S. HRG. 117–629

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

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

ON

H.R. 8239

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2023, AND FOR OTHER PURPOSES

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

THURSDAY, APRIL 28, 2022

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:04 a.m. in Room SD–124, Dirksen Senate Office Building, Hon. Tammy Baldwin (chairwoman) presiding.

Present: Senators Baldwin, Tester, Hoeven, Hyde-Smith, and Braun.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF HON. ROBERT CALIFF, M.D., COMMISSIONER

OPENING STATEMENT OF SENATOR TAMMY BALDWIN

Senator BALDWIN. I want to welcome everybody to our first budget hearing for this subcommittee of fiscal year 2023. And Dr. Califf, welcome back to the subcommittee. We appreciate your being here this morning to discuss the Food and Drug Administration's fiscal year 2023 budget request. In fiscal year 2022, this subcommittee provided historic funding for a wide variety of activities at the agency, and I want to continue that upward trajectory of the FDA, so it remains the world's gold standard for protecting public health.

That starts with the budget before us, which includes increases for important initiatives, including a focus on food safety, addressing maternal and infant health, and continuing to address the COVID–19 pandemic.

The fiscal year 2023 budget request for the FDA is ambitious and reflects the vast responsibilities of the agency. We need to ensure FDA has the resources they need to continue their mission. We must invest in safer drugs, safer medical devices, and a safer food supply. Dr. Califf, I am looking forward to hearing your vision for the FDA and how this budget will advance that vision and support these important investments. And I am particularly interested in learning about your proposed increases for FDA's core safety programs.

The budget request includes significant increases for food and drug safety, device shortages, and focuses on the infrastructure

needs of the agency. The FDA has the ability, and frankly the duty, to serve the public in a range of ways that matter deeply to people's health.

We ask a lot of the FDA, from rigorous reviews of medications and medical devices, to addressing a rapidly changing food system. The work the FDA does impacts the lives of every American. Recent reports have raised serious concerns about the FDA's food mission and have identified many areas where the agency has both chronically and acutely fallen short of its mission to the public.

Americans rely on the FDA to ensure that the food they are eating is safe and that they have the information they need to make informed decisions about what to feed their families. In many cases, it seems that the FDA has put food safety issues on the back burner. The FDA has to do better, and I look forward to hearing your response to that reporting here this morning.

Additionally, I know from my constituents, there has been much frustration regarding standards of identity and FDA's lack of urgency when dealing with this issue. The FDA did issue a rule on standards of identity for yogurt, but many provisions were objected to by the dairy industry, and a stay was eventually put in place. It should not take the agency 40 years to update a rule.

These are major challenges, and as chair of the subcommittee, I want to make sure the FDA has the resources they need so that Americans aren't left waiting and can trust the food they are eating.

Again, I look forward to your testimony and appreciate your being here today. And with that, I will turn it over to Ranking Member Hoeven for any opening remarks he may have.

STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Thanks, Madam Chairman. Appreciate it. Thanks, Dr. Califf, for being here. Appreciate you being here to discuss FDA's funding priorities for 2023. Also appreciate visiting with you yesterday ahead of time so we could go through some things. We want to congratulate you on your return to the Commissioner's Office, and also thank you for your many years of public service.

And I was pulling for Duke, too, as I said, mainly because I wanted to see Krzyzewski win it on his last year coaching. He has just such a remarkable, incredible record. I met Dr. Wooden and of course thought he was the finest basketball coach of all time. But I would have to say Krzyzewski is right up there with him.

He is just a class act, too. Obviously, FDA plays a critical role in advancing the safety and prosperity of our Nation. You regulate more than $2.5 trillion worth of products on a daily basis. And so, you know, obviously, you are and have to be really the gold standard for food and drug safety. It is what the public requires.

And really the rest of the world looks to you in terms of setting that standard for that safety for our citizens, and not just citizens of America, but obviously there is consumers across the world that are affected by the products that you oversee in your duty for safety. So in the past decade, we have had seven FDA Commissioners, you know, which is a lot of turnover in the agency, obviously. And

so really, the challenge is of course, at the same time, pandemic, COVID–19.

We have also had to deal with Zika, Ebola, and other, you know, public health issues. Opioid epidemic. So all these things are incredibly important and are real issues of obviously life and death. And so, you know, creating some longevity in terms of, you know, planning and long term planning and, you know, stability for the agency is important. Over the decade, we have provided almost $850 million in additional baseline funding. That is about an almost 35 percent increase over the 10 year period.

More than $1 billion in emergency funding for public health emergencies. $500 million to implement 21st Century Cares Act. And then there is also a $1.1 billion in increased user fee assessments. So there is an increasing resource pool. I know resources are always a challenge, but we have got to deploy and utilize these resources wisely and as well as we can.

You know, so I think that investment certainly represents our commitment of this subcommittee, and really the whole Appropriations committee, you know, to the safety of our food and drug supply. With that said, we have got to continue to make strategic investments, something you and I have talked about. We have got to modernize.

The technology is incredibly important. It is going to play a huge role going forward as it is in almost every other aspect of what we do. But clearly, you have a challenge to get your technological capabilities up to where they need to be.

And as we talked about, that is a process. I don't know that you ever get there, right? Because as soon as you get there with one part, then you have got to upgrade some other part. The technology develops so fast, but it is obviously incredibly important that we upgrade your technology..

So again, I think that all comes as part of you trying to instill this, you know, longer term view, not only for your term as Commissioner, but for future Commissioners, getting a strategic plan that really you can work to deliver, and your successors can continue. They may modify it, you know, because everybody has their own ideas about things, particularly round here. And so but, you know, they will make changes, of course, but still, nailing down this plan, I think, can be a real legacy issue for you, particularly with your background and experience.

So I think that is incredibly important. I guess those are the main thoughts that I have for you. And again, thanks for being here today and for testifying and taking our questions. Appreciate it.

Senator BALDWIN. Thank you. We will now hear from Dr. Califf, Commissioner of the Food and Drug Administration.

SUMMARY STATEMENT OF DR. ROBERT CALIFF

Mr. CALIFF. Chair Baldwin and Ranking Member Hoeven and members of the subcommittee, thanks for the opportunity to appear before you today to discuss the 2023 budget request. Also, thanks for your kind comments and the delineation of the challenge, which I think is very real.

As a loyal Duke fan, I am not sure Chairwoman Baldwin is totally on board with that wearing her Wisconsin red, but, well, it is good to have something like sports which comes and goes, and it is perfectly okay. So let me thank the subcommittee for your continued support, which you have just enumerated, particularly over the last 2 years as the agency has worked tirelessly to respond to the COVID–19 pandemic.

I also want to thank the entire FDA staff. I am happy to be back with them and to join the effort to end this pandemic and ensure that we are prepared for the future. To realize our potential as we move forward, we need to look carefully and critically at the past 2 years. One of the most important lessons learned was the need to modernize the technology and scientific infrastructure that enables FDA's experts to do their work.

It is also important to consider the best technology will be to no avail if we don't attract and retain our first rate workforce. The same forces that are driving the amazing bioscience and digital revolutions are also causing intense competition for the limited cadre of well-trained experts. The budget I present to you today will build the foundation for FDA to continue this good work and ultimately allow 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 focus on three specific funding needs that do not get enough public attention, although you both mentioned them in your introductory remarks. The first is data and technology modernization. The second is people.

And the third is infrastructure. I know what most people are thinking, with 5 minutes to present, you want to talk to us about data, people, and buildings? The answer is yes. Data is used to support every decision the FDA makes, and modern computation holds the key to the efficiency and effectiveness that I know you want. There is a reason for the saying, in God we trust, all others must bring data.

The FDA houses more data than the Library of Congress and houses and protects trillions of dollars' worth of commercial and intellectual property, as well as clinical trial data that encompasses the health information of tens of millions of patients across the country and the world. But the technology and data systems are not of the quality we need for us to fully facilitate innovation in the rapidly moving industries that we regulate, nor to protect the public from the well-meaning, or from either well-meaning or intentionally harmful products.

We must modernize to be able to keep up with burgeoning industries and support innovation as underscored by the messenger RNA vaccine effort that was so essential to our pandemic response. Our budget requests approximately $68 million for data modernization to help bring the agency into the 21st century. Many of you have been concerned about the efficiency of the agency.

Much of FDA's work involves inspections and review of applications and data from companies developing and refining products through integration of increasingly complex biology and digital technology. A modernized technology and data infrastructure at FDA will have direct benefits on these core functions. At the same

time, we are inundated with claims from the real world of the post-market environment, where we often find major safety issues, some of those in the press as we speak, as these products are used by our diverse population in different environments.

It would be unwise for the FDA to be hobbled by inferior technology to deal with food outbreaks and importation, complex medical products, or understanding the consequences of toxins in our food. FDA inspectors, even during the pandemic, traveled to a variety of places or used virtual technology to record data about the quality of products and the quality of the systems and processes that make the products high quality and safe, whether the product is a food, a complex device, or a sophisticated drug or vaccine.

These inspectors currently must spend significant time entering data into systems that are outmoded and cannot integrate the information in a way that modern technology can support. FDA reviewers are also increasingly dealing with complex datasets that are generated through deep biological computations that involve integration of disparate sources of data from embedded biosensors and digital technology.

Each Center at FDA has invested in its own technology, remnants of a time when interoperability was not a consideration and artificial intelligence seemed like science fiction. This balkanization wastes time, drains resources, and creates safety vulnerabilities. In short, we need to be able to do more inspections, do better and more reviews, and much more efficiently detect signal from noise and post-market safety.

By embracing the full array of data science, advanced statistics, machine learning, and artificial intelligence, we can enable our inspectors and reviewers to focus their effort on areas where they can make a difference. This will not only enable our workforce to be more efficient, but also will make their jobs more interesting, and this is a win-win.

Our physical infrastructure is also in desperate need of modernization. The agency has a $300 million backlog of building maintenance and repairs, which increases every year. Our Nation depends on these facilities to test, review, and evaluate the safety of the food we eat and the medical products we use. The budget asked for approximately $40 million to support these physical upgrades.

I invite the subcommittee to visit our facilities across the Nation and see our work in action. I know you will agree our work is worth the investment. I know infrastructure doesn't have the same gluts as some topics, but unless we make these investments now, much of our ability to regulate and support the innovation that makes us competitive will go to waste.

Throughout this session, I am prepared to provide specific examples of how data and technology modernization, support of our workforce, and upkeep of our facilities will lead to improved health and competitive advantage in global competition. And before I close, I want to flag an issue I know is a keen interest to the subcommittee.

I am pleased to announce that this morning FDA will issue to propose tobacco standards, one prohibiting menthol as a characterizing flavor in cigarettes, and another prohibiting characterizing

flavors other than tobacco and cigars. Through careful consideration of the scientific evidence and our authorities under the Tobacco Control Act, we have determined that these actions are appropriate for protection of the public health.

The proposed product standards would, among other things, improve the health and reduce the mortality risk of current smokers of menthol cigarettes or flavored cigars by substantially decreasing their consumption and increasing the likelihood of cessation. This is another important move forward in the agency's efforts to combat youth tobacco use and promote health equity.

And we look forward to working with Congress and the public as we seek feedback on our proposed standards. Thank you for inviting me, and I look forward to answering your questions.

[The statement follows:]

PREPARED STATEMENT OF DR. ROBERT M. CALIFF, M.D.

Chair Baldwin, Ranking Member Hoeven, 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 fiscal Year 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 2 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 fiscal year 2023 Budget Request builds upon our fiscal year 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 fiscal Year 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 fiscal year 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.

ENHANCING FOOD SAFETY AND NUTRITION

FDA's Budget requests an increase of approximately $76 million above the fiscal year 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 fiscal year 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 fiscal year 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.

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 fiscal year 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 fiscal year 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 fiscal year 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.

INVESTING IN CORE OPERATIONS

The Budget requests an additional $158 million above the fiscal year 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 fiscal year 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.

MODERNIZING INFRASTRUCTURE, BUILDINGS & FACILITIES

FDA's fiscal year 2023 Budget also requests approximately $40 million above the fiscal year 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 fiscal Year 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.

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 3 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 percent 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.

PANDEMIC PREPAREDNESS

Finally, the Budget includes a request for $1.63 billion in new mandatory resources over a 5-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.

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.

Senator BALDWIN. Thank you, Dr. Califf. As I mentioned in my opening statement, there was a recent Politico article that highlighted what seems to be significant dysfunction and lack of urgency in the food safety mission of FDA.

Dr. Califf, I would like to give you an opportunity to respond to that article. And as Commissioner, I would like to ask you what fundamental changes are needed in order to make food safety more of a priority within the agency?

Mr. CALIFF. Well, I do appreciate the opportunity to respond. And I want to assure you that any criticism like this is to be taken seriously, particularly since it did involve some former people that have worked at the FDA.

And so I have been looking at the criticism carefully, but also was aware of concerns before coming back. The first order of business is to assure you and the public that our food is as safe as it has ever been. And we know much more about nutrition now than we did 5 years ago when I was here, thanks to the good work of the people who are at the FDA and at other Federal agencies, not to mention the States and people involved.

And I have spent some time going to sources to verify that this is the case. And the people who keep the data are assuring me that this is the case. But that doesn't mean we can't do better. And in fact, a lot of what I tried to lay out in the opening comments was that it really is a combination of the people involved, with their skills and talents and the technology that will make a difference going forward.

We have a plan which is on record already before I came back about the smarter era of food safety, which is based on the concept that, you know, we have a rapidly growing industry that has many, many facets, and the only way to really keep track of it and assure safety is going to be increasingly to use digital technologies so that we can make the best of the human talent that we have.

And this is very much baked into our plan, but it is also very dependent on the funding that we have asked for. In addition to those measures, of course, we are looking at our internal operations and it is absolutely essential that the industries know who they—is accountable, who they are talking with. I will have more to say about that over the next few months, but we are intensively looking at the issue of how we are organized.

Senator Hoeven already mentioned, there have been a large number of Commissioners in this chair, and that is very destabilizing for any place that you work if the bosses are changing at such a high frequency.

So I don't want to rush into something and immediately react to suggestions that have been made. I want to do something that has a lasting effect so the next person in this chair will not be feeling like they need to start from scratch.

Senator BALDWIN. Dr. Califf, rebuilding public trust in the functions of the food mission area is going to take time. This is important for consumers and public health, but it is also critical for industry. Farmers, food processors, and retailers build their businesses to meet the process and ingredient claims that FDA regulates.

These businesses need certainty so that they can focus on their important work of providing food that consumers can trust. A key way FDA has fallen short is the way it has handled the use of dairy terms.

You and I have talked about this extensively before. Despite providing clear requirements for what products must do in order to use a dairy term on their label, FDA has failed to enforce these labels and has stood by while a wide range of dairy alternatives have emerged and market themselves using dairy terms, dairy labels.

When we met prior to your confirmation, I appreciated the commitments you made to look into this and find a resolution. Could you share an update on where we are at?

Mr. CALIFF. Glad to share an update. I mean, first, just a background, which you know well is that there are approximately 280 standards of identity. The process to deal with these is quite cumbersome, involving rulemaking, as you know. And when objections are raised, then a lot of additional time goes by. But that doesn't mean that I am happy or anyone at FDA is happy with how long it has taken to get things done.

So we do appreciate the money that has been allocated in this year's budget and also we have asked for more going forward to optimize this. Specifically, as you know, the milk related issues are under consideration as we speak. So I can't give details of exactly what is being said, but I will just mention two.

One key principle and one finding, which is publicly known from the public meetings that we have held, I think all of us believe that people who buy a product should be able to understand what is in the product and also what the value of the product is, particularly when it comes to food in terms of nutritional value.

And in that score, so far in the public meetings, the tenor has been that people generally do know the difference between plant and animal milk. They can tell that difference, but they are not very equipped to deal with what is the nutritional value.

And so those are just considerations from the meeting. We are moving along quickly, and it is a priority to get this done, so I can assure you we will get done. And I know that you will be calling me to account for every day that it is not done.

Senator BALDWIN. Thank you. Senator Hoeven.

Senator HOEVEN. Thank you, Madam Chair. Going back to something that I mentioned in the outset and that you mentioned as well, and that is the turnover we have had, 7 Commissioners in 10 years. I want to acknowledge Dr. Woodcock for her work at the Center for Drugs and also for acting as Acting Commissioner for the past year. So I want to do that. And then, but then I also want to follow up with you on it, Commissioner, you know, with regard to your plans to modernize the agency.

Talk a little bit about your multi-year build out plan, and specifically metrics and goals that you plan to use to guide that effort, to track results, you know, set goals and benchmarks for your team, also, again, with the idea that kind of setting it up for the next Commissioner as well, so it is something that continues.

Mr. CALIFF. Yes, I really appreciate the question. I also want to publicly acknowledge Dr. Woodcock who graciously has agreed to stay on. And I think this is really a critical part of what I hope to accomplish. Neither she nor I are youngsters. I am 70 years old. She was actually overseeing my clinical trials when I was a young cardiologist.

Senator HOEVEN. Didn't you tell me you have a student at Duke, though? So you are a young 70 if you still got kids in school, man?

Mr. CALIFF. No, no. My student at Duke graduated years ago. Got his time on ESPN for having attended the——

Senator HOEVEN. Oh, okay.

Mr. CALIFF [continuing]. but he is almost 40 years old now. But I do have two 18 year old grandkids, so that—who are going to college next year. And neither at Duke, you know, I must say, but quite proud of them and where they are headed. Dr. Woodcock is going to be a great asset because she knows the FDA really well and she is going to be focused on the operations of the FDA and the kinds of improvements that I will talk about.

I tried to get across in my opening comments, I think I have learned a lot both in my academic, medical, clinical practice and having worked at Alphabet. I have learned a lot about how computers can improve the efficiency of human work, but also make it more fun. And when we think about a job at the FDA, you know, it is hard work, and you get criticized every day and that is understood as part of it. And for us to attract the best people, we have got to have really first rate technology on that front.

But from the point of view of our ultimate customer, the American public, given the expansiveness of the industries that we are regulating, I mean, they are really succeeding. America is a leader in biotechnology. We are feeding large parts of the world and we have the capability of doing more of it if we employ the technology that is in front of us.

So how are we going to regulate this if the FDA doesn't have the right technology? How would you even know if it had an algorithm in a software that is in a tractor on a farm has a problem or not if you don't have people at the FDA with the technology that they need in order to oversee it. And the same would hold for the vast importation of seafood, for example, which has been of great interest to Congress.

A majority of our seafood is imported, coming from faraway places. We can't inspect every batch of seafood, but we have a pilot project which we are going to expand. We are using the same technology that Amazon or Google would use, using algorithms and artificial intelligence. We can send the inspectors to where the highest probability of a problem is. So that is the kind of thing that I am talking about.

I am talking about people at FDA that have a better job where they are aided by technology and can do a better job for the public. And one of the great things about this is that this will not reduce the number of people that we need because the industries are expanding so rapidly. It is just going to mean that they will be able to do a better job. It is not a loss of jobs. It is really making the jobs better.

On another day, I hope we will engage in discussions about the job of the FDA Commissioner. There is a reason that there is a turnover that is so great. And, you know, I think it deserves careful thought by everyone involved about how to make this a job which maybe someone younger than age 70 would want to take.

That is sort of one way of saying it. But I think it does deserve some consideration the conditions of this particular job. None of our jobs are easy. This is a particularly tough one. I was glad to come back because I have been through it already and I see the chance to do something for the next generations.

But for someone in mid-career who you might want in this job, it is really hard to take it right now the way it is.

Senator HOEVEN. Well, I think that does merit discussion. And I think that is an important point you bring up and something we should discuss.

Mr. CALIFF. I mean, it is a matter of public record that all of the living former FDA Commissioners have written about this. And, you know, we come from a variety of political backgrounds, having all been political appointees, but there is a pretty common view of it among every single living FDA Commissioner, and that is a fairly large number now.

Senator HOEVEN. Right. I guess one more question, we may have to pick it up in the next round, but advanced manufacturing and manufacturing here. What can we do? You know, we provide significant funding.

I think it is around almost $40 million to promote domestic manufacturing. So there is a real concern about that now. So maybe start with—I am already over my time. I will save that one for the next round.

Mr. CALIFF. Yes, I look forward to answer on the next round. I think is really important.

Senator HOEVEN. Yes.

Senator HYDE-SMITH. Thank you, Chairwoman Baldwin and Ranking Member Hoeven for having this hearing today. And I would also like to thank Commissioner Califf for being here to discuss this budget with us and appreciate your efforts and willingness to step up.

Earlier this week, we had a very good conversation together and I really enjoyed learning about your experience in rural Quitman County in Mississippi and helping the folks there that are medically underserved, and that really hits home, since Mississippi is a very rural State, that you do have that interest.

But I look forward to finding ways to advance rural health and to work on this issue together in your new role. One of the other issues we spoke about on our call was the FDA's decision to remove the in-person dispensing requirement of the chemical abortion drug mifepristone, and how this change would expand the distribution of products like this that can be delivered directly to someone's mailbox, effectively permitting mail order abortion in this country.

And in February of this year, I sent you a bicameral letter requesting that you immediately rescind the removal of in-person dispensing requirements for this drug. And your response, which I did get last week, said that you had conducted a comprehensive review of the REMS program and that you concluded that even without the in-person dispensing requirement, this drug would be safe and effective.

And I and many others disagree with that. There is plenty of evidence showing this chemical abortion pill, there are dangers to women who take them and can be extremely dangerous in certain situations. It is the job of the FDA and your job as Commissioner to protect patients by ensuring the safety of drugs.

And the stronger REMS that had been in place since 2019 included safeguards to protect patients from unnecessary risks posed by this drug. And given your belief that your review was fully comprehensive, I will request full information on all literature reviewed by FDA during this process and other information related

to that specific review. And I will be following up with both the letter and questions for the record for this hearing about the review.

So I am just asking, can you provide full and complete information on this review to me in a timely manner?

Mr. CALIFF. Well, Senator, first of all, thanks for noting the places where we will work together. And on this matter, of course, we will be responsive to your concerns and in a timely manner. I have great confidence in the FDA staff who did this review, and it involved a variety of materials.

And as we also discussed, there are still a requirement for reporting adverse events related to this, and they will continue to look with due diligence.

Senator HYDE-SMITH. And do you commit to answer all the questions that we send you?

Mr. CALIFF. I will commit to being responsive to your requests.

Senator HYDE-SMITH. And additionally, you said on our call that data showed chemical abortion numbers were going down and you were certainly glad about that and in favor of that. But however, data analyzed by the Charlotte Lozier Institute shows the opposite. And chemical abortions now make up more than half of all abortions in the United States, in this country. I did not realize that.

And in 2019, chemical abortions jumped 11 percent in Mississippi. And this is obviously a very serious concern of mine from talking to OBGYN friends. And as you said, you want to see the number of abortions going down. What are you doing to reverse this trend of increasing chemical abortions and actually helping to lower those numbers?

Mr. CALIFF. Well, just to be clear, I hope I didn't misspeak on our phone conversation. The total number of abortions is going down. The proportion of that total that are chemical abortions is going up, you are correct. And I think we all would like to see as few abortions as possible in our future as a general goal. So I hope you didn't take it to mean that I was saying that the chemical abortions were going down because I didn't intend to say that. It is the total number of abortions.

Senator HYDE-SMITH. Okay. But you—obviously you are correcting that of what we thought that it was going down and you are stating that chemical abortions are going up.

Mr. CALIFF. The proportion—actually, I would have to go back to the record to see about the total number because of the total numbers coming down and the proportion that are chemical are going up, I actually don't have the number in front of me about the absolute number. I hope that makes sense to you.

Senator HYDE-SMITH. Oh, yes.

Mr. CALIFF. Okay.

Senator HYDE-SMITH. Thank you very much.

Senator BALDWIN. Senator Tester.

Senator TESTER. Thank you, Madam Chair and Ranking Member. Appreciate you doing this hearing. It is good to see you in front of the committee, Doctor. I am glad that you got confirmed and I am glad you are here, okay.

Mr. CALIFF. Thank you.

Senator TESTER. I just want to talk a little bit about FDA and its role in food. I could get you some statistics on what has been

spent on medicine versus what we spend on food 30, 40, 50 years ago. You are saying to yourself, where the hell is he going with this? And I can tell you right now we are spending a lot more money on medicine than we ever did 50 years ago. And quite frankly, food is a lot cheaper, which is not a bad thing.

But in the end, I ask myself things like being a farmer, raising wheat, and having wheat being—so many people allergic to wheat, okay. Is the staff for life really the staff for life today? And the question is for you is not anything more than what does FDA, what role does FDA play, if any, in our just our general food supply and making determinations whether things like grains reduce inflammation, and whether what we are really eating is medicine, is going to really nourish is moving forward.

Just curious, and I know this is from outer space coming in at you, but I am just curious to know where your vision is for the FDA on that, and if they want to play in that, or if they do play in that, or if they——

Mr. CALIFF. Thanks for that question. And I want to relate it to a couple of things. First, Senator Hyde-Smith brought up rural health. And, you know, I am a cardiologist. I had a very busy intensive care unit practice in North Carolina for many years, and I have seen the consequences of having the wrong diet.

My time in Quitman County, Mississippi, was dealing with obesity and diabetes as a problem, trying to figure out how to get electronic health records to interdigitate to do a better job of caring for it. And I would just say we are in the midst of it all the time. To point out one other particular thing, we talk a lot about vaccines and drugs and PPE for the pandemic.

We have sort of forgotten about the food supply, which was a major crisis, as you remember. And the FDA had a major role in helping deal with the supply chain as it related to foods, just as one example.

But on the science basis, and this is really critical to some of the discussion going on right now, Senator Baldwin referred to the Politico article, there is a thing at the National Academy of Sciences, it is called a convergence, which means because more of our knowledge is becoming digital, when we talk about chemistry, biology, physics, agriculture, and nutrition, it is all becoming the same underlying structure of knowledge.

And so there is a real advantage to FDA dealing with the kind of things that you mentioned about what is safe and unsafe, what are the safe levels? Because across the FDA, we have a tremendous amount of scientific expertise. And as you know, we do have the responsibility for food labels.

That is a huge part of what affects the way Americans eat. And then finally, you know, and a lot of this is shared with the Department of Agriculture, as you well know. But I think we are going to be looking, you know, regardless of what you think is causing climate change, just look at the—you know, I lived in San Francisco until coming back to Washington here.

Look at what the drought is look like in California right now. We are going to have tremendous capability to feed the world if we take advantage of the technology that is before us. And I think the FDA is almost uniquely equipped to deal with that because we deal

with it across human health, whether it is a drug or device, biologic or food.

Senator TESTER. So, we happen to have some bills, and the Administration has done some things on the supply chain for food. Senator Hyde-Smith spoke eloquently two days ago on a couple of bills that we have that deals with supply chain issues in food. And look, in my real life, I am a farmer and I do believe that we raise some of the safest food in the world.

The thought does cross my mind that who is kind of watching to make sure what we are doing, because we tend to manipulate food all the time, because we know more than we have ever known in the history of man, that the manipulation is actually not making a sick, that is making us healthy?

Mr. CALIFF. Well, Senator Baldwin referred to the metrics. I think compared to what I saw in the industry I just worked in Silicon Valley, the metrics and readiness of the metrics that we have right now related to health are just not where they need to be. And I was on a call yesterday with a Dr. Walensky at CDC, which keeps a lot of the metrics.

We have a shared responsibility to upgrade the system because there is no reason with our data capabilities now that we shouldn't be able to sort of like the weather, you are used to, you know, turning on the TV and the weather report is saying, here is what is going to happen tomorrow, here is what is going to happen a month from now, or here is the next 3 months.

The further out you get, the less precise you are. But we should have that for our health, too. And in fact, I am 100 percent sure we are capable of doing it. We just have to work with you to get the right funding and the right technology.

And last thing I would mention about that, we have to work with the American people to build confidence that the data that comes up is going to be used for good purpose. And I don't want to make light of that other responsibility.

Senator TESTER. Well, look, I appreciate your history and where you have been and your knowledge, and like I said in the beginning, I think it is great you are in this position. I think you are the right person for this position. And I look forward to your guidance that you can help give Congress to make sure that we are meeting the needs of the agency, but ultimately the people. So, thank you. Thank you.

Mr. CALIFF. Thank you.

Senator BALDWIN. Thank you. We are going to undertake a second round of questioning. Dr. Califf, even before the COVID–19 pandemic, FDA did face backlogs and delays with regard to inspections. Last year, a Baltimore facility that was manufacturing the J&J vaccine was found to have contaminated material in their vaccines. And a recent report cited problems at an infant formula manufacturing site that left babies sick.

What you are doing now to ensure more rigorous inspections are occurring? What are your plans for ramping those things up in the future? And the budget is requesting an additional $23.8 million for increased site inspections. How will this funding support decreasing the backlogs that we have right now?

Mr. CALIFF. Thanks for bringing up the chance to talk about this. And, you know, I think it is obvious to everybody in the midst of a pandemic, it is going to be hard to physically get to locations. And we even have cases, as in the infant formula case, which is in the press now, where a COVID outbreak in the facility makes it so the inspectors sometimes can't go in.

But we are recovering now in terms of the numbers. We will be able to provide you with exact numbers after the meeting if you want to have them. But we are recovering. But we do need additional funding to get more inspectors out there because there is a backlog that is very real. What I also wanted to get across in my opening comments and repetitively today that we are dealing with an expanding industry, and a global industry, and Americans like homegrown food and products, but they are buying a lot of things that come from overseas.

So we have got to put money into technology that allow our workforce to get more done, more intelligently using computational and artificial intelligence so that they are inspecting the right things at the right time.

Senator BALDWIN. Yes. On that topic, you know, aside from the physical plant inspections, tell me about the current availability of the technology and tools that you are describing, and how quickly those could be implemented to supplement the physical inspections.

Mr. CALIFF. Well, I think the best way to say it is there is a synergy here between the plans for the people and the way the technology works. So just think about yourself, for better or worse, the way you buy things now by looking at on the Internet, there is three dimensional viewing you can do. You can test that all out and it is all done without having to travel and physically go to the store.

Now, some of us will wish we more often physically went to stores nearby, but you can do that because of technology. So then imagine an FDA inspector at a mail facility and I would urge you to go look at this. Americans are buying all sorts of stuff, much of which is dangerous.

And an inspector has to record tremendous amounts of data when something is picked up because every importer has a recourse to go to court to contest seizures and findings. Imagine that you are having to use the technology like you were buying stuff 15 years ago and then apply it to an inspector on the job today. A lot of things that the inspectors would otherwise stop are getting through because there is just not time to do it.

And I think if we modernize the technology, they will be much more efficient. I think Dr. Hoeven got it right. You know, if we are synergistic, it is not linear it is more than that. But it is an ongoing, at least a five year effort.

And if I might say so, the Federal Government in general is not ideally suited for the kind of technology outfit that is needed. And I think we are all going to have to work together at HHS on this issue. I know CDC has talked on the Hill extensively about the needs there.

Senator BALDWIN. Thank you. Senator Braun, have I given you enough time to ask your questions? Okay. Go right ahead, you are recognized.

Senator BRAUN. It would seem like it, but I am prepared.

Senator BALDWIN. Excellent.

Senator BRAUN. Thank you, Madam Chair. Good to see you again. I think it has probably been covered somewhat, but I know that your leadership at the FDA in 2016 and we have discussed it before to kind of weaken the risk evaluation and mitigation strategy protocol on the drugs used in chemical abortions. And studies have shown that the rate of abortion related emergency room visits after chemical abortions have risen by about almost 500 percent.

And when we last spoke, you testified that the FDA had filed a court document about the evaluation of the data on the chemical abortion drug and that the reevaluation is imminent. My question is, why has the FDA allowed these weakened protocols for chemical abortion drugs, and are they undergoing FDA and court review for safety and efficacy?

And a follow up would be, should REMS be strengthened to protect women from dangerous effects from chemical abortion drugs as well? So if you could answer those two questions, I would appreciate it.

Mr. CALIFF. Yes. Senator Braun, we did cover this a little bit earlier, but I know that you are very interested in this and see this topic as very important. As we discussed before, the Commissioner doesn't make decisions about individual products.

There is a team within FDA that does that. But of course, Commissioner gets to see the work. I have great confidence in the team. They have thoroughly done the job and they are going to continue to monitor as required by law.

There is a requirement to submit adverse events to the FDA and they will continue to look. And if there is a need for a change, I have every confidence they will do so.

Senator BRAUN. Well, I think as we transition to where that looks like the modality preference, I think it needs to be paid attention to. And it will be interesting to see if the same standards are adhered to with that as maybe what has been done in the past. Let's move to another subject on opioids.

The National Academies report on combating the opioid epidemic suggested the FDA develop a new process for reviewing the safety of all approved opioids. I understand that you were confirmed not too long ago, obviously, but this information has been out there since 2017. Since your confirmation, have you reviewed the recommendations from the National Academies report?

Mr. CALIFF. Yes. In fact, I am a member of the National Academies, and I asked for that report during my tenure in 2016. So I followed it pretty carefully since I thought it was an important component of changing the paradigm that the FDA was working under.

And there is now a draft guidance that takes into account one of the most important parts of that report, which is normally the way a decision about risk and benefit for a drug works is, is the risk and benefit to the individual to whom the product is prescribed, but that is not adequate for opioids.

Senator BRAUN. So you have done a formal review of it in addition to reading it.

Mr. CALIFF. Yes. And there is a—well, when you say formal review, yes. I mean I have read it and I have thought about it, and we have a whole team working on implementing a number of changes.

Senator BRAUN. So then I guess to cut to the chase, when it comes to any rulemaking that might change vis a vis that report, do you anticipate that happening and when?

Mr. CALIFF. I think you will see over the course of the next year or starting imminently, and you are probably familiar with the opioid summit that happens in Atlanta that Congressman Rogers started over a decade ago. I attended that and gave a very detailed speech about our plans. And it is a matter of public record, and we will make sure your staff gets it and you can look at it.

There are a whole number of things, some of which are in process now and some of what you will see in the next month, and there are—I must say, there are a couple of areas where we are probably going to come back to you if there's concurrence within HHS and say that we need some new legal authority. Just to give an example of one that I am particularly concerned about that we have talked about a lot.

Right now, the FDA doesn't have legal authority when it comes to a new drug application to require that it provide superiority to drugs that are already on the market. The comparator legal comparator standard is compared to placebo or nothing.

And I think for opioids don't work like other drugs. And I think that is something that I would like to see happen that may require something from Congress to institute that. That is one example.

Senator BRAUN. I think at the level of where the crisis still is relative to opioids, that additional authority and then subsequent rulemaking that tries to do more there, most of us would expect that to happen and would be warranted.

Mr. CALIFF. Well, thank you. And I just want to remind you, as we discussed, that between my two sons, we started a not for profit in Dayton, Ohio, that dealt with everything from detox for people that were trying to withdraw from opiates all the way up to finding jobs and dealing with the legal system.

So I have a pretty comprehensive list. And I know Dr. Gupta from West Virginia, who is now at Office of National Drug Control Policy (ONDCP), just released the plan from the Government. And we are totally in support of that, and we will work as hard as we possibly can. And I have seen this in real life in Ohio, and it is something we have got to deal with.

Senator BRAUN. So on both issues, we will be watching. It sounds like you are willing to engage on it. And thank you for the time today.

Mr. CALIFF. Thank you.

Senator BALDWIN. Senator Hoeven.

Senator HOEVEN. Thank you, Madam Chair. So back to the advanced manufacturing and drugs, biological products, and devices. You know, how do we do more to produce and manufacture those things here at home? So, clearly something we need to do, and people are well aware of it.

Mr. CALIFF. It is so essential. And I was serving on the National Academies Supply Chain Committee until I was nominated, and I

had to drop off. Their report is now out so I can talk about it. And I think it is useful to divide this into several categories. And there are other reports that you have in hand from various agencies.

Resilience of the supply chain is a critical issue. And I think given the internationals strife right now, things that we didn't think were possible, we now have to also potentially anticipate. So we have got to have a resilient manufacturing base that Americans have access to. That doesn't mean that everything needs to be made in America because there is value in international trade, I think, as everyone knows.

But if we get ourselves in a situation where another country could either due to a natural disaster, or intention, or the way markets would cut off our supply. That is a real problem. So FDA has been working hard on this, as you know, and we appreciate the funding that we have gotten. And a lot of energy is being spent on upgrading our own capabilities. The reason the FDA needs to be so involved, I see it as twofold.

You might say, why does an industry just do this? Well, the markets don't necessarily work that way. And so there are areas where we think we can help industry quite a bit by creating prototypes and public, private partnerships. And the advanced manufacturing for our messenger RNA is one example that is pretty far along that you will see come to fruition fairly soon.

But the other part is, as we get to the more advanced part of advanced manufacturing, where you can, for example, make drugs locally in a small little shop, which is, you know, going to become possible sometime in the near term, the future of regulating that means that we have got to be sure that we can tell the difference when a good job is being done and not a good job.

And so the funding is much appreciated. We got more requests but the purpose is for exactly what you said. We think Americans should be secure, that the essential products that they need, whether it is food or drugs or devices, will be in hand when the time comes using all of our capabilities and technology.

Senator HOEVEN. I think so. And I think that is an area where, you know, we do have to put an emphasis and a focus on, because I think the public very much wants just given what is going on and has gone on nowadays with COVID and everything else. Along those lines, investment in gene therapy.

You know, clearly we need to do more there. Talk about that. I didn't see a significant request in the budget for investment, you know, to expedite reviews for gene and cell therapies. Clearly, though, that is an area with incredible promise. So would you please address that?

Mr. CALIFF. This is something that personally, as an intensive care unit doctor, I am very interested in and have spent a lot of time in the rare disease communities. In my time at Duke, colleagues developed the treatment for Pompe disease, which used to almost uniformly lead to death of young children and now gives some life.

So I very much want to make this work. We did get some funding in this past year's budget due to some overlap issues. You know, people said, well, what more do you want? And we do appreciate the funding we have gone. But I also want to report that in

the user fee agreements, the industry recognizes that this is an area where FDA needs more resources.

So we have, I think, reached a good agreement and the user fees to increase the support for this area. That doesn't mean we are not going to come back to you later or whether areas where the user fees aren't going to cover.

And again, I think a general principle, as I work with you all this time around, I am much more aware now of the role of FDA and Government in places where there is not an incentive for industry to develop things that society needs.

And I think what happened with a vaccine is like the super example where the investment that we made early in getting all members, Government and private, to the table made a big difference. There are other areas, I might point to antibiotics is another area, and some areas of gene therapy and regenerative medicine where there is not a ready market, or no one is sure how it is going to be paid for.

So we will be back in touch about that for sure.

Senator HOEVEN. Yes. And I think it really does also correlate into being ready to prevent the next kind of pandemic, so we don't have what happened with COVID–19.

Mr. CALIFF. We will do everything in our power on that. And I do want to call your attention there to One Health, which is something I think this committee ought to have a particular interest in. I have a daughter-in-law who is a veterinarian, so I have heard a little bit about this personally also. But even going back 15 years, Duke started a medical school in Singapore.

And I saw firsthand what was happening with transmission of viruses and bacteria from animals all over the world to humans and back and forth. It is due to the fact that we all travel these days and the international commerce. So essentially, then my first stint at FDA, I saw the technology evolving. Now, of course, we have whole genome sequencing so we can actually track.

But the informatics of this and the technology involved is far advanced over what we currently have on hand. But so we have got an ask in about One Health to start something in the center for Veterinary Medicine. I want to put in my pitch here. You all are all from rural areas. So I think CBM is the most underappreciated part of the FDA.

And typically, people only think about it when, you know, when we had the dog food problem, a lot of people wrote in and probably the biggest response until COVID times. But we do have a One Health request in which is mostly oriented to how do we create a data systems that allow us to track what is happening around the world so that we can intervene early and prevent the next pandemic.

Senator BALDWIN. Thank you. Senator Hyde-Smith.

Mr. CALIFF. Thank you very much, Madam Chairwoman. I am just going to change to another issue right now on medical gases. More than a million patients use medical gases every day with like oxygen playing a critical role when we were responding to COVID–19.

And the Food and Drug Administration Safety and Innovation Act of 2012 did an APA to issue regulations for medical gases by

July of 2016. However, no regulations had been issued to date despite the requirement in place by law. And there is a plant in Walnut, Mississippi—I think the population of Walnut, Mississippi is a little over 700 people, but they produce medical gases.

And the lack of regulations surrounding medical gases make it very difficult for my constituents in Mississippi to produce these lifesaving products and they have approached us with this issue. But where does the significantly overdue rulemaking on medical gases currently stand? And I know you are probably going to have to get back with me on this since you wouldn't know that immediately, I wouldn't think.

And just asking for your commitment that the FDA will publish this rule—there is a deadline of May of 2022, right, this right now, which was set in the fall of 2021 on the unified agenda. And I would just like to see if you had any responses to that and how they should be regulated rather than continuing to be regulated as drug products.

Mr. CALIFF. You know. Well, thank you for the question. And I am getting a little worried now because maybe I am so old that I can say I have been involved in just about everything. But in my younger days, I founded a company dealing with nitric oxide, which is in that category.

And so I am very familiar with the issues and also an intensive care practice we use a lot of medical gases. And we will have to get back with you, but just about one thing, my understanding is there was a regulation. It didn't quite go over that well. There were other issues brought up, and we are taking those into account now.

And my understanding is that we are on track. And it is part of the unified agenda, so it is definitely a priority, not just at FDA, but across the Administration. So we will get back with you on the details. But I think I have a pretty good understanding of the issues that are involved, and we will make sure they are taken care of.

Senator HYDE-SMITH. Great. Thank you. I appreciate that.

Senator BALDWIN. We are going to do a speed third round of questions. Okay. I think I have a couple more and ranking member does too. So we spoke earlier about the proliferation of synthetic nicotine products. And in the 2022 omnibus, that loophole was closed.

We made it clear that FDA had the authority to go after bad actors in this space to protect public health. I would love a report on progress in this space. Dr. Califf, can you provide an update on the FDA's efforts to address synthetic nicotine products? How many companies have filed applications seeking authorization? And are there additional resources that need to be applied to this part of the mission?

Mr. CALIFF. Well, thanks for bringing this up. And it gives me a chance to thank Congress for rapidly passing a law, because just for those not familiar with the issue was, we are regulating nicotine, but the law said tobacco and products derived from tobacco. And of course, if you are making nicotine in a synthetic laboratory, you can claim that it doesn't fall under the regulation.

So that loophole was closed in a very rapid timeline, in about a month for people to absorb it, then a month or two to get applica-

tions in for those who wanted to go through regular pathways that are available. And we will have to get back with you on the exact numbers.

But by mid-May, we should pretty well have this cleared up with those who shouldn't be on the market off of it, and or at least getting warning letters, and those who are applying, having their applications reviewed. I will take this moment to point out that all of our work at the Center for Tobacco Products has been done without user fees from the vaping industry. So, and you are aware of, you know, 6.7 million products.

Actually I sort of heard the number, but when I came into the chair and they said, what we are trying to deal with 6.7 million products that is a tall order. And a lot of work has been done, basically borrowing people's time from other funded areas. So we have got a request in for $100 million in user fees from the vaping industry because we still got a lot of work to do. Two million, at least two million teenagers are currently vaping.

Knowing what we know about nicotine addiction, and it is safe to assume the majority of those are already seriously addicted to nicotine. And I got to say, talking to my two 18 year old teenage grandkids, I am a little bit worried that there is underreporting going on among the teenage population, which would be understandable.

I think this is a big problem that we want to work on and help with, but we have no resources dedicated to it now.

Senator BALDWIN. Not to mention, my understanding is that there is not an approved treatment for adolescents and youth as there are for adults in this space.

Mr. CALIFF. Perhaps another time I would love to visit with you. And I think a general comment I would make is that if you look at people currently using tobacco products or addicted to nicotine with vaping, we need a care package to help them quit. People don't realize that the addictiveness of nicotine ranks right up there with opioids.

Now, you know, nicotine doesn't make you stop breathing. So there is not an acute overdose issue in general. But this is not an easy thing to quit. And we actually, I think, could do a better job of putting together products, including digital technologies now that could help people trying to get off of this addiction.

Senator BALDWIN. Thank you. Senator Hoeven.

Senator HOEVEN. Thanks, Madam Chair. The public health emergency declaration in 2020 allows the FDA to issue emergency use authorizations. But when that public health emergency declaration expires, that doesn't mean your emergency use authorizations necessarily expire. So how do you plan to phase those out?

Mr. CALIFF. Yes. So that is a great question and one that is sort of pressing now with the funding issue that is going on. We need to have these products transitioned at some point. The question of when is important. So on the drug side, this has pretty much been, I don't want to call it straightforward, but the same studies that were used for a EUA, as continued with modifications, are producing the data that you would need for a standard approval.

So I think we feel on the drug side that we are in pretty good shape over time to phase out the EUAs and phase on the standard

approval that a company could use. On the device, there is a definite plan in place that would involve notification and transition. We are sort of waiting on that time to come.

The device side, I think, you know, has many more products because it includes, you know, all sorts of tests and things that don't usually have the same level of study that would be needed even for an Emergency Use Authorization (EUA), for a drug. And so there is work to do there, but there is definitely a plan, and we would be glad to get back to you with the details of that plan.

Senator HOEVEN. Going back to actually the question that the chairman started with, some of the articles that have been critical of the FDA recently in the food area as probably even more so than on the drug side with reference to the structure at FDA.

So as you are doing your planning here, and as we talk about not only updating your technology, but the other things you want to do in terms of a strategic plan, goals, metrics, benchmarks, all those kind of things, you know, creating not only that stability, but strengthening the agency, whether it is the technology or anything else, both during your tenure, but for the future, are there restructuring or structural aspects to that that you are, you know, kind of considering in that strategic plan, you know, that we should be aware of, talking about, looking at?

Do you think that is going to be part of what you want to do as you embark on this long term planning?

Mr. CALIFF. Again, at my age, I have worked in every industry. I have been in, you know, health care, academic medicine, computer industry, biotech, Government. I think there are always are opportunities to improve structures, so I would say everything is on the table, but I don't think the problems that I have discussed today, that the primary problem is one of structure.

There is some elements of structure at FDA that would be really hard to change, like, you know, the drug device, biologic food centers, and animal centers. They each have constituencies and industries that they interact with and ecosystems. And yet if you look across centers, as I have said before, there is a common base of science and technology that we need.

That is where I think we need to work. And I don't know if you have looked at the latest Federal regulations on changing structures and Government agencies, but if you have like a good night when you want to take a, you know, go to sleep, you should try reading it. It is a challenge though.

I don't want to wait on those structural changes to do the things because I think in most businesses and systems I have been in, having the right functions, having the right people doing the right functions makes the biggest difference.

You can spend a lot of time changing a structure, and if you don't really figure out how to get the functionality right, you change your structure and you can write about it and talk about it but doesn't solve the problem. But the short answer would be everything is on the table. I don't think structural change is a primary issue that we need to deal with.

Senator HOEVEN. Okay. The reason I ask is because of your experience, your broad experience in the medical industry, both in the

public and private sector, but also the fact that you had a stint at FDA before.

So you are coming in, you are looking at these things, gives you some perspective, and so I am just curious as to your analysis of what, you know, what is going to make this agency as effective as it can possibly be?

Mr. CALIFF. Yes, Senator. I mean, you are right to point out the FDA has been criticized. In fact, you are not FDA Commissioner if you are not waking up at 5:00 a.m. every day to a whole list of criticisms. That was true in 2016. It is true today.

But one of the things that made me want to come back and that gave me great solace when I got here, is if you look at the center directors at the FDA, they have been there a while. They are very dedicated to their work. They keep coming to work every day despite all the criticism.

And I know what their capabilities are. So I think there is continuity. It is important. And I think you pointed out a major issue we need to deal with, which is as the Commissioner is changing every year, priorities change, and every new person has some new things, and they don't necessarily want to be held to the old person's way of thinking. So more continuity there, I think, would make a big difference.

Senator HOEVEN. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator BALDWIN. Thank you. Dr. Califf, thank you so much for being here today. I think we had a good interaction and discussion, and I look forward to working with the FDA and members of the committee as we start the 2023 appropriations process this year. Questions for the record are due by next Thursday, May 5th. And we would certainly appreciate the FDA's responses within 30 days. And with that, this hearing is adjourned.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

Question. Thank you for your past leadership at FDA and continuing to prioritize efforts on ensuring the safety of personal care products. We spoke last week about the FDA still being woefully underequipped to ensure the safety of personal care products that we use on a daily basis, such as shampoo and deodorant.

What authorities and resources does the FDA need in order to adequately protect Americans from harmful cosmetics?

Answer. FDA's regulatory authority for cosmetics, which dates to the 1938 Food, Drug & Cosmetic (FD&C) Act, gives FDA very limited post-market authority over cosmetic safety. In order to adequately protect Americans from harmful cosmetics, FDA would need explicit authority to: (1) require domestic and foreign cosmetic firms to register their establishments and list their products with FDA; (2) require domestic and foreign cosmetic firms to report serious and frequently occurring adverse events to FDA; (3) promulgate and require compliance with Good Manufacturing Practices regulations; (4) require domestic and foreign cosmetic firms to allow FDA access to records (including consumer complaints and safety data) during a routine or for-cause inspection; (5) require recalls for cosmetics that pose serious risk to the public health; and (6) require listing of known cosmetic allergens in the ingredient list on the product label for all cosmetic products. Additionally, FDA would need adequate funding for the increased resources needed to modernize FDA's Cosmetic Safety Program. Such new authority and additional funding would enable FDA to significantly strengthen its post-market surveillance systems and

better protect the public health by helping to ensure the safety of cosmetic products and ingredients that are in use in the United States. A legislative proposal to this effect was offered in the fiscal Year2023 FDA Congressional Justification.

Question. What concerns to public health has FDA documented as a result of lacking these authorities and resources?

Answer. As part of FDA's work to protect consumers from unsafe cosmetic products on the market, the FDA routinely monitors the market for products and ingredients that may pose a public health risk. Over the past 17 years there have been numerous public health issues related to cosmetic safety that highlight FDA's limitations under current law in regulating these products, for example:

—Asbestos Contamination of Talc-Containing Cosmetics: FDA is continuing its efforts to have additional talc-containing cosmetics tested for asbestos. However, the 1938 FD&C Act does not require cosmetics establishments or manufacturers to register their facilities or file cosmetic product ingredient statements with FDA. Thus, the major source of information available to FDA about cosmetics marketed in the U.S., and their ingredients, is the Voluntary Cosmetic Registration Program (VCRP). Because the VCRP is voluntary, it provides FDA with only a limited picture of cosmetics that are being sold to consumers. Furthermore, the lack of information makes it difficult for the agency to efficiently target its limited inspectional resources.

—Hair products (shampoo and conditioners): During an inspection FDA became aware of more than 21,000 consumer complaints of hair loss, including alopecia associated with one company's hair products. Because companies are not required to show their consumer complaint records to FDA, the company has not provided all of these consumer complaints to FDA.

—Microbiological contamination of cosmetic products: A number of no-rinse cleansers, wipes, washes and mouth rinses have been recalled from the market due to potential microbiological contamination. For example: in early 2018, a no-rinse cleansing foam contaminated with Burkholderia cepacia caused outbreaks in several health care facilities in six States. In 2020, a baby wash was recalled because of potential Pseudomonas aeruginosa contamination. These outbreaks emphasize the importance of following appropriate good manufacturing practices to reduce the risk of microbial contamination of cosmetic products during processing.

—Lip products: FDA received 126 reports between August 6, 2014 and June 12, 2017, of consumers developing rashes around the mouth as well as blistering and cracking of the lips following the use of certain lip products. FDA was not able to determine the cause of the reactions because of inadequate information provided by the company. The law does not require cosmetic companies to list known cosmetic allergens found in fragrances or flavors in the ingredient list on the product label or share their safety data, or consumer complaints with FDA. In addition, the complaints that came to FDA mostly from consumers did not provide enough information to determine why some consumers experienced reactions when they used these products.

These examples are just a few that highlight the challenges FDA faces when working to protect the safety of cosmetic products in the marketplace. With the growth and innovation in the cosmetics industry, many new cosmetics products are being marketed to consumers in the U.S. It will be challenging to ensure the safety of these products without updated authorities and new resources. For example, cosmetics products marketed as containing probiotics (i.e., live microorganisms) are found increasingly in the cosmetic marketplace, with potential implications for skin integrity and health, and product safety, and preservation. Yet, there is no requirement for manufacturers to provide safety data to FDA for such ingredients. In light of both the pace of innovation and the growth of the industry, FDA has inadequate, incomplete, and often outdated baseline data on marketed cosmetic products and ingredients. FDA also has limited data on serious or frequent adverse events associated with cosmetic products, due to the lack of mandatory notification of adverse event reports. FDA appreciates your ongoing support for modern cosmetic authorities and adequate resources for the FDA Cosmetic Safety Program.

Question. In your previous tenure at FDA, you oversaw implementation of many food safety regulations stemming from the "Food Safety Modernization Act." I certainly appreciate the strides that the agency has made, but outbreaks of Listeria, Salmonella, and E. coli continue to happen regularly. What steps are you taking to implement all the authorities provided to FDA in the "Food Safety Modernization Act," including for agricultural water?

Answer. The FDA Food Safety Modernization Act (FSMA) is revolutionizing how we regulate our food supply. Since the law's passage in 2011, with the support of Congress we have been working diligently to implement the landmark law and modernize our food safety capabilities. We have published eight foundational final rules and more than 50 draft and final guidances to help transform our Nation's food safety system into a prevention-oriented framework. Currently, we have teams continuing the work needed to fully implement FSMA through additional rulemakings (such as for food traceability recordkeeping requirements), guidance development, training, inspections, and other implementation activities. As with any complex, scientific issue, FSMA rulemakings have involved research, analysis of data, and, in certain cases, engagement with the scientific community to inform decision-making and adjustments when new science emerges. Stakeholder input also is essential to ensure that requirements we put into place are feasible to implement once enacted.

This is true for FDA's agricultural water requirements. FDA originally promulgated requirements for pre-harvest, harvest, and post-harvest agricultural water in 2015 as part of the Produce Safety Rule. When it became apparent that some provisions were too complex and difficult to implement, and as new science emerged as part of our investigations of produce-related outbreaks, the Agency pursued a rigorous and thorough process for engaging with stakeholders as FDA considered the practical implementation of the agricultural water requirements and how to best achieve related public health protections for covered produce other than sprouts. FDA experts participated in hundreds of farm visits to better understand the diversity of uses of agriculture water, as well as listening sessions and meetings with industry, consumer groups, academia, and regulatory partners. The Agency believes this was time well-spent to ensure that the proposed approach would be deeply rooted in the most current science and protective of public health. In late 2021, these efforts culminated in proposed new requirements for pre-harvest water for covered produce other than sprouts that we believe would be both feasible and effective, if finalized.

Looking ahead, FDA is committed to building on the work of FSMA while taking a new approach to food safety that leverages technology and other tools and approaches to create a safer and more digital, traceable food system. This approach, which we're calling the New Era of Smarter Food Safety, aims to bend the curve of foodborne illness in this country by reducing the number of illnesses attributed to FDA-regulated foods.

Question. As we have discussed previously, the creation of appropriate regulations for the use of antibiotics in livestock must be a priority for the FDA. For many years, I introduced the "Preventing Antibiotic Resistance Act," which would have required a medical need before administering antibiotics to food-producing animals. I appreciate the steps FDA has taken since 2017 to implement regulations in line with the provisions in my bill, but I am concerned about the potential for continued overuse of antibiotics in animals under the carve-out for preventive use. In broiler chickens, for example, the window FDA has allowed for administering preventive antibiotics is longer than the chicken's lifespan. What steps are you taking to ensure that antibiotics administered to food-producing animals have a medically-relevant need and appropriate duration?

Answer. Establishing appropriately targeted durations of use for medically important antimicrobials used in the feed of food-producing animals is a priority and a component of FDA's overall effort to support antimicrobial stewardship in animals and combat antibiotic resistant bacteria. FDA has already initiated public comment on this issue and is gathering the data necessary to address the issue in a science-based manner, including through funding several ongoing studies. Our primary objective is to get product dosage regimens updated to better target when and for how long a medically important antimicrobial drug may be used in the feed of food-producing animals to provide effective therapy while minimizing drug exposure and resistance selection pressure.

Question. Research has identified phthalates as neurotoxic chemicals that can do lasting harm to child brain development and increase children's risks for learning, attention, and behavioral disorders. Phthalates have also been long known to harm reproductive tract development in males and there is growing evidence that reproductive problems also occur in females. In addition, recent analysis of fast food restaurants found phthalates were detected in the vast majority of sampled foods, demonstrating that phthalates leach from processing equipment and packaging into food. In 2016, health and environmental organizations petitioned FDA to ban harmful chemicals called phthalates in food packaging and processing materials.

What actions has FDA taken since then in response to this petition?

Answer. On May 19, 2022, FDA issued a rule to amend its food additive regulations to no longer provide for most previously-authorized phthalates to be used as

food additives because these uses have been abandoned by industry. FDA revoked authorizations for the food contact use of 23 phthalates and two other substances used as plasticizers, adhesives, defoaming agents, lubricants, resins, and slimicides. The Agency also issued a request for information about the current specific food contact uses, use levels, dietary exposure, and safety data for the remaining phthalates still authorized as plasticizers for use in food contact applications.

In addition, over the last few years, FDA has analyzed numerous samples of PVC and non-PVC fast food packaging and food contact articles (for example, gaskets, tubing, and conveyer belts) available on the U.S. market for the presence of phthalates. Data from these studies were published in 2018, 2021, and 2022, and suggest that manufacturers have been replacing phthalates as their primary plasticizer with alternative compounds. For example, no phthalates were detected in eight representative samples of food contact tubing that FDA obtained and analyzed in 2021. That evidence suggests that at this time the use of phthalates in food contact applications is limited and consumer exposures to phthalates from food contact uses is decreasing.

Question. Does FDA have any plans to address the issue of harmful phthalates in food packaging and other food contact materials this year?

Answer. As mentioned above, FDA issued a request for information about the current specific food contact uses, use levels, dietary exposure, and safety data for the remaining phthalates still authorized as plasticizers for use in food contact applications. The Agency may use this information to update the dietary exposure estimates and safety assessments for the permitted food contact uses of phthalates.

FDA also intends to continue work investigating possible sources of phthalates in food contact applications. The Agency has recently evaluated the effectiveness of portable devices that industry and FDA could use to identify plasticizers, including phthalates, in PVC tubing as part of our continued efforts to identify phthalates in food packaging and processing materials.

QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

Question. The COVID–19 pandemic has had a devastating effect on opioid usage across the Nation. The Vermont Department of Health recently reported that nearly 210 Vermonters died from opioid overdoses in 2021, the highest number of fatal opioid overdoses the State has ever recorded. A large contributor to the increase in overdose cases has been the presence of fentanyl in counterfeit opioid products. The FDA's budget includes a requested increase of $30 million above FY22 to support the Administration's goal of ending the opioid epidemic. How will this funding be used to combat the explosion of counterfeit pharmaceuticals and fraudulent products?

Answer. The Agency is actively targeting illegal online sales of unapproved and misbranded opioids, including fentanyl, through surveillance and compliance activities. Our collaboration with the Department of Justice has led to successful prosecution of numerous defendants for illegal conduct involving the online sale of prescription opioids. Unfortunately, this exemplifies the availability of counterfeit and unapproved opioids for sale on the internet. We continue to send warning letters to operators of websites marketing potentially dangerous, unapproved and misbranded opioids, as well as other controlled substances such as benzodiazepines and Schedule II stimulants. In June 2020, FDA partnered with the National Telecommunications and Information Administration to launch a 120-day pilot with participating domain name registries to help reduce the availability of unapproved opioids illegally offered for sale online. As a result of the pilot, nearly 30 websites illegally offering opioids for sale became inaccessible to the public. Since 2018, FDA has hosted three Online Opioid Summits to look for innovative solutions to prevent the illegal sale of opioids through internet platforms and services, with the most recent held virtually in September 2021. In April 2022, FDA and DEA issued joint warning letters to operators of two websites illegally selling Schedule II stimulants, including amphetamine drugs products marketed as Adderall. FDA has also recently approved research funding for the development and deployment of new survey modules to collect self-reported data on awareness, experiences, etc. with falsified/counterfeit drugs.

The decision to buy opioids on the internet and through other channels where counterfeit medications are more likely to be encountered reflects the significant misuse and use of opioids. Some of this use may be spurred by exposure to opioids for pain management. Inappropriate opioid prescribing and lack of proper disposal of opioid pain medications might contribute to the exposure. It may also reflect

undertreatment of opioid use disorder (OUD). The tragic deaths that result from use of opioids and other drugs contaminated with fentanyl or fentanyl analogs, might be prevented by better access to opioid overdose reversal agents.

In addition to continued focus on counterfeit opioid products, the $30 million increase in funding will go to address these underlying issues, by increases in staff and targeted funding into research and policy development in the following areas:

—Additional research to address appropriate pain management as well as opioid and polysubstance misuse, use, and overdose. These activities include dynamic system modeling and analysis of real-world evidence (e.g., surveys of persons using opioids alone and in combination with other substances).

—Supporting the development of novel treatments for opioid overdose reversal and for OUD. These activities include modeling to examine the role of naloxone administration paradigm on ability to revive a person experiencing drug overdose when opioid use is suspected (single substance and polysubstance use).

—FDA's implementation of SUPPORT Act Section 3041. These activities include studies on opioid packaging and disposal.

—Expanding and promoting prescriber education to improve pain management, reduce inappropriate prescribing of opioids, advance development of evidence-based clinical practice guidelines for acute pain, and broaden patient access to OUD treatment.

In addition, some of the funding will be invested in our Opioid Data Warehouse to enable FDA to use the best data and analytics in implementing policy and identifying emerging issues that need to be addressed.

Question. I have championed legislation to increase competition between generic and brand name prescription drugs and to target anticompetitive behaviors of pharmaceutical companies. Generic alternatives saved the U.S. health care system $338 billion in 2020 alone. Despite this, many generic drug makers still report challenges in bringing these more affordable drugs to market. This includes slow application turnarounds from the FDA and continuing anticompetitive actions from brand name drug companies. What does the FDA need to bring more generic drugs to market and bolster anticompetitive enforcement?

Answer. FDA is committed to increasing competition for prescription drug and biological products to help facilitate the entry of lower-cost alternatives and improve patient access to affordable medicine. FDA is working to advance the Administration's initiatives outlined in the President's Executive Order on Competition in the American Economy to increase competition and reduce gaming of the system, including through FDA's Drug Competition Action Plan and Biosimilars Action Plan, and will continue these and other efforts this year.

The President's fiscal year 2023 budget proposal also included a legislative proposal titled "Amend the 180–Day Exclusivity Provisions to Encourage Timely Marketing of First Generics". FDA is proposing to amend sections 505(j)(5)(B)(iv) and (D)(i)-(iii) of the FD&C Act, more commonly known as "Hatch-Waxman", that govern the 180-day patent challenge exclusivity provisions to specify that FDA can approve subsequent applications unless and until a first applicant begins commercial marketing of the drug, at which point approval of subsequent applications would be blocked for 180 days, ensuring that the exclusivity period actually lasts 180 days (i.e., from the date of first commercial marketing by a first applicant until 180 days later) rather than multiple years as can occur under current law. In practice, patent challenge exclusivity is not operating as expected to encourage early generic entry, because this exclusivity is often "parked" by first applicants who either receive approval but do not begin marketing for extended periods of time following approval, or by first applicants who delay in seeking final approval of their ANDAs for extended periods of time. FDA believes this proposal would substantially increase the likelihood that generic versions of patent-protected drugs will come into the market in a timely fashion, and that multiple versions of generic products will be approved quickly (leading to significant cost savings).

Question. As the sale of CBD and other hemp-derived foods, supplements and animal feeds continues to grow in the marketplace, there is increasing concern and confusion about the safety of such products in light of the continuing absence of FDA regulation. I understand one of the barriers may be the FDA's earlier approval of a drug made with CBD, even though the CBD in that product may not even be derived from hemp. The FY23 Omnibus Bill directed FDA to establish a policy of enforcement discretion so it could properly address these issues?

Can such enforcement discretion be used to enable FDA to regulate the introduction of hemp into food, dietary supplements and animal feed, such as by distin-

guishing the broad range of hemp CBD products currently in the market from the specific FDA-approved drug?

Answer. FDA understands the significant interest in this space and is committed to addressing this issue, including ongoing work to evaluate enforcement policy options. While the Agency encourages the development of safe and effective therapeutics, many consumers and stakeholders want access to more readily available products. With respect to potentially relevant pathways outside of the drug approval context, it should be noted that even if there were no restriction on marketing certain drug ingredients in dietary supplements or food, cannabidiol (CBD) and cannabis-derived products would still be subject to the same safety requirements as apply to any other ingredient in the products FDA regulates. The Agency knows that CBD is not a risk-free substance, as is the case with many other compounds found in cannabis and must carefully consider those risks. As an additional matter, we note that any policies FDA adopts would only directly impact products subject to our jurisdiction. There may be CBD or other cannabis-derived products not subject to the Agency's jurisdiction.

Question. What other approaches to enforcement discretion can enable FDA to address these issues, and by when can we expect such a policy to be instituted?

Answer. As noted in the previous response, CBD is not a risk-free substance and even if FDA exercised enforcement discretion for the restrictions on using certain drug ingredients in food and dietary supplements, the CBD products would still be subject to the same safety standards that apply to any other ingredient in the products FDA regulates. FDA is prioritizing the evaluation of potential options and looks forward to discussing this further with Congress when there is additional information to share.

Question. What additional resources, if any, does your Agency need in order to implement a policy of enforcement discretion to effectively address these issues?

Answer. As noted in the previous responses, CBD is not a risk-free substance and, outside of the drug approval context, even if FDA exercised an enforcement discretion policy for certain cases, the CBD and cannabis-derived products would still be subject to the safety requirements that apply to any other ingredient in the products FDA regulates.

However, should CBD or other cannabinoids be legally permitted in additional products, FDA would require additional resources to effectively regulate those markets.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. At-home over-the-counter antigen tests are an important public health tool to mitigate the spread of COVID–19. These tests can be manufactured cheaply and at-scale and should be broadly available to all U.S. residents and visitors. While the Biden Administration has invested billions of dollars to increase the production and accessibility of these tests, only 18 at-home, over-the-counter antigen tests are authorized for emergency use by the FDA, and only 5 have been authorized so far in 2022.

What is the scientific rationale for FDA's performance requirement for over-the-counter at-home antigen tests of a minimum sensitivity of 80 percent when it is broadly understood that there are limits to the technology's ability to perform at lower viral loads?

Answer. On July 29, 2020, FDA posted a template for at-home diagnostic tests, including at-home antigen tests, which include recommendations for validating such tests, including FDA's expectation of 80 percent sensitivity. This is much lower than the expectation of 95 percent sensitivity for lab-based molecular tests, most of which perform at over 98 percent. FDA recognized that antigen test technology is generally not as sensitive as PCR technology, but has several advantages, including lack of reliance on large lab-based instruments, rapid turnaround time, and potentially less expensive manufacturing which can facilitate greater access to testing and faster results. We knew that available, at-home, over the counter (OTC) tests would supplement laboratory testing by increasing the overall amount of testing performed and as a result identify more infections and help mitigate the spread of the virus, bolstering our pandemic response. Therefore, FDA accepted lower sensitivity for antigen tests to help increase availability of tests and provide a feasible pathway for authorization. 80 percent sensitivity is feasible as evidenced by the 19 authorized OTC at-home tests to date. We recognize, however, that a lower bar, could result in tests missing more people, particularly those in early stages of infection or who

are about to become infectious, and could lead to spread of disease from this false sense of security.

FDA has also monitored evolving circumstances and growing scientific knowledge and made adjustments when appropriate to help streamline and expedite the path to market for these and other tests as much as possible while assuring they are supported by sound science. In March 2021, FDA obtained results from an NIH-sponsored study that supported further streamlining of FDA's at-home test recommendations. Based on these data, on March 16, 2021, FDA provided a supplemental EUA template for test developers who are interested in a streamlined path to authorize tests with at least 80 percent sensitivity in symptomatic individuals, with sensitivity falling in a range as low as 70 percent in certain circumstances, for developers to offer their test for OTC serial screening without additional data collection. Multiple tests were authorized under this approach within weeks.

Question. As variants and subvariants emerge, how does FDA plan to use clinical data to ensure that the 18 approved at-home antigen tests do not become obsolete if future variants no longer have the gene that the test detects?

Answer. FDA uses multiple techniques to monitor the performance of at-home tests with current and future viral mutations. First, all Emergency Use Authorization (EUA) holders, including those for at-home tests, are required by their letter of authorization to evaluate the impact of SARS-CoV–2 viral mutations on their test's performance. These evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns the EUA holder or FDA identify during routine evaluation. If the EUA holder's evaluation identifies viral mutations that affect the stated expected performance of their device, they must notify FDA immediately. As the FDA's or the developer's analysis identifies tests whose performance could be impacted by SARS-CoV–2 viral mutations, these tests are added to FDA's SARS-CoV–2 Viral Mutations: Impact on COVID–19 Tests[1] webpage. This includes posting the latest information on variants and testing implications as they become available.

FDA is collaborating with NIH's Variant Task Force[2] (VTF) program to identify and prioritize over the counter (OTC) tests for additional testing of clinical samples on currently circulating variants. VTF's activities "currently comprise in silico genomic bioanalytical testing, sample collection, and clinical in vitro lab testing of technologies supported by the RADx program to ensure their detection efficacy with variants entering the population matches that of the original strain."[3] FDA uses this clinical and analytical data to determine whether and how a test's performance is impacted by emerging variants. As part of this collaboration, the VTF and FDA use antibody epitope mapping, a way to identify the part of the virus that is recognized by the test, to predict reactivity of existing tests with future variants.

In addition to these pandemic specific activities, FDA leverages its robust medical device postmarket surveillance and signal management program. Monitoring adverse event reports and other safety signals has enabled FDA to identify problems with tests on the market and work with developers to correct the issue or conduct recalls as appropriate.

Question. Although COVID–19 poses less risk to children than older Americans, infants and young children are vulnerable to hospitalization, ICU admission, and long-term health effects of COVID–19. The CDC found these serious consequences were exacerbated when the Omicron variant predominated in December 2021 through February 2022. U.S. families are concerned about their young children's health, particularly as precautions, such as mask wearing requirements, are easing in their communities. Parents are anxiously awaiting an approved vaccine and there have been a series of delays to FDA's emergency use authorization for the Pfizer-BioNTech and Moderna vaccines for children under 6 years old. In December 2021, Pfizer-BioNTech announced data indicating a two dose 3 μg series of its vaccine generated similar immunogenicity for children ages 6 months to 2 years as 16- to 25-year-olds.

Did FDA have a role in the postponement of the Pfizer-BioNTech vaccine EUA amendment in December 2021? If so, what was behind that decision-making?

Answer. On February 1, 2022, Pfizer announced that it had initiated a "rolling" submission for an emergency use authorization (EUA) of their COVID–19 vaccine in children 6 months through 4 years of age. In a February 11, 2022 press release, Pfizer and BioNTech announced their plans to extend their rolling EUA submission

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[1] https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests

[2] RADx Variant Task Force Program for Assessing the Impact of Variants on SARS-CoV–2 Molecular and Antigen Tests—PMC (nih.gov)

[3] Id.

to FDA and to wait for data for the three-dose series that may provide a higher level of protection in this age group.[4] Pfizer stated that their independent Data Monitoring Committee (DMC) for the study supported the continuation of the trial.

On February 11, FDA announced in a press release that it was notified by Pfizer of their plans to extend their rolling EUA submission because of the new data that had emerged in children 6 months through 4 years of age.[5] Based on the Agency's preliminary assessment of the totality of data from the ongoing trial that had been provided by Pfizer at that time, we believed that additional information regarding the ongoing evaluation of a third dose should be considered as part of our decision-making for potential authorization. As a result, FDA postponed the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting originally scheduled for February 15, 2022.

On April 29, 2022, FDA announced that it anticipates convening its VRBPAC to discuss the pediatric data for the Pfizer-BioNTech COVID–19 Vaccine and Moderna COVID–19 Vaccine and the requests for emergency use authorization by the companies for pediatric populations. Since then, FDA has publicly confirmed that on June 14, 2022, the VRBPAC will meet in open session to discuss amending the EUA of the Moderna COVID–19 Vaccine to include the administration of the primary series to children and adolescents 6 years through 17 years of age. On June 15, 2022, the VRBPAC will meet in open session to discuss amending the Moderna COVID–19 Vaccine EUA to include the administration of the primary series to individuals 6 months through 5 years of age, and also to discuss amending the Pfizer-BioNTech COVID–19 Vaccine EUA to include the administration of the primary series to individuals 6 months through 4 years of age.

Having safe and effective COVID–19 vaccines available for children is a priority for FDA. The Agency understands the urgency to authorize a vaccine for age groups who are not currently eligible for vaccination and is working diligently to complete our evaluation of the data. Following a transparent public dialogue with our VRBPAC, the Agency will only authorize COVID–19 vaccines for children that meet our scientific and regulatory standards and for which the known and potential benefits outweigh the known and potential risks.

Question. Why did FDA postpone its February 2022 Vaccines and Related Biological Products Advisory Committee meeting instead of using this forum to review data on Pfizer-BioNTech's two dose vaccine series for children ages 6 months to 2 years?

Answer. See response above.

Question. I am very concerned about youth use of e-cigarettes. According to the most recent State-level data (2019), 30 percent of high school students in Hawaii use e-cigarettes. Despite a court order setting a timeframe for FDA to complete required premarket reviews of e-cigarettes, an alarming variety of youth-appealing flavored e-cigarette products are still available online and in stores. FDA should fully use its regulatory authority to prevent manufacturers from making and selling tobacco products that are enormously appealing to kids.

When does the FDA anticipate completing its required premarket review process and will it use this process to remove from the market all e-cigarettes that are likely to attract young people, such as flavored e-cigarettes?

Answer. FDA received premarket tobacco product application (PMTA) submissions for about 6.7 million products by the court-ordered September 9, 2020, deadline and we have taken action on over 99 percent of those total applications. There are three major phases of PMTA review—acceptance review, filing review, and then scientific review. If an application fails to satisfy regulatory and/or statutory requirements at any of these stages, FDA issues a negative action, such as a Refuse to Accept Letter, a Refuse to File Letter, or a Marketing Denial Order (MDO). If an application provides scientific data that demonstrates permitting the marketing of a product is appropriate for the protection of the public health, FDA issues a Marketing Granted Order (MGO).

To date, FDA has made significant progress and has taken action on over 99 percent of the applications submitted by September 9, 2020. FDA has:

—Refused to accept applications for over 200,000 products

—Refused to file applications for over 5 million products

—Issued MDOs for more than 1 million flavored electronic nicotine delivery systems (ENDS)

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[4] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-rolling-submission

[5] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-postpones-advisory-committee-meeting-discuss-request-authorization

—Issued MGOs for 23 ENDS products (for devices and tobacco-flavored products)

Reviewing this volume of applications is unprecedented for the Agency, and we remain focused on completing our review of the remaining product applications. FDA allocated significant resources to review applications from the five companies whose brands represented over 95 percent of the e-cigarette market because FDA believes these products would have the greatest chance, either positively or negatively, of impacting public health due to their market share- Fontem (myblu), JUUL, Logic, NJOY, and R.J. Reynolds (Vuse). FDA has issued decisions on many of these products, including:

—JUUL Labs Inc. (JUUL device and JUULpods) on June 23, 2022

—NJOY LLC (NJOY Daily) on June 10, 2022

—R.J. Reynolds Vapor Company (Vuse Ciro and Vuse Vibe) on May 12, 2022

—NJOY LLC (NJOY Ace) on April 26, 2022

—Fontem, US, LLC (myblu) on April 8, 2022

—Logic Technology Development, LLC (Logic Vapeleaf, Logic Pro, and Logic Power) on March 24, 2022

—R.J. Reynolds Vapor Company (Vuse Solo) on October 12, 2021

Question. How many e-cigarettes remain on the market despite having failed to file a premarket application or having received a marketing order denial?

Answer. Products for which no application is pending, including, for example, those for which no application was submitted, are among our highest enforcement priorities. From January 2021 through April 2022, FDA issued warning letters to 240 firms that collectively have more than 17 million unauthorized electronic nicotine delivery system (ENDS) products listed with the FDA and that had not submitted premarket applications for these products by the September 9, 2020 deadline.

Additionally, any products subject to a negative decision may not be introduced or delivered for introduction into interstate commerce. Any products receiving a negative decision that are already on the market must be removed from the market or risk enforcement. To date, FDA has issued warning letters to more than 115 firms for continuing to unlawfully market ENDS products that are the subject of marketing denial orders (MDOs), Refuse to File (RTF) letters, or Refuse to Accept (RTA) letters.

Many firms comply after receiving a warning letter. FDA typically confirms the firm's corrective action by subsequent inspection and surveillance. If a firm continues to violate the law, investigators collect evidence and depending on the facts in the case, enforcement action, such as an injunction or seizure, may be pursued.

Question. Given the risk of flavored e-cigarettes to youth, why does the FDA allow manufacturers to continue to sell their products while the agency is reviewing their applications?

Answer. All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement by FDA. FDA will continue to make enforcement decisions on a case-by-case basis according to our enforcement priorities and the individual circumstances.

The Agency works closely with the Department of Justice (DOJ), without whose support neither injunctive actions nor seizures can be taken. FDA consults the DOJ regularly with respect to potential enforcement actions, including in relation to unauthorized tobacco products that are the subject of pending applications.

Question. Is FDA evaluating menthol flavored e-cigarettes under the same criteria used in evaluating other flavors of e-cigarettes?

Answer. Under Section 910(c)(4) of the Federal Food, Drug, and Cosmetic Act, FDA reviews all premarket tobacco product applications to determine if the marketing of the new product would be appropriate for the protection of the public health (APPH). In doing so, the statute requires FDA to consider the risks and benefits to the population as a whole, including both tobacco users and nonusers, 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. In making the APPH assessment for an electronic nicotine delivery system (ENDS) product, FDA weighs, among other things, the negative public health impact stemming from youth initiation and use of the product against the potential positive public health impact stemming from adult cigarette smokers transitioning away from combustible cigarettes to the ENDS product. ENDS product flavors are an important consideration in ascertaining the health risks of these products because of a flavor's poten-

tial impact on appeal to youth and young adults, consumer perceptions, and product toxicity.

Question. Menthol cigarettes and flavored cigars mask the harshness and soothe irritation caused by tobacco smoke, which makes it easier for beginners, particularly youth, to experiment and become addicted to these products. Menthol cigarettes are the only flavored cigarette left on the market and remain popular, particularly among Black communities targeted by the tobacco industry. I applaud the FDA's recent rulemakings prohibiting menthol cigarettes and flavored cigars. Is it still FDA's view that enforcement of the menthol cigarette and flavored cigar prohibitions would "only address manufacturers, distributors, wholesalers, importers, and retailers" not individual consumers who possess or use these products?

Answer. Yes. If these proposed rules are finalized and implemented, FDA enforcement will address only manufacturers, distributors, wholesalers, importers, and retailers who manufacture, distribute, or sell such products within the U.S. that are not in compliance with applicable requirements. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes or flavored cigars. FDA notes that State and local law enforcement agencies do not independently enforce the Federal Food, Drug and Cosmetic Act. These entities do not and cannot enforce against any violation of the act or this regulation on FDA's behalf.

Question. In recent years, interest in research on psychedelics has increased rapidly, including in the development of new medicines.

What is the current status of FDA's efforts to work collaboratively with NIH to identify research needs that would serve all medicine developers in the field of psychedelic research for therapeutic purposes?

Answer. The Agency has long worked with NIH and supports its efforts to investigate the use of psychedelic drugs to treat mental health conditions. Most recently, in January 2022, we worked with NIH to conduct a joint 2-day workshop focusing on psychedelics and entactogens as therapeutics for serious mental illness and substance use, with participation from NIH, FDA, NIDA, and NIAAA. There were roughly 4,500 participants from all continents (except Antarctica) and presenters from academia, government, and industry. The workshop was divided in three parts: the first part of the workshop focused on basic and translational research, the second part on the results of recent clinical trials and lessons learned, and the third part focused on overcoming challenges and considering the consequences of real-world use.

We also note that in fiscal year 2022, FDA designated psychedelics as a research area of interest through our Broad Agency Announcement mechanism. Specifically, the Agency stated in the announcement that we intend to "Improve scientific understanding of psychedelics: Develop methods and carry out studies to better understand the trajectory of psychedelics use and associated public health consequences."[6]

Question. Please provide a list of Investigational New Drug applications for psychedelics on which FDA is currently engaged with medicine developers.

Answer. Consistent with Federal statutes and FDA's implementing regulations concerning the confidentiality of commercial information, and to protect the integrity of the review process, FDA generally cannot disclose information about an unapproved application or an investigational new drug application, including the status of the Agency's review of a particular drug product[7]. Therefore, the Agency is unable to provide updates about specific pending applications, including whether a specific application has been filed. We suggest reaching out to the company directly for information about a specific development program because they can choose to disclose information about their product development, including any interactions with the FDA. Another possible source of information would be the website www.ClinicalTrials.gov.

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[6] Food and Drug Administration Broad Agency Announcement for the Advanced Research and Develop//ment of Regulatory Science (Page19) https://sam.gov/api/prod/opps/v3/opportunities/resources/files/47c7fd2ac6374a70acf8579beb81cbdf/download?&token=

[7] Relevant law includes the Trade Secrets Act (18 U.S.C. 1905), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 33l(j)), (21 U.S.C. 360bbb-3(h)), and FDA regulations (21 CFR 20.61(c); 21 CFR 312.130(b); 21 CFR 314.430(c) and (d)(l)).

QUESTIONS SUBMITTED BY SENATOR MARTIN HEINRICH

Question. Colorectal cancer is the third leading cause of cancer-related deaths in men and women in the United States. According to the American Cancer Society, it was expected to cause roughly 53,000 deaths in 2021. That's why I introduced the Colorectal Cancer Detection Act, which would increase access to blood-based screening tests. Can you share the importance of the FDA evaluating and approving blood based screening tests, for early cancer and disease detection especially for rural and Tribal communities, and even when there are other albeit more invasive methods of detection?

Answer. FDA believes that marketing authorization of a well-validated, blood-based screening test for early cancer detection will benefit these communities, as it will increase accessibility and compliance to screening, due to the less invasive nature of this type of testing. However, the test should be well-validated, and have acceptable performance characteristics, so as to minimize the number of individuals receiving false negative or false positive results, which can lead to failure to provide appropriate treatment or unnecessary follow-up testing, with its own attendant risks, due to the need to confirm the presence or absence of cancer with invasive procedures. FDA review and authorization of an analytically and clinically validated test with favorable benefit/risk assessments and transparent performance is very important for public health and to ensure that patients and their physicians are informed of the strengths and weaknesses of different testing options.

An advantage of blood-based testing is the opportunity to expand the number of individuals who undergo colon cancer screening because stool-based testing procedures have limited adherence. Approximately 20 percent of eligible individuals aged 50 to 75 years have never been screened for colon cancer, and half are inadequately screened.[8] Blood-based cancer screening has the potential to offer a convenient testing option, which is expected to improve compliance with early detection, when treatment may be curative.

In 2016, FDA approved the first blood-based screening test for colon cancer.[9] The test (Epi proColon) relies on qualitative detection of DNA in the blood stream from colorectal cancer (CRC) cells and represents an advancement in cancer screening technologies. The indications for use for Epi proColon places this test as second line (ordered only after other CRC screening tests recommended by the U.S. Preventive Services Task Force (USPSTF) have been offered and rejected by the patient). This is because the sensitivity and specificity of the test is lower than stool-based methods. The benefit of the test was that patients may be more compliant with blood-based CRC screening methods compared to stool-based methods. At this time, blood-based testing is not recommended by the USPSTF, due to the limited evidence supporting its use.

Question. Over 30 years, the FDA's accelerated approval pathway has had important successes, particularly with oncology treatments, which have approval around 3.4 years earlier than with the traditional FDA approval. Many patients suffering from neurological conditions and serious rare diseases are wondering if this success can extend to their own, or their loved one's condition. Can the accelerated approval pathway be optimized for treatments to neurological disorders and rare diseases?

Answer. FDA has several programs intended to facilitate and expedite the development, review, and approval of products intended to address unmet medical need in the treatment of serious conditions, including: Fast Track, Breakthrough Therapy Designation, Regenerative Medicine Advanced Therapy Designation, Accelerated Approval, and Priority Review. Drugs granted accelerated approval or developed under any of the expedited programs must meet the same statutory standards for safety and effectiveness as those granted traditional approval. While traditional approval is based on a showing of a drug's clinical benefit to patients, accelerated approval is based on a different study endpoint: most commonly, the drug's effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. Consequently, drugs approved under accelerated approval are required to conduct a post-approval trial to verify that the drug provides the expected clinical benefit.

Accelerated approval and other expedited programs for the development, review, and approval of drugs and biologics are a critical part of addressing unmet medical needs related to neurological disorders and rare diseases. Through these approaches, FDA can speed the availability of drugs that treat serious diseases bene-

[8] Richardson, Lisa et al 2022. Adults who have never been screened for colorectal cancer, behavioral risk factor surveillance System, 2012 and 2020. https://www.cdc.gov/pcd/issues/2022/22_0001.htm

[9] Food and Drug Administration Summary of Safety and Effectiveness Premarket Approval submission number P130001

fits patients and their families, while ensuring that rigorous standards for safety and effectiveness are met. This is especially true when the drugs are the first available treatment which is often the case for rare diseases. We are committed to ensuring the continued availability, transparency, and advancement of these programs to deliver drugs and biologics that meet FDA's gold standard to patients with rare diseases.

Question. Over the last 2+ years, we have seen that vaccines are the best way to protect ourselves from COVID–19. That is why I led a letter to Acting Commissioner Woodcock advocating for the FDA to work as quickly as science allowed to authorize safe and effective COVID–19 vaccines for children 5–11. I know the FDA is working diligently to evaluate vaccines for children under 5, but my constituents in New Mexico are eager to vaccinate their kids as soon as possible. Can you share an update on the FDA's timeline to evaluate and approve vaccines for kids under 5? Can also you share any insight about how the roll out of vaccines for children under 5 may differ from the rollout for ages 5 to 11 and 12 to 17?

Answer. Having safe and effective COVID–19 vaccines available for children is a priority for FDA. The Agency ensures that the data support a vaccine's safety and effectiveness, and a favorable benefit-risk balance, in any pediatric population before authorizing for emergency use or approving a COVID–19 vaccine for use in that population. As with other regulatory and scientific decisions about COVID–19 vaccines that we have made during this pandemic, we will thoroughly evaluate the data on the use of COVID–19 vaccines in pediatric populations. Our multi-disciplinary teams of doctors, scientists, statisticians, and other experts will thoroughly assess the data when making any determination about the use of COVID–19 vaccines in pediatric populations.

FDA has been working closely with vaccine manufacturers to provide advice as data accrue about safety and effectiveness of the vaccines. FDA is convening its Vaccines and Related Biological Products Advisory Committee (VRBPAC) meetings to discuss amending the Moderna and Pfizer-BioNTech emergency use authorizations (EUAs) for their COVID–19 vaccines to include younger populations. Specifically, on June 14, 2022, the VRBPAC will meet in open session to discuss amending the EUA of the Moderna COVID–19 Vaccine to include the administration of the primary series to children and adolescents 6 years through 17 years of age. On June 15, 2022, the VRBPAC will meet in open session to discuss amending the Moderna COVID–19 Vaccine EUA to include the administration of the primary series to individuals 6 months through 5 years of age, and also to discuss amending the Pfizer-BioNTech COVID–19 Vaccine EUA to include the administration of the primary series to individuals 6 months through 4 years of age.

The agency understands the urgency to authorize a safe and effective vaccine for age groups who are not currently eligible for vaccination and is working diligently to complete our evaluation of the data. Following a transparent public dialogue with our VRBPAC, the agency will only authorize COVID–19 vaccines for children if the Agency finds that the evidence shows the vaccines meet our scientific and regulatory standards and the Agency finds that the known and potential benefits outweigh the known and potential risks. After a vaccine receives authorization, vaccine distribution and prioritization is coordinated by HHS and CDC.

QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

Question. Breakthrough and expedited approval pathways allow FDA efficient development opportunities for treatments of diseases and conditions that have few or no therapeutic options. Drug repurposing could be a viable option to meet unmet medical needs, if approval pathway qualifying criteria specifically included drug repurposing use cases. An example of this could be allowing preliminary clinical evidence from real-world data sources such as off-label use in clinical settings. Another could be creating pathways for accelerated or priority review of labeling supplements of previously approved FDA products that have demonstrated a clinical benefit for rare/infectious disease populations. Does FDA plan to use existing funding under your current operating budget or the requested funding for FY 23 to specify, update, or create expedited or accelerate approval pathway(s) such as drug repurposing to maximize the value of FDA regulated products for all populations, especially those with rare conditions or special populations?

Answer. The Agency agrees that data on how approved drugs are being repurposed may inform the development of new clinical uses for these drugs as potential treatments for diseases and conditions that have few or no therapeutic options. FDA has and will continue to consider fit-for-purpose real-world data in regu-

latory decisions relating to the use of repurposed drugs, including utilizing such data when appropriate under our expedited programs for drugs and biologics to treat serious conditions. These programs have been and will continue to be utilized to advance consideration of repurposed drugs.

The agency has also devoted significant resources to exploring the use of repurposed drugs for diseases or conditions with unmet medical needs. In December 2019 the agency launched the CURE ID repository (a website and mobile application) globally, and rapidly expanded it in June of 2020 to respond to the COVID–19 pandemic.[10] The repository captures clinical outcomes from the clinical community when drugs are used for new conditions, in new populations, in new doses or in new combinations. Health care professionals generally may choose to prescribe or use a legally marketed human drug or medical device for an unapproved or uncleared use when they judge that the unapproved use is medically appropriate for an individual patient. The systematic collection of real-world experience in the CURE ID platform can help identify drug candidates for additional study, encourage further drug development and serve as a resource for physicians to share information where no FDA-approved product proven to be safe and effective exists for the new use. Repurposing approved drugs for new clinical uses can potentially offer an efficient drug-development pathway for treatments of diseases and conditions that have few or no therapeutic options.

In June of 2020, the agency also announced the creation of a public-private partnership (PPP), convened by the Critical Path Institute, called the CURE Drug Repurposing Collaboratory (CDRC) and provided funding to initiate this effort. The Agency plans to continue our work with the CDRC, which has since received additional support from HHS. Additionally, the Agency has continued to work with National Institutes of Health (NIH), the Reagan Udall Foundation,[11] and the Critical Path (C-Path) Institute [12] to explore avenues to advance research and policy regarding existing therapeutics.

The agency believes that the existing expedited programs for drug development and the agency's ability to leverage these programs when approved drugs show promise with rare diseases are sufficiently flexible and robust to address public health needs, including with respect to repurposing, or expanding the approved uses of, approved drugs. The agency is committed to utilizing these programs when appropriate to expedite development of repurposed drugs, including drugs repurposed for rare diseases. The Agency will also continue working with sponsors pursuing repurposing opportunities for areas of unmet medical need. The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need, based on a surrogate endpoint reasonably likely to predict benefit. Validated surrogate endpoints can be used for traditional approvals. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval.

While the agency believes the current accelerated approval pathway, enhanced by the agency's other expedited programs, provide an appropriate means for expanding the approved uses of approved drugs, the President's budget includes a legislative proposal titled "Ensuring Feasibility and Timeliness of Confirmatory Studies and Enhancing Withdrawal Procedures for Prescription Drugs Approved through Accelerated Approval". This proposal seeks to amend the accelerated approval provisions of the FD&C Act to (1) revise section 506(c)(2)(A) of the FD&C Act such that FDA may require, as a condition of a drug product application's acceptance for filing, or as a condition of a drug product's receipt of accelerated approval, that a drug sponsor must first demonstrate that a proposed post-approval (i.e., confirmatory) study is adequately designed to verify and describe clinical benefit and can be completed in a timely manner; (2) revise section 506(c)(3) so that FDA can follow its dispute resolution procedures for drug applications when withdrawing a drug product's accelerated approval; and (3) revise the withdrawal standard at FD&C Act 506(c)(3)(C) so that it mirrors the analogous withdrawal standard set forth in section 505(e) for drugs with traditional approvals. The FD&C Act does not provide FDA with easily implementable legal authorities to help target the problem of studies that progress too slowly. FDA believes that such a provision would help provide greater assurance

[10] https://www.fda.gov/drugs/science-and-research-drugs/cure-id-app-lets-clinicians-report-novel-uses-existing-drugs

[11] https://www.fda.gov/drugs/news-events-human-drugs/repurposing-patent-drugs-research-regulatory-challenges-12052019–12062019

[12] https://c-path.org/programs/cdrc/

at the time of a drug product's accelerated approval that the confirmatory study can progress in a timely manner, and reap high-quality, interpretable results. Enhancing the timeliness and quality of confirmatory studies will help support FDA's regulatory decision-making for drugs approved through the accelerated approval pathway and minimize the time that a product is marketed based on accelerated approval before its clinical benefit can be confirmed.

Question. It is important to ensure that those who require compounded hormone therapies are able to access them in a safe manner. As FDA reviews recommendations from the National Academies of Sciences, Engineering, and Medicine's report on the Clinical Utility of Compounded Hormones, will you commit to work with, and be responsive to, all relevant stakeholders as part of FDA's review of the report and its recommendations?

Answer. This is an issue the Agency takes seriously. As you know, to help inform the public and FDA's policies regarding compounded bioidentical hormone replacement therapy (cBHRT), the Agency entered into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM) to convene an ad hoc committee to conduct a study on the clinical utility of cBHRT drug products. The committee also reviewed which populations may benefit from the use of these preparations and considered whether the available evidence supports their use to treat patients. The committee issued its report, "The Clinical Utility of Compounded Bioidentical Hormone Therapy," on July 1, 2020.[13]

Reports published by NASEM aim to provide independent, objective expert advice. With regard to cBHRT, NASEM held six open session meetings for the Committee on Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy. According to NASEM, these meetings provided an opportunity for the committee to gather data and contextual information from relevant BHRT compounders and BHRT medical professionals.

The NASEM report discusses some of the uncertainties of the potential benefits and safety risks associated with the use of these compounded products. FDA believes the results of NASEM's research provide important information that will increase public understanding regarding cBHRT products. When developing Agency policies, FDA intends to consider the information in the NASEM report, along with information and comments received from members of the public, while taking into account patient access concerns.

Question. We understand that FDA expects to issue revised long-term sodium reduction targets in the next few years. How will FDA ensure these targets are scientifically-based and achievable, while at the same time taking into account the need to preserve consumer choice?

Answer. FDA is committed to voluntary sodium reduction efforts, and providing consumers with the education and resources needed to choose lower-sodium foods will be important to reducing risk for negative health outcomes like hypertension and cardiovascular disease. Reducing sodium intake has the potential to prevent hundreds of thousands of premature deaths and illnesses in the coming years. FDA is focusing its work with industry on meeting the short-term goals. Any longer-term voluntary sodium reduction targets would be science-based and achievable, and would provide an opportunity for public input and stakeholder engagement, in keeping with the Agency's mission and established procedures.

Question. At the urging of Congress, FDA published final guidance on mitigation of bacteria in blood platelets, which took effect in October of 2021. This guidance suggested multiple options to address the problem of bacterial contamination in platelets, which due to their nature must be stored at room temperature. In December, FDA issued a notice stating that one bacterial mitigation method in particular has been implicated in recent cases of sepsis and two patient deaths. The FDA also said it is investigating more cases. Can you provide me with a status update of the investigation?

Answer. FDA shares the goal of enhancing the safety of the blood supply through controlling the risk of bacterial contamination of platelets. With respect to the cases of septic transfusion reactions, as explained in our April 2019 and December 2021 safety communications, FDA continues to investigate cases of septic reactions and bacterial contamination where additional genetic testing indicated a potential common source, and which involved various bacterial risk mitigation approaches. To facilitate further investigation, FDA encourages blood establishments and transfusion services to contact FDA when they identify suspected contamination of platelets with the implicated organisms, or suspected septic transfusion reactions involving pathogen-reduced platelet components.

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[13] https://www.nationalacademies.org/our-work/clinical-utility-of-treating-patients-with-compounded-bioidentical-hormone-replacement-therapy

Regarding cases of septic transfusion reactions which involved certain bacterial species, further genetic testing by CDC indicates a high probability that the organisms are related. Although genetic testing conducted by the CDC indicated these organisms may have a common source, no such source has been identified to date. As part of our ongoing investigation, CDC and FDA maintain regular communication and coordination. This also includes interactions with blood collectors and device manufacturers. We continue to monitor and investigate any reports where the implicated organisms are identified either by bacterial testing or during investigation of clinical reactions.

Question. Is FDA seeing instances of health care systems limiting consumer choice by providing patients with only one bacterial mitigation methodology? If so, do you believe this is concerning?

Answer. Hospitals generally make the decisions on what blood components they would prefer to use for their patients, and these decisions may depend on what their blood collector can provide. FDA has been contacted by a few health care providers regarding the bacterial mitigation strategies implemented by their blood suppliers. However, patients are not usually offered choices of different types of blood components, and we are not aware that recipients of platelets have expressed concern. FDA is aware of the unique operational and inventory challenges in various hospital settings; consequently, our recommendations present blood collection establishments and transfusion services multiple options for complying with FDA's regulations that require blood establishments to reduce the risk of bacterial contamination of platelets.

FDA works with blood establishments and transfusion services equally to implement FDA's requirements, based on the options they choose. While we recognize that blood suppliers make business decisions that may affect their hospital customers, such negotiations or contractual relationships fall outside the statutory provisions and regulations that we enforce.

Question. The FDA determines whether drugs are safe and effective, and is the gold standard in science-based, rigorous drug review. Are you familiar with a National Coverage Determination (NCD) recently finalized by the Centers for Medicare and Medicaid Services related to an Alzheimer's disease drug approved by FDA under the accelerated approval process? Are you concerned that this NCD appears to establish new requirements for FDA-approved drugs, and if so, could this undermine FDA's gold standard? Do you believe this could cause companies who are seeking accelerated approval to reconsider moving forward with their applications?

Answer. 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 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 drug is safe and effective for its intended use. The agency cannot speak for CMS. We continue to see sponsors pursue accelerated approval.

QUESTIONS SUBMITTED BY SENATOR MITCH MCCONNELL

Question. In 2021, FDA stated to my office that FDA was continuing to accept ingredients listed in the Office Publication (OP) of the Association of American Feed Control Officials (AAFCO) for use in animal food, as long as no safety issue arises. FDA stated that "at this time no approved animal food additive petitions, or ingredients definitions listed in the AAFCO OP, for any substances derived from hemp, and FDA is unaware of any generally recognized as safe (GRAS) conclusions regarding the use of any substances derived from hemp in animal food." FDA stated the Agency is continuing to encourage stakeholders to develop the necessary data and submit GRAS notices, food additive petitions, or AAFCO ingredient definitions for hemp-derived animal food ingredients that do not contain CBD. FDA stated the Agency has no plans to issue guidance on this topic at the time (2021), but that FDA has been actively engaged with the industry and researches on the data needed to access the correct safety measures for hemp-derived animal feed. As FDA continues to study the safety measures, what is the timeline for issuing guidance the FDA may offer about using hemp grain as an additive for livestock feed?

Answer. At this time, FDA does not have plans to issue guidance about hemp grain in particular, but has referred interested parties to other available guidance on the animal food review process (GFI 221: Recommendations for Preparation and Submission of Animal Food Additive Petitions and GFI 262: Pre-Submission Con-

sultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices). FDA continues to actively engage with the hemp industry regarding data needed to demonstrate the safety of these ingredients for animal food. As announced publicly by the submitter, the Agency is currently reviewing the first submission for hemp-derived ingredients for use in animal food.

Question. In 2020 and 2021, Congress provided FDA with increases totaling $7 million for additional research and work on CBD. FDA's March 2020 report to Congress on potential regulatory pathways included a number of key questions FDA wanted to address including the effects of daily use, comparing different methods of exposure, effects on children and others.

Despite this Congressional priority, there is no further clarity for the CBD market today than there was in 2018. It has been more than 3 years since passage of the Farm Bill that legalized hemp. President Biden's 2023 FDA budget notes that the agency is continuing to research CBD, but provides no details on movement and no additional funding is requested.

How has FDA allocated the appropriations funding from Congress, and how have these steps advanced FDA's plans to regulate CBD?

Answer. FDA appreciates the funding Congress has provided since fiscal Year2020 to support the Agency's efforts on cannabis and cannabis derivatives. Of the $7 million appropriated for these efforts, FDA has allocated funding to the Center for Food Safety and Applied Nutrition ($3 million), the Office of Regulatory Affairs ($2 million), the Center for Veterinary Medicine ($1 million), and FDA headquarters ($1 million). These resources are being used for a variety of purposes, including to support additional FTE in several programs to support the work in this quickly expanding area.

Funds have also supported efforts including:

—Several ongoing toxicology studies with CBD, including an in vitro evaluation of male reproductive toxicity of CBD and its main metabolites, developmental neurotoxicity of CBD in rats, immune modulating effects of perinatal exposure to CBD in rats, and multiple studies on CBD pharmacokinetics

—A large-scale product sampling and testing study targeting approximately 1400 samples to test for toxic elements, pesticides, residual solvents, microbes, and 11 cannabinoids

—Monitoring and analyzing adverse event data from multiple sources

—Partnering with external groups to obtain market, consumer, and safety data

—Ongoing monitoring of scientific literature

—Issuance of warning letters to firms marketing products that pose particular public health concerns, including products with unsubstantiated claims for treating serious diseases, including cancer, ALS, and COVID–19; products marketed towards children; products marketed for use in food producing animals; and products with concerning routes of administration (e.g. ophthalmic).

Question. FDA's March 2020 report to Congress identified six additional next steps FDA would undertake while evaluating potential pathways to market CBD. These included establishing Enforcement policy, gathering additional safety information, further engagement with Federal, State, Local, Territorial, Tribal, and International Partners, further evaluation of "Full Spectrum" and "Broad Spectrum" hemp extracts, additional research, and product sampling. What actions has FDA taken to implement these six steps? What does FDA plan to continue doing in each of these six areas?

Answer. FDA has undertaken a number of actions to implement the steps outlined in the report issued in response to the Further Consolidated Appropriations Act of 2020. Specifically, the Agency has initiated the following:

—Gathering additional research and safety information, including the evaluation of "Full Spectrum" and "Broad Spectrum" hemp extracts and product sampling: FDA participated in a Health Canada study to establish a consistent, validated, analytical method for the quantitation of hemp and cannabinoids broadly in a variety of products. Additionally, the Agency has four ongoing method development and chemical profiling projects and seven in vitro testing projects, all working with hemp extracts provided by the FDA Center of Excellence, National Center for Natural Product Research. FDA is also finalizing the results of a long-term sampling study, which collected and tested nearly 1,400 products (including tinctures/oils, capsules, gummies, drinks, food, pet products, and cosmetics) from both internet purchases and brick and mortar locations. FDA anticipates this report being finalized in Fall 2022. A second year of the study is

being initiated and will focus on further sampling of pet products and an additional evaluation of variability within and between products.

—Engagement with Federal, State, Local, Territorial, Tribal, and International Partners: According to the National Conference of State Legislatures, as of February 3, 2022, 37 States, four territories and the District of Columbia allow the medical use of cannabis products; and as of May 27, 2022, 19 States, two territories and the District of Columbia have enacted measures to regulate cannabis for adult non-medical use. It is estimated that nearly 1 in 3 Americans now lives in a State where adult-use is legal. However, each State legislates, regulates, and operates its cannabis programs differently. FDA has fielded inquiries from nearly every State and territory, and from a number of Tribal governments. In addition, we engage with these important stakeholders in many ways, including:

—speaking with several States' cannabis regulatory agencies and departments of health to learn more about their regulatory cannabis programs and adverse event reporting systems;

—encouraging States to submit adverse event reports to FDA through the MedWatch Program;

—holding discussions and panels with state cannabis regulators and state associations;

—encouraging stakeholder feedback to our draft guidances regarding drug products containing cannabis or cannabis-derived compounds;

—talking with States and encouraging them to share information so FDA can learn more about their approaches and requirements, as well as any challenges they may be facing, related to quality considerations for cannabis and cannabis-derived compounds within their systems; and

—interacting with States' Attorneys General.

—Enforcement Policy: The Agency understands the significant interest in this space and is prioritizing the evaluation of potential enforcement policy options. FDA looks forward to discussing this further when there is additional information to share.

Question. Can you provide an update on the activities laid out in the FDA Fall 2021 Data Acceleration Plan?

Answer. FDA has undertaken a number of activities to meet the goals laid out in the Data Acceleration Plan. Some safety vigilance activities include performing comprehensive evaluations of existing FDA safety surveillance and epidemiologic databases, such as the FDA Adverse Event Reporting System and the American Association of Poison Control Centers National Poison Data System; funding a pilot project to explore the utility of media reports and social media (i.e., Reddit) for the identification of new safety signals with cannabis-derived products (CDPs); developing custom based surveys to obtain data related to CDP utilization and associated adverse events; and exploring the capabilities of different electronic health record (EHR) data sources to capture exposure information and for safety signal detection. As a result of data obtained through some of these activities, FDA has taken a number of actions related to safety of CDPs, such as issuing a consumer update for delta-8 THC[14] and issuing a safety alert for edible products containing THC and the potential for accidental pediatric exposures.[15]

Question. Please provide a review of what information has been collected by FDA to determine the parameters for safety.

Answer. During review of the marketing application for the CBD-based drug Epidiolex, FDA identified certain safety risks, including the potential for liver injury and for adverse reactions caused by the interaction between Epidiolex and other medications. FDA has reviewed published literature to assess the safety of the use of CBD in human food. FDA identified potential for liver injury from CBD and potentially harmful interactions with certain drugs, and studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels, and impair sexual behavior in males.

In order to better understand potential effects of CBD, as stated above, FDA is investigating potential CBD interference with testosterone production and underlying mechanisms of toxicity. The results of this study align with other studies indicating that CBD might have negative effects on the male reproductive system. The

[14] https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc

[15] https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc

first results from this study have been published. Other ongoing FDA studies include investigation of developmental neurotoxicity of CBD in rats, a study of immune modulating effects of perinatal exposure to CBD in rats, and multiple studies on CBD pharmacokinetics.

Other data collection efforts are ongoing including a large-scale product sampling and testing study targeting approximately 1400 samples to test for toxic elements, pesticides, residual solvents, microbes, and 11 cannabinoids, monitoring and analyzing adverse event data from multiple sources, and partnering with external groups to obtain market, consumer, and safety data.

Question. Does FDA ever expect to issue a proposed rule? If not, why not and what barriers continue to exist?

Answer. Over the past several years, the Agency has worked to collect data about the effects of CBD in animals and humans, including potential adverse effects. Based on the information FDA currently has obtained, the appropriate regulatory pathway is still uncertain. FDA is prioritizing the evaluation of potential options and looks forward to discussing this further with Congress when there is additional information to share.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

Question. The accelerated approval pathway has been successful in ensuring patient access to new medications, and has been especially effective for patients with cancer. Previously, you have recognized the benefits of the pathway, while also looking for additional ways to confirm clinical benefit for the drugs approved under accelerated approval. As part your approval process, you noted that you would reform the agency's accelerated approval pathway? What reforms do you see implementing? Are you committed to continuing the accelerated approval pathway?

Answer. The President's budget includes a legislative proposal titled "Ensuring Feasibility and Timeliness of Confirmatory Studies and Enhancing Withdrawal Procedures for Prescription Drugs Approved through Accelerated Approval". This proposal seeks to amend the accelerated approval provisions of the FD&C Act to (1) revise section 506(c)(2)(A) of the FD&C Act such that FDA may require, as a condition of a drug product application's acceptance for filing, or as a condition of a drug product's receipt of accelerated approval, that a drug sponsor must first demonstrate that a proposed post-approval (i.e., confirmatory) study is adequately designed to verify and describe clinical benefit and can be completed in a timely manner; (2) revise section 506(c)(3) so that FDA can follow its dispute resolution procedures for drug applications when withdrawing a drug product's accelerated approval; and (3) revise the withdrawal standard at FD&C Act 506(c)(3)(C) so that it mirrors the analogous withdrawal standard set forth in section 505(e) for drugs with traditional approvals. The FD&C Act does not provide FDA with easily implementable legal authorities to help target the problem of studies that progress too slowly. FDA believes that such a provision would help provide greater assurance at the time of a drug product's accelerated approval that the confirmatory study can progress in a timely manner, and reap high-quality, interpretable results. Enhancing the timeliness and quality of confirmatory studies will help support FDA's regulatory decision-making for drugs approved through the accelerated approval pathway and minimize the time that a product is marketed based on accelerated approval before its clinical benefit can be confirmed.

Question. Dr. Califf, there has been concern from several different companies about FDA review, and how long the process to get clearance from the agency. We have heard from constituent companies, including Avadel Therapeutics, with concern how long the timeline has stretched.

Can you share how the agency is prioritizing review of drugs?

Answer. Earlier this year the Agency released our PDUFA[16], BsUFA[17] and GDUFA[18] annual performance reports. In these reports the agency delineates the previous year's performance on various user fee goals, including review timelines, within the three programs. Despite an increased workload, FDA has maintained a high level of performance in meeting PDUFA, BsUFA, and GDUFA goals and initiatives.

In PDUFA, FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times—Standard Review and Priority Review.

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[16] https://www.fda.gov/media/156077/download
[17] https://www.fda.gov/media/155870/download
[18] https://www.fda.gov/media/155760/download

A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

A Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

Significant improvement may be demonstrated by the following examples:

—evidence of increased effectiveness in treatment, prevention, or diagnosis of condition;

—elimination or substantial reduction of a treatment-limiting drug reaction;

—documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or

—evidence of safety and effectiveness in a new subpopulation.

While the agency cannot speak to any specific product due to commercially confidential information, we encourage the company to reach out to the relevant review division for more information on their specific product.

Question. How has COVID–19 contributed to this issue, and would you agree that there is a backlog of drugs that have not been reviewed?

Answer. The continuing COVID–19 epidemic has certainly made for unique circumstances in the agency. For PDUFA in fiscal Year 2021, despite the sustained high workload, the increased use of expedited programs, and the development and review of new therapeutics and vaccines to address the public health emergency, FDA rose to the challenge and maintained its high level of performance in meeting PDUFA goals and initiatives. As noted in the PDUFA Performance Report for fiscal Year 2021, FDA completed 2,055 actions as of September 30, 2021. FDA is currently meeting or exceeding 9 of the 12 review performance goals for fiscal Year2021. With 1,466 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 10 of the 12 review performance goals for fiscal Year 2021.

Question. Does this issue extend to other product reviews, such as devices?

Answer. Review times for tests and other device Emergency Use Authorization (EUA) requests have increased over time as the number of EUA and Pre-EUA submissions quickly surged to unprecedented levels during the COVID–19 pandemic. Since January 2020, FDA has received over 8,000 EUA requests and Pre-EUA submissions for devices (including over 1,000 so far in Fiscal Year 2022). The Agency continues to receive nearly 120 device EUA requests and pre-EUA submissions each month, the majority for tests, and has begun receiving conventional submissions from firms intending to transition their products beyond emergency use.

In order to address high submission levels of device EUA requests, FDA has implemented important measures to reduce review times. These steps include:

—Temporarily reassigning staff to increase review capacity;

—Leveraging contractors from outside organizations to provide technical expertise to supplement our review staff (personnel authorized to work alongside full-time employees, integrated into our internal review teams);

—Using supplemental funds from Congress to hire 30 new, temporary staff to support review of EUAs;

—Implementing a triage process for new EUA requests; and

—Working to efficiently use resources for low-impact and poor-quality submissions, including expanding the use of holds when important data is missing, and instituting a process to prioritize submissions where our resources should be focused (namely, on those submissions that would have the greatest impact on public health).

Additionally, as a result of the unprecedented number of EUA requests and pre-EUA submissions that FDA received for COVID–19 tests and collection kits, we have not been able to review some non-COVID in vitro diagnostic (IVD) pre-submissions. To address this issue, FDA's IVD office has focused on increasing staffing to address the increased volume of work, allowing us to provide more resources to our conventional premarket workload. We are pleased to announce that, as of June 1, 2022, FDA plans to accept all non-COVID IVD pre-submissions. Due to the continued elevated workload related to COVID–19, it is likely that these IVD pre-submissions will initially be reviewed under an extended timeline.

FDA looks forward to our continued interactions with device submission sponsors and appreciates their patience and understanding as we work to return to normal

operations while continuing to respond to the public health emergency. The commitment that FDA and the medical device industry share to prioritize innovation and increase patient access is central to our mission to protect and promote the public health. This commitment is exemplified by the recommendations for the reauthorization of Medical Device User Fee Amendments for Fiscal Years 2023–2027 (MDUFA V) in the commitment letter, which has been submitted to Congress. The recommendations in the MDUFA V commitment letter are intended to increase efficiency of regulatory processes and reduce the time it takes to bring safe and effective medical devices to the U.S. market.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

Question. The Drug Quality and Security Act of 2013 (DQSA) includes strong protections intended to promote patient safety and to strengthen the integrity of the FDA drug approval process. The Agency has said it will clarify its position on DQSA's prohibition on compounding drugs that are "essentially a copy of an approved drug" when using FDA-approved drugs as the starting material. When will the Agency provide this clarity? Does the Agency intend to ensure that the use of FDA-approved drugs as a starting point, and that a change in a container closure system (eg, a transition from vial to a syringe), would not fall within the meaning of the essentially a copy prohibition? This lack of regulatory clarity has led to numerous, very costly lawsuits that are driving up the price of compounded medications and resulting in a shortage of ready-to-administer drugs. As a result, patients are encountering increased barriers inhibiting their access to essential medications.

Answer. Since the enactment of the Drug Quality and Security Act, FDA has made significant progress on clarifying the Agency's policies on compounding drugs that are "essentially a copy of an approved drug," taking into consideration real world implications as well as comments and concerns expressed by the public. The questions and comments regarding compounding raise complex issues requiring extensive review by Agency officials, and efforts have been made to provide the Agency's thinking. Most recently, on January 1, 2018, FDA issued a final guidance for industry, "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act," that aimed to provide further clarity on the Agency's policies. The Agency has since received further questions and comments related to its policies for applying the "essentially a copy" provision, including questions regarding when outsourcing facilities compound drugs starting with an approved drug rather than a bulk drug substance. While we cannot provide a specific timeline, FDA understands that these questions are important to stakeholders and is currently working diligently to address them, including addressing these issues in an updated guidance.

Question. The Agency announced earlier this year that it will undertake notice-and-comment rulemaking related to the Memorandum of Understanding (MOU) between the FDA and States that regulates the number of compounded therapies distributed across state lines. As the Agency drafts this proposal, it's important to ensure that patients have unfettered access to the compounded medications they need to live. A recent version of the MOU issued by the FDA included dispensed (patient specific prescriptions) within the definition of distribution which would limit the distribution of compounded preparations shipped across state lines to 50 percent of all prescriptions each month for States signing the MOU. Although many compounding pharmacies do not exceed this threshold, low-volume pharmacies located near state borders who will be disproportionately and adversely impacted. This means patients who receive their compounded therapies from out of state may have to find a new pharmacy to provide their medicines at the end of each month. This is unacceptable. One way to fix this patient access problem is to exclude the number of drugs dispensed to specific patients, pursuant to a prescription, from the total number of drugs pharmacies distribute across state lines. Will the revised MOU proposal do this?

Answer. As you noted, in February 2022, the Agency publicly stated that FDA intends to undertake notice-and-comment rulemaking related to statutory provisions regarding certain distributions of compounded human drug products and a standard memorandum of understanding (MOU) between FDA and States. The standard MOU is an agreement that is intended to address interstate distribution of inordinate amounts of compounded drugs and complaint investigation by a State regulator relating to compounded drugs distributed outside the state. Federal law limits distribution of compounded drugs outside the state by a pharmacist, pharmacy, or physician located in a State that has not entered into the MOU to 5 percent of total

prescription orders dispensed or distributed. An essential element of FDA's rulemaking process is a public comment period, which provides an important opportunity for stakeholder engagement. We wish to also note that under the most recently published MOU (which is now suspended) States signing the MOU would have agreed to report, among other things, information about compounders who have distributed interstate more than the 50 percent threshold described. We would like to emphasize that this reporting threshold would not have placed any limit on the distribution of compounded drugs interstate by a pharmacy located in a State that entered into the MOU.

Question. I have been outspoken about shortages in our Nation's blood supply, which is of great concern to patients and hospitals in Kansas. I recently became aware of some actions by blood centers which may restrict hospital choice when it comes to blood platelets intended for transfusion and further exacerbate shortages of this particular blood product. I am specifically referring to FDA's guidance addressing the mitigation of bacterial contamination in blood platelets, which became effective in October of 2021. This guidance to industry suggests up to three clinically equivalent mitigation strategies for blood platelets. Yet some major blood centers are forcing hospitals to purchase blood platelets prepared with only one of the options which I understand is not only the most expensive option, but is also associated with a shorter product shelf-life than the other options resulting in more wastage. Importantly, this option has been linked to multiple cases of sepsis and fatalities per an FDA bulletin in December of 2021. FDA stated in this bulletin that it is investigating even more cases. This is of concern to me, from a hospital choice, cost, and patient safety perspective—what steps will FDA take to ensure that hospital choice is preserved and blood shortages are minimized?

Answer. FDA guidance addressing the mitigation of bacterial contamination in platelets presents blood collection establishments and transfusion services multiple options for complying with FDA's regulations to reduce the risk of bacterial contamination of platelets. FDA will continue to monitor the safety and availability of the blood supply and the effectiveness of the strategies recommended for controlling the risk of bacterial contamination of platelets, included in the December 2020 guidance. While we recognize that blood suppliers make business decisions that may affect their hospital customers, such negotiations or contractual relationships fall outside the statutory provisions and regulations that we enforce.

With respect to the cases of septic transfusion reactions, as explained in April 2019 and December 2021 safety communications, FDA continues to investigate cases of septic reactions and bacterial contamination where additional genetic testing indicated a potential common source, and which involved various bacterial risk mitigation approaches. To facilitate further investigation, FDA encourages blood establishments and transfusion services to contact FDA when they identify suspected contamination of platelets with the implicated organisms, or suspected septic transfusion reactions involving pathogen-reduced platelet components.

Question. As you know, the law Congress approved is clear that OTC hearing devices are intended only for those over the age of 18 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, it means individuals suffering from greater levels of hearing loss could put off a needed visit with a licensed hearing professional. Doing so could lead to worsening their existing symptoms, delaying an accurate diagnosis and treatment, and even creating irreparable damage to their hearing. Secondly, it means those with perceived mild-to-moderate hearing loss would be exposed to harmful levels of noise that could result in further damage to their long-term hearing. In order to avoid these concerns, FDA should impose a gain limit of 25 dB and an overall output limit of 110 dB.

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 University of Kansas Medical Center, 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.

The Kansas Board of Hearing Aid Examiners expressed the following concerns with the proposed rule:

> "We concede that a lower output limit of 110 dB SPL may be suboptimal for enjoyment of some live music, but we feel that this is a worthy tradeoff to mitigate the risk of noise-induced auditory damage from the hearing

aid. The FDA proposed rule suggests that consumers can remove a hearing aid within 30 to 60 seconds following onset of loud acoustic events. This may be true for many but we are concerned that vulnerable populations, such as those with cognitive and/or physical limitations, may be unable to remove the hearing aids quickly enough to avoid acoustic trauma."

Dr. Califf, I think you would agree it is important to protect consumers. Can you tell me what is being done to ensure OTC hearing aids will not cause greater hearing loss for individuals?

Answer. FDA appreciates the feedback you have provided with respect to the proposed rule, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, and for sharing your concerns about the output limits proposed for over-the-counter hearing aids, as well as the views of stakeholders who express similar concerns based upon their professional judgment. As you know, section 709(b)(2) of the FDA Reauthorization Act of 2017 (Public Law 115–52) directs FDA to establish or adopt output limits appropriate for over-the-counter hearing aids as well as other requirements that provide reasonable assurance of the safety and effectiveness of the devices.

FDA is currently reviewing and considering the comments submitted to the docket. Many of them cited quantitative methods to develop an output limit they believe is appropriate to over-the-counter hearing aids. Further, as you noted, many such comments suggested that FDA establish a limit on gain, separate from and additional to the appropriate output limit. Conversely, several current hearing aid users provided comments describing the benefits they personally receive at specific (quantified) amplification levels. People with expertise in electronics and sound amplification similarly added to our knowledge of real-world performance. In sum, while many professionals back a lower output limit, many other professionals-some of them hearing aid users themselves-voiced support for FDA's proposed output limit.

All of these perspectives addressed a nexus of complex medical and scientific issues, the real-world effects for hearing aid users, and protecting and promoting the public health. To determine appropriate output and, potentially, a gain limit, FDA continues to engage with the comments addressing the scientific literature, patient perspectives, institutional knowledge (e.g., adverse event reports), and expertise of other agencies, including the National Institutes of Health. Our scientific deliberations are ongoing.

As we finalize the requirements, we are keeping in mind concerns about users who might delay a productive visit with a hearing health care provider and users who might be exposed to harmful amplification levels from over-the-counter hearing aids. These concerns are some of the most important considerations for the safety and effectiveness of over-the-counter hearing aids and carry over into additional requirements (e.g., labeling, electroacoustic performance, design features, and conditions for sale).

FDA remains committed to establishing a science-based regulatory category for over-the-counter hearing aids that provides reasonable assurance of safety and effectiveness while promoting access to devices that will help address a significant public health need.

Question. New innovations in plant breeding techniques, such as genome editing, will be crucial to sustainably increase agricultural production and enhance food and nutritional security. Clear FDA policy for food derived from genome editing improved varieties is critical if we are to expand the diversity and availability of food.

FDA's biotechnology consultative process for food derived from biotech plant variety is over 25 years old. In the last several years, there has been observable decline in the predictability and timeliness of the process. The ability of our farmers to remain competitive globally depends on timely access to the newest and best varieties.

How do you plan to expediate modernization of the FDA process so it doesn't become an unnecessary hurdle to innovation, especially from small and medium sized public and private enterprises?

Answer. FDA agrees that innovation in plant breeding techniques is important for the future of agriculture and that the voluntary consultation process can take longer than it has in the past. Some of this is due to the complexity of products entering FDA's program. For example, the Agency recently completed voluntary consultations on two separate products that contained 8 and 13 new genes. There are also many new, smaller companies engaging with the Agency, and it requires greater staff time to walk them through the voluntary consultation process.

FDA is taking steps to help address the timeliness concern. For example, the Agency is beginning to strengthen the Center for Food Safety and Applied Nutrition's Biotechnology Team to help address the new, complex and innovative products coming through the door, and has improved the process work-flow for the consulta-

tion process. FDA also intends to update its guidance on voluntary consultation procedures, last updated in 1997, to reflect what it has learned over the past 25 years.

FDA is also in the process of developing draft guidance for industry regarding foods from genome edited plant varieties. Issuing this draft guidance is a priority. FDA has already taken several steps to help inform our drafting process, including issuing a request for information in January 2017. The Agency has reviewed the comments and has been following (and participating in) the international conversation around these techniques while developing the draft guidance. While this draft guidance is under development, FDA is actively working with developers of genome edited plants. Many of these firms are small and medium sized entities that benefit from FDA's iterative voluntary consultation process to help them understand their legal responsibilities as they bring safe and innovative products to market.

Question. FDA, CVM holds the regulatory authority for gene-edited (GE) farm animals and is currently exercising their regulatory authority using the proposed GFI #187 that seeks to treat the genetic application like a new animal drug. Does FDA intend to publish their finalized version of GFI #187 within the next year to give increased clarity to their future regulatory process for GE animals and is the agency considering how their final guidance could support the MOU signed with USDA, APHIS in January 2021 for shared regulatory authority for GE farm animals?

Answer. FDA's regulation of intentional genomic alterations (IGAs) in animals is focused on ensuring that the IGAs are safe to animals, safe to consumers, and accomplish what their developer claims they will accomplish. FDA regulates them under the Federal Food, Drug, and Cosmetic Act and FDA's existing regulations. GFI #187, as with all FDA guidance documents, represented the FDA's current thinking on a particular subject. While guidance documents are not binding on the public or FDA, they are an important way to communicate FDA's recommendations to developers of FDA-regulated products.

FDA first issued GFI #187 in 2009 and issued a draft revised version in 2017. In response to stakeholder concerns, FDA has now significantly revised GFI #187 including splitting it into two parts. The resulting guidances are currently under OMB review. The need to publish GFI #187 to provide greater clarity to stakeholders and the public is independent of the HHS-signed MOU, which is currently not in effect.

FDA is making continuous improvements to its regulatory oversight to ensure a transparent, flexible and science-based approach to efficiently get safe products to market. One such improvement is FDA's implementation of additional risk-based flexibilities as demonstrated by FDA's recent low risk determination for the marketing of food and other products from genome edited SLICK cattle.

FDA supports both FDA and USDA utilization of their respective expertise under existing authorities to help provide regulatory certainty to the animal biotechnology industry. It is critical to continue progress in this field so that developers of innovative biotechnology products have the information they need to bring beneficial products to market without further delay.

Question. FDA, CVM has recently engaged in stakeholder meetings, facilitated by the Reagan-Udall Foundation, to discuss public-private partnerships for antimicrobial use data collection for food-producing animals. Will the agency pursue any antimicrobial use data collection process purely on a voluntary basis or are there plans by the agency for mandatory antimicrobial use data collection and reporting for food-producing animals in the near future?

Answer. Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) amended section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA) to require antimicrobial drug sponsors to annually report to FDA the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals. There is no parallel statutory requirement for producer and veterinary practitioner reporting of antimicrobial use data. Although sales and distribution data are useful, antimicrobial use data would better inform FDA and other interested stakeholders about how antimicrobial drugs are being used, enhance understanding about the drivers of antimicrobial resistance, and help to identify use practices opportunities that reflect good stewardship of antimicrobials.

Given the importance of this information, FDA has pursued strategies for collecting antimicrobial use data, including funding several cooperative agreements with researchers to develop pilot data collection methodologies. The initial findings from these pilot projects were published in a series of papers in Zoonoses and Public Health [19] in November 2020. The agency hopes to gain additional insight into the feasibility of establishing a voluntary data collection system from a report drafted

[19] https://onlinelibrary.wiley.com/toc/18632378/2020/67/S1

by the Reagan-Udall Foundation (the Foundation) for the Food and Drug Administration. The report, entitled Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals [20], summarizes key findings from a series of targeted conversations with stakeholders from animal agriculture, veterinary, and public health organizations, along with other key representatives. The objective is to determine the feasibility of establishing a voluntary public-private partnership to collect and analyze data on antimicrobial use in food-producing animals. FDA has opened a docket through August 21, 2022 to receive public comment on the report and the Foundation plans to host a public meeting on June 14, 2022, to share insights from the report and to allow for questions from the public.

Question. What steps does FDA intend to take to improve the standards of identity review process going forward?

Answer. FDA recognizes the importance of updating standards of identity in an efficient and transparent manner and appreciates the $1.5 million in new funding for standards of identity (SOIs) work in fiscal Year 2022. FDA is working to support innovation, especially when it can increase the availability of healthier foods in the food marketplace, by continuing its work to modernize food SOIs. This is part of our daily work and we are taking several steps to facilitate the process, including:

—Developing principles to more transparently communicate what we consider when we establish, revise, or eliminate a food standard. FDA started this process in 2005 when it published a joint proposed rule with USDA to provide each agency a set of general principles. After re-opening the comment period on the 2005 proposed rule, FDA is working with USDA to re-issue a proposed rule for stakeholders to provide input on.

—Prioritizing SOI work that supports FDA's nutrition initiatives.

—Using new strategies to more efficiently work on SOIs, such as making amendments across multiple SOIs—allowing FDA to update more than one in a single rulemaking when applicable.

—Updating individual standards of identity that focus on (1) improving public health and (2) to allow the use of modern technologies. Many standards are outdated and, as a matter of good government, need to be updated to better serve our stakeholders.

—Continuing to review citizen petitions that request FDA to establish, revise, or eliminate a standard of identity. Citizen petitions for standards of identity that do not promote honesty and fair dealing in the interest in consumers or do not contain sufficient data will be denied.

—Continuing to transparently communicate about FDA's recent actions and current activities on the Agency's recently developed SOIs webpage (see https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food).

—In November 2021, FDA published guidance for industry to clarify aspects of the temporary marketing permit (TMP) process and to describe changes that streamline and simplify the TMP application process. TMPs allow a company to test the market acceptance of products that deviate from an SOI, in order to obtain data necessary for reasonable grounds in support of their citizen petition to amend an SOI and ensure the interests of consumers are adequately safeguarded.

Modernizing SOIs will enhance industry's ability to innovate and produce healthier food while maintaining the basic nature, essential characteristics, and nutritional integrity of the food.

Question. Will FDA commit to establishing a transparent standards review process that includes reasonable deadlines for agency action and greater accountability to consumers, industry and Congress in the future?

Answer. Yes, FDA is committed to establishing a transparent standards review process and, as part of this commitment, launched an SOI webpage in April 2022 that includes a general overview of what an SOI is and its purpose, priorities for updating SOIs, a list of current SOIs that are being reviewed, and updates and current statuses (https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food).

Question. What actions is FDA taking to address stakeholders' objections and requests for hearings regarding the recently updated standard of identity for yogurt?

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[20] https://reaganudall.org/sites/default/files/2022–05/Tracking%20and%20Monitoring%20of%20Antimicrobial%20Use%20in%20Food-Producing%20Animals%20Preliminary%20Summary%20Report.pdf

Answer. On March 22, 2022, FDA published a notice to clarify that the effectiveness of certain provisions of the yogurt standard of identity have been stayed. Dairy standards of identity are subject to formal rulemaking procedures, which provide a 30-day period for any person adversely affected to file an objection and request a hearing. If objections are properly filed, then the provisions to which objections were made do not go into effect (i.e., they are "stayed"). FDA received properly filed objections to certain provisions of the final rule within this timeframe; those provisions are stayed pending final FDA action on the objections. FDA is actively evaluating the objections. Publishing a response to the objections received is a CFSAN priority.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Califf, as you know medical oxygen is an essential and indispensable front line treatment for COVID–19 that has been saving lives across America. We have seen tragic news from India about what can happen when there is a shortage of medical oxygen. In 2012, Congress enacted historic and bipartisan reforms for medical gases—which include medical oxygen—included in the Food and Drug Administration Safety and Innovation Act (FDASIA Section 1112) that required the Food and Drug Administration (FDA) to promulgate new regulations for medical gases by July 9, 2016. When FDA failed to meet the FDASIA statutory deadline, in a further effort to get FDA to comply, language was enacted in the Fiscal Year 2017 Consolidated Appropriations Act which required FDA to publish final medical gas regulations by July 15, 2017. Separate regulations for medical gases will ensure that these products are regulated in a way that takes into account the unique safety considerations of medical gases and will ensure they are available to the health systems that need them, especially as the Nation continues to treat individuals for COVID–19.

I am concerned that the FDA has failed to follow through on its statutory obligations from 2012 and 2017 to establish separate regulations for medical gases especially in light of their significant use in treating COVID–19. Where does this significantly overdue rulemaking on medical gases currently stand and will you commit to me that the FDA will publish this rule by this month (May 2022)'s deadline set in the Fall 2021 Unified Agenda?

Answer. On May 20th, FDA announced a notice of proposed rulemaking[21],[22] that proposes to establish regulations regarding certification of designated medical gases and that proposes to amend the current good manufacturing practice (CGMP), postmarketing safety reporting, and labeling regulations that apply to certain medical gases.

FDA has engaged with stakeholders and Congress for several years to gather input and evaluate the need for changes to regulatory requirements for medical gases. If finalized, this proposed rule would clarify the regulatory obligations of entities that manufacture, process, pack, label, or distribute medical gases.

Examples of proposed key provisions include:

—Proposed labeling requirements to clarify the statement of ingredients and quantity of contents for designated medical gases, revise warning statements for certain designated medical gases, and establish more limited labeling requirements for bulk or transport containers.

—Proposed CGMP requirements that recognize important differences in how medical gases are manufactured, processed, packed, and held compared to other types of drugs, including the reuse of containers and labeling; mixing and commingling of gases; that gases are generally manufactured in a closed, pressurized system; and that many medical gases are generally not expected to expire or degrade.

—Proposed regulations to codify the certification process for designated medical gases, including provisions regarding supplements to granted certifications, annual reporting, and withdrawal or revocation of approval of an application.

—Proposed safety reporting requirements under which certain events related to designated medical gases would not need to be reported to the Agency.

Question. Dr. Califf, I received your April 21, 2022, letter responding to a bicameral letter I sent you on February 18, 2022. Our letter had requested that you

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[21] https://www.federalregister.gov/public-inspection/2022–10458/current-good-manufacturing-practice-certification-postmarketing-safety-reporting-and-labeling

[22] https://public-inspection.federalregister.gov/2022–10458.pdf

immediately rescind the removal of in-person dispensing requirements for the chemical abortion drug mifepristone (Mifeprex). Your recent response said that you had conducted "a comprehensive review of the Mifepristone REMS Program," and that you concluded that without the in-person dispensing requirement, the drug would remain "safe and effective." However, as I noted at the hearing, I disagree, as do many others.

I have reviewed quite a lot of evidence showing that this drug is actually quite dangerous to the women and girls who take them. Given your unequivocal statement that your review was comprehensive, then, I have a list of questions for you. Thank you for your commitment at the hearing to be responsive to all of my questions about this.

Did your "comprehensive" review include the following relevant studies? If so, please indicate how FDA considered them, referencing all correspondence, analysis or conclusions FDA reached related to them. If not, please explain why you excluded them from the review and how your review can be considered "comprehensive" without them.

—https://doi.org/10.1177 percent2F23333928211053965 James Studnicki, et al., A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015, Health Services Research and Managerial Epidemiology. Vol. 8 1–11 (2021).

—https://doi.org/10.1093/humrep/der016 Mentula MJ, Niinimaki M, Suhonen S, et al., Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a nationwide registry study, Human Reproduction. 2011;26(4):927–932;

—https://doi.org/10.1097/aog.0000000000000897 Chen MJ, Creinin MD, Mifepristone with Buccal Misoprostol for Medical Abortion, Obstet. Gynecol 126 (1) July 2015 12–21

—https://doi.org/10.1186/s12905–018–0645–6 Carlsson I, Breding K, Larsson PG, 2018, Complications Related to Induced Abortion: A Combined Retrospective and Longitudinal Follow-up Study, BMC Women's Health 18:158.

Answer. With the exception of the Studnicki study, which was published in November 2021, after the completion of our literature review, the Agency considered these studies, as well as other studies, as part of its review of the Mifepristone REMS Program. A discussion of these studies can be found in the citizen petition response we reference in the April 15, 2022 letter.

Question. In reviewing the data to determine safety, the FDA would necessarily have had to make calculations to determine rate of complications or incidents. What was the rate of complications as determined by the FDA? Please describe the calculations, including the numerator and denominators used and how those numbers were determined adequate for statistical purposes. What rate did FDA determine would exceed safety and therefore require the REMS for mifepristone to have remained unchanged?

Answer. FDA's determination as to whether a REMS is necessary to ensure that the benefits of a drug outweigh its risks is a complex, drug-specific inquiry, reflecting an analysis of multiple, interrelated factors (such as the seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug; and the expected or actual duration of treatment with the drug) and of how those factors apply in a particular case. In conducting this analysis, FDA considers (based on premarketing or postmarketing risk assessments) whether there is a particular risk or risks associated with the use of the drug that, on balance, outweigh its benefits and whether additional interventions beyond FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks.

Question. In the course of this review, did FDA consult with non-government employees during this process, and if so, whom? Please provide names, titles and organizations for all outside individuals consulted in the review.

Answer. The Agency did not consult with any non-government employees during the course of its review of the Mifepristone REMS Program.

QUESTIONS SUBMITTED BY SENATOR MIKE BRAUN

Question. Since Congress legalized hemp in 2018, the FDA has failed to provide a pathway for the industry to bring their products to market. Congress has provided funding increases to support research on CBD products. This data is to help FDA

provide regulatory clarity. In 2020, FDA put out two reports requested by this Committee on CBD, including one on mislabeled or adulterated CBD products and the other on potential regulatory pathways and data gathering efforts on CBD. What steps has FDA taken with this funding to evaluate a potential pathway to market CBD that preserves the spirit of free market competition and transparency?

Answer. FDA appreciates the funding Congress has provided since fiscal Year 2020 to support the Agency's efforts on cannabis and cannabis derivatives. Unfortunately, prior to passage of the Agriculture Improvement Act of 2018, there was very little research into this area, so this funding has been critical in helping the Agency begin to fill knowledge gaps.

These resources are being used for a variety of purposes, in particular to study and collect data on cannabidiol (CBD) and other cannabinoids to better understand their effect on humans and animals. In addition, FDA is using funds to better understand the marketplace for cannabis-derived products (CDPs), for policy development, and to hire additional FTE in several of our programs to support the work in this quickly expanding area. These are necessary steps as FDA prioritizes the evaluation of potential regulatory options. The Agency looks forward to discussing this further with Congress when there is additional information to share.

Question. In recent years, the animal nutrition industry has made significant strides with respect to developing technologies that can help reduce on-farm emissions. Yet FDA's regulatory process administered by the Agency's Center for Veterinary Medicine (CVM) does not facilitate the deployment of these innovations.

For environmental claims and performance claims for animal feed additives, the CVM still reviews these claims as if they were animal drug claims. In my view, these regulations are overdue for an update. For example, the CVM Program Policy and Procedures Manual Guide 1240.3605 was last updated on September 18, 1998.

Can you detail for the committee what steps you intend to take and are currently taking to ensure the FDA regulatory review of these claims is updated expeditiously to reflect the important environmental benefits of modern animal nutrition technologies?

Answer. CVM has established a workgroup and is currently evaluating the possibility of environmental and performance claims for foods under existing authorities. We are looking at all the options under our current authority to address this issue and exploring ways in which our historic approach could change to reflect the evolving scientific knowledge while still maintaining safety standards and consistency with current laws. This evaluation will inform CVM's plans to update policies in the Program Policy and Procedures Manual Guide 1240.3605. If new animal food additive review policies are developed, additional resources would be needed to support review of the anticipated increase in submissions and to ensure timely safety review of any new claims on currently marketed products.

Question. I'm concerned that over the past few years, while FDAs Center for Drug Evaluation and Research (CDER) has announced a draft guidance titled "Innovative Approaches for Nonprescription Drug Products," no further action has been taken to date. Potential changes were first described in 2012 and while some progress has been made, we are, years later, still waiting for a rule. The pandemic has illustrated the importance of consumers having ready access to a range of over-the-counter (OTC) self-care products. This lengthy delay is standing in the way of a potential pathway that could allow for more complex switches of OTC products, increasing access, affordability, equity, and convenience for consumers.

Without this rule, consumers will further be denied the cost savings from prescription to OTC switches and the convenience of the availability of these medicines over-the-counter. I am concerned that while we have heard this administration discuss the importance of OTC medicines, we've seen little action on this rule. What can you tell me about the FDAs delayed action on prescription-to-OTC Switch?

Answer. Currently, nonprescription drug products are limited to drugs that, among other things, can be labeled with sufficient information for consumers to appropriately self-select and use the drug product without the supervision of a health care practitioner. For certain drug products, limitations of labeling present challenges for adequate communication of such information needed for consumers.

On June 27, 2022, FDA announced the issuance of a proposed rule which, if finalized, would establish requirements for certain nonprescription drug products that would need an additional condition that an applicant must implement to ensure appropriate self-selection and/or appropriate actual use, by consumers without the supervision of a health care practitioner.[23] The proposed rule is be intended to address situations when labeling alone is not sufficient to ensure that the consumer can ap-

[23] https://www.fda.gov/news-events/press-announcements/fda-introduces-innovative-proposal-advance-consumeraccess-nonprescription-drugs

propriately self-select or use a drug product correctly in a nonprescription setting, and would allow an applicant to submit an application proposing an additional condition that a consumer must successfully fulfill before accessing the drug product. The proposed rule is intended to increase the availability of safe and effective nonprescription drug products.

Question. Breakthrough and expedited approval pathways allow FDA an expanded universe of flexibility to unlock efficient development pathways for treatments of diseases and conditions that have few or no therapeutic options. Drug repurposing could be a viable option to close unmet medical needs if approval pathway qualifying criteria specifically included drug repurposing use cases.

Does FDA envision using a portion of existing funding under their current operating budget or the requested funding for FY23 to specify, update, or create expedited or accelerate approval pathways to maximize the value of FDA regulated products for all populations, especially those with rare conditions?

Answer. The Agency agrees that data on how approved drugs are being repurposed may inform the development of new clinical uses for these drugs as potential treatments for diseases and conditions that have few or no therapeutic options. FDA has and will continue to consider fit-for-purpose real-world data in regulatory decisions relating to the use of repurposed drugs, including utilizing such data when appropriate to support the criteria for our expedited programs for drugs and biologics to treat serious conditions. These programs have been and will continue to be utilized to advance consideration of repurposed drugs.

The agency has also devoted significant resources to exploring the use of repurposed drugs for diseases or conditions with unmet medical needs. In December 2019 the agency launched the CURE ID repository (a website and mobile application) globally, and rapidly expanded it in June of 2020 to respond to the COVID–19 pandemic.[24] The repository captures clinical outcomes from the clinical community when drugs are used for new conditions, in new populations, in new doses or in new combinations. Health care professionals generally may choose to prescribe or use a legally marketed human drug or medical device for an unapproved or uncleared use when they judge that the unapproved use is medically appropriate for an individual patient. The systematic collection of real-world experience in the CURE ID platform can help identify drug candidates for additional study, encourage further drug development and serve as a resource for physicians to share information where no FDA-approved product proven to be safe and effective exists for the new use. Repurposing approved drugs for new clinical uses can potentially offer an efficient drug-development pathway for treatments of diseases and conditions that have few or no therapeutic options.

In June of 2020, the agency also announced the creation of a public-private partnership (PPP), convened by the Critical Path Institute, called the CURE Drug Repurposing Collaboratory (CDRC) and provided funding to initiate this effort. The Agency plans to continue our work with the CDRC, which has since received additional support from HHS. Additionally, the Agency has continued to work with National Institutes of Health (NIH), the Reagan Udall Foundation,[25] and the Critical Path (C-Path) Institute[26] to explore avenues to advance research and policy regarding existing therapeutics.

The agency believes that the existing expedited programs for drug development and the agency's ability to leverage these programs when approved drugs show promise with rare diseases are sufficiently flexible and robust to address public health needs, including with respect to repurposing, or expanding the approved uses of, approved drugs. The agency is committed to utilizing these programs when appropriate to expedite development of repurposed drugs, including repurposed drugs for rare diseases. The Agency will also continue working with sponsors pursuing repurposing opportunities for areas of unmet medical need. The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need, based on a surrogate endpoint reasonably likely to predict clinical benefit. Validated surrogate endpoints can be used for traditional approvals. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval.

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[24] https://www.fda.gov/drugs/science-and-research-drugs/cure-id-app-lets-clinicians-report-novel-uses-existing-drugs

[25] https://www.fda.gov/drugs/news-events-human-drugs/repurposing-patent-drugs-research-regulatory-challenges-12052019–12062019

[26] https://c-path.org/programs/cdrc/

While the agency believes the current expedited approval pathway, enhanced by the agency's other expedited programs, provides an appropriate pathway for expanding the approved uses of approved drugs, the President's budget includes a legislative proposal titled "Ensuring Feasibility and Timeliness of Confirmatory Studies and Enhancing Withdrawal Procedures for Prescription Drugs Approved through Accelerated Approval". This proposal seeks to amend the accelerated approval provisions of the FD&C Act to (1) revise section 506(c)(2)(A) of the FD&C Act such that FDA may require, as a condition of a drug product application's acceptance for filing, or as a condition of a drug product's receipt of accelerated approval, that a drug sponsor must first demonstrate that a proposed post-approval (i.e., confirmatory) study is adequately designed to verify and describe clinical benefit and can be completed in a timely manner; (2) revise section 506(c)(3) so that FDA can follow its dispute resolution procedures for drug applications when withdrawing a drug product's accelerated approval; and (3) revise the withdrawal standard at FD&C Act 506(c)(3)(C) so that it mirrors the analogous withdrawal standard set forth in section 505(e) for drugs with traditional approvals. The FD&C Act does not provide FDA with easily implementable legal authorities to help target the problem of studies that progress too slowly. FDA believes that such a provision would help provide greater assurance at the time of a drug product's accelerated approval that the confirmatory study can progress in a timely manner, and reap high-quality, interpretable results. Enhancing the timeliness and quality of confirmatory studies will help support FDA's regulatory decision-making for drugs approved through the accelerated approval pathway and minimize the time that a product is marketed based on accelerated approval before its clinical benefit can be confirmed.

SUBCOMMITTEE RECESS

Senator BALDWIN. The hearing was adjourned.

[Whereupon, at 11:21 a.m., Thursday April 28, the subommittee was recessed, to reconvene subject to the call of the Chair.]

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

TUESDAY, MAY 10, 2022

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:00 a.m. in Room SD–124, Dirksen Senate Office Building, Hon. Tammy Baldwin (chairwoman) presiding.

Present: Senators Baldwin, Feinstein, Tester, Leahy, Heinrich, Hoeven, Collins, Blunt, Moran, Hyde-Smith, and Braun.

DEPARTMENT OF AGRICULTURE

STATEMENT OF HON. THOMAS J. VILSACK, SECRETARY

ACCOMPANIED BY:

MR. JOHN RAPP, DIRECTOR, OFFICE OF BUDGET AND PROGRAM ANALYSIS

OPENING STATEMENT OF SENATOR TAMMY BALDWIN

Senator BALDWIN. I am going to call the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies to order.

Good morning, and welcome to the second budget hearing for this subcommittee for fiscal year 2023.

Secretary Vilsack, welcome back, and thank you for joining us. And Mr. Rapp, we welcome you here too. We are glad to have both of you here today.

The Department of Agriculture's vast mission includes ensuring the health and care of our Nation's land, plants, and animals, as well as improving the quality of life and economies in rural America. The Department serves Americans at the county, state, and national level with even more locations overseas. We are grateful for the work of the USDA employees that support our farmers and ranchers at home and abroad.

The fiscal year 2023 Budget Request for USDA is ambitious, and I am pleased that this request continues investments in climate resilience, as well as support for our rural economies. It also includes funds to ensure that socially and geographically disadvantaged farmers and ranchers are able to access the services and opportunities that are essential to their success.

I look forward to discussing these initiatives, among the many others included in your budget request. I am also pleased the budget continues to invest in programs that support our rural communities, the backbone of this country.

Rural development includes significant increases from broadband, to housing, to water, and wastewater infrastructure. As inflation drives up home ownership opportunities and rental prices it is essential that we ensure rural Americans have access to affordable housing. I am pleased to see a number of proposed increases for rural housing programs.

One issue that I know is important to both of us, Mr. Secretary, is ensuring USDA employees have the resources they need to get the job done. We spoke last week about some of the staffing challenges you face, and I hope we can have a good discussion this morning about solving this problem, and how this subcommittee can be helpful.

This subcommittee has a long tradition of bipartisanship, and I look forward to working with our Ranking Member as we begin the process of drafting the fiscal year 2023 Bill.

Again, thank you for being here this morning. I look forward to your testimony.

And as he has not yet arrived, I think we will recognize Ranking Member Hoeven as soon as he does appear. But why don't we begin right now with your testimony and at the conclusion of that we can recognize the Ranking Member.

SUMMARY STATEMENT OF HON. THOMAS J. VILSACK

Secretary VILSACK. Well, thank you, Madam Chair, and I certainly appreciate the opportunity to be here this morning, and appreciate the attention of the committee members as well.

Let me start with a very important, and I think significant statistic about the AG appropriations process. Non-defense discretionary spending over the last eight or 9 years has grown by 27.4 percent across all departments, while the USDA's discretionary budget has grown about 14.3 percent, roughly half.

And essentially what this has done is it has created some challenges with reference to the Department, and I appreciate the Chair's commenting on two of the three that I am going to discuss today.

You mentioned the issue of staffing. Madam Chair, I will tell you, this is a serious issue for us, and when you look at our nutrition programs we have seen a doubling of the amount of resources that goes through those programs, but we have seen the workforce at FNS be cut by 25 percent.

When we talk about rural development, the department that basically is in the mission areas that is in charge of 3,142 rural counties across the United States, 15 percent of America's population, roughly 75 percent of America's land mass, deals with 30- to $40 billion in loans and grants each and every year, oversees a significant portion of the $230 billion loan portfolio that we have at USDA, but it is short about 500 workers.

And when we take a look at the backroom operations of USDA, the departmental administration, we have seen a nearly doubling of procurement responsibilities in that department, but the work-

force has been cut by 43 percent. So I think it is essential and necessary for us to talk about the staffing levels at USDA. I think it is also necessary for us to talk about research. While health care research has, understandably, grown significantly by as much as 400 percent over the last decade, research in the AG area has flatlined after you take inflation into consideration.

At one point in time it represented 4.3 percent of the overall nondefense research allocations and appropriations for the Federal Government, today it is 2.3 percent. So it has been literally cut in half. This, despite the fact that for every dollar we invest in agricultural research there is a return of investment of $17. And I would say that—most would say that is a pretty good return on investment.

So our hope would be that as we talk about the budget that we focus on the important role of agricultural research.

And you mentioned rural housing. That is also a challenge. We appreciate the additional support and help that this committee has provided in this space, but the reality is that we continue to struggle to maintain adequate housing. And we are going to see, over time, a significant reduction in the number of units as loans are paid off.

Essentially what happens is those units convert from being subsidized to being available at market rates. So we are encouraging this committee to take a look at ways in which we could decouple the mortgage—the interest rates, and the mortgage and the loan from the subsidization, so that we would continue to be able to provide additional units, and also investing in their rehab of existing units so that the housing is not only available, but also decent.

And in the time that I have remaining, Madam Chair, let me talk about something that is really of concern to me, that is a bit outside the purview of this particular Department but it is—of this budget committee, but it is something I think we all ought to be concerned about.

There are 61,670 farm families in America today that are on the brink, 61,670 farm families that are either delinquent in their loans to USDA, are bankrupt, or are pending foreclosure. This is a serious issue that—and I am pretty confident that every single member of this committee probably has a number of those 61,000 farmers living in their states.

It is important and necessary for us to put a spotlight on the challenges. Now, these are people who have borrowed from USDA, or who have had a guaranteed loan from USDA, which means that they haven't been able, on their own, to go to a commercial bank and be able to secure financing. So these are folks who need help, they need assistance.

I have represented farmers during the 1980s as a small town lawyer, I can tell you the pain, I can tell you the stress, I can tell you that the decisions that folks make under these circumstances. I can tell you of very tragic decisions that they make under these circumstances. So I would hope that as we talk about the future of agriculture in this country, that we don't lose sight of those 61,670 farm families.

They deserve our attention, they deserve some creative thought about how we might be able to assist them during this pandemic-

stricken time, and I sincerely hope that we can work, collaboratively, together in a bipartisan way to make sure that they have a hopeful future, as opposed to one that is currently stress-filled today.

I see the Ranking Member is here, and so I am going to stop talking.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS J. VILSACK

Thank you, Chair Baldwin, Ranking Member Hoeven, and members of this subcommittee, for inviting me here today to discuss the Administration's priorities for the Department of Agriculture (USDA) and to provide you an overview of the President's fiscal year 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 percent, the strongest growth in nearly 40 years. The unemployment rate has fallen to 3.8 percent, 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 fiscal year 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 pro-

grams, 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 fiscal year 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 bil-

lion 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 fiscal Year2021, the Research, Education, and Economics Mission Area was successful in hiring above their fiscal Year2020 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 2-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 fiscal Year2023 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 shoestring 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 fiscal year 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 fiscal Year2023 Budget. I look forward to working with this subcommittee and to answering any questions you may have about our Budget proposals.

Senator BALDWIN. Senator Hoeven.

STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Thank you, Madam Chair. And thank you, Secretary, for joining us today. Good to see you. Appreciate our conversation earlier; and of course your testimony today. Welcome back in front of the committee.

I have heard you say before that the Department of AG touches the lives of all Americans every day, and in every way and that is certainly true. Probably more true now than ever.

Really current events highlight the importance of our food supply, and the importance of what our farmers and ranchers do for our country every single day. Food security is national security, and our farmers provide the lowest cost, highest quality food supply in the world.

Right now of course we are struggling with inflation. We see it obviously for our farmers and ranchers, we see it for consumers across the board, we see it in the prices that people pay at the grocery store, we see it at the pump, today gasoline hit a record price average across the country of about $4.40 a gallon, right in that range.

And so we have got to find ways to produce more energy in this country, to find ways to address the supply chain issues, and the other challenges that are creating inflation. And our farmers are a big part of that. They are seeing it in the price that they pay, not only for fuel for their tractor, and other equipment that they have to run every year to plant a crop, and harvest a crop, but also, obviously, in fertilizer, and their other inputs.

And so it is very important that we do everything we can in terms of the Department of Agriculture, and as well as in the energy patch to address these issues. And I know that you are working hard on it, we need to continue to do that. And of course we are making significant investments here in this AG Appropriations Committee to make sure that you are able to do that on behalf of our farmers.

Just in recent years, in Fiscal 2022, USDA programs actually received an increase of 6.2 percent over the fiscal year 2021 levels, and that included a funding increase of 6.5 percent for research, which has been amazing in terms of what it has done for our farmers and ranchers, and their ability to raise crops and animals across this Nation. I have seen it in my own state. I know you have seen it in yours. It is truly, truly remarkable.

Also the resources for the FSA are incredibly important too to help get our farmers through drought, through floods, through tough weather, tough prices, and in some cases trade agreements

that aren't fair, FSA has a major role to play in keeping our farmers going.

I want to be sure that our commitment to support rural America is as strong as ever. I know you share that. I know you have got some ideas on how to do that, we do too, we will talk about those this morning. Also, I want to make sure that the funding that we have put in place for things like the Livestock Emergency Relief Program, WHIP+ for our farmers, that those funds get out to our farmers.

You and I have talked about that. We will talk about it some more today. And I know you are coming up with some ideas to expedite that, I appreciate that, and look forward to working with you on it.

Thanks again for being here today. I appreciate it very much.

Thank you, Madam Chair.

Senator BALDWIN. Thank you. We are going to now begin rounds of five-minute questions. And I will begin.

Mr. Secretary, rural America has historically lagged behind urban regions in educational attainment, poverty levels, and overall well-being, and data shows that rural America has recovered from the great recession at a slower pace than urban America, which has major implications for rural America's ability to adapt to the current economic and inflationary trends. So I was excited to see USDA formally launch the Rural Partners Network, which we provided initial funding for in the fiscal year 2022 Appropriations Act.

Secretary, can you provide an update on how the Rural Partners Network is being implemented, and how it will target funding to distressed communities? Additionally, talk about the fiscal year 2023 budget proposal of 39 million for this initiative, and what additional resources will these funds provide?

And lastly, which agencies at USDA and other departments play a role in implementation of this initiative?

Secretary VILSACK. Madam Chair, this is I think a pretty significant question you have asked. The Rural Partnership Network is really designed to provide intensive care, and direction, and focus on communities that have been persistently poor, communities that have had a poverty rate in excess of 20 percent for more than 20 or 30 years.

They require folks on the ground, living, working raising their own families in these communities, and then helping community leaders and community building organizations access the variety of programs that are available. We have started this in five states, Georgia, Kentucky, Mississippi, New Mexico, and Arizona. We have targeted communities within each of those five states. We are in the process of hiring staff today who will actually live in communities within those states that we have selected through a process, a data process, data-driven process.

Those individuals will begin to identify programs, and challenges, and projects, that folks are interested in pursuing, and then they will work collaboratively with 13 Federal agencies, and three commissions who will have what are called "rural desk officers" in each of those agencies; so this is Transportation, HHS, Education, et cetera.

Those rural desk officers will be responsible for working collaboratively with the folks on the ground in those five states, in those communities, to identify the programs, and to short-circuit, if you will, the process for applying for, successfully, resources.

Our belief is, that by providing this intensive care, and by providing an all-of-government approach, we will be in a position to provide a meaningful progress, that folks will be able to see, and that they will actually learn, if you will, how to participate in Federal programs, and they will see a Federal government that is working collaboratively with state and local governments to make life better.

Our goal and hope is that we are able to expand this program significantly, which is why we have asked for an additional $39 million. This is going to, essentially, pay for individuals who will be living in those communities, and working in those communities, as well as state directors overseeing those operations. It will also provide additional training. We know that there is a significant amount of training that is required for community leaders to understand the processes that they have to go through in applying for various grants.

So these resources will allow us to expand the program, we have designated an additional five states, hopefully, to be able to select by the end of this year, this fiscal year, and with this additional resources we would be able to significantly expand this effort across the United States in places where we just have had poverty that just hasn't gone away.

Senator BALDWIN. Thank you. Have you identified these five additional states? Or are you still in the process of that data collection effort?

Secretary VILSACK. We have identified those five additional states. And I am sorry, I know a few of them but I don't know—I can't tell.

Senator BALDWIN. You can follow up with that.

Secretary VILSACK. Actually I think Wisconsin happens to be one of them.

Senator BALDWIN. Okay.

Secretary VILSACK. North Carolina happens to be one of them, and I can't—I am sorry I can't remember the others.

Senator BALDWIN. Please just follow up afterwards, that is totally fine.

Next, I am going to recognize Senator Hoeven for your questions, first round of questions.

Senator HOEVEN. Thank you Madam Chairwoman.

Mr. Secretary, at the end of September we authorized funding both for WHIP+, and for the livestock assistance. That was about $10 billion, 750 million for what, you know, is referred to as the Emergency Livestock Relief Program, and then $10.23—excuse me—$9.23 billion that is actually available for WHIP+. We have talked about both, not only with you, but with Zach Ducheneaux.

We appreciate the working relationship. The emergency livestock relief assistance is out there for the livestock producers, about 560 million of it. The remaining part I know you are working on, we will work with you on that, we appreciate that; that is underway.

But I want to ask you about WHIP+. Where are we with WHIP+ and in getting it out to our farmers?

Secretary VILSACK. I appreciate the support from Congress. Senator, we are in the process of finalizing the work that will allow us to pre-fill the application that will be required for farmers to benefit from the WHIP+ Program. In the past there were roughly 250 questions that would be asked of a farmer to be answered, to be able to apply for WHIP funding.

We are going to pre-fill that application, so at the end of the day it will be just a handful of boxes that have to be checked, and signed. Our hope and belief is that within the next couple of weeks, we announce the structure and the framework for how you go about applying for these resources so that payments can, potentially, start in June.

Senator HOEVEN. Yeah. And what you have explained to me, and I appreciate, is that it has taken longer on the frontend to get it set, but that once you announce it, it will be quicker to get it out, correct?

Secretary VILSACK. Correct. And we are going to do this in two tranches. You mentioned the livestock situation, $560 million has been provided, the additional resources will be provided in a second tranche, for those that the folks that aren't—that weren't covered by Livestock Forage Program, or they had shallow losses, or they had a loss that wasn't quite covered by some of those programs.

Senator HOEVEN. Right.

Secretary VILSACK. What we have done is we have taken the information and data from those programs, like Crop Insurance, like the NAP Program, and we pre-fill these applications for the grain folks. There may be people who will be left out in that process as well, so there will be a smaller second round of funding after the June payments.

Senator HOEVEN. And once it is out, we would like you to have somebody get out there with us, and talk to the livestock groups, or in this case the commodity groups, the farm groups, so we can explain it, if that would—if that is something that you would work with us to do.

Secretary VILSACK. Absolutely. And our state folks will continue to do this at a state level, our state directors that is part of their responsibility to make sure people understand about this.

Senator HOEVEN. Yeah. And we want to join with them in doing that so we can explain it to producers. Livestock Indemnity Program, again, we appreciate that, we have had blizzards, we have had some calf mortality, not only in our state but other places. So the Livestock Indemnity Program, very important this year.

One of things we talked about, and that is for calves under 250 pounds, which is typically where you have a lot of the mortality in these spring blizzards, that payment rate for 2022 really is not reflective of the cost of those animals. And I have asked if you would work on adjustment there. And then also making sure that for animals that get sick because of that weather, they may not die right away, but they get anthrax, pneumonia, or something else, and then they die later, that that they are—you know, that the Livestock Indemnity Program applies to those animals. So would you address those two things under that program?

Secretary VILSACK. Sure. Actually we are focusing on those two, plus the issue of timeliness, so those are three issues that we are taking a look at. The payment rate is obviously a challenging one, because it is essentially, we have tried to marry the livestock program to—what kind of what we do on the crop side, where essentially we take a look at a less than market weight, as being almost like a freshly sewn crop, and comparing it, and contrasting it to that.

We are in the process of taking a look at this, because you have raised the issue about what has happened in North Dakota, and we are taking a look at this. We are also taking a look at the cause of loss, recognizing, as you point out, that it could be delayed. There may be a problem that occurs initially during a blizzard, whatever, but it doesn't surface until many, many months later.

And we recognize and appreciate that may have an impact on value, so both of those issues are being looked at by the team. And we are also trying to figure out ways in which we could, potentially, provide for more annual production information as we do with crops, which might make it easier for us to have a better understanding of how to value livestock at various times depending upon the disaster, and depending upon weight.

As it is now we have to basically collect the stat on a disaster-by-disaster basis, and that is problematic.

Senator HOEVEN. Yeah I appreciate that. But it is particularly that one category. So we are not saying cross off categories, we are saying in that category 250 pounds and less, so that is what we want you to take a look at, and I know you understand that. Thank you.

Thank you, Madam Chair.

Senator BALDWIN. Thank you, Senator Hoeven.

I understand there is a special birthday today. Happy Birthday, Senator Hyde-Smith.

Senator HOEVEN. Is this where we sing, or not?

Senator LEAHY. No. I think that would ruin her birthday.

Senator BALDWIN. Open to suggestions. It doesn't move you up in the queue though. Sorry about that.

Senator Leahy.

Senator LEAHY. Thank you Chair. I wished the Senator a happy birthday earlier, and I said, I am glad to see these young people here, in so far as everybody is in the Senate.

Secretary, it is great to see you. I appreciate all the times we have been able to chat and good to see you.

And Secretary, I want to discuss a new initiative. I have worked with Senators Baldwin, Hoeven, and Shelby to put in the fiscal year 2022 Spending Bill for the Department, a new investment for the Department which helped establish Institutes of Rural Partnerships. Whether it was when Tropical Storm Irene tore through Vermont, devastating and isolating so many communities, or challenges brought out around the country with COVID–19, Vermont is trying to find new ways to collaboratively tackle these problems.

The Institutes for Rural Partnerships through the USDA can help rural America plan for future challenges. That is a priority of this committee, and they can forge connections between public and

private entities across every level of government. And I think they are extremely important.

You, probably more than any, Mr. Secretary, understand rural America. When do you anticipate the Department is going to move forward with this initiative? How will USDA partner with these institutes to promulgate best practices that can be used in rural areas?

Secretary VILSACK. Senator, our National Institute of Food and Agriculture is our lead agency on this. They are in the process of working with staff to make sure that we are structuring this program in a way that is consistent with congressional intent, and the feedback that we have recently received about how these institutes should be set up. I foresee that they will work closely and collaboratively with missionaries like the Economic Research Service, ERS, to collect data and information. I am sure that they work closely with Rural Development to make sure that we know what kind of programs.

As I have shared with the Chair, we have the Rural Partnership Network, and I would imagine the institutes will be quite interested in studying the impact and effect of those partnerships. They will obviously continue to work with the research aspect of USDA, so I think there is great possibilities, and potential.

The challenge I think for us is to make sure we know exactly what it is you want us to do because it could be an incredibly broad array of things we could do, but that is the reason why we are spending a little time listening but we are—I would anticipate and expect that we are going to get this thing going before the end of the fiscal year.

Senator LEAHY. And one thing I am sure you are hearing from everybody because of COVID, the food insecurity in our country. I know our food banks in Vermont are feeling this. I think that can probably be said about every state. Schools are now facing the expiration of USDA child nutrition waivers that allowed them to expand especially during the summer months.

I am pleased to see the administration propose increased funding for the Emergency Food Assistance Program (TEFAP), a vital source of funding for food banks, which I support. There is another area, I know again—without being too parochial, Vermont has been a leader in growing local and organic food, but it is very difficult to get that included in Federal nutrition programs such as TEFAP. Can we find ways to get Federal dollars more involved in this?

Secretary VILSACK. Senator, we established a local and regional food aspect of TEFAP this year, in which we are asking the state agencies to work with us to provide, and we are providing roughly $600 million as an initial effort, so that food banks would be able to access locally grown and raised foods, that could include organic.

So the State of Vermont, for example, could encourage that, for both the food banks as well as for the school meal program. And what we want to be able to do is create a stronger, local, and regional food system that complement our commodity production agriculture so that we have a more resilient food system. So that is in the works.

Senator LEAHY. Good. And we will work with you any way we can. I just want to thank you, Mr. Secretary. I know the final

spending package for fiscal year 2022 saw a responsible, and I believe very transparent, return to congressionally directed spending. I want to applaud this subcommittee for the way they worked, and worked across the aisle. I know you are working with us on that, and I think you will find broad bipartisan support to get it done. So I thank you. And I thank you, Chair.

Senator BALDWIN. Senator Collins.

Senator COLLINS. Thank you. Welcome, Mr. Secretary. Prior to your confirmation we had an in-depth conversation that led to my decision to vote for your confirmation. We discussed two issues in particular, and I am going to follow up on those two issues today, and express my disappointment.

The first is the issue of PFAS, those forever chemicals, Maine is in the forefront of efforts to address contamination on our farms from PFAS. I told you that in 2016 a dairy farmer in Arundel, Maine, had discovered that the milk that was being produced by his cattle contains some of the highest levels ever reported from a PFAS contaminant.

Since that time these forever chemicals have been found in feed, in soil, and water, in crops, in livestock, on farms all across Maine. So this is obviously devastating for these farmers, and their livelihoods, and their families, they are facing extreme financial hardship, and we have learned that the USDA's Dairy Indemnity Payment Program only covers fluid milk, so it does not begin to cover all of the problems for these dairy farmers, in particular.

In October last year I sent you a letter and asked you to provide me with an update on what USDA could do to assist these farmers. I received no response. Then in March, I again sent you a letter that was signed by all the members of Maine's delegation, requesting that USDA use all of its existing authorities and programs to provide assistance.

Mr. Secretary, we received a response to that letter at 1:24 a.m. this morning. We never received a response to my October letter, and the letter to you that we sent in March, we got the response literally at 1:24 a.m. this morning.

Putting that aside. Will you work with us, and I mean really work with us to identify programs that you either have now, or that we could ask to be modified so that we can assist these affected farmers?

Secretary VILSACK. Senator, I am surprised by your question. And the reason I am is because I am under the impression that we, in fact, are providing indemnity for livestock as opposed to fluid milk. Recognize, we started this process with just basically paying for the milk that was damaged, and realized that that was not adequate, and so we are in the process—I think we have done this, begin paying farmers for the loss of livestock.

So I think we want to check on that but—so we have taken action. Certainly apologize for not answering letters. I can tell you the young lady behind me can attest to the fact that I have put a concerted effort to try to get a response to congressional inquiries. I am embarrassed by this, and I apologize for it. We are going to try to do better on the correspondence side, which is why you got the response at 1:48 this morning, better late than never, but certainly not responsible as it should be.

The PFAS issue. Let me explain to you what I think we need to do. We are working with EPA to try to establish a national standard on what is an acceptable level, or not, of PFAS, and the reason for this is so that we can, basically, help to define the level of assistance and help that is required.

You are absolutely right. This is pervasive. It is not just in Maine, it is everywhere, because basically sludge was used to fertilize farm fields for many, many, many years without an understanding and appreciation of the challenge.

So I would say two things, one, happy to work with you, happy to work with the EPA to set a national standard, happy to work with this committee, or whatever committee to establish an amount of resources that would help deal with this issue. It is going to be a large amount. And then I would certainly say, we need to make sure we continue to fund research, because I think we are going to continue to find some challenges with reference to things that we have done for years, and years, and years that are now cropping up as being problems.

Senator COLLINS. Thank you. I look forward to our second round.

Senator BALDWIN. Senator Heinrich.

Senator HEINRICH. Thank you, Madam Chair.

Secretary, last week President Biden announced a major disaster declaration in New Mexico as a result of multiple, severe wildfires, including one that was initiated by a U.S. Forest Service prescribed fire that simply escaped control.

I want to make sure that the USDA is fully prepared to assist affected communities, and mitigate potential flood damages before this year's upcoming monsoon season which starts, typically, in early July. The Emergency Watershed Protection Program is going to be really essential in that recovery.

The village of Ruidoso, which was subject to a wildfire that caused several fatalities, destroyed over 200 homes, they have already requested EWP assistance, and I am expecting that a number of communities in northern New Mexico may do so soon.

My concern is really that the NRCS office in New Mexico has just never had to deal with this quantity of EWP assistance before, and may need additional personnel, or other resources to be able to conduct those assessments and implement some recovery on the ground before we get hit by those big thunderstorms.

So just given the severity of the fire's destruction and the upcoming monsoon season, I want to ask that you would work with NRCS to make sure that they can meet that urgent need.

Secretary VILSACK. Happy to do it. And we are adding additional personnel, Senator, across NRCS, to try to beef up significantly capacities at the state level.

Senator HEINRICH. That is great news. One of the other areas that I think is going to be important, from the same sort of perspective, is like EWP, other disaster programs within Farm Service Agency, for example the Livestock Indemnity Program, is going to be another one of those places where it is just not set up for the scale of—you know, the demand that we are going to see in the immediate after-effects of these fires.

And so I would also just ask that you look closely at FSA, and make sure that they are able to get on the ground, and really meet

people in these communities, and get them to understand what they need to do to access those sorts of programs.

Secretary VILSACK. We will certainly do that. And if it turns out that the staffing is not adequate, there are surge teams that we can put in place. We, unfortunately, and tragically have had far too much experience with this issue, not just in New Mexico but in many other western states. So we understand and appreciate what we have to do.

Senator HEINRICH. No, I appreciate that. One of the related issues I want to raise for you, and it actually goes back to when you were talking about the Rural Partners Network, many of the communities affected by these particular wildfires are really under resourced, persistently poor, as I believe you described it.

And because of the significant need for assistance in those communities, the New Mexico delegation actually requested that President Biden waive the Federal cost share for FEMA assistance. I would like to be able to work with you to look at the appropriate cost share for USDA disaster programs simply because these are the exact same communities that—on the New Mexico list that you referenced before that were barely getting by before, they were just devastated by these fires. So would like to be able to work with you to develop some guidelines for what might be an appropriate cost share in this case.

Secretary VILSACK. That is an appropriate request, and to the extent that we have the capacity through our regulations and statutes to do so, we will be happy to work with you.

Senator HEINRICH. Great. To shift gears for a second; on last year's Agriculture Appropriations Bill, this subcommittee encouraged USDA to conduct demonstration programs on dual-use renewable energy systems, these are otherwise known as agrivoltaics.

I wanted to ask, does USDA have enough funding for the renewable energy infrastructure, and the research expertise to really conduct some of these demonstration programs that we have looked at through this committee?

Secretary VILSACK. Well I think it has the expertise, I don't know that we necessarily have the resources. It is just why part of what would be involved here would be NIFA, our National Institute of Food and Agriculture, as well as our ARS facilities, and I am frank to say we think that we need more resources in those areas, across the board, not just in this area, but in terms of staffing, in terms of facilities, and in terms of the capacity to do more work with land-grant universities.

Senator HEINRICH. Madam Chair, I hope the committee will look at this, as we have had a number of places around the country where there has been a direct conflict between taking land out of production to do renewable projects, and we have seen great success in a few places where they have actually been able to effectively produce energy and farm on the same footprint, and increase the income for the farmer as a result. And I think it has a lot of promise.

Senator BALDWIN. Next, Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Chairwoman Baldwin.

And thank you, Secretary Vilsack, and Mr. Rapp for being here today, and your willingness to serve and participate.

Mr. Secretary, as you know, the USDA, Natural Resources Conservation Service, the NRCS, assists state and local bodies with flood mitigation, and water quality improvements, erosion control, and several things related to that through the watershed, and Flood Prevention Operations Program, which is really important to a state like Mississippi.

Like many rural communities and landowners across the country, Mississippi and its people have been hit particularly hard in recent years by excessive rainfall, flooding and other problems caused by natural disasters. The Watershed and Flood Prevention Operations Program has been invaluable in allowing small towns to recover from these events and, importantly, to prepare for the next one, because we know the next one will be coming as well.

In early June 2021, many parts of Mississippi experienced just unprecedented rainfall, some receiving more than 12 inches of rain in less than 12 hours. My office was getting phone calls all day, and videos, during that time. And, as you might expect, it caused severe flooding, and the roads and bridges, and failures of dams, and levees, and everything that such an event as that would cause, and thousands of Mississippians were affected, and millions in damages occurred.

Fortunately, we have programs like Watershed and Flood Prevention Operations administered by NRCS, but because of the problems and similar problems I have mentioned, I requested 8.4 million in watershed operations funds in the fiscal year 2022 Agriculture Appropriations Bill for NRCS Mississippi, to help address some of our challenges.

Funds were used to support nearly ten or more projects across nine Mississippi counties. That provision became law with the enactment of the Consolidated Appropriations Act 2022.

And I thank Chair Baldwin and Ranking Member Hoeven for supporting my request throughout that conference process. But all along with my staff and many constituents, we have a great respect, and don't know what we would do without the NRCS, and we appreciate the many services that they provide.

But Mr. Secretary, what is the status of the Watershed and Flood Prevention Operations Funding provided in that fiscal year 2022 Omnibus? And I am looking for some feel-good news that it is, you know, being put to very good use. But please share any updates that you may have as to how the funds provided by NRCS and Mississippi are, or will soon be utilized to help rural communities and landowners addressing flood water and these issues that I have just articulated?

Secretary VILSACK. With specifically, the $8.4 million, the NRCS folks are working with the local sponsors of the projects that were identified to basically work through the implementation plan, so that process is in place. In addition, the State of Mississippi was the recipient of $47.8 million of additional resources under the Bipartisan Infrastructure Law of the 500 million that was allocated under that law for watershed and flood prevention operations, Mississippi receiving $47.8 million of additional resources.

So NRCS is working on a variety of projects in Mississippi. My staff will be able to give you the list of the projects that were identified in that 47.8 million. You know, we are working on, for exam-

ple, a big project with Madison County on a stream bank erosion issue. We know that a lot of the sediment issues in Mississippi are not a result of your losing your topsoil, it is a result of the banks, basically, eroding and over time creating some challenges.

And so I think you are going to see significant activity in this space in the Mississippi because of the money and resources that have been provided through the appropriations process, and through the infrastructure law.

Senator HYDE-SMITH. Wonderful. I appreciate that answer. And I have got a few seconds left. Rural communities across U.S., we will always be faced with these weather-related challenges, and I was pleased that the fiscal year 2023 budget request for USDA included the WFPO funding in it as well.

Should Congress provide funding to address project, or watershed specific challenges through the WFPO in fiscal year 2023? How confident are you that the NRCS can put those funds to good use?

Secretary VILSACK. Well, I am confident they can as long as we continue to increase the staffing levels. I think the key here is not just increasing the resources, but making sure that you have got the staff on the ground that can implement these resources in a proper way.

Senator HYDE-SMITH. Great. Thank you, Madam Chairman.

Senator BALDWIN. Thank you. Senator Feinstein.

Senator FEINSTEIN. Thanks very much Madam Chairman.

I just want to say you have a very tough job, to start with. My understanding is that the west has become a real problem for fire. Since 2017 wildfire has burned 10 million acres in my state, California, killed nearly 200 people, and destroyed more than 32,000 homes. Even as we speak I understand that large wildfires are burning in New Mexico and Arizona.

So what do we do? The agencies have been chronically understaffed, many Federal wildland firefighters are moving to state jobs, particularly in my state because the pay is better. So Mr. Secretary, I want to know what you think would help most? Is it that rise in pay? What is it? Because we have got to hire enough people to handle what is going to happen with global warming? And that particularly goes for my state. And I am very concerned.

Secretary VILSACK. Senator, thanks for the question. I think it is important for us to do two things—actually three things. One, transition some of our part-time people to full-time status, which would provide them additional pay and benefits, and we are doing that we are literally transitioning hundreds of firefighters.

Two, a new classification system for wildland firefighting, we are in the process, as directed by Congress and the President, we are in the process of working with the Department of Interior and the Office of Personnel Management to develop a new classification that will create a more competitive salary scale for wildfire fighters.

And then three, we are going to continue to implement the additional resources that were provided under the Infrastructure Law to provide additional pay this year that will allow us to be able to do a better job of recruiting and retaining our workforce. So those three things are in the process of being done, and I think you are going to see more firefighters on the ground which is going to be

absolutely necessary, because we are not going to see an abatement of these wildfires for some time.

Senator FEINSTEIN. Well, in your recently released ten-year strategy to address this crisis, you indicated your focus would be on communities most at risk, and this is especially important for more rural communities in California at the Wildland Urban Interface. It is my understanding that your fireshed map identified that many at-risk communities in California are not near Federal lands, which means they won't be eligible for most Forest Service funding for wildfire mitigation.

How is the Department going to help rural communities, especially those not adjacent to Federal land; to reduce their risk and become more resilient?

Secretary VILSACK. Well, your support and the support of others in the Senate for the passage of the Bipartisan Infrastructure Law is a response to that question, because $1.5 billion of the resources that you allocated for the Forest Service will be provided to state and local communities for that very purpose, giving them the resources to be able to work collaboratively with us.

It is collaboration, Senator. The fact that it may not be on a particular map doesn't mean that we won't work with those local communities, provide the technical assistance, direction, and assistance. We do that all the time. But now we have the resources, and we can give those local and state—states resources to be able to provide more community preparedness, more training, more support for their volunteer fire departments, et cetera. So that $1.5 billion is incredibly important.

Senator FEINSTEIN. Well, you certainly have my support. And I want to say, I think, you know, for the largest state in the union my concern about fire in the last 10 years has just gone straight up. I see these fires and I see what can happen, and I really don't know what we can do to give you the resources to put up those—the ability to stop big massive fire in our state.

Secretary VILSACK. Well, the ten-year fire mitigation strategy is designed to do that, and certainly the Bipartisan Infrastructure Law was a start in terms of the financial resources necessary.

But committees are going to have to continue to provide that support over the next decade for us to see a significant reduction in the risk, because we have hundreds of millions of acres of dead trees as a result of pine bark beetle, and climate. We have got a substantial amount of hazardous fuel buildup that has to be addressed. It is going to require resources. We have got them for the next couple of years. The key will be to continue that effort over a ten-year period.

Senator FEINSTEIN. Well, let me ask this. I would be most interested in helping with a plan if you have one, to see that we can provide what we need to provide. I am really very worried because California is extraordinarily dry, and fire is a real enemy.

Secretary VILSACK. We will absolutely work with you, Senator.

Senator FEINSTEIN. Thank you. I appreciate that.

Thanks, Madam Chairwoman.

Senator BALDWIN. Thank you. Senator Blunt, you are next.

Senator BLUNT. Thank you, Chairman.

Secretary, great to see you; and I think every appearance may be some kind of record, because of your long service in this job. And I am grateful that you have done that and continue to be willing to do it.

You and I have talked about this before. I was a supporter of relocating the headquarters of ERS and NIFA to another location, that turned out to be in Kansas City, and of course I was even more pleased with that. There was a report issued by GAO that stated that the previous administration's decision to relocate those agencies was not fully consistent with an evidence-based approach.

You then pointed out, or the Department pointed out that the GAO used metrics established after the relocation, and that that was not exactly a fair analysis of what they would have been looking at at the time. I have I have been to that location recently, they are about to really come alive, frankly, for the first time. A great space but highly underutilized, because people have been working from home.

I am wondering, based on your previous role, and the perspective you would have, if you have seen yet a way that this move alters operations or applications. I think that location with three-hour car drive from eight different land-grant universities, which we thought was one of the principal advantages you might have in the future. But are you seeing any difference yet in operations there? Or what have you seen in terms of filling job vacancies in that location?

Secretary VILSACK. Senator, we have a goal of about 750 people between the ERS facility and the NIFA Mission area. We are about 650. We have seen about 450 folks who have been hired in those two mission areas, so the hiring has been, I think, robust. I think people are anxious and interested in working in that environment.

You know, we have got some great people who work over there, and they turn out the work, regardless of pandemics, regardless of whatever the challenges may be. We had a morale issue which we are dealing with, and I think as we hire more folks, that issue, it becomes less, less of an issue.

The work is getting done, and it is getting done on time. You know, the reality is that those agencies have great working relationships with land-grant universities and minority serving institutions all across America.

You know, I think I would say that as we look at this concept the challenge I think is to do it in a way that provides less disruption than the way it was handled before, and I think there are ways to do that, and I think this is, you know, I think we are going to see a lot of good work coming out of that facility. I have no doubt about that.

Senator BLUNT. Well, I appreciate that. And I think for lots of reasons, cost of living, and other things, there are reasons to look at other locations now as we think about expanding here, or moving somewhere else. And I appreciate your sense that what the impact on the current workforce, and how you maybe transition is important there.

You know, those agencies, among others, really looking carefully at world food need right now, and what happens as a result of what is happening in Ukraine. What concerns do you have, and

what should the Department do? Should we make more American acreage available for—in some foreseeable window that might not be available otherwise? Or should we step back from taking more acres offline as we try to figure out what happens with this great food producing part of the world being so impacted, in Africa, and other places that have benefited from that raw, unprocessed food stuff being impacted?

Secretary VILSACK. Senator, I am traveling to Germany tomorrow, and then to Poland in order to get a first-hand look at the situation in Ukraine. We have a twin challenge here. We have got an immediate global food security challenge by virtue of the disruption that the invasion has caused, and the impact it is going to have on unstable, potentially, unstable conditions in the Middle East and North Africa because of food shortages.

So we need to address that. And that is one of the reasons why we tapped the Bill Emerson Trust, part of the challenge there isn't just tapping the Trust but making sure that it is replenished, which I think is important, and the supplemental appropriations bill that you are considering would begin that process.

The other challenge with that Trust is the transportation cost. It is amazing to me that it costs more than the value of the product we are transporting to get that food to Ethiopia, and some of the North African countries. So I think there is an opportunity for us to look at ways in which that could potentially be addressed.

I would say with the second challenge we have is the issue of climate, because that is going to impact our long-term capacity to meet global food needs, and I am really, really excited about the reaction to the Climate-Smart and Forestry Product Partnership Initiative. We got 450 applications from 350 organizations and groups; commodity groups non-profits, for profit organizations, all 50 states, probably three to four times the billion dollars that we put on the table. So there is tremendous interest in doing that as well.

So I think what we have to do is figure out ways in which we could do both. And one thing we could do is look for ways, creative ways to help double-cropping opportunities, expand the number of counties that are insured, figure out the other administrative ways to make it easier for farmers reducing the risk of double cropping.

Senator BLUNT. Thank you. Thank you, Chairman. I have, there may be other questions either for the record, or for a second round, if there is one.

Senator BALDWIN. Well, we are starting it right now. And I will recognize myself for five minutes of questions in the second round.

Mr. Secretary, I want to talk a little bit about climate-smart agriculture. Our farmers, ranchers, and producers experience first-hand the impacts of climate change. I appreciate this administration's whole-of-government approach to combating the climate crisis, including the U.S. Department of Agriculture's efforts to conserve and protect our Nation's natural resources, while enhancing economic growth and creating new streams of income for our producers.

Can you give the committee an update on the climate-smart agriculture activities of the Department? And also what is the Department doing to ensure that farmers, ranchers, and producers of all

backgrounds are able to access the resources needed to strengthen their climate-smart agricultural practices?

Secretary VILSACK. There are three ways I would like to respond to that question. First, there has been a significant effort on the part of NRCS to catalog, and to characterize climate-smart practices, and to provide information on different activities that farmers and producers can take to be climate smart. Whether it is reducing greenhouse gas emissions, or whether it is sequestering more carbon, and we are going to continue to do a better job of providing that information.

NRCS has worked with a grant program with 118 different organizations that are connected to minority producers, and socially disadvantaged producers, historically underserved producers, in an effort to try to make sure that those individuals who may, in the past, have had a hard time accessing that kind of information, get that information, and that program is going to continue. That is something we feel very strongly about.

That is in addition to the additional technical assistance—efforts underway under the American Rescue Plan under Section 1006, you provided resources to be able to expand. We currently have 20 larger community building organizations that are connected to minority producers that are also working to make sure that they have the full array of FSA and NRCS programs.

Secondly, as I just mentioned to Senator Blunt, we are really excited about the response to the billion dollars that was put on the table, to ask producers to put together pilot projects and demonstration projects.

The fact that we got 450 applications from 350 different organizations and entities across all 50 states, even at the minimum, we are talking about $2.2 billion. I know some of those applications were for $50 million or more. So I am pretty sure we are probably 3X or 4X to what we put on the table. So there is obviously tremendous interest there.

And then finally, I think there is, again, a research component to this in which we are working with NIFA, and working with ARS to provide the tools, and the technologies, and the capacity for farmers to have a better understanding of what climate smart actually means, and be able to measure, and quantify, and verify it.

Senator BALDWIN. Thank you. I know we are on our second round of questions, but I am going to interrupt the back and forth of Democrat and Republican, to allow Senator Tester to ask his first round of questions.

Senator TESTER. Goodness, if I only knew what I was going to ask. I want to, first of all, thank you for being here, Secretary Vilsack. It is always good to see you, doing the Lord's work, making sure that family, farmers, and ranchers have a shot out there. And we all know that rural America has been declining, and is going to continue to decline unless we do some things a little differently.

And you know where I am going with this. A few weeks back the Senate Agricultural Committee, and I am sure you were watching it, held a hearing on two bills that deal with consolidation in the marketplace when it comes to the cattle industry.

You know, the statistics for companies control over 80 percent of the marketplace, capitalism doesn't work in situations like that.

And we want capitalism to work. We want there to be competition in the marketplace, so that both the cow-calf operators and consumers can reap the benefits of a good competitive system.

The President's budget asks for $35 million for packers and stockyards, given the issues that I just said, and I just brought up beef, pork, poultry, and others are in a very similar situation. Do you think that level of funding is adequate, the 35 million for packers and stockyards?

Secretary VILSACK. It would represent a very significant increase, Senator. And I think it would be adequate for us as we strengthen packers and stockyards, this year you will see probably three rules coming out from the Department in an effort to try to strengthen the enforcement capacity of the Department. And those resources would be very important to being able to do that.

Senator TESTER. That is good because it is going to be—I mean you are the key to unlocking this, you or your Department, and you. And so making sure you have the resources to deal with the situation a fair way is really critically important. As I told you before, I am not for putting anybody out of business, what I am for is add more competition to the marketplace. And the Packers and Stockyards Act, was originally set up to do that, and we just haven't had the enforcement capabilities.

I don't need to tell you about the, historically, bad drought west of the Mississippi. Last year was the worst year I ever had, this is 44 years on the farm, grandfathered homestead at 110, and I think with the exception of 1919 and 1920 when they had to move back the Red River Valley after the historic homesteading because of drought, this may be the worst year since then.

And by the way, where I happen to live in North Central Montana, I have been seeding the last weekend in dry dirt. If we don't get rain it is going to be worse than last year.

We passed billion in disaster relief last fall, including 750 million bucks for livestock producers. This is critically life-and-death money, I mean truthfully, it is nobody wants to get a check from the Federal government, but the bottom line is the drought has caused hay prices to go through the roof, there has been no grass resource because there has been no water, there has been no crops raised because there has been no water.

And so can the USDA, can you share any update on the progress of getting that $10 billion in disaster relief out the door?

Secretary VILSACK. Livestock producers have received checks in the amount of $560 million last month and this month. So there will be a second round of funding for the livestock producers who weren't necessarily covered by the Livestock Forage Program, or the Livestock Indemnity Program. We took information from that, from those programs and basically pre-filled the application so that we could move the money out more quickly than in the past.

In terms of on the crop side, we anticipate and expect announcing this month the structure for how the crop reimbursements will take place, that will also involve pre-filled applications, there are roughly 250 questions that are asked of a producer in order to be able to access WHIP+, most of those questions will be pre-filled from crop insurance and NAP data, and we expect and anticipate the checks will come out in June.

Senator TESTER. So doing some quick math in my head so there is about 190 million on the livestock side that is yet to be allocated?

Secretary VILSACK. It is because we want to make sure we cover those producers that didn't necessarily have, they may have had a shallow loss, they may have had a loss that didn't qualify for one of those programs, so therefore there wouldn't have been the data, or the information available to the Department. So we will go through a process of having them apply for the resources.

Senator TESTER. And thank you for that. And one really, really quick; I was talking to, sitting in the airport last Thursday, and I was talking to a guy that said that he had received some money on cattle shipping to be able to move his cattle. Is that number one—I certainly don't have a problem with that, with the price of fuel, and lack of trucks. Are you aware of that program, because it is not one I was aware of?

Secretary VILSACK. Well, we are providing it. We have expanded the Livestock Indemnity Program, or I believe that is the Livestock Indemnity or the Forage Program, to include additional assistance for transportation.

Senator TESTER. Okay, good.

Secretary VILSACK. I am not sure whether it is the cattle, or whether I think it is transporting the cattle to where there may be feed or grain.

Senator TESTER. That is correct.

Secretary VILSACK. Yeah.

Senator TESTER. That is exactly it.

Secretary VILSACK. We have expanded the program to include reimbursement for that transportation expense.

Senator TESTER. I don't know whose idea that was, but great idea. Thank you.

Thank you, Madam Chair.

Senator BALDWIN. Thank you. Next, Senator Moran.

Senator MORAN. Thank you, Chairwoman.

Mr. Secretary, hello. Seems like every conversation with the Secretary of Agriculture, for as long as I have been in the Congress, includes conversations about disaster, and I want to highlight a problem we have with the Emergency Livestock Relief Program, we have had drought and wildfires across our state, but most recently, in December of 2021, 160,000 acres across 13 counties in Kansas burned, grassland, forage sorghum, and other feed sources that producers rely on to get through the winter. Since those fires occurred outside the quote, "normal grazing period" these producers are not eligible for LFP, and therefore are not being helped by disaster assistance.

USDA described in the announcement, on March 1st, as Phase One, will Phase Two of the Disaster Assistance provide support to livestock producers who lost forage and grazing lands to wildfires outside normal grazing periods?

Secretary VILSACK. Senator, we are in the process of developing a list of those non-covered disasters, as the one you have just mentioned, to make sure we have a comprehensive list, and then from that list we are going to make a determination of how best to spend and invest the second tranche of resources.

Certainly understand what you have outlined, and I will tell you that the concerns that you have expressed are on the list, they have been placed on the list. You know, I want to make sure that I check with our folks to make sure that I am right when I say, we are going to consider this seriously. I don't know that we have necessarily made a decision yet about exactly who gets what, but I know that is on the list.

Senator MORAN. If you would give me the chance to make the case, it should be high on the list, I would appreciate that.

Secretary VILSACK. Certainly.

Senator MORAN. Does USDA expect to need additional funding for Ad Hoc Disaster Assistance?

Secretary VILSACK. Well, I am never going to ask or question where, do you need additional resources? Here is the problem, Senator, and you have addressed it. Our disaster assistance programs are sort of a one-size-fits-all, and the reality is we are now learning that there are multiple types of disasters in multiple different areas, involving multiple commodities, and in multiple different ways.

And it is going to be important and necessary for us, I think, to have enough flexibility and resources to be able to try to tailor the disaster assistance to the actual disaster, as opposed to having a one-size-fits-all, and sometimes your folks don't fit in it, and that is unfortunate.

You know, more resources, but I would say in addition to more resources let us make sure it is flexible enough to be able to use it for multiple disasters.

Senator MORAN. I always like that flexibility until it doesn't cover something that I think needs to be covered. And I appreciate the conversation, and perhaps you are leveraging me to suggest we need more disaster assistance, or more dollars.

Input costs, fertilizer prices, I have asked the subcommittee that I am the lead Republican on, has jurisdiction over the Department of Commerce. We are trying to do something about countervailing duties on phosphates from Morocco, and to stop the implementation of duties on nitrogen fertilizer from Trinidad and Tobago. Can you help? Can you be an ally in any of this?

Secretary VILSACK. Well, we have certainly indicated a necessity of looking at those countervailing duties. In addition, as you know, we have announced an effort to try to put resources on the table to see what we could do here in the United States to produce more fertilizer. We are also working with producers on crop choice, and conservation practices that could potentially reduce fertilizer use.

We are also focusing on a split nitrogen policy for crop insurance that will basically cover crop losses if you decide to half your nitrogen application. I mean there are a series of things we are doing. And we are also working with state attorney generals to take a look at whether or not the fertilizer costs that are currently being paid by farmers are legitimate.

It is an interesting, a very interesting graft, if you take a look at the history, of fertilizer and crop prices as crop prices go up so do fertilizer costs. And may just—no reason for that, but.

Senator MORAN. Mr. Secretary, thank you. I don't understand the love affair with the countervailing duties on components of fer-

tilizer. And I will continue my efforts, and I appreciate any help you can give.

The supplemental—the double cropping issue, planting soybeans after winter wheat just announced a week or so ago, I would remind you that sorghum is a major food crop for many African nations, and it is a crop that can be planted behind wheat in many parts of Kansas. Additionally, much of the world's sunflower oil comes from Ukraine, another crop that could be utilized in that fashion.

Why does the administration's supplemental request only propose to incentivize soybean and not include other food crops, like sorghum and sunflowers?

Secretary VILSACK. It was conservation starter, and you are absolutely right, and there is no reason why we couldn't include those, and should.

Senator MORAN. And would that include the $10 per acre incentive for——

Secretary VILSACK. To the extent that there are incentives that we are looking at, or flexibilities that we are looking at, we are going to try to be as comprehensive as we can be.

Senator MORAN. Right. Thank you, Mr. Secretary. I appreciate your answers.

Senator BALDWIN. Thank you. Next, I am going to go a little bit out of order. I know Senator Collins has a time schedule issue. So I am going to call on you for your second round; then Senator Braun for your first round.

Senator COLLINS. Thank you very much, Madam Chair. And thank you, Senator Braun.

Secretary Vilsack, you won't be surprised that the second issue that I am going to bring up with you today concerns potatoes. Potatoes are an extremely nutritious vegetable. They contain more potassium than bananas, they are a good source of fiber, vitamin B6, vitamin C, and very important today to families that are struggling to buy groceries. They are affordable.

During the Obama administration, and I won't relive this, but we went back and forth on whether potatoes should be restricted in the school lunch, and school breakfast programs, and the WIC programs, and they were not.

When you appeared before the subcommittee last year, I questioned USDA's proposed elimination of funding for the highly successful Potato Breeding Research Program. Congress, on a bipartisan basis, not only rejected the elimination of that program, but rather than zeroing it out, actually increased it somewhat to $3 million a year.

Given the strong congressional support, I was very surprised to see that your budget is again proposing to zero out this program, especially when the administration is seeking an overall increase of more than $2 billion in discretionary spending for USDA.

The University of Maine is the leader in the research in this program, and has worked with growers to develop a new variety named the Caribou Russet, that is producing high yields, and is much more disease resistant. And one needs to look no further than the recent outbreak of the potato wart in Prince Edward Island in Canada to understand the importance of continuing to in-

vest in research that produces hardier crops, and protects our domestic markets.

So my question for you: Given Congress' action last year, given what a small amount this is in the context of your entire budget; why are you again seeking to completely eliminate funding for the Potato Breeding Research Program which has been proven successful in helping our growers prevent agricultural and economic losses?

Secretary VILSACK. Senator, I rely on the professionals at ARS to give me a list of their priorities and, you know, I think it goes back to my earlier comments about the importance of investing more money in research, and investing more money in ARS. I mean the reality is that these have been flatlined for an extended period of time, and when they are flatlined, you establish priorities. And obviously if Congress, basically, directs us to maintain that program we obviously will, but I would hope that it does so in the context of significantly increased resources for ARS, including resources to improve the facilities.

Part of the challenges that we are now facing, we have 118 facility projects roughly 30 of them are either fully or partially funded, that leaves quite a few that aren't. And so it is a matter of resources. But if we have more resources, we can do more work.

Senator COLLINS. Well, I am going to give you the chart that I always hand out on potatoes. And which you have received from me previously, but it doesn't make sense you end up spending more money if you have to provide disaster assistance, or other kinds of assistance, than if you invest upfront in the research that produces a more disease-resistant crop.

Secretary VILSACK. Well, Senator that would be true if that was the only crop that we had to be concerned about, and the only research project, but it is not, that is the problem. We have, as we have already discussed here today, a multitude of disasters and challenges, and that is the issue. If we have more resources, then we can obviously cover more research projects.

Senator COLLINS. But potatoes do not receive crop support money, they do not receive price support.

Secretary VILSACK. They don't receive that support.

Senator COLLINS. They don't.

Secretary VILSACK. But there is 9.9 billion pounds of food that we purchase through our commodity purchasing programs, which includes potatoes. So in a sense there is also that kind of support. Sometimes there is a tendency to forget that the other ways in which we provide assistance for specialty crops that is one way, not the only way.

Senator COLLINS. I just, you know, when I look at your previous efforts to eliminate the University of Maine's Agricultural Lab altogether during the Obama administration, and restrict the use of potatoes, despite the Institute of Medicine's study, that there was no basis for doing so.

Secretary VILSACK. That that wasn't the reason for the WIC decision, as we have explained before. It was a situation where we were trying to encourage folks to purchase those items that they would not otherwise purchase with their own resources. It wasn't that we didn't think potatoes were nutritious, obviously, and we

have just most recently expanded opportunities for potato exports in Mexico. So it is, you know, I have nothing against potatoes.

Senator COLLINS. Well, it feels like it. I can tell you.

Thank you, Madam Chair.

Senator BALDWIN. Senator Braun.

Senator BRAUN. Thank you, Madam Chair. You know, agriculture has gotten so complicated. I mean, didn't grow up on a farm but have lived on one ever since I moved back to my hometown. Fell in love with the forestry side of agriculture. In Indiana we were probably 90 percent forested at one time, and got through subsistence farming, cut down to like 5 percent.

It is kind of reforested to the tune of about maybe 30- 35 percent, and value-added it is equal to, if not exceeds, the value-add that you get from row crops. I think that is something that most people don't understand. They see the vast fields of corn, and soybeans. So I think it is important to keep that in mind, to keep our forest owners healthy, and to make sure that is as important part of the equation as the row crop side is.

Since that is simple, the trees just grow and get larger, don't involve any inputs, you know, and it is kind of a generational crop. What I hear most about currently is two things. It would be the concentration of AG when it comes to industries across the input spectrum that used to have so many local options, fewer and fewer companies.

I think that is something that we got to be aware of. The individual farmer has had to go from small acres to many acres to keep economic—economy of scale in place, frustrated each year that they have maybe got fewer options.

I would like your comment on, is that side of farming in peril because markets aren't as broad and available as they used to be? We recently discussed it in the AG Committee on the meatpacking industry. Would you want to weigh in on that?

Secretary VILSACK. Well, Senator, I think there are two issues here. One, you have identified, which is the concentration, and that is absolutely true. You know, we are dealing with fertilizer issues right now. That is a very concentrated industry at this point, the processing industry, and we are trying to address that with some of the work that we are doing at USDA.

I think the second issue, and you also alluded to it, is the fact that there is a limited number of ways in which farmers today profit. They grow crops and sell them, or they grow crops and feed to the livestock, and sell the products of livestock. What we need to do is be able to create additional ways in which profit centers and income sources can come from the farm.

That is why your work, and Senator Stabenow's work, and others on the Climate-Smart Agriculture effort was important, because it basically creates the platform, and the structure for that possibility, that climate and climate-related activities could create a revenue stream, an opportunity.

The conversion of agricultural waste to chemicals, materials, fabrics, and fibers also creates another new revenue stream that we are in the process of trying to support. So I think the key here is for us to address the concentration issue but also to address creating multiple income streams on the farm.

Senator BRAUN. I think that is very important. Any business that prospers over time, I can tell you, I ran one for 37 years, whatever you are knocking it out of the park with currently, is sure to be different five to 10 years down the road. And agriculture is a monoculture in terms of really what you have been used to doing; it has got to reflect what you are talking about.

The other real concern I hear, which is palpable was what farmers are going to do in 2023. Let us put the cost aside. That was a big challenge this year. Most ended up getting the inputs they needed to get a crop out. With the current dynamic in place, with our dependency on certain inputs that look like they are in places of peril, do you think farmers will be able to get the inputs for 2023, setting the cost aside? I hear real concern about, they just limp through 2022, what are we going to do for 2023?

Secretary VILSACK. Well, one of the things we were looking at is, whether or not there is a possibility of taking a look at our storage programs, because there may very well be the capacity to purchase and store, which farmers could potentially utilize to get them through a potentially tough 2023 crop year.

Then secondly, obviously, we work on strategies to try to reduce the amount of these inputs. That takes us into precision agriculture. I will just share with you, there is sensor technology that is being developed at Iowa State University that suggests that 30 percent of the corn acres in America today, in the Midwest, do not require fertilizer. So if we can accelerate that kind of research, and accelerate the capacity of farmers to have that kind of precise information about their farms, we may be able to get them through a process maybe not 2023, but in the future where they are not as reliant as they have been on those inputs.

Senator BRAUN. Leveraging technology and finding new markets would be the hallmark of any successful sector of our economy; and never more applicable than in agriculture today. Thank you.

Senator BALDWIN. Senator Hoeven, you are now recognized for a second round.

Senator HOEVEN. Thank you, Madam Chair. Did you already do your second round? I don't want to jump in.

Senator BALDWIN. Yes, I did.

Senator HOEVEN. Okay. Good to know, all right.

Secretary, I am concerned about the increase in the TRQ for sugar, it has been raised twice now, 170,000 tons and then more recently. I guess in April it was 220,000 tons, and then more recently another 170,000 tons. That is about a 400,000-ton increase.

I know that some of this came from production shortfall in Michigan, but that certainly wouldn't be anything near 400,000 tons. So can you address that?

Secretary VILSACK. Senator, I want to be able to check our numbers with your numbers, because we are under the assumption it is a little bit less than what you have outlined. But having said that, the key here, from our perspective, is to maintain a proper balance; and the stocks to ratio has historically been somewhere between 13.5 to 15.5, we got it down to 12.5.

And what we have been able to do with this additional purchase is to put us within that 13.5 to 15.5 range. And that is where we

are comfortable, where we think the program works particularly well balancing the equities that are involved.

Senator HOEVEN. Okay. Well, we are concerned it is going to take you above that range, and so again we want to make sure that that—you know, that those increases do keep it in that range, and we are not getting above it.

Rural broadband, obviously you have got significant funds in terms of rural broadband, and obviously it is a priority, and I think a bipartisan priority so, you know, what is—where are you at with getting those dollars out, and what is your plan to do it?

Secretary VILSACK. We made a—so there are two pots of money, the first pot came from American Rescue Plan, the Pandemic Assistance Programs, and so forth, that pot has gone through several rounds. We most recently completed a round. We received 305 applications for roughly $1.15 billion. Those applications I think were in the neighborhood of two to three times that amount. So obviously, great interest.

We also received the bipartisan infrastructure resources of 1.9 billion. We are now taking a look and analyzing the applications of 305 applications, Senator, to determine whether or not there is a possibility of accelerating and utilizing some of the BIL money, in that third round, because essentially they would potentially qualify for the same requirements. That would allow us to put several billion dollars into awards to get action this year.

And then the balance of whatever is left from the Infrastructure Law, we would announce availability sometime later this year, for awards, probably, early part of 2023.

Senator HOEVEN. Being around four, or would that be——

Secretary VILSACK. It would three and——

Senator HOEVEN. You would just keep going?

Secretary VILSACK. Right.

Senator HOEVEN. In other words, you are going to continue on?

Secretary VILSACK. Yes.

Senator HOEVEN. Okay. And so when do you anticipate funding announcements then for round three?

Secretary VILSACK. This summer.

Senator HOEVEN. This summer.

Secretary VILSACK. We are going to complete the—we would be able to make these announcements sooner, but we want to see whether or not there is a way of accelerating the BIL money into this round. And that requires us to analyze where these applications are, you know, how many of them would, in fact, qualify.

And it just—it is going to take some time. But we think by the latter part of this month we will have a better understanding of how much of that BIL money could actually be incorporated in this round.

Senator HOEVEN. Okay.

Secretary VILSACK. And then that will be the set of announcements this summer.

Senator HOEVEN. All right. On the child nutrition waivers, what steps are you taking as we get back to the traditional program to be ready for next year, what are you doing?

Secretary VILSACK. Let me tell you something, Senator, this is going to be chaotic. Just make no mistake about it, the failure to

have these waivers is going to create a lot of chaos in schools across the United States. There is, very limited things that we can do, we don't have the flexibility to provide waivers to the extent that we have provided them, very, very limited.

We can't increase the reimbursement rate, we can't expand universal free school meals, so we will focus on community eligibility, we will focus on the limited waivers that we have, we will take a look at any additional capacity we have with resources in terms of commodity purchases, but schools are going to have a very difficult time. Make no mistake about it.

Senator HOEVEN. So Madam Chair, I have a couple questions left that I do want to ask—but I am happy to defer if you want to. But then, I would like another shot at it.

Senator BALDWIN. We can give you a special third round.

Senator HOEVEN. Fantastic.

Senator BALDWIN. Senator Hyde-Smith.

Senator HYDE-SMITH. Mr. Secretary, in recent years this subcommittee has made just historic investments in developing methods to better understand, and detect, and respond to chronic wasting disease. And, you know, an incurable, always fatal disease affecting the white-tailed deer, and other members of the deer family. Historically, there have been many questions and unknowns about the disease, but thanks to the new CWD research being conducted by USDA, and its university partners, along with the better surveillance and response efforts carried out by the states' wildlife agencies; we are starting to make great strides in CWD.

And hunting and outdoor recreation contributes billions to the American economy, more than 2.7 billion in annual economic output in Mississippi alone. Would you agree that our investments in CWD are paying off, that we are seeing a positive return on our investments? And would you agree that we need to continue investing in activities related to chronic waste disease in fiscal year 2023, and beyond that?

Secretary VILSACK. I think I would answer that yes, yes, and yes. I think you asked three questions. Yes. We have got 35 herds, there is no vaccine or cure yet, it is in 25 states, there is a need for more and additional resources, those resources will allow us to do more surveillance, more testing, more management, and hopefully more responsive activities. So clearly we need additional resources.

Senator HYDE-SMITH. Thank you very much.

Thank you, Madam Chairwoman.

Senator BALDWIN. Senator Hoeven.

Senator HOEVEN. I want to commend Senator Hyde-Smith, just in general, but here specifically for setting up my question. Which is, we have legislation to do more with chronic wasting disease, it is bipartisan. Martin Heinrich's lead on the Majority side, but we have got others on both sides of the aisle.

So clearly you would, based on your last comment, support that legislation which would provide more funding for research, relative to chronic wasting disease, because it affects both domestic and wild animals.

Secretary VILSACK. Yes.

Senator HOEVEN. Okay, great. FCIS—excise me—FSIS overtime, we have got food safety, and inspection challenges I mean we have workforce challenges everywhere, right, but with our inspectors in FSIS we have some challenges, and so we included some provisions that give you more flexibility so where are we at with implementing that?

Secretary VILSACK. It is implemented, Senator, the problem is, it is a 1 year—you have got to do it every year.

Senator HOEVEN. Right.

Secretary VILSACK. But it does give us a tremendous amount of flexibility, and it makes it a little bit easier, reduces the stress, workers still have the option of working those overtime hours, but if for whatever reason they are just spent, this gives us the ability to continue to keep the plan open but have the flexibility to have the inspectors on staff, who want to be there.

Senator HOEVEN. Which is something you need right now.

Secretary VILSACK. Absolutely.

Senator HOEVEN. Yeah. Okay. And then, my last question relates to the—is also a workforce question, and that is getting the H–2A-eligible people through the process, and on the job. And there two aspects to it, one, as for some of the Ukrainians that are coming, you know, Ukraine is so similar to us in terms of their AG base, as a matter of fact some of their livestock, and so forth, come from my state where we have actually—some of our producers have flown breeding stock over on 747s, if you can believe that, and you maybe have seen some of that. It is unbelievable.

Secretary VILSACK. Well, Iowa started that a long time ago.

Senator HOEVEN. Yeah. I figured you probably have been involved with it too. It is really impressive.

Secretary VILSACK. We did it in Japan in the—when they had a typhoon back in the 1960s.

Senator HOEVEN. Yeah. But you would think they would go by boat, but they actually put them on these huge aircrafts. It is amazing.

Secretary VILSACK. Yeah.

Senator HOEVEN. Yeah. You mean when pigs fly, right, how crazy is that?

Secretary VILSACK. Yeah, they did, they really did.

Senator HOEVEN. You have probably said that a few times as governor. But you didn't mean it literally, necessarily. But it is both processing these H–2A applications which we need to get these folks, who are eligible, through the system, and in a lot of cases are folks that have come before. And you know the need out there for workers in the AG area.

So utilizing some of these Ukrainians that are coming here, expediting their ability to get those work permits would be good for them, good for us. That is one aspect of the question. Then the other is, in terms of some flexibility in the work, in that they can be out there and do fieldwork, and that kind of stuff, or on farm work, but then we also need folks in the processing plants, and their visa doesn't necessarily allow them to do both, but it is really very—you know, it is just a continuation of pretty much the same thing.

And it has some of the seasonality to it. So in is there a way we can, maybe, do both of these things to kind of help with the labor issue?

Secretary VILSACK. You know, I will make you a deal, Senator.

Senator HOEVEN. Sure—well, maybe.

Secretary VILSACK. I will help you with this problem if you can get your colleagues to vote on the AG Workforce Modernization Act, and actually get these things solved in a permanent way. This is nuts. This is just crazy what is going on here with the workforce.

We are sort of nickleing-and-dime it, we are putting a Band-Aid on it, we are constantly talking about H–2A, when we all know that, fundamentally, we have got to fix the immigration system, and the AG community and the labor community has come and said: Here is the fix that we would like to see in our part of the industry, and it passes the House in a bipartisan way. I just don't understand why it can't pass this body.

Senator HOEVEN. Well, it gets pulled into everything else, you know that. But in the meantime though——

Secretary VILSACK. But why? Why does it get pulled into everything else?

Senator HOEVEN. Well, you know how that—you know how that process works here, but in the meantime are these some things we can do?

Secretary VILSACK. In the meantime we will work—in the meantime we will continue to look for ways in which we can try to alleviate the stress, but it is a temporary fix; it is not going to solve the problem, it is not going to relieve the underlying lack of confidence that farmers now feel. They just don't know if they are ever going to have the workforce. And they are they are scared about this. They are really concerned about it.

Senator HOEVEN. Well, and that is where the merit-based aspect comes in that is very important. But again, our guys are concerned about getting these folks through the system people who are eligible now, and so we need your help on it.

Secretary VILSACK. I am happy to help.

Senator HOEVEN. Good.

Secretary VILSACK. And I would hope that you will help me get 59 other Senators to vote for the AG Worker Modernization Act.

Senator HOEVEN. Thanks for your work on all these things, Secretary. We have had opportunity to work together as governors, 8 years during the Obama administration, and so I do appreciate your help on these things, thanks; and thank you for being here today. And to your crew, to people like Zach Ducheneaux, you have a lot of folks out there working really hard for our farmers, and ranchers. And so I want to express my appreciation for that.

Secretary VILSACK. Thank you, Senator.

Senator BALDWIN. And Mr. Secretary, I want to add my words of thank you, to both you and Mr. Rapp for being here today. I think we had a good discussion, and I look forward to continuing to work with you as we begin the appropriations process for fiscal year 2023.

ADDITIONAL COMMITTEE QUESTIONS

Questions for the record are due by next Tuesday, May 17th, and we would appreciate responses from the USDA within 30 days.

Secretary VILSACK. Madam Chair.

Senator BALDWIN. Yes, you may.

Secretary VILSACK. Can I say just one thing? Because Senator Hoeven was not here, I don't think, when I gave my opening comments, and maybe he got in at the tail end.

Senator, I just want to leave with you the same statistic that I left with the rest of the committee members. 61,670 farm families are currently on the brink, these are people that have borrowed money from USDA that are either delinquent, bankrupt, or pending foreclosure. And it is an issue that we have got to address.

Thank you, Madam Chair.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

SUPPLY CHAIN DISRUPTIONS

Question. Supply chain disruptions over the past year have resulted in massive losses for the agricultural industry, particularly in California. A study out of UC Davis indicated that the California agriculture sector lost $2.1 billion from May through September of last year alone because of their inability to export products. These losses are compounded by rising input costs, including more expensive gasoline and fertilizer.

Secretary Vilsack, what is your Department doing to support the agricultural sector during this unprecedented disruption to our export capabilities, particularly the many California farmers who grow perishable crops and have lost more than $2 billion as a result?

Answer. USDA is acutely aware that fewer shipping containers have been made available for U.S. agricultural commodities as ocean carriers have circumvented traditional marketing channels. To this end, earlier this year, I announced plans to increase capacity at the Port of Oakland in Oakland, California, and improve service for shippers of U.S. grown agricultural commodities. Part of this effort included helping establish the Howard Terminal "pop-up" site at the Port of Oakland, which is providing space to prepare empty containers. Specifically, USDA's Agricultural Marketing Service (AMS) covered 60 percent of the start-up costs for the pop-up terminal. Through the use of Howard Terminal, agricultural companies and cooperatives have easier access to containers, which they can fill with commodities; this additional capacity will help relieve congestion and restore shipping services.

On May 25, 2022, USDA shared that it would also begin accepting applications for the new Commodity Container Assistance Program (CCAP), which includes partnerships with both the Port of Oakland and the Northwest Seaport Alliance, a marine cargo operating partnership in Washington State. Under CCAP, USDA's Farm Service Agency (FSA) is providing a $125 per container payment to partially assist agricultural commodity owners for the additional logistical expenses associated with picking up empty shipping containers to be filled with agricultural commodities and products at the Port of Oakland. FSA is also providing payments of $200 per dry container and $400 per refrigerated, or reefer, container to help cover additional logistical costs associated with moving a shipping container twice, first to the preposition site and then to the terminal loading the vessel, along with cost of temporary storage. FSA will make monthly direct payments to agricultural companies and cooperatives on a per-container basis, based on the location of the port and the type of shipping container. Additional information about CCAP can be found at farmers.gov/pandemic-assistance/CCAP.

Ongoing market disruptions have created logistical challenges associated with the availability and flow of shipping containers to transport agricultural commodities, which has prevented or delayed American-grown agricultural commodities from reaching their markets. USDA continues to work with industry partners throughout the supply chain to relieve the disruption created by the COVID–19 pandemic. The

following are examples of additional USDA activities to support solutions to best address specific challenges agricultural producers are facing along the supply chain:

—USDA formed partnerships with several west coast ports as part of the Administration's Supply Chain Task Force efforts with State and local governments and builds on earlier efforts including a US Department of Transportation partnership with the Port of Savannah in Georgia. The benefits of relieving congestion and addressing capacity issues at ports through partnerships go well beyond the local region, as commodities and agricultural products grown and processed from thousands of miles away flow through these ports.

—Beyond the CCAP program described above, USDA continues to seek opportunities to partner with additional ports or other intermodal container facilities to help American farmers and agricultural producers move their product to market and manage the short-term challenges while pressing the ocean carriers to restore better levels of service.

—USDA will also continue to partner with other Federal agencies and State and local governments to address port operation challenges resulting from the ongoing pandemic.

—As Secretary, I've pressed executives of five major ocean carriers to address concerns about service and availability raised by agricultural exporters, and encouraged greater cooperation with agricultural export efforts, including committing to providing needed empty containers.

—USDA will announce its Food System Transformation framework on June 1, 2022, targeted at strengthening critical domestic supply chains and addressing structural challenges that benefit consumers, producers, and rural communities, including California farmers. USDA is limited in its domestic use of market development funds to address supply chain issues. Programs such as the Market Access Program (MAP), Emerging Markets Program (EMP), and Technical Assistance for Specialty Crops (TASC) assist California farmers who grow perishable crops with increasing their export capabilities.

—The Farm Bill authorized Market Access Program, administered by the Foreign Agricultural Service, provides Commodity Credit Corporation (CCC) funding to U.S. commodity and trade associations to aid in developing, expanding, and maintaining foreign markets for U.S. agricultural commodities and products. For fiscal year 2022, USDA awarded $28.4 million of this $200 million program to 16 non-profit California trade organizations and cooperatives to promote U.S. agriculture products. Despite supply chain issues causing a dent in their export numbers, recipients continue to conduct export marketing efforts and build demand for U.S. agriculture and affirm the U.S. is a consistent supplier of high-quality agricultural goods.

—The Farm Bill authorized Emerging Markets Program, which provides funding for technical assistance activities intended to develop, maintain, or expand markets for U.S. agricultural exports in emerging market countries. The program underwrites assessments of the food and rural business system needs of emerging markets and can also fund knowledge transfer activities aimed at developing the food and rural business systems in eligible markets. For fiscal Year2022, USDA awarded $368,560 to support California entities in emerging markets throughout India, Southeast Asia, Mexico, and South America.

—The Foreign Agricultural Service-administered Technical Assistance for the Specialty Crops program is designed to assist public and private U.S. organizations by providing funding for projects that seek to remove, resolve, or mitigate existing or potential sanitary, phytosanitary, or technical barriers that prohibit or threaten the export of U.S. specialty crops. For fiscal year 2022, USDA awarded $1.2 million to non-profit California organizations promoting blueberries, avocadoes, and wine to address technical trade barriers and counterfeiting.

Question. Many school districts across California-and the country-are already dealing with many challenges because of the pandemic and disruptions to U.S. supply chains. I appreciate your efforts to mitigate the impact to children and families of ending nationwide child nutrition waivers on June 30, 2022.

Secretary Vilsack, can you discuss the impact that the loss of the waivers will have on children, families, and schools this summer and during the 2022–2023 school year, and do you think that there is still a need for the Senate to extend your nationwide child nutrition waiver authority?

Answer. In March 2020, Congress first provided USDA with the authority to waive the statute and regulations for Child Nutrition Programs through the Families First Coronavirus Response Act of 2020 (the FFCRA), and later through the

Continuing Appropriations Act, 2021 and Other Extensions Act. These Acts allowed USDA to address the urgent need for nutrition assistance during the COVID–19 pandemic by granting USDA broader waiver authority than provided through Section 12(l) of the National School Lunch Act, including the ability to grant waivers nationwide and allow waivers that increased program costs. These waivers allowed us to equip schools and other program operators with resources and operational flexibilities that are still desperately needed as our schools still grapple with the ongoing challenges resulting from the pandemic. However, this authority expires June 30, 2022, and Congress has not been able to reach a deal to extend those vital waivers yet. This means USDA can no longer offer the full range of waivers that are currently available.

We know that Child Nutrition Program operators, including schools, childcare providers, and community organizations, are still facing tremendous challenges, and USDA has worked as quickly as possible to identify everything we can do within our permanent statutory authority to support them in this transition. Unfortunately, without the broader nationwide waiver authority, our toolbox is limited.

Going forward, USDA won't be able to offer the full range of waivers that have been available to schools, child and adult care providers, and summer meal providers. Without the waiver to provide all students meals that are reimbursed at the free rate and the waiver providing the higher reimbursement rates for schools, we estimate that the average school will see a 40 percent decrease in the reimbursements they receive next school year. In addition, we expect average reimbursement rates for CACFP family day care homes to drop starting July 1, 2022, due to the lapse in waiver authority that allowed some providers to receive higher reimbursements, many summer meals and at-risk afterschool sites will no longer be able to operate as they are located in areas that are not eligible for participation without the waivers.

USDA is able to issue waivers on a State-by-state basis under the permanent Child Nutrition waiver authority found in Section 12(l) of the National School Lunch Act when certain conditions are met, including that the waiver cannot increase the cost to the Federal Government. Therefore, USDA has offered, on a State-by-state basis, some "no cost" flexibilities that were previously available nationwide. We are hearing from our stakeholders that the flexibilities USDA is able to offer this summer and next school year simply don't address all the challenges schools and other operators are facing and will face in the fall. USDA would need additional waiver authority, similar to the authority provided in FFCRA, to address ongoing critical needs and meet our program operators where they are.

We are deeply concerned that without additional support, school meal programs will struggle to manage the serious challenges they are facing. The school meals marketplace has some specific features which make it particularly vulnerable to current market disruptions. We have engaged extensively with stakeholders, including school nutrition professionals, industry representatives and others, who report numerous concerns. School districts are putting out bids for next school year and getting no responses, and many items, both food and supplies, are very difficult to obtain. School nutrition staff report turning to local retail outlets or other sources at the last minute to obtain items needed to maintain meal service. School districts have unique transportation, storage and distribution needs, and those networks are extremely strained. Finally, school meals programs consistently report major challenges with staff vacancies.

As a result, we are very concerned about program operators' ability to maintain the high standards of quality, customer service, and nutrition support which our students need and deserve. Schools will likely be forced to reduce menu offerings and will likely have to repeat service of available items very frequently. Popular items may be unavailable, and schools will be forced to make substitutions of less favored products, often on the day of service, frustrating students and parents by not providing what is expected. Nutrition quality may suffer if schools are unable to obtain the range of products needed to provide healthy meals and instead must rely on whatever is available to them, but waivers would help mitigate this concern. In this environment, schools may struggle to maintain participation levels, further exacerbating their financial challenges caused by the expiration of the waivers.

While we do not necessarily expect large-scale exit from school lunch and breakfast programs, we are concerned that more will consider scaling back on other critical nutrition programs, such as after-school snack and supper programs. We are also concerned that the return to application-based programs will likely result in a rise in unpaid meal charges, as eligible families who have not had to apply for free or reduced-price meals for 2 years may be slow to do so. This would further strain school meals programs financial status, as well as increase the potential for "lunch

shaming" whereby students without funds to pay for a meal are denied service or otherwise singled out.

QUESTION SUBMITTED BY SENATOR PATRICK J. LEAHY

PARTNERSHIP FOR CLIMATE SMART COMMODITIES

Question. On February 7, 2022, the USDA announced the Partnerships for Climate-Smart Commodities program, which will finance partnerships to support the production and marketing of climate-smart commodities. The pilot projects, which will last between one and 5 years, will provide technical and financial assistance to producers, and pilot innovative and cost-effective methods for quantification, monitoring, reporting, and verification of greenhouse gas benefits.

The effects of climate change will vary geographically. We know that agriculture is one of the most vulnerable sectors to climate change in New England and in Vermont, specifically. Rising temperatures and changes in water availability hit hard for a region that is home to so many dairies, maple syrup, and small and diversified farming operations. These farms may not, individually, fall within the typical definition of "commodity scale" production. Would you agree that the challenges related to climate change are regionally distinct, and that as a result of being so, can you promise that Partnerships for Climate-Smart Commodities will consider pilot projects in a variety of geographic areas, including New England and the Northern Forest?

Answer. As you can see through the funding opportunity, there are a variety of goals and objectives of the Partnerships for Climate Smart Commodities. USDA intends to fund a diverse set of projects and will not discriminate based on size of the project. Diversity of applications, including geographic diversity and size and scale of projects, will be considered when making award decisions. USDA will select a variety of projects so that this emerging marketplace starts out with robust competition and options for producers.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

ILLEGAL LOGGING

Question. Illegal logging and associated trade has been ranked as the third-largest global transnational crime after counterfeiting and drug trafficking, generating between $52–157 billion per year. In many tropical countries, over half of deforestation is illegal. Left unaddressed, persistent illegality and impunity undermine all conservation and climate efforts, including the recent pledge by the United States and 140 countries to halt and reverse forest loss by 2030.

In 2008, the United States, the world's largest consumer of forest products, became the first country to ban trafficking of products containing illegally sourced wood. The Lacey Act Amendments of 2008 were adopted with bipartisan support and have demonstrated their potential for impact. Yet unacceptable delays in full implementation and sporadic enforcement continue to limit their effectiveness.

In 2009, the Department provided a schedule where major product categories would be phased in by September 30, 2010.[1] However, the current Lacey Act declaration requirements, which are managed by USDA APHIS, still only apply to approximately 42 percent of the value of wood products imported into the United States. This leaves $45 billion of annual imports subject to the prohibition in the Lacey Act, in practice, uncovered by the declaration requirement. This includes nearly all imports of wooden furniture, pulp and paper, particleboard, and fiberboard. It is long past due that APHIS fully implement the Lacey Act Amendments of 2008—and there a growing chorus from industry, civil society, and lawmakers to complete this phase in by the end of 2022.

What is your plan to phase in all outstanding plant and wood product categories—including wood furniture, pulp and paper, particleboard, and fiberboard?

Answer. I agree that illegal logging and the resulting deforestation are enormous problems. The scope of the material covered by the Lacey Act is also significant-APHIS currently receives approximately 1 million declarations each year (1.1 million in fiscal year 2021) but estimates that when the declaration requirement is

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[1] https://www.federalregister.gov/documents/2009/02/03/E9–2232/implementation-of-revised-lacey-act-provisions

fully implemented, the number could be as high as 12 million per year. Prior to fiscal Year2022, APHIS' annual appropriation for the Lacey Act was $1.9 million. APHIS implemented the program and rolled out the declaration requirement in six phases, starting with raw wood and working towards more processed products. APHIS also worked to implement an electronic filing system for the Lacey Act and to connect it to the Department of Homeland Security's (DHS) Customs and Border Protection's (CBP) Automatic Commercial Environment (ACE) system to allow for more efficient processing of declarations.

The program's annual appropriation supported the development and maintenance of the electronic filing system and staff. Additionally, APHIS works cooperatively with industry groups to effectively implement the declaration requirements, including reaching out to industry ahead of time to learn about the details of their supply chains, storage, and manufacturing processes. The most recent implementation phase; Phase 6 covering wooden pallets and essential oils among other products, was originally to be effective October 1, 2020, but it took an additional 12 months due to issues raised by the pallet industry and the government of Canada. Our lessons learned from Phase 6 show that adding more products to the implementation schedule will require significant outreach to launch effectively, a minimum of 12 months. Accordingly, APHIS will not be able to incorporate additional products by the end of fiscal year 2022.

Question. If your plan is not to complete the full phase in by the end of 2022, please explain why this deadline is not attainable?

Answer. The Agency has a plan to add remaining products in two large phases and appreciates the additional funding provided for the Lacey Act in the fiscal year 2022 appropriation, which will allow the program to expand capacity to handle additional declarations. Phase 7 will include as many non-composite products as possible, including furniture, remaining essential oils, baskets, cribs, and cabinets, among other products. Phase 8 would then include the remaining products, those made with composite materials that include mechanically or chemically broken-down materials such as pulp and paper, particleboard, and fiberboard, among others. Many composite plant materials are currently manufactured in a manner that makes identification of the genus, species, and country of harvest of the plant content extremely difficult and costly. APHIS is continuing to evaluate and address the issues associated with composite products.

QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

NATIONAL ACCURACY CLEARINGHOUSE FOR FOOD AND NUTRITION PROGAMS

Question. As you know, the 2018 Farm Bill established the National Accuracy Clearinghouse (NAC) in order to prevent duplicate receipts of the Supplemental Nutrition Assistance Program (SNAP) in more than one state. I remain concerned about the implementation delay for the NAC.

Can you explain the reasons for the delay and how the Department intends to implement the statute before Congress writes the next Farm Bill?

Answer. Food and Nutrition Service (FNS) is committed to ensuring the NAC is built and deployed with maximum effectiveness for long term program integrity. We take seriously our responsibility to do this in a way that minimizes burdens on participants and delays in benefit determination and leverages optimal security arrangements using the latest and best technology to protect the personally identifiable information (PII) of SNAP participants.

In its original design, the NAC would have stored the names, social security numbers, and dates of birth of all SNAP participants nationwide. While all appropriate security protocols were included in the design, the Department decided to pause development in June of 2021, to explore options to enhance the protections for applicants and participants by revising the technical requirements of the system to a solution that does not store PII. On July 2, 2021, FNS briefed staff for the House and Senate Agriculture and Appropriations Committees on the Department's decision.

The updated NAC system design provides a method for States to de-identify the name, social security number, and date of birth of individuals before sharing this information to the NAC through a privacy-preserving record linkage (PPRL) process. The PPRL process accurately matches individuals, while preventing the collection and storage of PII in the NAC system.

The first four States expected to implement the NAC (Iowa, Louisiana, Massachusetts, and Montana) are already working closely with the NAC project design and development team. These initial adopters of the Nationwide NAC have committed

to making the necessary technical and programmatic changes to implement the NAC matching processes as part of the initial system launch planned for December 2022.

Question. Has the Food and Nutrition Service (FNS) considered allowing States to use the NAC data for other programs such as TANF, Medicaid, and CHIP?

Answer. The 2018 Farm Bill provision that required the establishment of the NAC (Sec. 4011) specified that NAC data shall be used only "to prevent multiple issuances of supplemental nutrition assistance program benefits to an individual by more than 1 State agency simultaneously." Nevertheless, we are mindful that if successful, other programs may want to consider building upon the NAC framework.

DIETARY GUIDELINES FOR AMERICA

Question. The Consolidated Appropriations Act of 2021 required, within 1 year of enactment, the National Academy of Sciences, Engineering, and Medicine (NASEM) to complete a detailed review of the development of the 2020 edition of the Dietary Guidelines for Americans (DGAs), and to provide a report to the Secretary of Agriculture, the Secretary of Health and Human Services and Congress. However, this report is now months overdue.

Regardless, the Departments of Agriculture and Health and Human Services have moved forward in initiating the next 2025 DGA process by proposing scientific questions and calling for public comment without having the benefit of NASEM's review of the 2020 process.

When can Congress expect the full NASEM report, and will Congress receive notice and briefings on it?

Answer. It is my understanding that NASEM will provide Congress with the study's midcourse report on May 18, 2022. NASEM requested an extension to complete the study, and the committee now expects to submit its final report to Congress by the end of this calendar year. NASEM has told us it is their standard practice to offer Congress a briefing on its study Committee's work. USDA is also happy to brief Congress on the midcourse report that will be released publicly on May 19, 2022, and on the final report once we receive it ourselves.

Question. Given the Departments, relevant Congressional committees, the scientific community, and general public have not first had the benefit of learning from the NASEM report on the 2020 guidelines, do you believe it may be premature to move forward with the 2025 DGA process?

Answer. While the DGA is published every 5 years, the work to develop each new edition is a multiyear process. In order to ensure we release the next edition of the DGA on time, as mandated by Congress, we had to begin work when we did, particularly to ensure we have enough time to give the public ample opportunities to weigh in and participate throughout.

The purpose of the NASEM study currently underway is to assess the process for developing the 2020–2025 Guidelines in light of the 2017 NASEM study recommendations. While the current NASEM study will not include recommendations on the process to develop the Dietary Guidelines for Americans, continuous quality advancement is critical to our work, and we'll continue to work towards integrating the recommendations from the 2017 NASEM study into our process as we move forward.

We appreciate the ongoing work by NASEM on this analysis, described in the midcourse report, and look forward to the final report once it is published. This is one of many tools we will use to help support our continuous process improvement and promote science-based decision making across all that we do.

RURAL PARTNERS AND STRIKEFORCE

Question. Rural Partners/Strike Force, the Fiscal Year 2022 Appropriations bill provided Rural Development up to $5 million for the Rural Partners/Strike Force program.

Please provide a detailed budget breakout for the fiscal year 2022 funding, as well as a breakout of the fiscal year 2023 budget request. The information should include a breakdown of FTE costs associated with the proposal (including Salaries/FERS expenses) both at Headquarters and in the field, information technology needs, funding provided to other Federal Agencies/Departments, and funding provided to outside groups.

Answer. The Rural Partners Network is a first-of-its-kind collaboration between Federal agencies and local leaders and residents. This Network is focused on improving social and economic well-being bolstered by existing local partnerships and assets. The Network will launch in selected communities in Georgia, Kentucky, Mississippi, New Mexico as well as certain Tribes within Arizona. Community networks

within these States will receive individualized support with the expertise to navigate Federal programs, build relationships and identify additional resources to promote community-driven solutions.

The table below displays how the funding will be used to support this effort:

Rural Development Rural Partner Network (Dollars in Thousands)		
	FY 2022 Enacted Amount	FY 2023 Budget Estimated Amount
Personnel Costs		
Headquarters	$49	$775
Field Staff	329	8,438
Subtotal personnel Costs	378	9,213
Personal benefits	161	4,147
Subtotal, personnel comp. and benefits	539	13,360
Other Costs		
Travel and transportation of persons	250	3,000
Rental payments to GSA	0	335
IT and non-IT contracts	3,950	15,206
Training	250	1,000
Interagency agreements with other USDA/Federal agencies	0	6,100
Subtotal, Other Costs	4,450	25,640
Total,	4,989	39,000
Staff	17	107

QUESTIONS SUBMITTED BY SENATOR MITCH MCCONNELL

GRAIN STORAGE AFTER TORNADOS

Question. Following the devastating tornadoes that hit Kentucky in December 2021, the FY22 Appropriations bill included report language that instructed USDA to identify funds to build temporary grain storage facilities at public and private inland waterway ports for the 2022 harvest season.

Please provide an update on identification of funds for the FY22 directive for a grain storage facility in Kentucky.

Answer. USDA acknowledges the report language in the 2022 Enacted appropriations; however, we have limited authorities when it comes to providing funding for temporary grain storage facilities. Grain storage facilities are commercial in nature, therefore programs such as Rural Development Community Facilities (CF) programs do not have statutory authority to support such a project since the CF authorities are targeted at essential public services and facilities. Within the Guaranteed Business and Industry Loan program regulation requires projects to meet credit standards, collateral must be adequate, and the term of the loan cannot exceed the useful time of the temporary facility. A short-term project such as a temporary grain storage facility is unlikely to meet those requirements.

I understand that our staff continue to discuss the need on the ground and what the best option could be to support the challenges your producers are facing, given our statutory limitations.

Question. On March 15, 2022, the FY22 Appropriations package, which began in the Democrat controlled House and was supported by all 50 Democrat Senators, became law. At no point did the Biden Administration request the extension of COVID-related USDA nutrition waivers. While legislation to extend these COVID-related waivers carried a cost of $11 billion, several of these waivers can be extended under existing law with no cost.

Does USDA have authority to issue a State-by-state extension of these no-cost nutrition waivers?

Answer. USDA is able to issue waivers on a State-by-state basis under the permanent Child Nutrition waiver authority found in Section 12(l) of the National School

Lunch Act when certain conditions are met, including that the waiver cannot increase the cost to the Federal Government. Therefore, USDA has offered, on a State-by-state basis, some "no cost" flexibilities that were previously available nationwide through COVID-related nationwide waiver authority. In addition, Section 12(l) explicitly prohibits waivers that pertain to nutrition standards, Federal reimbursement rates, and free/reduced price meal eligibility. Given these constraints, Section 12(l), cannot be used to grant a number of waivers that have supported program operators during the pandemic, including:

—Waivers of area eligibility requirements, which allowed summer and afterschool feeding programs to operate anywhere, as well as allow all Child and Adult Care Food Program (CACFP) family day care homes to receive the higher tier 1 rate;

—Operating the Seamless Summer Option during the school year, which allowed schools to be reimbursed at the free rate for all meals served, without having to collect and process applications;

—Offering the higher Summer Food Service Program reimbursement rate for school meals served during the school year; and

—Waivers of meal pattern requirements.

Although USDA has worked hard to expeditiously approve state requests for individual waivers that meet 12(l) requirements, USDA is hearing from our stakeholders that the available flexibilities simply do not address all of the challenges schools and other operators are facing this summer and will face in the fall. For example, without the ability to offer all students meals that are reimbursed at the free rate or the higher reimbursement rates for schools, we estimate that the average school will see a 40 percent decrease in the reimbursements they receive next school year.

In addition, we expect average reimbursement rates for CACFP family day care homes to drop starting July 1, 2022, due to the lapse in waiver authority that allowed some providers to receive higher reimbursements, and many summer meals and at-risk afterschool sites will no longer be able to operate as they are located in areas that are not eligible for participation without the waivers. USDA would need additional waiver authority, similar to the authority provided in Families First Coronavirus Response Act (FFCRA), to address these and other ongoing critical needs.

COVID STATE WAIVERS

Question. Which waivers, and for which States, has USDA approved a no-cost extension in advance of the expected end of the universal COVID waivers?

Answer. As of May 31, 2022, USDA has approved 884 individual State waivers related to COVID–19 using the waiver authority in Section 12(l) of the National School Lunch Act. These approvals reflect the requests submitted by each individual State; therefore, the specific waivers approved vary by State. Waivers approved using 12(l) authority may not increase costs to the Federal Government.

For the Summer of fiscal Year 2022 and School Year 2022–23, waivers include:

Summer Food Service Program/Seamless Summer Option:

—Non-Congregate feeding

—Parent/Guardian Pickup

School Lunch and Breakfast:

—Non-Congregate feeding

—/Guardian Pickup

—Meal Service Times

—Offer Vs. Serve

School Meals Administration:

—Local School Wellness Policy Triennial Assessment

—Food Service Management Company Contract Duration

—Administrative Review Onsite Requirements

Reporting Requirements:

—Second (Independent) Review

—Administrative Review Data

Special Milk Program:

—Non-congregate Milk Service
—Parent/Guardian Milk Pickup

Fresh Fruit and Vegetable Program:

—Parent/guardian Fresh Fruit and Vegetable Program Pickup
—Alternate Site
—Unanticipated School Closures (USC):
—Non-congregate Meal Service during USCs
—Parent/Guardian Pickup during USCs
—Meal Service Time during USCs

Child and Adult Care Food Program:

—Non-congregate Meal Service
—Parent/Guardian Pickup
—Meal Service Times
—State Agency On-Site Monitoring
—Sponsoring Organization Monitoring On-Site

Additional Flexibilities:

—Paid Lunch Equity
—Carryover Eligibility

States requesting Child Nutrition operations waivers include those displayed on the following table:

State Agencies Requesting Child Nutrition Operating Waivers for Summer 2022 and School Year 2022–23 as of May, 2022

State Agency	Total number of waivers requested
Alaska Department of Education and Early Development; (DEED)	20
California Department of Education; (CDE)	19
California Department of Social Services; (CDSS)	5
Colorado Department of Education; (CDE)	19
Colorado Department of Education; (CDE)	21
Colorado Department of Public Health and Environment; (CDPHE)	5
Connecticut State Department of Education; (CSDE)	24
DC Office of the State Superintendent of Education; (OSSE)	26
Delaware Department of Education; (DDOE)	24
Georgia Department of Early Care and Learning; (DECAL)	10
Georgia State Department of Education; (GaDOE)	17
Georgia State Department of Education; (GaDOE)	2
Hawaii State Department of Education; (HSDOE)	20
Idaho Department of Education; (IDE)	3
Idaho Department of Education; (IDE)	3
Idaho Department of Education; (IDE)	2
Illinois State Board of Education; (ISBE)	24
Illinois State Board of Education; (ISBE)	2
Indiana Department of Education; (IDOE)	24
Kansas State Board of Education; (KSDE)	21
Kansas State Board of Education; (KSDE)	2
Kentucky Department of Education; (KDE)	15
Louisiana Department of Education; (LA DOE)	24
Maine Department of Education; (Maine DOE)	24
Maine Department of Education; (Maine DOE)	2
Maryland Department of Education; (MSDE)	23
Massachusetts Department of Elementary and Secondary Education; (MA DESE)	24
Massachusetts Department of Elementary and Secondary Education; (MA DESE)	2
Michigan Department of Education; (MDE)	22
Nevada Department of Agriculture; (NDE)	24
Nevada Department of Agriculture; (NDE)	2
New Hampshire Department of Education; (NHDOE)	15

State Agencies Requesting Child Nutrition Operating Waivers for Summer 2022 and School Year 2022–23 as of May, 2022—Continued

State Agency	Total number of waivers requested
New Hampshire Department of Education; (NHDOE)	2
New Jersey Department of Agriculture; (NJDA)	24
New Jersey Department of Agriculture; (NJDA)	2
New York State Department of Health; (NYDOH)	5
New York State Education Department; (SED)	19
New York State Education Department; (SED)	2
Ohio Department of Education; (ODE)	24
Ohio Department of Education; (ODE)	26
Oregon Department of Education; (ODE)	24
Oregon Department of Education; (ODE)	26
Pennsylvania Department of Education; (PDE)	24
Pennsylvania Department of Education; (PDE)	2
Puerto Rico Department of Education; (AESAN)	6
Rhode Island Department of Elementary and Secondary Education; (RIDE)	23
Rhode Island Department of Elementary and Secondary Education; (RIDE)	2
South Carolina Department of Education; (SCDE)	19
Tennessee Department of Education; (TDOESNP)	19
Tennessee Department of Human Services; (DHS)	11
Texas Department of Agriculture; (TDA)	22
Texas Department of Agriculture; (TDA)	24
Vermont Department of Education; (VTAOE)	24
Virginia Department of Education; (VDOE)	15
Virginia Department of Education; (VDOE)	1
West Virginia Department of Education; (WVDE)	22
Wisconsin Department of Public Instruction; (WDPI)	22
Wisconsin Department of Public Instruction; (WDPI)	24
Total—All Waivers Requested for Summer 2022 and SY 2022–23	884

MEXICO BAN ON GLYPHOSATE

Question. At the end of 2020, Mexico adopted a decree that progressively bans the use, distribution, and importation of glyphosate by 2024. This decree adopted by Mexico violated Mexico's obligations under USMCA. The Mexican government's justification for eliminating glyphosate creates a dangerous precedent and it is vital our trade partners uphold their commitments in trade agreements. Being that Mexico is the second largest market for U.S. agriculture exports totaling $18.4 billion annually,

What has USDA done so far to investigate and help mitigate this violation of the USMCA trade agreement?

Answer. USDA is carefully monitoring Mexico's implementation of the decree and related developments. We have frequently communicated our concerns to Mexican officials. In fact, during my recent visit to Mexico, I personally raised these concerns at the highest level of the Mexican government, and USDA has been working diligently to explore all possible avenues toward a satisfactory resolution.

Question. Is USDA currently working with any other agency to ensure Mexico and other countries uphold their trade agreements?

Answer. USDA continues to work closely with the Office of the U.S. Trade Representative on these issues in Mexico to ensure compliance with USMCA trade agreement commitments.

Question. Last year, USDA announced that $500 million in funds would be set aside to expand meat and poultry processing capacity across the U.S, with $150 million for existing small and very small processing facilities. Kentucky is the largest cattle producer east of the Mississippi River and the eighth most nationally but remains underserved in slaughter capacity.

How will the distribution of these funds ensure that facilities in States with an imbalance of capacity are prioritized?

Answer. USDA recognizes that strengthening the meat and poultry supply chain requires geographic diversity. The scoring process for the Meat and Poultry Processing Expansion Program allows for Discretionary Points which are to be used, as noted in the Request for Applications (RFA), "...for projects to maximize diversity among awards on the basis of geography (including those located in underserved

communities), operation size, species, ownership, and business model." Similarly, discretionary points may be awarded under the new Meat and Poultry Intermediary Lending Program, "to facilitate geographic, species, or project diversity that increases capacity of the supply chain or makes it more diverse, secure, or resilient."

QUESTIONS SUBMITTED BY SENATOR SUSAN M. COLLINS

PFAS IMPACTS TO PRODUCERS

Question. Secretary Vilsack, in response to my question about relief to producers impacted by PFAS, you stated that "you were under the impression you are providing indemnity for livestock in addition to fluid milk." You also stated you "think you have done this" and are "paying farmers for the loss of livestock." Unfortunately, this is not the case in Maine. The Maine Executive Director of Farm Service Agency in Maine confirmed to me that "no DIPP payments [have been made] for livestock depopulated due to PFAS."

While USDA may be willing to provide indemnity for depopulated livestock and has made the regulatory changes that allows the Department to do so, the reality in Maine is that no payments have been made thus far. It is important that the record be corrected on this issue. When will DIPP payments be made to Maine farmers for contaminated livestock?

Answer. I appreciate your continued focus on this important issue for both impacted Maine producers, and those across the country. When I was asked about this at the hearing, it was my understanding that the Farm Service Agency's (FSA's) County and State Offices had received and reviewed a DIPP cow indemnity application, along with supporting documentation, from a producer in Maine, as well as other applications from a producer in another state, which is the first step in this process to begin paying farmers in the Dairy Indemnity Payment Program (DIPP) for the loss of the livestock, or more specifically for a dairy cow contaminated with PFAS. What I was not aware of at the time of the hearing was that the State and County offices determined that the documentation provided by the Maine producer did not substantiate the number of cows for which compensation was requested. The State Office has contacted the producer and provided appeal rights. I am sorry for the confusion I may have caused at the hearing when I stated that we are in the process to begin paying farmers for the loss of livestock. Specific to the timeline you asked about for making the DIPP payments to Maine farmers for contaminated dairy cattle, in this particular case that is dependent on that appeal process and our receiving the appropriate documentation to substantiate the requested compensation level.

Question. Vegetable farmers across Maine are now finding PFAS in their soil and have no program at USDA to turn to for relief. What relief can you provide to these vegetable farmers today? How to you plan to expand the scope of existing USDA programs to serve the needs of all affected farmers, not just dairy farmers?

Answer. The Farm Production and Conservation (FPAC) agencies; Farm Service Agency (FSA), Natural Resources Conservation Service (NRCS) and Risk Management Agency (RMA) are evaluating existing safety net and conservation programs for their applicability to provide immediate or longer-term support to our customers that are directly impacted by PFAS.

Currently, there is no FPAC program that is statutorily designed to address PFAS contamination for agricultural producers. Several key programs that could possibly be utilized include the Conservation Reserve Program (CRP), Farm Loan Programs, Environmental Quality Incentives Program (EQIP), and RMA Multi-Peril Crop Insurance, among others. NRCS is actively developing a new Conservation Evaluation and Monitoring Activity (CEMA) to support PFAS testing in water and soil at agricultural farms that may be contaminated with PFAS, which could be utilized in EQIP and other programs. FSA is actively looking at options and requirements for the establishment of a Conservation Reserve Enhancement Program (CREP) agreement that could be applicable to agricultural producers, which includes vegetable farmers, impacted by PFAS and is also soliciting proposals for research related to PFAS and plant uptake. For crop insurance, by law, PFAS is not currently an insurable cause of loss. However, RMA is reviewing options for providing some relief if PFAS contamination is confirmed.

Finally, because the Environmental Protection Agency (EPA) is leading regulatory actions on PFAS, USDA is working with EPA and other Federal partners to develop solutions and a coordinated strategy for moving forward.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

COVID RELIEF PROGAM IMPLEMENTATION

Question. The COVID–19 pandemic had a dramatic impact on farmers of all commodities and of all sizes. When constructing and implementing relief programs, I respect your goal of making sure they reach the producers who require the most assistance and your use of guardrails to prevent abuse. However, at times, these guardrails can be a roadblock to producers who are in dire need of assistance.

I have heard from several pork producers in Missouri that this problem has occurred with the Spot Market Hog Pandemic Program's exclusion of hogs that were sold on a formula agreement based on spot prices. Were Congress to make funding available, would USDA be able to use a framework similar to SMHPP to make these formula/LMR Code 3 producers whole?

Answer. As part of USDA's Pandemic Assistance for Producers initiative, which has been focused on addressing gaps in previous assistance, USDA created the Spot Market Hog Pandemic Program (SMHPP) to assist producers who sold hogs through a spot market sale from April 16, 2020, through September 1, 2020. If Congress were to provide additional funding to provide relief to a different subset of the hog industry impacted by the pandemic, USDA would ensure it is ready to expeditiously distribute that funding to eligible producers.

RECONNECT PROGRAM

Question. In November 2021, I joined my colleagues in sending a letter to you expressing concern regarding a new policy in USDA's ReConnect Program that would favor broadband grant applicants that commit to net neutrality principles. In my view, this represents a backdoor way to impose heavy-handed net neutrality rules on the industry. USDA should instead be focusing on rural broadband, not politicizing the ReConnect Program and dragging the net neutrality fight into it.

Moreover, the ReConnect program has been criticized for unduly favoring grants for local governments, to the detriment of private broadband investment, and for inadequately coordinating with other government programs, such as the FCC's Universal Service Fund.

Secretary Vilsack, will you commit to focusing squarely on unserved households in distributing the current round of ReConnect funding? To that end, will USDA stop using ReConnect funding to advance partisan priorities like net neutrality, broadband rate regulation, and government-owned networks?

Answer. The third funding round of the ReConnect Program closed on March 9, 2022, and the Rural Utilities Service is currently reviewing the applications submitted. USDA is committed to working to close the digital divide in rural communities and we know this effort is an all-hands-on-deck effort. Acknowledging that, the third round revised the scoring points structure that sought to encourage more partners to join this effort and prioritize the communities with the most need. Seventy out of the total 175 voluntary points possible, 40 percent of those points, were offered for applications that prioritized the most unserved rural communities: 25 points for applications that would serve the least dense rural areas, 25 points for applications that would connect areas without access to 25 Mbps downstream and 3 Mbps upstream speeds, and 20 points for applications that would serve areas with a high economic need. In addition, 15 points, which is only 8.5 percent of the total available, were offered to encourage municipalities and cooperatives to join this all-hands-on-deck effort. To get those 15 points, it is also important to note that a private corporation could collaborate with a municipality or a cooperative to receive those points. Even with this voluntary points structure, the majority of applicants continued to be for profit and private entities.

USDA also offered 10 additional points for applicants that volunteered to practice the principles of no blocking lawful content, no degrading lawful traffic, and no engaging in paid prioritization of content. USDA did not impose these principles, but instead presented an opportunity for applicants to choose these additional points if they so desired.

These basic "net neutrality" principles have been publicly embraced by many large and small Internet Service Providers (ISPs) as a way to ensure that consumers and businesses get the quality service they pay for: full access to the Internet, unhampered by blocking, impairment or degrading of lawful Internet content. The principles also protect competition and innovation by ensuring that an ISP's subscribers are not trapped in a service that favors its own or paid content or services over content or services offered by others. These principals are not partisan priorities, but rather a way to help equip rural America to have the kind of broadband access that is meaningful and that actually can make a difference to these rural

communities that are currently unserved and underserved. Adherence to these principles has proven beneficial to broadband customers, particularly in areas without multiple ISPs, where switching between providers is not an option.

USDA is not involved in broadband rate regulation—that is the realm of the Federal Communications Commission as the Federal authority with the power to regulate the telecommunications industry.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

BILL EMERSON HUMANITARIAN TRUST

Question. Does USDA have recommendations for policy changes that Congress should consider to improve the functionality of the Bill Emerson Humanitarian Trust and make it more accessible in the future?

Answer. Under the current law the Bill Emerson Humanitarian Trust (BEHT) is not triggered until USAID has fully allocated the Food for Peace program funds. USAID makes the commodity selections and also identifies the recipients for the commodities purchased under the fund. The proposal is then sent to USDA for concurrence. Under current law, there is no USDA role in the process relative to the identification of commodities. USAID makes the commodity selections to align with countries that are both in need and where the product would be culturally appropriate, and does not factor in U.S. prices or supply. In addition, as we have seen with the current food security crisis, there are countries that need food assistance, but do not meet the threshold of USAID's emergency assistance programming.

When the BEHT is fully tapped, as it was earlier this year, the current replenishment rate of $20 million per year, may preclude the BEHT purchase of U.S. commodities to meet future global food security needs. As Congress considers reauthorization of the Farm Bill next year, USDA looks forward to engaging in the process to ensure that all USDA programs, including international food assistance efforts are maximized to benefit U.S. farmers producing high quality and nutritious commodities and combat global food insecurity.

COST EFFECTIVE MALNUTRITION INTERVENTIONS

Question. Secretary Vilsack, with over 44 million children on the brink of starvation in the Horn of Africa alone, there is a strong need for proven and cost-effective malnutrition interventions such as ready-to-use therapeutic food (RUTF). I understand that two countries (South Sudan and Ethiopia) have already requested RUTF through the Bill Emerson Humanitarian Trust. Do you support including funding for RUTF via the Bill Emerson Humanitarian Trust, the emergency supplemental package, or annual appropriations process to ensure that this lifesaving product gets into the hands of those who need it most?

Answer. USAID in consultation with USDA has selected Ready to Use Supplemental Food (RUSF) through the BEHT to targeted beneficiaries in Ethiopia and South Sudan. RUSF is designed to treat children ages 6 months to 5 years who have been diagnosed with moderate acute malnutrition (MAM). While RUTF is meant as a meal replacement, RUSF is typically a supplement to other feeding. RUSF treats the low-grade malnutrition that leads to stunting and a multitude of other health problems. It lowers the cost of intervention as a child only needs one packet per day—not three. The BEHT commodity choices are meant to supplement existing food interventions where we have current shortfalls.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE–SMITH

GUARANTEED LOAN PROGRAM

Question. USDA's Business and Guaranteed Loan Program (B&I program) has successfully grown rural businesses, created new jobs, and expanded rural economies for many years by increasing access to capital through loan guarantees. Because of the COVID pandemic and current inflation, more small banks in rural areas are timid to make large financial loans. This, along with the growth in popularity of the program, has rapidly increased the demand for guaranteed loans. Currently, the B&I Program will soon run out of funding, well before the end of the fiscal year, leaving many rural businesses eager to grow with no access to capital. How do you plan to use your authority to ensure the B&I Program is funded through the fiscal year? Are there funds within USDA that can be transferred to

fully support the B&I Program? If so, will you ensure that the B&I Program, which has successfully grown rural economies and local food systems, will be funded by USDA through the fiscal year?

Answer. The budget authority (BA) provided by Congress for the B&I Guaranteed Loan Program, along with carryover BA, will support the authorized lending level for fiscal year 2022 of $1.4 billion. As in any fiscal year, the discretionary appropriation provides a specific funding level for loans and grants. These levels are meant to provide a specific amount of assistance for the program. These are not mandatory programs, and, as such, not funded to meet the annual demand. There are many programs across government where the annual demand is greater than the funding amount available, and the government does not routinely increase these programs mid-year when demand is higher than expected. We consider the program delivery to be successful in carrying out the will of Congress if we are funding the full loan level provided by Congress in the annual appropriation bill. However, we recognize that the COVID pandemic and current inflation rates have put an unanticipated demand on the B&I loan guarantees.

Consequently, USDA is investigating options that will allow additional loan level within fiscal year 2022 to address this. We are hopeful that our efforts prove successful but caution that there is no guarantee that the additional funding will be sufficient to meet the demand for the year, since it is not possible to know what that amount is with any precision.

SUBCOMMITTEE RECESS

Senator BALDWIN. Thank you Mr. Secretary.

And with that, the subcommittee is adjourned.

[Whereupon, at 11:40 a.m., Tuesday, May 10, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

SUBJECT INDEX

DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF AGRICULTURE