be examined so when situations like this hit, how does it impact that particular market.

And it is obviously going to have a bigger impact because, you know, these companies use the WIC market to get into the overall non-WIC market, to even increase the share of their market. So that creates further shortage problems.

You know, in terms of your question about what Congress can do in terms of fixing FDA, I mean, I think this is going to be a several-step process. The first step that the FDA can take is to appoint that empowered Deputy Commissioner expert leader that could provide the leadership and accountability in the Foods Program, be that single person in charge to hold the agency accountable.

You know, the next step is to maybe consider legislation that Chairwoman DeLauro and Dr. Harris had discussed about the splitting the food part of the FDA and creating a separate agency while still under the HHS umbrella.

And the third ultimate step long term is ultimately creating this independent food safety agency, much like the EPA.

Mr. POCAN. So let me just ask. None of those actually address the monopoly issues, right?

Mr. RONHOLM. Right.

Mr. POCAN. So I understand that is being decided. I think that has been well talked about, but how about this monopoly side?

Are we actually creating a bigger problem by allowing WIC dollars to be used in the way they currently are because we have really now made it not just a monopoly of the three companies bidding, but like you said, it is really one company that is left out there?

Mr. RONHOLM. Yes, it is absolutely a problem when that one company can control that much of the market. You know, I am not the market concentration expert, FTC expert, but certainly anyone can identify this as an issue that needs to be addressed, for certain.

Mr. POCAN. Great. Thank you.

And very quickly, Mr. Gay, if you can do it in like 20 seconds or less, I have got 28 seconds. How is your store making purchase decisions about formula impacted by WIC?

Mr. GAY. Like I said, with it being 90 percent of the thing, we basically only carry WIC formula, and so you know, whatever they use we carry that almost exclusively.

Mr. POCAN. Got you.

I yield back, Mr. Chairman. Thank you very much.

Mr. BISHOP. Thank you very much, Mr. Pocan.

And at this time I am pleased to yield to the gentlelady from Illinois, Ms. Underwood. You are now recognized for five minutes.

Ms. Underwood.

Ms. UNDERWOOD. Well, thank you, Mr. Chairman.

I want to begin today by acknowledging just how terrifying our Nation's infant formula shortage is for parents and how urgent our response must be from the administration, from formula manufacturers, retailers, and all other stakeholders. We need an all hands on deck response until every family has access to the same formula they need.

We also need to be thinking more broadly about what this crisis says about our Nation's support system for growing families. While the current infant formula shortage is unique, it is a symptom of long-term policy failures to prioritize the nutrition needs of infants.

This is happening in a country with a glaring lack of sufficient support for breastfeeding, in a country with a higher maternal mortality rate than any other high income nation, and in a country where even before the current shortage, low-income families struggled to access the nutrition their children need due to the highly concentrated infant formula market in which four companies make up approximately 90 percent of formula available, and the Special Supplemental Nutrition Program for Women, Infants, and Children, known as WIC, offers limited formula option for participating parents.

Today's infant formula shortages are a symptom of both market failures and policy failures, and both issues must be addressed to not only get more formula onto shelves now, but also to prevent something like this from ever happening again, and to ensure that America is the most supportive place in the world to grow a family.

Ms. Carney, how would a more robust support system for growing families in the United States, including support for breastfeeding, help parents access the nutrition their infants need and address maternal and infant disparities?

Ms. CARNEY. Thank you, Ms. Underwood, for that question. I would love to address that.

First of all, just a word about WIC and—excuse me—and our supply of formula here at St. Jude, and we are so blessed here at St. Jude from our donors that we are able to get any formula not based on WIC bids or anything that the WIC Program has put the babies or children on before they arrived at St. Jude.

So we do provide whatever formula our dieticians think is best for these children.

To address your question, I do think in my work in public health in graduate school, we always looked at working upstream rather than downstream, so to find something that would promote public health before we go dealing with the problem.

So instead of curing things, let's do prevention, and I always think that breastfeeding or, well, we know that breastfeeding is optimal feeding for infants. So if we can think about upstream for a few minutes, to answer your question, and have more effort to support moms and babies to successfully breastfeed, we are not looking at so much formula usage, and the infants and children that do need formula, more would be available for them.

I know that—

Ms. UNDERWOOD. We also know—oh, go ahead.

Ms. CARNEY. I know that women, mothers face challenges, and they have to return to work and to school, and they do not get the support they need. So I think, you know, us looking at ways to provide possibly more paid maternity leave after delivery of a baby and more support from lactation consultants like I am so that they can successfully breastfeed would really help address this problem and increase breastfeeding rates in this country.

Ms. UNDERWOOD. Yes, ma'am. Increasing access to lactation consultants and making sure that, you know, we are avoiding moms and babies going hungry so that they can achieve their milestones and grow into healthy, thriving children is very important.

Ms. Carney, Federal agencies have released guidance on the current infant formula shortage, which includes a recommendation that parents contact their child's pediatrician if they have questions about safely providing the nutrition their infant needs.

What about the parents of children who do not have a consistent pediatric health provider? Where can they turn to for guidance?

Ms. CARNEY. So if a child does not have a primary care provider, I would suggest they would check with their local WIC Office, who could guide them, and also the Health Department Clinic in their community, and there you will find pediatric registered dieticians to help them decide or to consult what is the best formula for them.

Ms. UNDERWOOD. Thank you so much for providing that information.

As a registered nurse, I know how important it is to share clear, accurate, and evidence-based information with patients to address their concerns and answer questions. Many of us do have these WIC Offices in our communities. We all have Health Departments that are great resources for all of us to consult.

And I would encourage the American people to be in touch.

Thank you so much to our witnesses, and I yield back.

Mr. BISHOP. Thank you, Ms. Underwood.

At this time I yield to the gentlelady from California, the chair of the Foreign OPS Subcommittee of Appropriations, Ms. Lee. You are now recognized for five minutes.

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

And thank you, Ranking Member and members and witnesses, for this very important hearing.

You know, for the life of me, initially when I heard about this baby formula shortage, I asked myself how could this happen in the wealthiest and most powerful country in the world. Baby formula shortage, unbelievable.

Then I realized this is an example of what we call monopoly capitalism where only four companies own actually 90 percent of the market. So this has got to change just in terms of the structural issues because if you do not have competition in a capitalist society, this is what happens.

And so I am just wondering if any of you could tell us how you see this in terms of agencies, Federal agencies, working to address these unfair practices because like stock buybacks, price gouging, you know, all of the issues that led to this.

I do not know if you are looking at how this happened structurally, but if you are, I would like your take on that.

And then secondly, and I guess, Mr. Ronholm, this would be a question for you or Mr. Gay. In terms of WIC and low-income and disadvantaged communities, of course, they are suffering tremendously from the consequences of this infant formula recall having already disproportionately suffered from COVID-19 and the resulting economic pressures.

And now with the new strategies to try to immediately bring formulas to our children, our babies, what kind of hesitancy do you see or do you see any hesitancy, given the long history of medical racism in this country?

Are WIC recipients, especially recipients of color, are they reluctant or resistant or questioning the efficacy and the safety of the formulas that now will be available?

Mr. GAY. I guess I will jump in on that one. This is Michael Gay.

A great question. The biggest issue, I think, here as far as hesitancy is just like yesterday. Not only has Georgia WIC been slow to make a substitution, but especially younger mothers in general are very hesitant to even change formula for their baby, even though nutritionally it may be the same quality and a fair swap. They are very hesitant and skittish to take their baby off of whatever they have talked about with their doctor about feeding their child.

So even though there may be, like we did get a different national brand available, they walked out of the store and did not buy anything because, you know, you could tell they were a little hesitant just to buy it because it was not what was on their WIC, even after telling them to go back to the WIC office and check with them.

So there is definitely an issue there with WIC and the way they handle formula.

Ms. LEE. Well, are we looking at outreach strategies?

And I asked the other day in our prior hearing about this. So it was actually a meeting with the White House. Are there strategies, and we used some during COVID, to have trusted messengers, peo-

ple that the communities can relate to provide the information about the safety of the formulas that are coming in?

Has anyone looked at that as being important at this point given the medical racism and hesitancy we have in many of our communities?

Mr. GAY. Honestly, ma'am, the first email I received about using different formulas was Monday of this week from WIC. Other than that, we have heard zero from our WIC Offices as to how to proceed, more as we just kind of do the best we can at the store level to provide, but we are not really given any direction from the WIC Office at all.

Ms. LEE. Okay, Mr. Chairman. I think that is something we need to follow up with because I know in many communities this is an issue, as it was with regard to the vaccines and the COVID treatments and the outreach efforts, and the real reluctance because of the history of what we know in terms of systemic racism in this country in low-income and minority communities.

The other question, maybe, Mr. Ronholm, can you just—is it Ronholm?—tell me what you think?

Have any of your reports looked at how this monopoly can be broken up?

Mr. RONHOLM. Yes, I mean, it certainly has an impact, as Mr. Pocan alluded to as well.

I think another big piece of this, too, that we can look at is how can we work with the States in terms of fixing that system and changing that contract structure.

Because you know, at FNS, at USDA, they do not approve these, you know, WIC contracts. It is the States that do them, and so, you know, it is how can we work with State partners in order to change that system. Can they break up those contracts where they are splitting them up by region to give other companies an opportunity to bid on them?

Because, you know, when one company has the contract of 30-plus States, that is a pretty significant share, and that can have a big impact on supply when we face the situation.

So if there is a way we can work with States to kind of figure out how to break up contracts by region to give more companies an opportunity to make those bids, to get into those markets, I think that might be an important step to consider.

Ms. LEE. A good idea.

Mr. BISHOP. I thank you, Ms. Lee. Your time has expired.

Ms. LEE. Thank you.

Mr. BISHOP. And at this time I am delighted to yield to the gentlelady from Minnesota, the chair of the Defense Subcommittee, Ms. McCollum.

Ms. McCollum, you are now recognized for five minutes.

Ms. MCCOLLUM. Thank you, Mr. Chair, and I am glad you had a good night last night.

Ms. Carney, I want to start with you. Thank you for your testimony.

A member of the Academy of Nutrition and Dietetics in Minnesota recently shared her experience dealing with the infant formula crisis. She found parents getting conflicting information, awful from some unqualified people on social media who were

showing misinformation, how to do home formula ingredients using goat milk. And I saw some of that even before I had spoken with the dietician myself.

And then as many of my rural colleagues have pointed out, you know, they do not often have registered dieticians on local staff at clinics and doctors. They are not necessarily familiar with formula option brands that they do not get.

So my point is as the administration is working on its plans to address this immediate formula shortage, as Ms. Lee said, a horrible environment of mistrust has also been created.

Maybe can you speak a little bit about this environment of mistrust and what you think needs to be done in the future and better ways to help WIC with participants so that they are not, you know, so disproportionately impacted by this?

Now, a lot of this, as has been pointed out, is Federal and it is State. This is an opportunity for me, and I am going to be doing it at our sessions ending here in Minnesota for the State legislators, to reach out to my State legislators and talk about how we can be better partners on this and how we can streamline it and what may need to happen federally to do it.

Can you just share some of your thoughts and experiences on this?

And are the online media sites, is Twitter, is anybody helping? Is anybody recommending this is a safe site to go if you are looking for something to help your child?

Ms. CARNEY. Thank you for that question so much.

Yes, I have seen the social media, too. It is rampant with home-made formula recipes and suggestions, and they will get goat's milk or almond milk, like I mentioned in my testimony, and I also mentioned the dietician said that one of her clients told her, "I do not think I want to get any formula that is on the shelf because it could all be contaminated. When is the next time I am going to go reach for a formula and they are going to recall it and say do not give it to your baby?"

So there is a huge mistrust feeling out there among all of our mothers and fathers and parents in the country, and we have got to address this.

And I want to go back a minute. We were talking about what are we doing with the companies out here that have so much of the market share of our whole entire country for infant formula.

And one thing that we really have not talked about is the WHO code for marketing breastmilk substitutes, and that is what these formulas are, you know. They are breastmilk substitutes.

Ms. MCCOLLUM. Right.

Ms. CARNEY. So if we look at the WHO code, in other countries, other developed countries are abiding by the WHO Code, and this gives guidelines for how companies can market their infant formulas in a safe way.

So maybe we should go back to that and think about what is it about the WHO Code that would benefit all of our families in the country so that they are assured when they do have to reach for infant formula, when breastfeeding cannot be an option or will not be an option, what are the things that are marketed directly to our families that tell them about the formula.

There is a lot of confusion about that. So I did want to mention that, too.

Ms. MCCOLLUM. Thank you.

Mr. Ronholm, anything you want to add on that?

You are out there in the heartbeat of Consumer Reports, and you are watching consumers just get misled with bad information.

Mr. RONHOLM. Yes, absolutely, Congresswoman. You know, the stories that we have been getting are very heartbreaking. You hear the desperation, and you know, they are just at a loss of what they can do, and of course, low-income WIC recipients have it especially tough when you consider that they do not have the resources to drive all around to try to find product.

So, yes, I mean, I do not think I can add anything more than what Ms. Carney had stated.

Again, it is just heartbreaking to hear the stories come in that we are compiling. I actually did some of them as part of my testimony, and certainly it has compelled all of us to act.

Ms. MCCOLLUM. So, Mr. Chair, I think I see an opportunity to communicate better with my State legislators, but I also see a failed opportunity for, quite frankly, our public media organizations to get the facts out, to get them right, whether it is news, radio, or whatever, or social media.

We have been trying to do it the best we can on our Website. These are our public airways. This is a public crisis, just as COVID was, and rather than just slice a news story here and there without any follow-up, I just think it was a huge failure also for some of these companies that manufacture it not to put out public announcements.

Thank you, Mr. Chair, for having this hearing, and let's hope we never have to have a hearing like this again.

Mr. BISHOP. Thank you, Ms. McCollum.

At this time I will recognize the gentlelady from Florida, the chair of the Military Construction, Veterans Affairs Subcommittee, Ms. Wasserman Schultz. You are now recognized for five minutes.

Ms. WASSERMAN SCHULTZ. Thank you, Mr. Chairman.

You know, the brutal truth is that four companies control nearly 90 percent of America's baby formula market, and that is the very definition of an oligopoly.

This corporate consolidation hurts all of our families, but especially lower income workers. It is the same with greedy oil CEOs who keep energy supplies low and pump prices high, hurting those who do the real work.

At the end of the day, we need to make sure that we have adequate supply, and that we can keep children safe. And the Biden administration is doing all it can to fix this, from boosting supplies to importing massive shipments from Europe with Operation Fly Formula, but the long-term problem will not go away until we address corporate consolidation, improve WIC, and adopt sensible FDA safety standards.

Now, the WIC Program provides information on healthy eating and helps millions of families buy nutritious foods, including baby formula. Half of all U.S. formula consumption goes through the WIC Program, which provides free infant formula, as we have been

talking about today, where States negotiate bulk discounts in exchange for market exclusivity.

I will take you back to 1989 when Republican President George Bush enacted legislation requiring all State WIC Programs to use competitive bidding for the purchase of infant formulas. In practice, this means that the State of Florida, for example, is required to use a single supplier for the entire State supply of WIC baby formula.

The competitive bidding process has yielded 1.3 billion to \$2 billion a year in savings and allowing WIC to serve about two million more participants annually because of the discount.

However, when there is a supply shock caused by one of the four market participants, like what happened with Abbott in this case, it creates a serious risk to infant health across the country.

And that problem is further exacerbated when the interests of private monopolists are put ahead of American families.

And you may remember when the Trump administration actually threatened countries with trade sanctions and withdrawal of military aid if they supported an international resolution in support of breastfeeding as a healthy option for infants. I mean, that is completely outrageous.

So my first question is to Mr. Ronholm. We need to find a long-term solution for this problem that is caused by a monopolized industry. Can you explain for us really how the single source contracting for WIC baby formula might have contributed to consolidation in the industry?

Mr. RONHOLM. Thank you, Congresswoman.

Yes, absolutely. I think as you rightly pointed out, when you have only these folks' WIC contracts, what ends up happening is these companies assess their ability to meet the demand for these particular contracts and place those bids.

And right now, you know, as we have discussed, there are only three companies that do that right now, and Abbott being the largest one because they have that ability and they have the infrastructure to meet the demand in a particular State, especially larger population ones. And as a result, you only see them in 30-plus States.

And to your point about supply shock, so when we are faced with these types of situations, it makes it more difficult for these other companies to rebuild the market share for the supply that is lost with these supply shocks because they may not be as big as Abbott and so they may have not had infrastructure to ramp up production quickly enough to get to that point where we can rebuild that supply.

So, yeah, I mean, this certainly is an issue that deserves careful examination. How do those contracts get broken up where you allow for multiple bidders to minimize any supply shocks that happen?

Ms. WASSERMAN SCHULTZ. And why does the U.S. market not support more competition in the baby formula industry outside of WIC sales? It certainly seems like there is a tremendous amount of desire and need out there.

Mr. RONHOLM. It could be for any number of reasons: you know, cost of entry to the market, the availability of limited supply ingredients, you know, the cost of those supplies.

So, again, when you are faced with those market dynamics, it is only the kind of larger players that are able to afford the ingredients that go into these products, and to be able to produce them in the mass scale.

That is not to say that that applied in this particular situation specifically, but typically with markets, that is what ends up happening.

Ms. WASSERMAN SCHULTZ. And I want to just ask you really quickly because we know that in Europe, they consistently produce a baby formula surplus. But there are rigid labeling and nutritional requirements for formula containers here in the U.S. that the FDA requires, and they prohibit the sale of many European-made products even though the formulas themselves meet FDA nutritional and purity standards.

So what sort of policy changes would you like to see undertaken to ease restrictions on baby formula imports while still ensuring that the product meets our safety standards?

Mr. RONHOLM. Yes. I think it is critical that we maintain those safety standards that FDA has set on infant formula. That is absolutely critical.

So there is a comfort level with consumers when they are able to purchase something that they knew is an FDA inspected facility overseas.

But to your point, you know, sometimes these regulations, these really strict regulations are thinly disguised trade protection measures, and so you know, that is certainly an issue that we would have to examine carefully to make sure that we can have that access.

Mr. BISHOP. Well, thank you, Ms. Wasserman Schultz. I believe your time has expired.

Ms. WASSERMAN SCHULTZ. Thank you.

Mr. BISHOP. At this time I would like to yield to the gentlelady from New York, Ms. Meng.

Ms. Meng, you are now recognized for five minutes.

Ms. MENG. Thank you. Mr. Chairman.

My question is for Mr. Ronholm. Consumer Reports published an article in March where your organization described FOIA requests for FDA inspection reports in 2019, 2021, and 2022.

These reports show that FDA had documented serious and ongoing safety concerns at Abbott's plants just as the outbreak emerged in March.

These reports also review that Abbott received 17 consumer complaints between 2019 to 2021, including 15 complaints of infants having tested positive for another pathogen, salmonella, and one complaint related to Cronobacter.

I wanted to find out, relatively speaking, is the number of complaints about this product, for example, lower or higher compared to another product.

And how many complaints, let's say, would raise the level to cause alarm or how can we ensure that the public is aware of these consumer complaints much earlier on in the process to allow consumers to make the most informed choices?

FDA obviously reacted too slowly, and the company obviously did not reveal to the public the number of complaints that they had received.

Mr. RONHOLM. Yes, Ms. Meng. I do not have a specific frame of reference of what threshold for complaints, you know, would trigger concern. I would say that I think overall 17 is a notable number, and I think it would certainly gain some attention at a Federal agency, just based on my experience at USDA.

And when you combined that with the inspection reports that FDA had of the Sturgis facility in the years that you mentioned, combine that with the consumer complaints, clearly, there were some red flags there that needed to be addressed.

And so the concern from the consumer standpoint is these complaints are being filed. You have these inspection reports that encounter, you know, the Salmonella test sample, the Cronobacter, et cetera. That is cause for concern. That should be a sign to FDA that there is a problem at this particular facility. They need to set up shop there to figure out what the problem is.

Ms. MENG. So, no, thank you. That is very helpful.

And you know, I know we have talked a lot about needed reform at the FDA, but on top of that, do you think there are things that we can require, let's say, of private companies when complaints are being made?

I know there is not necessarily a framework of a minimum threshold or trigger level, but are there things that companies should be doing when they are receiving complaints over complaints of relatively serious illnesses resulting from their product?

Mr. RONHOLM. Yes. I think certainly companies when they get these complaints, they should share them immediately with the FDA.

I think what they also should be doing is sharing their test results, microbial test results that they take at their particular facilities. So when they take those samples and if there is an issue, they need to share them with the FDA so there can be some sort of record so in the event there is a problem, they have the ability to go back, see that this facility experienced the problem in the past, and they need to fix it.

So I think as much information sharing as there can be between the company and the FDA certainly would be beneficial.

Would it prevent the situation altogether? I think that remains to be seen, but it certainly helps everyone get educated on precisely what the issues are at a particular facility, absolutely.

Ms. MENG. Right. So if the FDA does not react appropriately, let's say there were 100 complaints to a business like Abbott. If FDA had not done its due diligence and a company like Abbott does not reveal anything to the public, if there are 100, 200 complaints, that means they would keep selling this product and no one in the public would even know that complaints were being made, right?

Mr. RONHOLM. That is right. And I think it also speaks to the question of the fragmented leadership at FDA. You know, you have the major whistleblower report come in, and you know, they did not bother to share it with everybody within the agency, let alone react to it. So that is certainly an issue as well.

Ms. MENG. Thank you. I yield back.

Mr. BISHOP. Thank you very much, Ms. Meng.

I believe we have completed the round of questions. I understand that there are no more questions, except for the chairlady, Ms. DeLauro, who I believe has one additional question.

So I will at this time yield to Chairwoman DeLauro for your final question.

I yield to Ms. DeLauro.

The CHAIR. Thank you.

Very, very quick, first of all I just said to my colleague, Congresswoman Meng, what the FDA needs to do is to understand that they are a regulatory agency and what that entails.

We do not produce infant formula at the Federal level. That is not our job. Our job is, through the FDA, is to be able to make sure that those who do produce it are held to a standard and to make sure that standard is adhered to, and if it is not adhered to, they need to be accountable for that.

The product should come off the market until we have a solution to it.

Very, very quickly because I just wanted to get the answers from you, Dr. Carney. If you could unmute, because of the inability to track the cases, as you have mentioned, we know two infants have died, four others were hospitalized. Do you think that there is underreporting because we do not have a tracking system so there could be more cases out there?

Ms. CARNEY. Thank you, Chair DeLauro.

I am not a doctor. So I appreciate that honor, but I am a dietitian.

I definitely agree with you that there is a problem if we cannot track that. We need to, and I know that we were just talking about informing the parents and out there in the public, but there are so many sick children already in hospitals, if we give them contaminated formula on top of their current illness, it would be devastating.

So we have got to have some tracking and reporting on consistent basis.

The CHAIR. So many of the women that I spoke to yesterday at the round table had a child. They took them to the emergency room. Then they came out of the emergency room, but then they looked at the product that they had, and it was a recalled product. So there is every likelihood that it could be connected to it.

Thank you very much, and thank you so much, Mr. Chairman. Thank you for doing the hearing today. It really is a critical issue.

Thanks.

Mr. BISHOP. Thank you, Ms. DeLauro.

And let me say thank you again to our witnesses, Ms. Chamberlin, Mr. Gay, Ms. Carney, and Mr. Ronholm. We very much appreciate this discussion. Your testimony was powerful and informative.

As we continue to look for answers and solutions to this crisis, it is important that you all have a voice. You are on the ground, and you experience the consequences of something like this firsthand.

Thank you also for the hard work that you do, from advocating for important policies to supporting your local communities.

Dr. Harris, do you have any closing remarks?

Mr. HARRIS. Thank you, Mr. Chair.

Just to say thank you to the witnesses today. Ms. Chamberlin, thank you very much for testifying. I know how incredibly difficult it must be for you and people who you know who have children with PKU to have this happen, and rest assured that we will do our best to make sure it does not happen again because we know that for some children the specialty infant formulas are very, very essential.

Again, thanks to all of the witnesses today.

Thank you, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you, Dr. Harris.

And thanks to all of the members who were in attendance, and let me say a thank you to our staff who worked so hard to put this hearing together quickly.

So thank you so much, and with that, this subcommittee is adjourned.

WEDNESDAY, MAY 25, 2022.

MEMBERS' DAY

WITNESSES

**HON. JAMES R. BAIRD, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF INDIANA**

**HON. SHONTEL M. BROWN, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF OHIO**

**HON. KIM SCHRIER, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF WASHINGTON**

Mr. BISHOP. This hearing will now come to order.

As this hearing is fully virtual, I must address a few house-keeping matters. For today's meeting, the chair or staff designated by the chair may mute participants' microphones when they are not under recognition for the purposes of eliminating inadvertent background noise.

Members are responsible for muting and unmuting themselves. If I notice that you have not unmuted yourself, I will ask you if you would like the staff to unmute you. If you indicate approval by nodding, staff will unmute your microphone.

I remind all members that the 5-minute clock still applies. If there is a technology issue, we will move to the next member until the issue is resolved, and you will retain the balance of your time.

You will notice a clock on your screen that will show how much time is remaining. At 1 minute remaining, the clock will turn yellow. At 30 seconds remaining, I will gently tap the gavel to remind members that your time is almost expired. When your time has expired, the clock will turn red, and I will begin to recognize the next member.

In terms of the speaking order, we will follow the predetermined order that has been provided to your offices, beginning with the chair's and acting ranking member's brief opening remarks. We will then begin with the first member on the schedule and move forward from there.

Finally, House rules require me to remind you that we have set up an email address to which members may send anything they wish to submit in writing at any of our hearings or markups. That email address has been provided in advance to your staff.

Last reminder, please ensure that your video is turned on at this time.

Good afternoon. Today we will hear testimony from our colleagues on both sides of the aisle on the agencies under our subcommittee's jurisdiction. As I have often noted, these agencies conduct vital work that touches the lives of all Americans, and today's hearing represents a great opportunity to listen to a diverse group of members from across the country share their views on a wide range of issues related to our bill.

We look forward to hearing your thoughts on the appropriations process and learning more about the programs and issues that affect your district and your constituents. Your input is invaluable as we draft funding legislation for the upcoming fiscal year for the U.S. Department of Agriculture, the Food and Drug Administration, the Commodities Futures Trading Commission, and the Farm Credit Administration.

Before we begin, I would like to express my sincere appreciation for the ranking member and all of the members testifying for accommodating our busy schedule. Given the lateness of the day, I would like to adhere to the 5-minute rule, so that we can remain on schedule.

I want to thank every member who has taken the time to participate. We appreciate your interest in the work of this subcommittee.

Now I would like to recognize our distinguished acting ranking member, Dr. Harris, if he has any opening remarks, and, if so, Dr. Harris, the floor is yours. You are now recognized.

Mr. HARRIS. Thank you, Mr. Chairman, for holding today's hearing to receive testimony from our colleagues. I look forward to hearing more about the projects and programs in the ag appropriations bill that are important to each of your districts and to communities across the country. Your input will be crucial as we work to fund the agencies under this subcommittee's jurisdiction.

I look forward to working with Chairman Bishop to accommodate these priorities as best we can as the fiscal year 2023 appropriations process moves forward. Thank you again to each of our colleagues who have taken time out of your busy schedules this afternoon to speak with us and bring these ideas to our attention.

Thank you, Mr. Chairman, and I yield back.

Mr. BISHOP. Thank you, Dr. Harris.

We will now proceed with member testimony. Each member will have 5 minutes to give your oral statement.

I will now recognize our first witness, the gentleman from Indiana, Mr. Jim Baird, for 5 minutes.

Mr. Baird, you are now recognized.

WEDNESDAY, MAY 25, 2022.

WITNESS

HON. JAMES R. BAIRD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. BAIRD. Thank you, Chairman Bishop and Ranking Member Harris, for the opportunity to join you today and share the issues that I feel are priorities for the agricultural industry.

For those of you who do not know me well, I represent Indiana's 4th Congressional District, the largest ag district in an already-ag-heavy state. I am a Ph.D. animal scientist and a farmer myself. So needless to say, I have a great passion for serving our Nation's farmers and ranchers and providing the tools needed to keep America's food system healthy, affordable, and stable.

The first initiative that I would like to call your attention to is increasing the funding and the direction for FDA's Center for Veterinary Medicine for evaluation and approval of animal food ingre-

dients. Animal food manufacturers are researching and bringing to market innovative feed ingredients that can improve animal nutrition, health, and production, and also make food safer and reduce the industry's environmental footprint.

They are able to do this because regulatory schemes elsewhere in the world have kept pace with the evolving science of animal nutrition. Unfortunately, our farmers and ranchers in the United States are missing out on using these same ingredients due to the Food and Drug Administration's outdated way of regulating these products and the restrictions on how they are marketed. By hiring more staff, improving the infrastructure and regulatory processes, and providing IT assistance, the FDA's Center for Veterinary Medicine would be able to alleviate long-existing backlogs and delays for animal feed ingredient reviews, as well as providing the center with the capacity needed to focus on these emerging needs in regulation of important products.

With this in mind, I request the committee provide \$5 million in funding for the CBM for needed improvements in timeliness and from process.

The next important issue I would like to discuss is the regulation of animal biotechnology products, which falls squarely into the subcommittee's jurisdiction as it remains mired between the USDA and FDA. Animal biotechnology products have the potential—

Mr. BISHOP. Excuse me. Mr. Baird, can I ask you to turn on your camera?

Mr. BAIRD. Sure.

Mr. BISHOP. Thank you.

Mr. BAIRD. Is that better?

Mr. BISHOP. Your camera just went off.

Mr. BAIRD. Mr. Chairman, I am using—

Mr. BISHOP. Thank you.

Mr. BAIRD. Mr. Chairman?

Mr. BISHOP. Yes.

Mr. BAIRD. I am using the same iPad for both the video as well as my testimony. So if I—

Mr. BISHOP. We can hear you fine, and we can see you also.

Mr. BAIRD. Yeah. But as soon as I go back to my testimony, it will—

Mr. BISHOP. Oh, I see.

Mr. BAIRD [continuing]. The camera will go off. So—

Mr. BISHOP. All right.

Mr. BAIRD. So if you can tolerate my camera being off, I think you can still hear me.

Mr. BISHOP. Very good, sir. Go ahead.

Mr. BAIRD. Thank you.

Mr. BISHOP. You may proceed.

Mr. BAIRD. Thank you. I am getting there.

Mr. BISHOP. We will give you additional time, sir.

Mr. BAIRD. Okay. Can you still hear me okay?

Mr. BISHOP. Yes, I can. And I will ask the staff if they would restart your clock to I think it was somewhere around 4 minutes, if I am not mistaken.

Mr. BAIRD. Thank you, sir.

Mr. BISHOP. And of course you don't have to use all of the time. We will receive your full testimony for the record.

Mr. BAIRD. So how much time do I have left, Mr. Chairman?

Mr. BISHOP. We are giving you 4 minutes.

Mr. BAIRD. Okay. We were talking about animal biotechnology products, and they have the potential to bring tremendous benefits to the world of animal agriculture. These remarkably innovative new tools have the capacities and the ability to address some of the zoonotic disease infection, markedly improve the sustainability of livestock production, help mitigate climate change, enhance animal welfare, and provide for the additional production efficiency to meet the growing global demand for animal protein.

Unfortunately, the existing regulatory system is not conducive to timely adoption of these innovations. In the past 25 years, only two animals intended for agricultural purposes have been approved for use domestically by the FDA. A continuation of this costly, protracted regulatory system will only serve to further stifle important new agricultural innovations.

And as we look to new solutions to address the myriad of challenges facing American agriculture, I strongly encourage the committee to direct the Department of Agriculture to advance their rulemaking for establishing regulations governing agricultural applications of these technologies and to direct the FDA to finally sign and implement the Memorandum of Understanding developed with the Department of Agriculture regarding animal biologics and develop a more appropriate regulatory approach.

Related to the important new possibilities that animal biotechnology can yield for our Nation's food system are two new priority issues I would like to emphasize before the committee with the February—for fiscal year 2023—excuse me.

Your continued support of plant biotechnologies by providing FDA with the necessary resources to support the issuance of guidance for the industry on food derived from plants produced from using genome editing and to modernize and improve the timeliness and productivity of the Plant Biotechnology Consultation Program, the other being include language to direct USDA's APHIS to take measurable steps to establish predictable and science-based regulatory pathways for innovation in genetically engineered microbes.

As we have seen through the year following Russia's invasion of Ukraine, we must adjust to meet the challenges of global food insecurity caused by geopolitical tensions, now and in the future, and continue innovating—just one moment—to overcome other numerous production challenges faced by American farmers and ranchers.

I strongly encourage your support of these important provisions in fiscal year 2023. The relative stability and self-sufficiency in the American food supply would not be possible without the numerous research activities conducted by USDA on countless commodity crops and farming practices.

Amongst all of the tremendously important projects, I would like to call your attention to a few that I feel are of particular value. ARS research activities not only increase commodity yields and disease resistance but also ensure that American consumers continue to have abundant and affordable access to milled grain products to meet nutritional needs.

I urge the committee to increase ARS genetic oak research funding by \$1.5 million in fiscal year 2023 and continue to fund the U.S. wheat and barley scab initiative at the fully authorized amount of \$15 million.

[The information follows:]

**Testimony of
The Honorable James Baird
Members' Day Hearing
May 25, 2022**

Thank you, Chairman Bishop and Ranking Member Harris, for the opportunity to join you today and share initiatives that I feel are priorities for the agriculture industry. For those of you who don't know me well, I represent Indiana's 4th Congressional District – the largest ag district in an already ag-heavy state. I am a Ph.D. Animal Scientist and a farmer myself, so needless to say, I have a great passion for serving our Nation's farmers and ranchers and providing the tools needed to keep America's food system healthy, affordable, and stable.

The first of initiative I'd like to call to your attention is increased funding and direction for FDA's Center for Veterinary Medicine, for evaluation and approval of animal food ingredients.

Animal food manufacturers are researching and bringing to market innovative feed ingredients that can improve animal nutrition, health, and production, make food safer, and reduce the industry's environmental footprint. They are able to do this because regulatory schemes elsewhere in the world have kept pace with the evolving science of animal nutrition. Unfortunately, our farmers and ranchers in the United States are missing out on using these same ingredients due to the Food and Drug Administration's outdated way of regulating these products and restrictions on how they are marketed. By hiring more staff, improving infrastructure and regulatory processes, and providing IT assistance, the FDA's Center for Veterinary Medicine would be able to alleviate long existing backlogs and delays for animal feed ingredient reviews, as well as providing the Center with the capacity needed to focus on these emerging needs in the regulation of important products. With this in mind, I request the Committee provide \$5,000,000 in funding for the CVM for needed improvements in timeliness and process.

The next important issue I'd like to discuss is the regulation of animal biotechnology products, which falls squarely into this Subcommittee's jurisdiction as it remains mired between USDA and FDA. Animal biotechnology products have the potential to bring tremendous benefits to the world of animal agriculture. These remarkably innovative new tools have the capabilities to address the risks of zoonotic disease infection, markedly improve the sustainability of livestock production, help mitigate climate change, enhance animal welfare, and provide for the additional production efficiency to meet the growing global demand for animal protein.

Unfortunately, the existing regulatory system is not conducive to the timely adoption of these innovations. In the past 25 years, only two animals intended for agricultural purposes have been approved for use domestically by the FDA. A continuation of this costly, protracted regulatory system will only serve to further stifle important new agricultural innovations. As we look to new solutions to address the myriad challenges facing American agriculture, I strongly encourage the Committee to direct the Department of Agriculture to advance their rulemakings for establishing regulations governing agricultural applications of these technologies, and to

direct the FDA to finally sign and implement the Memorandum of Understanding developed with the Department of Agriculture regarding animal biotechnologies to develop a more appropriate regulatory approach for these important innovations.

Related to the important new possibilities that animal biotechnology can yield for our Nation's food system are two new priority issues I'd like to emphasize before the Committee for FY23 – your continued support of plant biotechnologies by providing the FDA with the necessary resources to support the issuance of guidance for industry on food derived from plants produced from using genome editing and to modernize and improve the timelines and predictability of the Plant Biotechnology Consultation Program; the other being to include language to direct USDA's APHIS to take measurable steps to establish a predictable and science-based regulatory pathway for innovations in genetically engineered microbes. As we've seen throughout the year following Russia's invasion of Ukraine, we must adjust to meet the challenges of global food insecurity caused by geopolitical tensions now and in the future, and continue innovating to overcome the other numerous production challenges faced by American farmers and ranchers. I strongly encourage your support of these important provisions in FY23.

The relative stability and self-sufficiency in the American food supply would not be possible without the numerous research activities conducted by USDA on countless commodity crops and farming practices. Amongst all of these tremendously important projects I'd like to call attention to a few I feel are of particular value. ARS research activities not only increase commodity yields and disease resistance, but also ensure that American consumers continue to have abundant and affordable access to milled grain products to meet their nutritional needs. I urge the Committee to increase ARS Genetic Oat Research funding by \$1.5 million in FY23 and continue to fund the U.S. Wheat and Barley Scab Initiative at the fully authorized amount of \$15 million.

The National Institute for Food and Agriculture's Genome to Phenome Initiative is an important program for providing plant researchers with the tools to measure and analyze plant characteristics to grow better crops regardless of the environment – advancing the efficiency and sustainability of producers. For FY23, I ask that the Committee provide the program with \$10 million to support the development of tools and datasets for the analysis of phenotypes that can be used to improve the output and efficiency of agriculture.

In addition to the previously described programs whose funding I feel is of critical importance to the success of the modern agriculture industry moving forward, I would also like to express the importance of, and my broad support for: The Rural Development Cooperative Grant Program, full funding for the critically important National Animal Health Laboratory Network (NAHLN), full funding of the Agriculture Advanced Research and Development Authority (AGARDA), broad support for funding that increases the adoption and consumer access to biofuels like ethanol, and broad support for USDA programs that help provide access to broadband connectivity for those in Rural America who currently lack that access.

I feel strongly that the programs I've highlighted for you this afternoon are critical for the continued success of the agriculture industry and will all play critical roles in providing a healthier, more affordable, and more sustainable food system situated to help solve some of our Nation's most pressing issues. I hope that you'll share my passion for this effort and support these requests. I look forward to working with you on these and other issues moving forward and thank you for your time today.

With that Mr. Chair, unless you have any questions, I yield back.

Thank you,

James R. Baird

Member of Congress

Mr. BISHOP. Thank you, Mr. Baird.

Mr. BAIRD. Yes.

Mr. BISHOP. We appreciate your testimony and your expert knowledge on animal science. With both of our being members of the agriculture committee, I look forward to working with you to continue support for our farmers and our ranchers.

Dr. Harris, do you have any questions or comments?

Mr. HARRIS. No. I just want to thank the gentleman from Indiana.

Mr. BAIRD. And I thank you for the opportunity. Have a great day.

Mr. BISHOP. Thank you for speaking with us today. And without objection, your entire written testimony will be included for the record. Thank you.

Mr. BAIRD. Thank you, Mr. Chairman.

Mr. BISHOP. The chair now recognizes the gentlelady from Ohio, Ms. Shontel Brown. Ms. Brown, you are now recognized for 5 minutes, and we look forward to your testimony.

WEDNESDAY, MAY 25, 2022.

WITNESS

HON. SHONTEL M. BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Ms. BROWN. Thank you, Chairman Bishop, Ranking Member Harris, and members of the committee. Thank you for the opportunity to testify. I am especially grateful for the opportunity to work with Representative Meng to craft report language that addresses key child nutrition issues. Congresswoman Meng has been a proven leader in fighting hunger and strengthening food security, and I am honored to join her in this effort to ensure no child goes hungry.

Due to the public health emergency and subsequent economic fallout, child hunger has spiked dramatically. Data shows that student participation in the school breakfast and lunch program has dropped significantly.

The waiver authorities that Congress gave USDA through the Families First Coronavirus Response Act have made it possible for school nutrition programs and community organizations to continue to feed students in wake of school closures, virtual learning, and social distancing, as well as the challenges faced by ongoing supply chain disruptions and staffing shortages.

Unfortunately, these critical waivers are set to expire at the end of June. This creates uncertainty as schools prepare for the next school year. It is important that Congress fully recognize how useful and critical these waivers have been and continue to be. For these reasons, I urge the committee to include language accompanying the final agriculture appropriations bill that expresses the committee's support for the child nutrition waivers authorized in the Families First Coronavirus Response Act and directs the Secretary of Agriculture to submit a report to Congress on the effectiveness and use of these waivers.

Additionally, we must ensure that children are being fed year-round including in the summers. For millions of children, summer is the hungriest time of year. With school buses not running and feeding sites often at different locations for multiple children in one household, few children can get to meal sites twice or even once a day in the summer. This is a serious issue that children living in both rural and urban areas face.

Therefore, I am urging the committee to include language that—including language accompanying the final agriculture appropriations bill that highlights the support for the USDA Food and Nutrition Service and allows state agencies to enable the Summer Food Service Program service institution that operate in areas where children and youth have barriers to access to a congregate feeding site to use their reimbursement payments to develop creative ways to make food available to children through non-congregate means.

Thank you again, Chairman Bishop, Ranking Member Harris, and members of the committee for the opportunity to submit the testimony. I stand ready to work with you all to help fight child hunger and food insecurity. And with that, I yield the balance of my time to my good friend, Ms. Grace Meng.

Mr. BISHOP. Ms. Meng, you are recognized.

Ms. MENG. Thank you, Mr. Chairman and Ranking Member Harris. And thank you to my colleague, Representative Brown. I want to associate myself with the remarks of Representative Brown and thank her for her important and compassionate leadership.

If there is one thing the pandemic has taught us all it is that the world can and sometimes must pivot on a dime. We must ensure our nutrition and food policies provide the flexibility necessary to adjust in an ever-changing world.

The child nutrition waivers authorized in the Families First Coronavirus Response Act are critical in this flexibility, and I thank Representative Brown for her remarks and her partnership on this issue, as well as the issue of non-congregate settings for the Summer Food Service Program.

Thank you, and I yield back.

[The information follows:]

**Testimony of
The Honorable Shontel M. Brown
Members' Day Hearing
May 25, 2022**

Chairman Bishop, Ranking Member Harris, and members of the Committee: Thank you for the opportunity to testify. Today, I want to address several issues related to child nutrition.

Due to the public health emergency and subsequent economic fallout, childhood hunger has spiked dramatically. Data¹ shows that student participation in the school breakfast and lunch programs has dropped significantly. The waiver authorities that Congress gave USDA through the Families First Coronavirus Response Act have made it possible for school nutrition programs and community organizations to continue to feed students in wake of school closures, virtual learning, and social distancing, as well as the challenges faced by ongoing supply chain disruptions and staffing shortages. Unfortunately, these critical waivers are set to expire at the end of June. This creates uncertainty as schools prepare for the next school year. It is important that Congress fully recognizes how useful and critical these waivers have been and continue to be.

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Therefore, I am urging the Committee to include language accompanying the final agriculture appropriations bill that highlights support for the USDA Food and Nutrition Service and allows State Agencies to enable the Summer Food Service Program service institutions that operate in areas where children and youth have barriers to access to a congregate feeding site to use their reimbursement payments to develop creative ways to make food available to children through non-congregate means.

¹ <https://www.brookings.edu/blog/up-front/2020/05/06/the-covid-19-crisis-has-already-left-too-many-children-hungry-in-america/>

Thank you again, Chairman Bishop, Ranking Member Harris, and the members of the Committee for the opportunity to submit testimony. I stand ready to work with you all to help fight child food insecurity.

Mr. BISHOP. Thank you, Ms. Meng and Ms. Brown.

Dr. Harris, do you have any questions?

Mr. HARRIS. No. Just thank you for your interest in childhood nutrition.

Mr. BISHOP. And I join Dr. Harris. We appreciate your strong interest and support for the nutrition programs, especially for our children, and we look forward to working with you to continue the conversation and to ensure that these programs have the resources that they need to succeed.

Thanks for speaking with us today. And without objection, Ms. Brown, your entire written testimony will be included for the record.

And thank you, Ms. Meng, for your comments.

At this time, I am delighted to recognize the gentlelady from Washington, Ms. Kim Schrier. Ms. Schrier, you are now recognized for 5 minutes.

WEDNESDAY, MAY 25, 2022.

WITNESS

HON. KIM SCHRIER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Ms. SCHRIER. Well, thank you, Chairman Bishop, and thank you, Ranking Member Harris. And, first, I want to associate myself with Representatives Brown and Meng on their attention to child nutrition.

Today I appreciate the opportunity to share my priorities and concerns as a representative of Washington State's 8th Congressional District, including agricultural research infrastructure and the community project funding request.

I submitted my full testimony for the record, which includes a few requests I won't have time to touch on today, including funding for specialty crop research, nutrition programs, and the school kitchen equipment grants.

So, first, I want to ask for your support to fund agricultural research infrastructure. Along with my colleague from Kansas, Representative Tracey Mann, and a strong group of bipartisan members, I sent a letter to the committee urging \$365 million in investment for agricultural research infrastructure as authorized through the Research Facilities Act, which was included in the 2018 Farm Bill.

Within NEFA, funding for the Research Facilities Act will support competitive grants to land grant universities and non-land grant colleges of agriculture for facility construction, acquisition, modernization, renovation, or remodeling. And these facilities need it. Without specific investment in the facilities, many from the 1950s and 1960s, the U.S. really risks its competitiveness and its ability to properly recruit and train the next generation of world-class researchers.

Modern ag research and education facilities serve as the backbone of our Nation's cutting edge ag and food research enterprise, but 69 percent of research facilities are U.S. colleges are really at the end of their useful life. Some don't even have indoor plumbing.

That is why we need to address our deferred research maintenance backlog and increase investments in the next generation of ag research work.

This investment will reposition the United States for long-term success, competitiveness, and leadership in global ag and food research.

Second, I want to highlight a community project funding request for my district. This one is a request for \$3 million for the development of a new food distribution center for the Chelan-Douglas Community Action Council, or CDCAC. This organization provides support for individuals experiencing food insecurity.

They currently support 22 area food pantries, meal sites, and low-income senior housing facilities with over 2 million pounds of food annually, providing good nutrition to those who are facing food insecurity. And the quantity of food that CDCAC receives and distributes has doubled in the past 3 years. In fact, their current food distribution facility is really inadequate to meet this kind of demand, avoid food waste, and to ensure the safe storage of food products and the safety of employees and volunteers.

And a new facility will reduce travel times, will expand programs focusing on the local purchasing of farm goods—and this is an agricultural area—through the expansion of commercial processing equipment, improved safety measures, and provisions for dedicated volunteer and employee training space. It is a really worthwhile investment for rural America and rural Washington State.

I want to thank you for your attention. Again, I will refer to my written testimony for details on my other priorities. And I just want to thank you, Mr. Chairman and Mr. Ranking Member, for your leadership during this process, for consideration of needs in my district, and for your attention to child nutrition.

I yield back.

[The information follows:]

KIM SCHRIER
8TH DISTRICT, WASHINGTON

WASHINGTON OFFICE
1123 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-7761

Congress of the United States
House of Representatives
Washington, DC 20515

May 25, 2022

The Honorable Sanford Bishop, Jr.
Chairman
2362-A Rayburn House Office Building
Washington, DC 20515

The Honorable Andy Harris
Ranking Member
1036 Longworth House Office Building
Washington, DC 20515

Dear Chairman Bishop and Ranking Member Harris,

I appreciate the opportunity to share my priorities and concerns as representative of Washington state's 8th congressional district. I write to respectfully request consideration of the following priorities in the Fiscal Year 2023 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill.

First, I ask for your support to fund agriculture research infrastructure. Along with my colleague from Kansas, Rep. Tracey Mann, and a strong group of bipartisan members, I sent a letter to the Committee urging \$365 million in investment for **agricultural research infrastructure as authorized through the Research Facilities Act (RFA) in Section 7503** of the 2018 Farm Bill.

Within NIFA, RFA funding will support competitive grants to land-grant universities and non- land-grant colleges of agriculture for facility construction, alteration, acquisition, modernization, renovation, or remodeling. Without specific investment in research facilities, many from the 1950s and 1960s, the U.S. risks its competitiveness and ability to properly recruit and train the next generation of world-class researchers. This investment will reposition the United States for long-term success, competitiveness, and leadership in global agricultural and food research.

Modern agricultural research and education facilities serve as the backbone of our nation's cutting-edge agricultural and food research enterprise. But 69 percent of research facilities at U.S. colleges are at the end of their useful life. Our research facilities not only generate solutions, but also aid in recruiting a new generation of diverse scientists, innovators, and agricultural leaders. That's why we need to address our deferred research maintenance backlog and increase investments in next

generation agriculture research.

Second, I want to highlight a **Community Project Funding** request from my district. I am requesting **\$3 million for the development of a new Food Distribution Center for the Chelan–Douglas Community Action Council (CDCAC)**. CDCAC provides support for individuals experiencing food insecurity: they currently support twenty-two area food pantries, meal sites and low-income senior housing facilities with over 2-million pounds of food annually; providing nutritional food to those who face food insecurity. The quantity of food CDCAC receives and distributes has doubled in the past three years. CDCAC's current food distribution facility is inadequate to meet this increased demand, avoid food waste, and ensure the safe storage of food products and safety of employees and volunteers. A new facility will reduce travel times; expand programs focusing on local purchasing of farm goods through expansion of commercial processing equipment; improve safety measures; and provide for a dedicated volunteer and employee training space.

Third, the **Specialty Crop Research Initiative (SCRI) and Specialty Crop Block Grant Program** fund research that supports hundreds of specialty crops in Washington State. Past funding for projects in Washington have supported efforts to combat fungicide resistance in wine grapes, precision irrigation for fruit growers, and pest prevention in onions.

In the past several years, I have worked very hard to make sure specialty crop researchers have access to the resources they need and was pleased that my fix to allow waiver authority for SCRI was included in the FY 2020, 2021, and 2022 appropriations bills. Until a permanent fix is enacted, the FY 2020 language restoring the waiver authority must be included in annual appropriations bills. I urge the committee to continue to support specialty crop research by providing full funding for the Specialty Crop Research Initiative and Block Grant in FY 2023

Next, I want to touch on the importance of funding federal nutrition assistance programs. Recent data from the U.S. Census Bureau show 11.2 percent of households in the U.S. reporting food insecurity. The number is higher for families with children, at 14.5 percent. Overall, 1 in 6 children don't always have enough to eat. Clearly, these programs are more important than ever.

As a pediatrician, I cannot overstate the importance of ensuring our children not only have access to food - clearly priority number 1 - but also that foods are nutritious. Poor nutrition is linked to chronic diseases, such as diabetes and heart disease. I ask the Committee to provide the necessary funding to ensure kids have access to nutritious food. That should include supporting **WIC, SNAP, TEFAP**, and more.

Within the TEFAP program, I also want to emphasize the importance of **Emergency Food Program Infrastructure Grants**, which Congress established in 2008 specifically to help emergency feeding organizations with capital, infrastructure, and operating costs associated with the collection, storage, distribution, and transportation of perishable food. Feeding America estimates that the unfunded critical capacity needs across the nation's network of 200 food banks and 60,000 partners agencies could be well over \$500 million. To begin closing this

gap, I request that the committee provide \$15 million to fully fund the Emergency Food Program Infrastructure Grant program.

Lastly, I ask that you fund **school kitchen equipment grants at a level of at least \$60 million** to enable schools to serve healthier, more nutritious meals by modernizing their kitchens and updating the essential equipment needed to prepare foods that our children will enjoy. I further request you include report language lowering the minimum limit for school equipment from \$5,000 to \$1,000 to allow schools the flexibility to procure equipment needed the most.

Since 2009, Congress has made funding available to schools for the purchase of updated school kitchen equipment through the USDA School Kitchen Equipment Grant program. This support is vital, as nearly 90% of schools need at least one piece of updated kitchen equipment and many school administrators lack the funds needed to make these investments. Many school kitchens were built decades ago and designed with little capacity beyond reheating and holding food for dining service. Without the right tools, school districts rely on expensive, unsustainable workarounds. This is especially important at a time when we are focusing on improving school nutrition and setting the stage for a lifetime of healthy eating. It doesn't matter how healthy foods are if our children won't eat them. Let's give our schools the tools they need to make healthy food taste great. I can think of no better way to support local educators, school food service, and students.

Thank you for your leadership during this process and for your consideration of the needs of my District.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kim Schrier".

Kim Schrier, M.D.
Member of Congress

Mr. BISHOP. Thank you, Dr. Schrier. We appreciate your dedication and your passion for the programs that are in our bill, and we look forward to working with you to address the issues that you have raised on the community project funding requests. Our staff is still working to vet the requests, and it is our hope that we can fund as many of these projects as possible.

Dr. Harris, do you have any questions or comments?

Mr. HARRIS. I just want to thank Dr. Schrier and agree that research is very, very important in agriculture and is going to keep us the leading country in the world in our agricultural sector.

Thank you for taking the time this afternoon.

Mr. BISHOP. Okay. I see Representative Newhouse is on the call. Do you have any comments or questions, Mr. Newhouse?

Mr. NEWHOUSE. Thank you, Mr. Chairman, Mr. Ranking Member. Not really. Just I do appreciate the engagement of all of the witnesses that we have had today. Like you said, many of the things that we touched on are very important, and it is good to know that they are priorities for other members outside the committee.

I am particularly interested in Dr. Schrier's emphasis on helping the food safety net that we have in central Washington State. That bleeds over into my district as well—the investment that she is talking about—so I particularly appreciate that and look forward to working with all of our witnesses in furthering the development of our agricultural industry and meeting the needs of our growing population.

Thank you.

Mr. BISHOP. Well, thank you very much, Dr. Schrier, for speaking with us today. And without objection, your entire written testimony will be included in the record.

I want to thank all of the members again for testifying before our subcommittee today. We appreciate your coming out and taking the time to talk with us about the projects and the programs that are important to your constituents. Your input will be vital as we move forward with the 2023 appropriations process.

At this time, I would like to recognize Dr. Harris for any comments that he would like to make before we close. Do you have any closing remarks, Dr. Harris?

Mr. HARRIS. No, Mr. Chairman. I just want to associate myself with your closing remarks. I want to thank our members for their interest and, you know, keeping our agricultural economy moving forward in the important work we do in our subcommittee. And, again, thank the members for taking time this afternoon.

Mr. BISHOP. Thank you, Dr. Harris. And thanks to all of the members who were in attendance. Thanks to our wonderful staff who put this hearing together.

For members who were not able to attend this hearing to testify in person, if you wish to submit written testimony, please do so by the end of the day. Your entire testimony will be included in the record.

With that, the subcommittee is now adjourned.

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