

**AGRICULTURE, RURAL DEVELOPMENT, FOOD AND  
DRUG ADMINISTRATION, AND RELATED AGEN-  
CIES APPROPRIATIONS FOR FISCAL YEAR 2025**

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**HEARINGS**

BEFORE A

SUBCOMMITTEE OF THE  
COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

ON

**H.R. 9027/S. 4690**

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2025, AND FOR OTHER PURPOSES

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**Department of Agriculture  
Department of Health and Human Services: Food and Drug  
Administration**

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**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2025**

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**TUESDAY, APRIL 16, 2024**

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

The subcommittee met, pursuant to notice, at 10:03 a.m. in Room SR-124, Dirksen Senate Office Building, Hon. Martin Heinrich (chairman) presiding.

Present: Senators Heinrich, Manchin, Hoeven, Moran, Hyde-Smith, and Fischer.

**DEPARTMENT OF AGRICULTURE**

**STATEMENT OF HON. TOM VILSACK, SECRETARY**

**ACCOMPANIED BY:**

**MR. CHRIS NELSON, ASSOCIATE BUDGET DIRECTOR**

OPENING STATEMENT OF SENATOR MARTIN HEINRICH

Senator HEINRICH. The Agricultural Appropriations subcommittee is now called to order.

And I would like to begin by welcoming Secretary Vilsack. Joining the Secretary is Mr. Chris Nelson, Associate Budget Director for the Department of Agriculture.

We welcome you both here today. And there is no doubt that fiscal year 2024 presented us with many challenges. We had to make some tough decisions, but I made sure we maintained our support for United States Department of Agriculture (USDA)'s vital programs that support American families, farmers, and producers in rural communities. I am not going to sugarcoat things; fiscal year 2025 will come with its own set of complications that we must navigate together, Mr. Secretary.

While we are under austere spending constraints, this subcommittee must ensure that USDA has the resources that you need to fulfill your broad and critical mission. The programs and activities of this Department affect nearly every American, from farmers and rural communities to children and families who depend on programs like Special Supplemental Nutrition Program for Women and Children (WIC) and Supplemental Nutrition Assistance Program (SNAP), to put healthy and nutritious food on the table.

The President's budget request for USDA totals \$25.1 billion, which is an increase of \$2 billion. I am pleased that this budget request maintains our focus on providing tools to producers in rural communities to become part of our overall effort to solve climate change. Of particular importance to me is supporting our conservation programs to help producers be good stewards of our land. We know these programs are vital to managing lands and combating climate change.

While the fiscal year 2024 Budget Bill did not provide all the funding for conservation that I would have liked, I am pleased to see the budget restore these important programs. And I will certainly do everything I can to ensure that conservation is a priority in the fiscal year 2025 Bill. And it calls for increased research and management of Per- and polyfluoroalkyl substances (PFAS) contamination in the agriculture sector, which has impacted many farmers in my home state of New Mexico. I look forward to discussing these initiatives and how this subcommittee can play a role in this critical issue.

We also know that affordable housing has become a major challenge, especially in rural areas. This budget includes needed increases and innovative policy proposals to grow our affordable housing stock in rural communities. This is absolutely essential if we want to ensure that all Americans can access a safe and affordable place to call home.

Another issue of great importance to both of us is ensuring all of our children can receive healthy and nutritious food. Without this, our children cannot learn effectively or thrive. I am proud we were able to fully fund WIC last year, and continue the fruit and vegetable voucher. This will continue to be a priority of mine as we start this fiscal year 2025 process.

It is clear that USDA has many ambitious goals, and I look forward to a robust discussion today. And I want to reiterate my support for drafting a bipartisan bill this year, and look forward to working with the Ranking Member, and all the members of this committee.

And with that, I will turn to our ranking member, Senator Hoeven, for any statement that he has this morning.

#### STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Thanks, Chairman. Thanks for your work. And also, I was pleased that we were able to move our Appropriations Bill for 2024 across the finish line. Albeit 6 months late, but again I think it was a good work product, and I appreciate working with you on it. And obviously, we are already into 2025 as we need to be, but it is important we get it done. And I sure hope we can get it done, you know, closer to on time, but very important that we do get it done. And that takes a lot of bipartisan work.

Mr. Secretary, thank you for being here today, thank you for your work, you know, for many years on behalf of Agriculture. It is incredibly important. And as they say, now more important than ever, appreciate you being here today.

Now every single American benefits every single day from good farm policy. And think about it. And we need to talk about it because so many folks now don't have that nexus to the farm that

they once had. Some of us come out of an Agriculture (AG) background, some of us are still involved—as a matter of fact, we have two cattle ranchers on our panel here, so they not only know it, they live it. But certainly, Jerry and I come from farm country, Kansas, and North Dakota, and Iowa.

But a lot of people figure food comes from the grocery store, you know, and they don't have that nexus to the farmers and ranchers that so many of us once had. And so it is really important to understand that understand when we talk about these farm programs, we are talking about keeping a network of about 16 million people involved in agriculture across this country both directly and indirectly.

A system that is primarily family farms and ranches, and when you look at so many industries that have developed this industry concentration to have that network is incredibly important in and of itself, but didn't think of what it means for every single American, highest quality, lowest cost food supply in the world, with Americans spending less of their disposable income on their food budget than any other developed country in the world. Good grief, we can't take that for granted.

And I know you know that, Mr. Secretary, and that is why it is so important that as we talk about all these programs that are in the Farm Bill, that we are very mindful of the programs that that create that highest quality lowest cost food supply because it benefits all these other programs. When we talk about the nutrition program, or we talk about any of the other aspects of what has become, you know, the largest part of the Farm Bill, we have to understand that if we don't maintain that system of family, farms, and ranches, and it is food, fuel, and fiber now, as you well know, those costs are going to rise.

That affects every other aspect, not only of all of the SNAP programs and everything else, it is going to cost more to provide, and you won't be able to provide as much if we don't sustain those farm programs that maintain that network of family, farms, and ranches. It is truly the engine in the car. And so we have to be mindful, as we look at this budget we have to keep that absolutely in mind, and right now as you know, again, our farmers and ranchers are facing real pressures they are seeing commodity prices that they get go down at the same time that their input costs are going up significantly.

When they look at their fuel cost, and of course that fuel cost drives their fertilizer cost all their other inputs, right, chemical, spray, everything they do, they are getting squeezed this year, we are seeing a significant reduction in farm income this year. Which is why it is so important we maintain these programs.

Along that line, you may have seen that I, along with other members of our AG Committee filed the Farmer Act which is designed to increase support for crop insurance, the number one risk management tool that our farmers and ranchers have. Also the AG research I mean it is just critically important, not only National Institute of Food and Agriculture (NIFA), the industry-based AG research, as well as the Agricultural Research Service (ARS), and they do a tremendous job continuing to support Farm Service Agency (FSA), incredibly important we have talked about that, that

network out there, and having that face-to-face, you know, they can't do it all, they can do a lot on the Internet, but having that face-to-face is incredibly important.

And you know, and we will talk about it here today, we are seeing real pressures on this budget in terms of things like WIC, and some of these other programs, increase of more than a \$1 billion last year, I think a \$700 million proposed increase this year. You know, we have got to talk about that a little bit, and determine how we are going to handle some of these costs, again while maintaining that safety net, that countercyclical safety net for our farmers and ranchers, in this great system of agriculture, so diverse.

I mean every state in the country I think. Boozman has been on a challenge to find a state, if there is one, that isn't involved in agriculture, because he is going to every single state in the country. And he was up in Alaska, and I said well maybe, you know, maybe you finally found one up there that doesn't, but there is something about seaweed, or kelp, or something that they are doing up there. So I think it is safe to say all 50 states have agriculture.

With that, again, thanks for being here today we appreciate it, Mr. Secretary. Thanks, Chairman,  
Senator HEINRICH. Mr. Secretary.

#### SUMMARY STATEMENT OF HON. TOM VILSACK

Secretary VILSACK. Mr. Chairman, Senator Hoeven, and Members of the Committee, thank you very much for the opportunity to be here this morning.

Each year the Department of Agriculture puts out a Rural Development at a Glance, an opportunity to take a look at the rural economy, and determine how things are going. This year's edition of that report has some positive news.

It appears that rural employment is now down, now back to pre-pandemic levels; it appears that the poverty rate is significantly reduced, the unemployment rate is at an historic low in rural America, and in fact we have actually seen a reduction in counties that have been characterized as persistently poor. These are counties that have experienced a poverty rate of 20 percent or more for over 30 years. We had a net reduction of 29 counties out of 260 that have left that characterization.

I raise this just simply to put a focus on the importance of investing in the Rural Partnership Network which is included in our budget. The chairman indicated the importance of housing, and making sure that we continue to support our housing programs. And I would also encourage you as you look at congressionally directed spending in the community facility program that you do so with an eye on those areas of persistent poverty so that we can continue the momentum that we have seen in the last couple of years.

I appreciate Senator Hoeven's comments about research, clearly, we need to continue to look at ways in which we can focus on things like PFAS, Highly Pathogenic Avian Influenza (HPAI), and some of the other challenges that are faced out in the countryside, I appreciate the opportunity to acquaint the committee with the challenges of our ARS facilities, particularly in Beltsville, the need for significant investment there, and the importance of containing

and retaining the flexibility within the Commodity Credit Corporation (CCC), in order to allow us to respond to situations that crop up from time to time.

The most recent example, fertilizer. We are now in the process of funding at least 42 projects that are helping to tamp down the cost and increase in fertilizer. We should also point out that after 3 years of record farm income, the best farm income that we have had in at least 50 years, or maybe ever we, and as Senator Hoeven indicated, are seeing income rates that will likely be closer to historic norms.

We are also seeing, as well, an aging nature of our farm population, and I bring to the attention of the committee concerns that I have about the loss of farms and the loss of farmland. In 1981, Secretary Bergland, as he was leaving office, expressed concern about the changes that we had made in the way in which we supported agriculture from a supply management system to a more market orientation. He expressed concerns that this might result in a significant reduction in farms and farmland. He was absolutely right.

Since he issued that report, we have lost 544,970 farms. Now, to give you a sense of how many farms that is, that is all the farms that exist today in North Dakota, South Dakota, Minnesota, Wisconsin, Illinois, Iowa, Nebraska, Colorado, Missouri, and Oklahoma. We have lost 151 million acres of farmland. That is land that was in farming that is no longer in farming. That is the entire landmass of Florida, Georgia, North Carolina, South Carolina, Maryland, and a good part of Virginia.

I don't think anybody on this Committee, and I don't think anybody in this Congress, in the Senate, or the House, or in this Federal Government believes that that is an appropriate direction for agriculture, which is why we have, for the first time, put together a comprehensive effort to provide support for small- and mid-sized farming operations, in addition to the extraordinarily important productive agriculture that Senator Hoeven alluded to.

We are creating opportunities for value-added products through climate-smart agriculture. We are creating the opportunity for farmers to generate additional income by the sale, if you will, of the environmental results that only farmers can obtain because they have the land that can sequester carbon. They have the operations that can reduce greenhouse gas emissions below net zero, and they have the opportunity to participate in ecosystem service markets, a new stream of income for farm families.

They have the opportunity to convert agricultural waste into a wide variety of bioproducts, the most exciting of which is sustainable aviation fuel that I think we are going to see an explosion of over the course of the next several years, another income source, another commodity, if you will.

We have the ability to take renewable energy, and not only reduce costs on the farm, but also utilize that renewable energy to create a new revenue stream for farmers as well, as they work with their elected co-op, as they work with local facilities to provide less expensive, renewably produced energy. Another commodity, if you will, another income source.

And also sponsoring and supporting local and regional food systems, the ability to expand processing capacity owned and operated independently of the large processing facilities. We have done over close to 400 investments in expanded processing opportunities across the United States, additional investments at the state level, to shore up the supply chain, to create opportunities for non-meat and poultry processing as well. And the reason we do this is because when you go to the grocery store and you put a dollar on the counter, Senator Hoeven is absolutely right, it is the less expensive, as a percentage of income that we spend on food than anybody else in the world.

But the reality is the farmer only gets anywhere from 15 to 20 cents of that dollar. When you sell directly to your customer, as many farmers are beginning to do, they get 50 to 75 cents of every food dollar. So it is an opportunity for us to expand the income base for small- and mid-size farming operations, to begin the process of slowing down, and ultimately reversing the loss of farms and farm families.

I am excited about this budget because it does contain additional tools at FSA to provide assistance and help to farmers who might be struggling. We are looking at increasing the microloan limit, looking at ways in which we perhaps provide less experience requirements in order to access some of our larger loan programs, increasing the ownership loan limits so that we have access for small- and mid-size producers to expand their operation, more flexibility in the amount of down payment that they may be required to provide, and the way in which it is financed, and more opportunity to provide some degree of relief in the form of debt forgiveness, or loan servicing, and allowing a refinancing of debt.

I look forward to the questions from this committee, but I think this is a pivotal time. Senator Hoeven mentioned the Farm Bill; obviously, we are anxious to work with the Congress to get that Farm Bill done. But I think it is going to be important for us to focus, in addition to productive agricultural—production agriculture, on agriculture that also benefits and increases income streams for small- and mid-sized farmers because that is important to rural America.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS J. VILSACK

Thank you, Chair Heinrich, Ranking Member Hoeven, and distinguished members of this subcommittee, for the opportunity to come before you today to discuss the Administration's priorities for the Department of Agriculture (USDA) and to provide you an overview of the 2025 President's Budget.

USDA's work touches every community, and nearly every landscape, across the entire country. Since our founding, the "People's Department" has provided safety nets to farmers, nutrition assistance to some of our country's most vulnerable citizens, support for renewable clean energy, firefighters to keep our communities safe, food safety inspections—and much, much more. It is an honor to lead this department, and I am excited to share with you some of the progress we have made to support America's farmers and ranchers, create opportunity in rural areas, and improve USDA's processes and customer service.

Through the FY 2025 Budget, the Biden-Harris Administration and USDA have embraced a path where the future of American agriculture is secure and where there is greater equity and economic opportunity for agricultural and rural communities. We are now seeing farm income mirroring the stronger economy that President Biden and his economic team have advanced coming out of the pandemic. Farm income over the 2021–2023 period represented the highest level of farm income in

the last 50 years. We saw that the bulk of that income has been driven by the market, namely high commodity prices and the three highest years on record for agricultural exports, and not by farm safety net payments. And while the first farm income forecast of 2024 indicates net farm income this year will return to prior levels that are slightly below these historic levels for farm income, this forecast underscores the critical importance of USDA's ongoing work to help foster prosperity for producers and the communities they love by supporting an economy that grows from the bottom up and the middle out, and by creating new market opportunities that promote competition in the marketplace. At the end of the day, a strong farm economy inarguably contributes to a strong rural economy and makes rural communities a more attractive place to live—and we are doing everything within our control to focus our efforts on enhancing economic resiliency.

As we look forward to FY2025, USDA will continue to focus on policies that add value for farms of every shape and every size as well as ensuring the policies are designed for the real needs of rural America. This includes recognizing the undeniable challenges of climate change and addressing the need for greater equity in our food system. We will continue to draw strength from the USDA Equity Commission final recommendations<sup>1</sup>, because they are a roadmap for ensuring USDA lives up to its name as the People's Department for everyone. There is nothing more foundational to a country's security and stability than its food supply; an inclusive agriculture and rural life is necessary if we want to create more opportunity in this country.

The 2025 USDA President's Budget recognizes the investment Congress has made available through the American Rescue Plan Act (ARPA), Bipartisan Infrastructure Law (BIL), and Inflation Reduction Act (IRA). This investment has allowed USDA to create, not diminish, opportunities for rural communities as well as invest in farmers, ranchers, and small businesses. USDA is delivering on these investments, and the 2025 Budget continues to confront challenges, rebuild the rural economy, and support a new, innovative approach to the future of agriculture. A strong agriculture sector is key to strong rural communities, supporting over 22 million people and 10 percent of jobs in the economy, providing access to essential services like housing, healthcare facilities, and fast reliable internet; it's how we ensure there's safe, nutritious, affordable food on the table for everyone, supporting the more than 10.2 percent of Americans that experience food insecurity<sup>2</sup>; it's how we support and protect forests, grasslands, and farms—nearly 50 percent of this nation's total land mass; and it's how we provide for the communities that depend on them. The proposals in this budget will address these challenges and spur new job creation and opportunities in rural America; support a stronger nutrition safety net; build resilience in the food supply chain and restore America's advantage in agriculture; and leverage USDA's expertise to address climate change.

The 2025 USDA President's Budget request totals \$213.3 billion, of which \$181.7 billion is mandatory funding and \$31.6 billion is discretionary funding to continue advancing the vision to create an equitable and climate-smart food and agriculture economy that protects and improves the health, nutrition, and quality of life of all Americans.

#### REBUILDING RURAL AMERICA

The Biden-Harris Administration's historic investments in infrastructure and new market opportunities have provided USDA with a powerful set of tools for restructuring our food and agriculture economy so small- and mid-sized producers are able to access opportunities to maintain and grow, catalyzing strong rural economies where people have the opportunity and tools they need to build a good life in the communities they love.

It has been said that Rural Development (RD) can build a town from the ground up. However, over the last decade, RD's portfolio has increased 85 percent, but its staffing levels decreased by 30 percent. Recruiting and retaining staff is a critical component in our ability to meet the growing priorities in areas that have a direct effect on our ability to be sustainable, relevant, and results-oriented in delivering much-needed programs and services across rural America. USDA is committed to ensuring we have sufficient levels of RD staff to deliver these vital programs by requesting \$881 million for S&E.

<sup>1</sup>USDA Equity Commission. (2024). Final Report 2024: Recommendations made to the U.S. Department of Agriculture to Advance equity for all. <https://www.usda.gov/equity-commission/reports>

<sup>2</sup>USDA, Economic Research Service using data from U.S. Department of Commerce, Bureau of the Census, 2021 Current Population Survey Food Security Supplement. <https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/key-statistics-graphics/>

Affordable housing has been a long-standing problem for low-income residents in rural communities, one that is exacerbated by low energy efficiency of the aging housing stock which means higher costs to families. The 2025 Budget requests \$1.25 billion for the Section 502 Single Family Housing (SFH) Direct Loan program that will provide over 5,000 low and very-low income rural residents the dream of home ownership. The Budget also provides \$1.69 billion in budget authority for Rental Assistance (RA) to renew 270,158 existing contracts, ensuring that these very low income tenants can continue to live in decent, safe and affordable housing. In addition, the Budget continues to request the authority to decouple rental assistance from USDA financed properties to allow USDA financed properties the option to continue to offer affordable rents when projects reach loan maturity. For paid off properties that do not decouple, the Budget continues to include \$20 million within the HUD Tenant Protection Vouchers, which provides a fully portable voucher for the tenant, reduces duplication across Federal programs, and allows USDA to focus more on its priority mission of preservation.

Improved connectivity through broadband access means rural communities can offer robust business services, expand access to modern healthcare, and improve education. The Broadband ReConnect Program provides capital access for strengthening e-connectivity that broadens economic opportunities and job creation in rural America. Thanks to the President's Bipartisan Infrastructure Law, USDA has provided \$2.26 billion to deploy broadband to people living and working in rural areas across 35 States and Territories, which is expected to expand access to 137,366 households. The Budget requests \$112.4 million in budget authority for the Broadband ReConnect Program to provide service to about 56,000 households. In addition, the Budget continues to include \$35 million for broadband grants to support new or improved broadband access in communities with populations of up to 20,000.

Safe drinking water and sanitary waste disposal systems are key elements to achieving a high quality of life for rural residents. Across the country, there are millions of Americans that lack indoor plumbing and millions more that live in homes that still have poisonous lead pipes. The Budget supports nearly \$1.4 billion in regular direct loans and \$50 million in guaranteed loans to support nearly 450 direct and guaranteed loans for water and waste disposal facilities to provide safe and sanitary water services. Overall, the Budget requests \$785 million in budget authority, which supports a total program level of nearly \$2.1 billion for the water and waste disposal program. Of \$785 million in budget authority, \$639 million are for grant funding for water and waste disposal projects, including grants targeted to Colonias, Native Americans, and Alaska Native Villages.

The Farm Service Agency (FSA) Farm Loan Programs provide an important safety net for producers, by providing a source of credit to producers who commercial lenders may be unwilling to serve. USDA is committed to ensuring that as we administer the Farm Loan Programs, we can provide targeted assistance based on need, reaching everyone who is eligible, and removing the bureaucratic burden on producers. The Budget is projected to support over 32,000 loans to farmers and ranchers by financing operating expenses and providing opportunities to acquire a farm or keep an existing one. Building on efforts begun in the 2024 Budget to connect more producers with the financing they need for successful farm operations, the 2025 Budget continues to propose legislative changes to Farm Loan Programs to ensure more producers would be able to get the financial assistance they need to keep farming and keep the farm in the family. Specifically, the proposals will 1) authorize Direct Farm Ownership loans to be used to refinance debt; 2) make a technical correction to certain special program interest rate requirements; 3) require preferred lenders to obtain FSA approval prior to taking a foreclosure action; 4) expand the lifetime limitation on debt forgiveness from \$300,000 to \$600,000; 5) authorize future loans to those with previous debt forgiveness; 6) give the Secretary maximum flexibility for applicant eligibility for emergency loans; 7) increase the microloan limit from \$50,000 to \$100,000; 8) eliminate the number of years that a borrower can apply for Direct Operating Loan or Direct Farm Ownership loan; 9) revise beginning farmer definition to require individuals of an entity to be beginning farmers without regard to relationship; 10) reduce required farming experience for Direct Farm Ownership Loans from 3 years to 1 year, with a waiver of experience for those who have an established mentorship; 11) correct the historical linkage for Farm Ownership down payment direct loan limit to match the direct Farm Ownership loan limit; and 12) revise beginning farmer lending targets required "to the extent practicable." This suite of changes expands access to farm loans to strengthen agriculture while remaining budget neutral.

To improve equity in rural America, the Budget proposes \$10 million to expand the Rural Partners Network (RPN) initiative, improve leveraging of USDA's extensive network of county-based offices, and continue to help people and communities

in high poverty counties. Through RPN and collaboration with other USDA and Federal agencies, RD has been able to improve its connection with rural stakeholders. 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. It is critical that we ensure that our rural and Tribal communities can benefit from Federal investments as the Biden-Harris Administration delivers unprecedented resources provided through ARPA, BIL, and IRA. We can only expand this innovative work of RPN into more rural communities and additional States if Congress builds on the progress made over the last year and provides additional funding for RPN.

#### SUPPORTING NUTRITION FOR THE NATION

USDA’s core nutrition programs are the most far-reaching, powerful tools available that ensure all Americans, regardless of race, ethnicity, or background, have access to healthy, affordable food. Across America, one in four individuals is served by one of USDA’s 16 nutrition assistance programs over the course of the year. The Budget makes strategic investments to advance nutrition security through education and evidence-based interventions, and to support the purchase of nutritious and local foods.

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 for addressing disparities in maternal and child health outcomes. WIC serves about half of all babies in the United States. The Budget includes \$7.7 billion for WIC in 2025 to serve nearly 7 million low-income women, infants, and children each month in 2025, up from 6.6 million in 2023. This funding request reflects the longstanding bipartisan commitment to serve all projected participants seeking WIC benefits. WIC participation rose rapidly in 2023 across all eligible categories—women, children and infants and further growth is expected in 2025. The Food and Nutrition Service (FNS) is continuing to work to modernize the program through outreach, improving the shopping experience, modernizing technology and service delivery, expanding access to farmers’ markets and investing in the workforce.

The Supplemental Nutrition Assistance Program (SNAP) stretches the food budget for many low-income people and research shows that participation in SNAP reduces food insecurity and allows families to have healthier diets. The Budget requests \$123.3 billion for SNAP, which will serve an estimated average of 41.9 million participants. The Budget also includes \$95 million for The Emergency Food Assistance Program (TEFAP) administration to support soup kitchens and food banks and \$242 million for the Food Distribution Program on Indian Reservations (FDPIR) to improve participant nutrition and provide culturally appropriate foods for an estimated average of 80,000 participants.

Child Nutrition programs, including National School Lunch Program (NSLP), the School Breakfast Program (SBP), the Summer Food Service Program, the Child and Adult Care Food Program (CACFP) Fresh Fruit and Vegetable Program, and Special Milk Program assist State and local governments and private non-profit organizations in ensuring that meals provided to children in schools and child and adult care programs meet their nutritional needs, foster healthy eating habits, and safeguard their health with a goal of reducing the number of overweight and obese children. Summer is perhaps the most challenging time of the year for children at risk of food insecurity because they lose access to daily school meals, and some face structural barriers to accessing summer meals through the traditional programs. To meet the nutritional needs of children during the summer, this Budget requests nearly \$3.3 billion in funding to provide Summer EBT to the approximately 21.5 million children that will participate in 2025. In addition to Summer EBT, USDA administers a suite of child nutrition programs that provide reimbursement to State and local governments for nutritious meals and snacks served to children in schools, childcare institutions, summer sites, and after school care programs. The Budget also requests nearly \$29 billion to serve a projected 5 billion lunches and snacks and 2.7 billion breakfasts in schools, 1.9 billion meals in child and adult care food programs, and 281 million meals through the Summer Food Service Program. The increases will strengthen integrity controls, modernize food ordering and inventory management systems, and provide critical staffing to enhance FNS’s ability to provide technical assistance and oversight of child nutrition programs.

#### CREATING MORE, NEW, AND BETTER MARKETS

USDA works to create more options for producers and consumers and improve the resiliency of our food supply chain. As we invest in new solutions, we must create new and better markets for all producers and consumers and promote a safe,

healthy work environment for agricultural workers. USDA is working to transform the food system, from how food is produced to how it is purchased, in a fairer, more competitive, and more resilient system. These investments will benefit consumers, producers, and rural communities by providing more options, increasing access, and creating new, more, and better markets for small and mid-sized producers. The success of American agriculture hinges on innovation and the development of new markets, both at home and abroad, to ensure everyone has access to affordable nutritious food.

Despite record-breaking farm income in recent years, typically about 7 percent of U.S. farms receive 85 percent of overall farm income, which means 93 percent of our farms share only 15 percent of farm income. We also know that over half of farm households had negative farm income, and 84 percent of farm families obtain most of their income from off the farm. On top of this, farmers are receiving less of the food dollar today than ever before. It's obvious that the system needs to be revisited to find a way to create a system that benefits small and mid-sized farms, expands opportunity, and values their products.

To do so, USDA is increasing market opportunities for producers to sell their products. We are strengthening local and regional food systems and providing producers with more options to market their products. The Budget invests over \$383 million in supporting new supply chains and markets that uplift small and mid-sized farmers through programs such as the Local Agriculture Market Program, Farmers Market and Local Food Production, and Transportation and Market Development, through Agriculture and Food Research Initiative (AFRI) grants and the Gus Schumacher Nutrition Incentive Program at the National Institute of Food and Agriculture (NIFA), as well as through Farmers Market Nutrition Programs at FNS. Investments will also help strengthen supply chain resiliency by improving access to and encouraging consumption of locally grown foods, shortening the food supply chain by supporting direct farmer-to-consumer transactions.

Last year marked the 10th anniversary of the Farm to School Grant Program at FNS, which has awarded more than 1,100 projects totaling more than \$85 million and reaching more than 28 million students in nearly 63,000 schools. These grants play an important role in expanding USDA's farm to school efforts across the country and strengthening the school meal programs. Funded projects increase the amount of local foods served through child nutrition programs and help educate children about where their food comes from. These efforts make school meal programs more resilient in the face of recent supply chain disruptions by building connections within local communities while also creating healthier school food environments and improving student health behaviors. This program also allows producers, large or small, to have additional market opportunities in their own backyard and a chance for their commodities to nourish children in their community. The Budget requests \$12 million in the Farm to School Grant funding in addition to \$5 million in permanent funding to assist in making local food and agricultural education available to child nutrition program participants.

The Budget supports investments to assist in transitioning away from fossil fuels while creating manufacturing jobs across rural America by creating market opportunities in the bio-based economy. The Sustainable Aviation Fuel (SAF) Grand Challenge, in partnership with Department of Energy and Department of Transportation, is meeting the demand to reduce cost, enhance sustainability, and expand SAF production which currently has a high demand. USDA is committed to continuing investments and building expertise in sustainable crop and other biomass production system and supply chains; investing in biomanufacturing capability, workforce development, and community and individual education; and providing outreach and technology transfer to producer's processors. USDA ensures farmers, foresters, small businesses, and rural economies benefit from these opportunities with attention to cost, quality, and quantity of agricultural-based feedstock for producing SAF.

One way USDA promotes the creation and expansion of rural businesses, by providing additional access to capital, which helps to diversify the rural economy, is through the B&I Guaranteed Loan Program. The Budget supports \$2.3 billion in Business and Industry (B&I) loan guarantees, which bolsters the availability of private credit by guaranteeing loans made by lenders to rural businesses. At the average loan level of \$7 million, this request will support more than 300 loans. This program improves the economic health of rural communities by increasing access to business capital through loan guarantees that enable commercial lenders to provide affordable financing for businesses in eligible rural areas.

## RESEARCH AND INNOVATION

This pivotal moment calls for additional investment in research and innovation that influence every program we implement at USDA. Agricultural research has a return on investment of \$17 for every \$1 invested. 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 research and development that often have a less-told story, but we live and reap the benefits of these investments every single day. Production agriculture requires constant innovation and adaptation as farmers and ranchers pursue climate-smart solutions to extreme weather, rural businesses seek new markets, and underserved communities seek trusted partners to tackle systemic concerns.

The Budget proposes a \$3.8 billion investment in our research, education, and economics programs. The Budget includes discretionary funding of \$1.7 billion for NIFA of which \$475 million is for the Agriculture and Food Research Initiative (AFRI). Demand for AFRI's competitive funds grows annually and the awards focus on promoting enhanced profitability and productivity in U.S. agriculture, food and nutrition security, and boosting rural prosperity through a circular economy with support for clean energy technologies, climate-smart agriculture and forestry, and education and workforce development. An additional \$1.8 billion for the Agricultural Research Service (ARS) includes increases from 2023 of \$17 million in support of the Cancer Moonshot, \$13 million for the operations and maintenance of the new National Bio and Agro-Defense Facility, \$13 million for climate science and monitoring greenhouse gas emissions from agriculture, and \$17 million for additional high priority investments. These funds enable ARS to find solutions to agricultural problems that affect Americans every day from field to table. This is done through the delivery of cutting-edge, scientific tools and innovative solutions for American farmers, producers, industry, and communities to support the nourishment and well-being of all people; sustain our Nation's agroecosystems and natural resources; and ensure the economic competitiveness and excellence of our agriculture.

Science and research are our best defenses to protect our resources against the climate crisis. The changes in our environment have allowed invasive plants, pests, and diseases to move around the world more easily and become established in new areas. Without the tools and sufficient resources to protect ourselves against invasive species and safeguard the health, welfare, and value of American agriculture and natural resources, our farmers and our economy will suffer.

## TACKLING THE CLIMATE CRISIS

Producers and land managers across the country are experiencing real and increasing threats from climate change that have serious implications-not just for farmers, ranchers, and forest landowners- but also for surrounding communities and all Americans. In 2022, nearly 80 percent of the western region experienced extreme drought, wildfires burned over 7.6 million acres of our forestland, and communities across the country are dealing with the impacts of severe flooding and record snow fall exacerbated by climate change. Agriculture has a critical role in delivering climate change solutions and our Nations farmers, ranchers, and foresters are already leading the way through the adoption of voluntary and farmer friendly incentive-based climate-smart agricultural and forestry practices.

Through the Conservation Technical Assistance (CTA) Program, the Natural Resources Conservation Service (NRCS) provides landowners and managers with the knowledge and tools they need to develop conservation plans to implement specific conservation practices needed to improve farm operations and conserve, restore and maintain the natural resources on their lands. The Budget requests \$985 million for Private Lands Conservation Operation, of which almost \$870 million is for the CTA program. An additional \$30 million in CTA funding will be used to continue Equity Conservation Cooperative Agreements, which support historically underserved farmers and ranchers with climate-smart agriculture and forestry, will bring in additional new customers to work with NRCS. In 2022, NRCS offered \$50 million in funding for Equity Conservation Cooperative Agreements. Two-hundred fifty applications were received requesting \$202 million, of which 117 agreements were funded for \$49 million. In 2023, NRCS offered \$70 million in funding. Three hundred applications were received requesting \$210 million, of which 139 were selected for funding for \$69.2 million.

The Budget supports the USDA Climate Hubs, a cross departmental effort to provide technical assistance in tackling the climate crisis, expanding USDA's ability to develop and deliver science-based, region-specific information and technologies. The Budget requests an additional \$14 million from 2023 for the Climate Hubs to support the adoption of climate-smart practices. Investments will assist farmers, ranchers, and foresters make region specific climate-informed decisions and provide technical assistance to implement those decisions.

#### REBUILDING USDA THROUGH DIVERSITY, EQUITY, AND INCLUSION

Building a better USDA means bringing people of all backgrounds and lived experiences to be a part of a healthy, safe, and inclusive workplace. This includes ensuring we are recruiting the best and the brightest across our great country, and investing in our employees through recognition, wellness programs, and support to our employees. Building a better America is about ensuring all 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 2025 Budget focuses on building a USDA that is a model employer and 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.

It's an honor and a privilege to have the dedicated and talented staff of over 100,000 employees supporting USDA. However, the historic lack of investment throughout the Department over the years has resulted in a decline in staffing that we still struggle to recover from and has meant that we have not had the necessary resources to modernize critical IT systems or make other improvements to the way we do business here in USDA in support of rural Americans. USDA appreciates that Congress broadened the purpose of the Department's Non-recurring Expense Fund to address both facilities and information technology needs. For IT systems alone, USDA is projecting a FY 2025 need of at least \$190 million for modernization of our platforms to best serve the public accessing USDA programs. As USDA reimagines and transforms the way it delivers its mission and services to the American public, it must also invest in IT modernization to address vulnerabilities in government legacy systems to ensure those services are provided in an effective, efficient, and secure manner.

USDA is committed to not only hiring, developing, and advancing a workforce that truly reflects America's rich and diverse characteristics, but also to creating an inclusive workplace environment so that everyone can rise to their highest potential and flourish in supporting our mission. We are committed to making USDA the best place to work so that we can attract and train the best and the brightest in the field of agriculture. The need for growing the next generation of professionals is timely and important and this funding is aimed at attracting, inspiring, and retaining diverse and talented students at eligible minority-serving institutions for careers in food, agriculture, and related disciplines, with an emphasis on Federal Government sector employment. The Budget requests \$365 million directly invested in Minority Serving Institution (MSI) programs to fight against the historic inequity in access to higher education. Partnerships with MSI programs support capacity building initiatives, education, and pathways to employment for students and faculty and help develop a strong pipeline of talented individuals for USDA and USDA partner jobs. These capacity-building funds will bolster the impact of the recently announced Inflation Reduction Act program "From Learning to Leading: Cultivating the Next Generation of Diverse Food and Agriculture Professionals (NextGen)". This historic \$262.5 million investment supports 33 projects across 24 States and competitively established six HBCUs as NextGen lead institutions. NextGen projects are led by HBCUs, TCUs, Alaska Native-serving Institutions and Native Hawaiian-serving Institutions, HSIs, or institutions of higher education located in the Insular Areas. Working with 60+ MSI partners, projects will provide training and support to more than 20,000 future food and agricultural leaders. These investments in future agricultural leaders will help USDA attract the best and brightest to face the growing challenges of the agricultural economy.

#### CONCLUSION

If we are going to create an agriculture system that works for the many and the most, I believe the answer is a holistic approach. Not one focused just on bushels per acre, but one that also measures success as rural families being able to pay their bills, preserving our lands, and making their communities a place our children and grandchildren can call home. Producers of all kinds should be able to make a living and support their families through farming, not just those with the biggest operations. As decision makers in USDA and Congress, we should use the market,

climate-based tools, and food systems to create new income opportunities and value for producers and rural communities. This budget is not a wish list; rather, it is a to do list to fulfill the items that Congress and USDA have been talking about fixing for decades. It is a plan for what we need to do to continue to get USDA back on track and to help the U.S. outcompete the rest of the world. USDA needs the support of this subcommittee and of Congress to make the much-needed investments called for in the President's FY 2025 Budget. I look forward to working with this subcommittee and to answering any questions you may have about our budget proposals.

Senator HEINRICH. Mr. Secretary, I appreciate your response to my recent letter regarding ready-to-use therapeutic foods (RUTF). Can you talk a little bit about what more the Department can do to provide RUTFs as an option within the food aid toolbox? What authorities you may need, and talk a little bit about the incredible impact that ready-to-use therapeutic foods can have on malnourished children?

#### READY TO USE THERAPUIC FOOD

Secretary VILSACK. I think, Mr. Chairman, the distinction is between trying to address malnutrition as it exists today in an emergency circumstance versus a longer-term commitment to increase food security in nations that are challenged. Our programs are primarily through the Food for Peace Program. Our progress programs are primarily focused on the latter. USAID's efforts are focused primarily on the former. So we work collaboratively with USAID to ensure that our resources are utilized in a proper way.

The use of CCC, in this particular circumstance, provided us an opportunity to double down on the latter. But because of the nature of the charter, the new CCC charter, we were not able to, essentially, utilize any of those resources for the packets. We are advised that because of what we are doing with the CCC, we are creating greater flexibility within USAID, and I would suspect and anticipate that in the very near future, you are going to see a significant commitment from USAID on the use of those packets.

So it is a combination, it is a partnership. I mean, I think you could look at changing the CCC, but I think it is probably better to adequately finance the Food for Peace and Food for Progress programs and encourage USDA and USAID to continue working collaboratively together.

#### BISON PRODUCTION

Senator HEINRICH. Can you talk a little bit, give us a little bit of an update on implementation of the two bison production-related provisions that were in the fiscal year 24 Bill related both to inspection fees for processing and then also production and marketing?

Secretary VILSACK. As Senator Hoeven pointed out, that bill just passed recently, and so we are in the process of taking a look at trying to better define what a Native American establishment and institution is, so we know where that resource and that assistance needs to be directed. We are engaged in consultations this week and next week with tribes in an effort to discuss self-determination as it relates to processing, and as you know, we are investing resources under the American Rescue Plan (ARP) in expanded processing capacity.

So I think you are going to continue to see us work collaboratively with tribes. I think you are going to continue to see us work in a way that will dovetail and parallel what we do with states where we basically try, I think we can, to pick up roughly 50 percent of the cost. I think you are going to see that kind of arrangement discussed with the tribes, and hopefully we reach a consensus on steps forward.

Senator HEINRICH. Thank you. I was glad to see the Western Water Framework announced by Natural Resources Conservation Service (NRCS) last year. This as a foundation to build on, how is USDA planning a sort of all-of-department approach to tackle the western drought resilience challenges that we have from, you know, large-scale upstream watershed restoration, all the way down to small-scale on-the-farm kind of measures?

#### WESTERN DROUGHT RESILIENCE

Secretary VILSACK. The Western Water and Working Lands Initiative is an initiative focused on six strategies, thirteen different ways in which we approach preserving groundwater, surface water, focused on preserving rangeland, pastureland, agricultural productivity, and the tools to do so.

In fiscal year 2023, we invested \$1.9 billion across a variety of programs within USDA. You saw aggressive use of Environmental Quality Incentives Program, Conservation Stewardship Program, Regional Conservation Partnership Program (EQIP), (CSP), (RCPP) within the NRCS. You saw research being conducted at ARS as well as grants in NIFA. So it is an extensive effort on our part to try to address and to provide tools for farmers, ranchers, and producers to be able to address concerted issues.

And I think we work collaboratively with our partners in the Federal Government, in an interagency effort focused on everything from storage to more conservation and better utilization of the scarce water resources we have.

Senator HEINRICH. This will be my last question for you, Mr. Secretary, and then I will turn it over to my colleague. But we know affordable housing has become just such an enormous challenge across my state and many states across the country. Can you talk a little bit about how USDA is planning to implement the decoupling of rental assistance from the multifamily loan program that was included in the fiscal year 2024 bill?

#### RENTAL ASSISTANCE

Secretary VILSACK. First of all, I express appreciation for the Senate and the House providing us this tool. We have identified approximately 1,700 units between this year and next fiscal year that will become available that could potentially be incorporated in that program. I think you will see roughly 600 units this year, and 1,100 units, potentially, next year depending upon what decisions you make in reference to a decoupling. You have instructed us up to 1,000 units. We might suggest maybe going to 1,700.

Senator HEINRICH. Great, fantastic. Senator Hoeven.

Senator HOEVEN. Secretary, I want to pick up on, you know, the loss of farms concerns me greatly, that you referenced and actually it is more than I realized. You and I have talked about this before,

but you brought it home pretty dramatically in your opening comments. What is most effective, in your opinion, to stem that tide?

#### LOSS OF FARMLAND

Secretary VILSACK. I think it is a combination. Senator, I think first and foremost, you obviously have to have a safety net to try to keep people on the farm, which goes to the loan programs, it goes to crop insurance and the risk management tools that you know so much about. But I think it is also expanding markets.

I think it is important for these small- and mid-size producers not to have a single commodity-based income stream. I think they have to have a stream that is climate-related. I think they have to have a stream that is ecosystem service-related. I think we have to encourage more conversion of agricultural waste into a variety of products instead of over-application in many parts of the country.

I think we need to continue to strengthen our local and regional food system, because they get a better bang for the buck. I think we need to continue to look at concentration and do what we can to provide more independently owned, maybe farmer-owned processing. So it is a combination of safety net and markets.

Senator HOEVEN. So I agree, we work on all those things in Iowa, and North Dakota, Kansas, across the country. So I agree with those. In terms of crop insurance, the countercyclical safety net crop insurance, are there some things that ought to be included in those things as we look at the Farm Bill that you think would go at this problem?

#### CROP INSURANCE

Secretary VILSACK. Well, I think we need to continue to look for ways in which we can expand coverage, more products, more crops basically being covered. There is still not everything that is grown and raised in this country has the same level or opportunity. We have had 12 new products and 50 modifications to existing policies. I think we need to do more of that.

I think we do need to take—and you know there is a conflicting set of messages coming out of this Capitol on crop insurance, there is some who in your circumstances suggesting an increase in commitment from the Federal Government so that the farmers have to pay a little bit less for more coverage. Then there are some folks on the House side who are suggesting significant reductions in that safety net. I think we need perhaps some consistency in the approach here, would be helpful.

Senator HOEVEN. Well, we prefer our approach.

Secretary VILSACK. Well, I am sure you do, but there are 166 Members of the House Republican Caucus that feel that crop insurance should be cut.

Senator HOEVEN. Well, it seems to me as we look at this Farm Bill, crop insurance, countercyclical safety net, access to credit, beginning farmer, those kind of programs, some of the livestock programs, we actually want to make more consistent and dependable, whether it is, you know, livestock forage, livestock indemnity, emergency livestock assistance, where you know, like the on the

farm side it is more dependable, these ranchers, particularly the smaller ranchers the one starting up.

I think as we look at the Farm Bill, those things, we have to take into account, those numbers that you just laid out, and think about our programs and make sure we are getting the job done.

Secretary VILSACK. You do, but I think if you only do that—

Senator HOEVEN. Not only that, yeah.

Secretary VILSACK. If that is all you do, that is not—that is half-way.

Senator HOEVEN. Right, which is why I asked you—we have always had a surplus in AG trade, we have a deficit right now in AG trade, back to your comment about markets, right?

Secretary VILSACK. Well, there is a reason for that.

Senator HOEVEN. High dollar is one.

#### AGRICULTURAL TRADE

Secretary VILSACK. Well, high dollar, strong dollar no doubt, the economy worldwide that is not as strong as the U.S. economy, however, this is an interesting statistic, maybe it is just coincidental, our trade deficit for the first 3 months of fiscal year 2024 was \$6 billion, bought \$6 billion more than we sold. China purchased \$6 billion less.

Senator HOEVEN. I knew that is where you were going, yeah, coincidence no. Right?

Secretary VILSACK. Well, look, if you continually rap your number one customer it is not surprising that your number one customer would send you a signal about, hey, we are paying attention. So what has to happen I think is a much more nuanced and sophisticated conversation about China.

You know you mentioned family farms, what is at greater risk, Chinese ownership of farmland, or the fact that Wall Street and investment banks own a third of the largest farm operations in the country, 50,000 farms or so, owned by investors not by farm families; which is a greater risk?

Senator HOEVEN. Let us say we do on the trade front but, again, we do on the trade, I think there is both trade barriers, and non-trade barriers, that we have got to knock down, and we have got to be tougher there. What do we do?

Secretary VILSACK. I can give you a list of \$20 million of trade wins we have had, they are doubles and singles, they are not home runs, but they are the cumulative impact and effect is important. The Regional Agricultural Promotion Program (RAPP) program that we initiated at the request of Senator Boozman and Senator Stabenow, is important because it expands our opportunity to diversify, more people, more presence, more promotion, and more opportunities for trade missions, you are going to see that. More emphasis in Africa, and Southeast Asia, moving away from the over-reliance on China, I think that is an important consideration.

Senator HOEVEN. Okay. Well, I have used my time up. I will come back with some other questions in the next round. Thanks, Mr. Chairman.

Senator HEINRICH. Senator Fischer. That is what you get for showing up on time.

Senator FISCHER. Well, my colleagues here, I would love to bump them. Senator Moran followed me, and before the gavel.

Senator HEINRICH. Senator Moran.

Senator FISCHER. So now you owe me, Jerry.

Senator MORAN. So now, I didn't come out ahead on this deal.

Secretary Vilsack, thank you. My expectation is that I need a couple of rounds for questions, so I am happy to take this beginning. First of all, I appreciate your leadership in agriculture. I appreciate the relationship we have had for a long time. I want to highlight the importance that I see in the consideration and ultimate passage of a Farm Bill. I am disappointed that there is a pause taking place and it seems to be that there are those in the Senate who believe the current Farm Bill is satisfactory, it meets their needs.

I also recognize the challenges that would exist in the House in trying to pass a Farm Bill as well, so there is plenty of responsibility here that needs to be met, but it is the first time in, I don't know, I have been maybe through four Farm Bills, been on the Conference Committee for two or three of them. It is the first time that I have ever seen that we voluntarily decide that we can't get a Farm Bill done.

And you outlined the challenges that producers face, and I don't expect you to respond to this, but I did not want the moment to pass without again asking the Senate leadership of the AG Committee, and the leadership of the Senate, to reemphasize and refocus on getting a Farm Bill done. I have a lot of interest in trying to deal with drought and water issues in the Farm Bill, conservation practices.

On the farm income, you predicted, the USDA predicted it would be down 43 percent in the last 5 years since the last Farm Bill input costs are dramatically rising, have risen, and so I don't want us to walk away from this.

Mr. Secretary, about a year ago we were in Manhattan Kansas, cut a ribbon on the National Agro-Bioscience Research Facility, its importance becomes it is more evident all the time? Would you update me and the committee on the transition activities, and the mission transfer from Plum Island to Manhattan?

#### NATIONAL AGRO-BIOSCIENCE RESEARCH FACILITY

Secretary VILSACK. The official transfer from the Department of Home Homeland Security to USDA has occurred, and we are in the process now of, as you say, moving select agents and other matters from Plum Island to Manhattan, Kansas, and we are doing this in a very thoughtful, and very careful, and a very systematic way. I am pleased with the progress that we have made so far. I anticipate more progress being made this summer and this fall, and I think we are going to be significantly operational by the end of this year.

Senator MORAN. Any challenges, workforce or otherwise that you need help with?

Secretary VILSACK. Well, there is always the issue of budget Senator, this is a state-of-the-art facility that is unique, and so when things don't work, and you have to get them fixed, or you have to get them repaired, or you have to get them replaced. There is a sig-

nificant expense because of the level of security that we now have in this facility. But I am confident that we have got the workforce that is dedicated to the mission, and that we are going to help American agriculture and the country.

Senator MORAN. In fiscal year 2024 we appropriated the President's request; we will work to do so in fiscal year '25. Staying a bit on this topic, I recently visited with the Kansas Department of Agriculture, its Secretary, and staff of the Animal Health Commissioner, USDA Regional Veterinary Director, and livestock producers throughout Kansas.

Mr. Secretary, what we are talking about is H5N1, and it has spread to mammals; can Animal and Plant Health Inspection Service (APHIS) through, either its contingency funds or emergency response work with land grant and diagnostic labs that have the expertise in livestock management and biodefense to make funds available to research H5N1 that could either treat infected animals or develop the therapies that stop the spread, or mutation of the current strain?

#### H5N1

Secretary VILSACK. I think that work is already underway.

Senator MORAN. With any success that you could report or challenges you would face?

Secretary VILSACK. Well there are significant challenges from a scientific perspective, but you know we are going to continue to work on them, and we hope that within 12 to 18 months we are in a much better place than we are today. It is going to take time, you have got to match the virus, if you are looking at vaccines you got to match the vaccine to the virus, you have to make sure that there are markers that can distinguish, especially in poultry, between diseased birds and vaccinated birds.

You have the trade implications, I mean it is a pretty complicated question it doesn't lend itself to a five-minute question and answer.

Senator MORAN. I would be glad to have a long cup of coffee with you.

Secretary VILSACK. Sure.

Senator MORAN. On that topic, and then I will save my other questions for the next round, if there is one. What is the status of scientific study on the H5N1 threat to new mammals? And what are you seeing in trade implications to date?

Secretary VILSACK. We have made a concerted effort to reach out to our trading partners, and so far I think there has been an understanding and appreciation for the amount of information we have provided our trade partners, we have seen very little restriction, if you will, a couple of countries expressing concerns, but for the most part our trading partners understand that we are on top of this, that we expect and anticipate our dairy cows to recover, that our milk is safe, and that is very, very low risk to people.

Senator MORAN. We are going to continue to do a lot of research on this, so that we understand and appreciate the transition and transmission of this. We know that there is heavy virus in the milk, we know that that milk when it is pasteurized it is safe. But there may very well be a circumstance and situation where we

need to be ever vigilant, in terms of biosecurity especially around the milking parlor, in terms of having access to what may be virus filled milk that in turn can be transitioned.

We also have facilities that are both poultry and dairy, we want to make sure that the transport between those two is very carefully thought through, because there can also be biosecurity issues there.

Senator MORAN. Kansas has become such a dairy state Mr. Secretary. And thanks to Senator Fischer. Thank you Mr. Chairman.

Senator HEINRICH. Mr. Secretary, please keep all of us up to speed on this issue, because it is something I think everything single member of the committee is following.

We are going to continue the tradition of order of arrival. So we are going to go with Senator Fischer, and then Senator Hyde-Smith.

Senator FISCHER. Thank you, Mr. Chairman.

Secretary, it is nice to see you again. In fiscal year 2024 I was glad to secure \$25 million toward USDA's ARS National Center for Resilience and Regenerative Precision Agriculture to be collocated at the University of Nebraska-Lincoln. And I am excited that we will be holding a groundbreaking in a few weeks alongside some of your leadership at USDA, and I look forward to continuing to work with USDA on that facility and to advance that very important technology.

I also want to discuss the USDA Meat Animal Research Center at Clay Center (USMARC), Nebraska. As you know, livestock is the largest segment in the—for agriculture in Nebraska. I was glad to see the budget request included a request for additional employees at USMARC, in Clay Center. Your ARS budget request also highlighted some of the important advancements that USMARC has accomplished such as a development that could protect cattle from Bovine Viral Diarrhea (BVD), which is estimated to cause annual losses of \$1 billion in the United States alone.

So Mr. Secretary, could you discuss how that increase staff at USMARC can help carry out research related to critical livestock industry priorities including increased environmental sustainability, improved production efficiencies, and optimized use of natural resources?

#### MEAT ANIMAL RESEARCH CENTER

Secretary VILSACK. I think the easiest way for me to answer that question is to suggest that we will approach these challenges in the same way we approach all challenges relative to agriculture, and that is in a cooperative and collaborative way, working not just with the university, but also working with those who are directly impacted and affected by the research.

Critically important to any of this, is the cooperation of producers, and producers are in the best position to inform us as to where they think priorities should be, and we should be responsive to those priorities, and the research should be driven, in part, by virtue of those priorities. It should also work in concert with the research that we are independently investing in through our National Institute of Food and Agriculture, as well as the private foundation that was established in a previous Farm Bill.

So we have a comprehensive approach, a coordinated approach so that we are not basically spending \$2 when \$1 will do. So I think it is a collaborative approach, it is a cooperative approach, and it is a comprehensive approach.

Senator FISCHER. Have you seen that approach at Clay Center, working with producers in Nebraska?

Secretary VILSACK. I have seen that in ARS facilities across the United States. I haven't had the opportunity to specifically visit that particular Center, but I would be surprised if that is not the way in which they are approaching their business, because that is the most successful way to do their business.

Senator FISCHER. I have heard very positive things about the center obviously our AG producers, our beef producers are extremely aware of the value that that Center has, not just for the state of Nebraska, but across this country as well, so I thank you for the interest there.

I also believe it is important to maximize the funding that broadband programs are receiving, and to get Broadband to unserved areas in order to do that I think it would make sense that we have one data source that we can rely on about where broadband is and where it is not.

Can you share how the USDA tried to promote a more consistent challenge process comparing what is used by rural utility service versus what is used by the Federal Communications Commission (FCC), in connection with the national broadband map, and has USDA considered measures to improve transparency or challenges by publishing written reason, decisions on those challenges?

#### BROADBAND ACCESS

Secretary VILSACK. When we received the resource under the Bipartisan Infrastructure Law (BIL), the White House convened the FCC, the Department of Commerce, and the USDA, and expressed concern for collaboration and cooperation between the three entities. We made the decision that we would try to get our resources out under the ReConnect Program as quickly as possible, which we have. We have obligated those resources. We will continue to make announcements for the rest of this year, where roughly 320 projects will be funded.

And the location, scope, and the nature of those projects were provided to the FCC and the Department of Commerce so they, in turn, could take that into consideration as they made decisions concerning the allocation of a far greater amount of money that they received. They, in turn, provide to the states to encourage the states then to make the necessary changes to ensure that we do, in fact, ultimately have access to decent Broadband everywhere in the country.

Senator FISCHER. Right. And you know, being able to have that accurate mapping is extremely important, and that, again, takes cooperation, collaboration not just from providers but their customers as well to be make sure it is accurate.

Secretary VILSACK. You know, I think states were given an opportunity to weigh in, and hopefully Governors understood the importance of that, and I am sure they did.

Senator FISCHER. Okay. Thank you.

Senator HEINRICH. Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman.

And thank you, Mr. Secretary, for being here. Good to see you again. I first and foremost want to thank you so very much for the work and helping me address the pine beetle disaster in Mississippi when we had that tremendous drought. It really affected our timber in softwood in Mississippi. And as you know, forest landowners and homeowners across the state have just been devastated by this pine beetle infestation.

And due to the problem Mississippians are facing, just enormous economic hardship and risk such as forest fires, and trees falling on their homes, power lines falling on the roads. I mean, it is really significant in our state, with this that I don't remember happening in a very long time.

But yesterday the national FSA Office announced the Emergency Forest Restoration Program (EFRP). The sign-up was beginning, they announced yesterday for all 82 Mississippi counties, and this was much quicker than we anticipated, and I am grateful that you made it happen quickly following our conversation at the last Senate AG Committee Hearing just a few weeks ago. It has been very helpful. And I am relieved that the forest owners will have some access to the funds for costs associated with the commercial thinning, the fire breaks, and the debris removal.

I think everybody in my church has had a tree down on their house or close to it, from attending church and listening to all the concerns. But even driving the interstates throughout the state, it is really affecting us.

But however, there is still a long road ahead of getting Mississippi forest landowners, homeowners, and municipalities back on their feet. And I am continuing to explore multiple angles to assist them. The Emergency Forest Restoration Program Authorization is certainly a huge step forward for landowners, and I want to make sure as many eligible Mississippians get help as soon as possible. That they know they are supposed to go sign up, where to go sign up, so I just want to ask you for your commitment to continuing to help me with that, and help ensure a smooth sign-up process for my constituents.

So many times they will go to the office and they will say, it was so complicated, or I didn't get the right help. But I am just asking for your commitment to continue to do that.

#### EMERGENCY FOREST RESTORATION PROGRAM

Secretary VILSACK. Senator, you have that commitment, and I think you can take some credit for the early sign-up, and for the fact that we extended the sign-up period, traditionally 60 days, in this case, it is 120 days.

Senator HYDE-SMITH. Thank you so much. We have gotten a lot of calls. Now, I am going to switch to the Veterinary Medicine Loan Repayment Program, and last year's budget hearings we discussed this program, an important program that provides awards to help offset the educational loans of veterinarians who agree to serve in USDA designated rural veterinary shortage areas, which is very critical.

I also mentioned the significance withholding tax applied to these awards, which diminishes the effectiveness of the program. You know, we give out these great awards, and then they have to turn around and give so much of it back to us in those taxes, but the Explanatory Notes accompanying your 2025 budget request for the National Institute of Food and Agriculture proposed legislation to end the withholding tax on these awards. And I truly appreciate your drawing attention to this issue.

Would you just, because it is in so many states, that this is effective, would you share with the subcommittee how burdensome this withholding tax is and how eliminating it would free more resources for your Department to help address the rural veterinarian shortage?

#### VETERINARY MEDICINE LOAN FORGIVENESS PROGRAM

Secretary VILSACK. Well, it costs roughly \$200,000 to get that veterinary degree, and most of the folks who are getting it are not in a position to, basically, put that kind of cash into their career, so they have to borrow it. So anything that provides help and assistance or anything that diminishes that help and assistance, obviously, is something we do need to be concerned about.

Frankly, the Veterinary Loan Forgiveness Program, as good as it is, probably could be better, and with tight budget concerns and considerations, we did the best we could. And one way to make it better is to make sure that it isn't reduced by the tax, and we would hope that that we get some direction from all of you that gives us the ability to go to our friends at Internal Revenue Service (IRS) and essentially say that this shouldn't be a taxable event.

Senator HYDE-SMITH. Yeah. Well, I certainly appreciate your approach to that because the shortage in rural areas is so significant. And we are talking our food supply here.

Secretary VILSACK. Absolutely.

Senator HYDE-SMITH. And we want healthy animals. So thank you so much for that.

Senator HEINRICH. I am going to go back to Senator Moran for his second round.

Senator MORAN. Thank you for your kind consideration this time. Mr. Chairman, thank you.

Senator HEINRICH. I am so tough on you, Jerry.

Senator MORAN. Mr. Secretary, Final Rule on WIC Program, I am concerned, and I am pleased and you have expanded the access to fruits and vegetables, but you have diminished the availability of dairy; not true?

#### WIC PROGRAM

Secretary VILSACK. No, sir.

Senator MORAN. That is good to know because we specifically directed, there was an agreement in increasing the—in the Appropriation Bill, there was a direction in the lease report language not to reduce that. So maybe just explain to me, what the rule is on WIC?

Secretary VILSACK. We did reduce the commitment to fluid milk, and the reason we did is this is a supplemental program. We were basically providing 120 percent of the average daily milk consump-

tion under the previous WIC rule, so we reduced that down to 78 percent, so consistent with the supplemental nature of WIC. Having said that, we also made the packaging for other dairy products, like yogurt, easier, so the expected anticipation is that more dairy is going to be consumed as a result.

In addition, we are seeing an increased number of participants in WIC, so we expect and we project that roughly 130 million more quarts of milk will be sold in the program than the previous year. So I think I can make the argument that, in fact, dairy is being assisted notwithstanding the fact that the percentage of milk may be down a bit.

I would also point out that there are a multitude of ways in which this Department is assisting the dairy industry, and I won't go into them, but I am happy to give you the infographic that shows billions of dollars of assistance to the dairy industry.

Senator MORAN. Thank you for your answer. I will find out what the response to your answer is, and may be back in touch with you. I think it was last week that NASS, the National Agricultural Statistics Service, announced that it was canceling the July Cattle Report and discontinuing the Cotton Objective Yield Survey. I think that creates some concern among state departments and commodity groups. Is there more information that USDA can make available so that this information is there? Can you look into that, Mr. Secretary?

#### NASS REPORTS

Secretary VILSACK. I mean, the problem, Senator, is that budgets have consequences, and when the NASS budget was reduced there is a consequence, and more importantly, to this particular topic, when it takes five or 6 months for the budget to be passed then the ability and the options available for dealing with a cut in the budget are limited, limited in this case to the estimates that are—future estimates as opposed to estimates that have occurred in the previous 5 months of the fiscal year.

So I would encourage adequate funding, and encourage earlier decisionmaking, with all due respect, because it makes it easier. And in addition it is not just the NASS budget, it is also the fact that none of the pay increases were incorporated in the budget, so NASS and everyone else in USDA had to find the resources to deal with pay increases as well. So it is a complicated.

Senator MORAN. It is a cost-saving measure, in part, but it is also lack of information, timely information to create the statistic that is needed.

Secretary VILSACK. Well, I understand but—

Senator MORAN. No. I am just reiterating what you told me to make sure I understand. Is that true?

Secretary VILSACK. That is correct. Yeah.

Senator MORAN. Okay. Well, I certainly wouldn't defend the timeliness of Congress.

Secretary VILSACK. That would be hard to do.

Senator MORAN. It would be hard to do, and I wouldn't try. I can assure you—the people that you have been visiting with this morning in this room share that view, that we ought to get our work done on time.

I think my last question, Mr. Chairman, this is a narrow issue but has consequences. In my meeting with conservation district leaders, the conversation turned to, they were contracting for employees to do NRCS work, contract employees who operate NRCS vehicles, and act within their scope of NRCS contract duties, it has been determined that nonFederal partner employees like those are not covered by the Federal Tort Claims Act, and therefore it is hard to find the folks who are willing to take the risk to drive the NRCS vehicles and not have insurance coverage to do so. Is there a plan for fixing, or is this is another one that you can put the responsibility? We need to amend the Tort Claims Act?

#### NRCS CONTRACTOR FLEET INSURANCE

Secretary VILSACK. I would ask for the opportunity to ask our General Counsel's office about that particular issue, so that I give you an accurate response. We will get a response to you in the next couple of days, if that is soon enough.

Senator MORAN. I didn't necessarily expect, although it wouldn't surprise me if you knew this topic, but I wanted to raise it because the pace to—the challenges of finding employees in NRCS, it has become—

Secretary VILSACK. It is a fair question, and we ought to have an answer to it.

Senator MORAN. Okay. Thank you, Mr. Secretary.

Senator HEINRICH. Senator Manchin.

Senator MANCHIN. Thank you, Chairman.

Secretary, thank you for being here, I appreciate all your hard work. Last year, I had the privilege, truly, and you and I have had a relationship, and been friends for a long time, but collaborating with you and watching how you and your team worked, it is unbelievable.

Coming to the aid of apple growers throughout the Mountain State, we had a heck of a problem, together we facilitated the successful harvest of our apple crop after unprecedented oversupply issues threatened the livelihoods of farms, bad weather left a significant share of apples cosmetically unsuitable for the fresh market in just a few short weeks.

Our teams working together hand-in-hand to establish a brand new emergency apple buyback program, which worked tremendously, saving tens of millions of apples from rotting in the fields, the salvaged apples were then donated to charitable organizations, and food banks, not only in West Virginia, but nationwide.

So I want to express my gratitude for your staff, and most importantly, yourself for taking the initiative and lead on this. However, oversupply challenges in the apple industry are widespread affecting growers nationwide. Maybe you can share the USDA strategy for achieving a sustainable long-term solution to this issue, and then some—it is going to go away.

#### APPLE OVER SUPPLY

Secretary VILSACK. Normally, we have sufficient resources within Section 32, and perhaps the Commodity Credit Corporation to address surpluses of commodities, which is the traditional way. However, this year, for whatever reason, there seems to be a lot of sur-

pluses of a lot of commodities. In fact, we have probably \$2 billion of need compared to roughly a billion dollars of resource. So to the extent that we could get, you know, either additional resources within section 32 or maintain the flexibility that we utilize to solve these problems from time to time through the CCC, those two ways—those are the most effective and efficient ways.

I think we are hopeful that with some of the other work that we are doing with the school meal rule, with the WIC and more and more consumption of fruits and vegetables that we will see over time, a diminishment of those surpluses, but in the meantime, we will continue to use the tools we have as long as there is no interference with those tools.

Senator MANCHIN. All right. Also, Mr. Secretary, the COVID-19 pandemic resulted in an unprecedented nationwide shutdown, resulting in the prolonged office closures, and significant disruptions in the labor market leading to millions of job vacancies across the nation. In your written testimony, you highlighted staffing challenges at the USDA, particularly within the USDA Office of Rural Development (RD).

You have noted a concerning trend where the portfolio is expanded by 85 percent, yet staffing levels have declined by 30 percent. As a Senator representing a predominately rural state, that is going to be troubling for all of us, especially in our states. So can the Department of Agriculture, can you believe with the staffing you have, or the reduction you have, with the demand you are having for services, can you meet the challenges, and what can we do to help?

#### RURAL DEVELOPMENT STAFFING CHALLENGES

Secretary VILSACK. Well, Senator, we are going to meet the challenge as best we can, because the people who work for USDA are incredibly committed and are hard workers, and they are people that actually risk their mental health to get the job done. I can't tell you how many conversations I have had with folks who work for USDA who basically talk about the stress and strain of working not one job, but oftentimes two jobs, or two-and-a-half jobs.

So to the extent that you can provide—that you can right-size programs for people that would help, to the extent that you can provide resources to adequately enable RD, to hire additional people. There was a period of time where they were under a freeze for a period of time that made it more difficult. And also to recognize that we, like is the case in many other areas of agriculture we have an aging workforce and we have significant retirements, so giving us the tools to be able to retain good people, or to attract new people with recruitment tools.

Senator MANCHIN. How is the recruitment going as far as—in rural areas especially?

Secretary VILSACK. Well, the problem is, this is a much bigger problem, Senator. Your Federal pay scale used to be the—it used to be the best job in a rural place, in West Virginia, in Pennsylvania, in my home State, Iowa, where I now live. But it is not necessarily the best job today. So there needs to be a discussion here about—are we serious about Federal employment? And if we are

we need to take a look at the pay structure, and system so that it is more competitive.

Senator MANCHIN. How many, and this is across the whole spectrum, but as far as in USDA, how many are still working from home, or remote, and how many are back in? What percentage is back into the office?

#### TELEWORK AND REMOTE WORK

Secretary VILSACK. The best way I can describe this is roughly 82 percent of our workforce is sort of on the job where the job needs to be done. Now, that doesn't mean that they are necessarily—

Senator MANCHIN. Is that the same as it was before the pandemic? I mean, they are back to where they were working.

Secretary VILSACK. I would say for the most part, not in every mission area, but for the most part, collaboratively, or comprehensively, the work is getting—I can guarantee the work is getting done, and I can give you chapter and verse of how many loans we have done, and compare that to where it was before the pandemic. We are cranking out the work. There is no question about that.

Senator MANCHIN. Let me just say one thing. I get more compliments working with your office, than I do with almost any agencies in the Federal Government because it is a rural state, we are so interacting with you all the time. So I just want to thank you, and all your staff here, they have done a great job. We are very appreciative.

Secretary VILSACK. That may be because you have my cell number.

Senator MANCHIN. That may be because we both know, where we both live.

[Laughter.]

Senator MANCHIN. Thank you, sir.

Senator HEINRICH. Secretary, first off I want to recognize the inherent challenges that exist to expanding tribal self-determination within different parts of your Department, but I would just ask that you commit to working closely with me and my colleagues this year to determine what is needed for USDA to expand tribal self-determination opportunities, including through 638 Contracting Authority.

#### TRIBAL SELF DETERMINATION

Secretary VILSACK. Senator, we are more than happy to work with you, and more importantly, or as importantly with the tribes. I mentioned the consultations that are going to take place. They are in nutrition, they are in forestry, they are in food safety, in an effort to try to figure out how to structure the self-determination that fits the mission of USDA. We are a little different than the Department of Interior, because many of the programs that the Interior Department have are expressly in and confined to tribal areas and tribal nations.

Our programs bleed over into non-tribal areas, so it is important for us to make sure that we are aligning it appropriately, but we are very committed to this, as I think expressed by the fact that we have over 160 stewardship arrangements on the Forest Service,

that is a good example, the work that we have done in the food distribution program, another example.

Senator HEINRICH. Yeah. And you have been very good about visiting New Mexico if you ever want to see a 638 contract that is been very successful, the Pueblo Santa Clara's 638 contract with USDA has been a real success.

I am going to turn things back over to the Ranking Member for his final questions, and then I think we will probably wrap up.

Senator HOEVEN. Thanks Mr. Chair, the CCC, incredibly important because it is a flexible tool that we use for a lot of different purposes, as you know, and I believe it is something that that needs to be there because we never know what is going to happen in this—again this huge diverse world of agriculture. And so I think how we use it really matters, there is a number of things that we have used it for recently, going back to the drought issue that 2021, for example, my state was included, and there is about \$5.5 billion right there, right now, that we have designated for some of these different uses, some you like better, some I like better. But again a number of or a variety of things that I think are really important.

So again, my first point is, that CCC is an important tool, we need to be able to use it, we need to have flexibility, and I think you and I both agree the AG Secretary needs some ability, hopefully, working closely with us to utilize that tool and have it for the future but also where are you in terms of getting some of the current programs dispersed that we have utilize CCC—funding for?

#### CCC UTILIZATION

Secretary VILSACK. Several of those areas. I will take the fertilizer area, for example, there is an opportunity for us to do significantly more projects, but we have to go through the Environmental Review, oftentimes there is a process by which before we can make an award, or finalize an award, we have to go through the National Environmental Policy Act (NEPA) process, that takes time, it takes staff, it takes resources, which we have.

We have done 42 projects, but I anticipate that we would probably see another 50 projects in that space, so that is ongoing. There are ways in which we are working on the drought issue, and specifically with our sister agencies to determine whether or not there is a—an interesting collaborative that could potentially be between the Department of Interior and USDA, in terms of those resources, and then we are trying to work through our—the OGCs of the two departments.

There are HPAI, those ongoing expenses continue to accrue, and we continue to pay them out, the Climate-Smart Agriculture Initiative was structured at the request of farmers, and ranchers, in 80 different organizations to be a three- to five-year commitment, so those resources will go out over a period of time.

So it is a question of the structure of the storage request that Senator McConnell requested. Well, it turned out that there was quite a bit of demand for that, to the point that it far exceeded the amount of money that we had allocated, so we are taking a step back and trying to figure out how to restructure that program to provide the assistance for the folks who actually need it, imme-

diately, and an additional maybe modified approach for those who are confronted with a slightly different risk.

I mean, so it depends on the specific item within CCC, but it is not for lack of effort, it is not for—we are not sitting on the resources, every single one of those is being advanced, and if you look at the resources that have been invested, I think you will find there is been significant activity in all of those accounts.

Senator HOEVEN. Well, and I think that is an example of program where you and I both recognize that creates an opportunity for us to work together to do some important things between Farm Bills. And so I think we need to make sure that we continue to work together to ensure we have, because there is some that seem to want to take it away.

Secretary VILSACK. No. That is right.

Senator HOEVEN. And it has got to be collaborative, right, it has got to be a working relationship.

Secretary VILSACK. Absolutely, and I think, frankly, if we could be a bit more creative about the structure of the Farm Bill, that this is a vehicle as we did with, Agricultural Risk Coverage (ARC), and Price Loss Coverage (PLC), and Conservation Reserve Program (CRP) that essentially provides the resources for funding of those programs.

And the commitment I would make to you, Senator, is that we will never, ever, ever drain the account. We will never just for one thing, as has happened in the past, drain the account and force you to replenish it. We are very sensitive to the importance of maintaining some set of responsibility, fiscal responsibility in the utilization of those tools.

Senator HOEVEN. That is good. There are two other questions I want to try to get here. I know you addressed some of the Avian flu stuff which is, obviously, very important but one is on advancing some of these new initiatives on precision AG like we have in our state. We have this great partnership between North Dakota State University, Grant Farm, and ARS, and I think that this is just a huge benefit for farmers, in terms of precision AG which is such a big deal.

If you will address how we can do more there? And then I do want to come back and ask you, we are getting budget pressure from things like WIC where we saw a \$1 billion increase this past year, and then another \$700 million increase this year. So we don't want our AG research and some of these new initiatives so vital to farmers, crowded out of this budget. So if you could kind of address those two in the time we have remaining?

Secretary VILSACK. Well, the answer to the first question is, continue to be supportive of, and increase the funding for research, education, and extension. Every year we ask for significant increases in those—Research, Education, and Economics (REE) (ph.), and every year, we get a significant amount, but often less than what we were asking for. So that is the answer to that question.

The answer to your question is I think eventually you all are going to have to confront the notion that this is a program that is very difficult to—with specific accuracy—to define precisely how many people will use it from day-to-day, week-to-week, month-to-month, and it is very similar in that vein as the SNAP Program.

The SNAP Program is a mandatory program. WIC should be a mandatory program.

Senator HOEVEN. Thank you, Mr. Chair. Just by closing comments, to hand it back to you then would be, again appreciate your work on all of these things I kind of laid out how important I think it is in terms of when we talk farm policy, it affects everybody in the country. So again, thanks for being here today.

Senator HEINRICH. Thank you, Ranking Member Hoeven, and I want to thank the Secretary and Mr. Nelson for being here today. This has been a great hearing.

ADDITIONAL COMMITTEE QUESTIONS

Questions for the record are due by next Tuesday, April 23rd. And we would appreciate responses back within—from USDA within 30 days if you can.

SUBCOMMITTEE RECESS

[Whereupon, at 11:08 a.m., Tuesday, April 16, the hearing was adjourned, and the subcommittee was recessed, to reconvene at a time subject to the call of the Chair.]



**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2025**

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WEDNESDAY, MAY 8, 2024

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

The subcommittee met, pursuant to notice, at 10:00 a.m. in Room SD-124, Dirksen Senate Office Building, Hon. Martin Heinrich (chairman) presiding.

Present: Senators Heinrich, Murray, Baldwin, Manchin, Peters, Hoeven, and Hyde-Smith.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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

OPENING STATEMENT OF SENATOR MARTIN HEINRICH

Senator HEINRICH. This hearing of the Agriculture Appropriation Subcommittee is now called to order.

And I would like to begin by welcoming FDA Commissioner, Dr. Robert Califf, and thank you for being here today.

I look forward to discussing the fiscal year 2025 Budget Request for the FDA. The responsibilities of the Food and Drug Administration are vast, and impact the lives of nearly every American. We need to ensure we have the resources to continue your critical mission. And I am committed to working with you during the Appropriations process to provide the funding that you need.

That begins now with the fiscal year 2025 Budget Request that is in front of us. The request includes a total of 3.695 billion in discretionary funding, a \$168 million increase, a relatively modest increase for this Agency. I am interested in hearing about your priorities within this budget request, Dr. Califf, and what role this committee can play in ensuring we continue to have the world's safest food and drug supply.

I will say that I am frustrated with FDA's lack of urgency in regulating the tobacco products and e-cigarettes that are flooding the market. And I am also concerned with highly pathogenic avian influenza and its potential impact to our food supply.

I continue to be interested in investing resources in our domestic infant formula supply as we continue to recover from the 2022 for-

mula crisis. All of these issues continue to be public health threats to our nation, and the FDA should be using all tools available to address them. I look forward to hearing your thoughts on these issues, and what FDA is doing to address them.

Dr. Califf, I want to reiterate my continued support for FDA and the dedicated employees at your Agency. Last year we had to make some pretty difficult budget decisions under grim spending caps, and I am afraid that it is likely this year will not be much better. That is why it is important for us to hear your priorities, and the priorities of members of this committee. And thanks again for being here.

And I will turn things over to my ranking member, Senator Hoeven.

STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Thank you, Mr. Chairman. And Dr. Califf, thanks for being here, and for your service as the leader at FDA, incredibly important position.

I know it has been a busy time since your return, as Commissioner from the COVID-19 pandemic, to the infant formula crisis, and the current highly pathogenic avian influenza outbreak, which we will talk about a little bit, among dairy cattle, as well as ongoing drug and device shortages.

So all of that on top of what you have to do every single day, which is, of course, to keep the food and drug supply safe for, you know, well more than 300 million Americans.

Your Agency has authority over 160 (sic) foreign establishments and—excuse me—160,000 foreign establishments, and 135,000 domestic establishments, which is really incredible. And that ranges from food processing plants to facilities that manufacture life-saving medications, also countless individual products. So I appreciate that when it comes to keeping food and drugs safe and effective. You have got to get it right. And you really have got to get it right every single time, which is an incredible task.

And that is, of course, why we provide the budgetary increases, you know, that we have, which have been substantial over the last 10 years. And Americans expect that. I mean, they expect, you know, you have set a high standard, and they expect that to be maintained in an ever more complex and interconnected world.

So there are a lot of things we will talk about today, obviously no shortage of food safety issues. I appreciate the steps you are taking in terms of the reorg. I know that has been a massive task, and we want to talk about how that is going. Also, I am concerned in your budget plans for adequately funding state food inspectors, which we want to touch on. And then the drug shortage we are seeing across the country with various drugs, and that is something that we will need to discuss here as well; also, the rare diseases, lab-developed testing regulations, and of course, artificial intelligence, right.

So a lot of important topics in your job, it is kind of like you touch on everything, and everybody, every day. Thanks for being here. Appreciate it.

Senator HEINRICH. Dr. Califf.

## SUMMARY STATEMENT OF DR. ROBERT CALIFF

Dr. CALIFF. Thanks, your commenting about everything every day. I just had my 55th high school reunion, and everyone there had some opinion about what the FDA should or should not be doing. I can assure you.

So Chairman Heinrich, and Ranking Member Hoeven, and Members of the Subcommittee, thanks for the chance to be here before you today. I do want to start by thanking the subcommittee for your continued support of the FDA in a difficult fiscal environment. The Agency greatly appreciates the subcommittee's sustained commitment to our mission.

The budget I am pleased to present to you today requests a total of \$7.22 billion for the Agency, an increase of \$341 million above the fiscal year 2024 enacted levels. Looking ahead to fiscal year 2025, we intend to take significant new steps in our approach to addressing our numerous challenges, in particular through the largest reorganization in the history of the FDA. Virtually every component of the Agency will be impacted in some way by the changes, which will affect over 8,000 of our 18,000 employees. At the center of this reorganization, we are building a newly Unified Human Foods Program.

Following the independent evaluation by the Reagan-Udall Foundation and an internal review, we are bringing together human foods functions, resources, and personnel from across the Agency, all under a single leader. Importantly, this new Human Foods Program will create a clear line of authority. The new Deputy Commissioner has full decisionmaking authority over the entire program.

We are also, renaming the Office of Regulatory Affairs as the Office of Inspections and Investigations, signaling a refocusing of that office on its core function of inspections, investigations, and import operations, eliminating duplication and increasing efficiency in how we handle these activities.

As part of this effort, we are shifting the Office of Regulatory Affairs Medical Products, Tobacco Products, and Specialty Labs into the Office of the Chief Scientist to form a highly integrated network of laboratories and laboratory scientists that provide coordinated, cutting-edge regulatory science research, and support for all of the FDA.

Additionally, we are making a number of other realignments to further improve efficiency and communication across the Agency, including moving cosmetics functions to the Office of the Chief Scientist, which is best positioned to support scientific expertise necessary to review cosmetic ingredients and implement the new authorities provided under the Modernization of the Cosmetics Regulation Act.

The fiscal year 2025 budget requests will provide a solid foundation for these newly envisioned programmatic changes, as well as strengthen the Agency's capacity to protect and promote a safe and secure U.S. Food and Medical Product supply.

Outside of the reorganization, we are also looking to make significant strides in other critical cross-cutting areas. For example, the past 4 years have demonstrated the importance of managing supply chains and mitigating shortages of critical products. Our fis-

cal year 2025 budget requests \$12.3 million for supply chain work across nearly all product areas, as well as establishing positions to coordinate these activities across the Agency.

Finally, I also want to emphasize the importance of the Agency's modernization of IT infrastructure and data processes at the FDA. We are requesting an increase of \$8.3 million to further build on our centralized enterprise data modernization capabilities, as well as \$2 million to implement common business processes and data optimization.

The rapidly changing world demands that our systems evolve to meet future needs. This includes incorporation of computing advances like artificial intelligence, and advanced cybersecurity methods to protect our data and information. The industries we regulate and our own workforce have focused on the use of AI coupled with better data and sophisticated computing infrastructure for innovative ways to benefit public health, from efforts to detect contamination patterns and screenings for imported food products, to helping to identify potential cancer therapies for certain ultra-rare cancers.

Finally, we have contributed significantly to the joint effort to deal with the highly pathogenic avian influenza outbreak. And I am pleased that our supply of milk products is safe. However, this virus, like all viruses, is mutating. We need to continue to prepare for the possibility that it might jump to humans.

Thank you for inviting me today. And I look forward to answering your questions.

[The statement follows:]

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

Chairman Heinrich, 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 2025 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. In a difficult fiscal environment, the Agency greatly appreciates the Committee's sustained commitment to our mission and providing vital resources which have been critical for FDA's protection of the public health, and we look forward to continuing to work with you to further address ongoing and emerging challenges.

During my second tenure at FDA, I have spoken regularly about the need for operational change to address the numerous emerging demands of new technology and the rapid transformation in how the products we regulate are manufactured, distributed, purchased, sold, and used. Looking ahead to FY 2025, we intend to take significant new steps in how we approach these challenges, including by implementing the largest reorganization in FDA's history. Following the independent evaluation by the Reagan-Udall Foundation and FDA's own review of how we addressed the infant formula supply chain response, this reorganization will establish a single, unified Human Foods Program by merging all human foods functions, resources, and personnel from across the Agency. We are also taking this opportunity to further improve other functions of the Agency to create an organization that will break down siloes and fragmentation, leading to enhanced efficiency and collaborative operations to more effectively meet FDA's public health mandate.

The funding requested in the President's FY 2025 Budget builds upon our existing work with additional resources crucial in helping the Agency adapt to a changing landscape. Our FY 2025 program level request totals \$7.22 billion, which represents an overall increase of approximately \$341 million in annual funding above the FY 2024 Enacted level. Of this total, \$3.5 billion is for user fees, which is an increase of approximately \$168 million over FY 2024 Enacted levels. As part of the total program level, the Budget also requests \$3.7 billion in budget authority, an increase of \$173 million. This funding will allow FDA to make significant progress on several important fronts, including (1) food safety and nutrition; (2) medical products; (3) crosscutting issues; (4) modernizing infrastructure, buildings, and facilities; (5) tobacco issues; and (6) strengthening biodefense. Of course, none of the crucial work

done at FDA would be possible without our talented and dedicated workforce, which is why we're also requesting an increase of \$114.8 million for public health employee pay costs as part of the total request for budget authority.

#### HUMAN FOODS PROGRAM

FDA has worked in concert with the broad ecosystem of States, territories, local governments, Tribes, and the vast array of industry entities to make the American food supply as safe as it's ever been. As our knowledge base expands, we continue to identify areas where improvement would further enhance the safety of our food.

FDA's Budget request includes key investments for the Agency's Human Foods Program with \$1.26 billion to support our continued efforts and commitment to strengthening FDA's food safety and nutrition capacity. FDA requests an increase of \$15 million, in part to support microbiological methods and sampling improvements, which will enable more rapid and effective mitigation of produce-borne outbreaks in pre-harvest produce production environments. This body of work will strengthen root-cause investigations essential to FDA's outbreak prevention strategy for produce. Such an increase would also help support FDA's food chemical safety programs, including an increased focus on post-market assessments of intentionally added ingredients and authorized substances used in food, food packaging, or color additives for food manufacturing to ensure they meet the safety standard in the Federal Food, Drug, and Cosmetic Act. An increase would also support our work to reduce exposure to contaminants that may enter food through the environment, processing, or other means.

In addition, funding in our request will be used to grow the Agency's nutrition program within the planned Center of Excellence in Nutrition, as envisioned in the Agency's proposed transformation of the Human Foods Program. With an emphasis on early childhood nutrition, this request assists FDA in addressing the enormous public health burden of diet-related chronic diseases. As a cardiologist, I've seen firsthand the results of poor nutrition and diet, often stemming from childhood, and the long-term impacts from diet-related chronic disease that can occur. This is almost certainly one key cause of our recent decline in life expectancy—more than a 5-year deficit in life expectancy compared with other high income countries. This request will also assist FDA with its nutrition and labeling work in alignment with the White House's National Strategy for Hunger, Nutrition, and Health.

#### MEDICAL PRODUCTS

FDA is dedicated to ensuring that safe and effective drugs, biological products, and devices are available to improve the health and quality of life for people in the United States. Without a doubt, responding to the rapid advancements made across regulated industries is one of the most challenging aspects of FDA's work, but one that we are excited about every day.

FDA is committed to ensuring that products it regulates meet the requirements for marketing authorization while facilitating innovations in their development. Through effective interactions with private industry, Congress, and the public, we believe that FDA can help harness these groundbreaking advancements, like gene editing and artificial intelligence. Since 2016, FDA has been implementing the 21st Century Cures Act (Cures Act), a law enacted to accelerate medical product development and bring new innovations and advances to patients. The Cures Act authorized \$500 million over 9 years to help FDA cover the cost of implementing the law.

Overall, the enactment of the Cures Act has been associated with a dramatic surge in biomarker-based genetic therapies for rare diseases as one example, but this may be just the front edge of a major surge in highly effective, specific therapies for previously untreatable diseases. FDA requests an increase of \$5 million for 21st Century Cures to reflect the last authorized level for Cures in FY 2025, for a total of \$55 million.

#### COSMETICS

FDA appreciates the Committee's support for this vital area, and requests \$8 million in FY 2025 to support the continued implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA provided the most significant expansion of FDA authority to regulate cosmetics since 1938. However, MoCRA did not include any new funding to implement these new authorities. These new resources would allow us to continue building on current efforts to better position the Agency to tackle issues such as asbestos contamination of talc-containing cosmetics, such as tattoo inks and permanent makeup. These requested resources will help bolster our activities in the cosmetics space, such as developing regulations and compliance policies; managing submission platforms associated with MoCRA provisions;

reviewing MoCRA-required information submitted to FDA for industry compliance; and hiring additional subject matter experts to manage critical projects, such as the assessments of the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products.

#### SHORTAGES AND SUPPLY CHAIN

Shortages of drugs, devices, and foods that Americans rely on for their everyday needs can occur for many reasons, including market failures, manufacturing and product quality problems, manufacturing delays, and discontinuations. FDA plans to continue to use a proactive approach towards shortages—to the extent possible within its resources and authorities—to make supply chains more resilient, increase regulatory oversight, and when possible, help prevent or mitigate shortages of critical medical and food products that Americans rely on. The FY 2025 budget includes \$12.3 million to advance FDA’s capabilities to help prepare for, build resilience to, and respond to shortages that are supply- or demand-driven. For example, FDA will use this funding to improve analytics to estimate risk of disruptions in drug manufacturing and identify vulnerabilities so that we can be in a better position to intervene sooner. Further, approximately \$3 million of this increase is dedicated to the recruitment of skilled investigators who will conduct inspections. This investment aims to bolster the regulatory oversight of the drugs, devices, and biologics industries, helping FDA to effectively provide inspection coverage to the increasing number of manufacturers within the medical products industry, and enhancing our ability to promote high-level manufacturing quality and a reliable supply chain.

#### ENTERPRISE TRANSFORMATION

To improve the efficiency of our operations, FDA has proposed targeted investments to support our modernization activities. We request \$2 million to support centralization of planning, implementation, and governance of high-priority business process improvement efforts. This funding will also support the work to build a unified data and operational platform to support our inspection work. This comprehensive initiative aims to modernize operational approaches and foster cohesion, with a specific focus to improve how we plan and conduct inspections so that more inspections can be done in the context of better supporting data and more efficient operations.

#### IT STABILIZATION AND MODERNIZATION

FDA requests an increase of \$8.3 million to further build FDA’s centralized Agency-wide data modernization capabilities and strengthen our common data infrastructure, data exchange, and IT tools. With these additional resources, FDA will continue to improve data exchange and underlying technology platforms in support of the Agency’s programs and mission-critical responsibilities to meet future challenges. Specifically, a stronger digital infrastructure better allows us to meet the challenges of emerging threats, support real-time evaluation, and more efficiently analyze information for recalls, adverse events, outbreaks, and biotreatments. The rapidly changing capability of the information technology ecosystem demands that our systems evolve to support the rapid adoption of artificial intelligence in the products we regulate, including ensuring the continued success with our intensive cybersecurity program.

FDA is requesting 2-year budget authority (FY 2025—FY 2026) for this funding to provide more flexibility and ensure the most effective use of these resources.

#### FOREIGN OFFICE EXPANSION

In addition to assessing the current state of our domestic enterprise, FDA continues to assess the state of our foreign offices and international work including inspections, oversight, and collaboration with foreign food and drug agencies. The dependence of the industries we regulate on increasingly complex and interdigitated global supply chains demands that we apply more resources to assuring the quality and integrity of these dependencies.

To support these efforts, FDA is requesting an increase of \$1 million for foreign office expansion. This funding will support the expansion of the Agency’s foreign office footprint by increasing our resources to improve oversight of quality management systems and supply chains, facilitate additional FDA foreign inspections, and increase our ability to engage with counterpart regulatory authorities to strengthen public health protections.

## MODERNIZING INFRASTRUCTURE, BUILDINGS &amp; FACILITIES

In addition to necessary investments in our core operations, the FY 2025 budget provides limited funding to support FDA's Infrastructure and Buildings & Facilities. These programs directly support FDA's priorities by providing office and laboratory space for FDA's workforce to perform its critical health work.

## TOBACCO REGULATION

Tobacco product regulation continues to be one of FDA's greatest opportunities to save lives and prevent devastating impairment of quality of life caused by cancer, strokes, and other consequences of tobacco use. FDA regulates the manufacture, marketing, and distribution of all tobacco products. Applications for more than 26 million tobacco products have been submitted over the last 3 years. FDA has resolved 99% of those submissions, while ensuring decisions are scientifically accurate, legally defensible, and aligned with the authorities granted by Congress. In addition to premarket review, key areas of focus include policy and rulemaking, compliance and enforcement, research support, and public education campaigns. The Budget provides \$798.6 million for the Tobacco program, which will further bolster resources to invest in these critical regulatory activities.

Within this request, there is an additional \$114.2 million in proposed user fees to ensure that FDA has the resources to effectively address all regulated tobacco products, including e-cigarettes and other novel products, particularly those popular among youth. These products represent an increasing share of FDA's tobacco regulatory activities. The additional funding will bolster compliance and enforcement efforts, enhance premarket application review, and expand tobacco public education campaigns and science and research programs, as we work to mitigate harms and to protect consumers from the dangers of tobacco use. To ensure that resources keep up with the evolving landscape, the proposal would also index future collections to inflation.

The Agency remains vigilant in overseeing the market and continuing to prioritize the use of our resources to maximize public health impact, including compliance and enforcement efforts to curb the unlawful marketing of all tobacco products, especially those used prominently by youth.

## STRENGTHENING BIODEFENSE

The COVID-19 pandemic also highlighted the need to proactively plan for the next public health emergency and ensure we have the resources and capacity in place to fully respond. The Agency has a unique and central role in the whole-of-government response to protect public health. The FY 2025 Budget's Strengthening Biodefense request for FDA includes \$670 million in new mandatory resources for spending over 5 years to advance activities to better prepare FDA for the next pandemic. These resources will help ensure an adequate level of regulatory capacity to respond rapidly and effectively to any future pandemic or biological threat by supporting the Agency's biodefense efforts, both domestic and globally, by bolstering FDA's capacity to provide timely recommendations and scientific advice to manufacturers designing and testing vaccines. Additionally, this funding will support increased research and development of diagnostics, next-generation personal protective equipment (PPE), and technology for biosurveillance and early warning. And finally, these resources will further strengthen data exchange and technology platforms to help ensure that FDA is in the position to respond to a public health crisis quickly and effectively.

## CONCLUSION

While we are in the midst of a challenging budget environment, FDA continues to work with the resources at its disposal to serve the Agency's critical public health mission. The additional resources requested in this year's Budget represent the areas of greatest need as we modernize to address evolving consumer and industry needs. Once again, I thank the subcommittee for your continued support and I look forward to our continued collaboration. I am happy to answer your questions.

Senator HEINRICH. Dr. Califf, why don't you start right there and just talk a little bit about what that preparation looks like?

Dr. CALIFF. Sure, first of all, it is important. As you all know, we have talked about One Health for a long time, the fact that we all live in a world and a universe where animals and humans are more and more connected because of international transportation,

the fact that more people are living closer to farms and on farms. But this is a real example of One Health.

Just roughly speaking, it is always a little more complicated than just the first take on it, but essentially, the Agriculture Department regulates the cows, we regulate the milk at the FDA, and the CDC has primary responsibility for the health of the workers on the dairy farms. And so we all have to work together across these organizations and agencies to take care of things.

And there are so many aspects, I can't go through them all, but primarily from the FDA perspective, today, we are accountable for the milk. So when we heard about the problem, we needed to launch a program of testing the milk to make sure that it was safe, knowing that it was likely that there were more infected herds than we initially knew.

And in fact, that is what we found. As you well know, when we looked at just milk before pasteurization, that is the raw milk coming into the bulk tanks, about 20 percent of a national sample turned out to have fragments of virus in it. And then the question was, is this infectious virus, or is it essentially fragments of dead virus that had been taken care of by pasteurization? We had a good reason to believe pasteurization would work because of 100 years of pasteurized milk. And in fact, it did. We found no evidence of live virus.

And I am pleased to say there are many NIH and Agriculture Department researchers around the country, and universities, who were also looking, and we all found the same thing. But now, the other part that we are accountable for at HHS and within FDA is the countermeasures in case this does jump to humans. So we got to have testing, got to have antivirals, and we need to have a vaccine ready to go. So we have been busy getting prepared for—if the virus does mutate in a way that jumps into humans on a larger level.

Throughout all of this, because there are so many agencies involved, countless hours of phone calls, and Zoom conferences to make sure that we are all coordinated, all in an environment where, let us just say it is not easy to get access to the farms because, you know, people are understandably protective of the environments in which they work.

So a lot of work across the agencies here, and I feel like it has been a good example of how One Health can come together.

Senator HEINRICH. Great. Dr. Califf, how do you see the infant formula being managed under the new Human Foods Program?

Dr. CALIFF. Well, I would really like to answer that question in two parts. And I think you may remember the day I was confirmed was the day of the Abbott recall, so it is not a very warm welcome to the FDA to hear that this is going to unfold. And so the first part is what we have already done, because just a comment about the reorganization, I am sure we will talk more about it with other questions, but we can't enact the reorganization until we get through Congressional notification process.

We are still waiting on one branch of the Four Corners to give us the okay. Then we have to negotiate, or really reach agreement with the unions, which I don't think it is going to be a big problem, but the unions that represent 80 percent of our employees have a

right to have a say. And then we are ready to go. We are amassed at the starting line to really get going.

We have hundreds of people across the FDA who have volunteered to be champions of change in this massive reorganization. But in the interim because of the urgency of the infant formula issue, we have already done a lot of the work that we had to do. We now have many more people working within currently CFSAN, the food, part of the FDA on this sort of basic science and regulation that needs to go on, and we have beefed up the inspectorate, so they are called investigators at the FDA. We have a dedicated corps; all of the infant formula facilities are being inspected at least once a year.

In the case of the Abbott Plant, there is a consent decree, so we are essentially there every day talking with them, and as issues come up, dealing with them jointly. But it is a whole different world now that the scientific experts, the investigators, and the leaders meet on a regular basis, plan the inspections, and when things are found, they are dealt with very quickly, as compared to a process which, in the routine prior, you know, it took some time to institute the changes.

And we have, as you know, hired Jim Jones as the head of the Human Foods Program, although it is not the Human Foods Program yet until we—and this better decisionmaking structure, there was nothing wrong with the people that were trying to make decisions before, but it was not optimally organized to lead to crisp decisions that would lead to action being taken.

Senator HEINRICH. Great. Ranking Member Hoeven.

Senator HOEVEN. Thanks, Mr. Chairman. Yeah, I feel like the question just always, with these issues, leads to more questions. On the avian flu, now that has jumped to humans in some—I know there was a case in Texas, and has gone from cattle to humans already, in some cases, correct?

Dr. CALIFF. So you might enjoy just a quick note about the biology here, not that I am—I mean I am a doctor, not a clinician, not a biological scientist, but the attachment of this virus is through receptors, that deal with something called sialic acid that are ubiquitous in all animals, including people. And it turns out the human conjunctiva, apparently, is the one part of the human that right now is susceptible.

And so the one case that we have was conjunctivitis, not a serious illness, but conjunctivitis. And that case has been worked up by the CDC as best they could. But like all viruses, it comes and goes. So you have got to really catch it while the person is actively infected to do all the things that you would like to do. The real worry is that it will jump to the human lungs, where, when that has happened in other parts of the world for brief outbreaks, the mortality rates been 25 percent, so one in four, that is about 10 times worse than COVID.

And so it is really, you know, we don't control how the virus mutates, and it is just a mathematical—viruses are always mutating; it is a mathematical probabilistic thing where the mutation will make it able to attach to these receptors in the human lining of the lung, that would make it perhaps transmissible through the airways, which would be really bad.

So we have to be ready, and we have to do everything we can to limit the spread of the virus, which has gone around the world multiple times now, in many different species, but there is this debate, but there is a concern that when it invades cattle for the first time, which are closer to the human being than a bird, say, and the cattle are often intermingling with pigs on farms, and with farm workers, you know, a lot of the experts have told us they are particularly worried right now.

So the public need not be worried. The risk is still low that that will happen, but it is sort of like I have — this may be a bad analogy—but I think of it, having had relatives go through this, I would rather have the low deductible insurance than the high deductible insurance. That is if we institute the countermeasures now and reduce the spread of the virus now, then we are much less likely to see a mutation that jumps the humans for which we are ill-prepared.

So the investment now, and the careful attention to management of the herds on the farms is really—and part of our job at FDA, we will have an active surveillance system on the milk so the public can be reassured that this, you know, critical part of the food supply is staying safe.

Senator HOEVEN. So I mean, it has moved from birds to cattle, and that process, you have got to be very careful, cattle, possibly hogs, or ultimately to people. How do you create a barrier there, that both, you know, the actual animal and then the byproducts? I mean, how do you create a very good barrier there so people are comfortable you got this thing, you know, contained or stopped from further migration?

Dr. CALIFF. Unfortunately, there is no absolute barrier that can be created. But there are elements of protection that are important, like farm workers, if they are on a farm with infected cattle, and one good thing here, the cattle don't die. The mortality rate of cows with this virus is less than 1 percent from what we are told.

So the cattle will recover, but the workers need to be protected with PPE, just like we all went through with hospital workers with COVID when you are around animals that are infected. In the poultry industry, as you may know, they have already been through this.

Senator HOEVEN. Right.

Dr. CALIFF. And the use of PPE is just routine in the poultry industry, but this is new for the cattle industry, and so there is a lot of work to be done to get to the right place there.

Senator HOEVEN. Is this our future with viruses, where we are just going to have to be with—across the board having that kind—you know the equipment, and the garb and everything, to stop it?

Dr. CALIFF. You know, there is such a hard balance here for people like me because it is 25 years, if you look at all the literature, and the establishment in the government, of elements of protecting against future pandemics. This has been predicted. It is just a matter of time. I mean it happened in 1918, that was probably a very similar incident of bird to human, or something like that, and so we are going to see these things cycle through, and what we want is to be better and better at dealing with it when it happens.

And as we learn measures to prevent it from happening, and try to do it, but like I say there is no absolute barrier that we know of now, so it is, when there is an outbreak containing it which we—you know that would mean, for example, what is happening now is not shipping—and I am not an expert on cattle ranching, but cows get sold all the time and move across state lines.

So containing it means if you got an infected herd, not doing that. And that is happening now, and I think it has been successful, but it also means having those countermeasures ready to go, so you got the antivirals, the vaccines, the monoclonal antibodies ready to go just in case it happens. So it is not new. It is going to be part of our lives, it probably happened a lot more historically in ways that we didn't even know because we didn't have ways of measuring it.

Senator HOEVEN. Thank you.

Senator HEINRICH. Senator Baldwin.

Senator BALDWIN. Thank you. You mentioned your high school reunion. I am heading to a big reunion in a couple weekends, and I am sure I am going to hear everyone will have an opinion on what should be happening in Congress. You are hearing from your old classmates.

Anyways, thank you for joining us today, Commissioner; and I am going to continue on the same uh theme that previous senators have asked, because I represent America's dairy land. And the outbreak of avian flu in dairy herds in the United States is a significant issue. Wisconsin is home to over 5,000 dairy farms—dairy herds, and roughly 22 percent of the nation's total herd count. So this is a big deal for us.

As you can imagine Wisconsin farmers and dairy producers are concerned about its potential to spread to their own operations. Two weeks ago I sent you a letter requesting robust coordination and communication on highly pathogenic avian influenza, in order to protect our nation's farmers, workers, and dairy supply chain.

So I am really interested in—you know, you outlined already the different agencies that have a role in this, human health, health of the herd, health of the food supply; please talk about that coordination and communication, and how it is happening?

Dr. CALIFF. Well, I would point to multiple levels of coordination. At the highest level, the OPPR, which you all helped create, through legislation and the White House, coordinates across agencies. I mean, as you all know, the Agriculture Department is a separate department. FDA is within Health and Human Services

Senator BALDWIN. Right.

Dr. CALIFF. And so there is an office there which has a call every single day, where leaders, in fact, I am missing the call today, but the leaders of each of the relevant agencies review what has happened the previous day, what the plan is, and what the long-term plan is. And then within HHS, because we have CDC, ASPR, and FDA, in particular, who have to be involved.

We have a separate call every day just for the HHS part of it, to make sure that we have our act together as it relates to human health. And of course, at FDA, we have a cross thing, because we also have the Center for Veterinary Medicine in the animal involvement.

So there is a lot of coordination. I think it is going well, and it is very strategic, but we do have some hurdles. And I just say, well beyond that, you also know that the states play a huge role in the management of the safety of the food and farms, in particular.

And so we are constantly in touch with all the regulators in the states, and every state system is different in terms of how it is configured. So access to the farms, for example, is something that really has to be negotiated through the states, the farmers, and the owners of dairy farms are more comfortable with people that they know that are in their state. So all this has to be coordinated. I feel like we are doing a good job of that.

Senator BALDWIN. Let me just ask a little bit. You talked about the difficulty in getting access to the farms, but you mentioned earlier the ability to test unpasteurized, and then test pasteurized milk, are you having any difficulty at the processing stage of getting that access?

Dr. CALIFF. The pasteurized milk is absolutely no problem to test, because we just have, we have people that go to stores and buy milk off the shelves anyway for all sorts of other testing. As I am sure you know, from the state that you are in, you have all these cows, the milk goes into bulk tanks which is a mixture of a number of cows, and that is a very sensitive area because it does point, if there are infected cows, as to where the infections are. And technically, it is no problem but we want to make sure that we have trust. And so there is negotiation that needs to go on to make sure that there is a safe way to handle the data, and that people are not going to be castigated if they happen to have an infected herd. So we are working through all that state by state.

Senator BALDWIN. Yeah. Okay. And can you share if you need any resources in order to increase your testing and treatment capacity?

Dr. CALIFF. Well as you might imagine, we have expended a lot of resources in the absence of any additional funding, and we are keeping track of that, and looking at potential sources within in our case within HHS, for example. I think it is predictable that we are going to be in a new environment for milk, in particular, because of this virus, the way it has affected other species as it sort of cycles around. And one thing about cattle they are always new cattle coming up, so they are always going to be cattle that are susceptible to getting infected.

So it is predictable there will be a need for resources. We are keeping track of things, and as we get a handle on what we need to do going forward, we will keep you completely informed about where we stand, including the reserve opportunities within HHS.

Senator BALDWIN. Thank you Dr. Califf.

Senator HEINRICH. Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman.

And thank you for being here today, Dr. Califf. I want to talk about medical gases. I hate to drive this nail into the wall but I have not seen any movement on this issue so we are going to continue to pursue this because I have constituents in Mississippi that this really affects. I have repeatedly brought up the issue of medical gas whether in previous hearings and several letters, and my colleagues and I continue to push on this issue.

Congress required the FDA to update its regulations for medical gases in July of 2016, and almost 8 years later the FDA has still failed to fulfill its obligation to the millions of American patients who rely on medical gas daily.

My colleagues and I have consistently encouraged the FDA to meet its statutory requirement and promulgate rules for medical gases. But instead the FDA continues to regulate medical gases under regulations written for traditional pharmaceuticals that do not share the unique characteristics of this category of drug products.

While I appreciate the fact that the FDA finally issued its long overdue proposed rule for medical gases in 2022, this month will mark 2 years since the rule was even published. The FDA only received four, 1 2 3 4, public comments, and yet your Agency still has not published the final rule making. And there is just really no excuse for the delay. It is time to finalize the rule. So what is your plan for publishing a final rule making in the 2024 calendar year?

Dr. CALIFF. Yeah. I am not going to beat around the bush about this. I distinctly remember you are bringing this up last year, and I also told you that time, it was a long time ago, but I was actually a co-founder of a medical gas company. So you know, that company no longer exists, so I don't have any conflict related to this, but I feel like I have a good understanding of it.

What I would say is just a couple of quick things. This rule involves every single part of FDA, and there has been a lot of negotiation that need to go on to make sure that we get it right as it affects things like veterinary health, and biologics, and devices, and drugs all relevant here. I also say we have a published date to have this concluded by October of 2024.

Senator HYDE-SMITH. So October of 2024 is when we can expect the final rule?

Dr. CALIFF. I would say before then.

Senator HYDE-SMITH. Wonderful, wonderful news, because I don't want to have to ask it again next year.

Dr. CALIFF. No, you don't. And I don't want to have to take the question again. I would love to see this thing out. And I can't give you the exact date but I think it will be—

Senator HYDE-SMITH. Okay. That is good enough. And I still have some time left, and I want to talk about the illegal advance prescribing. I have repeatedly brought to your attention to the dangers the women face when allowed dangerous life-ending chemical abortion drugs which can be ordered by consumers through the mail, are purchased in retail pharmacies without ever seeing a doctor in person.

My husband has a doctor's appointment Friday morning for a sinus medication that he can't get refilled until he sees the doctor. So it blows me away that you can get this with no doctor oversight, and it is a drug that will literally cause you, intentionally, to have an abortion and end your pregnancy, and the life of that child.

The FDA is supposed to protect Americans from taking medications that could be harmful, however, you continue to look the other way and claim that mifepristone is safe, in part, based on the lack of reports of nonfatal adverse events, due to the FDA's own

relaxed reporting requirements, and continue to allow the women to put their lives at risk in the name of the pro-abortion agenda.

And it has been reported on more than one instance, that American women are stockpiling the abortion pills through advanced prescribing from abortion companies and providers. And according to another article in Politico, an FDA spokesperson stated that the FDA is concerned about the advanced prescribing of mifepristone, and that mifepristone is not approved for advanced provision of a medical abortion, it is not even approved for that, and they can get it without even seeing a doctor.

So what concerns the does the FDA have with the advanced prescribing of this mifepristone? And is it true that the FDA has not approved mifepristone for advanced provisions of an abortion. And I have two follow-up questions with that?

Dr. CALIFF. Well, I know you are aware that I am limited in what I can say because the issues around this are currently under consideration by the Supreme Court.

Senator HYDE-SMITH. But what is FDA doing?

Dr. CALIFF. Well, remember that, first of all, just one technical point to make is that there has to be a prescription. The companies can't write prescriptions so it is doctors that writes prescriptions.

Senator HYDE-SMITH. Without seeing a doctor though, without physically seeing the doctor, they can just write the prescription with no visit.

Dr. CALIFF. All right, so—

Senator HYDE-SMITH. Like for sinus medication that he has to go in to see the doctor.

Dr. CALIFF. But remember we don't regulate the practice of medicine, so there has to be a doctor that writes the prescription the conditions under which that is done are—

Senator HYDE-SMITH. But when they are violated the law by allowing them to stockpile, what is your responsibility then?

Dr. CALIFF. We don't advocate stockpiling as a method but we don't—again we don't regulate the practice of medicine.

Senator HYDE-SMITH. So you have no role whatsoever in preventing the stockpiling of this.

Dr. CALIFF. I don't know how we would.

Senator HEINRICH. Senator, your time has expired.

Senator HYDE-SMITH. Thank you.

Senator HEINRICH. Senator Peters.

Senator PETERS. Thank you, Mr. Chairman.

Dr. Califf, good to see you again here. In 2021 the FDA found that some infant formula products had been released to the public while contaminated with Cronobacter, this didn't just cause widespread panic, and a nationwide formula shortage, it also revealed I think the effects of a glaring problem, that the FDA does not currently have the authority to inspect infant formula until after the product has left the manufacturer's control.

The FDA's two past budgets have requested additional authority to require industry to conduct testing of final infant formula products, and I have been working on legislation to provide this authority that is so essential for you to protect infant formula. The bill would require infant formula manufacturers to test for key con-

taminants before releasing their product out to the public, and give positive test results to the FDA.

So my question for you, sir, is if the FDA had the authority to test infant formula products before they went out to the market how would that prevent future recalls, and potential supply chain difficulties like we saw during 2021 infant formula crisis?

Dr. CALIFF. I really do appreciate the question, and the background there. And you are correct that there is no requirement of reporting to the FDA the results of testing the companies, so even if they find bacteria they are accountable for getting rid of those lots and not putting them into circulation. But it would really help us a lot if there were a requirement for testing, and if the tests are positive that we be notified.

So in the case of the recall that we had there were just a lot of bad conditions in that one plant, we would have known about that a lot earlier had we know about the results of testing the companies.

And I might add, in most of our regulatory paradigms that the first line of defense is the industry that we regulate, like in the production of medications. We don't test every lot of medications but the company that manufactures the drug is required to do it, and they have the records available for us to look at.

And we would like to see the same thing happen, not only with INF formula, but also with regard to all critical foods, particularly for children. You are aware that we recently had the contaminated apple sauce with lead. And so we are asking Congress to give us the authority to require that that be done.

Senator PETERS. Great. Thank you. Last year one of my constituents, Shandra Eisenga, lost her life after being treated for a tuberculosis infection with a contaminated bone graft from Aziyo Biologics. Her case, I think, just shows how dangerous it is when TB is spread through the transplantation of human cells tissue as well as cellular-based products.

Inspected lots were not just sent to Michigan, but also to California, Louisiana, New York, Oregon, and Texas, and this was the second outbreak from this company, which was also responsible for a 2021 outbreak that infected 80, and killed eight people.

I remain concerned that we are not doing enough to stop the spread of TB through transplantation of human cell tissues, and cellular-based products. And that is why I have introduced legislation that would conduct an educational campaign about the risk associated with human cell and tissue transplants, and would allow for civil monetary penalties for companies that violate compliance standards, similar to that of traditional medical devices, or tobacco products.

So my question for you, sir, does the FDA have the resources it needs to ensure that all registered human cell and tissue establishments are being properly inspected?

Dr. CALIFF. Again, I really appreciate the work you are putting into this. And I will just say the issue of cell and tissue therapy is one of the most promising things that we have in our armamentarium of developing treatments to prevent and treat human disease. But it also has a downside, and it gets very complicated because it intersects with the practice of medicine issues, and very

complicated interpretation of regulations about the type of tissue used, and how much it falls into a category more like a drug, or a device in terms of the way it is regulated.

So your efforts to clarify this are much appreciated. It is a focus of ours. The Civil Monetary penalties will be a big help to us because it is murky, it gives bad actors a chance to do bad things in a way that is hard for us to stop, when we have so many good actors who are doing so much good with this type of treatment.

I also applaud your efforts at education. It is a complicated area when you hear about stem cells, and cell therapy, and such, it is very exciting, but the details are important, and if there are, like I say, some people not acting above board in this regard.

I don't want that to detract from the majority of people who are really breaking new ground in ways that are going to be very good for human health.

Senator PETERS. Right, absolutely, but we do have to have the oversight. So I appreciate. Thank you for your comments.

Thank you, Mr. Chairman.

Senator HEINRICH. Senator Manchin.

Senator MANCHIN. Thank you, Mr. Chairman.

Dr. Califf, last year, during your previous testimony before the Committee and FDA held an Advisory Committee Meeting on opiates, which you know is extremely devastating to this entire country, especially to my State of West Virginia. In particular, the questionable clinical trial practice known as Enriched Enrollment. The Enriched Enrollment process has made it significantly easier for FDA to approve opiates and allow for broad marketing to the public. The process removes the patients with pre-existing opiate sensitivities from clinical trials instead of sticking with traditional double-blind studies.

This has skewed results and seriously underestimates risks associated with a proposed drug involved in the clinical trial. The Advisory Committee last year expressed concerns during the meeting about the Enriched Enrollment is able to really address whether an opiate is better than a non-opiate.

In September I sent a letter, sent you a letter asking for an update on what FDA is doing in response to these concerns. We haven't heard a thing. So what have you done, in response to concerns raised regarding the Enriched Enrollment?

Dr. CALIFF. Well, Senator, thanks for the question. As we have discussed before, I am a clinical trialist by profession, it has been my whole career, so I certainly understand the issue that you are raising. And you know that we had the Advisory Committee meeting, the advice is publicly available, and we take it seriously. I don't think you will see Enriched Enrollment as a practice in the routine management of the affairs of opioids. There are other circumstances in medicine and health care where it is a very important constituent of the armamentarium of clinical trial methods that are important to have available.

Senator MANCHIN. Let me go. Well, let me go into this then. And one of the recommendations in external review of the FDA regulations of opioids report that you ordered was to ensure the FDA be as transparent as possible regarding decisionmaking, which I appreciate. The Advisory Committee has presented complex scientific

reviews of safety and efficacy of medicines. And most patients and the general public really don't have a background to fully understand the scientific studies, which you are explaining.

But the FDA announced that it will be holding a listening session on June 13th to discuss the role of the advisory committees, specifically, to improve the public understanding. One element that you have stated is to reduce voting. How can you reduce voting with these scientists, and like yourself, being in that position before if you can't vote to where you think something is effective or not?

And that leads into another question. I could never believe this happened, okay, with Zohydro. When Zohydro, I don't think you were there at this time, 11 to 2, the Advisory Committee voted against putting this product on the market, and at that time, I think she was the Head, Woodcock, was the Head of it, did it anyway. And I could not believe it, could not believe it. So if you take voting out of the process.

Dr. CALIFF. I don't know. Senator, I don't know if anyone who has—first of all, as a clinical scientist, the epitome, the peak of my academic career was being on the Cardiorenal Advisory Committee where everything comes together.

Senator MANCHIN. Yeah.

Dr. CALIFF. I don't know if anyone is advocating the taking of voting completely away.

Senator MANCHIN. As to reduce the voting, how would that—

Dr. CALIFF. But let us remember, advisory committees are to give advice to the FDA, often not about a particular product, but about a field, how to think about a field, where the vote doesn't particularly have a purpose. In addition to that, what the FDA is most interested is what the Advisory Committee is thinking, what is behind the reasoning for the way they feel the way they do. That is much more important than the sort of excitement of having a vote from people that have convened for one day without all of the background that the FDA has, that has been meeting, and looking at the data for months.

So the Advisory Committees are very important. I am a big proponent of having them. We just need to make sure that they are meeting the purpose for which they exist. And with regard to votes that go the other way, if we always took the advice of advisory committees, we wouldn't need the FDA, just convene an advisory committee, so—

Senator MANCHIN. These are scientists giving you a different opinion. The only thing, when I look at an advisory committee, these are people that are not beholden to the company that is asking you to approve a new patent, or whatever it may be.

Dr. CALIFF. Well, they are—

Senator MANCHIN. Let me just say this, because my time is very limited and the thing that opiate is just a scourge on our society, and it has been for quite some time. It has devastated my state in ways that you can't even believe, and what it has done around the country. We killed more people with overdoses than we have in any wars we have ever fought in, starting back from the Civil War.

But I can't ever figure out why do we allow, I mean, and evaluate, if a new product is coming on the market, your job is to make

sure it is an improved product that will reduce the suffering of humans, it is better for a society, and these products keep coming at you all and they not taking anything off. If something is going to improve and be better, then don't you think something should be removed from the market? They are just flooding the market with the things they have had forever, killing Americans, and killing West Virginians, and bringing more things to do more damage.

Dr. CALIFF. Well, let me just say I, you know, my staff is available to yours, and I think they are talking.

Senator MANCHIN. Sure.

Dr. CALIFF. And as frequently as possible. In my view, we need a legal construct if we are going to pull things off the market.

Senator MANCHIN. We will work with you on that. If you are telling me we have to do something, you need legislation here to pull things off the market once they have been approved, and even though something is replacing, it is better.

Dr. CALIFF. I really, you know, Senator, as I have aged in this job, I really believe—

Senator MANCHIN. We are all aging right now.

Dr. CALIFF. [continued] we at the FDA are referees, primarily. The Rule Book is written by Congress, so when you write a law, we follow the law.

Senator MANCHIN. Okay. Fair enough.

Dr. CALIFF. Let me mention one other, just, you may be prepared to ask about this.

Senator MANCHIN. Okay.

Dr. CALIFF. The issue of—you know, personally, I am very much in favor of something you have advocated for, which is for a new opioid to come on the market, as opposed to all other drugs and the classes of drugs, it ought to have an advantage over what is—we don't need more opioids on the market, I think we agree on that.

Senator MANCHIN. Yeah. Yes, we do.

Dr. CALIFF. Unless there is something that is really a significant advantage. But right now the rule book that we referee upon, says if the drug is better for the indication than nothing, then it is allowed on the market, and so—

Senator MANCHIN. You need language basically saying, if it is an improved drug that will perform better than the existing drug is, so we will remove the existing drug.

Dr. CALIFF. That is right.

Senator MANCHIN. Okay. Got it.

Senator HEINRICH. Thank you, Senator. We are going to do a quick second round, so if you want to stick around we can have some more conversation about this.

Doctor, I don't want to put you in a situation with regard to the Supreme Court decision, but I do want to ask you just patently, is mifepristone safe?

Dr. CALIFF. You know, I am on the record multiple times about this. We stand by the decisions of the FDA over the years, and the constant looking at the surveillance data and clinical trials as they come in, mifepristone is safe and effective for its indication, and we stand by that.

Senator HEINRICH. Thank you. Talk to me about vaccine development and HPAI, and I know your role is to approve vaccines, but

where are we in that process, and if we do have a zoonotic transmission to humans; you know, what is our posture and are we ready for that?

Dr. CALIFF. I would say we are ready, you will notice that part of the budget has—sort of separate from the rest of the budget, has a pandemic preparedness part of the budget. The way I look at it, we are in an enviable position compared to any time in the history of the world, Senator Hoeven made—rhetorically, I think, made the point that pandemics have always been around. It is just that now because they used to be limited by the fact people didn't travel, now we are on airplanes, and as we saw with COVID, it moves quickly from one place to another.

The enviable position we are in now, is we have mRNA templates that are platforms that we have confidence in already, where what used to be a mystery, how do you make a vaccine, by the old method that would take many months, now we can do it in just a few weeks to a couple of months, but we have got to have the funding to keep the source warm, so that we can start up right away.

Senator HEINRICH. That mRNA platform is applicable in this case?

Dr. CALIFF. Yes, sir.

Senator HEINRICH. Great.

Dr. CALIFF. And you know, it is a great thing for many of the—viruses are relatively simple compared to other kinds of organisms. So coming up with a matching vaccine for the exact genetic make-up of the virus is entirely possible in a very short period of time. So it is another place, I didn't mention NIH before, is a critical player here. The NIH is doing a lot of the background work to characterize the virus with its excellent virologists, so that we can be ready, working with the industry that makes the vaccines.

Senator HEINRICH. Talk to me a little bit about vaping. Why are we not making faster progress on the incredible number of unapproved vaping products there are on the market?

Dr. CALIFF. If you will bear with me for just a minute, I would like to sort of go through my thinking on this, because it is—I am as frustrated as you are with it, I have to live with it every day, and I have relatives that are addicted to nicotine. I am from South Carolina, and practice medicine, and maybe the seat of the tobacco industry in the past, in Durham.

So first of all, I do want to point out that we are making progress in combustible tobacco, although we are still going to lose almost 500,000 Americans this year to tobacco-related illness. That and hypertension are the two biggest remediable causes of death that we are dealing with, but just as we are making that kind of progress with combustible tobacco, along came vaping.

It was 2016, during my first term, that we deemed vaping, but we had no idea it was going to result in 26 million applications for vaping products. That happened while I was away at Alphabet, and I came back to find a Center for Tobacco Products full of good, hardworking people, but an overwhelming number of applications from an industry.

I was in Silicon Valley, I must say, the combination of an addictive substance called nicotine, with marketing done through Silicon Valley techniques, was overwhelming. We had a Reagan-Udall Re-

port, we have a new Head of the Center for Tobacco Products, Brian King, and we have made tremendous progress in this regard. But just as we are getting a handle on the basics of vaping, and by the way, at least by the surveys, the number of teenagers vaping did decline last year, but it is nowhere where it needs to be.

Just as we are making that progress, along comes the Chinese manufacturing of vaping products, and the overwhelming vaping products now used by American youth and getting addicted is made in China. So can I go one more minute on this?

Senator HEINRICH. Please.

Dr. CALIFF. Here, we have products that are not legal to sell to Chinese people in China, made in China, and imported into the United States in large numbers. Now, the old regime of dealing with this, one of you had mention several hundred thousand establishments, it is actually a million, because we have 300,000 retail stores selling vaping products in the United States. If we take our 1,400 investigators, i.e. inspectors, and try to have them manage 300,000 vaping establishments, that math doesn't work.

So we have got to stop this at the point of import. So we are actively working now with the, you talk about multiple agencies, the Justice Department, remember, we can't enforce without the Justice Department agreement if we have to go to court on these issues. And CBP, the Border Force is very important here. So I want to work with you all to come up with a way—and you would be amazed if you saw what we have to go through to take action with one product coming into the international mail facility.

It is a very complicated legal proceeding because every company has a right to defend itself in court from actions that we take. I think the circumstance here, where we have a product that China won't sell to its own people, being imported into the United States to addict youth. We ought to be able to come up with a way to say it is pretty simple: When it comes in, destroy it.

And CBP, by the way, can recover the money from the importer for an illegal product that is an authority that we don't have at the FDA. So we are actively working on that mix. I don't blame—

Senator HEINRICH. If you need additional authorities from Congress, or additional direction to make sure that we are addressing this in a more efficient way, I think you would find a very receptive audience.

Dr. CALIFF. I wish I could tell you exactly what it is now, but we will have a composite view from the Justice Department, the FDA, and Border Patrol about what would be most effective.

Senator HEINRICH. The CBP. Yeah.

Dr. CALIFF. I want to just cut it off, just not even let it in, then we can deal with the vaping industry in the United States which has many additional issues, but at least we could deal with that.

Senator HEINRICH. Okay. Senator Murray.

Senator MURRAY. Mr. Chairman, thank you very much. And thank you, Commissioner Califf, good to see you again.

As I always say every time families head out to the grocery store, or sit down for a meal, they are putting their trust in the FDA. The health and safety of our Nation depend on the world-class experts at FDA who work diligently to protect our food supply, address

threats like shortages or contaminants, and a lot more. The stakes are always high as we saw during the infant formula crisis, something I want to see FDA to do more to learn from, because no parent should ever worry about whether the formula that they feed their baby is safe. So I am glad we have this opportunity to talk about the resources your Agency needs to fulfill its really important mission.

Before I start my questions, I also want to say one thing I think we both agree on, agree your Agency does not need, and that is political interference in FDA's science-driven decisionmaking processes. We have seen a number of baseless claims and disinformation from anti-abortion activists, and some Republican lawmakers which are really threatening to undermine FDA's credibility and its authority.

So let me set the record straight, and Dr. Califf, I hope you will continue to as well. Mifepristone is safe, it is effective, and that is just not me saying that, it is scientists, experts, and decades, decades of data.

Republican politicians should not be overruling experts on science or overruling women about their own health care decisions. And at a time when women across the country are facing rampant attacks on abortion access, this dangerous disinformation is an attack we all can and all should be fighting loudly and clearly.

I just wanted that on the record so thank you, Mrs. Chairman.

Dr. Califf, you, before I got here talked a little bit about H5N1 avian flu. This is something that Senator Burr and I put together, the Office of Pandemic Preparedness and Response Policy, and we got funding for it in the last bill; can you talk a little bit about how your Agency is coordinating with OPPr and other Federal agencies?

Dr. CALIFF. Yes, as we discussed just a few minutes ago, OPPr has been a central coordinator of the effort across agencies that, you know, have boundaries that have to be overcome to work together. So the Agriculture Department is in an entirely different sphere than FDA and CDC, which are within HHS.

So there is a daily call, I am actually missing it today for this hearing, of the leaders of the—and the top leaders in addition to the key people who carry out the operations, where what happened the day before is reviewed, what needs to be done that day is reviewed, and the long-term plans are made.

So I am glad that you put together the plan. I just hope that the funding is adequate in the future, because as Senator Hoeven pointed out, we are going to continue to have outbreaks and pandemics for the foreseeable future.

Senator MURRAY. Thank you. On cosmetics reform, I was really glad that we provided \$7 million for the implementation of the modernization of Cosmetics Regulation Act of 2022, that I negotiated and got signed into law. That bill, for the first time, provided much-needed new authority to FDA to make sure that families know the products we put on our bodies every day are safe. I want to ask you today what steps the Agency has taken over the last year to implement those new authorities and what resources are requested in your budget for this year?

Dr. CALIFF. Well, first of all, thanks for doing that. I think it was decades of trying before, this finally happening. People tend to think of cosmetics as just something you put on your skin for looks, but the skin, you know the quiz of the day, the skin is the largest organ in the human body and it absorbs what is put on it. And so there is good reason to at least know what is in the cosmetics that you are using.

You know, I am pleased to say we made a decision to put cosmetics in the Office of the Chief Scientist under the purview of Dr. Namandje Bumpus, who is our Chief Scientist who, by the way, I just was pleased to elevate to Principal Deputy. She has done such a great job.

The progress we have made really exceeded what we have planned, that is for the first year, which is that we now have the listing. So there is a place for the cosmetics companies to list that they are on the market, and what is in them, and there is also an adverse event reporting system for the first time. We were able to capitalize on CDER's Drug Adverse Reporting System to put one in quickly.

We have definitely—this is done on a shoe string and we have in the budget we have an \$8 million ask to really instantiate this office and get to the next level. As you also know, there are several Cosmetics that are very worrisome in terms of health, where we have to do a lot of work in order to take the kind of actions that are needed to protect health, and we need a budget to make sure those things can be done.

Senator MURRAY. Thank you. And this is something really important to me, so I appreciate the work that this committee did on that. I understand that the proposed Unified Human Foods Program continues to make its way through the administrative process. It has been well documented that these reforms are overdue, FDA's regulation and enforcement of Food Safety Standards on issues ranging from bacteria in vegetables, to arsenic in baby food are really critical. What is your Agency requesting in fiscal year 25, for implementation of the reorganization?

Dr. CALIFF. Well, in this budget we are asking for an additional \$15 million, and I honestly regard that as a hope for a down payment. I think you will—if you go to the Reagan-Udall Report you will see beautiful graphs, although they are somewhat depressing, of the funding of the drug and the medical product side of the FDA.

Thanks to the user fees it is, you know, meeting the mark. It could always be better, but the food side of the FDA has been increased but well below the even the cost of living inflationary increase at a time when the food's industry is increasingly complex, global, interdigitated with many issues.

So part of what we are doing in the reorg is to create a budget where you can really see exactly what is the money being spent on. I recognized when I came in, when I asked for the budget on the medical product side, it was really clear because the user fees institute a businesslike process, whereas on the food side, there was a lot of intermixing in ways that were harder to depict.

I think when you all see the places where it is needed, and I will just point to two examples that I think are really critical. We all know that, you know, we are in a global environment where more

and more things are getting into the food in the way of chemicals. We chose Jim Jones to be our leader of the Human Foods Program. He has a history in the EPA of dealing with chemical contamination.

We had, basically, a tiny little crew of people working on that, on the food side of the FDA. So as you see what is at stake and what needs to be done, I hope that will make clear, you know, what funding is needed, and also give you a way to make sure when you invest money that you can actually see what is being done.

The other one that is enormous is nutrition. We talk about three pillars of risk, obviously microbial which everyone understands, chemicals which are of great concern, but our biggest cause of death and disability from food is actually bad nutrition, and we have got this tremendous epidemic of obesity, diabetes, cardiovascular disease, and cancer emanating from all that in a setting in which our tools on the nutrition side are very limited.

So we are going to have a Center of Excellence in Nutrition, nested in that is going to be the Critical Foods Group that was mandated in FDORA that will deal with infant formula and medical foods. So hopefully this will all clarify where the money is actually going to be useful, as opposed to just asking for money based on a broad concept.

Senator MURRAY. Okay. Thank you. Thank you very much. And Mr. Chairman, thank you for the extra time.

Senator HEINRICH. Ranking Member Hoeven.

Senator HOEVEN. Thanks Mr. Chairman. So Senator Peters and I are working on some legislation in regard to infant formula. He is really coming at it from the safety, and I am coming at it from adequacy, so we want to make sure it is helpful to you, doesn't impose costs and restrictions, and it would be counterproductive. Do you have any specific thoughts in regard to that?

Dr. CALIFF. The safety side is pretty straightforward, as you know, and there is just some things that we need. And again just to reemphasize, as I learned at my high school reunion, people think the FDA has magical powers to just march in and force people to—

Senator HOEVEN. And at the reunion you told them in fact you did.

[Laughter.]

Dr. CALIFF. No. I was asking for sympathy.

Senator HOEVEN. Okay.

Dr. CALIFF. So the safety side is—well, you know, we just need a few more things that would require that first line of defense that we always depend on, which is the industry doing what it should do, and our checking to make sure they are doing what they should do. On the adequacy part it is really complicated, and I would just say, I look forward to working with you. I have ideas, it is very complicated by the WIC Program, and the way the states purchased the formula.

Many of us believe that the industry is too concentrated in a few companies.

Senator HOEVEN. Yeah, right.

Dr. CALIFF. But it also turns out if you look globally, in every country, they are just a couple of companies that dominate in each

company, and we have programs now to entice people into the market, but if half the market in every state is WIC, it is very hard for new entrance to actually get a foothold and have enough sales.

So these are daunting problems, and we would love to work with you. It is not our primary responsibility, but we obviously have opinions, and it affects us when it is not working.

Senator HOEVEN. Yeah. Right, that is what we want to do. Drug shortages in your opinion what is the greatest challenges you face in this space, and you know, how can we improve that?

Dr. CALIFF. The answer is kind of similar. But let me break it in half. We have a set of things that I regard as a hole plugging activities, that is our primary issue there, when we know of an impending shortage, and there are over 200 per year happening now, we have a set of maneuvers we can do that are much like you would do if you were in a town and the grocery store was going out of business, you need to find another grocery store.

We get on the phone. We go to all resources to find alternatives either to produce the same product or a drug that is equivalent. And we need some help there from you all in filling in the holes in our knowledge base that would enable us to put together what we need to plug the holes much more efficiently. And we have asked for an additional \$12 million in the budget for analysts and people to, basically, anticipate when shortages may occur, so we can preempt. We are successful in preempting about 80 to 90 percent of the shortages, but we still have too many that are occurring.

But part two is actually the big deal, and it is very much like what I said about the formula. We have a market failure, and it is very hard to—just to quickly go through this—it is really important to understand that we have two industries essentially with some overlap, but two industries in the pharmaceutical arena. The innovator industries make patented drugs which have protection from patents from competition.

Senator HOEVEN. Right.

Dr. CALIFF. I believe the price is too high there. I know there are different opinions about that, but let us just say that the profits are good, and there is every incentive for the companies to make every drug they can sell because they make money.

Ninety-five percent of our prescriptions now are generic drugs, and they are essentially copies of the innovator drug after the patent is over. It is simple way to think about it. The prices there are too low, our generic prices are actually lower than Canada and Europe, and so the shortages we are seeing, the probability of a shortage is directly related to how low the price is.

Now, I am a capitalist American, just put yourself in the shoes of a CEO and say, you can either make a drug that is going to make a big profit for your company, or you can make a drug where you are guaranteed to lose money because the price is too low, which one are you going to do?

So the companies, even in India, where the cost of labor is so low, they are telling us they can't make and distribute the product at the price they are getting. And in the middle of all this, in America of course, is the middleman, the GPOs and PBMs, which I know you all have been talking about, they are not regulated by

anybody right now, basically, and this is an area where work needs to be done.

It is not my job to say exactly what should be done. Of course I have ideas, like I do about infant formula, but unless we fix the market failure, we at FDA are going to be expending more and more energy just plugging holes in the system that we could have predicted were going to happen in the first place. But we can't tell anyone to make a drug, we can't—we don't make the drugs ourselves, so we are just trying to line up the people that do make them, in a way that can be successful.

Senator HOEVEN. I want to follow up with you on that disparity, in terms of the pricing between, you know, the new name brand patent-protected drug and the generic. I have not heard that point on the generic before, so that is interesting. I think it is something we will try to follow up with you and understand better. But I think the drug shortage is important, we want to find ways to address it that are actually effective for consumers, and don't create you know market distortions or burdens.

Dr. CALIFF. If I may, I would refer you to an HHS Report that came out just a few weeks ago, that goes through this in great detail, and I think if your staff reads it, that they probably already have, but get a briefing on it because I think it will give you a lot of insight into what is happening here. I mean, I am personally traveling over to India to—because we are very dependent now on foreign manufacturing of these products because there is not enough American—

Senator HOEVEN. Which is a concern as well?

Dr. CALIFF. Yeah. It should be.

Senator HOEVEN. Thank you.

Senator HEINRICH. Senator Manchin.

Senator MANCHIN. Very carefully—very quickly on that. Do we produce any antibiotics here in America? Someone told me a strep throat could take us down.

Dr. CALIFF. Not many.

Senator MANCHIN. Has the alarm been raised why we should have some manufacturing producing the necessities for us just off the basic?

Dr. CALIFF. I feel like from the day I came into this job, this time, I have been screaming and shouting from the rooftops. But I mean, as you know, Senator, you have had family in the generic drug business.

Senator MANCHIN. Right. Well, they were told—well, they had to close down the plant because they had too many drugs they were producing.

Dr. CALIFF. Right. I mean, your cost of labor in West Virginia is competitive. I will just say.

Senator MANCHIN. Yeah.

Dr. CALIFF. And yet still, couldn't keep that going.

Senator MANCHIN. And they were taken down because of FDA, they were—back then it just made it impossible because they have so many drugs they were producing. They are producing those by the billions now, but we don't do any of that anymore. I just think it is a horrible situation. And I have talked to Secretary Becerra about this, and basically getting—we have manufacturers who

want to get back in business in making that and stockpiling it so we do have it here in America made.

The other thing I want to mention to you. On December 22nd, 2022, which was basically the fiscal year 2023 Omnibus Bill that we passed, it included my FREED of Opioids Act, which requires FDA to review how they approve new opioid drugs. So that is in the law. Okay.

Now, also May 26th of that same time, and right now it is the SUPPORT Act it passed the HELP Committee. And the SUPPORT Act, I think does what you wanted, it was myself and Senator Braun, it is ensuring the FDA fully examines Clinical Trial Impact and Vitalness Before Endorsement Act, which is the EFFECTIVE Act, which would allow the Food and Drug Administration to deny a new drug application for an opioid analgesic drug, on the basis of the drugs not being clinically superior to other commercially available drugs. Would that help?

Dr. CALIFF. That bill we have—

Senator MANCHIN. And that bill has gone through the gambit, we have just got to attach it to something right now.

Dr. CALIFF. Yeah. We will have to get with your staff—there are always details in these things.

Senator MANCHIN. Well, Audrey will be happy to reach out to you.

Dr. CALIFF. The basic concept is one—you know, this is an exception to the rule for opiates, but I think the destruction of and deaths that you have talked about merit it in this case.

Senator MANCHIN. Sir, what is happening? Is this, I mean, I understand the lobbying force up here, you know, and Big Pharma, and all that, but the bottom line is, there is a lot of drugs we depend on, and I support them a thousand percent. This is one I never grew up with it, I never had, and these things weren't on the market when I was a kid. I got taken care of pretty good. When I was in the hospital, if I ever went to the hospital they took care of me, what I needed.

When I got out of the hospital I couldn't get—if I still liked what they gave me in the hospital, I couldn't get anywhere else; so all of a sudden. And we know the history on that one. But we have a couple of things here we would like to work with you on. And I think you might have some powers already, and we are trying to give you more let us make sure this other one is done the right way. Okay. Thank you, sir.

Senator HEINRICH. Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman.

The gulf shrimp industry is very important to Mississippi, Dr Califf, and right now because of bad actors in other countries Mississippi shrimpers and processors don't know if they are going to survive another season, and this is a real situation. I was on the coast night before last in Mississippi, and the primary reason for this is that many foreign countries unfairly subsidize shrimp production and dump shrimp on to the market at prices that domestic producers can't compete with because we do not subsidize.

Ecuador is one of the primary bad actors, and shrimp imports from Ecuador are growing faster than imports from any other country. It is also important for inspection of imported shrimp to be ro-

bust, especially during times like these when gulf shrimpers are struggling so much with unfair trade practices.

I was happy to see that in August 2023 FDA signed a regulatory partnership agreement with Ecuador to strengthen food safety and shrimp intended for the U.S. market. This is important both for public health and for the future of our domestic shrimp industry. Domestic shrimpers should not have to compete with unfair trade practices, but they should especially not have to compete with shrimp riddled with illegal or dangerous chemicals and drugs.

What percentage of imports from Ecuador has FDA inspected since this arrangement was signed and have any imports been refused to your knowledge?

Dr. CALIFF. Sorry. I would have to get back with you on the exact numbers, but I sure agree with you that first of all, you all gave us additional funding to implement programs like this. We have to keep foreign imports to the same standards that we have in the U.S., and the more we can get these countries to do a good job on their own, the better off we are going to be in terms of using our resources to double-check and make sure things are okay.

So the agreement with Ecuador is the first of three that we hope to have. The other two big importers are India and Indonesia, very similar issues there. You are right, over 90 percent of our shrimp that we eat now is imported. Personally when I eat shrimp and grits, as we discussed last year, it is South Carolina or North Carolina shrimp are my preference, but I put Louisiana and Mississippi right up there too.

And I agree with everything you said about needing to fortify the industry here. As you all know we don't—our remit is not within the economics of the industry, we have to regulate whatever the economics are dictating, but we do have this obligation that you are refer to keep the chemicals out. But we will get back to you with the details of the number of inspections, and what has been done in the way of detecting things, and preventing them from getting into the country, if they are not up to snuff.

Senator HYDE-SMITH. Thank you. That would be very much appreciated.

Thank you, Mr. Chairman.

Senator HEINRICH. I want to thank you, Commissioner Califf, for being here today. And I look forward to working with you, and the members of this committee, as we work through this year's Appropriations process.

#### ADDITIONAL SUBCOMMITTEE QUESTIONS

For members questions for the record are due by next Wednesday, the 15th of May. And we would appreciate responses back from FDA within 30 days.

#### QUESTIONS SUBMITTED BY SENATOR MARTIN HEINRICH

##### CESSATION PRODUCTS

*Question.* Last year, on June 1, 2023, at a Cancer Moonshot event at The White House, Commissioner Califf acknowledged some of the challenges those seeking to bring forward new cessation products may encounter and said that there are things that FDA is trying to do to reduce the "friction" related to bringing forward medical products in this space.

*Answer.* Please see response to next question.

*Question.* What actions, if any, has CDER taken since Dr. Califf made these comments last year with respect to helping to bring forward new, innovative smoking cessation medicines for patients and their doctors and/or reducing the “friction” he referenced? What new actions does CDER plan to take, if any, in addition to the guidance previously issued?

*Answer.* As smoking results in many serious or life-threatening conditions (e.g., heart and lung disease and cancer), FDA recognizes there is an unmet need for novel therapies particularly for individuals who have not been able to quit despite available therapies.

Because we consider nicotine dependence to be a serious or life-threatening condition with an unmet medical need, we are encouraging development of novel smoking cessation drug therapies that show benefit over existing products by outlining how to qualify expedited development pathways such as fast track, breakthrough, and priority review.

In May 2023, CDER finalized the draft guidance *Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy [NRT] Drug Products*.<sup>1</sup>

The NRT Guidance outlines strategies for applicants to make NRT development easier, efficient, and streamlined:

- Clarifying the appropriate pathways for companies that seek approval for a product that alters the route of administration compared to approved NRT drug products, e.g., products with pulmonary route of administration rather than an oral route of administration.
- Explaining when simplified efficacy study requirements may be used (e.g., recommending a 4-week study as the minimum period of efficacy ascertainment).
- Clearly outlining abbreviated pathways for NRT products, including how to use FDA’s previous findings of safety and how already approved NRT products and published literature can be leveraged.
- Encouraging sponsors to consider expedited development and review pathways, as well as providing details on how to qualify.

In addition, because the data are so strong in demonstrating that quitting smoking can lower a person’s chance of having lung disease, heart disease, and certain types of cancer, drug products that have been demonstrated to be effective for cessation are approved with labeling claims regarding these benefits without additional data supporting benefit of the particular product on these outcomes.

To support the majority of smokers who wish to quit and to increase utilization of cessation products and interventions, FDA and the National Institutes of Health (NIH) are collaborating to identify opportunities for the development of novel therapies, support innovative trial designs, and facilitate product development for smoking cessation therapies. Opportunities for innovation exist in many areas including collaboration with researchers to help identify novel targets, use of innovative clinical trial design and conduct, inclusion of individuals underrepresented in research, developing a better understanding of quit failures and relapse, and utilizing FDA’s expedited programs for medical product development.

To this end, FDA will hold a joint public meeting with NIH this fall to discuss innovations in development of smoking cessation products, and we anticipate the Federal Register notice for that meeting to be announced in the near future.

*Question.* Smoking cessation products have been approved for decades. Why does FDA believe patients seeking to quit with available smoking cessation medicines are not more successful in their quit attempts?

*Answer.* Nicotine is a highly addictive substance, making nicotine dependence a very challenging condition to treat. The reasons for low success quit rates include multiple factors unrelated to availability of safe and effective smoking cessation products, such as weight gain, lack of access to effective therapies due to financial hardship, exposure to other smokers and secondhand smoke, loss of an ability to manage stress, and comorbid alcohol and other substance use disorders.

Unfortunately, less than one-third of smokers who try to quit use counseling and FDA-approved smoking cessation drug products, which is one potential area for intervention. That is why we have worked to improve access by making so many of these products available in the nonprescription setting via the prescription to nonprescription switch pathway.

FDA’s 2023 Nicotine Replacement Therapy (NRT) Guidance contemplates the need to get novel therapies directly in the hands of consumers in the nonprescription setting, without going through development as a prescription product first. As

<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/smoking-cessation-and-related-indications-developing-nicotine-replacement-therapy-drug-products>

such, we outline pathways to get approval direct to over-the-counter (OTC), which reduces potential hurdles for access, and work with manufacturers to get novel products over the goal line for approval. It also outlines abbreviated pathways for NRT products, including how to use FDA's previous findings of safety and how already approved NRT products and published literature can be leveraged. Finally, the NRT Guidance encourages sponsors to consider expedited development and review pathways and provides details on how to qualify for this review.

*Question.* Does the agency agree new smoking cessation therapies are needed to help patients be more successful in their quit attempts? If so, what new actions will CDER take to expand and improve treatment options for smokers seeking to be more successful in their quit attempts.

*Answer.* Please see response to previous question.

*Question.* Does CDER see an opportunity to modernize the regulatory framework for nicotine replacement therapies to better balance public health benefits with real-world experience akin to FDA's approach to the development of therapies to treat stimulant use disorders?

*Answer.* Nicotine use disorder and other substance use disorders (e.g., opioid use disorder) are very different, even though they fall into the same general category of addictive disorders.

In the case of smoking cigarettes, we are concerned primarily with long-term health effects. There are limited and mixed data on whether reduction in smoking short of cessation leads to net positive clinical outcomes, while smoking cessation is associated with demonstrated positive clinical outcomes. However, we are eager to work with sponsors and other stakeholders to advance scientific understanding of novel endpoints demonstrating meaningful reductions in harms associated with smoking. These differences make shorter-term endpoints regarding reduction in use more clinically meaningful in the case of, for example, opioid use disorder than in the case of nicotine use disorder.

In general, different substance use disorders have different mechanisms of action and clinical effects that may lead to differences in clinical presentation and responses to treatment. As a result, study designs, patient populations, and endpoints may differ across therapeutic areas targeting different forms of addiction.

*Question.* Does FDA see a path for additional endpoints that reflect a more realistic experience with the challenges individuals, and their clinical teams, are experiencing in quitting nicotine and which reflects the real-world realities of the staggering public health toll smoking continues to take in our country? If so, what steps is FDA taking to encourage discussion with developers on such endpoints?

*Answer.* FDA's 2023 Nicotine Replacement Therapy (NRT) Guidance provides recommendations to sponsors in the clinical development of NRT drug products intended to help cigarette smokers stop smoking cigarettes or maintain abstinence from smoking. While the guidance reflects FDA's current thinking on the topics it covers, it does not bind sponsors or the FDA. FDA encourages sponsors that wish to discuss their drug development program to request a meeting with the appropriate review division. Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of investigational new drugs and biologics, and drug or biological product marketing applications. FDA reviews New Drug Applications (NDAs) based on the best available science as applied to the data submitted in the NDA.

*Question.* What steps is the Commissioner taking to make sure that CDER's approach to the regulation of cessation medicines is keeping pace with the ongoing unmet clinical needs and public health urgency in helping patients be more successful in their quit attempts? Please specify the timeline for such action underway and or planned for the future. Please also specify the metrics the agency is using to track progress against these actions.

*Answer.* As referenced our prior responses, we are encouraging development of novel smoking cessation drug therapies that show benefit over existing products by outlining how to qualify expedited development pathways such as fast track, breakthrough, and priority review.

Additionally, it is important to note that FDA does not develop drugs. Historically, FDA has seen limited interest from sponsors in developing NRT products and we have not seen a recent change. All New Drug Applications (NDAs) are subject to the performance goals and procedures for the Prescription Drug User Fee Act (PDUFA VII) 2023–2027. Please see the PDUFA VII commitment letter for more in-

formation.<sup>2</sup> The goals letter represents the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress.

*Question.* What metrics does FDA believe Congress should use to measure the agency's progress in advancing smoking cessation therapeutic innovations and, ultimately, helping smokers be more successful in their quit attempts?

*Answer.* Please see response to previous question.

#### FOREIGN MANUFACTURER TOBACCO REGISTRATION

*Question.* In 2009, Congress required under the Tobacco Control Act that the FDA publish a rule requiring foreign manufacturers to register with the FDA if they wanted to sell tobacco products in the U.S.

It has been more than a decade—since the 2012 Unified Agenda to be exact—since FDA first told us it would issue the foreign manufacturer registration rule—so companies like those in China—could not import products unless they were registered. Earlier this year—in the latest Unified Agenda, FDA again pushed the date for a proposed rule.

When will FDA publish this rule?

*Answer.* The Center continues to weigh competing priorities given available resources and updates the policy agenda annually. In the meantime, FDA receives information about foreign manufacturers as part of the premarket tobacco product application (PMTA) process. A PMTA must include information including a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation and a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation. This is true for applications from both domestic and foreign manufacturers.

#### TOBACCO PRODUCT EXPOS

*Question.* In February of this year, the Total Product Expo took place in Las Vegas, NV. The Expo's purpose was to showcase vapor products to independent retailers.

I understand you were made aware of the potential for illicit manufacturers attending and participating in this expo ahead. I also understand that, even though FDA was present at the expo, they did not seem to take any actions regarding these illegal products.

Why did you refuse to act after FDA was present and witnessed this illegal activity? Do you plan to take action against any of the manufacturers who were selling illegal product at the Las Vegas expo?

*Answer.* Tobacco industry trade events and industry conferences are one way for CTP to engage with stakeholders and monitor the marketplace. This engagement with industry provides an opportunity to gather information on shifts in the tobacco product market, marketing techniques, and novel products. As has been the case in the past few years, CTP staff attended the Total Product Expo in 2024. However, CTP did not attend a similar expo in Miami in 2024.

Following the May 8th hearing, CTP attended the Houston expo in June. CTP makes decisions about which events to attend on a case-by-case basis depending on a consideration of factors, including available resources.

We collect information during these types of events; we take action based on the specifics of an investigation. The information gathered at this type of event, along with other information received through monitoring the marketplace, including inspecting manufacturers, distributors, or importers; compliance checks of tobacco product retailers; monitoring and surveillance of a tobacco product manufacturer's or retailer's website; and reports submitted by the public or other interested stakeholders, help to inform compliance and enforcement efforts, which could include potential actions. FDA does not publicly disclose enforcement strategy or discuss potential future enforcement activities.

*Question.* There was a similar E-vapor product expo in Miami, FL on March 14–16, 2024. Was FDA aware of this expo? Did FDA send enforcement agents or any other FDA personnel? Were there any enforcement actions taken at the Miami expo?

*Answer.* Please see response to previous question.

*Question.* There is an Alternative Product Expo show coming up in Houston in June. Will FDA be present at this show. Can you commit to taking action against any manufacturers who are present and are exhibiting illegal products?

*Answer.* Please see response to previous question.

<sup>2</sup><https://www.fda.gov/media/151712/download?attachment>

## DORA CLASS DRUGS

*Question.* We understand that FDA is waiting for DEA to ask them to conduct their 8 Factor Analysis for the DORA Class. Is there anything FDA can do in the meantime to prepare?

*Answer.* The Drug Enforcement Administration (DEA) is the lead agency for scheduling under the Controlled Substances Act (CSA). With the exception of some general information provided in the responses to Questions 14, 16, and 17, any questions regarding the process for CSA scheduling (including the removal of a drug or other substance from the schedules), or the current status of a particular drug scheduling evaluation, should be directed to the DEA.

*Question.* How does FDA's 8 Factor Analysis overlap with DEA's own 8 Factor Analysis? If there are differences, how are they reconciled?

*Answer.* While DEA is the lead Federal Agency responsible for regulating controlled substances and enforcing the Controlled Substances Act (CSA), HHS has a number of responsibilities under the CSA, several of which are performed by FDA on behalf of HHS.

As a part of this work, FDA provides scientific and medical recommendations to HHS about the appropriate controls for controlled substances. To make this recommendation, FDA's Center for Drug Evaluation and Research, including the Controlled Substance Staff (CSS), is responsible for preparing the "eight-factor analysis" (or 8FA), in consultation with the National Institute on Drug Abuse (NIDA), that serves as the basis for the scheduling recommendation to HHS and DEA.

When requested by DEA pursuant to 21 U.S.C. 811(b), the CSA requires HHS to conduct a "scientific and medical evaluation," under which the following eight factors set forth 21 U.S.C. 811(c) must be considered with respect to the drug or other substance proposed to be controlled or removed from the schedules:

- Actual or relative potential for abuse
- Scientific evidence of pharmacological effect
- Current scientific knowledge regarding the substance (including whether the substance has a currently accepted medical use in the U.S.)
- History and current patterns of abuse
- Scope, duration, and significance of abuse
- Risk to public health
- Psychic or physiological dependence liability
- Whether the substance is an immediate precursor of a substance already controlled

The circumstances and relevant data sources may differ for the particular substance under evaluation for drug scheduling considerations, e.g., for drugs proposed under a new drug application. Such circumstances include where such drug may warrant scheduling under the CSA, or drugs or other substances emergent in patterns of nonmedical use and drug abuse, or drugs that are subject of a petition submitted to DEA that requests a particular drug scheduling action. At the time of a DEA request for FDA to conduct an 8FA for an emergent substance of concern, DEA typically will provide FDA with law enforcement and drug seizure data, and sometimes also with basic pharmacological data from studies they have conducted (e.g., under agreements or contracts). For petitions submitted to DEA, DEA may provide supplementary law enforcement and seizure data in referring a petition to FDA with an 8FA request. For drugs that are subject of a petition to DEA or a drug application submitted to FDA, the petitioner or applicant will have responsibility to provide some of the data relevant under the Eight Factors.

Some of the data gathering from these various sources can occur concurrently, but the totality of data must be considered by FDA during our process of conducting an 8FA.

The drafted 8FA and the recommendation on scheduling are transmitted from FDA's Office of the Commissioner to the HHS Office of the Assistant Secretary for Health, and then from HHS to DEA. It is DEA that, after reviewing the HHS documents and recommendation, makes the final determination of whether to initiate rulemaking proceedings to control a drug or other substance or remove it entirely from the schedules in accordance with 21 U.S.C. 811(a)-(c).

*Question.* Can DEA and FDA do their 8 Factor Analysis concurrently?

*Answer.* Please refer to the response to previous question.

*Question.* What is the typical process FDA goes through to conduct an 8 Factor Analysis? How long will it take; Is there a way to speed it up; What happens once it's complete; What if DEA has a reason to disagree with it; Then what?

*Answer.* Please refer to the response to previous question. Based on differing circumstances and data availability for the drugs or other substances under evaluation, there is considerable variability in the time it may take to proceed through the administrative review process. Scientific and medical findings made by HHS are binding on DEA. The agencies also may communicate as necessary under our Memorandum of Understanding to discuss data, viewpoints, or process matters for pending drug evaluations.

*Question.* Does FDA consider any other agencies' interest, such as NIH, when completing the 8 Factor Analysis?

*Answer.* Please refer to the response to previous question. Also, please note that FDA always shares a drafted 8FA with colleagues at the National Institute on Drug Abuse (NIDA), and seeks their concurrence on our scientific and medical findings before transmitting documents to the HHS Office of the Assistant Secretary for Health (OASH). When the 8FA and scheduling recommendation are transmitted from FDA to OASH, NIDA is also welcome to share any additional input with OASH at that time if they so choose.

#### ARTIFICIAL INTELLIGENCE

*Question.* Commissioner Califf, artificial intelligence (AI) is dramatically impacting every aspect of our lives, including the field of drug development, and it is critical that the FDA is prepared to address AI-related issues in a systematic way. I note that in May of 2023, the Drug and Device Centers at FDA published a discussion paper, "Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products," that aimed to foster dialogue on the use of AI and machine learning in drug and biological product development.

Is the FDA planning to establish an FDA-wide team to serve as a centralized point of entry for early-stage drug developers? By doing so, this would allow developers to receive specific agency guidance on the utilization of artificial intelligence modes and techniques that fall within the scope of the agency's regulatory authorities, as well as provide clarity on whether proposed uses do not require any agency oversight or review.

*Answer.* FDA has taken significant steps to coordinate a cross-center approach to regulating AI in drug development, as recently outlined Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together. FDA is in the process of forming a team of internal experts focused on AI in drug development. However, a centralized, FDA-wide AI team might not be the optimal entry point for drug developers, as working with the appropriate review team with relevant experience on the particular type of product would likely be more efficient.

Such a team might coordinate with staff possessing AI expertise that is relevant to the AI model being proposed.

FDA maintains open channels for engagement with industry on using emerging technologies in drug development. There are various mechanisms to engage with the Agency depending on how the sponsor intends to use the AI model; for example, a sponsor could request a formal meeting, attend an FDA program, or utilize a specific Agency pathway.

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#### QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

##### TOBACCO PRODUCTS

*Question.* Under a Federal court order, the FDA had from September 9, 2020, to September 9, 2021, to review premarket tobacco product applications (PMTAs) for e-cigarettes.

However, after more than 2.5 years, the FDA has not met the deadline to complete its review of these products. FDA also failed to meet its own deadline to finalize the review of e-cigarettes with a large market share by the end of last year.

In the FDA's most recent filing with the court, the FDA indicates that it will not complete its review of large market share products until June of this year.

In 2023, 7.7% of students or more than 2.1 million youth reported the use of e-cigarettes and more than 25% of youth e-cigarette users use an e-cigarette product every day.

Studies have also found that young people who use e-cigarettes are more likely to become smokers, and many are low-risk youth who would not have otherwise smoked cigarettes.

Why is the FDA taking so long to complete its review of product premarket tobacco applications (PMTAs) for e-cigarettes and why has it been unable to meet its own deadlines?

*Answer.* To date, FDA has received PMTAs for nearly 27 million e-cigarette products, and has resolved over 26 million. The PMTAs that FDA has received have included applications for nearly one million non-tobacco nicotine products from more than 200 applicants. These determinations also include agency action on applications for 99.5 percent of the larger market-share products, the applications for which are generally the most voluminous and complex.

Due to the unprecedented number of applications submitted for premarket review as well as the large number of applications moving through review at the same time, the finite nature of our review resources, and the necessarily rate-limiting effects of ensuring consistency across reviews, among other things, this process takes time.

FDA must also ensure review decisions are legally defensible and consider all submitted information. Amendments submitted by applicants during the review process and outcomes in litigation that impacts our approach are two examples of the many internal and external factors that can significantly impact review timelines. These issues can lengthen the review timeline and impact review resources. Despite these factors, FDA remains committed to working as expeditiously as possible to resolve pending applications.

Since youth use of e-cigarettes peaked in 2019 at 5.3 million kids, youth use of these products has declined substantially. The 2023 National Youth Tobacco Survey (NYTS) shows further progress, with an estimated 2.1 million kids who were using e-cigarettes in 2023, which includes 580,000 fewer U.S. high school students using e-cigarettes since 2022. More recent 2024 NYTS data<sup>27</sup> shows that another half a million fewer U.S. youth reported current use of e-cigarettes in 2024 compared to 2023. This decline is a good public health outcome, as well as a positive reinforcement of the work that has been done and that the Agency will continue to do as it strives for additional progress on this issue.

*Question.* Will the FDA commit to finalizing all reviews for pending large market share products by the agency's current June deadline?

*Answer.* At this time, FDA has taken action on 99.5 percent of the Covered Applications. FDA remains committed to making determinations on all remaining applications, including the Covered Applications, as expeditiously as possible, while ensuring the decisions are scientifically accurate, legally defensible, and aligned with the authorities granted by Congress.

*Question.* On June 23, 2022, FDA issued a marketing denial order for several of JUUL's e-cigarette products, after it found that JUUL's premarket tobacco product applications (PMTAs) lacked sufficient evidence to demonstrate that marketing of the products would be appropriate for the protection of public health.

However, on July 5, 2022, the FDA issued an administrative stay of its marketing denial order, saying there were scientific issues that warranted further review of JUUL's application.

FDA's re-review of JUUL's application has been going on for almost 2 years, and during this time, JUUL has been allowed to keep its products on the market.

Recently, FDA indicated that it would complete the review of all large market share e-cigarette products by June 2024.

JUUL is the brand most responsible for fueling the youth e-cigarette epidemic, and, according to FDA and CDC data, JUUL was the fourth most popular brand with youth in 2023.

All JUUL e-cigarettes also have a high level of nicotine. According to the manufacturer, a single JUUL pod contains as much nicotine as a pack of 20 regular cigarettes.

Will FDA complete an additional review of JUUL products by June, which is its deadline to complete the review of all large market share e-cigarette products?

*Answer.* Following the May 8th hearing, in June 2024, FDA rescinded the marketing denial orders (MDOs) issued in June 2022 to JUUL Labs, Inc. This action was taken, in part, as a result of new case law, as well as FDA's review of information provided by the applicant. Rescission of the MDOs is not an authorization or a denial and does not indicate whether the applications are likely to be authorized or denied. Rescission of the MDOs returns the applications to pending status, under substantive review by FDA. The Agency's regulations significantly limit what FDA can disclose regarding the content of pending applications.

<sup>27</sup> <https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-drops-lowest-level-decade>

## QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN

## EERW CLINICAL TRIALS

*Question.* Last year, on April 19, 2023, the FDA held an Advisory Committee meeting on opioids, in particular the questionable clinical trial practice known as “enriched enrollment”.

The enriched enrollment or EERW process has made it significantly easier for the FDA to approve opioids and allow for broad marketing to the public. The process removes patients with pre-existing opioid sensitivities from clinical trials, instead of sticking with traditional double-blind studies. This has skewed results and seriously underestimates risks associated with the proposed drug involved in the clinical trial.

The Advisory Committee last year expressed concerns during the meeting about if EERW is able to really address whether an opioid is better than a non-opioid.

What has FDA done in response to concerns raised regarding the use of EERW clinical trials?

*Answer.* As you note, on April 19, 2023, FDA held a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee to discuss how to evaluate long-term efficacy of opioid analgesics and the risk of opioid-induced hyperalgesia with a focus on proposed clinical trial designs to research these issues, including EERW trial designs. There were detailed presentations on, and discussions of, the advantages and limitations of EERW trial designs in this context. FDA is currently considering the experts’ recommendations and other available evidence and data, and the Agency agrees that it is important to continue reviewing the value of EERW and other trial design methodologies.

## ADVISORY COMMITTEES

*Question.* One of the recommendations in the External Review of FDA Regulations of Opioids Report—that you ordered—was to ensure that the FDA “be as transparent as possible regarding decision-making”. Advisory Committees present complex scientific reviews of safety and efficacy of medicines. Most patients and the general public don’t have a background to fully understand the scientific studies discussed in these settings.

The FDA announced that it will be holding a listening session on June 13th to discuss the role of Advisory Committees, specifically “to improve the public understanding of advisory committees”. One element of this you have stated is to reduce voting.

Voting has helped with conveying complex analysis to the public. Even FDA’s Director of Oncology Center of Excellence, Dr. Richard Pazdur, has said voting is necessary because “[FDA] needs that clarity—[FDA] has to make a decision”.

Can you clarify when you believe an Advisory Committee should or should not vote?

*Answer.* Whether FDA will include voting questions at an Advisory Committee (AC) meeting depends on the subject of the meeting and the advice FDA is seeking from the AC. Voting is not a mandatory part of AC meetings, and votes are typically not taken at meetings discussing general issues, such as clinical trial design or the development of guidance documents. At other AC meetings, members may cast formal votes on particular issues, such as whether benefits outweigh risks in a product submission.<sup>3</sup>

The feedback FDA obtains from votes on discrete questions can help the Agency gauge a committee’s collective view on complex issues. However, many of the issues considered by ACs are nuanced, and FDA staff may be primarily interested in the discussions and interpretation of particular aspects of the data rather than a summative conclusion regarding risks and benefits of a product.

*Question.* I introduced the bipartisan FDA Accountability for Public Safety Act to help provide greater transparency to FDA’s approval process. Specifically, if an Advisory Committee votes against approval and the FDA decides to go against this vote, like in the case of the 11–2 vote against Zohydro, the FDA must submit a report to Congress that includes the medical and scientific evidence to justify its approval.

This commonsense bill helps with providing the greater transparency needed. Dr. Califf, you cited concerns with the public misunderstanding that votes are non-binding, however it is important that the FDA provide an explanation as to why they rejected the Advisory Committee’s recommendations.

<sup>3</sup>Voting Procedures for Advisory Committee Meetings FDA

My bill does not make votes binding, but it does require that the FDA provides this explanation. Advisory Committees are outside experts whose recommendations are made based on scientific evidence.

Dr. Califf, how will you ensure Advisory Committee discussions are clear and transparent?

*Answer.* FDA continues to explore ways to optimize its advisory committees (ACs). Following the May 8th hearing, the Agency held a public listening session on June 13, 2024, where we received public comments about FDA's use of and processes for AC meetings. FDA also established a docket that was open for public comment until August 13, 2024. FDA will consider public feedback as we move forward with our optimization initiatives.

We note that ACs do not vote to approve products—that is a regulatory decision for FDA alone. Rather, ACs provide valuable input on issues that would be helpful to FDA in considering the information and data submitted to support a marketing application. FDA carefully considers AC input in its decision-making.

#### DRUG SUPPLY CHAINS

*Question.* The FDA has previously reported that nearly 40 percent of finished drugs and roughly 80 percent of active pharmaceutical ingredients are manufactured abroad. During the COVID pandemic we saw disrupted drug-supply chains lead to increased drug shortages.

In particular, Americans' access to essential medicines—as defined by FDA's report—are reliant on international supply chains putting them at risk of shortage.

Has the FDA provided an updated report on current domestic manufacturing capacity and our reliance on international supply chains?

*Answer.* We note that the figures you cite in your question come from a 2017 Government Accountability Office (GAO) report.<sup>4</sup> We want to clarify a misconception that the data in that report reflect the volume of drug product produced by foreign manufacturers. In the report it is noted that “FDA estimates that nearly 40 percent of finished drugs and approximately 80 percent of active pharmaceutical ingredients (API) are manufactured in registered establishments in more than 150 countries . . .” (emphasis added). This is referring to the number of finished product and the number of APIs that are manufactured in foreign registered establishments, not the volume of finished drugs and API manufactured at foreign registered establishments. The Agency does not currently have a full picture of the actual volume of foreign drug reliance.

In February 2024 we published our final guidance, “Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act”<sup>5</sup>, on reporting to the Agency under this FD&C Act provision (as added by the CARES Act). This final guidance recommends that for calendar year 2023, the annual reports required by section 510(j)(3) should be submitted no later than July 31, 2024; reports for subsequent calendar years should be submitted by March 31st of the following calendar year (e.g., CY 2024 reports should be submitted by March 31, 2025). Now that the guidance is final, we expect more firms to fulfill their obligation to submit this data.

Following the May 8th hearing, CDER published its FY 2023 Report on the State of Pharmaceutical Quality. This report, like its five annual predecessors<sup>6</sup> shares multiple presentations of data on site and product demographics that help to characterize the source and quality of drugs marketed in the U.S. However, the full picture of the volume of drugs manufactured in each country is not currently feasible.

*Question.* Will the FDA work with the Administration for Strategic Preparedness and Response to identify areas of concern and potential opportunities to support production of essential medicines in the United States?

*Answer.* Reliance on foreign manufacturing is not a new concern for FDA. There are some things we can do to make it easier for manufacturing to be done in the United States, however there are significant economic issues that are out of our purview that have contributed to increased foreign manufacturing, specifically, pricing pressures, labor, and regulatory costs. We have been working closely with colleagues across HHS to identify authorities and capabilities available to address those other market forces. The Administration for Strategic Preparedness and Response is a critical partner in this, via the Supply Chain Control Tower and other capabilities, all as part of the HHS Supply Chain Working Group.

<sup>4</sup> <https://www.gao.gov/assets/gao-17-143.pdf>

<sup>5</sup> <https://www.fda.gov/media/175933/download>

<sup>6</sup> <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/report-state-pharmaceutical-quality>

Within FDA, one of the most important things we can do to help reduce our reliance on foreign manufacturing is to encourage and facilitate the adoption of advanced manufacturing. Ensuring that both innovator product and generic drug manufacturers will have access to information regarding advanced manufacturing technologies is vitally important because advanced manufacturing requires a skilled workforce and can help domestic companies operate in smaller facilities with lower costs and fewer potential quality issues, improving the global competitiveness of U.S. manufacturing.

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QUESTIONS SUBMITTED BY SENATOR KYRSTEN SINEMA

ETHYLENE OXIDE

*Question.* As I've expressed to you and Administrator Regan in the past, I have serious concerns with how the rulemaking around Ethylene Oxide (EtO) was handled. The potential impact of this rule on the safety and availability of sterilized medical devices is one that I still don't believe EPA has taken with full seriousness, including comments made by your Agency about the risks to medical device supply chains.

Can you explain how the EPA worked with you and your Agency to address concerns about medical device supply chains requiring EtO for sterilization in the final rulemaking? Are there currently alternative modalities that don't use EtO that would be able to handle the volume and kinds of medical device sterilization should this rule be implemented? Are you and your staff satisfied with the final rulemaking with confidence that it will not endanger public health by impeding the sterilization of necessary medical devices?

*Answer.* FDA shares the same goals of protecting the public health by lowering ethylene oxide (EtO) exposure to workers and community members, while also maintaining the availability of supplies of sterile medical devices for patients in the U.S. The Environment Protection Agency final rule reflects key changes to help achieve both goals after engagement with FDA.

More than 20 billion devices sold in the U.S. every year are sterilized with EtO, accounting for approximately 50% of devices that require sterilization. These include critical devices, such as wound dressings, stents, and kits used in routine hospital procedures or surgeries. In many cases, EtO may be the only method that effectively sterilizes and does not damage the device during the sterilization process. Even for devices that may be able to use an alternative, sponsors likely will need to undertake testing and new validation, and in some cases, redesign of the device may be necessary—a process that can take several years, depending on the device and material. While some innovations appear promising, other methods of sterilization cannot replace the use of EtO for many devices.

Understanding the fixed nature of EtO sterilization capacity in the U.S., FDA has implemented programs and initiatives to support innovation in medical device sterilization, and we remain committed to this effort. This work includes developing Sterilization Master File Pilot programs to support certain changes for sterilization processes, launching innovation challenges to encourage new strategies to reduce EtO emissions and the development of new sterilization methods or technologies, proactive engagement with industry to help advance innovative alternatives to EtO, and our medical device town hall series.<sup>28</sup>

DRUG CLINICAL TRIALS

*Question.* The FDA is currently implementing guidance to improve the diversity of patient populations represented in clinical trials, including new requirements that study sponsors provide diversity action plans for phase 3 trials of new drugs and medical devices to ensure medical products are safe and effective for all intended populations. I've been proud to support the work of Arizona universities, researchers, and patients who are participating in the National Institutes of Health (NIH) All of Us program and other efforts to diversify health research and ensure health innovations work for all Arizonans, including our Tribal communities.

However, clinical trials used for U.S. drug approval can occur outside the United States and may not appropriately reflect the unique demographics, health care systems, and lifestyles represented in Arizona and in the U.S. nationally. There may also be challenges in the U.S. to overcome common barriers to participation for rare

<sup>28</sup> <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices-unpublished/medical-device-sterilization-town-hall-fda-activities-and-challenges-reducing-reliance-ethylene>

and rare pediatric diseases, given smaller populations, especially in our rural and underserved areas.

What is the FDA doing to improve the proportion of patients from the U.S. represented in overseas clinical trials and how does the FDA assess the representativeness of populations outside of the U.S. relative to the U.S. population? How is the FDA working with study sponsors to address the challenges in rural and rare disease communities?

*Answer.* Participants in clinical trials should be representative of the patients who will use the medical products. FDA has a longstanding commitment to promote the inclusion of underrepresented populations in clinical trials and to help reduce barriers that may prevent the enrollment and retention of a diverse trial population. For global medical product development, the Agency supports the use of well-designed and conducted multi-regional clinical studies; however, foreign clinical data must be relevant to the patient population in the United States and our practice of medicine.

FDA has also published a number of guidances with recommendations on enhancing diversity in clinical trials to help ensure that results are generalizable to the intended use population, including recommendations that can help increase enrollment of populations with rare diseases, and those in rural locations. Some of these actions include:

- The November 2020 final guidance *Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs*<sup>29</sup>, to provide sponsors recommendations to help increase clinical trial diversity and better reflect the population most likely to use the future medical product.
- The 2023 published guidance *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations*<sup>30</sup> and draft guidance *Decentralized Clinical Trials for Drugs, Biological Products, and Devices*<sup>31</sup> to help sponsors design more patient-centric trials with flexible locations.

#### FIRST CYCLE DRUG APPROVALS

*Question.* Given the stated goals in the Prescription Drug User Fee Act to promote the efficiency and effectiveness of the first cycle review process, how is the FDA working with sponsors to better identify and resolve potential issues during the first cycle review to ensure faster patient access to safe and effective novel prescription drugs and generics? How have first cycle approval rates changed in the past 7 years for generics and for novel approvals, and what factors have impacted the most recent increases or decreases in first cycle approvals?

*Answer.* FDA understands the importance of efficient review cycles to ensure access to safe and effective prescription drugs. For new drugs covered by PDUFA, FDA provides timely advice and feedback to sponsors at various points during the drug development process, potentially addressing new issues quickly before the application review process.

FDA's first-cycle approval rates for "novel" drugs (NME NDAs and original 351(a) BLAs) are generally high, although there has been year-to-year variability over the past 7 years with lows in FY 2021 that have started to increase. Since FDA reviews each drug application on a case-by-case basis, it is challenging to retrospectively categorize the issues identified into distinct themes or trends; general percentages are presented below.

FY 17

- NME NDA/Original 351(a) BLA—priority review 100%
- NME NDA/Original 351(a) BLA—standard review 75%

FY 18

- NME NDA/Original 351(a) BLA—priority review 87%
- NME NDA/Original 351(a) BLA—standard review 67%

FY 19

- NME NDA/Original 351(a) BLA—priority review 91%
- NME NDA/Original 351(a) BLA—standard review 86%

FY 20

<sup>29</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial>

<sup>30</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations>

<sup>31</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices>

- NME NDA/Original 351(a) BLA—priority review 85%
- NME NDA/Original 351(a) BLA—standard review 48%
- FY 21
  - NME NDA/Original 351(a) BLA—priority review 60%
  - NME NDA/Original 351(a) BLA—standard review 42%
- FY 22
  - NME NDA/Original 351(a) BLA—priority review 78%
  - NME NDA/Original 351(a) BLA—standard review 56%
- FY 23
  - NME NDA/Original 351(a) BLA—priority review 80%
  - NME NDA/Original 351(a) BLA—standard review 59%

With respect to generic drugs covered by the Generic Drug User Fee Amendments (GDUFA), one of FDA’s goals is to maximize the efficiency and utility of each assessment cycle, so that we can reduce the number of assessment cycles for abbreviated new drug applications (ANDAs) and facilitate timely access to quality, affordable, safe and effective generic medicines. To achieve this, FDA communicates frequently with industry, similar to PDUFA, and funds research under the GDUFA Science and Research Program to better understand drug products and develop new tools to evaluate generic drug equivalence. FDA also develops Product-Specific Guidances to assist generic drug developers and established the Drug Competition Action Plan (DCAP) in 2017 to further encourage robust and timely market competition for generic products.

As a result of these and other efforts, FDA’s times to approval for ANDAs have decreased under the GDUFA program, and we have also made progress in minimizing the number of review cycles for applications to obtain approval. While there is some year-to-year variability, in more recent years (FY 2018–FY 2023), the rate of first cycle approvals has generally increased, as noted below:

- FY 18 17.1%
- FY 19 15.1%
- FY 20 15.2%
- FY 21 16.7%
- FY 22 15.9%
- FY 23 17.6%

FDA works with all sponsors to resolve issues and help speed development of new and generic drug products, while maintaining high, scientifically-based assessment standards.

#### REAL-WORLD DATA

*Question.* More and more of our health care system is now digitized and there are more potential sources to pull data and information from to help clinicians and researchers. Data is fragmented across multiple, complex systems however and there must be the strongest protections to preserve and protect patient data and personally identifiable information. Does FDA guidance currently allow for or is the FDA working with organizations who can help connect researchers and clinicians to de-identified health care data across real-world data sources like electronic health records, payor claims, and mortality data? What specifications or guidance does the FDA currently provide regarding use of encryption tools and privacy-preserving record locators to optimize the collection of comprehensive real-world data?

*Answer.* FDA guidance provides sponsors, researchers, and other interested parties with recommendations related to the use of real-world data—such as from electronic health records (EHRs), claims, and registries—to support a regulatory decision. As FDA seeks to improve the comprehensiveness and validity of studies using de-identified data while protecting privacy, the Agency supports research projects with external organizations that use methods of encryption to link data in commercial EHR systems with claims and mortality data.

With regard to the use of encryption tools and privacy-preserving record locators, such standardizing specifications are not generally within the purview of the Agency. Nonetheless, FDA guidance addresses considerations to ensure that linkages of de-identified data lead to datasets that are complete and fit-for-use in regulatory decision-making.

## QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

## HUMAN FOODS PROGRAM

*Question.* As touched upon during our hearing, we appreciate the work FDA is undertaking to establish the unified Human Foods Program and the reworking of the Office of Regulatory Affairs. It's been said this is the largest reorganization in FDA's history. At the end of the day, Americans want to be assured that the food they eat it is safe.

What are the specific objectives of the reorganization, and what metrics will you use to determine whether or not the new programs are achieving said objectives while increasing the safety of our food supply system?

*Answer.* Among other things, the changes in the Human Foods Program (HFP) reorganization will allow the Agency to more effectively realize the preventive vision laid out in the FDA Food Safety Modernization Act; elevate the importance of nutrition to help reduce diet-related diseases; and strengthen state partnerships and embrace innovative food and agricultural technologies that will position the Agency to more effectively regulate and uphold the safety of the Nation's food supply. As the reorganization is implemented, communicating these strategic goals and priorities of the newly established HFP, for both transparency and accountability, will be important. We are developing strategic management processes for the new organization and are working on communicating HFP priorities and accomplishments in FY 2025. In the longer-term, a key component of the HFP is the Office of Strategic Programs, which will facilitate strategic planning and performance management across the program and evaluate progress toward annual and multi-year priorities.

## LABORATORY DEVELOPED TESTS

*Question.* FDA recently finalized its Laboratory Developed Tests (LDT) regulation, which as I understand it, is an attempt to improve the safety of lab tests, pathology results, diagnosis, and treatment.

While well-intentioned, we should make sure to avoid one-size-fits-all rules that may result in unintended consequences or lead to the stifling of innovation.

Can you describe the feedback FDA received during the rulemaking process, and how the comments received are addressed in the final rule?

*Answer.* FDA received more than 6,500 comments on the notice of proposed rulemaking from a variety of entities including medical device associations, members of the medical device and pharmaceutical industries, medical and healthcare professional associations, hospitals and academic medical centers, accreditation organizations, other advocacy organizations, government agencies, and individuals.

Comments supporting FDA's proposal pointed to problems with laboratory developed tests (LDTs), concerns about the significant impact of problematic LDTs on patients and the treatment decisions of healthcare providers, and the need for increased oversight of LDTs by FDA. Some comments also emphasized the importance of creating a "level playing field" between laboratory and non-laboratory manufacturers of in vitro diagnostics (IVDs), and described how phasing out the general enforcement discretion approach for LDTs would incentivize innovation by non-laboratory IVD manufacturers.

Some comments also raised concerns or requested clarification regarding the evidence related to the safety or effectiveness of IVDs offered as LDTs; the sufficiency of regulation by the Centers for Medicare & Medicaid Services and other non-FDA entities; FDA's legal authority to regulate LDTs; the impact of the phaseout policy on access to and the pricing of IVDs offered as LDTs; the impact of the phaseout policy on test innovation; the impact of the phaseout policy on small laboratories; the impact of the phaseout policy on specific patient populations; the details of the phaseout policy; the types of IVDs offered as LDTs for which the FDA intends to continue the general enforcement discretion approach and generally not enforce some or all applicable requirements; and FDA's implementation of the phaseout policy and the resources needed for such implementation. FDA responded to comments in the preamble to the final rule.

In part based on comments received on the notice of proposed rulemaking, FDA's final phaseout policy described in the preamble to the final rule includes several targeted enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, which were not included in the proposed phaseout policy described in the preamble to the proposed rule.

Specifically, FDA intends to:

- Exercise enforcement discretion and generally not enforce requirements for LDTs manufactured and performed within the Veterans Health Administration or the Department of Defense.

- Exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by, conditionally approved by, or within an approved exemption from full technical documentation under the New York State Department of Health Clinical Laboratory Evaluation Program, as described in the preamble to the final rule.
- Exercise enforcement discretion and generally not enforce premarket review requirements and most quality system (QS) requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.
- Exercise enforcement discretion and generally not enforce premarket review and most QS requirements for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of the rule and that are not modified, or that are modified in certain limited ways as described in the preamble.
- Exercise enforcement discretion and generally not enforce premarket review and most QS requirements for non-molecular antisera LDTs for rare red blood cell antigens where such tests are manufactured and performed in blood establishments, including transfusion services and immunohematology laboratories, and where there is no alternative available to meet the patient's need for a compatible blood transfusion. These serological tests are used for typing red blood cell units for non-ABO/Rh(D) antigens to ensure the patient receives a compatible blood transfusion.

*Question.* How will FDA work to ensure this is not a regulatory barrier that contributes to paperwork burdens on physicians and hospitals, or negatively impacts the development of new, innovative tests?

*Answer.* Increased FDA oversight is important to realize the potential of innovative laboratory developed tests (LDTs) by, for example, motivating the development of robust scientific data on safety and effectiveness. FDA believes the final phaseout policy will also incentivize innovation by non-laboratory manufacturers and help ensure that innovation from laboratory manufacturers yields in vitro diagnostics (IVDs) for which there is a reasonable assurance of safety and effectiveness. FDA's previous enforcement discretion approach for LDTs may have disincentivized innovation by non-laboratory manufacturers who compete with laboratory manufacturers that offered their tests without complying with FDA requirements. Addressing the current imbalance in oversight may foster innovation by manufacturers who can make safe and effective novel tests available to many labs. Moreover, by applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs, FDA will give stakeholders greater clarity regarding compliance expectations.

The final phaseout policy includes several enforcement discretion policies that the Agency anticipates will reduce burdens for physicians and hospitals. For example, FDA intends to exercise enforcement discretion and generally not enforce premarket review and quality system requirements for certain LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

#### FDA STAFFING AND TELEWORK ISSUES

*Question.* Like many organizations, FDA utilized telework during the height of the Public Health Emergency. At FDA, there are certain activities during drug development that still require in-person collaboration, including meeting management, inspections, and first cycle approvals for products.

Can you summarize FDA's current telework policy?

Does FDA's current telework policy allow for critical in-person meetings, i.e. meetings with drug developers on drug reviews?

*Answer.* FDA understands the value of in-person interactions to foster deeper connections, creativity, and seamless teamwork. The Agency remains steadfast in our commitment to facilitating in-person meetings while accommodating the diverse needs of our workforce and stakeholders.

FDA's current telework policy prioritizes meaningful in-person engagement while providing eligible employees with flexibility for remote work, telework, or on-site work arrangements according to job roles and organizational goals. Business needs may require certain positions to work on-site more frequently and vary between the various components of FDA. Positions may therefore be required to regularly attend in-person meetings with internal team members, industry sponsors, or other interested parties.

One example are formal meetings with industry, as agreed to in the Prescription Drug User Fee Act (PDUFA) VII<sup>7</sup> and Biosimilar User Fee Amendments (BsUFA) III.<sup>8</sup> As of January 22, 2024,<sup>9</sup> FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research expanded in-person face-to-face industry meetings with a hybrid component to allow maximum participation to include all PDUFA, BsUFA, and Over-The-Counter Monograph Drug User Fee Program (OMUFA) meeting types. All meetings have a hybrid component to enable attendees who may not be able to attend in-person to participate. However, anyone who is invited may attend in-person if they prefer. Thus far, FDA has received positive feedback from industry regarding the flexibility that virtual, hybrid, and in-person meetings provide. FDA will continue to work with industry to fully meet our user fee commitments and to ensure FDA's workforce operates at the highest level as we work to further our public health mission.

#### FACILITY INSPECTIONS

*Question.* There continues to be high demand for drug and biologic facility inspections.

What other tools, beyond on-site inspections, does the Agency have to help assess compliance of drug manufacturing facilities?

*Answer.* The Agency has a set of alternate tools it can use, as applicable and appropriate, as standalone or in conjunction with an FDA-conducted on-site inspection to provide oversight for FDA-regulated products, including mandatory requests for records under section 704(a)(4) of the FD&C Act and voluntary remote interactive evaluations. FDA used remote records requests to obtain information on the compliance of manufacturers when inspections were curtailed due to risk to agency and industry personnel during the COVID-19 public health emergency. These records requests help the Agency to maintain oversight over regulated establishments, determine best use of limited Agency inspectional resources, and when appropriate, help FDA make decisions on new drug applications and abbreviated new drug applications. Additionally, these records help the Agency determine whether sufficient corrective actions have been taken by previously compliant manufacturers to address identified objectionable conditions, allowing more efficient use of Agency resources.

For foreign inspections, records requests under section 704(a)(4) and other remote regulatory assessments continue to serve as a valuable tool for the Agency when inspections cannot be conducted in certain countries or regions due to factors such as security issues. FDA also has Mutual Recognition Agreements (MRAs) in place with several foreign regulatory authorities (e.g., European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), and SwissMedic) allowing the Agency to rely in part on inspections conducted by foreign regulatory authorities meeting U.S. requirements. These MRAs can help avoid duplication of inspections by multiple regulatory authorities for manufacturers and also enables the Agency to reallocate resources to other drug manufacturing facilities with higher risk profiles.

*Question.* The Agency has issued a number of draft guidances on the use of alternative tools, including remote regulatory assessments and remote interactive evaluations.

Has FDA begun using these tools to optimize their resources and capabilities in gathering data? If so, what has the Agency's experience been?

*Answer.* The Agency frequently used the authority for records requests under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) during the COVID-19 public health emergency to collect information on the compliance of drug manufacturers, when facility inspections were curtailed due to risk to Agency and industry personnel. The Agency continues to use authority for section 704(a)(4) records requests-which were expanded by Congress in 2022 to device establishments and facilities subject to bioresearch monitoring inspections-when an on-site inspection is not feasible. These records requests, under which FDA can require the provision of records in advance or in lieu of an inspection, allow the Agency to help maintain oversight over regulated establishments and have also been used, as appropriate, to help make decisions on new drug applications and abbreviated new drug

<sup>7</sup>PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027

<sup>8</sup>Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027

<sup>9</sup>Beginning February 13, 2023, prior to expiration of the COVID-19 Public Health Emergency, CDER and CBER started a phased return to in-person meetings. From Feb. 13, 2023 until Jan. 21, 2024, industry requested 83 in-person meetings. 90% of those meetings were granted as in-person. No meetings were delayed or denied due to conference room availability.

applications. Lastly, records requests and other types of remote regulatory assessments (RRAs) continue to serve as a valuable tool for the Agency when inspections cannot be conducted in certain countries or regions due to security issues. They have also been beneficial in providing FDA with information to help show corrective actions have been taken based on previous inspection findings, allowing more efficient use of Agency resources.

In FY 2023, FDA Office of Regulatory Affairs, Office of Import Operations (OIO), conducted 1,155 remote foreign supplier verification program (FSVP) inspections, with respect to human and animal foods; currently in FY 2024, OIO has conducted approximately 523 remote FSVP inspections. While such remote activities are a good tool, more time is needed to enable improved efficiencies in the process and to address challenges seen by industry. FDA has also seen some challenges regarding document sharing and communications, particularly with foreign facilities. Additionally, the collection of information via section 704(a)(4) records requests were sometimes more time- and resource-intensive than expected and at times, does not necessarily result in time and human resource savings. Although they are useful and viable tools, RRAs including section 704(a)(4) records requests and remote interactive evaluations, they are not a replacement for an onsite inspection.

#### BIOPHARMACEUTICAL PRODUCTION

*Question.* There has been an increased focus on enhancing the availability and production of drugs and biologics domestically to improve supply chain capabilities and avoid disruptions and shortages of critical medical products.

What is FDA doing to incentivize domestic biopharmaceutical production and capacity?

*Answer.* Reliance on foreign manufacturing is not a new concern for FDA. There are some things we can do to make it easier for manufacturing to be done in the United States, however there are significant economic issues that are out of our purview that have contributed to increased foreign manufacturing, specifically, pricing pressures, labor, and regulatory costs. We have been working closely with colleagues across HHS to identify authorities and capabilities available to address those other market forces. The Administration for Strategic Preparedness and Response is a critical partner in this, via the Supply Chain Control Tower and other capabilities, all as part of the HHS Supply Chain Working Group.

Within FDA, one of the most important things we can do to help reduce our reliance on foreign manufacturing is to encourage and facilitate the adoption of advanced manufacturing. Ensuring that both innovator product and generic drug manufacturers will have access to information regarding advanced manufacturing technologies is vitally important because advanced manufacturing requires a skilled workforce and can help domestic companies operate in smaller facilities with lower costs and fewer potential quality issues, improving the global competitiveness of U.S. manufacturing.

#### COUNTERFEIT PRODUCTS

*Question.* How is FDA addressing concerns over counterfeit and substandard products potentially making their way into the country?

*Answer.* FDA's Office of Criminal Investigations (OCI) plays a crucial role in investigating and helping prosecute individuals involved in the shipment of illegal FDA-regulated products into the United States. OCI created the International Operations Program (IOP) to help address this issue, and special agents assigned to IOP work closely with Customs and Border Protection at the international mail facilities, express parcel carriers, and air cargo facilities to detect shipments involving illegal FDA-regulated products and to investigate those involved in these illegal activities, as appropriate. OCI also collaborates with international counterparts, including United Kingdom agencies, Interpol, and Europol, to seize violative shipments and stop the flow of illegal FDA-regulated products destined for the United States; degrade (if not eliminate) the capabilities of those trading in these illegal products; and prosecute those engaging in these illegal practices.

FDA also accomplishes this important work through the refusal of imported FDA-regulated products that appear to be adulterated, misbranded, or unapproved new drugs. In 2012, FDA was granted the authority to administratively destroy adulterated, misbranded, or counterfeit drugs valued at \$2,500 or less. In 2018, FDA was also granted the authority to detain, refuse, and administratively destroy imported articles containing certain active pharmaceutical ingredients even if the article has little to no explicit evidence of intended drug use. These authorities are intended to protect the integrity of the United States drug supply chain and the public by preventing distribution or use of violative drugs that potentially pose a threat to

consumer's health. FDA investigators also examine allegations of counterfeit and substandard products that have been introduced into the country. These actions can form the basis for initiating the types of criminal investigations or interdiction activities as described above, as well as domestic enforcement actions that would stop further distribution of such products.

#### PDUFA PERFORMANCE GOALS

*Question.* Patients have come to rely on the FDA as the gold standard for ensuring the safety and efficacy of new medications. PDUFA was put in place over 30 years ago to address unacceptable delays, with program funds used to help ensure that the agency has the necessary resources to keep pace with innovation. Under PDUFA, FDA commits to certain performance goals for the timely conduct of sponsor meetings where alignment can be reached on data and study design expectations that would support future product approvals. In the most recent PDUFA performance report (FY 2022), FDA met 6 out of the 20 procedural meeting goals. This results in sponsors either delaying study starts or proceeding at risk without FDA alignment, either of which may result in delayed access for patients.

What efforts are being taken to ensure the review capabilities and workforce capacity exists to meet PDUFA's performance goals?

*Answer.* FDA plays a vital role during drug development by providing advice and feedback to sponsors at various points during the process. Timely interactive communication with sponsors during drug development is a core Agency activity and helps ensure that new and innovative products are developed and available to the American public as soon as possible.

After FDA receives an application, the Agency's obligation is to manage the review process and determine whether a submitted application meets the legal and scientific requirements for approval of the product. FDA staff are expected to adhere to internal review timelines, established in part through user fee agreements. To increase the likelihood of first cycle approval, however, the applicant's continued active involvement is important, especially in responding to requests for additional information that may be prompted by the ongoing reviews. FDA works with all sponsors to resolve issues and help speed development of new products, while maintaining high, scientifically-based safety and efficacy standards.

To efficiently conduct reviews of human drug applications and meet PDUFA commitments, FDA must be able to hire and retain sufficient numbers and types of technical and scientific experts.

To strengthen this core capability, FDA has established a modernized position management system, more efficient recruiting practices, a dedicated scientific recruiting function, and metric goals for human drug review staff hiring. The vital hiring authorities in the CURES Act have also greatly improved FDA's ability to hire and retain scientific experts in more complex and specialized areas and meet our growing responsibilities. The Agency continues to put every effort into meeting our hiring goals.

From FY23–25, 333 newly funded FTE positions were provided with the passage of PDUFA VII as shown on Page 59 of the PDUFA VII commitment letter available online.<sup>10</sup>

A current update on our hiring efforts can be found on our website and is updated quarterly.<sup>11</sup>

#### BIOSIMILARS

*Question.* Biosimilars offer a market-based approach to providing more affordable biologic products after the patent and exclusivity protections expire. These products, like generic drugs, can be an effective option for patients in the marketplace.

How is FDA ensuring the timely availability of safe and effective biosimilar products?

*Answer.* Just recently, the Agency approved our 50th biosimilar in April 2024. FDA has many activities in the biosimilar space and many of them are reflected in the overarching goals outlined in the Agency's Biosimilar Action Plan:

- Enhancing the efficiency of the biosimilar product development and approval process.
- Maximizing scientific and regulatory clarity for the biosimilar product development community.

<sup>10</sup> <https://www.fda.gov/media/151712/download?attachment>

<sup>11</sup> <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa- quarterly-hiring-updates>.

- Developing effective communications to improve understanding of biosimilars.
- Supporting market competition by reducing attempts to unfairly delay competition.

We also included a legislative proposal in the President’s FY 2025 Budget request to eliminate the statutory distinction between biosimilar and interchangeable biosimilar products. This proposal would deem all approved biosimilars to be interchangeable with their respective reference products. This proposal would also help eliminate any confusion caused by the statutory distinction between biosimilars and interchangeable biosimilars and could save patients and the Federal Government money.

FDA has developed a variety of educational resources for both health care providers and patients to provide unbiased, accurate information about biosimilars. We are continuing that work by developing additional materials and using innovative dissemination methods to reach intended audiences.

#### SUNSCREEN

*Question.* In accordance with the President’s Cancer Moonshot goals to continue reducing cancer death rates, the Committee is interested in understanding what progress is being made in the approval of next general sunscreen products. The FDA last approved a new over-the-counter monograph sunscreen active ingredient, or UV filter, in the 1990s. Since that time, other countries around the world have moved ahead of the United States in the development of new products, and eight new products submitted to the FDA under the sunscreen monograph Time and Extent Application process have been stalled in the approval process. In 2014, Congress enacted the Sunscreen Innovation Act, which authorized the issuance of guidance for the criteria for a generally recognized as safe and effective (“GRASE”) determination for nonprescription sunscreen products, and required the agency to finalize the sunscreen monograph within 5 years of enactment. Despite these efforts, no new sunscreen active ingredients have been approved. In 2022, CDER Director of the Office of Nonprescription Drugs Theresa Michele noted that research studies were ongoing on the eight products noted above that were submitted to the FDA. No new updates have been provided since that time.

Will you provide the latest status regarding an update to the sunscreen monograph, including the status of research studies and a timeline of when FDA expects to be ready to approve new sunscreen products?

*Answer.* At the outset, we note that the question cites to a webpage published in 2022 with comments from Dr. Theresa Michele.<sup>12</sup> The scope of ingredients addressed in the 2022 webpage is limited to ingredients that are currently permitted to be lawfully marketed in the U.S. However, the question seems to be addressing a different subset of ingredients—specifically, those that are not currently permitted to be lawfully marketed in the U.S. as active ingredients in sunscreen products. While there are data gaps relevant to both sets of ingredients, the regulatory status of these two groups of ingredients is not identical. Given the emphasis of the question on “new” ingredients, we assume the intent of the question is to inquire as to the status of ingredients that are not currently permitted to be marketed in the United States. Accordingly, our response addresses that group of ingredients.

Many Americans rely on sunscreens as part of their skin cancer prevention strategy, which makes satisfactory evidence of both safety and effectiveness of these products critical for public health. To help reduce the risk of skin cancer, sunscreen products are often used on a near-daily basis over a whole lifetime, starting at age 6 months, and are applied over much of the body surface—thus frequently involving extensive, repeated, cumulative exposure to their active ingredients.

Since sunscreens were originally evaluated, newer data emerged showing that a number of sunscreen active ingredients are absorbed through the skin and into the body. Consequently, safety questions about sunscreens—particularly questions related to long-term use of absorbed ingredients—remain a priority. FDA’s safety testing framework for sunscreens was strongly supported by an independent advisory committee.

As such, FDA encourages sunscreen manufacturers to submit data showing that sunscreens containing active ingredients that are not yet available in the United States are generally recognized as safe and effective. To that end, we have directed industry to helpful guidance documents FDA has published on the safety and effectiveness data needed to determine whether a nonprescription sunscreen active in-

<sup>12</sup> <https://www.fda.gov/drugs/cder-conversations/update-sunscreen-requirements-deemed-final-order-and-proposed-order>

redient is GRASE<sup>13</sup> and on conducting Maximal Usage Trials (MUsT)<sup>14</sup> needed to assess how much of a sunscreen ingredient is absorbed through the skin into the body. In addition, FDA conducted and published two pilot trials<sup>15 16</sup>, evaluating the absorption of various sunscreen ingredients. Wherever possible, FDA has also taken steps to offer industry tailored study recommendations that take into consideration the specific pharmacological properties of sunscreens and that could reduce testing burdens.

*Question.* Regarding timeline, if and when FDA receives a needed data for sunscreen active ingredients that are not currently permitted to be marketed in the U.S., FDA will review it in a timely manner and in accordance with the timeframes set forth in user fee letters negotiated with industry.

FDA also notes that while having additional sunscreen choices may be desirable to consumers, new sunscreen active ingredients are not necessarily safer or more effective than the ones already available in the U.S. by virtue of being available in markets other than the U.S. Many currently marketed and widely available sunscreen products provide broad-spectrum protection with an SPF of 15 or more and are effective not only in helping to prevent sunburn, but also in reducing the risk of skin cancer and early skin aging caused by the sun, when used as directed in their labeling.

FDA is committed to working with industry and public health stakeholders to help ensure that the sunscreens consumers use to protect themselves and their families are safe and effective for their intended use.

#### FOREIGN MANUFACTURER TOBACCO REGISTRATION

*Question.* In 2009, Congress required under the Tobacco Control Act that the FDA publish a rule requiring foreign manufacturers to register with the FDA if they wanted to sell tobacco products in the

U.S. Like many, I am concerned with the influx of illicit vapor products manufactured in China that are being illegally imported into the United States.

Can you share what FDA is doing in terms of enforcement on this issue, and when we can expect the rule required by the Tobacco Control Act?

*Answer.* FDA continues to work on the Establishment Registration and Product Listing for Tobacco Products proposed rule, which appeared in the most recent Unified Agenda.<sup>17</sup> CTP also included the rule on its recently published policy agenda which outlines rules and guidance documents that are in development or planned for development.<sup>18</sup> The proposed regulation would prescribe the format, content, and procedures for establishment registration and tobacco product listings for both domestic and foreign manufacturers of tobacco products.

The Center continues to weigh competing priorities given available resources and updates the policy agenda annually. In the meantime, FDA receives information about foreign manufacturers as part of the premarket tobacco product application (PMTA) process. A PMTA must include information including a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation and a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation. This is true for applications from both domestic and foreign manufacturers.

#### UNAPPROVED DRUGS

*Question.* I'm told there are reports of numerous unapproved phenobarbital drugs containing prohibited excipients that are currently marketed for use in neonates with seizures, which would present a serious safety threat for vulnerable infants.

Has the FDA utilized its enforcement authority to remove unapproved phenobarbital drugs from the market and if not, does the Agency plan to do so this year?

*Answer.* FDA approved Sezaby (phenobarbital sodium) in November 2022 for the treatment of neonatal seizures in term and pre-term infants. Sezaby is an FDA-approved phenobarbital sodium injection product, and it is preservative-free. It is not approved for use in adolescents or adults, and its labeling includes a boxed warning that the product is only for short-term use.

FDA is aware that there are a number of unapproved phenobarbital sodium injection products currently on the market. According to the labeling for some of these

<sup>13</sup> <https://www.fda.gov/media/94513/download>

<sup>14</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/maximal-usage-trials-topically-applied-active-ingredients-being-considered-inclusion-over-counter>

<sup>15</sup> <https://jamanetwork.com/journals/jama/fullarticle/2733085>

<sup>16</sup> <https://jamanetwork.com/journals/jama/fullarticle/2759002>

<sup>17</sup> <https://www.reginfo.gov/public/do/eAgendaMain>

unapproved phenobarbital sodium products, these products are intended for use in the adult population as a sedative, hypnotic, preanesthetic, or long-term anticonvulsant and for use in pediatric patients as an anticonvulsant and sedative.

In general, as with FDA's compliance activities across the Agency, we follow a risk-based enforcement approach that involves prioritization in light of the facts of a given circumstance. This includes prioritizing enforcement for drug products that pose the highest risk to public health. This risk-based enforcement approach best supports FDA's public health priorities. The Agency is currently reviewing a Citizen Petition regarding the marketing status of phenobarbital drugs and will respond to the Petition as soon as possible and post the response to the public petition docket.

#### FOOD REGULATION

*Question.* As I have stated before, FDA is the gold standard for safety and efficacy. However, I am concerned that some States are going beyond FDA in banning certain chemicals, ingredients, and additives in food.

Is FDA concerned that these actions have the potential to leave us with a patchwork of food regulations, while at the same time, relinquishing FDA's authorities to the States?

*Answer.* Yes, a strong national food safety system is not built state by state. Clearly, having States issue these types of bans, while they may be within their rights under our current regulatory system, is not ideal. States play a crucial role as our partners in regulating the food supply and coordinating our efforts is integral to our success. FDA must lead the way on food chemical safety. Not only because it is confusing for consumers for there to be different standards and impractical for industry, but because the determination of safety should be based entirely on science, and not on where you live in the U.S.

FDA maintains active, and widely used, regulatory programs to assist industry in meeting its pre-market requirement to ensure all substances (including food chemicals) are safe under their intended conditions of use. All assessments of these ingredients are conducted by the Office of Food Additive Safety in FDA's Center for Food Safety and Applied Nutrition (CFSAN).

Regardless of the regulatory program used (food additive or color additive petition process, food contact notification, or the Generally Recognized as Safe (GRAS) Notification Process), the safety standard must be met for all substances used by industry for use in food or food packaging that there is a reasonable certainty of no harm under the intended use conditions.

Chemical safety is one of the three fundamental risk management pillars of the new FDA Human Foods Program, which is a recognition of the importance of our food chemical safety work. As the reorganization is finalized, we are continuing to implement our enhanced approach to food chemical safety designed to ensure we keep pace with innovation while maintaining as our first priority the safety of foods available to consumers.

#### FOOD TRACEABILITY RULE

*Question.* Will you commit to engage with the food industry to address the most challenging aspects of the Food Traceability Rule, including working with industry stakeholders to determine any changes that may be necessary to allow for successful compliance with the Rule?

*Answer.* FDA remains committed to serious engagement with the food industry regarding the Food Traceability Rule. We continue to work closely with industry to help them prepare for implementation of the rule, including by providing technical assistance. We also are engaging in ongoing discussions with industry, organized by the Reagan-Udall Foundation, regarding challenges, opportunities, and potential solutions for implementation.

Together, we can attain the Food Traceability Rule's public health goals of faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

#### SMOKING CESSATION

*Question.* HHS recently released an updated Framework to Support and Accelerate Smoking Cessation (the Framework). The Framework acknowledges that despite the progress made in the last 60 years to reduce the rates of cigarette smoking among U.S. adults cigarette smoking and secondhand smoke exposure still claim nearly half a million lives in the United States each year.

Last year, on June 1, 2023, at a Cancer Moonshot event at The White House, you acknowledged some of the challenges those seeking to bring forward new smoking cessation products may encounter.

What actions, if any, has CDER taken to help bring forward new, innovative smoking cessation medicines for patients?

*Answer.* As smoking results in many serious or life-threatening conditions (e.g., heart and lung disease and cancer), FDA recognizes there is an unmet need for novel therapies particularly for individuals who have not been able to quit despite available therapies.

Because we consider nicotine dependence to be a serious or life-threatening condition with an unmet medical need, we are encouraging development of novel smoking cessation drug therapies that show benefit over existing products by outlining how to qualify expedited development pathways such as fast track, breakthrough, and priority review.

In May 2023, CDER finalized the draft guidance Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy [NRT] Drug Products.<sup>19</sup> The NRT Guidance outlines strategies for applicants to make NRT development easier, efficient, and streamlined:

- Clarifying the appropriate pathways for companies that seek approval for a product that alters the route of administration compared to approved NRT drug products, e.g., products with pulmonary route of administration rather than an oral route of administration.
- Explaining when simplified efficacy study requirements may be used (e.g., recommending a 4-week study as the minimum period of efficacy ascertainment)
- Clearly outlining abbreviated pathways for NRT products, including how to use FDA's previous findings of safety and how already approved NRT products and published literature can be leveraged.
- Encouraging sponsors to consider expedited development and review pathways, as well as providing details on how to qualify.

In addition, because the data are so strong in demonstrating that quitting smoking can lower a person's chance of having lung disease, heart disease, and certain types of cancer, drug products that have been demonstrated to be effective for cessation are approved with labeling claims regarding these benefits without additional data supporting benefit of the particular product on these outcomes.

To support the majority of smokers who wish to quit and to increase utilization of cessation products and interventions, FDA and the National Institutes of Health (NIH) are collaborating to identify opportunities for the development of novel therapies, support innovative trial designs, and facilitate product development for smoking cessation therapies. Opportunities for innovation exist in many areas including collaboration with researchers to help identify novel targets, use of innovative clinical trial design and conduct, inclusion of individuals underrepresented in research, developing a better understanding of quit failures and relapse, and utilizing FDA's expedited programs for medical product development.

To this end, FDA will hold a joint public meeting with NIH this Fall to discuss innovations in development of smoking cessation products, and we anticipate the Federal Register notice for that meeting to be announced in the near future.

*Question.* What new actions does CDER plan to take, if any, in addition to the guidance previously issued?

*Answer.* Please see response to previous question.

*Question.* Does the agency believe additional, new smoking cessation therapies are needed to help patients be more successful in their quit attempts? If so, what new actions will CDER take to expand and improve treatment options for smokers seeking to be more successful in their quit attempts.

*Answer.* Please see response to previous question.

*Question.* What steps is FDA taking to make sure that the regulation of cessation medicines is keeping pace with the ongoing unmet clinical needs and public health urgency in helping patients be more successful in their quit attempts? Please specify the timeline for such action underway and or planned for the future. Please also specify the metrics the agency is using to track progress on these actions.

*Answer.* Please see response to previous question.

Additionally, it is important to note that FDA does not develop drugs. Historically, FDA has seen limited interest from sponsors in developing nicotine replacement therapy products and we have not seen a recent change. All New Drug Applications are subject to the performance goals and procedures for the Prescription Drug User Fee Act (PDUFA VII) 2023–2027. Please see the PDUFA VII commitment letter for

<sup>18</sup> <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/center-tobacco-products-regulation-and-guidance-policy-agenda>

more information.<sup>20</sup> The goals letter represents the product of FDA’s discussions with the regulated industry and public stakeholders, as mandated by Congress.

DRAFT REPORT AND PLAN ON BEST PRACTICES FOR GUIDANCE

*Question.* Earlier this year, FDA published a “Draft Report and Plan on Best Practices for Guidance” which proposes eliminating the notice and comment period for Level 1 guidance documents. FDA currently has the authority to issue Level 1 guidance documents without prior public participation when responding to urgent issues, and did so during the COVID–19 pandemic.

What policy objective is FDA seeking to achieve by seemingly expanding this policy?

Has FDA examined the costs and any potential unintended consequences associated with this policy, and if so, what has the agency found?

How does publication of a draft version of significant guidance documents allow patient groups, health care professionals, and other stakeholders the opportunity to prepare prior to implementation? Is FDA concerned this policy change could impact productive stakeholder engagement with FDA?

*Answer.* Following FDA’s rapid issuance of over 80 guidance documents (not including revisions) related to the COVID–19 public health emergency, including many that were issued without prior public comment, section 2505(a) of the Consolidated Appropriations Act, 2023 was enacted. In that provision, Congress directed FDA to examine our practices for the efficient prioritization, development, review, clearance, issuance, and use of FDA guidance documents.

FDA guidance documents are prepared for regulated industry, FDA staff, and the public to describe the Agency’s interpretation of, or policy on, a regulatory issue.<sup>21</sup> Unlike statutes and regulations, guidance documents do not establish legally enforceable rights or responsibilities and are thus exempt from notice and comment requirements applicable to most rulemaking under the Administrative Procedure Act.<sup>22</sup> However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA’s Good Guidance Practices regulation require FDA to provide an opportunity for public comment prior to publication for all Level 1 guidance documents (i.e., guidance documents that include initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues), unless FDA determines that prior public participation is not feasible or appropriate.<sup>23</sup> If FDA determines that public participation is not feasible or appropriate prior to publication of a guidance document, FDA must invite public comment upon publication and take such comment into consideration.<sup>24</sup> For Level 2 guidance documents (i.e., guidance documents that set forth existing practices or minor changes in interpretation or policy), FDA invites public comment upon publication.<sup>25</sup>

In accordance with the directive in section 2505(a) of the Consolidated Appropriations Act, 2023, FDA issued a “Draft Report and Plan on Best Practices for Guidance” (2023 Draft Report and Plan) identifying proposed best practices for the efficient prioritization, development, review, clearance, issuance, and use of guidance documents. This included considering whether, consistent with the FD&C Act, there are additional categories of Level 1 documents for which, or circumstances under which, FDA could use our authority to issue Level 1 guidance documents “for immediate implementation,” meaning without prior public comment. This proposal is consistent with recommendations FDA made in its 2011 report “Food and Drug Administration Report on Good Guidance Practices Improving Efficiency and Transparency” and is based upon over 20 years of FDA experience in implementing its Good Guidance Practices and experience gained during the COVID–19 Public Health Emergency.

Consistent with section 2505(c) of the Consolidated Appropriations Act, 2023, in a Federal Register notice announcing the availability of the 2023 Draft Report and Plan, FDA sought public comment from a broad range of commenters, including regulated industry; researchers; academic organizations; pharmaceutical, biotechnology, and medical device developers; clinical research organizations; clinical laboratories; health care providers; food manufacturers; and consumer and patient groups. FDA is carefully considering comments as it prepares its final report and plan.

<sup>20</sup> <https://www.fda.gov/media/151712/download?attachment>

<sup>21</sup> See 21 CFR 10.115(b)

<sup>22</sup> See 21 CFR 10.115(d); 5 U.S.C. 553(b)(A); (d)(2)

<sup>23</sup> See 21 U.S.C. 371(h)(1)(C)(i); 21 CFR 10.115(g)

<sup>24</sup> See 21 U.S.C. 371(h)(1)(C)(i); 21 CFR 10.115(g)(3)

<sup>25</sup> See 21 U.S.C. 371(h)(1)(D); 21 CFR 10.115(g)(4)

## GRAIN RECONDITIONING

*Question.* The FDA's grain reconditioning process plays a critical role in the exporting of U.S. bulk commodities, which gets high-quality crops from American farmers to their customers around the world. Recently, I have heard concerns regarding the timing of reconditioning plan approvals.

Is the FDA reviewing the reconditioning process to identify ways to minimize delays? If so, please provide details and a timeline for implementation.

*Answer.* FDA is aware of the concerns from industry regarding reconditioning proposals and is collaborating with our Federal partners at the USDA Federal Grain Inspection Service (FGIS) to address them. For background, the reconditioning process can occur when adulterated grain is identified at a point of export. In order to address food safety concerns, a firm can propose a reconditioning plan, which FDA may accept. FDA and FGIS work under a Memorandum of Understanding (MOU 225–80–2000)<sup>26</sup> to facilitate interagency coordination on the inspection and standardization of grain, rice, pulses, and other food products assigned to FGIS by the Secretary of Agriculture. FDA and FGIS have worked to identify procedures involved in the grain reconditioning process that can be streamlined to help address these timeliness concerns and are working to finalize these modified procedures in FY 2025.

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 QUESTIONS SUBMITTED BY SENATOR MITCH MCCONNELL

## TOBACCO 21

*Question.* In 2019, to address growing youth tobacco use, Congress passed legislation raising the minimum age to purchase tobacco from 18 to 21. 180 days after enactment of that legislation, FDA was required to promulgate a rule to update all references to persons younger than 18 years of age in subpart B of part 1140 of title 21, Code of Federal Regulations, and to update the relevant age verification requirements under part 1140 to require age verification for individuals under the age of 30. However, nearly 4 years after the congressionally mandated deadline, FDA has not produced a final rule. In response to questions from letters in 2022 and 2023, FDA indicate that regulations would be forthcoming. A final rule has been repeatedly delayed without explanation, and in response to previous letters, FDA indicated it cannot provide an update on specific timing of the rulemaking process.

Please provide an update on the status of the final rule, including an explanation for the continuous delays.

Please explain the impact of the delayed rulemaking on implementation of the Tobacco 21 legislation. What negative effects on public health are occurring because of the lack of updated regulation?

In the absence of the congressionally mandated final rule, how does FDA plan to measure retailer compliance of ID checks and communicate these requirements to States and retailers?

*Answer.* Soon after the enactment of the Tobacco 21 legislation in December 2019, FDA began implementing and enforcing the law's increased Federal minimum age of sale by incorporating the increased age into FDA's tobacco retail inspections and other surveillance activities.

Importantly, the Agency has continued to enforce the statutory requirement that retailers not sell tobacco products to anyone under the age of 21.

Following the May 8th hearing, on August 30, 2024, FDA published the Prohibition of Sale of Tobacco Products to Persons Younger than 21 Years of Age final rule. Until the final rule goes into effect on September 30, 2024, the current requirement of verifying identification by means of photo identification for those under 27 years of age remains. Once the final rule goes into effect on September 30, 2024, verifying identification will be required for those under 30 years of age. In the interim, FDA has provided educational materials to retailers, such as updated webinars, describing how brick-and-mortar and online retailers must comply with FDA's tobacco sale regulations, and we continue to use our compliance and enforcement tools to ensure retailers comply with requirements.

As noted above, FDA implemented and began enforcing the Tobacco 21 law by incorporating changes into FDA's tobacco retail inspection program. From January 1, 2020, to April 30, 2024, FDA conducted over 330,000 inspections and issued over 43,200 warning letters (over 12,200 pertained to sales of electronic nicotine delivery

<sup>26</sup> <https://www.fda.gov/about-fda/domestic-mous/mou-225-80-2000>

system (ENDS) products to individuals under the age of 21), and filed over 8,900 complaints for civil money penalties (2,500 pertained to sales of ENDS products to individuals under the age of 21), and 33 complaints for no-tobacco-sale orders to retail establishments where violations were found during compliance check inspections.

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QUESTIONS SUBMITTED BY SENATOR SUSAN M. COLLINS

NEUROLOGY DRUG PROGRAM

*Question.* I have led efforts in Congress to provide funding for the Neurology Drug Program to help streamline the delivery of innovative treatments to individuals with brain diseases, mental health conditions, and brain injuries. Congress provided \$2 million for the Neurology Drug Program in FY23 and FY24. My understanding is that FDA has hired 2 FTEs to carry out this work so far. Can you share more about the responsibilities of these individuals, including tangible examples of the work they are leading with the support of NDP funding? Do you plan to hire additional staff to support these efforts? How could you use additional funding to advance treatments for brain diseases and disorders? Please speak directly to patient engagement efforts that the agency could expand or begin.

*Answer.* While this is a non-exhaustive list, please find several examples below of how FDA has utilized this critical funding, and how the Agency would propose to utilize additional funding.

CDER

In FY 2023, FDA's Center for Drug Evaluation and Research (CDER) utilized the appropriated funding for the NDP to hire 2 FTEs to support the program. In FY 2024, a third FTE, with training in neurodevelopmental disorders, has been hired to support drug development for rare pediatric neurogenetic disorders. These staff members have provided critical support to develop new policy and guidance in this area, as well in supporting product review. Specifically, these CDER staff were instrumental to the approvals of four new therapies for neurological disease in 2023: Skyclaris (omaveloxolone) for the treatment of Friedreich's ataxia approved on February 28, 2023; Qalsody (tofersen) for the treatment of amyotrophic lateral sclerosis (ALS) in patients who have a mutation in the superoxide dismutase 1 (SOD1) gene approved on April 25, 2023; Leqembi (lecanemab) on January 6, 2023 and July 6, 2023 for the treatment of Alzheimer's disease; and Agamree (vamorolone) for the treatment of Duchenne muscular dystrophy. For 2024, these staff have contributed to the approval of two new therapies for neurologic disease: Duuvyzat (givinostat) for the treatment of Duchenne muscular dystrophy approved on March 21, 2024, and Kisunla (donanemab) for the treatment of Alzheimer's disease approved on July 2, 2024, among other activities. CDER staff have also directed a multi-year grant to address challenges in neurological disease drug development through the development of innovative model-informed drug development to inform clinical trial design.

CBER

Within the Center for Biologics Evaluation and Research (CBER), funding has been utilized to initiate a research project focused on the identification of neural stem cell (NSC) quality attributes that can be used to evaluate cellular therapy products and to improve manufacturing. Results from this research may be useful in defining methods and standards for the evaluation of the quality of NSC products. CBER has also used the NDP funds to implement FDA's Action Plan for Rare Neurodegenerative Diseases. This included participating in a Pelizaeus Merzbacher Disease patient listening session held on August 22, 2023. Additionally, CBER is in the process of hiring two staff. One of the planned FTE is for a neurology specialist to support additional guidance to industry, building on the final guidance CBER published last year on Human Gene Therapy for Neurodegenerative Diseases. The new staff will also contribute to CBER's engagement in the activities outlined in FDA's Action Plan for Rare Neurodegenerative Diseases, including the development of disease-specific science strategies and engagement in the Public-Private Partnership for Rare Neurodegenerative Diseases.

CDRH

The Center for Devices and Radiological Health (CDRH) has utilized NDP funds to hire a medical officer with expertise in neurology and device development. This

individual has taken clinical lead on novel brain neurostimulation device submissions focused on Movement Disorders such as Parkinson's Disease. This includes several files as part of CDRH's Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot which focuses on including external stakeholder voices, such as patient advocacy organizations and clinical professional societies, in the device development process. Increased staff through the NDP program enables continued outreach to community partners.

PROPOSED USES OF ADDITIONAL NDP DOLLARS

Additional funding would help support NDP efforts in three ways. First, the Agency currently receives a large number of requests for external engagement activities in the neuroscience space, and many of these requests must be declined due to inadequate resources. Additional funding would allow for the recruitment of additional FTEs to be hired and trained to assist with these activities. Second, additional funding would allow for the NDP to fund more research efforts in the neuroscience space to address and advance drug development. And finally, additional funding would allow for continued expansion of patient engagement and educational activities specific to neurologic and psychiatric diseases. The NDP staff recognize the need for patient engagement and the critical information that both FDA and patients learn from one another.

With the growing innovation in clinical trial design and the uptake of innovation in neurology and psychiatry trials, the NDP will need to actively engage with key stakeholders to better understand, develop and implement these innovations into clinical trials.

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QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

FOOD TRACEABILITY RULE

*Question.* Dr. Califf, your agency, issued the final Food Traceability Rule with a compliance date of January 2026. Based on the information I am receiving from the food industry, from growers to point-of-sale, this Rule intends to regulate tens of thousands of products, costing tens of billions of dollars for the food industry to implement, and ultimately, consumers will pay the price at the grocery store.

Food industry stakeholders have serious concerns about meeting the compliance standards with the Food Traceability Rule by the current implementation date.

I do want to be clear: I agree we should have a sense of food traceability, but this Rule, according to the industry, is overly broad and complex, which will create a huge burden that is, at this time, unworkable for the industry and I think it would be in the interest of your agency to work with the industry more effectively.

Given the importance of the States in assisting FDA to achieve its public health goals, what alternatives are you considering to support an integrated food safety system and ensure an over one hundred year relationship between the States and FDA continues and flourishes from this cooperation between Federal and State governments?

*Answer.* FDA's Food Traceability Rule establishes traceability recordkeeping requirements to allow for faster identification and rapid removal of potentially contaminated food from the market, so as to reduce foodborne illnesses and deaths.

The Agency continues to work closely with industry to help them prepare for implementation of the rule, including by providing technical assistance. We also are engaging in ongoing discussions with industry, organized by the Reagan-Udall Foundation, regarding challenges, opportunities, and potential solutions for implementation. Working together on implementation is expected to offer industry benefits by helping narrow the scope of necessary recall actions, which reduces expenditures by avoiding overly broad market withdrawals and mitigates potential loss of consumer confidence in their brands. Industry benefits from the rule may also include increased food supply system efficiencies, such as improvements in supply chain management and inventory control.

FDA values its longstanding partnerships with the States, and we have enhanced our collaborative activities over the past decade by building an Integrated Food Safety System (IFSS), which provides a coordinated approach to food safety. FDA recognizes the importance of engaging our State and local regulatory partners who will play a key role in successful implementation of the Food Traceability Rule. Their input is particularly important given their role in primarily regulating retail food establishments and restaurants. FDA is currently in the process of soliciting feedback from state/local partners on a proposed Food Traceability Rule inspectional

framework as well as engaging state partners in development of a compliance strategy for the rule.

We are committed to working with industry and IFSS partners towards our shared public health goal of reducing foodborne illness. In a complex and global food system, it is critical to protect consumers from contaminated products by being able to rapidly identify the source of these products and removing them from the marketplace as quickly as possible.

*Question.* Can you commit that the FDA will begin serious engagement with the food industry to address the most problematic provisions of the Rule while extending the compliance deadline to allow both FDA and industry to work collaboratively to refine the Rule?

*Answer.* FDA remains committed to serious engagement with the food industry regarding the Food Traceability Rule. We continue to work closely with industry to help them prepare for implementation of the rule, including by providing technical assistance. We also are engaging in ongoing discussions, organized by the Reagan-Udall Foundation, regarding challenges, opportunities, and potential solutions for implementation.

To give industry additional time, we extended the compliance date when we finalized the Food Traceability Rule from 2 years to 3 years from the effective date. We have also communicated that routine inspections under the Food Traceability Rule will not begin until 2027 to give covered entities additional time to work together and ensure that traceability information is being maintained and shared.

Together, we can attain the Food Traceability Rule's public health goals of faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

#### ANIMAL FOOD ADDITIVES

*Question.* Thank you for your agency's acknowledgment of our work in the Senate and the House to address animal feed ingredients in your budget request.

Dairy farmers in Kansas and across the United States are eager for proactive tools to help them build on their environmental stewardship work. One opportunity lies with FDA approval of animal feed ingredients with a proven track record in other countries. That last point is important because everyday products aren't approved here, and our farmers lose a competitive edge over their global counterparts.

Are you able to update us on your agency's efforts to authorize these products?

*Answer.* In the EU and Canada, the regulatory structures for animal food ingredients allow many products that are currently classified as drugs in the U.S. to be classified as animal food additives in those countries. This is not the case under FDA's statutory authority, which is why the Agency's fiscal year 2025 budget request included a legislative proposal that would establish a new legal framework for the approval and marketing of ingredients that would be defined as "zootechnical animal food substances" (ZAFS). This new regulatory authority would deem to be animal food additives certain substances for use in animal food or drinking water that function solely in the gut of an animal to: affect the byproducts of the digestive process of an animal, affect the gastrointestinal microbiome of the animal, or reduce pathogens in food products made from the animal. We believe the proposal to regulate these substances as animal food additives is responsive to the interests of stakeholders in developing and marketing such innovative products while still providing the appropriate safety review. We look forward to working with Congress to continue to advance this proposal.

More broadly, thanks to additional funding provided by Congress in recent years, timelines for animal food ingredient reviews have moved from 44% of reviews on time to 90% of reviews on time. Continued support would assist in improving our timelines and preparing FDA to receive additional product submissions if the ZAFS legislation is enacted. Our goal is to achieve faster market access and availability of safe animal food additive products for farmers.

*Question.* We have been working with stakeholders to find a way to create a pathway for your agency to approve innovative feed ingredients through the standard feed ingredient review process instead of the cumbersome, inappropriate, and unnecessary drug approval process.

Towards this end, I introduced the Innovative FEED Act with several of my colleagues, including Senator Baldwin, and we have the support of the full committee Vice Chair Senator Collins.

Dr. Califf, can you talk a little about how the passage of this bill would change or improve the process that is used today? Would the legislation provide the Center for Veterinary Medicine (CVM) with greater regulatory certainty or help streamline workstreams and regulation approaches at FDA?

*Answer.* FDA cannot comment on pending legislation. However, FDA does share the goal of the legislation, which is consistent with a legislative proposal included in FDA's FY 2025 Budget request to create a new category of animal food additives called zootechnical animal food substances (ZAFS). Specifically, certain substances would meet the definition of ZAFS if they are intended to be added to animal food or drinking water, act solely in the animal's GI tract, and have no nutritive value or technical effect on the animal food but have other important benefits, such as affecting the byproducts of digestion, reducing foodborne pathogens in food animals, or altering the animal's GI microbiome. This legislative change would give FDA increased flexibility to provide risk-based oversight and facilitate more timely availability of innovative animal food additives. Under this proposal, ZAFSs would be deemed to be food additives, and would not be animal drugs, despite having intended uses that could otherwise make them animal drugs under the FD&C Act.

#### SODIUM

*Question.* Dr. Califf, given your background as a cardiologist, I want to discuss sodium and the complex nature of food supply chains and dietary habits.

How does the FDA intend to assess the effectiveness of sodium reduction efforts on population-wide sodium intake and associated health outcomes? Are there specific metrics or studies planned to evaluate the impact of these initiatives?

*Answer.* A key part of the FDA's sodium reduction plan is to monitor progress toward our goals on a regular basis to understand changes that are occurring. Following the May 8th hearing, in August 2024, the Agency issued a draft guidance<sup>32</sup> for new 3-year voluntary sodium reduction targets in foods as part of Phase II of the Agency's ongoing work building on the Phase I reduction efforts<sup>33</sup> issued in October 2021 using food label, restaurant, and sales data.

Preliminary data<sup>34</sup> from the first phase has shown that about 40% of food categories had already reached the targets set in the 2021 guidance, or were close. The new voluntary targets, when finalized, would support reducing sodium intake to about 2,750 milligrams/day (mg/day), approximately 20% lower than intake prior to the Phase 1 targets outlined in the FDA's 2021 final guidance.

These new targets for industry are also intended to help address the excess intake of sodium in the U.S., which is currently almost 50 percent more on average than the recommended limit. Going forward, the Agency intends to conduct an assessment of progress on sodium reduction to the targets about every 3 years. As more data becomes available, FDA will also continue to work with other government agencies, such as the U.S. Department of Agriculture and the Centers for Disease Control and Prevention on these monitoring efforts.

*Question.* Are there plans to establish further sodium reduction targets beyond the current voluntary initiatives? If so, what factors will be considered in setting these targets, and how will stakeholders, including industry representatives and public health experts, be involved in the process?

*Answer.* FDA is currently evaluating progress towards the 2.5 year targets in the voluntary sodium reduction guidance that the FDA issued in October 2021<sup>35</sup> using food label, restaurant, and sales data, and has engaged extensively with stakeholders on sodium reduction efforts and the targets. Preliminary data has shown that about 40% of food categories had already reached the targets set in the 2021 guidance, or were very close. Additionally, FDA intends to conduct an assessment of progress on sodium reduction relative to the targets about every 3 years.

Additionally, following the May 8th hearing, on August 15, 2024, FDA issued a draft guidance<sup>36</sup> to establish Phase 2 of the voluntary sodium reduction targets to continue facilitating a gradual, iterative process to reduce sodium intake. The new targets focus on commercially processed, packaged and prepared foods in the marketplace, because more than 70 percent of sodium intake in the U.S. population is from sodium added during food manufacturing and commercial food preparation. While the new targets are still higher than the recommended 2,300 mg/day for those 14 years and older, the new targets are part of an iterative approach that balances

<sup>32</sup> Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2)

<sup>33</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals>

<sup>34</sup> <https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress>

<sup>35</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals>

<sup>36</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2>

the public health objective with the practicality of shifting industry practices and consumer preferences to advance public health. The draft guidance is also available for public comment.

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QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

TOBACCO PRODUCTS

*Question.* The FDA writes regulatory rules all the time. Yet, in two House hearings in April, you described the FDA as “the referee” that “doesn’t write the rules, Congress does.” There are at least two FDA rules that would go a long way toward dealing with the illicit e-vapor market that FDA has been sitting on for some time. First, you stated you were unaware of the pending Foreign Manufacturer Rule, which has been on FDA’s Unified Agenda in some form since 2012. It is currently listed in the “Long Term Actions” stage of rulemaking and the Notice of Proposed Rulemaking date was pushed back again—from May 2024 to November 2024. Why hasn’t the FDA issued the rule requiring foreign tobacco product manufacturers to register with the Center for Tobacco Products (a loophole that is being exploited by the Chinese manufacturers now making illegal e-vapor products)? Why can’t the FDA issue an Interim Final Rule given the level of urgency we are facing?

*Answer.* To issue an interim final rule, FDA must for good cause find that the notice and public comment procedures for such rulemaking are impracticable, unnecessary, or contrary to the public interest. At this time, FDA has not identified a strong basis to make such conclusions for purposes of issuing the tobacco manufacturer registration rule. FDA will continue to work on the Establishment Registration and Product Listing for Tobacco Products proposed rule, which appeared in the most recent Unified Agenda.<sup>37</sup> CTP also included the rule on its recently published policy agenda which outlines rules and guidance documents that are in development or planned for development.<sup>38</sup>

The Center has gained valuable experience in implementing registration and listing for domestic establishments that is informing development of the rule. The proposed regulation would prescribe the format, content, and procedures for establishment registration and tobacco product listings for both domestic and foreign manufacturers of tobacco products. Although the requirement for domestic manufacturers to register and list is in the statute, the proposed rule would describe the types of data required for submission and help ensure the data submitted by industry can best be used by FDA.

The Center continues to weigh competing priorities given available resources and updates the policy agenda annually. In the meantime, FDA receives information about foreign manufacturers as part of the premarket tobacco product application (PMTA) process. A PMTA must include information including a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation and a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation. This is true for applications from both domestic and foreign manufacturers.

*Question.* Second, an FDA rule to require an importer of e-vapor products to submit the product’s FDA PMTA number at the time of entry in U.S. Customs and Border Protection’s (CBP) Automated Commercial Environment (ACE) system has been on FDA’s Unified Agenda since publication in the Fall 2021 Agenda. This rule could potentially help CBP and FDA prevent illicit products from ever entering the country. The Notice of Proposed Rulemaking is currently listed as January 2024. When FDA has continually stated that the importation of illicit, non-compliant e-cigarettes from China is a major problem, why has this rule been pushed back? Why can’t the FDA issue an Interim Final Rule given the level of urgency we are facing?

*Answer.* Following the May 8th hearing, the Agency, with the Department of Treasury’s concurrence, issued a proposed rule to require that the submission tracking number for electronic nicotine delivery system tobacco products that are being imported or offered for import be submitted in the Automated Commercial Environment or any other electronic data interchange system authorized by U.S. Customs and Border Protection, at the time of entry. The proposed rule was issued on August

<sup>37</sup> <https://www.reginfo.gov/public/do/eAgendaMain>

<sup>38</sup> <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/center-tobacco-products-regulation-and-guidance-policy-agenda>

16, 2024, and the Agency is accepting public comment on the rulemaking through October 15, 2024.<sup>39</sup>

*Question.* We know that FDA has issued import alerts for some e-vapor products, but that not all e-vapor products that are the subject of warning letters are covered in the current import alerts. Can you issue a product-wide import alert for all e-vapor products, with the products that have been FDA-authorized or that have pending applications being the exception? If not, why not? If yes, will you commit to issue that blanket import alert as soon as possible?

*Answer.* Taking action against illegal tobacco products across the supply chain—including importation—is a top priority for FDA in coordination with Federal partners. FDA works with Customs and Border Protection (CBP) to prevent illegal tobacco products, including e-cigarettes, from entering the country. Additionally, CBP and FDA, as well as the U.S. Postal Service at the International Mail Facilities, work collaboratively to screen products at entry for compliance with applicable requirements.

FDA uses import alerts to help flag for its staff products that can be detained without physical examination, including many unauthorized e-cigarettes from China. However, import alerts only help when products are accurately declared at the time of import, and bad actors are not typically inclined to do that. CBP and other Federal partners are best suited to identify and interdict against fraudulently declared products and we continue to coordinate with them. For example, CBP is able to identify and can seize a mis-declared product under their authority—such as the 1.4 million units of unauthorized e-cigarettes products seized at LAX airport last year.

Given that multiple agencies serve an important role in preventing entry of unauthorized e-cigarettes into the United States, an “All of Government” approach is critical. Accordingly, following the May 8th hearing, on June 10, 2024, FDA and the Department of Justice announced the establishment of a Task Force to bring together and coordinate relevant expertise, operational abilities, and enforcement authority to strengthen our efforts related to unauthorized e-cigarettes. FDA and DOJ co-lead the Task Force, which includes CBP, the Bureau of Alcohol, Tobacco, Firearms, and Explosives, the Federal Trade Commission, the U.S. Marshals Service, and the

U.S. Postal Inspection Service. The Task Force will provide more opportunities for communications and collaborations in this “All of Government” approach. We are committed to engaging in more joint operations with our Federal partners, and prioritizing this work, while maintaining our comprehensive approach along the entire supply chain to address unauthorized products from being imported, manufactured, distributed, and sold domestically.

*Question.* During your testimony in the House, you described how there are many tricks that importers use to evade proper inspection and denial or seizure of their goods—such as mislabeling e-vapor products as “lanterns.” You testified that “there is a timeframe by which if we [FDA] don’t do something, the product goes on through.” Please expand on that testimony—what is that timeframe? Is it administrative or statutory law? What other rules govern the authorities to hold product for inspection or seize product for destruction at international mail ports that Congress should consider amending to extend the FDA timeframe to respond?

*Answer.* An FDA entry decision must be made prior to the end of the conditional release period (within 30 calendar days after CBP has conditionally released the product), unless otherwise extended. FDA is evaluating our enforcement authorities, including where there may be challenges or barriers to using these tools effectively.

Additionally, FDA uses import alerts to help flag for its staff products that can be detained without physical examination, including many unauthorized e-cigarettes from China. There are multiple import alerts in place; one is for detention without examination of e-cigarettes that do not have premarket authorization. If an imported product is not on the list of authorized products, then FDA and CBP consult on detainment. However, import alerts only help when products are accurately declared at the time of import, and bad actors are not typically inclined to do that. CBP and other Federal partners are best suited to identify and interdict against fraudulently declared products and we continue to coordinate with them.

It is important to note that CBP and FDA have different authorities. CBP can seize a product under their authority for mis-declared products. CBP can also seize unauthorized tobacco products that are in violation of the Federal Food, Drug, and Cosmetic Act. FDA can refuse admission of unauthorized tobacco products. If FDA were to seize a product, we must work with the Department of Justice (DOJ) to ob-

<sup>39</sup> <https://www.federalregister.gov/documents/2024/08/16/2024-18343/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment-for>

tain a court order and engage with U.S. Marshals to seize the product. Seizures must be coordinated and filed through the U.S. Attorney's Office for the district where the goods are physically located. Therefore, we rely on other Federal agencies to assist with such enforcement actions and we must prioritize our requests.

We also work with CBP to conduct targeted operations and seize products. For example, in December 2023, FDA, in collaboration with CBP, announced the seizure of approximately 1.4 million units of unauthorized e-cigarette products, including brands such as Elf Bar. These actions were part of a three-day joint operation which resulted in the seizure of 41 shipments containing illegal e-cigarettes with a total value of more than \$18 million. This mis-declared product investigation took 3 months. Enforcement against mis-declared products is resource- and time- intensive. FDA continues to explore additional authorities or tools that would help us better execute our public health mission.

*Question.* In the House, you testified that FDA “can’t be in 300,000 stores” and that you need more user fee money to “put many more people on the ground.” FDA already has inspection contracts in place in all 50 States with entities whose specific task is to perform on-site inspections of retailers at those 300,000 stores. FDA has spent more than \$480 million on this critically important and comprehensive enforcement and monitoring system. That is how you were able to issue thousands of citations for underage sales last year. It seems the same inspectors can be used for illicit e-vapor enforcement, just like they are used for underage sales enforcement. What direction have you given to your state inspection contractors to look for the presence of illicit e- vapor products, including Chinese disposable vapor products, and to take enforcement action?

*Answer.* FDA has a comprehensive compliance and enforcement program that spans the entire supply chain, including targeting manufacturers, importers, distributors, and retailers.

FDA has an inventory of over 300,000 tobacco retailers that it inspects, which includes those selling e-cigarette products. FDA’s tobacco retailer inspections cover the marketing, sale, and distribution of tobacco products at retail locations and is currently set up to identify unauthorized tobacco products along with underage sales. FDA-commissioned inspectors conduct two types of compliance check inspections for the Agency. During Undercover Buy Inspections, the retailer is unaware an inspection is taking place and a trained underage person, working with an FDA-commissioned inspector, attempts to purchase regulated tobacco products to determine compliance with identification check and minimum age of sale requirements. Currently, underage inspectors are not used to identify other violations, such as unauthorized products.

Expanding Underage Buy Inspections to other violations is a complex process that FDA is currently looking in to. During an Advertising and Labeling Inspection, FDA-commissioned inspectors present the retailer with a Notice of Inspection and announce their presence. The inspectors determine compliance with other retail provisions in effect, including for example, premarket authorization requirements.

As a result of concentrated efforts to identify retailers that violated the premarket authorization requirements, FDA has issued over 600 warning letters and 140 civil money penalties (CMPs) to brick-and-mortar and online retailers for selling unauthorized e-cigarette products.

We continue to do this work with limited resources. Currently, the Family Smoking Prevention and Tobacco Control Act does not provide FDA the authority to collect user fees from e- cigarettes, despite the very significant resources that CTP expends to regulate these products.

More resources are needed to increase inspections and enhanced enforcement actions.

*Question.* This question is perhaps the most important of them all. During the April House hearings you described how the FDA “needs to work with Congress to come up with a way to deal with this specific problem that cuts all of the red tape” your agency has to go through. You testified that there are “things that are bogging [the FDA] down” and explained that “by law, we have to treat offshore and internal people with the same rights in terms of their products” and “we’re going to need a more efficient system.” Now that you and your staff have had time to reflect since the hearing, please list for us the law changes or additional authorities you—or your partners at Customs—need to efficiently and effectively keep these products out of the United States.

Please do not hold back; we would like all ideas to be on the table.

*Answer.* We are working on an approach to enhance our ability to stop unauthorized products from entering the country—both products that are properly declared and mis-declared. We are working both internally and with our Federal partners to enhance communication, engage in more joint operations, and prioritize work to ad-

dress imports of illegal tobacco products. This includes streamlining processes, where possible, and cutting red tape to make it easier to stop products at the border.

FDA is actively taking a very close look at existing statutes to identify opportunities for updates that could help address illegal e-cigarettes, such as potentially extending authorities FDA has been granted related to other product categories we regulate, such as food and drugs. In general, we are looking to:

- Better identify and hold accountable the responsible party in the U.S;
- Increase consequences for activities related to offering illegal products for import; and
- Strengthen our ability to refuse importation.

In addition to efforts to examine our existing statutes and authorities, FDA is also continuing to enforce against illicit products in partnership with other agencies. Following the May 8th hearing, on June 10, 2024, FDA and the U.S. Department of Justice (DOJ) announced the creation of a Federal multi-agency task force to combat the illegal distribution and sale of e-cigarettes. Along with FDA and DOJ, the task force will bring together multiple law enforcement partners, including the Bureau of Alcohol, Tobacco, Firearms and Explosives; Customs and Border Protection; the U.S. Marshals Service (USMS); the U.S. Postal Inspection Service; and the Federal Trade Commission, to coordinate and streamline efforts to bring all available criminal and civil tools to bear against the illegal distribution and sale of e-cigarettes responsible for nicotine addiction among American youth.

The task force will focus on several topics, including investigating and prosecuting new criminal, civil, seizure, and forfeiture actions under the PACT Act; the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; and other authorities. Violations of these statutes can result in felony convictions and significant criminal fines and civil monetary penalties. They can also result in seizures of unauthorized products, which can help to make illegal e-cigarettes less accessible, including to young people. Through their participation in the task force, USMS will help FDA and DOJ effectuate seizures of unauthorized e-cigarettes within the United States.

In order to clear shelves, it would require bringing thousands of individual seizure actions across the country against the products on the shelves today. We are working strategically to address the issue in three ways. First, we are developing a strategy to focus our actions across and up the supply chain at the importer, distributor, and manufacturer levels to have impact. Second, DOJ is FDA's counsel on these types of enforcement actions, and we work collaboratively to bring the best cases forward. Third, the task force can bring to bear the resources across the Federal Government to take a variety of compliance and enforcement actions.

We will keep the Committee informed of this work and would be happy to work with the Committee on legislative efforts to further address this problem. Importantly, this is a whole supply chain issue and an "All Government" approach is needed. With more resources and continued and collective engagement across agencies, FDA can increase compliance and enforcement actions both at the border and elsewhere in the supply chain.

#### UNAPPROVED DRUGS

*Question.* I was pleased to see the FDA approve the first product specifically indicated in the United States for the treatment of neonatal seizures in term and preterm infants. It is my understanding that this product is the only approved product that does not contain preservatives, such as benzyl alcohol, ethyl alcohol or propylene glycol, all of which have been strictly prohibited by FDA guidance since 2022 for products intended for neonates. Yet, there are reports that numerous unapproved phenobarbital drugs containing these prohibited excipients are currently marketed for use in neonates with seizures, which presents a serious safety threat for vulnerable infants.

Why has the FDA not utilized its enforcement authority to remove unapproved phenobarbital drugs from the market, and does the Agency plan to do so this year?

*Answer.* Sezaby (phenobarbital sodium), an FDA-approved phenobarbital sodium injection product, is approved for the short-term treatment of neonatal seizures in term and pre-term infants.

However, there are a number of unapproved phenobarbital sodium injection products currently on the market which, according to the unapproved labeling, are for the adult population as a sedative, hypnotic, preanesthetic, or long-term anticonvulsant and for use in pediatric patients as an anticonvulsant and sedative.

In general, as with FDA's compliance activities across the Agency, we follow a risk-based enforcement approach that involves prioritization in light of the facts of a given circumstance. This includes prioritizing enforcement for drug products that pose the highest risk to public health. This risk-based enforcement approach best supports FDA's public health priorities. The Agency is currently reviewing a Citizen Petition regarding the specific marketing status of phenobarbital drugs and will respond to the Petition as soon as possible and post the response to the public petition docket.

*Question.* The FDA Commissioner commented on the Agency's unapproved drug guidance at a July 2017 hearing before the House Judiciary subcommittee on Regulatory Reform, Commercial and Antitrust Law. The then-Commissioner explained that "if you want these unapproved drugs to come through a regulatory process and develop the data to demonstrate safety and effectiveness and go through the manufacturing requirements, you have to provide an incentive"- the incentive being that "if [manufacturers] go through that process and spend the money to do it, they're going to get a short period of exclusivity, and the FDA is going to make an attempt to clear the market of potential competitors." Why is the FDA not following through on its guidance to industry by granting a period of exclusivity to companies that invest in the regulatory process to prove safety and efficacy?

*Answer.* New drugs that lack required FDA approval can pose significant risks to patients because they have not been evaluated by FDA for safety, effectiveness, or quality before they are marketed. FDA works diligently to protect patients by both encouraging FDA approval for unapproved new drugs, and removing illegally marketed unapproved new drugs from the U.S. market.

First, the Agency encourages manufacturers of unapproved new drugs that are subject to approval to voluntarily come into compliance by obtaining approval for their drugs to be legally marketed in the U.S. Upon approval, certain drugs may qualify for exclusivity, such as 3-year or 5-year exclusivities under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 7-year orphan drug exclusivity under the Orphan Drug Act if they meet eligibility requirements. Determinations regarding periods of exclusivity are made upon approval and necessitate a review of the data and information submitted to FDA in the New Drug Application.

Second, FDA may take regulatory action against firms that illegally market unapproved new drugs. FDA plans to issue guidance consistent with FDA's good guidance practices regarding its enforcement priorities for marketed unapproved new drugs. In general, as with FDA's compliance activities across the Agency, we follow a risk-based enforcement approach that involves prioritization in light of the facts of a given circumstance. This includes prioritizing enforcement for drug products that pose the highest risk to public health. This risk-based enforcement approach best supports FDA's public health priorities.

#### CELL AND GENE THERAPIES

*Question.* Dr. Califf, I am concerned about the growing backlog and seeming delays for cell and gene therapies, including disproportionate and increasing clinical holds issued by the FDA for therapies under development. I am glad FDA has approved nine additional cell and gene therapies over the last year, including two sickle cell treatments and the first cancer cell therapy. However, these faced multiple clinical holds while under development and continue to see large numbers of holds on other breakthrough treatments, including for other forms of cancer and curative treatment for type 1 diabetes. I am concerned this leads to delayed access to life-changing therapies for serious conditions. Please provide more information about efforts at HHS to accelerate the advancement and access of cell and gene therapies.

*Answer.* Clinical holds for Investigational New Drug applications (INDs) investigating cell and gene therapy (C&GT) products have markedly decreased in the past few years. Clinical holds for new INDs investigating C&GT products declined from 24% in 2021 to 9% in 2024 to date. Clinical holds for all active INDs investigating C&GT products declined from 6% in 2021 to 1% in 2024.

The decline results from various factors, including outreach efforts to better inform sponsors of IND content necessary to assess risks and address safety issues, and internal Agency efforts to ensure timely review of potential clinical hold issues, which enables sponsors to provide missing/additional information when feasible. C&GT products are complex and often novel biologics manufactured with new technologies which can present regulatory challenges.

FDA works with all sponsors to resolve issues and help speed development of new products, while maintaining high, scientifically based safety and efficacy standards. FDA remains committed to advancing the development of safe and effective C&GT

products that have the potential to treat serious or life-threatening conditions, including various rare diseases, forms of cancer, and type 1 Diabetes.

#### SUNSCREEN

*Question.* No new sunscreen active ingredients have been approved in the United States since the 1990s. Since then, the rest of the world has moved one or two generations of sunscreen ahead of the United States. In 2014, Congress unanimously passed the Sunscreen Innovation Act (SIA) to address administrative burdens identified by FDA as barriers to timely evaluation. Officials suggested that new sunscreens would be made available in the United States within 6 months of SIA's enactment—nearly a decade ago.

The SIA resulted in the establishment of timelines for consideration of both TEA and new sunscreen active ingredients, authorized the issuance of guidance for the criteria for a generally recognized as safe and effective (“GRASE”) determination for nonprescription sunscreen products, and required the agency to finalize the sunscreen monograph within 5 years of enactment, or November 26, 2019. At the time, FDA indicated SIA would streamline the agency's review process without weakening safety requirements. Despite the SIA, FDA approved no new sunscreen active ingredients.

Moreover, in anticipation of the November 2019 deadline, the FDA published a proposed order that would, if finalized, lead to the market withdrawal of two sunscreen active ingredients and removal of an additional 12 sunscreen active ingredients, which would leave only two UV filters as generally recognized as safe and effective, unless sunscreen manufacturers conducted additional scientific studies. The proposed order not only failed to achieve Congress' intended goal of approving new sunscreen active ingredients—it could result in the United States having only two sunscreen active ingredients available to consumers while the rest of the world continues to invest in new, broad spectrum sunscreen innovation. Skin cancer is the most prevalent cancer in the United States, and it is also the most preventable. Use of broad spectrum sunscreen is a proven and effective prevention tool against skin cancer. What is the FDA doing to ensure that Americans have access to the latest sunscreen technology?

*Answer.* FDA is strongly committed to supporting the availability of new sunscreen active ingredients to the U.S. market. To that end, we have directed industry to helpful guidance documents FDA has published on the safety and effectiveness data needed to determine whether a nonprescription sunscreen active ingredient is generally recognized as safe and effective (GRASE)<sup>40</sup> and on conducting Maximal Usage Trials (MUsT)<sup>41</sup> needed to assess how much of a sunscreen ingredient is absorbed through the skin into the body. In addition, FDA conducted and published two pilot trials,<sup>42 43</sup> evaluating the absorption of various sunscreen ingredients. Regarding the TEA active ingredients in particular, when the Agency reviewed eight applications to market new sunscreen ingredients several years ago, reviewers found that the applications lacked the necessary data to support finding the ingredients GRASE. Nine years ago, FDA described this informational gap and the data that would enable the Agency to complete its review to the public. To bring new active ingredients to market, manufacturers need to show they are safe and effective for their intended use in sunscreen products. If and when FDA receives the data needed to determine whether an active ingredient that may not be currently marketed as an active ingredient in sunscreen products in the U.S., whether or not it was previously the subject of a TEA proposed order, the Agency will review the data and make a determination in accordance with section 505G of the FDCA. Until then, there is no new data that has been provided to the Agency for it to review and to determine whether a new active ingredient intended for use in a sunscreen product is GRASE.

FDA also notes that while having additional sunscreen choices may be desirable to consumers, new sunscreen active ingredients are not necessarily safer or more effective than the ones already available in the U.S. by virtue of being available in markets other than the U.S. Many currently marketed and widely available sunscreen products provide broad-spectrum protection with an SPF of 15 or more and are effective not only in helping to prevent sunburn, but also in reducing the risk of skin cancer and early skin aging caused by the sun, when used as directed in their labeling.

<sup>40</sup> <https://www.fda.gov/media/94513/download>

<sup>41</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/maximal-usage-trials-topically-applied-active-ingredients-being-considered-inclusion-over-counter>

<sup>42</sup> <https://jamanetwork.com/journals/jama/fullarticle/2733085>

*Question.* The United States is falling behind the rest of the world in terms of access to sunscreen active ingredients. For instance, the United States has only 16 sunscreen active ingredients available—potentially less upon the finalization of the sunscreen final administrative order. In contrast, the European Union has 34 approved sunscreen active ingredients. How can FDA’s regulatory framework be streamlined for ingredients currently on the market globally?

*Answer.* As noted above, important work has been done to streamline bringing new sunscreen ingredients to market—including through the CARES Act and other efforts. However, without data to review, FDA is unable to make use of the new, more streamlined processes set forth by the CARES Act. In order to accelerate its review of sunscreen ingredients, FDA needs data demonstrating that these ingredients are generally recognized as safe and effective for their intended use in sunscreen products. The requested data is consistent with the data routinely requested for drug products that are absorbed through the skin and into the body, and the need for this data was strongly supported by an independent expert advisory committee. That expert committee noted that the requested data was the minimum that would be needed to establish the safety of new sunscreen ingredients. FDA is committed to initiating our review of this data as soon as we receive it.

*Question.* The FDA’s final administrative order could significantly hinder Americans’ access to the vast majority of sunscreens on the market today. How is FDA engaging with experts and public health groups to ensure it is utilizing appropriate sunscreen ingredient testing requirements?

*Answer.* When considering appropriate testing for sunscreen products, FDA has updated the advice to sunscreen manufacturers to follow the most recent international standards for determining the safety of drug products, including sunscreens. For example, FDA worked with the International Conference on Harmonization (ICH) to update the guidance on carcinogenicity testing in 2022 to improve safety assessments and reduce animal testing, where it makes sense, without sacrificing the safety of consumers using these products.

Wherever possible, FDA has also taken steps to offer industry tailored study recommendations that account for sunscreens’ specific pharmacological properties and potentially reduce testing burdens. FDA is committed to working with industry and public health stakeholders to ensure that the sunscreens are safe and effective for daily, life-long use.

*Question.* The FDA’s public statements, after the proposed rulemaking issuance, suggested that existing sunscreens might not be safe. Although FDA subsequently modified its statements, this led to public confusion about the safety and efficacy of sunscreen. As it prepared to issue the final administrative order, is the FDA being careful to ensure its rhetoric does not lead to inaccurate conclusions that currently marketed sunscreens are unsafe?

*Answer.* FDA continues to regularly emphasize the importance of sunscreen use in its public messaging. The Agency conducts several educational efforts to promote sunscreen use, raise awareness about the importance of sun protection, and ensure consumers have accurate information.

Additionally, FDA produces a variety of educational materials, including online news, videos, and social media content, concerning sunscreen use and the importance of reapplication. Our educational and outreach efforts are designed to enhance public understanding of the risk associated with sun exposure and the role of sunscreen in reducing these risks, consistent with our mission to protect public health.

#### GRAIN RECONDITIONING

*Question.* The FDA’s reconditioning process for Distinct Low Quality grain is a critical part of the official grain inspection process for the export of U.S. bulk commodities. One area of concern I am hearing about is the timing of approval for reconditioning grain, particularly as the reconditioning process takes additional time to complete if an incident occurs at night or on the weekends and results in delays and increased costs for grain export facilities. Is the FDA reviewing the reconditioning process to identify ways to minimize delays in the process? If so, please describe in detail and when a new process will be implemented.

*Answer.* FDA is aware of the concerns from industry regarding reconditioning proposals and is taking steps to address them. There is an existing Memorandum of Understanding (MOU 225-80-2000)<sup>44</sup> between USDA’s Federal Grain Inspection Service (FGIS) and FDA to facilitate interagency coordination on the inspection and standardization of grain, rice, pulses, and other food products assigned to FGIS by the Secretary of Agriculture. There is a crosscutting FDA work group consisting of

<sup>43</sup> <https://jamanetwork.com/journals/jama/fullarticle/2759002>

members from the Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and Office of Regulatory Affairs working with FGIS to revise the FGIS Directive A<sup>45</sup> on implementation of the MOU, to help expedite and enhance interagency coordination of the processes currently in place. An FDA Standard Operating Procedure (SOP) is also in development to detail procedures and processes for grain reconditioning, which will help streamline and standardize the process when FGIS notifies FDA of actionable lots. FDA and FGIS are continuing to work through the specifics and are targeting updates to the directive and SOP in FY 2025.

SUBCOMMITTEE RECESS

Senator HEINRICH. And with that, this hearing is adjourned.  
[Whereupon, at 11:22 a.m., Wednesday, May 8, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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<sup>44</sup> <https://www.fda.gov/about-fda/domestic-mous/mou-225-80-2000>



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