S. HRG. 119–061

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2026

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED NINETEENTH CONGRESS

FIRST SESSION

ON

H.R. 4121/S. 2256

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2026, AND FOR OTHER PURPOSES

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 RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2026

TUESDAY, MAY 6, 2025

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

The subcommittee met at 10:35 a.m. in Room SD–124, Dirksen Senate Office Building, Hon. John Hoeven (chairman) presiding.

Present: Senators Hoeven, Collins, Moran, Hyde-Smith, Fischer, Shaheen, Murray, Merkley, Baldwin, Heinrich, Peters, and Ossoff.

DEPARTMENT OF AGRICULTURE

STATEMENT OF HON. BROOKE L. ROLLINS, SECRETARY

OPENING STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. We will call this meeting of the Ag Appropriations Subcommittee to order.

And I want to begin by thanking Secretary of Agriculture, Brooke Rollins, for being here today. We appreciate you being here. We also appreciate you getting out and about around the country, as you have, and getting a chance to meet with our great farmers and ranchers in our respective states. So thanks so much for that as well.

I am very pleased to be joined by Senator Jeanne Shaheen. As you can tell, she is very young, but she and I were actually governors together.

Senator SHAHEEN. We were both very young. Yes.

Senator HOEVEN. Starting about 25 years ago, when she was a teenager and I was not as old as I am now. And so we have had an opportunity to work together as governors, and we work together on various appropriations committees, like Homeland Security, and others. And I just want to welcome her in this new role as the Ranking Member on the Ag Appropriations Committee, and just express how much I appreciate her and working with her; so welcome, and really good to have you on the committee.

Also, we are joined by our Chairman of the Full Appropriations Committee, who also, we have worked together a long time, and she is providing a strong leadership for the Appropriations Committee and doing everything in her power to see that we get back to regular order.

And so I would pause here for just a minute and ask if our Chairman would like to make a few comments. Chairman Collins.

STATEMENT OF SENATOR SUSAN COLLINS

Senator COLLINS. I just want to say that I am absolutely delighted that Senator Hoeven is chair of this committee and that Senator Shaheen is the vice chair. That means this subcommittee is in very good hands.

And we welcome the Secretary.

Senator HOEVEN. Thank you, Chairman.

Again, Secretary, thanks for being here today. We appreciate you, and appreciate you being here right away to talk about this Ag Appropriations Budget. You had a great chance out in North Dakota, and I know you have been to other states as well, to see what our farmers and ranchers are doing out there, firsthand. But I know you really don't—that is not new to you, having grown up on a ranch, which is incredibly important that you have that background, and then having gone to Texas A&M, an Ag school.

Secretary ROLLINS. Well said. Thank you.

Senator HOEVEN. And a very good one at that.

Secretary ROLLINS. Thanks.

Senator HOEVEN. And they play reasonably good football, too, last I checked.

Secretary ROLLINS. Until November, but yes.

Senator HOEVEN. Yes. Well, again, we are pleased that you are getting out and about like you are, and that you are with us here today.

Secretary ROLLINS. Thank you.

Senator HOEVEN. Obviously, our farmers and ranchers across the country are dealing with a lot of challenges right now. They always deal with challenges, whether it is markets, whether it is prices, and certainly always the weather, none of which they control. So it is vitally important that we do a good job for them in our farm program, but also in the things that we do here in the Ag Appropriations Committee, as well as the countercyclical safety net, and the other things that we think of, crop insurance, that our farmers and ranchers need every day to stay in business.

And we can't, as you and I talked about before, we have in agriculture about 16 million people that work either directly or indirectly in agriculture. We have a system of small businesses out there in farming and ranching, family-based small businesses that produce the highest quality, lowest cost food supply in the world that benefits every single American every single day.

And we, as Americans, spend less on our food and have the best food, and the best choice, and we spend less as a percent of our budget than pretty much any developed country in the world, brought to us by our family farms and ranches. And that we can't take that for granted.

Secretary ROLLINS. Yes.

Senator HOEVEN. There is so much concentration in so many industries, and we have to recognize that it is not by accident that we have this great system. And so good farm policy is so important to keeping that, and it benefits every single American. Well, you were out in our state. You saw North Dakota State University and

the incredible work that our land grant universities do, like A&M, and many others.

But you also got to see the amazing new technology that is coming with Precision Ag, Grand Farm, example that we showed you out there of really leading the world with precision agriculture, as well as the research, and so forth, that is being done in tandem with land-grant universities through National Institute of Food and Agriculture (NIFA), Agricultural Research Service (ARS), your research function, and our farmers and ranchers, which has revolutionized agriculture.

When I grew up in western North Dakota, we could grow a couple row crops. Now our state grows 40 different crops, and we lead the country in about 15 of them, which we try to rub into South Dakota as often as we can, because they do great stuff too, and we appreciate all of our ag states very much.

So again, that is what we are talking about here today. And so the funding for these programs, and we talked to you about, Farm Service Agency (FSA) and all these things, out on the ground, we have got to make sure we are getting it done for our farmers and our ranchers every single day. So we want to find savings, we want to work with you to find savings, but we have got to know that we are still going to deliver that service that keeps those family businesses, those farms and ranchers going every single day to the benefit of every single American.

So again, thanks for being here so much.

And I will turn to our ranking member, Senator Shaheen.

Secretary ROLLINS. Thank you, Senator.

STATEMENT OF SENATOR JEANNE SHAHEEN

Senator SHAHEEN. Thank you, Mr. Chairman. And I would just echo your comments about how nice it is to work together again. Thank you for those very nice remarks.

Secretary Rollins, thank you for coming before the committee.

I think it is helpful as we think about questions today to take stock of where we are and how we got here more than 100 days into this administration, because we all know that our farmers, producers, and rural communities are no strangers to uncertainty, the pressure from outside of their control, from fluctuating commodity prices, to rising output costs, to a rapidly changing climate and more extreme weather events.

But what I have heard from farmers in New Hampshire is that the Federal Government has always been a critical partner that our farmers could rely on. That is until now, sadly, because what I have heard from farmers over the past 100 days of this administration is that they are not sure they can trust the Federal Government anymore. I have heard from farmers across our state who no longer know if they can rely on the Federal Government honoring a basic signed contract, and I have heard in great detail from all kinds of farms in New Hampshire about the hardship that this uncertainty, this delayed reimbursement causes for their ability to run their businesses.

And as they say, in New England where the weather is very problematic, anything that contributes to that uncertainty and disruption is challenging. Rural communities can't be certain if their

small businesses and operations will survive the added costs of tariffs on top of the other uncertainties, farmers risk losing hard-fought market access due to President Trump's trade war.

And I am sorry that we had not yet received the fiscal year 2026 Budget when we were preparing for this hearing, because the limited information that I have seen to date has been extremely disappointing. The proposed budget top lines released last Friday fall well short of the President's purported commitments to farmers and rural communities.

I don't believe that we support farmers by gutting research that will boost yields and improve crop quality. And I don't believe we put rural America on a path to thrive by slashing core rural development programs, from housing, to water and waste infrastructure, to energy assistance. And when grocery prices are too high, we don't help families put food on the table by undercutting vital nutrition programs. Yet, that is exactly what this skinny budget would do.

I hope that we will have a chance to move forward with bipartisan appropriations, with a serious nondefense discretionary number that reflects the urgent needs that are facing families and communities in New Hampshire and across this country, because there are plenty of places where we can work together to ensure that these programs deliver for producers in rural America, from investing in our rural communities and boosting the rural housing supply, to supporting programs that help local food systems thrive, to investing in cutting-edge research that will allow our farmers and ranchers to feed our nation and the world.

So again, I appreciate your being here today, Secretary Rollins, and I look forward to the discussion.

Thank you, Chair Hoeven.

Secretary ROLLINS. Thank you.

Senator HOEVEN. Thank you, Senator Sheehan. At this point, we would turn to you, Secretary Rollins, for your opening comments.

SUMMARY STATEMENT OF HON. BROOKE ROLLINS

Secretary ROLLINS. Great. Thank you, Chairman Collins, Chairman Hoeven, Vice Chair Murray, Ranking Member Sheehan, and distinguished members of this subcommittee. I am so grateful for the opportunity to appear before you to share what we have accomplished at USDA in the last 100 days, but also to answer your questions on the President's budget request and the priorities moving forward.

When farmers prosper, rural America prospers, and I want to thank you all for your shared bipartisan commitment to that effort in ensuring that our farmers, and our ranchers, and our rural communities thrive.

During my confirmation hearing, which some of you attended, not all, I quoted Thomas Jefferson's 1787 letter to George Washington in which he wrote, "Agriculture is our wisest pursuit because it will, in the end, contribute most to real wealth, to good morals, and to happiness." I have had the distinct privilege of serving American farmers and ranchers for the past 82 days, and I can tell you our farmers continue to embody every single day the ideals

that Thomas Jefferson described over two centuries ago, and serving as their champion continues to be my greatest honor.

We at the Department of Agriculture have wasted no time in implementing President Trump's bold policy agenda. The President's fiscal year 2026 discretionary budget that we are talking about today identifies the priorities of our administration with the same degree of prudence and frugality our family farmers practice when they draft their annual budgets. Let me touch on a few highlights of the last 82 days and then turn it back to you, Mr. Chairman.

Upon taking office, I was tasked by President Trump to lower the cost of eggs in the short term, and also to provide farmers with resources that are needed to combat the avian influenza in the long term.

In February, at the direction of President Trump, we announced a five-point plan to meet this challenge head on, and I am proud to report that since that plan was introduced, the wholesale price of eggs has decreased 56 percent, with the retail price following. In taking this position, I fully understood that American agriculture was facing one of the most economically challenging times in our country's history.

For generations, American producers and consumers enjoyed the fruits of an agricultural trade surplus, but under the last 4 years, that surplus went from zero—or that trade deficit went from zero to a nearly $50 billion trade deficit, and the newest numbers coming in are actually significantly more than that.

President Trump and I know this problem will not solve itself. That is why he is taking action, bold action, which I am sure we are going to talk about today, to address our imbalanced trade commitments, and I am working tirelessly to promote American agricultural products on the world stage.

In April, USDA launched our agricultural trade promotion programs for fiscal year 2026 and is currently accepting applications for four export market development programs. As part of this effort, I will be traveling to seven countries in the next few months. The first trip begins Sunday when I head to the UK, where I will be making sure our trading partners know that American agriculture is the crown jewel of American production.

And in fact, Chairman Hoeven, I have to leave here at noon because the Secretary of Agriculture from Mexico has just landed here in Washington, and I am going to meet and talk with him momentarily as soon as we finish.

We are also streamlining unnecessary regulations and cutting red tape for agricultural producers and industries so that they can continue to do what they do best, and that is to every day feed, fuel, and clothe America and our world.

To that end, my team and I have sought to eliminate waste, fraud, and abuse in all USDA programs, including the SNAP improper payments, fraud, and programs that fail to fulfill the USDA mission of putting farmers first. Our team is meeting daily with our partners at the Department of Government Efficiency, with DOGE, which again I am sure we will get into, to ensure that we are doing right by the American taxpayer while also protecting critical USDA programs.

What is also of paramount importance at the United States Department of Agriculture is our mission to make America healthy again. We have been taking major steps to fulfill this mandate by accepting SNAP waivers and working alongside our country's great governors, both Republican and Democrat, as we move that project forward.

The Make America Healthy Again (MAHA) movement at USDA has also supported major, major voluntary changes to make food healthier, including just last week the International Dairy Foods Association's most recent announcement related to dyes in school lunch dairy products. We are also working around the clock to address major threats to our farmers and our ranchers, including the new world screw worm, which would devastate our cattle industry in this country.

Alongside Secretary of State, Marco Rubio, and Deputy Secretary of State Christopher Landau, we were pleased to share just last week that we have negotiated a deal with the Government of Mexico to allow the best preventative tools we have to land our response aircraft in Mexico without further hindrance, additionally working to ensure that Mexico abides by the 1944 Water Treaty, providing the water it owes to our ag producers in America.

Finally, and again, just a quick summary of the last 82 days: Just last week, alongside Senator Rounds and some other great Americans, we stood with Charles and Heather Maude, a South Dakota cattle family, fifth-generation cattle ranching family who operates small cattle and hogs, who endured a senseless, politically motivated prosecution over 25 acres of forest land that had had a fence line on it for almost 100 years.

The criminal charges against the family were dropped last week, and to prevent further injustices against our farmers and our ranchers, we launched a portal for farmers and ranchers to tell us their stories, if they, too, are being treated in a similar situation as to the Maudes.

And since we launched that a week ago, Thursday, so I guess just four or five days ago now, we have had over 100 farmers and ranchers reply and move their stories into our portal. So we are already following up on that.

Again, during my first 82 days, as the Secretary of Agriculture, we have visited 15 states. If we have not visited yours yet, we are coming very, very soon. I have attended over 100 events, given dozens and dozens of keynote speeches, and met with nearly 1,000 farmers and ranchers across this great country, both here in Washington and out in the states.

We will continue to build based on their feedback, based on their hard work, and based on reconstituting, rebuilding, and revivifying the United States Department of Agriculture to better serve our customers.

American ag does not rest, and I can assure you that under my tenure, neither will the U.S. Department of Ag. I am proud to be at the helm of the People's Department, as President Lincoln so aptly launched and said in the 1860s, I am proud to be at the Department, I am proud to be at the table with President Trump, and I am so proud to be fighting for the most American of all Ameri-

cans, and that is our farmers, and our ranchers, and our agriculture communities.

Thank you so much.

[The statement follows:]

PREPARED STATEMENT OF HON. BROOKE ROLLINS

Chairman Hoeven, Ranking Member Shaheen, and distinguished members of this subcommittee, I appreciate the opportunity to appear before you to present on the U.S. Department of Agriculture (USDA) and what we've accomplished since President Trump took office. President Dwight D. Eisenhower said, "Farming looks mighty easy when your plow is a pencil, and you're a thousand miles from the corn field." I can assure you, being a part of agriculture and visiting with the people who tend the land and our Nation's livestock every day, farming isn't easy. I am proud of the work we are doing at USDA. Making Agriculture Great Again means promoting efficiencies, cutting regulatory red tape, and refocusing the mission to expand market opportunities for farmers rather than promoting programs that only satisfy the special interests of Washington D.C., bureaucrats who have never set foot in a field or pasture.

For far too long, the hardworking Americans who feed, fuel, and clothe the world were left on the sidelines. Farmers and Ranchers now have a seat at the table. We have had an action- packed first one hundred days of the Trump Administration, affirming the bold leadership of President Donald J. Trump. I've visited 15 States, attended or held over one hundred events, and have visited with hundreds of different agricultural stakeholders. In the first one hundred days we have reprioritized American Agriculture.

Since my first day, we have been intensely focused on tackling the avian influenza crisis. It was my very first briefing at USDA and I fully understand the importance of animal health issues and the effects they have not just on ranchers and producers, but on everyday consumers. In February, at the direction of President Trump, we announced a five-pronged plan to curb avian influenza to protect producers and lower egg prices for all Americans. A plan which has been applauded by agriculture and government leaders across the country. Today, a dozen eggs at wholesale cost less than half of what they did at the end of February. The expansion of biosecurity assessments available to commercial poultry producers has also been successful. I am happy to report that, since I've taken office, we have completed over four hundred wildlife biosecurity assessments and biosecurity incentive-focused assessments combined. As this program expands, we expect these results to continue to impress. We also know that America thrives when it innovates. That's why we have such hope for the up to one hundred million dollars announced as a funding opportunity to explore prevention, therapeutics, research, and potential vaccine candidates to protect poultry from avian influenza. These projects should give us new and innovative tools to use to keep the virus away, protect producers, and keep prices low for consumers.

While much of the public attention has been on avian influenza, we are also working around the clock to address the other threats to our farmers and ranchers, including New World screwworm. This pest feeds on livestock and could seriously jeopardize our food supply and create an economic impact of well over a billion dollars if it enters through our southern border. This devastating pest started spreading north through Central America under Joe Biden's failed leadership. Under President Trump, we are working to drive this pest south, out of Mexico by using proven sterile insect technology. This approach has been successful in previous eradication efforts, and it remains the most effective strategy to protect our domestic industry from this devastating pest. To address the ongoing spread of New World screwworm I recently sent a letter to my counterpart in Mexico demanding Mexico eliminate impediments to aircraft operations and landings that were impairing the U.S. response, which was successful, and we are now landing the planes we need to.

On the eve of a nearly fifty-billion-dollar agricultural trade deficit, USDA is not sitting idle, but taking action to move our industry back to becoming a net exporter. USDA's Trade and Foreign Agricultural Affairs is well positioned to help producers gain new market access opportunities. Since President Trump took office, USDA's Foreign Agricultural Service has expanded access to foreign markets for U.S. agricultural products. Panama partially opened its pork import quota mechanism, which will allow an estimated additional thirty million dollars in U.S. pork product exports. South Africa also restored market access for U.S. microwave popcorn shipments, valued at two to three million dollars. USDA conducted two trade missions

to Thailand and Guatemala and hosted USA Pavilions at six global trade shows with a combined total of two hundred and eighty-two million dollars in projected exports. In the last 2 months, FAS has worked with India to reduce India's tariff on U.S. bourbon imports by fifty percent, resulting in a likely two million dollar increase in distilled spirits exports to India in 2025. We worked with Japan to lift the mandatory aflatoxin testing requirements on U.S. almonds, resulting in a likely eight to 10 percent increase of U.S. almond exports to Japan annually.

Looking ahead, USDA will continue its efforts to improve foreign market access for U.S. producers and address the agricultural trade deficit. In April, USDA launched agricultural trade promotion programs for fiscal year 2026 and is accepting applications for four export market development programs totaling over two hundred and fifty million dollars. I will also visit seven countries in the next 6 months: Vietnam, Japan, India, Peru, Brazil, Italy, and the United Kingdom. Together with the U.S. Trade Representative, we will build new markets, expand current markets, and hold existing trading partners accountable to ensure trade is fair and reciprocal and that the competitive position of U.S. agriculture reaches new heights. USDA is committed to leveling the playing field by identifying unfair imports, breaking down export barriers, tackling non-tariff sanitary and phytosanitary obstacles, advocating for lower foreign tariffs on U.S. agricultural exports, and diversifying foreign markets for U.S. exports. USDA is dedicated to an America First policy, ensuring that every action USDA takes overseas makes America safer, stronger, and more prosperous.

On March 19, ahead of its statutory deadline, we issued 10 billion dollars in economic assistance for farmers and ranchers through the FSA-administered Emergency Commodity Assistance Program which was passed by congress in December of 2025. The program has been extremely efficient, paying farmers within three business days of an application submission. A note of thanks to all of you for your unwavering support for producers in times of economic crisis by passing that legislation. USDA is working to soon roll out its Congressionally authorized Supplemental Disaster Relief, over 20 billion dollars. On April 22, USDA dispersed three hundred and forty million Congressionally mandated disaster dollars across thirty-one States to deliver relief to farmers, ranchers and rural communities impacted by natural disasters such as hurricanes and wildfires that have caused devastation across the country. We are also making sure these programs are offering the most effective assistance where needed and not duplicating and wasting taxpayer money.

There is a very public, yet very important endeavor to make America healthy again through the President's Executive Order No. 14212. It is no secret diet-related, chronic disease is plaguing American families, including a substantial portion of children and adolescents from low-income households. At the direction of President Trump, I, along with relevant stakeholders, will continue to explore ways to encourage better health through the Make America Healthy Again Commission. In talking to Governors, many States are interested in testing innovative solutions to our Nation's many health crises. I have made it clear, and I will do so here, that I am open to these requests and look forward to providing technical assistance and dialogue. There have been significant developments on this around the country during State legislative sessions, and we look forward to receiving State requests to operate pilot programs to make the program more nutritious.

On February 13, upon my swearing in, I sent a letter to States and Tribal, territory, and local government partners. I reminded them that the mission of the Department's 16 nutrition programs is critical, but that the American taxpayer expects their generosity to be valued and for programs to be executed with integrity and accountability. The letter noted a suite of guiding principles, each of which can serve as catalysts for change, allowing the Department-and the American taxpayer-to better serve vulnerable families and communities. It is important to note, USDA spends four hundred and five million dollars a day on nutrition programs. Furthermore, USDA issued guidance to all State agencies directing them to enhance identity and immigration verification practices when determining eligibility for the Supplemental Nutrition Assistance Program (SNAP). This is to make certain that SNAP benefits exclude any ineligible alien who entered the United States illegally, or is otherwise unlawfully present in the U.S. A recent Government Accountability Office (GAO) report indicated a staggering 10 and a half billion dollars in improper SNAP payments were made in fiscal year 2023 alone. This was about 12 percent of total SNAP payments that year. The inadequate verification of an applicant's identity and citizenship by States is specifically highlighted as contributing to the improper payments of SNAP funds.

Under President Trump's leadership, we are streamlining unnecessary regulations and cutting red tape for agricultural producers, and other industries under the USDA purview, to allow them to feed, fuel, and clothe the world. This includes mak-

ing sweeping reforms to protect national forests and boost domestic timber production, ending regulations that have stifled energy and mineral development on Federal lands so we may reaffirm America's role as a global energy powerhouse, and reducing wildfire risk through public-private partnerships and many other actions. I have been fortunate to spend time with our wildland firefighters to thank them for their heroic service. I value their perspectives and feedback, and I am proud of the work they do to save lives and protect our beautiful homeland. We will continue to execute President Trump's agenda to make America's forests healthy and productive again.

In March, I announced new action to reduce burdens on the U.S. pork and poultry industries, allowing for greater efficiency while maintaining food safety standards. We are extending waivers allowing existing establishments to maintain higher line speeds and are moving towards rulemaking to make these standards permanent for more pork and poultry plants. We have also withdrawn overly burdensome proposals related to Salmonella in poultry as we reconsider more effective ways to achieve public health objectives. These reforms will strengthen U.S. food production, reduce costs for producers, and support a more resilient supply chain-all without compromising food safety. It is also important for farmers and ranchers to have access to timely, accurate, and useful statistics to help make important decisions about their operations; however, the Biden Administration ignored this directive and cancelled the July Cattle Report and the County Estimates for Crops and Livestock last year. I am so pleased to share that the National Agricultural Statistics Service has reinstated these critical reports, and they will be published later this year.

American agriculture began four centuries ago, when neighbors born across an ocean came together in a New World to clear fields, build homes, and plant crops on the edge of wilderness. That same spirit animates us now. Our farmers who tend the fields do not rest from their labor-neither do our ranchers and livestock producers who steward their lands, herds, and flocks-and neither do the American mothers and fathers who rely upon American agriculture to feed their families. American agriculture does not rest-and neither will we at USDA. I'm proud to be at the helm of the People's Department, at the table with President Trump, and fighting for the most American of industries—agriculture.

Senator HOEVEN. Thank you, Secretary Rollins.

We will now start rounds of five-minute questions.

And I am going to defer to our Full Committee Chairman, Senator Collins, to start that process.

Senator COLLINS. Thank you very much, Mr. Chairman. Welcome, Secretary Rollins.

Secretary ROLLINS. Thank you.

Senator COLLINS. It is great to see you here today. When we first met, we discussed Per-and Polyfluoroalkyl Substances PFAS.

Secretary ROLLINS. Yes.

Senator COLLINS. Those are the toxic class of forever chemicals that are being found in our soils, water, animal feed, crops, and livestock. In Maine, the presence of PFAS and wastewater sludge that was spread decades ago as a fertilizer is preventing some of our family farmers from being able to sell their products, causing them significant financial harm.

To support these affected farmers and to come up with solutions, the University of Maine is undertaking research on the presence of PFAS in agricultural land. To build upon this work, I secured $17 million in fiscal year 2024 for the ARS and the University of Maine to establish a new center of Excellence for PFAS solutions, and the whole purpose is to help address these very serious PFAS contamination in agriculture.

Madam Secretary, will you continue to support the partnership between ARS and the University of Maine in establishing this research center to help our farmers? And I would note that the re-

search that is being done there won't just help the farmers in Maine, but across the nation.

Secretary ROLLINS. Across the country. Well, Madam Chairman, as we discussed, this is an issue that is very close to my family's heart. My mom, Helen Kerwin, is almost 78. She is the youngest elected freshman to the Texas House of Representatives in Texas history, and her number one issue is PFAS. And she decided to run for a lot of reasons, but one of those was, I believe it was the New York Times did an expose or a big story, if you will, on a farm in Johnson County, Texas, which is close to where we grew up and where my mom still lives, rural Texas.

And she was so stunned by what had happened to these farmers, and specifically through the PFAS contamination, it had destroyed their lives. And so she became very, very passionate about this particular issue. She is crushing it in her first session in the Texas Legislature right now. And, in fact, her very first bill that she will get a hearing on is her PFAS Bill, and it will be tomorrow in Austin.

So I have been hearing a lot about this at the family dinner table for quite some time now. But yes, we remain committed to this research, very proud of that $7 million grant to the Center for Excellence. And I think that, at least according to my mom, who is amazing, raised my sisters and me, by herself, she was a single mom, but at least according to my mom, Maine leads the way in many respects on this important issue for all of our farmers and our ranchers.

And I am excited to learn more. Perhaps even come visit the center in Maine, see the work that they are doing firsthand, and to continue to support it. So thank you for your leadership on that.

Senator COLLINS. Thank you so much. And, in this case, listening to your mother makes all the sense in the world.

Secretary ROLLINS. All the sense in the world. I need to tell my four teenagers that.

Senator COLLINS. Yes. In late March, I wrote you a letter detailing my concerns about USDA's delay in releasing some program funds.

Secretary ROLLINS. Yes.

Senator COLLINS. I have heard from constituents who have received grant award letters from USDA in the previous administration, only to later receive letters from USDA informing them that their grant funding is frozen. Now, this is obviously very troubling to them. It creates a lot of uncertainty. And we are a state that has lost 600 farms in the past decade. And that is very troubling to me. I grew up in Northern Maine. One of my first jobs was picking potatoes for a farmer. And I am aware of how important that heritage is to our state and to our food supply.

So we have seen a situation where farmers, landowners, loggers, natural resource businesses that have applied for USDA loans, still have no clarity on what decisions will be made. And the timing of this funding is absolutely critical, because as you know well, agricultural producers are making purchases now for this year's crops, and processing facilities need to order equipment for the summer and the fall harvest.

Local farm economies are fragile. And timing is really important. So I know and appreciate that you have made some significant strides in releasing program funding over the past few weeks. Could you provide the subcommittee with an update on Federal funding at USDA that remains frozen, and a time line for when you plan to finish your reviews?

Secretary ROLLINS. I will, and I take to heart so sincerely everything you have said. And I know many of you have reached out during this process of frozen funds from both sides of the aisle. And my goal is to respond immediately. Sometimes it is at midnight. Sometimes it is at 5 a.m. But my goal is always to respond and to be available. I have an amazing team. Kailee Buller, is our chief of staff, she is here, Jen Tiller and a few others that you all probably know well. And we are working around the clock, going line, by line, by line. We are down to the final 5 billion out of, I believe, almost 20 billion of frozen funds. But $5 billion is a lot of money. And when you think about that in terms of, you know, grant or contract and moving that out quickly, we are very hopeful to keep moving through that very, very quickly and have that done very soon.

But what I will say, and you all know this that have worked with me, I am always available. So if there is one or a group in particular that you want us to make sure we are getting to, please just let me know. I know almost everybody here has my cell phone number, maybe not a few of you, but I am always available. Several of these guys have it too. So just call me and just know we are doing our very, very, very best.

Some of the funding that we have pulled back and then reopened, we have asked for reapplications to realign around this President's priorities, which, of course, not surprisingly, is not diversity, equity, and inclusion, or some climate programs, but instead to reapply where the farmer would receive, farmer or rancher would receive 65 percent of the funding or more, that is another piece of this as well.

So we, again, are going line by line. We are working around the clock. And believe me, we are on it. But please know to always reach out if there is something specific. And I hear you.

Senator COLLINS. Thank you very much.

Secretary ROLLINS. Thank you, Madam Chairman.

Senator HOEVEN. Appreciate it.

Senator Sheehan.

Senator SHAHEEN. Thank you, Mr. Chairman. And just to follow up on that. I referenced this in my opening statement, but in New Hampshire USDA has frozen an $11 million RCPP award for the Connecticut River Conservancy. It is a project that has leveraged public-private partnerships for critical ecosystem restoration across the watershed. And unfortunately, the months'-long delay has slowed seasonal work, and it has driven up the costs of the project.

Given that it is been more than 3 months since the administration froze this program, when will USDA release the funding?

Secretary ROLLINS. What is the name of it again?

Senator SHAHEEN. It is a Regional Conservation Partnership Program (RCPP) award for the Connecticut River Conservancy, and we are happy to follow up with whoever the appropriate person is. And

just to follow up on that, one of the things, as we know, that Congress did at the end of last year was to pass disaster funding, that included $220 million as a set-aside for small farms in the six New England States, plus Hawaii and Alaska. And we have got apple growers in New Hampshire who, in 2023, lost about 90 percent of their crop. Virtually all stone crops were wiped out in that season. They have been waiting desperately for the funding to be released from that emergency supplemental.

Senator Tillis and I sent you a letter back in March emphasizing the need to get this assistance out. So again, along the lines of Senator Collins' question, can you provide an update for when the remaining funds will be released, and how we will ensure that the funding goes particularly to the small farms in states like New Hampshire, where they are desperately in need of some assistance?

Secretary ROLLINS. Yes, ma'am. I appreciate that. The Emergency Commodity Assistance Program (ECAP) funding, the economic assistance, of course, we were given a statutory deadline of March 21st, I believe, when you all passed that, or when it was passed in late last year. I think March 16th or March 17th the portal opened, and it is a three-day turnaround in most cases. I think we have already moved out, I don't have the number in front of me, but of the $10 billion, almost $8 billion. You all correct me if I am wrong.

So we have actually moved almost all of that money out in, I would argue, record speed, but maybe there have been a few that we haven't. So please let us follow up on that.

I have got right in front of me, Madam Chairman, that in your state we have moved out $395 million just into New Hampshire to 17,476 of your producers in New Hampshire. So I think we have done pretty well on that. But again, if there are instances where you are not hearing those stories and that it hasn't moved as quickly as we believe it has, please let us know, and we will run that down.

On the disaster relief part of it, which is the additional $20 billion, in the coming weeks, by the end of May, that portal will open also. Obviously as part of that $20 billion there was specific funding for the Mexican water issue in Texas, and then of course up in the northeast where you are, and I believe Alaska was the third specific instance. But we are working with governors across the country. That was a little more complicated than the ECAP, the disaster—or the emergency relief payments; but we are really close, within a matter of days, where we certainly by the end of this month, that money will begin moving as well.

Senator SHAHEEN. Well, thank you. I appreciate that. As you know, farming is very different in New England than it is in the Midwest, and many states in the west, and anything that we can do to be helpful in terms of getting information from out farmers to make sure that they qualify for those programs, please work with us.

Secretary ROLLINS. Absolutely. Yes.

Senator SHAHEEN. I also served on the Foreign Relations Committee, and of the things the fiscal year 2026 Budget Request eliminates, is the Food for Peace Program, and the McGovern-Dole Food for Education Program. In 2023, those programs provided

over 1.1 million metric tons of U.S.-grown commodities to people abroad.

For weeks earlier this year, more than 550 metric tons of U.S.-grown rice, peas, wheat, beans, super cereal, and ready-to-use therapeutic food sat at risk of spoilage in ports, on ships, and in warehouses across the world, because of the dismantling of USAID. We are tracking that more than 350 metric tons of mixed commodities from American farmers are either pending purchase or will not be purchased this year due to the administration's terminations and delays.

So can you talk about what you are saying to farmers to address this and how we are replacing that food that is so desperately needed by people around the world?

Secretary ROLLINS. Yes. I will talk briefly about the McGovern-Dole Program first. And I think it is important to realize that that is a $240 million program, but our numbers show only about $37 million of that is directly tied to agriculture, which of course is what I am focused on. So as we are looking to realign the government, to reorganize, to make it more efficient for the American taxpayer, looking at programs like McGovern-Dole, which obviously all these government programs have a very worthy mission statement with very wonderful intentions, but at the end of the day, are they serving the American taxpayer who is funding them? And are we providing and meeting the metrics of what the original intent was?

And without knowing all the details of the McGovern-Dole Program, for example, the fact that of a $240 million program, only $37 million is being used regarding commodities, our American farmer commodities. And I don't say $37 million isn't a big number, and especially for our farmers and our ranchers, but I think in the context of what the effort is to ensure that everything we are doing is aligned with the best and highest use of taxpayer dollars, and understanding that the layers of bureaucracy, and the administration, and all of the money going to lots of other places other than our ag community, that we need a wholesale reapproach to all of it.

And that is what I realize, Senator, I will agree to disagree on this, but that is what President Trump's vision is. And while we are going through, it is never easy to change the status quo. The easiest thing for us to do is just say: Oh. It is great, and we don't want to make anyone mad, and let us just keep moving forward and keep adding money to the programs. This is what I believe the voters asked for and we will continue to have these discussions.

So I hear you. It is something we are looking at every day, and the Food for Peace Program as well. But programs like McGovern-Dole, it is time to really take a deep look and see what we are spending the money on, and if it is being effective.

Senator SHAHEEN. I am out of time. And I appreciate what you are saying. And I think most of us would agree that examining the programs and being more efficient and effective is something that we all support.

Secretary ROLLINS. Sure.

Senator SHAHEEN. But when we do it in a way that allows millions of tons of food and medicine to rot because we have cut off

funding to ensure that that goes where it is supposed to go, that is not efficient and effective.

Thank you, Mr. Chairman.

Senator HOEVEN. Thank you, Ranking Member Sheehan.

Secretary, so at the end of the year we ended up with a 1 year extension of the Farm Bill because we did not have agreement to update the countercyclical safety net like we need to, which as you know we are working on very hard. But with that 1 year extension we put in place $33.5 million (sic) in emergency assistance, for the $10 million excuse me, $33.5 billion—for the $10 billion that is market conditions based we put a number of conditions on it. One that you would provide it—start providing it within 90 days, and you would follow a format called WHIP+, which we put in statute back in 2017. You did both.

Secretary ROLLINS. Yes.

Senator HOEVEN. And you started dispersing, or started the process of dispersing March 19th. I think of that 10- you are probably closing on $7 billion. You have already dispersed states, my state it is about $0.5 billion, I think. You already referenced the Ranking Member and other states as well. That is how we want to work with you. So I want to put right out front, that is how we want to work between this subcommittee, and I think Senator Boozman will tell you our Ag Committee, Full Ag Committee and USDA.

So then I just want to step over now to the weather-based $20 billion. What is your plan on that for getting it going, and kind of the format so we know? We are getting questions on that now from our producers.

Secretary ROLLINS. That is right. So we are within days of announcing the application process. Of course, that is a little more complicated because we don't have the specifics and it isn't—yeah, as you mentioned in North Dakota, 15,794 of your farmers and ranchers have received money through that first tranche, through the first $10 billion, the emergency aid. On the weather-related programs, that application opens in the next week or two and we will be moving very, very quickly.

We realize that this is a long time coming and it is related to disasters that happened a while ago, and so ensuring that we get that out as quickly as we possibly can with the team that we have in place. I am really proud of, I believe, how efficiently and how quickly the team moved out that first tranche. And I believe that you will see the same sort of efficiency and effectiveness with the second tranche. So it is within the coming weeks.

Senator HOEVEN. And I know you have to wait until you get the data from the different locations that had the weather disasters. Like in our case, it was fires and ranchers, we lost lives.

Secretary ROLLINS. Right.

Senator HOEVEN. Not only cattle, but lives of people.

Secretary ROLLINS. Yeah.

Senator HOEVEN. And so I know you have to wait to get that data, but you are thinking within weeks, timeframe?

Secretary ROLLINS. Um-hum.

Senator HOEVEN. Okay.

Secretary ROLLINS. By the end of the month, the applications will be open, and we will be moving out. Now, we have already

moved out the $280 million to the Texas Department of Agriculture for the water issue in South Texas with the Mexicans, and so the ones that were specifically named in the legislation that you all worked on so hard.

Senator HOEVEN. Right.

Secretary ROLLINS. Those have already moved, those have been moving for a little while. But this next round, the big round, will be within the next few weeks.

Senator HOEVEN. Yes. And that is what I was referring to.

Secretary ROLLINS. Yes.

Senator HOEVEN. And that is, again, in line with what we passed, and so I appreciate that very much. Restructuring USDA, we all want to find waste, fraud, and abuse. We want to find savings, efficiencies, reductions, clearly, here in D.C., I think there is plenty of room for that in terms of reducing the size and scope of the bureaucracy. One of the keys for us, though, out on the ground, you and I have talked about it, and I know you know this, is FSA.

Talk to me about how we make sure that we have those frontline FSA officers or employees out there working directly with our farmers and ranchers; that is, you know, key. So talk about that. So again, yeah, we definitely—and we are seeing the reductions in the bureaucracy. Again, we want to find those, but we want the frontline folks out there, the hands-on folks.

Secretary ROLLINS. I don't know, at least at USDA, if there is any role more important than those frontline FSA offices, and those remain a priority. Of course, right next to that is our wildland firefighters as we are moving into wildfire season, that is extremely important in being operationally ready, which we are. Also, our Animal and Plant Health Inspection Service (APHIS), our veterinarians, et cetera, those are as important.

But the FSA operators that are managing and working with our farmers and our ranchers every single day, it is not in our plan to close any of those offices. There are 4,500, I think, total across the country, which is a big number, but we are also working to be, again, more efficient with online, et cetera, technical assistance, et cetera, that in the future may not rely so much on an on-the-ground presence.

But today we can't rip that rug out from underneath our farmers and producers, and that remains a priority. I signed a memorandum; I don't know, maybe last week, all the days are running together, that put as a priority ensuring that those offices are fully staffed. As I know we all in this room know, often hiring in rural America is a little bit more difficult because you just don't have the numbers of people.

But what I have told the team, and as we continue to focus on rural prosperity moving forward, is that finding the men and women out there, the patriotic Americans that are willing to work around the clock. We already have a lot of that in the FSA, but I think we can do better and more, so we will be spending some good time on that moving forward.

Senator HOEVEN. Thank you, Secretary.

Secretary ROLLINS. Thank you.

Senator HOEVEN. Excuse me. Thank you.

And I am going to turn to our ranking member on the Full Committee, Senator Murray.

Secretary ROLLINS. Good morning.

Senator MURRAY. Good morning. And thank you very much, Chair Hoeven. I look forward to working with you and with our new ranking member, Senator Shaheen, in her new role as the two of you lead this committee. It is a really critical one.

Secretary Rollins, thank you for being here. Let me be really frank with you. The very mission of USDA is under incredible threat from this administration. We are seeing dedicated researchers and experts who are being pushed out the door. Research, safety efforts have been put on hold, funds that Congress passed have been frozen and canceled by this administration, and nearly $17 billion in investments are now being held up at USDA.

That to me is really unacceptable and needs to change. We are seeing our food banks with less, increased prices at the grocery store. We are seeing Forest Service personnel who have been fired. They respond to our wildfires, we need them. Experts working on avian flu gone, and my farmers are extremely concerned about these illegal funding freezes and the illegal tariffs that are impacting them.

We also know that 15,000 employees have been pushed out, that is more than 15 percent of your Department. We know USDA cannot help farmers or communities without the people and the resources that it needs, which is really to me why this arbitrary workforce cuts combined with the sweeping cuts that President Trump proposed in the new budget that we just got is really alarming.

Secretary Rollins, let me just say to you, this committee needs a lot more information about how your Department is spending this funding that Congress provided earlier this year, and the fiscal year 2025 spend plan that you submitted last year, required by law, part of the Continuing Resolution, just isn't satisfactory. We need to have that information in order to write our appropriations bills.

And I just want you to know I expect you to work with members on both sides of this aisle to provide the details so we understand how you are spending money, and what is actually needed in the coming year. That is what I really want you to know and why I especially wanted to be here today.

But I do have some questions for you, because in Washington State, my home state and across the country, these abrupt terminations and resignations of ARS scientists and support staff have really gutted some of our vital agricultural research programs overnight. This is really undermining years of progress, research on plant diseases, making crops more resilient, extreme weather, that work is really fundamental to our farmers, and they are deeply worried about that being gone.

I know that many of the ARS scientists have been reinstated. Essential support staff has not. So will you commit to taking steps to reinstate the ARS support staff and stabilize these research units across the country?

Secretary ROLLINS. Well, there was a lot in that, Senator. So I will try to talk really quickly and answer as much as I can. And

then please, reach out to me directly, and we can always have this conversation anytime. I don't think you were in here, but I have had long conversations with members on both sides of the aisle about all of this in the last couple of months, so I welcome that conversation anytime.

The first thing I want to say is the 15,000 number it is less than 15 percent of our total workforce. I realize that is still a very, very big number, but I think it is important to realize in the context that every year, USDA, through attrition, loses between 8,000 and 10,000 employees, so as a massive government agency.

Senator MURRAY. But they are refilled.

Secretary ROLLINS. Well, and that is what we are looking to refill, the frontliners that is what I was talking about right now. So whether it is FSA, APHIS, the wildland firefighters, those are, through a memorandum I just signed, we are actively looking and recruiting to fill those positions that are integral to the efforts and the key frontlines.

Senator MURRAY. So you let people go and you are looking for new people to fill the positions that they had experience in?

Secretary ROLLINS. We are having those discussions right now. We are working with all of you around the country in your states. We believe our firefighters are operationally ready for wildfire season. Our FSA offices, we are looking, you know, we are making things more efficient, but bringing on new people that could potentially bring and be a game changer in those offices.

But by the way, the people that you are talking about, the 15,000, those are all deferred resignations. None of those people were fired. So if they want to come back and if they were in a key position, then we would love to have that conversation.

The other thing in the second round of Deferred Resignation Program (DRPs), which just happened about, I don't know, a couple of weeks ago, we did not accept the DRPs of employees that were in those key positions that I outlined, that a few of them, I think we had several hundred that said, all right, we are going to take it. And we said, no, those are, your role is too important right now. We are not going to accept it.

So we are very intentionally approaching this. Have we done it perfectly? No. Any type of whole scale change and big effort to basically realign an entire government agency is difficult. And we know that. And we know that it hasn't been perfect. But we are working every day to solve for a lot of this. And I think we are making a lot of really good progress.

Senator MURRAY. Okay. You didn't answer my question specifically on ARS scientists, research, the support staff.

Secretary ROLLINS. Well, what I would love if you or your team could get us exactly what you are talking about, who you are talking about, and where you are talking about it. Because we have been, like I say, line by line, keeping the staff in place where we believe it is of utmost importance and aligns with the Agency's mission in areas where we don't believe we haven't been as focused on that. But again, that is a conversation I would so welcome to understand exactly where and what that looks like.

Senator MURRAY. That is important. But this is on record. And so one of my concerns is that you let people go however you want

to characterize it, who knew these jobs, and now you are looking for people to fill these jobs because now we know how essential they are, that doesn't seem to me to be very efficient.

But I need to ask you about nutrition programs in my last minute here.

Secretary ROLLINS. Sure.

Senator MURRAY. Because we have about 134,000 people in Washington State, 7 million people nationwide who rely on Women, Infants, and Children (WIC) Program. It provides, as you know, essential nutrition support to moms and kids during the earliest, most vulnerable stages of life. It is one of the most effective programs that we have. It has always received bipartisan support on this committee, it is glaringly absent from the President's budget request.

WIC, Supplemental. Nutrition Assistance Program (SNAP), Commodity Supplemental Food Program (CSFP), these are really key, important programs for seniors. They are not optional. They are essential programs that feed moms and babies and the elderly. So I wanted to ask you, do you fully support funding WIC; yes or no?

Secretary ROLLINS. Well, okay, so are you talking about the Local Food for Schools Cooperative Agreement Program (LFS) and Local Food Purchase Assistance (LFPA) contracts that were canceled, or SNAP?

Senator MURRAY. I am talking about the budget that came over to us on Friday.

Secretary ROLLINS. WIC is fully funded. SNAP is, so that is why I am confused by your question. I am sorry, Senator.

Senator MURRAY. Well, in our looking at this, it is absent. I am happy to get the information to you. But this, for this committee, I know it is something we have always supported on a bipartisan basis. It is something we need to continue.

Secretary ROLLINS. Yeah. WIC is fully funded. I am happy to talk SNAP or some of the other cuts, but.

Senator MURRAY. Yeah, WIC, it is eliminated in the budget that the President sent on Friday.

Senator SHAHEEN. We also thought that, so.

Secretary ROLLINS. We will clarify that and get that right back to you. I know there had been some realigning in SNAP and in some of the food banks, et cetera, that is kind of where we have been talking and focusing on.

Senator MURRAY. The President—for the committee members, the President sent over his budget on Friday. It does eliminate WIC in it. So we obviously need to have better information from the administration.

Senator HOEVEN. Our understanding is that—I mean, number one, we fully funded WIC in the last go around in the CR, as you know, Senator. And our understanding is just in the skinny budget, it just wasn't included. It is funded for this year.

Secretary ROLLINS. Yeah, it is funded.

Senator HOEVEN. This is the skinny budget. There are things we don't have yet. So that, at least, was our understanding.

Secretary ROLLINS. It is fully funded.

Senator MURRAY. That would be interesting to see in writing.

Secretary ROLLINS. You are welcome.

Senator HOEVEN. Thank you, Senator Murray.

Secretary ROLLINS. Thank you, Senator Murray.

Senator HOEVEN. Let me turn to Senator Moran.

Senator MORAN. Chairman, thank you. Thank you to you and Senator Shaheen.

Secretary, welcome. Thank you for coming to Kansas, although you came when I had the flu.

Secretary ROLLINS. We missed you.

Senator MORAN. Please come back.

Secretary ROLLINS. Yes. I know.

Senator MORAN. On a day that is not 16 below zero, and we will show you a different side of our state. I want to talk a bit before I get to a couple other topics, about Food for Peace. Senator Hoeven and I, when we saw what was happening with Food for Peace at USAID and the State Department, we introduced legislation to transfer the authority to manage and operate Food for Peace to the Department of Agriculture.

It was my understanding that both OMB and the Department of Agriculture, your Department, responded to that idea favorably. And I am anxious to have you tell me what it is that I and my colleagues ought to be doing to keep providing the commodities that we grow in the United States to people who are starving around the globe, and is this something you are still interested in acquiring?

Secretary ROLLINS. Yes. And it is my understanding this program was started in Kansas; is that right?

Senator MORAN. That is true.

Secretary ROLLINS. Yes. The Great State of Kansas, with about 150 farmers who came together and came up with the program. So not surprisingly, I don't want to get ahead of my boss, and certainly Secretary Rubio and I have had very initial conversations about it.

Senator MORAN. And I would add. I also understood that Secretary Rubio was willing or capable of sharing that responsibility or giving you that responsibility.

Secretary ROLLINS. Yeah. We have had really great conversations about it. Obviously, we will follow your lead, and if in fact this is the will of Congress, I think we would be very willing to take that on if that was your direction and would be excited to partner on that.

Senator MORAN. And to the elimination of McGovern-Dole, which we call in Kansas Dole-McGovern, the elimination of that program is not an indication of the lack of interest in the Department of Agriculture making available American-grown commodities to people who are hungry around the globe; is that true?

Secretary ROLLINS. That is true. Thank you for that clarification. That is really important.

Senator MORAN. In the conversation that you have had about employees at USDA and the efforts to right-size, downsize, whatever the right words are, the Department, let me highlight for you the importance of FSA and NRCS employees in county offices across the state of Kansas and around the country, I assume. And it was particularly troublesome when those on probation were those who were eliminated. We love the circumstance when a

young man or woman out of college, returns home, goes to work for USDA in a county office. We do not have sufficient personnel in those county offices today.

Secretary ROLLINS. Right.

Senator MORAN. But we particularly love when they are somebody who is in their 20s, they come home, and they raise a family in a small county of Kansas. And so would you pay particular attention to trying to make certain that county offices where farmers sit across the table from USDA employees and have a conversation about—certainly about the farm programs and conservation programs takes place, that is different than ever trying to do that on a computer.

Secretary ROLLINS. That is right.

Senator MORAN. So what would you tell me about your commitment to that?

Secretary ROLLINS. Well, I think it is of paramount importance. And you think about what USDA who we are called to serve, the initial intention of the Agency, of course, in the founding of our country, we had the original four agencies, Treasury, Defense, the Attorney General, and Justice and then just a few years later, a couple decades later, Interior was added, and right after that was Agriculture.

So this goes back to almost the founding of our country, and certainly we take that very, very, very seriously. In President Lincoln's best vision and his intention in founding this agency, it was to have that on-the-ground support for our farmers and our ranchers.

So as President Trump is working to make America great again and restore prosperity across our country, my role in that is to ensure that rural America sees a level of prosperity that perhaps they haven't seen in our lifetimes. And there is a lot that goes into that formula, right, there is a lot we have got to do. We have got to get government off the back of our people. We have got to cut taxes.

Senator MORAN. Let me ask you one more question.

Secretary ROLLINS. We have got to deregulate but, yes, the FSA remains at the very top of that list.

Senator MORAN. Thank you. And I do appreciate having employees return to the office to work, it is as important as well.

Secretary ROLLINS. Yes. That is an important part, too, yes.

Senator MORAN. I had mentioned to you when we visited about the National Bio Ag Facility that is in Kansas, it is the replacement for Plum Island, we had this conversation when you were in my office before the confirmation.

Secretary ROLLINS. Yes.

Senator MORAN. I want to just highlight, because I have one second left, but I want to highlight that facility, that institution, and ask you to either tell me or get me a report on National Bio and Agro-Defense Facility (NBAF) operational status as of today?

Secretary ROLLINS. I think it is a huge asset, and it is an important asset to the greater good of the country. And as we talked about in your office that day, a couple of months ago now, my commitment in fulfilling Congress' intent has not changed. And so I think, Senator, you and I can just make sure you need to send me reports if you are hearing anything different. But we are com-

mitted to ensuring that that facility moves forward in a way that best serves all of America and, frankly, the world. It is a really important asset.

Senator MORAN. Thank you, Secretary.

Secretary ROLLINS. Thank you, Senator.

Senator HOEVEN. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

Secretary ROLLINS. Good morning.

Senator BALDWIN. Secretary Rollins, thank you for joining us today.

Secretary ROLLINS. Thank you.

Senator BALDWIN. The Dairy Business Innovation Initiative has delivered critical and high-impact support to small dairy farms and businesses in Wisconsin and across the country. Since its inclusion in the 2018 Farm Bill, the program has helped producers expand their product lines, access new markets, and modernize their operations. In Wisconsin, these small-dollar grants have made a real difference in helping expand a globally respected dairy industry.

As we consider additional funding for USDA in 2026, I am really deeply concerned about the treatment of the Dairy Business Innovation Initiative under this administration. Congress has secured funds annually in statute in the bipartisan annual appropriation bills, and they were promised to farmers by the USDA. Yet over 400 dairy businesses had nearly $30 million on the chopping block due to a Diversity, Equity, and Inclusion Executive Order issued by President Trump this February. I hope we don't confuse diversity and biodiversity, as important issues.

But I appreciated the opportunity to discuss this with you personally, and you know, the need to issue these funds to Wisconsin and other farmers expeditiously, especially when their margins are already incredibly slim. But I still have concerns. How are you planning to restore Congress' confidence in USDA's ability to implement and fund programs required by statute, like the Dairy Business Innovation Initiative? And how will you ensure the Agency's communication to farmers and small businesses can be relied upon when they make real-time investment decisions in their operations based on awards?

Secretary ROLLINS. Well, I appreciate that question. And on my second trip, it wasn't to your beautiful state, but it was to Kansas, as we talked about. I think Senator Moran stepped out. But we talked about—we actually visited a major dairy operation and have since visited half a dozen more in Pennsylvania and several other states. So I look forward to coming to Wisconsin and seeing the operation there.

The program you are talking about is not frozen. I think after we spoke, we looked into that. But I want to make sure that is clear from your understanding as well.

Senator BALDWIN. It is.

Secretary ROLLINS. So that is moving forward.

Senator BALDWIN. After my intervention and our conversation, the funds were released. But that was still, you know, people make expenditures in reliance of an award that they have gotten.

Secretary ROLLINS. I understand. It was maybe a 30-day delay, and I apologize for that. Any delay, I think, on a worthy program,

especially with our dairy farmers is, one day is one day too many. I know you understand.

Senator BALDWIN. There was uncertainty of whether they were ever going to get the funds.

Secretary ROLLINS. That is fair.

Senator BALDWIN. Let me move on to another one that you have already referenced briefly. I was really deeply concerned when the USDA abruptly cut funding to critical food assistance programs in March, including the Local Food Purchase Assistance Program and the Emergency Food Assistance Program (TEFAP).

In 2024, through the TEFAP program, Wisconsin distributed over 21 million pounds of food, serving over 618,000 households. Hunger Task Force in Milwaukee had about $615,000 worth of food they expected to help feed people during this summer, halted by the Trump administration.

And Wisconsin farmers and producers worked tirelessly to grow food that feeds hungry children and stocks our local food pantries. And the decision to cancel these vital programs only hurts families trying to put food on the table and the Wisconsin farmers who produce it.

So Secretary Rollins, will you reinstate these critical food assistance programs in fiscal year 2026?

Secretary ROLLINS. So let us talk about that for a second. First of all, those were COVID-era programs. They were never meant to go forever and ever. This is part of the problem with—and again, not Democrat or Republican, but any government, in general, you put an era program in, and then it literally never goes away, which, by the way, is not fair to taxpayers. But let me answer your question directly.

Senator BALDWIN. Well, I would also argue that the situation of hunger for——

Secretary ROLLINS. Well, that is what I was going to—may I respond to that part of it? So specifically to Wisconsin, your program in Wisconsin, aside from what was pulled back, still has $1.2 million left sitting in a bank account, out of $8.1 million in your Local Food Purchase Assistance Program. You also had your state, not you, Senator, but your state asked for a contract extension because they couldn't spend the money fast enough. Your tribes have 500,000 left out of 700,000.

Senator BALDWIN. I think you are confusing the programs, because the local food assistance purchased that creates opportunities for local farms to produce fresh produce. Secretary Rollins: I am not.

Secretary ROLLINS. That is the LFPA.

Senator BALDWIN. Some of these others, you know, get canned commodities, et cetera. I visited several food banks in Wisconsin.

Secretary ROLLINS. I am talking about the LFPA, Senator.

Senator BALDWIN. Right now and we have 200 to 300 farms that were engaged in this, and this was an expected customer that they no longer have.

Secretary ROLLINS. But, Senator, it was an era—it was COVID-era program that, by the way, you still have millions of dollars left, right, that you can use to pay those farmers.

Senator BALDWIN. The need is still there.

Secretary ROLLINS. That is the point. Most of that—a lot of that money was never spent, you couldn't spend it fast enough, that is not fair to the taxpayers. Do you know USDA spends $400 million a day on nutrition and food programs, just USDA? That is aside from this food bank. There is plenty of money in the system. We just have to be better about how we are spending it.

So I hear you. But I think that it is important to look at where this money is sitting, how it is being spent, and making sure that we are using the taxpayer dollars effectively. But thank you.

Senator HOEVEN. Senator Fischer.

Senator FISCHER. Thank you, Mr. Chairman.

Secretary Rollins, it is so good to see you here today. Thank you.

Secretary ROLLINS. Thank you.

Senator FISCHER. I share your desire to realign and reprioritize resources across USDA to put our ranchers and our farmers first. This is especially important for USDA's Agricultural Research Service to ensure that we are funding innovative and high-impact research that benefits our farmers and ranchers. I have been working to secure funding for an ARS facility that is focused on innovative, precision agriculture research that is co-located at the University of Nebraska-Lincoln.

And I look forward to continuing to work with you on that facility to ensure we can have high-impact, high-priority research taking place there. You have also talked about having more USDA's workforce located closer to the people that they serve.

Secretary ROLLINS. Yes.

Senator FISCHER. And while no official announcements have been made, I think this would be a great step, and I know Nebraska would be a great location to relocate parts of USDA, like the Ag Research Service, giving our proximity to a number of strong land-grant institutions, lower cost of living, and strong existing relationship with the Agency at the facilities I mentioned beforehand.

Can you talk about your plans for relocating parts of USDA to the heartland, and how do you anticipate relocation efforts could save taxpayer dollars and create greater efficiencies for the Agency itself?

Secretary ROLLINS. We are very close, I will say, in the coming weeks you will hear a lot more about these plans, and I have really—I am so grateful because I have gotten a lot of feedback from you and from others about potential locations around the country. What I am most excited about in this realignment, though, is exactly how you outlined it, Senator, that we have to move—this is a customer-service-oriented agency; and why do we have so many people in Washington, D.C.?

And then you bring the force part into that, and then the nutrition into that, and it just doesn't make as much sense. It will also be cheaper for the taxpayer, and the customer service agent will be closer to the people that they serve. So we are very in the weeds on that today, and an announcement is forthcoming.

Senator FISCHER. I appreciated your comments to Senator Moran about the FSA and keeping those local offices open. I am very well aware in rural communities across my state how important it is that farmers have that in-person access. And while we may be

using technology in many areas, there still, I think, at this point in time, needs to be that face-to-face contact.

Secretary ROLLINS. I agree.

Senator FISCHER. So thank you for that as well. In Nebraska, we are also so proud of the work that is being done at USDA's Meat Animal Research Center at Clay Center. That is a strong relationship that the Center has with our livestock producers in the state.

Last month, both Nebraska cattlemen and Nebraska pork producers talked to me about how they valued the research that is being done there. The President's budget does call for cuts to ARS funding, but I think it is also important for us to make sure that the dollars that we do spend on research and facilities gets stretched as far as it can. Due to overregulation, you have touched on that in some of your answers, a lot of burdensome contracting requirements out there, simple maintenance and upkeep costs end up costing sometimes three to four times more than they should.

And this is especially true for unique research centers like U.S. Meat Animal Research Center (USMARC) at Clay Center, who operate—they are working farms, they are working ranches, they handle livestock on a daily basis.

So would you agree that research done in collaboration with the livestock industry at USMARC's Working Farm and Ranch is important? And would your team work with mine to ensure that the improvements that we make to ARS facilities don't end up dramatically costing more than it would for the private sector to operate those?

Secretary ROLLINS. I will, Senator. And I appreciate that and the great research that happens in Nebraska. A quick note on ARS, while we are decreasing the budget, it is $2.1 billion currently under the President's budget from Friday. It goes down to $1.9 billion. that is about a 7.5 percent decrease, and that is really focused on just some facilities that are way behind on repair and just out of date, and not meeting the mark, obviously not yours in Nebraska. So that is a very targeted decrease in funding that shouldn't affect, we remain highly, highly focused on the priorities of ARS and ensuring those are funded.

Senator FISCHER. You know, I hope you can also look at that overregulation that we have with contracting that I mentioned, because a lot of times just those really simple maintenance, it does end up costing more, and more, and more, where if we can, you always hear about government regulation and how burdensome it is, and there is some good examples that we need to get rid of those good examples and make sure that we are dealing with common sense and in the real world to meet those lower costs that should be available.

Secretary ROLLINS. And the most important thing you can do is send us, have your team send us those examples, and we will get on it right away.

Senator FISCHER. Great.

Secretary ROLLINS. Thank you, Senator.

Senator FISCHER. Thank you, Madam Secretary.

Senator HOEVEN. Senator Heinrich.

Senator HEINRICH. Thank you, Chairman.

Secretary, the Iron Fire is currently burning in the Gila National Forest, and you and I have talked about the Silver City Dispatch Center, which is in charge of coordinating the response between air assets and frontline firefighters in the Southwest. It is still among the dispatch centers that DOGE is seeking to close. And in our conversations, you assured me that you would seek to keep this dispatch center open, that you would designate it mission critical. Talk to me about what you are doing to make good on that promise?

Secretary ROLLINS. Yeah, we have been in conversations with GSA on that, Senator, and certainly as we have many hands working across the Trump administration to deliver on our promise for a more effective and efficient government, we agree that this is important, and especially as wildfire season is heating up, ensuring that we are operationally ready at every turn in your state and in other states that are highly affected by that. So we remain focused on that. And if you hear something different, please call me.

Senator HEINRICH. Let us return to something that you discussed with my colleague from Wisconsin. The local Food Purchasing Assistance and Local Food for Schools programs, in my view, are two of the best, and they may be COVID programs, but they are two of the best examples of using American-grown produce to produce healthier outcomes in our students. To me, that is making America healthy again.

You have canceled both of those contracts, even though those contracts were signed and farmers had bought supplies for planting based on those contracts. So what would you say to both the producers and the schools who made financial decisions based on those commitments?

Secretary ROLLINS. Well, I would love, Senator—the first thing I will say is could you send me specific information on that, because that would be really helpful. We have talked a lot in broad strokes, but if I could see the details. In New Mexico, you still have $1.5 million of the last tranche left out of 6 million.

Senator HEINRICH. I can't speak to what the state is doing, and we will be happy to run that to ground. But the people I am hearing from are, literally, the schools and the producers who were impacted, the growers.

Secretary ROLLINS. Yeah. I would love to get more details on that and what that looks like. Again, it is a COVID-era program. The other side of this, and I want to make sure you have got plenty of time to ask your other questions, but the other side of this as far as the local nutritious farms, et cetera, I mean, I think that is a massive push.

I think it is important we remain prioritized on that. But again, the $400 million a day we spend at USDA on nutrition, just on nutrition, I believe sincerely that we will be able to check a lot of those boxes without continuing a program that was supposed to end at the end of COVID and that, in fact, most states still have a lot of money left in the bank. They haven't been able to spend it.

Senator HEINRICH. My colleague from Kansas mentioned Food for Peace and McGovern-Dole. These programs have provided lifesaving, American-grown food to people around the world. I have lit-

erally met with mothers and children who relied on American food aid for their survival. So I appreciate that you have had initial discussions with Secretary Rubio about these programs, but what I saw two weeks ago with several of my Republican colleagues on the ground at a refugee camp, was kids who were on fractional rations, who didn't have enough calories per day to thrive.

So what are we doing to fill the gap between the historic commitment of those programs and whatever that replaces them, in the meantime, when the impact is kids who are not getting enough to eat?

Secretary ROLLINS. And you are talking specifically on the international programs. Yes, that is a great conversation. We continue to talk about it. The President has been very clear that we have to ensure that our kids here in America that are hungry, that we are serving, obviously they are the priority. It doesn't mean that we don't care about or want to move out our American farmers' produce, and we should, and commodities across the world, but really focusing here in America first.

But secondly, understanding what those programs are, which I talked a little bit about with the back and forth with Senator Baldwin, I think—it may have been Senator Murray. But how important and effective those are, where we are spending the money, how it is being spent, and what that looks like.

Senator HEINRICH. I think you will get a lot of support from this committee to go after overhead, excess overhead.

Secretary ROLLINS. Yes.

Senator HEINRICH. I think we have to check too many boxes, and there are a lot of entities that have gotten good at running those contracts because they can check those boxes. But what we saw on the ground was kids who had malaria and other diseases because they simply didn't have enough food to eat, because commitments we made were not being made good on.

Secretary ROLLINS. Well, I would love more details on that. That would help me understand, in fact, where it was you all went, and then my commitment to you is to study that. And you know, my heart is with what you are saying, but again we, putting America first, understanding how we are feeding our children, and we haven't had a MAHA discussion yet, but if we do, we can talk a little bit more about that, is important.

But also understanding that, again, the mission and that the intention of these programs are always good, it is how we are effectuating them and putting them into play and really looking at that closely.

Senator HOEVEN. Thanks. Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman, and thank you, Ranking Member. And thank you, Madam Secretary, for being here.

Secretary ROLLINS. Thank you, Senator.

Senator HYDE-SMITH. I am thrilled to have you there. I think you have already proven to be a great Secretary of Agriculture, my hat is off to you, the challenges that you are facing in reorganization and a new administration is a tall drink of water.

Secretary ROLLINS. Yes.

Senator HYDE-SMITH. And I certainly want to be helpful any way I can, and I can attest to those 5 a.m. texts, that I don't know when you sleep. But there is so many challenges out there.

Secretary ROLLINS. There are.

Senator HYDE-SMITH. And of course, as the former Head of the Mississippi Department of Agriculture, I know all the players. And getting the calls I am getting now on the concerns that you are desperately trying to address is very much appreciated.

Secretary ROLLINS. Thank you.

Senator HYDE-SMITH. Because there is a lot of glaring concerns that we have to take a look at. And I just admire the speed that you are tackling this and the tasks that you have in front of you. And before I go to the questions, and I know that this is about the 2026 Budget Request, but before I go into these questions. I just want to say this to everybody in the room. Congress needs to address the outdated and inadequate safety nets that is in the Farm Bill during the budget reconciliation process.

Secretary ROLLINS. Right.

Senator HYDE-SMITH. There is a lot of farmers in Mississippi and across this country that are not going to be able to continue unless we do address this. It is so concerning for me. And addressing one aspect of the Farm Bill, SNAP, in reconciliation without making improvements to the farm safety net, it will make it extremely difficult to pass a Farm Bill, but it is so critical.

So American farmers, as you well know, desperately want a new and improved Farm Bill. And I think it is our job to improve the Farm Bill. So let us give that to them by addressing the safety net and reconciliation. I can't scream that enough. Like I said, I know this is about the budget, but that is so critically important that we do this now.

I want to just commend you on how efficiently and fast the Department got out the 10 billion in disaster aid Congress passed in December to help commodity producers cope with the unbelievable input and cost and the depressed commodity prices. You were excellent at doing that. And I have had my farmers call and thank me for that. But through the USDA's Emergency Commodity Assistance Program (ECAP) that you have referenced, you know, many farmers are able to farm this crop this year that, literally, they would not be able to otherwise.

Secretary ROLLINS. Yes.

Senator HYDE-SMITH. When I have bankers come to me and say, we are not going to finance your farmers next year without something, it was that critical. And it was not sounding the alarm; it was just pure fact is what we were dealing with.

Secretary ROLLINS. Yes.

Senator HYDE-SMITH. So thank you for that. But when can we expect USDA to distribute the remaining disaster funds for 2023 and 2024 for the weather-related losses? That is the questions that we are being asked right now; if you could address that?

Secretary ROLLINS. Yes, ma'am. And I appreciate all the good words. And just quickly, it is the team sitting over my right shoulder and the people back at USDA that literally worked seven days a week, 18- 20-hour days to get that first tranche of funding out. And I am so grateful to them and the unbelievable amount of time

and effort they put into it. They are putting that same amount of time and effort into this now second tranche on the disaster relief.

The portal should open within a matter of weeks, before the end of the month, to allow those grant applications to begin being processed, our goal is timely, efficient, and turn it around quickly. With the first tranche, that first $10 billion, the ECAP, we were turning it in two to three days, which I believe is unprecedented for any government program, but certainly for USDA.

Senator HYDE-SMITH. We had four.

Secretary ROLLINS. And our goal is to have the same sort of speed, timeliness, and hopefully effectiveness on the second tranche as well.

Senator HYDE-SMITH. And thank you for that. And there is no doubt that you are not going to accomplish that because you have done so well so far. And we have talked about the FSA county levels, and the staffing, and the decisions that have been made, but again, as I hear from all of my producers and so many throughout the country, we know that some of this is so necessary and it is going to benefit us in the long run. It is kind of like cleaning out a closet. You dread doing it, and you get everything out, and it is just stuff everywhere until you get it sorted and organized and put back.

Secretary ROLLINS. That is an amazing metaphor, but I can completely understand and appreciate.

Senator HYDE-SMITH. Yes, we have four children. We can clean out closets.

Secretary ROLLINS. Yes, we can.

Senator HYDE-SMITH. Because that is where we are.

Secretary ROLLINS. Yes, ma'am.

Senator HYDE-SMITH. And to get it organized, put in the proper place.

Secretary ROLLINS. Right.

Senator HYDE-SMITH. But to get to the end of, you know, the conclusions, is it being spent properly? And are we doing the most that we can to make it efficient? So my question is just, it is so critically important that support continues to reach these producers. And can we just ask that you work with the subcommittee on doing that?

Secretary ROLLINS. Absolutely. And it brings up a bigger question, I think, Senator, that the average age of the farmer is 58. That is a whole other hearing for another time, how we reverse that trend. But I think it goes to not to cast any of us, you know, around that age or older, aspersions at any of us, but that, you know, moving to online is important at some point.

But that is my point. It isn't today. And especially with all the challenges and the headwinds against our producers, we have to keep those front liners in place as we are moving these projects out.

Senator HYDE-SMITH. Well, you have an unbelievable task with a huge agency. But I just want you to know you have got my support. I have been on the frontlines. I have been there. And I am very, very pleased with what you are doing and the direction you are headed.

Secretary ROLLINS. Thank you.

Senator HYDE-SMITH. And thank you for being willing to do it.
Secretary ROLLINS. Thank you, Senator. Thank you.
Senator HOEVEN. Senator Peters.
Senator PETERS. Thank you, Mr. Chairman.
Secretary ROLLINS. Good morning.
Senator PETERS. Secretary Rollins, good to see you again.
Secretary ROLLINS. You, too.
Senator PETERS. And welcome to the committee.
Secretary ROLLINS. Thanks.

Senator PETERS. Secretary, as part of the 2018 Farm Bill, Congress passed the PAWS Act legislation, which I authored to establish a grant program to provide shelter options for domestic violence survivors with companion animals. Research had found that up to 84 percent of women entering domestic violence shelters reported that their partners had threatened, abused, or had killed the family pet, used that as a source of intimidation for these survivors.

In fact, nearly half the survivors report that they have stayed with their abuser longer, sometimes months, sometimes years, because of fear of what would happen to that beloved part of their family. PAWS funding is a priority that I pushed throughout my time on this committee and in the Senate. And it is a line item that I hope to see in the President's budget once we receive the details.

So my question for you, Secretary Rollins, is would you be willing to support this important issue, and certainly I would hope to count on you to get that continuing support that survivors have been able to get these last few years.

Secretary ROLLINS. Senator, if we could follow up and have a longer conversation, I would welcome that opportunity. This is the first I have heard of it, so I don't want to commit without knowing more. But I really appreciate your leadership and your quiet, steady hand in all of this, and I would love to have a longer conversation about that.

Senator PETERS. Great. We will follow up with you and your team.

Secretary ROLLINS. Yeah, it would be great.

Senator PETERS. I will be happy to do that. In my home state of Michigan, food and agriculture is the second largest contributor to our state's economy. Everybody thinks about manufacturing and making cars. We do that really well, but ag is incredibly important. And specialty crop industries are the biggest part of that equation. That is why I have long fought for strong, consistent funding for the APHIS Specialty Crop Pest Program. And that is also why I am so alarmed by some of the recent reports that more than 1,300 APHIS employees have accepted the deferred resignation option.

So my question for you, Madam Secretary, is how will your Agency continue to meet its responsibilities after such a major reduction in staffing?

Secretary ROLLINS. Well, it is a really important question, and one that I have been talking about quite a bit in media. I think that while we are moving through the reduction in force, one point that I made, Senator, I don't know if you were in the room, that while 15,000 of our employees of 106,000 staffed agencies, a little less than 15 percent have accepted the deferred resignation pro-

gram, our typical attrition is between 8,000 and 10,000. Now, obviously, this is a significant jump from that, but it is one that I believe is manageable.

I signed a memorandum a few weeks ago at USDA putting our key areas, such as APHIS, such as wildland firefighting, such as FSA offices, at the very top of the list. So as we have lost important employees as part of this process, we are out recruiting and ensuring that they become and are prioritized as we rehire, realign, and reorganize the Agency.

Senator PETERS. Okay. Well, I look forward to working with you on that as well.

Secretary ROLLINS. Yes, sir.

Senator PETERS. It is a major concern for us. As you know, public investment in agricultural research has decreased since 2002. While we have seen competitors such as China surge in their research efforts, they have now far surpassed U.S. investment in agricultural research as well as development. And given the critical importance of food security, to national security, China competitiveness in this context I think is of utmost importance for us to keep an eye on. That is why I am frustrated to see that the President's budget calls for hefty cuts in ag research funding.

So my question for you, Madam Secretary is, is ag research a priority for this administration? And if so, how do you square that with this year's budget request?

Secretary ROLLINS. Obviously, the research is a key component of this, of the work at USDA. In this budget discussion, we are just talking about the discretionary funding, which is about 30 billion of our total $200-plus billion annual budget, so at about 20 percent total is what we are discussing today. In total of that, the research part of it in the budget that came out Friday went from $2.1 billion down to $1.9 billion. So while it is a cut, it is not a massive cut. It is a 7 percent cut, and it is very much focused on outdated facilities.

So as we continue the high priority and the focus on the important research, I believe that none of that will be compromised, Senator. If you see something different on the ground in Michigan or across the country, would you please flag it for us, because it shouldn't affect the key, most important parts of the research.

Senator PETERS. Great. Well, thank you for that.

Thank you, Mr. Chairman.

Secretary ROLLINS. Thank you, Senator. Good to see you.

Senator HOEVEN. Senator Ossoff.

Secretary ROLLINS. Good morning.

Senator OSSOFF. Thank you, Mr. Chairman.

Good morning, Madam Secretary.

Secretary ROLLINS. Good morning.

Senator OSSOFF. Thank you for joining us. I want to follow up on hurricane disaster assistance, key, key priority for farmers in Georgia, Madam Secretary. It is worth noting that after Hurricane Michael in 2018, it took the Congress the better part of a year to pass disaster assistance. We worked together across the aisle here to get it done after Hurricane Helene in less than 90 days.

Here is a quote from Arren Moses, owner of Moses Pecan in Uvalda, Georgia, "We lost almost our entire 2024 pecan crop when

Hurricane Helene hit our orchards. We lost the majority of our mature pecan trees, which will set our farms' production back for years. We were thankful that Congress approved disaster assistance funding at the end of last year, but it is critical that these funds get to those that need help."

Here is a quote from Chris Hopkins, a cotton producer in Toombs County, he said that "The storm has created a void due to loss of yield and quality as well as cost of cleanup that has become untenable to a first-generation operation like mine."

When can farmers in Georgia expect that hurricane relief, which we passed timely in Congress, to be out the door?

Secretary ROLLINS. Yeah. And first of all, thank you for that. That relief was passed very quickly and very impressively at the end of last year, and so we have been tracking it very, very closely. I have visited Georgia. Hopefully next time I will see you. I have visited some of those peanut farmers especially. I have seen the devastation firsthand. It is heartbreaking to witness it. I had mentioned earlier, but it is good to keep repeating it, that within a matter of weeks, the portal will open on those grant applications. Under ECAP which was the first tranche, that first 10 billion that went out for emergency assistance.

Senator OSSOFF. That is the economic assistance.

Secretary ROLLINS. That is right.

Senator OSSOFF. I am referring to the disaster assistance.

Secretary ROLLINS. I understand, but I just want to use that as an explanation of how we are going to be also doing the second tranche, which is the disaster. We, on March 17th, announced it. On March 20th, funds were moving out and into farmers' bank accounts.

Senator OSSOFF. When will the portal be open for disaster assistance?

Secretary ROLLINS. By the end of the month, hopefully in the next week.

Senator OSSOFF. And how will that impact states that are using a block grant arrangement with USDA?

Secretary ROLLINS. Well, that is a state-by-state question, so I will be happy to follow up with Tyler Harper, your Ag Commissioner, who I know is tracking this very, very closely, and I ensure that we both understand——

Senator OSSOFF. When do you expect those discussions with the state to be resolved?

Secretary ROLLINS. Well, again, there are 50 states. We are talking to all of them. When we open that portal, hopefully it moves almost immediately. We have already moved the 280 million that was outlined in that disaster relief into Texas. Because it was outlined, it was obviously easier than, the open book on the rest of the states. But it will move very, very quickly.

Senator OSSOFF. Because time is of the essence.

Secretary ROLLINS. Then would you please let me know?

Senator OSSOFF. Yes, I will.

Secretary ROLLINS. And we will do everything we can.

Senator OSSOFF. Madam Secretary, are you familiar with the Local Foods for Schools Program?

Secretary ROLLINS. Yes, sir.

Senator OSSOFF. So here is a few quotes from my constituents, this is from Scott Richardson of the Dawson County School District: "Local Foods for Schools Program has transformed our ability to bring healthy, fresh, and locally grown fruits and vegetables to our students. Prior to the LFS, purchasing from local farmers was often cost prohibitive."

Here is a quote from Parrish Akins, he owns a family farm in Nashville, Georgia. Mr. Akins said, this program, quote, "Has allowed our farming operation to capture some of the profits, which in the past would have gone to another member of the supply chain, and has allowed us to increase our revenues."

Here is Colquitt County School Nutrition Office, "Purchasing local foods has significantly enriched our school community by providing fresher, healthier meal options for students."

Here is Atlanta Neighborhood Charter School Nutrition, "We bought some Georgia shrimp from a guy who has been in the shrimp industry since he was a teenager."

In Brunswick, Crisp County School Nutrition, "Through the Local Food for Schools Program, we were able to establish reliable and stable local food sources." This is a program, of course, that helps Georgia farmers sell food to Georgia schools. Why did you cancel the program?

Secretary ROLLINS. Well, let us talk about Georgia for a second.

Senator OSSOFF. I have 50 seconds left, so I just want to know about the——

Secretary ROLLINS. Well, that is a big question. You have got to give me a little bit more time.

Senator OSSOFF. You can take your time, but I want to know why you canceled the program.

Secretary ROLLINS. Well, we canceled the program. It was a COVID-era program, first of all. Second of all, the money was not being spent. In the current tranche, your state has $2 million of $7 million left in the account. You are asking for contract extensions because you cannot spend the money quickly enough. The food for the FPA and the LFPA, we have got $10 million of $20 million left, so you have got money in the bank.

Senator OSSOFF. Why rather than tailor the program did you cancel it?

Secretary ROLLINS. It is not a good use of taxpayer funds when you have got taxpayer dollars.

Senator OSSOFF. Well, my constituents believe that it Constituents, the farmers——

Secretary ROLLINS. Well, I would love to talk to your constituents, I wonder if they know that the State of Georgia has not moved that money out, we just can't continue that.

Senator OSSOFF. Constituents, the farmers—Will you please provide to the committee an economic justification for the outright cancellation of that program?

Secretary ROLLINS. An economic justification for the outright cancellation of the COVID-era program that was due to end, yes, we will do that.

Senator OSSOFF. Of the Local Food for Schools program that the constituents enjoy and rely on?

Secretary ROLLINS. Yes, we will be happy to do that, sir.

Senator OSSOFF. Thank you, Madam Secretary.
Secretary ROLLINS. Thank you.
Senator HOEVEN. Senator Merkley.
Secretary ROLLINS. Good morning.
Senator MERKLEY. Thank you, Mr. Chairman.
And welcome.
Secretary ROLLINS. Thank you.
Senator MERKLEY. So agricultural research is very important in the State of Oregon. We have such varied types of agricultural activity. Just to give you an example, in Corvallis the work is done on sudden oak death, which has a huge threat to our nursery stock industry but also a huge threat, potentially, to our timber. In Pendleton, the research being done on drought-resistant dry land wheat varieties is essential. In Burns, the research on how to reseed grasses that are beneficial to cattle after a fire, rather than having cheap grass take over, is essential.
Secretary ROLLINS. Sure.
Senator MERKLEY. So we were shocked when all these scientists were fired. We lobbied like hell to get them back. We got them back, thank you very much. But I am very concerned about the proposed cut of 160 million to research in the proposed budget.
Can you ensure, or can you assure the farmers and all the ranchers in all these different places in Oregon that the research will go on in a vibrant and significant way? Not only for these reasons, that is just a short list, I mean, we have invasive flies affecting the berries.
Secretary ROLLINS. Right.
Senator MERKLEY. You know, we have warmer conditions in the ocean affecting our shellfish. Can you assure us that we are not going to end up without this essential research being done?
Secretary ROLLINS. Yes, sir. And I really appreciate this question, Senator. So the ARS portion of USDA has a $2.1 billion budget. The President's budget suggests, as you mentioned, the $160 million decrease. That takes us down to 1.9. That is about a 7 percent decrease, so it is not, you know, as big as maybe it is being made out to be in the press. And that specifically is focused on closing outdated facilities around the country that have nothing to do with the different issues that are being researched that are outlined.
So yes, we can commit to ensure that the robust body of research that is so important to our agriculture producers continues. And I look forward to working with you. And if you hear anything differently, please call me direct.
Senator MERKLEY. Are there any outdated facilities that you think are outdated in Oregon?
Secretary ROLLINS. I do not believe so, but we will follow up on that.
Senator MERKLEY. Okay. Thank you.
Secretary ROLLINS. Thank you.
Senator MERKLEY. Because I don't know of it, I have visited, I think, all of them, and they are incredibly important.
Secretary ROLLINS. We will follow up on that today, sir.
Senator MERKLEY. Okay. I want to turn to the question about the funding to decrease, essentially, the challenge of food insecu-

rity. And we have one in six kids in Oregon who are facing that insecurity, which basically means they are going hungry. And so the suspension of the Commodity Credit Corporation payments to food assistance programs, including TEFAP, have really been shocking. I don't think President Trump campaigned on: I am going to help increase the number of hungry kids. So what is going on there with that?

Secretary ROLLINS. Well, and let me pull up the Oregon numbers just so you are aware. So again, USDA spends about, $400 million a day on nutrition programs. That is a stunning number. The specific program you are talking about, sir, to answer your question, was a COVID-era program that, at the time, probably made a tremendous amount of sense but never was meant to continue indefinitely.

And specifically to Oregon, of the $2 million under the LFS program and the $7 million under the LFPA, Oregon has $330,000 left in the first and $5 million left in the second. Almost every state was asking for contract extensions because they couldn't spend the money quickly enough. So I think it just goes to the balance we have to strike every single day on ensuring that every taxpayer dollar is spent to the best and highest use.

And it was the decision of our President and this administration that perhaps that COVID-era program had fulfilled its purpose. But we can still continue to make sure that we are supporting our farmers and getting nutritious foods into the schools and into the food banks, but through different and other programs.

Senator MERKLEY. You know, I guess I would like to have you look at this from the perspective: Is there a current need that needs to be addressed, whether or not it was originated under COVID or not? I have visited those food banks. I have seen the high increase in demand, which, it is kind of scary to see how that need has grown. I have the estimate from the Oregon Food Bank that the changes that are currently happening under the credit corporation, the suspension, will reduce their ability to provide about three million meals, 2.88 they said, three million meals.

It seems like a pretty significant impact to an ongoing problem, regardless of whether the program was created under COVID. So could you just take a look at that in more detail?

Secretary ROLLINS. I will.

Senator MERKLEY. All of those numbers you provided, I did not catch if one of those was a TEFAP number?

Secretary ROLLINS. Yes, sir.

Senator MERKLEY. Okay. Because I know that has been the top priority of the Oregon Food Bank, is being able to move produce around the state, which had been very helpful to our farmers in one place that have a surplus, or grocery stores that have a surplus, they are donating it, but it has to be moved to where it is needed, and it has to move in a timely fashion so it doesn't rot.

Secretary ROLLINS. Right.

Senator MERKLEY. And all the vegetables and so forth. So I see that five minutes have vanished, and my stack of another ten questions are ongoing.

Secretary ROLLINS. Well, I am always available. So I welcome a phone call. Just, you know, call me anytime, and we will be so happy to walk through any of this with you.

Senator MERKLEY. Thank you. Thank you very much.

Secretary ROLLINS. Yeah, thank you, Senator. Nice to meet you.

Senator HOEVEN. Secretary, we know you have a time line. We certainly want you visiting with the Mexican Ambassador. We will go to close up.

Let me turn to Ranking Member Shaheen for her final comment.

Secretary ROLLINS. Yeah. And Senator Shaheen, if you have any other questions, we can, we can go a few more minutes.

Senator SHAHEEN. Well, I just wanted to clarify what Senator Murray and I think we were asking you about with respect to the WIC Program which, as you pointed out, is not mentioned at all in the skinny budget. And what also is not mentioned is the cash value benefit for fruits and vegetables. So what we wanted to know from you is whether you would support fully funding WIC, including that cash benefit?

Secretary ROLLINS. If you do not mind, I would like to take a good look at it, since it wasn't in this particular round. I haven't spent the time on it, but obviously this administration believes that WIC is very important.

Secretary Kennedy and I have had conversations about it pretty extensively already. So the more that I can learn and be in contact with you all, I would welcome that.

Senator SHAHEEN. We would appreciate your getting back to us on whether you support both aspects of the WIC Program. The other thing I just wanted to clarify is, I was not quite clear where you got the numbers of money that has gone out to New Hampshire and the number of recipients, because when we check the online dashboard, New Hampshire has received 24,000 only, of the $10 billion in economic disaster assistance that was provided in the December supplemental, and the dashboard states that 51 applications have been approved. So I am not sure where those numbers came from, but they are a lot higher than any numbers I have ever heard related to the agricultural sector in New Hampshire.

Secretary ROLLINS. So you know what, Senator, my apologies, it looks like there was a typo on yours—you and South Dakota are exactly the same on this sheet. And we know that those are two very different states, so my sincere, sincere apologies. This is unacceptable. It will not happen again. And we will make sure and get it right, and today we will follow up. Now, I do not know we will get this up today.

Senator SHAHEEN. Thank you. And actually, the numbers are not as big a concern for me as making sure that the funding goes to the people who need it in New Hampshire.

Secretary ROLLINS. Yes, ma'am.

Senator SHAHEEN. That is the concern.

Secretary ROLLINS. We will follow up with your team today on that and make sure you have the up-to-date numbers.

Senator HOEVEN. Yeah. And I can add there. Again, I think that is weather-related, which you will have coming out. We put a number of different components in there.

Secretary ROLLINS. Right.

Senator HOEVEN. So I think, Senator Shaheen, correct me if I am wrong. You just want to make sure in that weather component they are cognizant of the language you talked about with the allocation specifically regarding small farms; is that right?

Senator SHAHEEN. Well, the $220 million set aside for the eight states for New England is a concern.

Senator HOEVEN. Yes.

Secretary ROLLINS. Yes.

Senator SHAHEEN. But the other concern is the halt on funding and the applications that have been submitted for all of the assistance programs. Thank you.

Secretary ROLLINS. Yeah. We will get direct information on that.

Senator SHAHEEN. Mr. Chairman, yes.

Senator HOEVEN. Right. There were like five different pieces to that, and so I think she is referring to a piece that was weather-related, separate from the market conditions base—the 10 billion-base that we talked about.

Secretary ROLLINS. That is right.

Senator HOEVEN. I think that is the confusion.

Secretary ROLLINS. We will fix that. Yes, ma'am.

Senator HOEVEN. So I will follow up with her on that. And again, from what I have seen, you are following very well what we laid out in that emergency assistance, and we appreciate it in getting this squared away.

Secretary ROLLINS. Thank you.

Senator HOEVEN. Just final couple comments or questions. Any update on tariff agreement timelines?

Secretary ROLLINS. Yes. I don't want to speak for Secretary Lutnick, Secretary Bessent, or our U.S. Trade Rep, Jamieson Greer, or the President, but we are exceedingly close to having significant announcements that of anyone that will be impacted, no one will be impacted positively more than our agriculture industry, as these announcements begin to roll out very quickly.

Senator HOEVEN. And we think weeks, not months?

Secretary ROLLINS. Oh yes. That is right.

Senator HOEVEN. Yes.

Secretary ROLLINS. That is exactly right, within week/weeks.

Senator HOEVEN. Yeah. Okay. And then there was some discussion regarding ARS restructuring, those kind of things. Obviously, the policy centers, you have got one at A&M, FAPRI, NDSU, Nebraska, Omaha, we are going to want to be involved in that very closely with you, very important, as well as the NIFA funding. So those are things that we are going to want to talk to you about closely more.

Secretary ROLLINS. We would welcome that.

Senator HOEVEN. Critically important.

Secretary ROLLINS. Yes. Thank you.

Senator HOEVEN. Yeah. And then, just anything else that you want to add for the record, Secretary, before we adjourn?

Secretary ROLLINS. I would just say that I really, really appreciate the opportunity. This is my first hearing, other than the confirmation hearing. And I have been—you know, obviously there are some differences of opinion, and we can agree to disagree, but the agriculture side of this effort, we are all in this together. And I

think even on the other side of the aisle, you know, understanding that every one of our elected officials on both sides really want what is best for our ag producers, and our farmers, and our ranchers.

And I know you know this, Senator Hoeven; and Senator Shaheen, you may not yet, but I am always available. And I just want this to be a productive conversation and productive 4 years where we can hopefully get these farmers and ranchers back to a place of prosperity, and where they are not worrying about losing their farm every single year. So that is my goal, and I look forward to working across party lines to do that.

Senator HOEVEN. Well again, Secretary, thank you for being here.

Secretary ROLLINS. Well, easy. Thank you. And I should not say that before the questions come in, but we will do that. And one other thing for you all to know too, we are working really hard on the letters to make sure we are timely on responding to letters. We have gotten about 140 since I took office about 80 days ago, and we have responded to more than half of those to date. And we have responded to everyone on this committee. So I feel really good, and we are way understaffed. So I think that we will be able to be much more timely, moving forward. And that is really important to me as well.

ADDITIONAL COMMITTEE QUESTIONS

Senator HOEVEN. Questions for the record are due by next Tuesday, May 13th. And we would appreciate responses back from USDA within 30 days.

QUESTIONS SUBMITTED TO HON. BROOKE ROLLINS

QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

Question. On May 16, I was informed of a round of terminations of the McGovern-Dole Food for Education grants; some of which were mid-way through a multi-year program. The FY2025 bill provided $240 million to this program, which is the largest global donor to school feeding efforts. The program provides U.S. agricultural commodities, funding, and technical assistance to reduce hunger, support nutrition, and improve literacy, primary education and training around the world. The McGovern-Dole Program supports domestic agricultural producers, advances U.S. diplomatic interests, and has received bipartisan support since 2002. Can you provide details such as which programs were terminated and the justification for termination?

Answer. In line with President Trump's January 20, 2025, Executive Order: Reevaluating and Realigning United States Foreign Aid, USDA terminated the below 17 McGovern-Dole projects that do not align with the foreign assistance objectives of the Department. USDA continues to maintain 30 active McGovern-Dole projects in 22 countries, and the FY25 Notice of Funding Opportunity for the program was posted on May 9.

FY	Country	Organization
FY19	Uzbekistan	Mercy Corps
FY19	Togo	CRS
FY20	Guatemala	CRS
FY20	Honduras	CRS
FY20	Mali	CRS
FY21	Benin	CRS
FY21	Burkina Faso	CRS

FY	Country	Organization
FY21	Kyrgyzstan	Mercy Corps
FY21	Laos	CRS
FY21	Sierra Leone	CRS
FY22	Burundi	CRS
FY22	Lesotho	CRS
FY22	Madagascar	CRS
FY22	Timor-Leste	CARE
FY23	Nepal	WFP
FY23	Nicaragua	Project Concern Int'l
FY24	Guinea-Bissau	CRS

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. USDA Watershed and Flood Prevention Operations administered by the Natural Resources Conservation Service (NRCS) are vital to rural Mississippi. Local sponsoring organizations throughout Mississippi are working constantly to prevent flood, erosion, and sedimentation damage in various watersheds—all of which affect conservation, water disposal, and land utilization. Should Congress provide funding for NRCS watershed operations above the FY2026 budget request, are you confident that the Department could effectively put those additional funds to good use?

Answer. NRCS is committed to supporting the technical and financial assistance needs of local sponsoring organizations who have watershed flooding, erosion and sedimentation concerns using funds provided to the Watershed and Flood Prevention Operations program.

Question. I was pleased to see that the FY26 USDA budget request calls for increased funding for the Food Safety and Inspection Service (FSIS). Since USDA assumed responsibility over catfish inspection, along with meat, poultry and egg products, the import of products containing substances that could be harmful to human health has declined. But USDA can do more to stop foreign countries, like Vietnam, from sending us catfish grown in unsanitary conditions and treated with chemicals not approved for U.S. aquaculture. With any additional funding provided for FSIS in FY26, will you work to make sure USDA catfish inspections are strengthened to the maximum—especially for imports from known violators?

Answer. FSIS is committed to ensuring foreign suppliers meet the same rigorous food safety standards as domestic catfish producers. USDA will also continue working with the Department of Commerce and across the Trump administration to ensure our producers have a level playing field with our trading partners, including for our catfish producers.

Question. USDA administers the National Veterinary Stockpile (NVS), a repository of materiel that can support State-based outbreaks of livestock infectious disease. The unabated threat from H5N1 avian influenza necessitates that those responding to these outbreaks have access to effective personal protective equipment (PPE). It also necessitates even more robust preparedness for any mutation of the virus that could be especially virulent and transmissible to people. This latter scenario would require significant levels of PPE to ensure the safety of all animal agriculture workers and outbreak response personnel. Can you please report back on the following: What specific PPE supplies have the USDA stockpiled in the NVS? What planning scenarios are these assets tied to? How many critical personnel could be supported by this PPE in these scenarios? Have you coordinated with the Department of Health and Human Services to plan for leveraging PPE assets in the Strategic National Stockpile in the event of an emergency that exceeds the assets in the NVS?

Answer. The PPE in the NVS includes goggles, disposable coveralls, respirators, gloves, boot covers, and bouffant caps. The NVS is designed to maintain sufficient amounts of countermeasures capable of deployment against the most damaging animal diseases within 24 hours. USDA is committed to working with our partners across the Federal Government and routinely communicates with other agencies to ensure the best outcomes in the event of large-scale emergencies.

QUESTIONS SUBMITTED BY SENATOR MIKE ROUNDS

Question. As you know, Highly Pathogenic Avian Influenza (HPAI) continues to devastate producers in South Dakota. While farmers in my state are taking proactive steps to protect poultry and dairy populations, the presence of migratory birds continues to exacerbate the spread of HPAI. These circumstances have led many producers to support the development of an HPAI vaccine.

Secretary Rollins, it was encouraging to see USDA support the conditional approval of an avian flu vaccine for poultry. Do you believe the USDA Agricultural Research Service (ARS) has the necessary resources to support the development of additional HPAI vaccine candidates?

Answer. ARS is fully committed to providing the necessary resources to combat HPAI through detection, biosecurity, and vaccine development and testing. Several vaccines against the currently circulating viruses for chickens have been tested by ARS and licensed by the USDA Center for Veterinary Biologics. ARS is currently receiving congressionally appropriated funding for poultry vaccine development and approaches, such as mass vaccination of birds and vaccines that enable differentiating infected from vaccinated animals (DIVA vaccines).

For other species (cattle, small ruminants, and swine), ARS received additional Commodity Credit Corporation funding through an interagency agreement with APHIS. These additional resources support foundational research on species-specific animal models and vaccine testing, thereby enhancing our knowledge and understanding of a disease previously unknown in these species.

Question. Secretary Rollins, South Dakota ranch families work tirelessly to produce the safest, highest quality and most affordable beef in the world. Yet as you know, foreign animal disease threats have the ability to halt the U.S. beef trade. Unfortunately, the previous administration lifted a long-standing ban on Paraguayan beef imports.

Secretary Rollins, does USDA's Animal and Plant Health Inspection Service (APHIS) currently have the necessary resources to effectively combat foreign animal diseases such as Foot and Mouth Disease (FMD) or New World Screwworm?

Answer. Yes, APHIS currently has the resources needed to combat foreign animal diseases and will continue to reassess needs as warranted.

Question. For too long, American producers have been forced to compete with lower quality foreign beef that falsely bears the 'Product of USA' label. I previously introduced the USA Beef Act to make certain the "Product of USA" label is only applied to beef derived from livestock raised and slaughtered in the United States. Since this time, USDA has implemented this change through rulemaking.

Secretary Rollins, with USDA set to implement this rule next year, can you confirm whether the Food Safety and Inspection Service (FSIS) will be fully prepared to administer the voluntary "Product of USA" labeling program?

Answer. USDA is thoroughly reviewing significant rules put in place by the previous administration, such as the voluntary "Product of the USA" labeling program. FSIS will continue to review stakeholder and Congressional input as this review is ongoing.

Question. USDA's Rural Utilities Service (RUS) provides critical financing to electric cooperatives across rural America, enabling many small South Dakota communities to upgrade their rural electric infrastructure. While the agency has traditionally worked well with rural leaders, cooperatives in my state have recently encountered lengthy delays due to RUS environmental reviews-a problem that originated during the previous administration.

Secretary Rollins, will you work to help resolve these bureaucratic delays and make sure that appropriated RUS funding is disbursed promptly to rural electric cooperatives?

Answer. RUS has been working to identify process improvements to streamline reviews to ensure compliance with the National Environmental Policy Act. We have already implemented emergency procedures to comply with Executive Order EO 14156, Declaring a National Emergency. USDA is actively participating with other Federal agencies to comply with EO 14154, Unleashing American Energy, by identifying and adopting agency level implementing regulations to expedite permitting approvals and meet deadlines established in the Fiscal Responsibility Act of 2023 (Public Law 118–5).

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

Question. There are several Regional Conservation Partnership Program awards in New Hampshire that have been disrupted by this administration's funding

freezes. The pauses and failure to provide clear communication to grantees about the review have injected unnecessary uncertainty in the process and delayed key seasonal work. Given that it has been more than 3 months since the administration froze this program and many others, when will USDA release the funding and allow RCPP projects to proceed?

Answer. On June 11, USDA notified all RCPP partners of the status of their project.

Question. More than 12,000 women, infants and children in New Hampshire rely on the WIC program for healthy food, breastfeeding support and nutrition education. An important part of this program is the WIC Cash Value Benefit, which helps participants afford the level of fresh fruits and vegetables each month recommended by the National Academies of Sciences, Engineering and Medicine. Do you agree that failing to fully fund the fruit and vegetable cash value voucher undermines the nutritional quality of the WIC program?

Answer. I appreciate the value of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to pregnant and postpartum mothers and their children. WIC has a proven track record of improving children's health by providing access to supplemental foods, nutrition education, and health referrals. It allows health- conscious food purchases that are adjusted according to participants' life stage nutritional needs. The President's Budget would continue to ensure WIC participants receive nutritious supplemental foods—including support for purchasing fresh fruits and vegetables—to promote healthy eating habits and improved health outcomes.

Question. The Snow Telemetry Network (SNOTEL) has been providing western States with vital measurements of snow accumulation and snow melt prediction data for decades. In recent years, this Committee provided additional funding to expand the SNOTEL program to the Northeast-this data will be key for the region to better understand flood potential, water supplies and the effects on seasonal businesses. Do you commit to continuing the SNOTEL expansion to the Northeast? What resources are needed in Fiscal Year 2026 to keep the expansion on track and what benchmarks does NRCS hope to reach over the course of the next year?

Answer. As our new Administration continues to evaluate all USDA agency programs to identify opportunities to reduce inefficiencies, and enhance customer service, especially to agricultural producers, NRCS is currently focused on protecting our historical investments in the Snow Survey and Water Supply Forecasting Program. We will continue to collaborate with other federal, State and local agencies to develop and encourage use of new techniques, improving data collection and processing. Additionally, NRCS is evaluating a request for a no cost extension of the existing Cooperative Agreement with the Northeast Snow Survey Feasibility Study partners to accomplish the following benchmarks though Fiscal Year 2026:

—Summary report on interest holder engagement process and outcomes to share with interest holders.

—Summary report of snow monitoring in northern New England and New York to share with NRCS colleagues and interest holders.

—Systems Engineering plan linking network objectives to data products, processing workflow, measurement specifications, and spatial design.

Question. New England experiences significant weather variability, including historically dry and historically wet years over the last decade. For many small and diversified operations in New Hampshire, protected agriculture systems are critical to reducing weather exposure, limiting damage from pests and diseases and helping farmers extend their growing seasons. There is an opportunity for ARS to do further research into optimal uses of these systems, and there are ready partners like the University of New Hampshire who have done related extension work.

Will you work with me on expanding investments in research relating to protected agriculture?

Answer. If ARS is provided with funding from Congress to support research relating to protected agriculture, I look forward to working with you and ARS leadership to find ways to work with ready partners to conduct this research.

Question. In Fiscal Year 2024, this Committee created a pilot program to add an additional tool to preserve the rural affordable housing portfolio. Do you commit to continuing to pursue and providing the committee with regular updates regarding the Multifamily Housing decoupling pilot? How many staff will be dedicated to affordable housing preservation, and how many properties does RD plan to offer decoupled rental assistance agreements to in Fiscal Year 2026?

Answer. We will ensure sufficient staff are dedicated to affordable housing preservation to meet the statutory requirements. In Fiscal Year 2026 there are 52 units

initially eligible for the pilot, with 1,209 units eligible for preservation through the pilot program.

Question. In October 2023, the Government Accountability Office released a report titled "Sugar Program: Alternative Methods for Implementing Import Restrictions Could Increase Effectiveness". GAO made recommendations on improving the trade aspects of the program, and USDA and USTR stated that they concurred with the recommendations. Career officials at USDA communicated to stakeholders that policy announcements to implement the GAO recommendations would be initiated within 18 months of the report's release. When will USDA announce policies to initiate implementation of the GAO recommendations?

Answer. USDA remains in close coordination with the Office of the United States Trade Representative as it implements its GAO recommendation. In 2024, USDA concurred with GAO's recommendation for USDA to evaluate the effectiveness of the WTO raw sugar tariff rate quota allocation methods. USDA committed to providing USTR an evaluation report within 2 years and expects to share this evaluation in 2025; USDA will inform GAO once the report has been shared to close out its recommendation.

QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

Question. According to the Oregon Food Bank, 1 in 8 people and 1 in 6 kids in Oregon and Southwest Washington are going hungry. However, earlier this year, the USDA announced that it would suspend Commodity Credit Corporation payments to food assistance programs, including the Emergency Food Assistance Program (TEFAP). As a result, this year, Oregon food banks will be unable to provide 2.88 million meals. How many fewer meals will be delivered as a result of the decision to spend Commodity Credit Corporation payments?

Do you agree that suspending CCC payments to food assistance programs has resulted in more individuals going hungry?

Answer. USDA spends roughly $400 million per day across its 16 nutrition programs. Currently, one in four Americans will participate in a USDA Food and Nutrition Service Program at some point over the course of the year. Taxpayers generously fund these programs to help ensure that no children, in Oregon or any other state, go hungry. We owe it to taxpayers to ensure these programs are effective and accountable. And with these nutrition programs and the Section 32 market support program in place, USDA remains focused on its core mission: supporting agricultural markets and ensuring access to nutritious food. The Department will continue to use its procurement authority to support producers and consumers where appropriate, and ensure families continue to have access to affordable and abundant food.

Question. When will Commodity Credit Corporation (CCC) payments to food assistance programs resume?

Answer. USDA continues to purchase food for TEFAP, with more than $669 million spent in Fiscal Year 2025, as of May 14, 2025, to connect families to food. Additionally, since March 27, 2025, USDA has announced $328 million in available fruits, vegetables, tree nuts, Atlantic groundfish, canned pears, dried sweet cherries, great northern beans, and Pacific pink shrimp made possible through Section 32 purchases. These foods go directly to food banks and other charitable organizations.

Question. At the hearing, you stated that the proposed $159 million decrease for the Agricultural Research Service is "specifically focused on closing outdated facilities around the country that have nothing to do with the different issues that are being researched... yes, we can commit to ensure that the robust body of research that is so important to our agriculture producers continues." You also committed to following up with me to assure that no facilities in Oregon were targeted for closure. Are any ARS units in Oregon proposed for closure or consolidation?

Answer. The President's Budget does not propose the closure or consolidation of any ARS units in Oregon.

Question. What facilities or ARS units are proposed for closure or consolidation? Why?

Answer. The President's Budget proposes the closure of three locations to support the Administration's priority of reducing the Federal footprint. These include Newark, Delaware; Riverside, California; and Urbana, Illinois. The research programs and resources will be consolidated with other existing ARS laboratories and locations.

Question. You stated clearly that the proposed funding cut to the Agricultural Research Service would only be used to close outdated facilities. This statement contradicts the President's so-called "skinny budget," which States, "The Budget re-

duces funding for research sites across the Nation that have exceeded their ideal lifespan and reduces funding for research projects that are not of the highest national priority." Please clarify whether the U.S. Department of Agriculture intends to cut funding for research projects. If so, which projects does the Department intend to cut?

Answer. The President's Budget proposal for ARS terminates $145 million for Climate Science research and the Climate Hubs. These activities are not aligned with the Administration's priorities.

Question. I am concerned with this administration's attempt to withhold funds that were directly allocated for specific purposes by Congress. For example, this administration initially froze the Partnerships for Climate-Smart Commodities (PCSC) program which had awarded grants to more than 130 agriculture projects across the country, including in some of Oregon's most rural communities. Now, the program has been rebranded by the Department of Agriculture and possesses a different set of criteria for applicants to reapply for funding. I have heard from ranchers in Oregon who received a PCSC grant that has been terminated. They do not intend to reapply for the rebranded program because they do not trust that the USDA will uphold its commitments for funding and because they do not believe that the USDA understands the time and resources it takes for small farms to apply to Federal grants. How does USDA intend to maintain trust with our farmers and ranchers while creating an environment of uncertainty and pulling funding from critical projects in agricultural communities across the country?

Answer. The Partnerships for Climate-Smart Commodities (PCSP) program was established by the previous administration utilizing discretionary authorities under the Commodity Credit Corporation without funding direction or input from Congress. In creating the Advancing Markets for Producers initiative, USDA will continue to support farmers and encourage partners to ensure their projects are farmer focused or re-apply to continue work that is aligned with the priorities of this Administration.

Question. On May 5th I sent a letter to the U.S. Department of Agriculture requesting that the Agricultural Marketing Service (AMS) approve the Westcoast Seafood Processors request for a Section 32 purchase of Pacific pink shrimp. If approved, the Section 32 purchase of Pacific pink shrimp would provide economic certainty to Oregon fisheries and coastal communities in addition to providing much needed relief in response to the impacts of this administration's tariff war. Although the U.S. and EU have paused tariffs and retaliatory tariffs, European customers cancelled their orders of American seafood products, including up to 50% of the Oregonian pacific pink shrimp in response to the President's announcement of tariffs. The pacific pink shrimp season opened on April 2, 2025—leaving no time for the industry to find alternative markets to offset the loss of consumers from the European market. Will the Agricultural Marketing Service approve of the Westcoast Seafood Processors request for a Section 32 purchase?

Answer. On May 23, AMS announced a Section 32 purchase of up to $16 million of Pacific Pink Shrimp.

Question. The Watershed and Flood Prevention Operations (WFPO) Program—also known as PL–566—has been integral to agricultural producers in the west to modernize their irrigation systems through piping to respond to increased drought conditions. This program is ran through USDA's Natural Resources Conservation Service (NRCS). During the President's first term, a group of NRCS State Conservationists developed a white paper proposing improvements to the PL–566 program to streamline the approval of watershed plans and break ground on more projects in a timely manner. In the years that followed, the recommendations in this white paper were never fully adopted/implemented by the agency. The President's "Skinny" Budget released last week would provide $0 for WFPO, which specifically supported multi-benefit projects in the West. Given the President's Budget request calls for eliminating funds specifically for projects that support Western farmers combat drought and implement multi-benefit projects, how do you plan to maintain these activities at the agency?

Answer. There is permanent funding of $50 million provided annually through the Farm Bill to support watershed projects. In addition, this program received an enormous influx of funding through IIJA, which NRCS is still working to obligate.

Question. Does the agency have plans to modernize the WFPO program to facilitate multi- benefit projects? What steps will you be taking to accomplish this modernization?

Answer. The NRCS WFPO program utilizes a continuous process improvement strategy to prioritize changes related to Congressional directions and local project sponsor feedback. Specifically, NRCS plans to streamline:

—the Preliminary Investigation and Findings Report (PIFR) development process,
—the Watershed Project Plan development, review and implementation authorization process,
—and the development of Environmental Assessments or Environmental Impact Statements for WFPO projects.

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

BIOFUELS

Question. What actions is USDA taking to ensure that EPA understands the importance to US agriculture of quickly getting the upcoming Renewable Volume Obligation rulemaking out the door that includes biomass-based diesel volumes at 5.25 billion gallons and implied ethanol volumes at no less than 15 billion gallons? When do you expect the EPA proposal to be released?

Answer. USDA staff have been and will continue to be in communication with EPA about rules that impact U.S. farmers and rural communities. On June 13, the Environmental Protection Agency released the Proposed Renewable Fuel Standards for 2026 and 2027 including a proposed 15 billion gallons of conventional renewable fuels.

Question. Once volumes are set, they must not be undermined by small refinery exemptions. What steps is USDA taking to ensure that EPA and the White House understand the need for a careful and judicious approach to any justified small refinery exemptions that ensures that blending requirements are not reduced?

Answer. USDA staff have been and will continue to be in communication with EPA about rules that impact U.S. farmers and rural communities.

CLIMATE SMART COMMODITIES

Question. On April 14, 2025, USDA announced cancellation of the Partnership for Climate Smart Commodities program. The program had funded 28 projects that had touch points and conservation enrollment opportunities for Wisconsin producers as well as sizeable projects focused on our State's vital dairy community. At the same time the cancellation notice was provided USDA also announced the new "Advancing Markets for Producers" initiative. Could USDA please share with the Committee:

—A breakdown (including funding allocations) of both terminated projects as well as projects selected to continue;
—What if any modifications were required for projects selected to continue;
—Specific details on Advancing Markets for Producers (AMP) initiative, including but not limited to:
  —Eligible applicants.
  —AMP objectives and timelines.
  —Size, scope and duration of projects sought through AMP.
  —Application materials and deadlines.
  —Expected Federal funding committed to AMP.
  —Application review and grant awarding process."

Answer. The Partnerships for Climate-Smart Commodities (PCSP) program was established by the previous administration utilizing funds under the Commodity Credit Corporation without funding direction or input from congress. In creating the Advancing Markets for Producers initiative, USDA will continue to support farmers and encourage partners to ensure their projects are farmer focused or re-apply to continue work that is aligned with the priorities of this Administration.

ORGANIC CONCERNS

Question. The Organic Agriculture Research and Extension Initiative (OREI) and the Organic Transition Program (ORG) run under the National Institute of Food and Agriculture (NIFA) are the only competitive grant programs dedicated to organic agriculture research topics. We are hearing from organic researchers across the country that OREI and ORG's request for applications (RFA's) have been pulled from the NIFA website. This is very concerning because under normal timelines, the review process for both of these programs would be almost done at this point. For OREI, which is Congressionally authorized and has permanent and mandatory

funding through the Farm Bill, we have also heard that the Scientific Review Board has been disbanded. No Scientific Review Board means no awards given out.

Can you confirm if the RFA's for the only two grant programs dedicated to organic agriculture topics will be released soon? Lastly, can you confirm if the Scientific Review Board for OREI has truly been disbanded?

Answer. The RFAs for both programs (OREI and ORG) are currently being reviewed and will be released in the near future.

Additionally, no scientific peer review panel for any NIFA program has disbanded. To make the scientific peer review panel more efficient, NIFA recently transitioned to using a "panel chair" selected from the members of the scientific peer review panel to manage the review process. This is a change from the previous "panel managers" who were recruited to serve as temporary Federal employees, and this recruitment slowed down the review process.

Question. Federal funding freezes and Federal employee deferments have crippled NIFA research projects as well as the in-house research efforts at ARS. ARS and NIFA research projects require steady monitoring and evaluation since they often revolve around organic materials such as animals, crops, soil, and so on. Shuttering agriculture research before their intended end date can risk spoiling research results and the tax payer dollars spent to find agricultural innovations.

What efforts is the USDA taking to protect ongoing research from being sullied by the deferments and funding freeze?

Answer. USDA continues to work with stakeholders to ensure that priority research continues by prioritizing their review and release.

Question. The Economic Research Service (ERS) States, "it is widely agreed that increased productivity, arising from innovation and changes in technology, is the main contributor to economic growth in U.S. agriculture." Increased agriculture productivity not only spurs growth but makes our products more competitive domestically and abroad. According to ERS, organic agriculture has grown by over 600% in the last 20 years to become a more than $64 billion industry. However, less than one percent of the Agriculture Research Service's (ARS) budget and less than two percent of NIFA's budget goes towards organic farming research. Meanwhile, ERS shows us having a more than 400% trade deficit in organics.

If you believe ERS' original statement about productivity deriving from innovation is true, what ways does the President's budget address our organic farming research funding problem so our organic producers can have the best innovation to better compete at home and abroad?

Answer. In addition to the two NIFA grants programs specific to organic agriculture (OREI and ORG), NIFA will continue to accept submission of proposals focusing on organic agriculture to other relevant programs like Agriculture and Food Research Initiative (AFRI).

APHIS STAFFING

Question. Recent reports indicate that USDA, and specifically APHIS, is experiencing significant staffing changes, including reductions in force (RIF) and delayed replacement practices (DRP). These workforce losses raise serious concerns about APHIS's ability to carry out its core functions, including disease detection and response, permitting, and safeguarding animal and plant health. Specifically, USDA does not have the personnel and resources to effectively manage multiple threats simultaneously with the four active threats to animal agriculture including the Highly Pathogenic Influenza (ongoing outbreak in the USA and globally); New World Screwworm (active in Mexico); Foot and Mouth Disease (active in many parts of the world, including recent outbreaks in Germany, Hungary, and Slovakia); and African Swine Fever (active on the island of Hispaniola).

What is the number of APHIS employees lost due to RIF, DRP, or other budgetary cuts?

Answer. APHIS has not initiated any layoffs in recent months. All APHIS employees were offered the opportunity to participate in DRP 1.0 and DRP 2.0. To date, 1,386, or approximately 17% of all APHIS employees participated in the DRP and the program has closed. USDA has not initiated a reduction in force (RIF).

Question. What part(s) of APHIS did they work for, and what were their job titles and roles?

Answer. APHIS employees taking the DRP were from all APHIS programs and support units and represent a wide range of positions.

Question. What are the impacts of employee losses on functionality?

Answer. APHIS has the resources needed to maintain mission critical activities.

Question. Given the severe understaffing in USDA APHIS's travel approval office-resulting in delayed approvals, reduced outreach capacity, missed deadlines, and in-

creased costs- what is the Department's plan to address this issue, and what is the timeline for implementation?

Answer. APHIS has the resources needed to maintain mission critical activities, including mission critical travel.

NATIONAL MILK TESTING STRATEGY

Question. Many States have agreed to participate but have yet to begin testing as part of the NMTS.

Will all States be required to actively participate in the NMTS?

Answer. Though States are not required to actively participate in the NMTS, 45 of the 48 continental States have enrolled in the program. USDA's goal is to enroll the remaining States by 2026.

Question. How will USDA sustainably fund NMTS to protect food security, trade, and animal agriculture over the next 2 years?

Answer. USDA will continue to use the CCC funding authorized by Congress and dedicated to NMTS and reassess any additional needs as warranted.

HIGHLY PATHOGENIC AVIAN INFLUENZA

Question. We understand the current CCC funds available to support HPAI-related activities to be $490 million.

What will happen if the current funds are expended in the next wave of HPAI outbreaks? Will the Secretary be requesting additional funds?

Answer. I will examine budgetary issues related to HPAI and report to Congress as appropriate.

LOCAL FOOD FOR SCHOOLS (LFS) & LOCAL FOOD PURCHASE ASSISTANCE PROGRAM

Question. The abrupt end to LFS and LFPA, after agreements had been signed for the second round, devastated farmers like Stacey and Tenzin Botsford of Red Door Family Farm in Marathon County, Wisconsin. How will you ensure farmers can trust this Administration and trust that a signed contract with USDA is honored? Will you re-obligate FY25 funds? Will you allow States to utilize FY26 funds?

Answer. Over $340 million is still available under existing agreements for LFPA and LFS, and these programs will continue to be in effect for the remainder of the period of performance. The period of performance varies by agreement, but entities with agreements may request extensions. Upon request, LFPA agreements may be extended through December 2026 and LFS agreements may be extended through June 2026.

Question. It's imperative that USDA support local food market channels through programs other than LFS, some of which the Secretary pointed to during her testimony. How will the agency ensure that these programs are strengthened, including fully funded and staffed? How will the agency ensure that they are accessible to small- and medium-sized operations, as well as beginning farmers?

Answer. I will continue to assess staffing needs to ensure mission critical activities are carried out and will use the funding provided by Congress to implement programs across the Department. I will also continue to work with agencies to understand where opportunities and challenges are for small and medium-sized operations and beginning farmers.

QUESTIONS SUBMITTED BY SENATOR MARTIN HEINRICH

Question. The New World Screwworm (NWS) is a serious threat to cattle and wildlife in New Mexico and throughout the west.

What do you need from this committee to ensure that we not only prevent the further spread of NWS but push it back south of the Darién gap in Panama?

Answer. Sterile insect technology is one key tool of several we have for fighting New World screwworm. Should the screwworm continue moving north, having access to many more flies than the existing production facility in Panama can produce will be important to protect U.S. agriculture. We are exploring possible options for increasing our capacity to produce these sterile insects, which could include a domestic facility here in the United States.

Question. The President's budget decreases USDA's Rural Development by $721 million, including the complete elimination of Community Facilities Grants. These grants are in incredibly high demand and have been critical to improving rural health and public safety. Many of these grants are also specifically directed by Members of Congress, who know their districts better than any bureaucrat in Wash-

ington DC. Is it this Administration's position that rural communities don't need or deserve these funds or that they should just be forced to fend for themselves?

Answer. The Administration is fully supportive of the Community Facilities program; the Budget proposes $1.2 billion in Community Facilities Direct Loans level and $650 million in loan guarantees, which will provide sufficient investment in rural infrastructure and is expected to have a measurable impact by fostering competition based on the program's point system and program design. Reducing Community Facilities Grants accounts for $18 million of the $721 million in decreases included for USDA Rural Development as part of the President's FY26 Budget, and will have little impact. Funds that are provided for these grants are 100 percent earmarked by Congress. This has resulted in carryover funding of $569M in unspent funds at the beginning of FY25, which could be seen as a waste of tax payer dollars.

Question. Some of this country's best wildlife and habitat conservation work has been done through voluntary partnerships with private landowners and has relied on NRCS Conservation Technical Assistance. The Working Lands for Wildlife program and the Migratory Big Game Initiative have been particularly successful. How do you plan to support these programs and other critical conservation efforts with a budget that completely eliminates Conservation Technical Assistance funding?

Answer. The Budget eliminates discretionary funding for conservation technical assistance because it has historically received over a billion dollars in mandatory funding, in addition to funding at the State and local levels. While funding has helped producers deploy conservation practices on their lands, many have been forced to participate in the program in order to comply with State environmental regulations such as California's Irrigated Lands Regulatory Program, which regulates agricultural runoff. These cost drivers should be connected to the resource demands they impose.

Question. Chronic Wasting Disease is an untreatable disease found in deer, elk, and moose that is always fatal. It has been detected in 34 States, including New Mexico. For years, the Animal and Plant Health Inspection Service has partnered with state fish and wildlife agencies to monitor and prevent the spread of Chronic Wasting Disease. Given the impact of chronic wasting disease, why does your budget request eliminate resources that would allow the USDA to continue its work to reduce the impact of this disease?

Answer. Since 2021, APHIS has invested over $41 million for projects to research, manage, and respond to CWD in conjunction with State and Tribal partners. USDA will continue to make decisions to accommodate the most pressing needs of the Department.

Question. There are approximately 321,370 people facing hunger due to food insecurity in New Mexico, including at least 37,500 seniors. For these seniors, the Commodity Supplemental Food Program funds local food banks to access their next meal. You intend to completely eliminate the $425 million Commodity Supplemental Food Program and replace it with "MAHA food boxes." How can these boxes be distributed without utilizing the already well-established food bank networks across the country?

Answer. All nutrition programs, old or new, should be oriented to promote healthy choices and healthy outcomes for the families that receive them. CSFP is a relatively small program, and it is crucial to focus limited resources on nutrition programs that are universally available to serve low-income populations, like SNAP. To promote healthier foods and support American farmers, the Administration envisions converting a portion of SNAP benefits into MAHA boxes. These boxes will be filled with commodities sourced from domestic farmers and distributed to American households. Current CSFP participants will be eligible for MAHA boxes. I look forward to discussing this legislative proposal in more detail in the future.

Question. As of March 2025, egg prices have continued to rise to a whopping cost of $6.23 for a dozen eggs, according to the U.S. Bureau of Labor Statistics. On February 7th, I asked what your plans were to combat Highly Pathogenic Avian Influenza and lower egg and poultry prices. You said you would use every tool at your disposal to eradicate this disease—including vaccine research at the Agricultural Research Service. But now, the President is proposing a $159 million cut to the Agriculture Research Services. How can USDA carry out critical vaccine research and fulfill its commitments to food affordability and animal health while slashing funding to one of the very agencies tasked with delivering on those goals?

Answer. The President's Budget does not reduce any research funding for animal vaccine development and testing. Instead, it proposes an increase of $51,221,000 to enhance efforts in protecting U.S. agriculture and food from invasive pests and diseases, as well as to develop advanced technologies that will improve animal and plant health and production.

Specific to HPAI, ARS is currently receiving congressionally appropriated funding for research in poultry and there are no proposed funding reductions to these programs in the President's Budget. For other species (cattle, small ruminants, and swine), ARS received additional Commodity Credit Corporation funding through an interagency agreement with APHIS. These additional resources support foundational research on species-specific animal models and vaccine testing, thereby enhancing our knowledge and understanding of a disease previously unknown in these species.

Question. With the ongoing threat of Highly Pathogenic Avian Influenza, USDA's mission to monitor and mitigate this disease is more critical than ever and yet, the Administration has sewn chaos throughout the workforce, pushing more than 2,632 employees from the Animal and Plant Health Inspection Service and the Agriculture Research Services. What is your plan for replacing this institutional knowledge and expertise essential to effectively dealing with and preventing future avian flu outbreaks?

Answer. APHIS has not pushed employees out or initiated any layoffs. APHIS and ARS employees were offered the opportunity to participate in the Deferred Resignation Programs, DRP 1.0 and DRP 2.0. Some APHIS job series were included in the Department's exemption from the hiring freeze for public safety mission delivery. ARS has also been able to use the exemption memo for filling key public safety positions. I will continue to work to optimize delivery of the Agency's critical mission to safeguard U.S. agriculture.

Question. On May 6, the Food and Nutrition Service (FNS) issued guidance to States requiring them to share with the Federal Government detailed records about more than 42 million past and current Supplemental Nutrition Assistance Program (SNAP) participants, including sensitive information such as names, dates of birth, addresses, Social Security numbers, and the amount of food benefits received. This information is protected by 7 U.S.C. 2020(e)(8)(A), which allows States to share information only with "persons directly connected with the administration or enforcement" of the Food and Nutrition Act, regulations issued pursuant to the Food and Nutrition Act, Federal assistance programs, or federally-assisted State programs. The law also limits the subsequent use of the information disclosed to such individuals "only for such administration or enforcement."

Please describe the individuals "directly connected" with administration or enforcement who will have access to these records.

How will FNS ensure this information is disclosed only to the individuals authorized under 7 U.S.C. 2020(e)(8)(A) and is not disclosed to unauthorized individuals?

How will FNS ensure this information is used only for the purposes allowable under 7 U.S.C. 2020(e)(8)(A) and is not used for unallowable purposes?

How long will FNS store these sensitive records?

What is the total cost associated with implementing this guidance, including collecting, protecting, storing, and analyzing these records? What funding will FNS use for this purpose?

Answer. Due to pending litigation, USDA does not have any comment.

QUESTIONS SUBMITTED BY SENATOR KIRSTEN GILLIBRAND

Question. Since 1981, Puerto Rico has been excluded from the Supplemental Nutrition Assistance Program (SNAP), resulting in the loss of billions of dollars in aid and reduced nutrition benefits. Yet, Puerto Ricans pay billions in Federal taxes every year, including $5 billion in 2023. Additionally, in 2022, the Food and Nutrition Service of the USDA published a feasibility study in which it concluded that Puerto Rico is ready to transition from the current Nutrition Assistance Program (NAP) to the Supplemental Nutrition Assistance Program (SNAP). I have legislation, the Puerto Rico Nutrition Assistance Fairness Act, which would authorize the transition from NAP to SNAP for Puerto Rico. Can you commit to working with my office to provide technical assistance and necessary budget information that would support development of this legislation and Puerto Rico's ability to transition?

Answer. USDA is available to provide technical assistance as you and your office draft legislation.

Question. The Community Eligibility Provision (CEP) for the National School Lunch Program is widely utilized in New York State as it reduces administrative burdens and helps to feed all students breakfast and lunch. In 2023, USDA changed the minimum Identified Student Percentage, or ISP, from 40 percent to 25 percent. This change has helped many schools and students in New York and throughout

the country. Can you commit to maintaining the ISP at 25 percent, or if you are planning to change the ISP, what level do you believe it should be?

Answer. States have a significant role in administering the National School Lunch Program (NSLP) and are granted various flexibilities to tailor its implementation to local needs and circumstances. As I mentioned at my confirmation hearing, children are suffering from diet-related chronic disease at unheard of rates. School lunch is an important part of that conversation, because we should all want it to be the best meal eaten, not just the best meal served. Like the rest of the Administration, USDA is conducting a comprehensive review of all rules from the previous administration to ensure they follow the law, align with current Administration priorities, and find opportunities to provide regulatory relief.

Question. During your confirmation hearing, you testified that USDA's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is an important part of the safety net, and that you hoped to learn more about the program in the weeks and days to come. The President's Budget Request for Fiscal Year 2026 discussed at the May 6 Agriculture subcommittee hearing is void of any mention of WIC. Accordingly, can you give this subcommittee your support for fully funding WIC in Fiscal Year 2026 so that no eligible mother or child will be turned away from receiving nutritional support and having their basic needs met?

Answer. The President's Budget would support all eligible women, infants, and children who seek WIC benefits in 2026, and adjusts the vegetables and fruits benefit allowing more women, infants, and children access to the program and driving them towards better health outcomes.

Question. More than 15,000 USDA staff have accepted the administration's offer of deferred resignation, and we are expecting Reductions in Force (RIFs) to eliminate more staff. The Plum Island Animal Disease Center, a mile off the North Fork of Long Island in New York, is transitioning its research mission to the National Bio and Agro-Defense Facility (NBAF) in Manhattan, Kansas. Right now, the Department of Homeland Security has an ongoing closure program that also relies on NBAF coming online and mission transfer to occur. Will the resignations and reductions-in-force affect this timeline, and can you provide an update on the status, timeline, and next steps of mission transfer from Plum Island to NBAF?

Answer. There have not been any reductions in force at USDA. The standup of NBAF continues to be a priority, and voluntary resignations at USDA will not negatively impact the mission transfer timeline.

Question. The President's Budget Request proposes to reduce funding for formula grants. This formula funding in the form of capacity grants, such as Smith-Lever capacity grants, goes to every single state and their land-grant university and cooperative extension. Capacity grants give each State flexibility to work on their State's agricultural and rural priorities. How do you propose to maintain youth and K–12 programs when a significant portion of that funding comes from formula grants?

Answer. The President's Budget reduces funding for formula grants because they generally do not achieve the same results as competitive programs. The President's Budget protects funding to youth and K–12 programs such as 4–H clubs, Tribal colleges, and universities. Additionally, NIFA will continue to accept submissions of education-related proposals for competitive funding opportunities.

SUBCOMMITTEE RECESS

Senator HOEVEN. With that, we are adjourned.

[Whereupon, at 12:14 p.m., Tuesday, May 6, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2026

THURSDAY, MAY 22, 2025

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

The subcommittee met at 10:40 a.m. in Room 124, Dirksen Senate Office Building, Hon. John Hoeven (chairman) presiding.

Present: Senators Hoeven, Collins, Hyde-Smith, Shaheen, Murray, Peters, and Ossoff.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF HON. DR. MARTIN A. MAKARY, M.D., M.P.H., COMMISSIONER

OPENING STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Good morning. We'll call this hearing to order. Dr. Makary, thanks for being here. We appreciate it very much.

Dr. MAKARY. Thank you.

Senator HOEVEN. I know it's a busy day for you, and so appreciate you being here. And, of course, Ranking Member Shaheen. Thank you. Look forward to working with you on this Approap' Subcommittee. You and I have worked before on Approap' Subcommittee, and so I'm pleased now we're—I have that opportunity here with Ag.

Agriculture is incredibly important. My state, and I know the ranking member's state, well, our great farmers and ranchers do every single day affects every American every single day with the highest quality, lowest cost food supply in the world. And of all the developed countries, Americans spend less their budget on food, and they have better choice and better quality than any other country in the world. And we can't take that for granted. And so, you'll, you'll find that we're pretty strong advocates for our farmers and ranchers.

Dr. MAKARY. Great.

Senator HOEVEN. We understand that your job at FDA is to keep people safe whether it's primarily the drugs they eat, but many food products obviously as well. I've appreciated the conversations

that we've had. And I must say, as I've told you in our conversations, I think you've got an incredible record in healthcare.

I certainly believe that John Hopkins is one of the finest hospitals, medical centers in the country. I have direct personal experience where I've taken family members to John Hopkins, and I've been impressed not only with the quality of healthcare, but with the culture of the people there and the caring. And then not only your tenure there, but all that you've accomplished is remarkable. And so, we appreciate your willing to take on this public service, this incredibly, incredibly important job.

In it, you're going to have to, of course, primarily make sure that our food and drugs are safe, that the organization is working as absolutely well as it can, which is why I appreciate your background, not only in medicine, but in business. Obviously, we're all trying to find savings across government to address the debt and the deficit. I know you've been charged with that task as well, but paramount, your job is safety. I understand, of course, they'll be releasing the Make America Healthy Again (MAHA) report today. You're looking at new ways to do things. That's important. We need to do those kinds of things.

At the same time, there are practical realities, which you and I have talked about, that our farmers and ranchers face every day producing that highest quality, low cost food supply that I just referenced, that benefits every Americans every single day.

So, whether it's the fertilizers, the pesticides, the equipment, all the things that go into them producing that food supply, they have to face the practical realities of operating in a market that every day they don't control. They don't control the weather, they don't control the prices, they don't control trade agreements, and on and on it goes.

And when you look across our economy, so many industries are a few big companies. A few big companies that run the whole thing. I personally am not a fan of that. But when you look at agriculture, 16 million people directly or indirectly involved in agriculture, small family farms and businesses across this country that have become quite sophisticated with precision Ag and everything else. And we do it better than anybody in the world and have higher standards. But that is what we have. And I firmly believe that that's what Americans want to make sure we have for long into the future.

So, I spent a little time on that in this opening statement, because we have to be aware, you have to be aware of how that works. And as we make changes, again, making sure we do all we can for a healthy America, that we understand those realities and the challenges that those people have, and that we can't just take it for granted, and that we have to understand and make sure that all of this works for everybody on both sides of the equation.

So, with that, I'll turn to our Ranking Member, and I'm going to have to ask to excuse myself to vote. I may miss some of your opening statement, but I'll see if I can't get anything that I miss via the written remarks, and then be back. Ranking Member.

STATEMENT OF SENATOR JEANNE SHAHEEN

Senator SHAHEEN. Well, thanks very much, Chair Hoeven. And let me just welcome, as you did, Commissioner Makary. Very nice to have you here this morning. And I would echo the chair's commitment to agriculture, and how important it is our farmers are to our food supply and to the economy of this country.

It's a very different enterprise in New Hampshire with our farms, because they are small family farms, but very important to the state nevertheless. But of course, this morning, we're here to talk about the role of the Food and Drug Administration. Federal investment and stability in biomedical innovation are vital not just for our competitiveness and national security, but also for local economies, in New Hampshire and across the country.

Right now, we have the earliest access to new cures and treatments, and we attract the best talent from across the globe because of the good paying jobs that are in emerging research. Those jobs fuel our small towns and cities, including in New Hampshire, where we have a growing industry in biomedical companies.

It's very exciting to see the growth that's occurring in our state. As we speak, they're developing cutting-edge cell and gene therapies to cure terrible diseases like diabetes and cancer. And I think when we met, we talked about some of the work that's being done in New Hampshire, particularly at the Advanced Regenerative Manufacturing Institute (ARMI).

But of course, to keep pioneering breakthroughs in curative treatments, they need stability and predictability, something this administration, sadly, has failed to provide so far. It's more than just a lack of stability. I fear the very mission of the FDA is at risk because of the actions of this administration. More than 4,000 people have been pushed out of FDA since January. The majority of those targeted by probationary terminations and reductions in force that don't seem to have any real analysis of who's important to keep and who is not critical to the mission.

To date, this committee has not received key information on where specifically these workforce cuts are happening across centers and offices at the FDA, and that's information that we need as we're going to write this budget. What I want to emphasize is that it didn't really have to be that way. I think there is bipartisan support to see how we make our government agencies and departments more effective and efficient. But to do that, we need to have a process that people understand or are engaged in. And I fear that the process that's been done so far is going to prove to be very wasteful to patients and families in New Hampshire and across the country.

Scientists at the FDA have been fired along with support staff who make their work possible, from those who assist with product reviewers to those who quite literally keep the lights on. Patients across this country are depending on the FDA, as you know, to review medical products to ensure that new and novel treatments are approved. And yet, reports now suggest that medical product reviews have slowed, that essential meetings have been postponed or canceled, and that deadlines for user fee agreements have been missed.

And as Congress has provided the FDA with new authorities and directives from the Tobacco Control Act, to the Food Safety Modernization Act, to the Modernizing of Cosmetics Regulation Act, the FDA has hired talented people who have gotten the work done to keep the American people safe.

Going backwards, I think, is unacceptable. I'm seriously concerned that the workforce cuts across the agency will harm the progress that this committee has supported on a bipartisan basis to ensure a strong FDA that supports innovative treatments and gives families peace of mind that the drugs we take, the food we eat, and the cosmetics we use are safe.

Now, moving on to the fiscal year 2026 budget, which is the topic of this hearing. I wish we'd received and had a chance to review the full President's budget request prior to this hearing, though I would point out that that's not unique to FDA. We haven't gotten the details of the budget in any other Appropriations hearings that I've been part of. The FDA was not mentioned in the preliminary budget materials we received three weeks ago. So, we are sitting here today talking about a budget that this committee has not received.

I'm disappointed to see the vast and drastic proposed cuts to the Department of Health and Human Services, and my priority is that the FDA has the resources that you need to carry out the core missions of the agency. But without a budget, it's hard for us to assume that the President's proposal will meet those goals.

Now, in closing, the FDA at its core has an incredibly hopeful mission. The agency has the power to bring hope and comfort to millions of people by approving groundbreaking cures and treatments developed here in America by the best scientific minds in the world. So, I think, we, on this committee, stand ready to be partners in this effort.

And I with that, Commissioner Makary, I appreciate your being here today, again, and I look forward to hearing your statement, and to the discussion that we will have with members of the committee about your budget proposals. Thank you.

SUMMARY STATEMENT OF HON. DR. MARTIN A. MAKARY

Dr. MAKARY. Thank you, Chair Hoeven, and thank you Ranking Member Shaheen, and members of the subcommittee. Thank you for having me here to testify on the FDA budget for 2026.

The Trump Administration is proposing a $6.8 billion budget for the FDA, including $3.2 billion in budget authority and 3.6 billion in user fees for fiscal year 2026. This allows us to take the necessary steps to support the Make America Healthy Again agenda, as we have already been busy implementing.

Now, I've been at the FDA for about seven weeks, and I'm proud of the early progress we've made working to remove all nine petroleum-based food diets from the U.S. food supply, eliminating unnecessary animal testing requirements for drugs. We approved a new blood test for Alzheimer's, which could help enable more early treatment. For the pharmaceutical manufacturing facilities overseas that the FDA inspects, there has been a routine of using scheduled inspections, which in my opinion, are no inspections at

all. They're a joke, and we are moving towards surprise inspections.

We don't allow FDA inspectors anymore to accept limo rides from the pharmaceutical manufacturing companies that they are there to inspect. I'm amazed at some of the stuff that I'm learning when I look under the hood. We've begun taking action against new challenges such as gas station heroin, and childhood vaping with illegal Chinese vaping products.

Our borders have been far too porous. Working with the Trump Administration's reenergized Customs and Border Protection, we're not wasting any time. Today, we are announcing the seizure of nearly 2 million illegal vaping products from China. Last week, we announced plans to withdraw from the market, chewable, ingestible fluoride tablets, currently prescribed to six-month-old babies.

And this week we published in the New England Journal of Medicine, our framework for Covid vaccine booster regulation, so that developers and companies can see what we're thinking and have predictability. And we are planning to bring back gold standard science and common sense.

We also have to modernize. On Day 1 of me being on the job, I actively began an effort to organize to use AI for our scientific reviewers to make their jobs easier. Well, two weeks ago, we just announced our first AI-assisted review with the latest generation AI technology. One reviewer said that what normally took him two to three days, the AI did in six minutes.

I've set an aggressive goal of June 30th to have AI-assisted scientific reviews help our reviewers agency-wide, and we're going to be ahead of schedule and under budget on meeting that aggressive goal. The goal is to reduce the paperwork burden of reviewers, which is tremendous, so that we can deliver more cures and meaningful treatments to the American people faster.

That's been the first seven weeks of my job at the FDA. Here are other important goals I have for the FDA, and we're already hard at work on them. Healthier food for children, a universal flu shot, meaningful treatments for ALS, Parkinson's and other neurodegenerative disorders, treatments for rare diseases, cancer therapies that are so powerful a tumor is eliminated without the need for surgery or chemo. That's not a theoretical, that something we've already seen.

And one of my highest priorities is to ensure that we are not wasting any time in evaluating novel treatments for PTSD. Many of our brave veterans served in unnecessary wars, and we owe it to them. I've not yet hit the two-month mark, so I'm doing a lot of listening. I appreciate all of your input, but one question we must ask is why does it take over 10 years for a new drug to come to market?

My team and I are working very actively to examine the approval process in all of its details so we can try to figure out how to deliver more cures, and meaningful treatments, and devices faster and in a more user-friendly way for developers without cutting any corners on the scientific review and independence.

We're also committed to President Trump's promise to lower drug prices at the FDA. We can help by bringing more low-cost generics

and biosimilars to market among many other strategies we're exploring.

In conclusion, the FDA is filled with an enormously talented and committed group of employees representing, in my opinion, one of the greatest brands in the world. It's my duty to make sure that everybody central to the core mission has all the resources they need to do their job well.

So, I look forward to answering your questions. Thank you.

[The statement follows:]

PREPARED STATEMENT OF HON. DR. MARTIN A. MAKARY, M.D.

Chairman Hoeven, Ranking Member Shaheen, and Members of the subcommittee, thank you for the opportunity to appear before you today to discuss the President's Fiscal Year 2026 Budget request for the Food and Drug Administration (FDA or the Agency). I would like to start by thanking the subcommittee for your continued support of FDA. The Agency 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 critical issues impacting the health and wellbeing of Americans.

Looking ahead to FY 2026, we will embrace President Trump and Secretary Robert F. Kennedy's Make America Healthy Again (MAHA) agenda by restoring trust in our food system, prioritizing public health, and strengthening national nutrition and food safety. America is facing an unprecedented chronic disease crisis, with heart disease, diabetes, and obesity affecting millions of lives. Meanwhile, food safety failures, contamination events, and formula shortages have exposed systemic weaknesses in our food and nutrition infrastructure. The FY 2026 budget directly supports the MAHA agenda by ensuring safety of the United States food supply, investing in nutrition, preventing food safety failures and infant formula contamination and shortages, and ensuring appropriations needed to meet certain spending triggers for user fee programs.

In my first 6 weeks or so at FDA, I have worked to make sure the reviewers and inspectors have what they need to help protect the public health of the American people. FDA will not go through a significant reorganization, we will be centralizing and streamlining shared functions that were previously duplicated throughout the centers and offices, such as IT, communications, and operations. In addition, we are exploring and moving to quickly implement where AI and novel technology can help reduce workload as a tool for the expert scientists and inspectors at the FDA. The initial response from the review staff has been very positive, and I look forward to building on this experience and expanding it throughout the centers at FDA.

The funding requested in the President's FY 2026 Budget includes critical elements to safeguard public health and the food supply for the American people. Our FY 2026 budget requests $6.8 billion, including $3.2 billion in budget authority and $3.6 billion in user fees. This includes an 11.5% reduction in budget authority compared to the current fiscal year, improving efficiency while still increasing investments in areas that are critical for the American people.

MAKE AMERICA HEALTHY AGAIN

FDA serves a critical role in supporting the Administration's extensive efforts to protect the food supply, protect against chronic disease, remove any dangerous chemicals and additives from foods, and address any shortages of critical foods such as infant formula.

FDA is committed to radical transparency to give Americans the latest information about the food ingredients they are eating and their effects—in alignment with both MAHA and FDA's mission. The Agency is leading efforts to protect the U.S. food supply to combat the growing risks associated with some chemical additives used in food, expand Closer to Zero efforts to reduce toxic elements, such as arsenic, from foods consumed by infants and young children, reduce sodium and added sugars, and provide new forms of nutrition labeling to better inform consumers about the foods they consume.

FDA will also expand a new pilot grant program to help schools transition to safer and healthier foods, as well as address failures in inspecting high-risk facilities, strengthen import oversight, reduce foodborne disease outbreak response times, and decrease the number of associated illnesses. This includes supporting advancements in technology to rapidly identify and combat food borne pathogens, such as Salmonella, E. coli, and Listeria. FDA will also continue its commitment to supporting

the safety, nutritional quality, and availability of infant formula; maintaining and expanding laboratory capabilities; and supporting cooperative agreements, grants, and contracts in support of federal-state initiatives. FDA and its regulatory partners have a shared mission to ensure the food Americans eat is safe. This mission can only be achieved by fully leveraging resources, expertise, and capabilities as part of an integrated food safety system.

CONTINUITY OF USER FEE FUNDING FOR MEDICAL DEVICES

FDA's user fee agreements are negotiated with regulated industry and implemented when Congress authorizes the user fees. Under the Medical Device User Fee Amendments (MDUFA), for FDA to collect and use the medical product user fees, a certain amount of non-user fee appropriations must be appropriated by Congress and spent by FDA on the application review process (known as the "non-user fee spending trigger"). The FY 2026 President's Budget intends to meet non-user fee spending triggers, including an $8.2 million increase for FDA's medical device program non-user fee spending trigger and to meet the goals and commitments under MDUFA V.

CONCLUSION

FDA believes the funding in the FY 2026 President's Budget will enable the Agency to operate more efficiently, while addressing critical public health and safety priorities, in particular restoring trust in our food system and prioritizing public health. FDA looks forward to working with the subcommittee to address these critical issues and improve the health and wellbeing of Americans. 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 SHAHEEN [presiding]. Thank you very much, Dr. Makary. We're honored to have the chair of the Appropriations Committee, Senator Collins, with us. And Senator Collins, Senator Hoeven went to vote, so he turned the gavel over to me. So, I will turn it over to you.

Senator COLLINS. Thank you very much, Temporary Chair.

[Laughter.]

Senator COLLINS. But it's been an honor to work with you on so many issues that we care about in this space, including Type 1 diabetes in particular. Doctor, I appreciated hearing your comments this morning. Americans have relied on the FDA for more than a century to ensure that their medicines are both safe and effective. Recognizing that America biotech leads the world in innovation, we in Congress have taken a number of actions to ensure that FDA's rigorous regulatory review keeps pace with the speed of science and solves problems in areas where we don't have cures, or effective treatments, or a means of prevention.

Recent staffing changes at the FDA appear to have affected the balance between innovation and regulatory review. From what I'm hearing, I'm particularly concerned about the downstream impact of delays on patients suffering from debilitating rare diseases like ataxia and birth syndrome, as well as more common terrible diseases like ALS, which you mentioned Alzheimer's and other neurodegenerative diseases.

As I mentioned, Senator Shaheen and I'm sorry, I am out of it today, apparently.

Senator SHAHEEN. It was a late night and early morning.

Senator COLLINS. We have worked together on Type 1 diabetes for many years. We're encouraged by what's going on in STEM therapy and immunotherapy in that area. And today, you, yourself, talked about the need for more efficient regulatory pathways and innovative treatments for rare life-threatening diseases, particu-

larly when there are no major safety issues and existing treatments, or either don't exist, or they're limited.

So, what I'm hearing is there's a real slow down in FDA, and that's not what you were committing to today, but that's what I'm hearing. The reality is, there are a number of rare disease new drug applications that have been pending at FDA for some time.

What specifically is FDA doing under your leadership to accelerate getting new treatments for rare diseases to patients safely and as soon as possible, particularly since we have developed these accelerated pathways, particularly for those patients, for which there are no treatment options now.

Dr. MAKARY. Good to see you, Senator Collins. I share in your interest in this topic because I have cared for people with rare diseases and rare cancers, and it is the worst feeling in the world to have to break bad news. And when people say, is there anything out there to be—to not have anything to respond with is a very difficult position.

So, we need to customize the regulatory process to the condition being treated. And so, if it is a rare condition, we have to drop our randomized control trial requirements in some instances. I will say, however, that the trains are running on time at the FDA. There have been no staffing changes that have changed any approval schedules. We are on track to meet all of our Prescription Drug User Fee Act (PDUFA) targets.

There are on occasion, every year, essentially every year, a couple drugs that are very complex, where the career scientists ask for more time, either to convene an advisory committee to weigh in or to design a very unique specific randomized trial.

So, in reference to one of the products that you had mentioned, I had gotten briefed and was assured that there was no delays related to staffing. These were additional time because of the complexity of the early data. And the staff truly believe career scientists truly believed they needed a few more weeks. And I thought, we're on track to meet our PDUFA targets. They believe we're completely on track to meet our PDUFA targets if they took a few more weeks. And I thought that was reasonable.

The trains are running on time. The food inspectors are doing their job. We have 12 food labs. There's no backlog at the food labs. The cuts that you referenced and Senator Shaheen referenced were to things like this 2,600: This is at the FDA 2,600 HR staff, Contract staff, and budget staff. Now, I think that's too much. And we, they, they were part of the reduction in force. In total, about 1,800, almost 1,900 people were involved in the reduction in force. And I think a lot of that is consolidation.

Just to be clear; there were no reductions in scientific reviewers as a part of the reduction in force, and we're actually hiring scientists because there's normally turnover with our scientific staff. And I hope the AI and the other tools will help make their jobs more efficient.

Senator COLLINS. Well, I am hearing something entirely different. So, I will convey directly to you the concerns that I'm hearing since Dr. Peter Marks was removed from his position. And it is disheartening for patients with serious diseases, as you know very, very well from your clinical practice for which I know you are

a dedicated physician, but it is disheartening when it appears that a new treatment or drug is on the horizon and then FDA says, no, we need three more months. We need three more months. We need three more months over and over again, despite the years that have gone into developing a particular treatment for an illness that has no treatment.

And, again, that's why we work so hard to establish these accelerated pathways. So, I'll be in further touch with you. I don't disagree with the need to look at the staffing of FDA and to make sure that as much of it as possible is going into the process that speeds food inspection, new drugs to the American people, sensible regulation and guidance on diet, lifestyle factors. All of that is extremely important. So, it's not that I object to looking at that, but I don't want it to come at the expense of drugs that are desperately needed. Thank you.

Dr. MAKARY. Thank you, Senator. I will just say that the person, the scientist replacing Peter Marks is outstanding. And I would say, take a close look at his credentials. He has published over 540 peer-reviewed scientific articles. He's a professor from UCSF, trained at the National Cancer Institute. He's a scientific genius.

So, I've rejected the idea that there's only one scientist in the world that can run Center for Biologics Evaluation and Research [CBER] well, and I think we need fresh new ideas. The new scientist replaced Peter Marks, 42-year-old. He brings a fresh new perspective, and it will not change our approach to rare diseases, or the predictability that people need in the market and development investment space to know that they need to continue to invest in those technologies.

Senator COLLINS. I look forward to meeting him. Thank you.

Dr. MAKARY. Thank you.

Senator HOEVEN [presiding]. Thank you, Madam Chair. Appreciate you being here. Doctor, you came into roughly a 19,000-person agency. Your budget top line is about 3 percent less. But there's been estimates as high as potentially 4,000 reduction in force, voluntary or actual rifs.

Where are you on that, and how's it going? You and I've again talked about this before. I was—you know, at that time, you know, we talked about how once you got in there and had more time, you were going to obviously have a better analysis of what your needs are and where you're at with the personnel situation. So, go through that for us, will you?

Dr. MAKARY. Sure. So, there have been about nearly 1,900 people involved in the reduction in force. Roughly, another 1,200-plus involved in the early retirement package. We are hiring scientists to replace scientists that may have left for an early retirement, but no scientific reviewer or inspector was cut as a part of the reduction in force.

Now, any discussion of the reduction in force, I believe, deserves one important fact of context which is always omitted in the media coverage. And that is in 2007, the FDA had not a little over 9,000 employees, and a few months ago was 19,000. So, there was a 100 percent increase in the number of employees at the FDA over the last 15, 16 years. And that is how we get 2,600 HR people, con-

tracts and budget people, at the agency. 380 communications positions, we're now down to about 160.

They're doing a good job, 160 people. That covers a lot of the communication work. Did we need 125 travel coordinators and travel offices in each center, or 13 strategy offices at the FDA? A lot of this reorganization is smart, and it's being smart with taxpayer dollars because I personally believe when this institution here, U.S. Congress is spending $2 trillion more than we have as a country, it is driving inflation, which is a backhanded tax on the poor.

And that is the harsh reality. It doesn't affect people of wealth like myself. It affects the 50 percent of Americans that have less than $500 of cash on hand. And they are forgotten when we spend too much money and we drive inflation. And that's why I support many of these reductions in force, where it makes sense.

Senator HOEVEN. Okay. But you also get fee agreements from, you know, drug companies that want to get new drugs to the market. And so, you have to be able to staff that so that you bring in that fee revenue, which of course is not a cost to the taxpayer. So, I agree with you. Yeah, we need to find better ways to do things. We need to find savings, and that's good. But talk to us how you're making sure that you manage things. I mean, again, paramount to your mission of safety, as we talked about on the front end. I know you understand that. You're a doctor, took the Hippocratic Oath.

But those fee agreements make it more complicated, but they bring in revenue. Talk about that, as well as making sure we get these new drugs to the market as safely and efficiently as possible, because that ultimately saves lives.

Dr. MAKARY. Yes, Senator. So, thank you for that question. And, again, I want to reassure the public to see through the headlines, and to know that the trains are running on time at the FDA, and we're on track to meet all of our user fee targets as an agency. And we need the staff to help with the user fee management. And that's why I've made sure that we have the appropriate staff to make sure that we can report on our user fees and sort of service conductors in managing the user fee targets.

Now, look, I'm a surgeon, and so the reductions in force are never perfect. So, I've done everything humanly possible since I've gotten there to try to make sure we heal and reorganize appropriately. We have brought back some people, and my job is to make sure that the scientists, and inspectors, that the law enforcement officials at FDA have all the resources they need to do their job well.

Senator HOEVEN. Okay. I think I'm going to give you a short question to save my long. Well, now I'm going to go with the longer one. I'm going to probably run over my time a little bit, ranking member, so I'll beg your indulgence and certainly return the favor. The MAHA Commissions coming out with their report, I think pretty much right after this hearing.

Dr. MAKARY. Yeah, noon.

Senator HOEVEN. Yeah. So, if you want to kind of give us all the details right now, that's great, and just get a jump on things.

[Laughter.]

Senator HOEVEN. But guessing that you might not, you do need to talk to us about it in that, as I laid out my opening statement, this committee has jurisdiction both in regard to all of your funding at FDA, but also USDA for our farmers and ranchers. And we have to address both.

So, I know you're coming out, you know, the Department of Health and Human Services (HHS) writ large, is coming out with this MAHA study plan today. But as I said in my opening, we're very concerned not only how that's going to affect the American consumers, but also how that's going to affect agriculture. And as you know, agriculture goes—I mean, they're regulated like everybody else. In fact, in my opinion, they're overregulated like everybody else.

And so, you know, with this report coming out, I get y'all are going to be working very hard to make sure it's scientifically-based and all that. But a lot of what our farmers and ranchers in producing that food supply have had to do, that's all scientifically-based, too, heavily regulated. And there's been years, and years, and years of that analysis and regulation done, and a heck of a lot of expertise.

So, how do you approach that in this plan of action, and the analysis that you're doing, and so forth, and the studies you're doing to make sure that that's adequately included in terms of your evaluation, and the results and the recommendations that you make?

Dr. MAKARY. Well, Senator, you shouldn't be concerned about the MAHA report. It is simply information. And it's important information about health written by people who have excellent citations, and are representing the many scientists that have been waving a flag in the air for many years saying, "Hey, look at root causes."

We have the sickest, most disabled, most medicated, most obese population in the history of the world. Half our nation's kids are sick. And why are they sick? Because when the immune system, or some inflammatory response is reacting to the many different chemicals that go down their GI tract, the immune—they feel, blah, they don't feel well. And so, we have got to look at root causes.

Now, there's no single chemical in the food supply that is accounting for a root cause for the driving our chronic disease epidemic, but I think everything has to be on the table. We, for example, at the FDA, just convened, two days ago, a round table on talc. Now, talc has been identified as a cancer-causing agent. It's been removed from baby powder.

There have been 30 studies saying that talc may cause ovarian cancer in women with a high odds ratio in statistical significance. International cancer bodies have warned about the cancer-causing effect and the mechanism of talc. And so, it's been removed from baby powder. But do you know kids are eating talc every day? It's in candy. You take chewing gum and the white powder on there, people think it's sugar. Sometimes, it's talc. Talc is in our food supply. Kids are eating talc.

And it's not just in food, it's in medicines. The number 1, 3, 9 and 10 most common medications in the United States have talc on it. Why? Because it's a lubricant. It's just the way we've been

doing business. It's a lubricant in the machines when it's mass produced. Well, there's a low-cost alternative that is generally considered to be safe.

This is the—we're not fighting anybody here. We're trying to bring the latest scientific information to inform good decisions. And I think you're going to be pleased with the MAHA Commission report. It puts at the forefront of our discussions of health many issues that sciences have been talking about for years.

Never in my oncology meetings do we talk about the root causes of cancer. Cancer's going up in kids, young people under age 50. It's everyone's scratching their heads. You get a diagnosis, they come to Johns Hopkins, we would look at them and parents would say, "What could possibly cause this?" Well, guess what? We don't talk about any of this in our national conferences. That is what the MAHA Commission report's going to talk about.

What have we been talking about? Insulin, chemotherapy, CAR–T therapy, radiation, sophisticated operations. We have got to talk about food and chemicals, not just chemo and insulin. And so, this MAHA Commission is going to put front and center as a setting our research priorities, setting a national conversation, setting our own internal goals so that we're going to deliver in another 100 days from today some of what we're going to do.

The MAHA Commission report is a diagnosis. And I think we have to do something differently. We have a healthcare system that's breaking the budget, that's resulting in inflation, that's burdening businesses. That's the number one cause of household bankruptcy in the United States; is medical bills. And no one is talking about the root cause. And that is the health of the population that is actively deteriorating right in front of our eyes.

And so, we've got to move from a reactionary healthcare system where we're playing whack-a-mole with all these treatments in the hospital and late stages, and be proactive and actually talk about the root causes, and why we don't see some of these problems in other countries. I think this report is going to be the cornerstone of a broader discussion, and there's no one single ingredient that's going to be vilified.

Senator HOEVEN. So, after the report comes out, after we do some work on your budget, we're going to want you to come back and talk to us. Are you going to be willing to do that?

Dr. MAKARY. Of course. I'd love to talk.

Senator HOEVEN. Good. Thank you very much. Ranking Member Shaheen.

Senator SHAHEEN. Well, thank you, Chair Hoeven. And I certainly agree with you that we ought to focus on the root causes of what's causing diseases. And I've been trying for years to get to change the sugar subsidy system that we have that encourages sugar to be added to our food supply in so many ways. But so far there hasn't been the political will to do that.

So, one of the things that I would urge you to do, Chair Hoeven suggested that we would like to have you come back and talk about this. I hope that there will be more of an effort to engage Congress in the changes that you're talking about making than there was in the cuts that were made.

Because again, I think there's a lot of appetite to try and look at how we do things better. But boy, there's not an appetite to have one person and a DOGE Commission go around and make all these decisions without engaging Congress, because so much of that has not only been not well received, it's been outright illegal.

That's not your problem. But I hope as you think about looking at the changes that we need to make to get at root causes, that you will come back and engage with us on what you're proposing because there's a lot of expertise on this committee, and I'm sure a lot of ideas for what we ought do better, too.

But I want to go back to diabetes, one of the most expensive chronic illnesses we have. It's one that you and I talked about. Senator Collins and I have done a lot of work as co-chairs of the Diabetes Caucus on this. As I explained to you, for me, it's not just a policy issue, it's a personal issue. I have a granddaughter with Type 1, so I know the struggles that the community has had, and many of those with the FDA before you got here.

But they have been real. And one of the issues right now that I'm hearing from the diabetes community is about C-peptide, which is a marker of the body's own insulin production. It's emerging as a potentially more accurate tool for measuring how well a person cells are functioning. However, the FDA does not currently recognize C-peptide as a validated surrogate endpoint. Meaning, that the community has to use other endpoints that are less—many people believe less accurate. So, will you commit to reviewing C-peptide as a validated surrogate endpoint?

Dr. MAKARY. I'm happy to, Senator. I love C-peptide. I'm a pancreatic specialist. And so, I don't understand why it would not be recognized. It is a naturally occurring hormone that is an indicator of the physiologic health of the pancreas. So, I'll take a look at that for you. Happy to.

Senator SHAHEEN. Good, thank you. I hope we can stay in touch on that. In the last couple of days, there have been a lot of news reports about the COVID–19 vaccine. I would think that one of the real accomplishments of the first Trump Administration was the development of the COVID–19 vaccine. I would think people would be very proud of that effort.

And so, I was surprised to hear about the FDA's announcement earlier this week that would limit access to COVID–19 boosters. And it seems like the announcement would take away people's ability to make that choice on their own by limiting it to only people 65 or at high risk.

So, can you help us understand why that decision was made, and why people who may think that that booster would be helpful to them will no longer be available?

Dr. MAKARY. Happy to. It's been four to 5 years since we've had a randomized controlled trial. And so, we don't know the right number of boosters that a healthy American should take. What is that number? Is it two, like the MMR vaccine? Is it two or three, like HPV or hepatitis B? Or is it 80? Do we believe in giving 80 mRNA shots to a healthy girl born today in her average lifespan of 80 years? Is that the right answer?

That has been a theory that the repeat booster strategy in healthy individuals is the correct evidence-based strategy, but

there's been no data to support it. So, we are doing our job to say that if we are going to approve a Covid vaccine for younger, healthy Americans, we'd like to see some clinical trial data, given that it's a much different population from 5 years ago.

There's broad ubiquitous population-based immunity, and there's also a different virus circulating. And this is a new vaccine formulation that creates a new protein in the body. Should we blindly rubber stamp a vaccine that creates a new protein in the body every year for the rest of our lives, for the next 100 years? I don't think so.

And so, that's why we published in the New England Journal of Medicine this week, a framework for sensible Covid vaccine booster regulation in the United States that uses an age-stratified approach. And really, honestly, we are catching up with the rest of the world. Some of the rest of the world has been laughing at us using this blind strategy.

We're now switching to a scientific strategy. The UK only recommends Covid boosters and people 75 years of age and high-risk. France, 80 years of age and high risk. I don't think we should be pushing this on healthy 6-year-old girls without any evidence every year for the rest of their lives. And so, that's why we've outlined this framework. And by the way, the vaccine manufacturers put out positive statements about the framework because I believe they like predictability.

Senator SHAHEEN. Well, so I understand that rationale. Do you have a timetable for when you expect to have the trials done and a decision made about the future?

Dr. MAKARY. When the companies present trials to us, and in the case of high risk, our New England Journal paper outlines how they can seek clinical trial data after approval in high-risk populations. But it's up to the companies to present data to us. It's always been that way where the FDA reviews clinical trial data that companies present, and we make a decision about safe and effective.

We have been suspending that role for the last 4 years with Covid boosters. And so, we're saying this is a reasonable time to check in and look at clinical trial data given how different it is. By the way, America doesn't want Covid boosters——

Senator SHAHEEN. But I assume—I'm sorry to interrupt, but I'm out of time. Actually, I assume that you're talking to some of those companies so you have some idea of their level of interest in coming back to do those clinical trials and what they may be thinking about in terms of a timeframe.

Dr. MAKARY. Look, some of these companies made $100 billion in the Covid booster. They can afford to run a clinical trial and they have time to run a clinical trial. The VRBPAC meeting meets later today to pick a strain. So, there's time and there's money. We're setting a well common-sense framework.

Senator SHAHEEN. Yes, but I get.

Dr. MAKARY. Eighty-five percent of healthcare workers——

Senator SHAHEEN. Are you talking about—are we talking about 6 months, 1 year, 5 years, 10 years? I'm just trying to get some ideas so that when people call our office and ask, when I run into people and say, well, "How come I can't get the Covid booster?"

That we can give them some kind of an answer for what they can expect.

Dr. MAKARY. Eighty-five percent of healthcare workers said no to the last Covid boosters. You're not suggesting that we blindly approve Covid boosters each year without clinical trial data?

Senator SHAHEEN. You're not listening to me, Dr. Makary.

Dr. MAKARY. Is that what you're——

Senator SHAHEEN. I'm not asking for a blind approval. I'm saying that I understand the argument you're making. What I'm asking you is, do you have any timeframe for when you think this might happen? And I'm sure you're talking to pharmaceutical companies so that they might have some idea so that we can just answer questions from the public. Part of what I'm objecting to here is that all of these decisions are being made without engaging the public, and I think that's a problem.

Dr. MAKARY. The public has said no to Covid boosters. Seventy percent of the public has not gotten a Covid booster, and they don't trust us because there's no——

Senator SHAHEEN. You're still not answering my question, though. Do you not have any idea?

Dr. MAKARY. The timeframe is reasonable, and it is amicable to what the industry thinks is they can do. And so, we've had these conversations and we do with industry. I can't share individual product conversations with manufacturer, but they think that the timeframes that we've outlined are reasonable and we think they're reasonable.

Senator SHAHEEN. But you still haven't said what they might be.

Dr. MAKARY. Well, there's plenty of time between now and the fall, and so there's plenty.

Senator SHAHEEN. So, you're looking—you think it's going to be more of a short-term timeline.

Dr. MAKARY. In the high-risk group.

Senator SHAHEEN. This is not a trick question. I'm not trying to trick you here. I'm just trying to get some answers.

Dr. MAKARY. And I'm not trying to not answer your question. It's just different for each age group. For young, healthy individuals, we have a different timeframe from the high-risk community where we are approving the Covid—well, I shouldn't say we are because we haven't reviewed all the data, and all the applications are not in.

But for high-risk individuals, we do have a framework now by which they can run the trials after the approval in high-risk individuals throughout the Covid season. And then Americans will know it either works or doesn't work. So, it's roughly a year. It's roughly a year. In Operation Warp Speed, they ran that Phase 3 clinical trial over the summer. And if they want to do the same thing, there's plenty of time, in my opinion.

Senator SHAHEEN. Thank you.

Dr. MAKARY. Thanks.

Senator SHAHEEN [presiding]. Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you very much. And thank you, Dr. Makary, for being here and joining us on the Hill today. We've discussed the issue of chemical abortion before. However, I'd like to revisit the topic in light of new data published last month by the

Ethics and Public Policy Center. This data reveals a much higher risk from the abortion drug, mifepristone, than previously acknowledged.

And this raises the questions whether it's time to reconsider the broadly unrestricted access to the drug. It makes me question if the FDA should reinstate the original safeguards in order to protect vulnerable women and minors from experiencing the horrible adverse and life-threatening complications that could follow the chemical abortion regimen.

First, let me summarize the new data. In April, 2025, researchers from Ethics and Public Policy Center and the Foundation of the Restoration of America reviewed the outcomes of 865,000-plus drug induced abortions from 2017 to 2023. These abortions occurred after the FDA in 2016 removed the requirement for doctors to report non-fatal but adverse complications. The data shows 94,605 serious adverse events proving conclusively that more than 1 out of 10 women are put at risk by the mifepristone.

This real-world rate is 20 times greater than the rate the FDA used when it originally approved the drug. Specifically, this status shows that, their words, "10.93 percent of women experience sepsis, infection, hemorrhaging, or other serious adverse events within 45 days following the chemical abortion."

If serious complications have increased as safety rules have been loosened over the last 25 years, then logically, it makes sense to bring those safety protections back. At the very least, the FDA should restore the original safety requirements from 2000 under its risk evaluation and mitigation strategies.

How do you view this new data, and will the FDA be taking this new data into consideration and commit to restoring common-sense protections, like requiring an in-person doctor visit before women can actually access mifepristone?

Dr. MAKARY. Thank you, Senator Hyde-Smith, and good to see you again. I think a lot of people are asking those questions. And so, I did see those top line results that you referenced, and we are going to take a look at those data as they become available. There is no peer-reviewed publication, and the underlying data set is not available. But when it does become available, we're going to take a hard look at it. Thank you.

Senator HYDE-SMITH. Thank you. I would appreciate that very, very much.

Dr. MAKARY. Thank you.

Senator HOEVEN. Senator Ossoff.

Senator OSSOFF. Thank you, Mr. Chairman. And Dr. Makary, good to see you.

Dr. MAKARY. Good to see you.

Senator OSSOFF. Thank you for joining us. I was pleased to see that the secretary has made the safety of infant formula a priority for the Department. Is that correct?

Dr. MAKARY. That's right. And the FDA will be convening the world experts on infant formula on June 4th, and we're going to be having a robust discussion because parents want infant formula options with a better supply chain, without added sugar and seed oils.

Senator OSSOFF. Did you see a recent consumer report study which found that of 41 tested infant formulas more than 30 were found to have potentially dangerous levels of lead?

Dr. MAKARY. Yeah. Heavy metals in infant formula is something that's getting a lot of attention, as it should. And so that is part of Operation Stork Speed to take a hard look at that. And it is one of the priorities of our infant formula roundtable at the FDA on June 4th.

Senator OSSOFF. And it's the Human Foods Division of your agency responsible for infant formula safety, at least in large part. Yes?

Dr. MAKARY. Yes.

Senator OSSOFF. I'm trying to make sure I understand some of the relevant personnel decisions given the concern that families in Georgia have about the safety of infant formula, the safety of the food supply. James Jones, the Deputy Commissioner for Human Foods, submitted a resignation letter February 17th, included the quote, "The indiscriminate firing of 89 staff in the Human Foods Program is beyond shortsighted. The foods program staff at FDA is the envy of the world in its technical, professional, and ethical standards."

It goes on, "The employees fired this past weekend are the most recent hires, and generally come to Federal service with the most recent education and represent the future of the agency. They included staff with highly technical expertise in nutrition, infant formula, food safety response, and even 10 chemical safety staff hired to review potentially unsafe ingredients in our food supply."

That was February 17th. You were asked on April 17th whether any of the personnel reductions had included personnel responsible for food safety or infant formula safety. You said, "There were no cuts to scientists, or reviewers, or inspectors. Absolutely none."

You were asked on April 23rd on CNN and said again, "There were no cuts to scientists, or inspectors. But then just two days later, an HHS spokesperson confirmed that, in fact, scientists had been fired and that you were scrambling to rehire them. Is that—did you in fact say on April 23rd, "There were no cuts to scientists or inspectors?" Just before we get into the details, is that an accurate quote?

Dr. MAKARY. No scientific reviewer was cut as a part of the reduction in force.

Senator OSSOFF. But you said there were no cuts to scientists or inspectors. Didn't you say that?

Dr. MAKARY. My understanding whether there was—that there were no cuts to the scientific staff, but specifically, the scientific reviewers is what I was referring to.

Senator OSSOFF. But you said there were—it's a very straightforward question. You said there were no cuts to scientists or inspectors. Correct?

Dr. MAKARY. Scientific reviewers is what I was referring to, that's the vast majority of scientists there.

Senator OSSOFF. But you said——

Dr. MAKARY. Jim Jones is an economist.

Senator OSSOFF. Five days before you had said there were no cuts to scientists. You said that right?

Dr. MAKARY. I was referring to scientific reviewers. There are a couple——

Senator OSSOFF. But scientists had been fired. Correct?

Dr. MAKARY. There have been a couple. There have been research scientists in some labs that have been doing some research. Some of that research is good, some of it is not good. And so there have been no cuts to scientific reviewers.

Senator OSSOFF. And, in fact, scientists who study the safety of infant formula had been fired. Correct?

Dr. MAKARY. I'm not aware of any scientists studying infant formula that——

Senator OSSOFF. Well, here's the reporting in the New York Times, which says the HHS spokesman said those employees called back had been inadvertently fired, and the decision to rehire specialists on outbreaks of food-related illnesses and those who study the safety of products like infant formula.

So, is this reporting accurate? Had, in fact, scientists who study outbreaks of food-related illnesses and the safety of infant formula been fired?

Dr. MAKARY. The reason it's not accurate, it's Senator, is that people were not fired. They were scheduled for the reduction in force. And when I—this was before I got there. When I got there, we did an assessment. And so, some of those individuals out of the 19,000 were restored. Jim Jones was an economist, and he was upset about the DOGE cuts. So, he self-doged. I didn't—he was not fired. I wish he would've stayed.

Senator OSSOFF. Have all scientists responsible for food safety and infant formula safety been rehired or reinstated?

Dr. MAKARY. Look, we have not reduced in force the scientific review staff. I know where you're going with this. We're not allowed to——

Senator OSSOFF. I'm trying to clarity on statements. You said there were no cuts to scientists, and then the HHS spokesperson said, actually there were cuts to scientists and now we're trying to rehire them. I mean, so it gives the impression you're not sure about the personnel actions ongoing in your own agency.

Dr. MAKARY. Again, No one was cut in the reduction of force.

Senator OSSOFF. And that's information from your testimony here today.

Dr. MAKARY. They were scheduled for the reduction in the future, down the road. It has not happened yet. So, the people scheduled to be cut. We did a review and found some research scientists—when I made those statements, it was very specific. I was very clear. We're talking about scientific reviewers because the trains have to run on time. And if you're concerned about backlog.

Senator OSSOFF. My time is up. You were very specific. You said there were no cuts to scientists. And then five days later, "There were no cuts to scientists." Those are your direct quotes. "There were no cuts to scientists," but there were cuts to scientists. Right?

Dr. MAKARY. No, there were no cuts to scientists because people were scheduled for the reduction in force down in the future. And the people scheduled were reevaluated and we restored a couple research scientists, and I was referring not only to them, but to to the scientific reviewers.

Senator OSSOFF. How many scientists responsible for preventing outbreaks of food-related illnesses and the safety of infant formula have been restored or reinstated?

Dr. MAKARY. There were no scientists that were in charge of preventing outbreaks that were part of reduction.

Senator OSSOFF. I didn't say in charge.

Dr. MAKARY. But, I mean, this is the problem in government. Somebody has a fancy sounding name like infant formula safety, and no one can ever touch them even if they're not doing their job.

Senator OSSOFF. Okay. Say, how about this? I'll send you so that you can get accurate information to the committee. I'll send you some very detailed questions about this and you'll respond in full. Yes?

Dr. MAKARY. Yes. Just keep in mind, the agency was half its size in 2007.

Senator OSSOFF. But you'll respond in full——

Dr. MAKARY. We didn't have outbreaks and rampages, and food outbreaks——

Senator OSSOFF. But we had a huge infant formula safety crisis in this country just a few years ago. Do you recall that?

Dr. MAKARY. That was because of several problems including——

Senator OSSOFF. So, you will respond in full to the questions that I send you.

Dr. MAKARY. I'm always happy to respond in full to you, Senator.

Senator OSSOFF. Thank you so much, Dr. Makary. Thank you.

Senator HOEVEN. Doctor, I know that that you're working on Operation Stork speed, speaking of baby formula, that Secretary Kennedy's already talked about Operation Stork Speed, which goes right to this issue. Yes. And you're already working on it, made it a priority. Would you like to address that?

Dr. MAKARY. We're working hard on it, and that's why we're convening the world's experts. And the part of the problem with infant formula that the Senator is alluding to, which is a real problem, is that the FDA has been so rigid in the way it evaluates infant formula.

Basically, we have for decades said you have to follow this recipe because we as the government know exactly what infants need and you can't deviate from this recipe. And guess what? They got added sugar on there and seed oils. And there's been no innovation in infant formula practically since 1998 when we saw the last change in infant formula on the monograph recipe, with the exception of selenium that was added. Basically, no innovation in, in infant formula since 1998.

And so that's what we're working to fix. That is one of the underlying problems. The more innovation, the more competitors that can come to market, the more predictability with the regulatory process, the better products. We're going to see more options for moms that want infant formula that's safe, low on heavy metals without seed oil, without added sugar. And that is, I think, going to help also lower prices and increase the supply chain.

Senator HOEVEN. And, of course, moms know, but there needs to be a choice in that baby formula so that you've got the product you need for your child.

Dr. MAKARY. Absolutely. We're all about choice.

Senator HOEVEN. And so, there's a lot to it, and again, I commend you for—and the secretary for making that a priority. And I do like the name Operation Stork Speed. That's a great name. I don't know if you came up with it or the secretary, but it's a good one.

Dr. MAKARY. I did not, but I'll pass all along to the person that did that.

Senator HOEVEN. You liked it. And the other thing is this seems like a timely thing to say because the senior Senator from the State of Michigan just showed up, and he and I actually have legislation on baby formula, bipartisan legislation.

I don't know if you had a chance to look at it yet, but I would ask that you work with us on it because it goes to some of these very same things. And I think we worked very hard to make it very practical, actually reflecting some of the things you just talked about; how do we make sure safe, but we innovate and have choice.

Dr. MAKARY. It's great legislation, Senator. Thank you for working on it.

Senator HOEVEN. That was the right answer. I've got another question, but I'm going to turn to Senator Murray before I ask my final question, and then of course, Senator Peters. Senator Murray.

Senator MURRAY. Thank you very much, Chair Hoeven. Look forward to working with you on this really important committee.

You know, Commissioner Makary, the FDA has a really important job to do. Lives literally are at stake. And that work requires the utmost diligence, and care, and commitment to following the science and upholding FDA's gold standard. We all expect to walk into the drugstore and know that what we are buying has passed a safety and efficacy standard. And we have to be assured of that, and we have to be assured that the work's been done, that we don't have to question that.

So, I don't think it's careful leadership when you do mass fire 1 in 5 people across FDA only to, frantically, then bring some back because you didn't stop and think two seconds about whether those jobs were actually important. We really, Mr. Chairman, cannot cheap out on the FDA and expect to maintain that gold standard. That means that people know that drugs are safe.

We can't just cut, and cut, and hope nobody gets sick when you're slow to issue a recall, or hope no one needs that medicine that had its approval delayed, or hope there isn't another infant formula issue while your staff are getting fired, or getting rehired, or wherever they are.

This work really takes investments. This committee knows that, and it expects expert staff, like the people that have been shoved out the door. Drug approvals are already getting delayed. Food and drug safety inspections are lagging behind. We are going in the wrong direction fast.

We still have yet to see from you a full budget request. That is unacceptable. You are now testifying that the budget proposes to slash FDA by more than 11 percent. That's actually news to all of us. And I'll tell you right now, it is not going to fly. It's reckless and it's not going to happen as long as I have anything to say about it.

Now, Commissioner Makary, when it comes to your mass firing of FDA employees in April, you said, "I can tell you there were no cuts to scientists or inspectors." Well, that is not true. I think Senator Ossoff covered that. And I think the point here is that all of this firing and rehiring, I don't see how that's efficient. Frankly, it kind of shows that you don't know what you're doing and you're breaking things in the process here.

And so let me ask you a question, and hopefully it is an easy one for you. Does it save taxpayer dollars to fire staff who work in centers that are fully funded by user fees, not taxpayer dollars, yes or no?

Dr. MAKARY. Nice to see you again, Senator Murray. You asked me to do an assessment of the staff when I came here for my confirmation hearing and, and I hear that you're criticizing me for bringing back some individuals after the cuts that I was not a part of.

Senator MURRAY. No, I'm saying that's good. I'm just saying in the long run, this has been very inefficient. But my question to you is not about that. And I know you've covered it with several other members. So, does it save taxpayer dollars to fire staff who work in centers that are fully funded by user fees, not taxpayer dollars. Is that efficient? Does it save much?

Dr. MAKARY. The cuts were to HR, IT, communications. There were 2,600 HR staff——

Senator MURRAY. But they're funded by user fees.

Dr. MAKARY. In part.

Senator MURRAY. It's not saving anymore.

Dr. MAKARY. In part.

Senator MURRAY. Well, the many of the staff you fired were in centers that are actually fully funded by user fees. You know that. Correct?

Dr. MAKARY. So, if we have 2,600 HR people, do you want me to not make any cuts to that number?

Senator MURRAY. No. I'm asking you a specific question about the centers that are fully funded by user fees.

Dr. MAKARY. That's one center. It's the tobacco center.

Senator MURRAY. Okay, well, let me just say——

Dr. MAKARY. You said we can't just keep cut and cut. We can't keep hiring and hiring. The agency doubled since 2007. So, let me ask you, what is the right number of employees?

Senator MURRAY. No. You're here to answer my questions and I'm going to ask some more. Without critical support staff you fired, inspectors cannot plan their trips. They cannot do their jobs. I want to ask you; what percent of planned inspections has FDA missed since those April 1st firings?

Dr. MAKARY. In the 12 labs that we have that evaluate food products in the food inspection realm, there are no—as of last week, I just did a check. There are no backlogs. They're running at 100 percent efficiency. There are no drug approval delays despite the—you know, what people want to attribute.

Senator MURRAY. Well, that is not what I have been told. I have been told, and I would like you to go back and check and report back to us because we know that some of the planned inspections at these—that supposed to take place have been missed. And to

me, why that's so important, if there is not inspections, the public doesn't have the information that they need. I am going to run out of time, so I want to move on.

Dr. MAKARY. There are no cuts to inspectors, Senator.

Senator MURRAY. Will you go back and check for me, please?

Dr. MAKARY. Absolutely.

Senator MURRAY. I understand. And, by the way, inspectors are one thing, but if you don't have this support staff to make sure that they know where the

Dr. MAKARY. But 2,600 HR staff and procurement staff?

Senator MURRAY. Okay. I understand that the Freedom of Information Act [FOIA] staff producing documents related to ongoing litigation by the Children's Health Defense, Secretary Kennedy's organization, were shielded from the rif, while other FOIA staff who are responsible for FOIA responses and other FDA centers were targeted for termination. Is that true?

Dr. MAKARY. That's not true, Senator. We are have our FOIA staff. They continue to work at the FDA. I've made sure that all the FOIA staff at the FDA are doing their job. We are also using AI to reduce the burden on that staff.

Senator MURRAY. Well, for the record, my understanding is that the Children's Health Defense FOIA staff were not fired when other ones were, all the FOIA staff were there. And that seems like a real conflict of interest to me, considering that the secretary's extensive history with that organization, Children's Health Defense, and his goal to remove authorizations for vaccines. So, I just want that on record.

Dr. MAKARY. It's not true.

Senator MURRAY. Well——

Dr. MAKARY. All FOIA staff are in place.

Senator MURRAY. Okay. So, if a study came out saying that people who took a certain medication experience a certain rate of "serious adverse effects", but the study's authors refuse to say what they were counting as an adverse event, would that raise serious questions for you about the study's validity?

Dr. MAKARY. Yes, Senator. So, I have the natural inquisition of a scientist that's done a lot of research. So, I would want to see the underlying data. Yes.

Senator MURRAY. Okay. Well, I am of course talking about the sham study from the Ethics and Public Policy Center. It's an anti-abortion group. It's bankrolled by extremists. They fought to overturn Roe v. Wade. And this study, if you can call it that, is unsound and has been widely panned by medical experts.

But days after its release, you and Secretary Kennedy are now suggesting that we need a complete review on the safety of mifepristone. Now, to be clear, mifepristone has been proven safe and effective in more than 100 studies over three decades. And the people that are now pushing that bogus study and saying that mifepristone is dangerous for women, are the exact same people who think that abortion is never necessary to save a woman's life, and that 10-year-olds should somehow be forced into childbirth.

I believe that this administration is laying the groundwork to rip away access to medication abortion across the country. This has

not gotten enough attention. And I know you'd prefer to keep it that way, but I want you to know I'm not going to let that happen.

Dr. MAKARY. I have not seen that study, Senator, and you have not seen that study. So, how can you call it a sham, bogus study? Neither of us have seen the study, the underlying data, or the methodology.

Senator MURRAY. Actually, that's not true. But I will say this, Mr. Chairman, we have a lot of differences here. I know you came before this committee to present your side of the story, but I am very clear that laying off people, cutting budgets is not going to improve the safety and efficacy that we count on when we go to the drugstore to get our drugs. And I know that sham studies that try to prove a point that came from a political group, is not going to tell the public that they can count on the medications they count on.

Thank you, Mr. Chairman. I yield back.

Senator HOEVEN. Senator Peters.

Senator PETERS. Thank you, Chairman Hoeven. And thank you for talking about infant formula and talking about our bill specifically. And thank you for eliciting a response from our witness that we both really appreciate. So, thank you for doing that.

Dr. Makary, as when I was chair of Homeland Security and Governmental Affairs, we did a study looking at persistent drug shortages throughout the country and found that a lot of us, because we're overreliant on foreign sources for those supplies, and many of the precursors are, as you know, all overseas.

And in fact, in that study when I put it out, I said it's pretty clear based on these challenges with the supply chain, that when there is a pandemic, we're going to find ourselves in a very difficult position. Six months later, that academic study became reality as we dealt with the pandemic and certainly saw that we had highly efficient supply chains, but they were not resilient.

And I remain concerned that the FDA does not have the visibility it needs into essential medicine supply chains from the key ingredients needed for manufacturing our drug products, to the distribution to the patients, and hospitals, and pharmacies. And these blind spots clearly limit our ability to accurately assess national security risk, including our over dependence on China, in particular, for many critical inputs.

So, last week, I reintroduced the MAPS Act with several of my bipartisan colleagues, which would address this critical gap by requiring HHS through public-private partnerships to essentially map out the medical supply chains using data analysis, and to assess all the threats and vulnerability.

So, my question for you is, do you agree that this is a significant concern? And if so, will you commit to work when we pass this legislation to make this a reality?

Dr. MAKARY. Senator Peters, I love this topic. It's so important. I'm glad you're raising it. I've written about it in a book in 2019. I've written about it in the Journal of the American Medical Association. I felt like no one has been paying attention. I warned about exactly what happened at the beginning of Covid, and it happened.

So, I am totally aligned with you that this is an important issue. I think there are root causes that we've not been talking about that

we need to talk about. I mean, we can get out a ruler and map out, you know, the supply chains, and I'm not opposed to that exercise, but the underlying problem is that manufacturing has moved overseas.

And it's not just one or two things. It is most of what we use in anesthesia to perform surgery. It is most antibiotics. It is most of these cutting-edge therapies is the vast majority of generic drugs. And so, I totally am in support of President Trump's agenda here to bring manufacturing back to the United States.

And we've already had a tremendous amount of success. There are companies announcing moving manufacturing in the United States. We're creating incentives, we're removing regulation. And this is a national security issue. So, I am 100 percent with you on this.

Senator PETERS. Very good. In April, FDA reported suspending programs to improve testing for potential bird flu virus contamination of milk, cheese, and pet food because of the mass layoffs that occurred. We know that the bird flu virus can kill pets who eat contaminated raw pet food, and it can pose a real danger to humans who also consume unpasteurized dairy products.

As you know, the more people and animals who get infected with bird flu the more opportunities there are for the virus to mutate. And I'm really worried that we only may be a couple, and it's not just me, others are worried that there may be a couple of mutations away from having another—potentially a pandemic.

So, my question for you, sir, is with the continued spread of bird flu in the country and the significant personnel disruptions at FDA food safety programs, could you tell me on the committee specifically what the FDA is currently doing to ensure our food is free from bird flu contamination?

Dr. MAKARY. Well, first of all, that story was debunked by The Washington Post. It was the normal procurement pause to recalibrate the equipment. And so, when that happened, people who were trying to make us look bad, sometimes internally, sometimes externally, said, aha, there were layoffs, and there's a pause in some of the milk inspection, and therefore the cuts may have been related to this, or were related to this, and that's going to affect food safety.

No. It was a normally scheduled pause to recalibrate equipment. It went through its normal schedule, and it is back up and running, and it's normally done to recalibrate the equipment. The cuts were to 380 communications people. What's the right number of communications people for the FDA? Not 380. 125 travel coordinators, 13 strategy offices, 2,600 HR people, and budget and procurement people. So, I mean, are we not supposed to address some of this redundancy?

Senator PETERS. My question is, what exactly are you doing to safeguard our food supply and to safeguard to people from bird flu? So, that was the question. I think you're prepared for a different question and you gave the answer to the different question. But the question is suggested specifically what you're doing, please.

Dr. MAKARY. You suggested the cuts increased our risk of bird flu, and I firmly reject that that's not true. And the inspection trains are running on time.

Senator PETERS. I think I said personnel disruptions, so.

Dr. MAKARY. There's no personnel disruptions involved.

Senator PETERS. There are no personnel disruption——

Dr. MAKARY. No calibration facility that was written about.

Senator PETERS. So, there are no personnel disruptions related to your work on bird flu. Is that what you're telling this committee?

Dr. MAKARY. What I'm saying is the story that you referenced was saying that our milk calibration facility paused because of disruptions.

Senator PETERS. I don't remember—I don't think I cited a particular article. I don't know where you—obviously, you're prepared. You may not—you're prepared for a question that I didn't ask. That's fine.

Dr. MAKARY. No, I mean, you referenced it.

Senator PETERS. You probably gave a good answer to a question that I didn't ask. And so, it shows you were prepped for it. I'm asking you, what are you doing about bird flu? Just answer that. Please don't give a runaround about other stuff.

Dr. MAKARY. Doing a lot on bird flu.

Senator PETERS. Don't use your prepared talking points. Tell me, what are you doing to help us and protect the American people from bird flu? Please tell me that?

Dr. MAKARY. We're doing a lot on bird flu.

Senator PETERS. Please tell me that. That's why we're here.

Dr. MAKARY. We got—so look, when there is an antigenic shift that represents an epidemic threat, when there is human-to-human transmission, that strain that is involved in that human-to-human transition is the strain that we should be using to base any potential future vaccines.

And in the interim, as I said in my opening comments, delivering on a universal flu shot is one of our top goals. And there are two universal flu shots that are in development. And we are not in a receive-only mode with those developers. We are actively trying to partner with those individuals because it may be that you could come in for a single birch, a single influenza vaccine, or a two-dose strategy, or something like that and be immune for life against multiple different variants of influenza, including bird flu.

And so, early preclinical data in animal studies has shown some promise that a universal flu shot using a traditional vaccine platform can actually create antibodies to the current strain of bird flu. The question, of course is, and I think this is really what you're getting at, is if we have a bird flu epidemic or even an outbreak in a human-to-human fashion, what strain is that going to be? Because one thing we know for sure is it's not going to be the strain that's circulating right now in millions of birds. So, it is a huge priority for us, Senator.

Senator PETERS. Good. Thank you.

Dr. MAKARY. Thank you.

Senator PETERS. Thank you, Mr. Chairman.

Senator HOEVEN. Doctor, and in just one follow-up on the avian flu. I've spent quite a bit of time visiting with Secretary Brooke Rollins on that issue as well. And she put out a comprehensive plan to address it and a very thoughtful plan because, for example, the issue of inoculation is really complicated because if you inocu-

late chickens, and then you got broilers, and then you have trouble with export to Europe and all these kinds of things.

Dr. MAKARY. Yes.

Senator HOEVEN. So, I think she put out a comprehensive plan, but she did it very judiciously because some of these things we still got to figure out. Right? So, any comments you have in terms of working with her and understanding that this it's very complicated, and as doctors say, we want to first do no harm but address it in a comprehensive way? Would that be a, a fair evaluation, and what are your thoughts?

Dr. MAKARY. 100 percent. Secretary Rollins has been on top of this, she has been in communication with the emergency preparedness scientists at HHS and our FDA team, as well as people in the Office of Science Technology Policy to evaluate whether or not we should be mandating preemptive bird flu vaccines to chickens in the United States.

Some countries have done it, and I think they made the right decision in saying that does not make sense at this time. Sometimes, it represents messing with mother nature in ways that we may not foresee. It may drive mutant strains of the virus. So, I think we need to be alert and ready. But at the same time, we need to wait until we see human-to-human transmission, and see what that strain is before we develop a strain specific vaccine.

And in the meantime, we can advance the universal flu shots that encompass those bird flu strains currently in circulation, provided that they are safe and effective. And, you know, not 100 percent of vaccines are wonderful. I love vaccines. I believe in vaccines. Vaccines save lives. Any death from a vaccine-preventable illness is a tragedy.

But the anthrax vaccine was a disaster. The swine flu vaccine was a disaster. The rotavirus vaccine was removed from the market. We had a vaccine that we had to remove from the market a few weeks ago for a rare infectious disease in the United States. And when the data clearly shows that there's not broad safety as we're commissioned by Congress to do, then we have to do our job.

Senator HOEVEN. And there is concern by producers in terms of, if you start inoculating some of the flock, then you actually have the disease in the flock. But then if you're still, you know, keeping that flock, then does the disease spread also, as I say, depending on whether they're layers or they're broilers. That makes—so there's a lot that that goes into this, and it's a really complicated. Very important we address it, but a really complicated issue.

And that's why I'm pleased that you and Brooke are working together in the way that you are on it.

Dr. MAKARY. Thank you, Senator.

Senator HOEVEN. Yeah. I want to ask about AI, and I don't mean AI as we talked about on the ranch. This I mean artificial intelligence. And, you know, talk to me—I hear so much about what AI's going to do in every field, but certainly in medicine. Just give me, you know, some of your thoughts on not only how we should be using it and what it will do for us, but how we make sure that we don't get ourselves into a problem with it.

Dr. MAKARY. Well, we spend a lot of time thinking about cybersecurity and proprietary information. We don't want a situation

where AI is stealing proprietary information. And we don't want to expose ourselves to any cyber risks, which is why we have ensured that the AI that we're using to summarize clinical data and background information for our scientific reviewers lives in a very secure space. And the reviewers love it.

And it's not just AI to assist in the scientific reviews. We're using AI to identify where we should be concentrating our food inspections. And it turns out the AI can sometimes figure out pattern recognition faster than, you know, we can as human beings. And we'd like to use this also to address the issue of illegal vapes coming into our border.

Senator HOEVEN. Okay. And how do we make sure it doesn't get off and running on us and we have problems?

Dr. MAKARY. We have to keep an eye on it always. I mean, we cannot have blind trust in anything, which is why all the areas where we are using AI currently at the FDA, we also have a human being reviewing the information and having full access to the underlying data.

Senator HOEVEN. Okay. Thank you, Doctor. Ranking Member Shaheen.

Senator SHAHEEN. Yes. I just have a couple more questions. One is, again, apropos the need to address Type 1 diabetes. One of the things that Senator Collins and I have worked on is a more efficient pathway for biosimilar drug approvals that are currently lacking competition.

So, can you give us an update on what you think is happening in that arena and whether there's any reason to hope that that's going to get expedited, and if there are any other approvals or anything that you need at the FDA to ensure that that is being addressed in a way that allows those biosimilars to come to market?

Dr. MAKARY. Well, thank you, Senator. This is a very important topic that directly relates to drug prices for everyday Americans. And there's a reason why when you watch the news now, you're basically watching, you know, people dancing in the fields and singing with these drug ads nonstop in the commercial breaks because they're so expensive.

And so, the companies have figured out that if they can get a few people to, you know, shake their doctor down to prescribe one of these drugs to them, or I guess somehow let their doctor know that they're a candidate—it might be a little insulting to the doctor that they don't already know it, in my opinion. But that's why these ads are running nonstop.

And so, there are low cost biosimilars that can be made available by the FDA, approved by the FDA, and that process is too slow, in my opinion. We have to look at whether or not we really need to require confirmatory trials for each biosimilar. I mean, we don't do that for generics with regular branded pills. We don't say, "Well, you make a generic with the same molecular structure, go out and do a confirmatory trial." I think we need to look at that.

There's a bill, I believe, that Senator Rand Paul is putting forward to take a look at that. And then finally, we can look at whether or not we can sort of approve a class of interchangeable drugs that they're very similar in the class. And so, an interchangeability

provision could help create more incentives because we want to incentivize companies to make safe biosimilars.

Senator SHAHEEN. I agree. You mentioned in your opening statement the seizure of vaping products from China. One of the things that I've been concerned about for a very long time is the increased use of vaping by young people. And the numbers have gone up dramatically in the last 10 years, and also the health impacts of that we're not even, I think, fully aware of at this point.

So, can you talk about what more you're doing at the FDA, and how you did that interdiction, who you're working with, again what more can be done to get those products off the market?

Dr. MAKARY. Well, Senator, thank you for your interest in this topic. We can do a lot more. And I've realized that what's happening now is these illegal Chinese vaping products designed to attract children, they are video game vaping products with an inhalation port designed to addict young children so they can vape as they play these games. These fruit video game products that are so small, they have an inhalation port.

What happens is these products that are banned in China, and made in China, show up in U.S. ports. And what's been happening, I learned, is that they are set aside, the FDA looks at them, and then we say, "Well, you know what? These are shouldn't be coming in our country. We'll put them back on the ship they came on, and then the ship goes to another U.S. port and will come in through. Basically, we're 100 percent porous.

It's been a joke, and they've been laughing at us, and so we are going to stop that. And we have incredible interest at DOJ, at Department of Homeland Security, and we are creating an endeavor that is going to basically say we're not going to send them back anymore. We're going to confiscate and seize these products because we've got to get serious about them.

These are designed to get kids addicted, and there are kids in America today who are addicted. They know they're addicted. They come from good families, they're good kids, and they can't stop. And that is something that we have to address. There are high schools in America now where kids are saying half of the kids in high school are addicted to these vaping products.

So, we cannot get burned, again, like we did on opioids, and Vioxx, and other things where the problem is so far down the road it's hard to undo some of the tragedy. And so, this is a top priority for this administration, for this President, for this secretary, and for me.

Senator SHAHEEN. Well, I agree. I think we ought to right out ban vaping products for anybody under a certain age, certainly. And one of the other things we need to do, as you know, is to get a treatment for people who are trying to get off vaping products. Because one of the other selling points that they use is that, well, it's a way to get cigarette users to stop smoking. They can vape and the harmful impacts are not as serious.

But I'm pleased to hear that you're doing everything possible. And I don't know if you, again, if this is an area where you need additional authorization or support, but I think there are a number of us in the Senate who are all in to try and address this because it is having a huge impact.

I've been to those schools in New Hampshire where I've talked to students who have gotten hooked on vaping, who can't get off, and who don't have any aids to help them do that. So, it's something that we've really got to address.

Dr. MAKARY. Thank you so much, Senator. And as you know, we confiscated today $34 million worth of illegal vaping products and e-cigarettes. And so that announcement is coming out today.

Senator SHAHEEN. Thank you.

Dr. MAKARY. Thank you.

Senator HOEVEN. Doctor, thanks for being here. Did you have anything else that you wanted to express for the record before we wrap?

Dr. MAKARY. I appreciate the input and the feedback. And, look, I'm on a listening tour. We're going to be traveling around the country, myself and some of the other FDA leaders, meeting with industry leaders, developers, inventors, scientists, academics, and we want to hear how we can perform better.

We don't claim to have all the answers. We don't claim to have the truth on health, but we do have a lot of intellectual curiosity, and we plan when we see something that needs action to take action. So, I want to thank you and this committee for the input that you've provided and made available to me.

ADDITIONAL COMMITTEE QUESTIONS

Senator HOEVEN. We appreciate you being here today. We look forward to having you back as well. Questions for the record are due by next Thursday, May 29th. And then, we'd appreciate responses from FDA within 30 days, so.

Dr. MAKARY. I can't wait.

QUESTIONS SUBMITTED TO HON. DR. MARTIN A. MAKARY

QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

MAHA COMMISSION REPORT

Question. The Make American Healthy Again (MAHA) Commission report was made public the day of our hearing. This subcommittee has a special interest in the recommendations in the report as we are at the intersection of food and health with jurisdiction over both the FDA and the USDA. I am curious about the next stage in the process for the MAHA Commission, which will entail the publication of a strategy to build upon the report which is due by August of this year.

Can you speak to the MAHA report and how you believe it will impact your work at the FDA? Will you work closely with the USDA on the next phase of the MAHA Commission Strategy development to ensure our farmers will continue to enjoy support for their work providing the fresh fruit, vegetables and other dietary staples that are important to ensuring the health and nourishment of all Americans?

Answer. On April 22, the U.S. Department of Health and Human Services and U.S. Food and Drug Administration (FDA) announced new measures to work with industry to phase out all petroleum-based synthetic dyes from the Nation's food supply-a significant milestone in the administration's initiative to Make America Healthy Again. The FDA is taking a number of actions, including:

—Initiating the process to revoke authorization for two petroleum-based food colorings-Citrus Red No. 2 and Orange B.

—Working with industry to phase out the use of six remaining petroleum-based dyes-FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, and FD&C Blue No. 2-from the food supply by the end of next year.

—Partnering with the National Institutes of Health (NIH) to conduct comprehensive research on how food additives impact children's health and development.

In partnership with the NIH Nutrition Regulatory Science and Research Program, the FDA will enhance nutrition and food-related research to better inform regulatory decisions.

—The FDA fast-tracked the review of calcium phosphate, Galdieria extract blue, gardenia blue, butterfly pea flower extract, which are color additives derived from natural sources. The agency is also taking steps to issue guidance and provide regulatory flexibilities to industries.

Lastly, FDA has and will continue to collaborate with USDA on a variety of cross-cutting work related to the MAHA Commission Report.

HUMAN FOODS PROGRAM

Question. As I mentioned in my opening statement, the FDA regulates 80 percent of our Nation's food supply. We know that there have been staffing changes and reductions at the Human Food Program this year. We have also heard of the possibility of changes in FDA's food inspections that would lead to a decrease in FDA's direct involvement. I assume this would lead to more support of state inspectors, which are more cost effective.

Can you speak to your vision for FDA's food regulation and inspections for the next year?

Answer. The President's proposed budget for Fiscal Year 2026 includes a plan to shift responsibility for many routine food facility inspections from FDA to State agencies. This shift is part of a larger proposal to enhance FDA's efficiency. As part of the plan, FDA and state co-regulators would work in a coordinated framework, sharing data and responsibilities to ensure coverage of regulatory responsibilities in a jurisdiction. It is anticipated that each State would have a unique distribution of work based on its capacity and capability, while FDA would focus on areas where its national scope and specialized expertise would be most impactful. This proposed framework will reduce duplication and streamline work planning between FDA and state co-regulators, as well as provide more complete food safety coverage and optimize resource utilization at both the State and Federal levels.

From a training perspective, FDA's Partnership for Regulatory Education and Training (PRET) program helps enable States to have more qualified personnel to conduct inspections. PRET is designed to assist State, local, Tribal, territorial and military (SLTTM) partners by equipping them to independently deliver training courses. By enhancing training capabilities and strengthening regulatory capacity across all levels, FDA is reinforcing our collective commitment to safeguarding public health. PRET offers an opportunity to empower jurisdictions to meet their own training needs while using FDA-designed course materials and utilizing FDA-trained qualified instructors from the SLTTM's own staff.

AI PRODUCT REVIEWS

Question. I noted your recent announcements around the use of AI at the FDA; including the hiring of the FDA's first Chief AI Officer and the completion of the first AI assisted product review, with the goal of scaling widespread use of AI in reviews at the agency by July. I am curious if you can discuss parameters of the rollout.

Specifically, can you touch on the safeguards you have in place that will protect proprietary information and ensure accuracy?

Answer. In June 2025, FDA deployed the generative AI Tool, Elsa, across the entire Agency. Elsa's development team was comprised of experts from every Center. Currently, we have approximately 11,400 users of Elsa, with 6,000–7,000 weekly active users, making it one of our most utilized applications. Elsa is an FDA-wide solution that can be employed to help with tasks in every Center/Office. The system supports diverse functions, from administrative tasks to Freedom of Information Act requests and human resources needs. We also expanded accessibility by developing mobile capabilities specifically for field investigators. In addition to Elsa, FDA is currently compiling the 2025 annual HHS AI use case inventory in accordance with Executive Order 13960, "Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government." FDA's 2024 use case list may be found here: AI Use Cases Inventory HHS.gov.

Regarding cybersecurity and information security measures, Elsa operates within the most robust security framework available to Federal agencies. The system is deployed in a FedRAMP/FISMA High environment, which represents the highest level of Federal cybersecurity standards. Our key security measures include comprehensive data protection protocols. The system is also not connected to the internet and operates securely behind the FDA firewall, allowing our staff to input FDA confiden-

tial information safely while maintaining the highest security standards. We maintain strict access controls, including user profile restrictions and the ability to create locked-down, user-specific document libraries. Staff can upload documents and data during individual chat sessions, and this information remains within that specific session and user context, preventing unauthorized access or data sharing. Additionally, we maintain rigorous vendor management protocols with our cloud solution providers and AI vendors, ensuring they meet all Federal security requirements while providing us with access to the latest modeling capabilities within our secure environment.

Question. Can you discuss how FDA reviewers are being trained, and any cost or savings this may bring to the agency?

Answer. Since Elsa's launch on June 2, 2025, over 6,290 FDA staff have completed initial training, and currently, we maintain 6–7,000 weekly active users out of approximately 11,400 total users Agency–wide. This makes Elsa one of our most utilized applications outside of standard Microsoft Office products.

Our training approach is deliberately structured and progressive. We have conducted extensive trainings paired with multiple office hours and video recordings, and to date, over 6,290 staff have attended training sessions. Our approach focuses heavily on prompt engineering—teaching users to craft specific, effective queries rather than relying on generic interactions. As new features and models are released, staff will be required to attend trainings to unlock such additional AI models and features. This ensures we have a process to continually train and reinforce the proper use of these tools as they advance.

Some administrative tasks that previously required days to weeks of work can now be completed in fractions of the time, representing significant labor cost savings across our large user base. For example, analyzing public docket comments for high-level themes could normally require days of efforts from several staff members, however, through Elsa such themes can now be identified more efficiently.

The system development and deployment occurred in 2–3 weeks using existing FDA staff with minimal contractor support, demonstrating relatively low implementation costs. Our training investment is generating returns through accelerated adoption and more effective utilization of AI capabilities across diverse Agency functions, including assisting staff in drafting warning letters, processing meeting transcripts, and supporting various aspects of our review processes.

FDA maintains rigorous mechanisms to ensure regulatory compliance and protection of sensitive information. All users are trained that Elsa is a supportive tool, not a decision-maker, and that they must verify all outputs through our established multiple levels of review. We maintain structured processes with extensive oversight, ensuring that AI-assisted work still meets our rigorous scientific and regulatory standards. Users learn to utilize feedback mechanisms, including rating systems that help our development team understand usage patterns and improve the system.

Finally, we have implemented features in our system such that when users are interacting with Document Libraries, Elsa is forced to read prompts in the context of those documents and cite relevant documents, significantly limiting the likelihood that Elsa hallucinates information or references. Regardless, FDA staff are required to validate sources and information in every instance.

We also plan to provide Center leadership with information about usage patterns, enabling them to understand how their teams are utilizing the tools and ensure appropriate application within their specific regulatory contexts. Finally, we maintain currency with the latest AI capabilities, while ensuring all updates meet our security and functionality requirements. We recently upgraded from Claude 3.5 to Claude 4.0 within our secure environment, demonstrating our commitment to providing staff with cutting-edge tools while maintaining the highest security standards.

Question. Will the use of AI have effects on staffing levels?

Answer. Our current focus is on Human-in-the-loop capabilities to support our workforce and not on replacing staff functions with AI.

INSPECTIONS

Question. Inspections are important to promote domestic manufacturing. In addition to modernizing the foreign inspection process, there are steps that could be taken to address avoidable inefficiencies that impact the time and expense of product reviews.

Inspections are a critical step in the safety assessment and the approval process. They need to be thorough and complete while at the same time being accurate and

rationale, particularly given the reliance on contract manufacturing sites, which can be spread across multiple buildings and with distinct products.

Can you share with the committee your plan to modernize inspections, and commit to working with Congress to identify and address improvements to current practices?

Answer. FDA has focused on more efficient and timely inspections and comprehensive but succinct inspection reports, as well as additional technological tools to assist in modernization. Together these approaches should allow for an increase in the number of inspections performed and allow broader coverage of industry.

The Agency is also utilizing remote assessment tools and other alternative inspectional tools to gather information and records in advance of or in lieu of inspections. This allows FDA to leverage such information and records to focus subsequent inspections or to forgo the need for inspection in certain cases, as appropriate, e.g., if the information in the reviewed records is sufficient for the agency's purposes. FDA is also using our authority under section 704(a)(4) of the FD&C Act, as recently amended by Congress, to require provision of records or other information in advance of or in lieu of an inspection.

Question. Will you commit to reporting back to the committee on how many inspection issues have led to delayed approvals in the form of Complete Response Letters (CRLs), particularly noting those cases in which the inspection issue that resulted in the delay is ultimately determined to be a non-issue or is unrelated to the product that was delayed?

Answer. The focus of current good manufacturing practice (CGMP) inspections is on system-wide controls that ensure manufacturing processes consistently produce quality drugs. FDA will use information gathered from inspections to assess an establishment's compliance with CGMP requirements, including, among other things, evaluating the effectiveness of the establishment's quality system.

FDA provides information on inspections, including the median time to start a pre-approval inspection (PAI) and the number of facilities that failed to address inspection issues leading to application Complete Response Letters (CRLs) for new drug applications (NDAs) and abbreviated new drug applications (ANDAs), in the publicly available FDARA 902 report. The number and type (e.g. PAI, surveillance, for-cause) of inspections resulting in Official Action Indicated (OAI) classifications is documented, but a categorical breakdown of the type requested pertaining to CRL reasons is not available with current systems.

FDA IT INFRASTRUCTURE

Question. Please provide details on FDA's IT modernization roadmap, including timelines, risk mitigation strategies, and how the agency plans to maintain continuity of operations during any system transitions.

Answer. The FDA has developed a roadmap to consolidate the agency's mission critical applications across all centers. The consolidation focuses on data intake systems, regulatory workflow management platforms, publishing platforms, and the aggregated data platforms. The implementation follows a three-phase timeline approach spanning calendar years 2025–2028, with the agency currently in the first phase which began in May 2025.

The first phase, spanning May 2025 through October 2025 (6 months), focuses on foundational setup beginning with the launch of frequent adverse event data publishing to provide more timely post-market data to the public, followed by the initiation of historical data digitization to enhance knowledge sources and cross-center system consolidation planning, including the deployment of the AI platform Elsa 2.0 and Adverse Event Monitoring (AEM) capabilities alongside five additional foundational initiatives.

The second phase, covering November 2025 through October 26 (12 months), concentrates on core transformation activities, including the completion of adverse event system consolidation from seven (7) separate databases into one (1) unified system that supports downstream regulatory reviews, analytics, reporting, and data mining functions without operational interruption. This phase also includes the deployment of more real-time sentinel capabilities, the launch of parallel real-time review processes for early-phase clinical trials, and the implementation of comprehensive real-time surveillance capabilities.

The third and final phase, planned for November 2026 through April 2028 (18 months), achieves full integration by completing historical data digitization, establishing full cross-center system integration, and scaling real-time review capabilities from early-phase trials to include late-phase trials, thereby creating a comprehensive and timely regulatory framework.

The consolidation effort employs an approach that minimizes the risk by maintaining all existing applications, systems, platforms, and resources in their current operational state until successful implementation, testing, and migration to the consolidated platform is completed. Each initiative involves representatives from every center, including both business subject matter experts and technical personnel, to ensure ownership of business and IT operations and to provide input on proposed changes before any code base modifications occur. Business continuity is ensured through embedded change management teams within each center that provide hands-on training and various training modalities to ensure smooth transitions without major disruptions.

Additionally, comprehensive backup plans maintain systems in their current operational state as contingency measures, ensuring that critical regulatory functions continue uninterrupted throughout the transformation process.

Question. Please provide the committee with an update on the current review process for reviewing contracts at FDA, including:

How long is it currently taking FDA to process procurement contracts?

Answer. The time to process procurement actions, receipt to contract award generally takes 2–3 months.

Question. How is HHS ensuring that FDA contract governance adheres to best practices in procurement, risk management, and operational resilience?

Answer. HHS is ensuring FDA contract governance adheres to best practices in procurement, risk management, and operational resilience through implementation of the Administration's priorities. Through HHS, the FDA is implementing changes to the Federal Acquisition Regulation (FAR) as part of the President's Executive Order (EO), "Restoring Common Sense to Federal Procurement" (EO 14275), through the Revolutionary FAR Overhaul [1] (RFO). HHS' oversight of FDA's acquisition activities helps ensure the FDA realizes the goals of the RFO: faster acquisitions, greater competition, and better results.

Additionally, HHS has enabled the FDA to be flexible and innovative in adopting best practices, risk management, and operational resilience through promotion of the HHS "Acquisition Innovation Program," which is transforming "the department's acquisition process through fostering a culture of innovation, streamlining procedures, and piloting new approaches to deliver best value to the taxpayer." In particular, HHS has provided "streamlined acquisition efficiencies to assist the HHS contracting workforce with year-end actions . . . [and] low-risk efficiencies that are easy to implement to ensure successful execution of FY25 year-end requirements," such as streamlined acquisition planning, small business-related reviews, and strategic sourcing opportunities (HHS Acquisition Alert 2025–07). The FDA is implementing many of these approaches to effectively support the FDA, including the Department of Homeland Security's Procurement Innovation Lab's (PIL) source selection techniques.

Question. What internal controls are in place to prevent potential bottlenecks during the contract approval process?

Answer. Controls include standardized review timelines, designated approval authorities at each organizational level, and systematic tracking mechanisms that monitor contract progress through each stage of the approval workflow. Additionally, the Agency maintains escalation procedures and regular communication protocols between contracting officers, program officials, and FDA leadership to identify and resolve any delays that may arise during the contract approval process.

Question. Building off the progress in genomic medicine/rare disease—Congress has spent decades providing regulatory tools and encouraging their use, from innovative trial designs to expedited programs, surrogate endpoints, and real-world evidence. In your efforts to build a more efficient FDA that upholds the world's "gold standard," it is imperative that FDA makes full use of the tools that Congress has provided in applying that standard. This is especially important for patients with serious rare diseases where randomized controlled trials may not be possible.

What does the Administration intend to do to ensure we are able to advance the field of cell and gene therapy, and will this Administration continue to support the full use of regulatory tools Congress has provided, including accelerated approval and single arm trials when placebo controls are not possible, in order to speed the delivery of these life-changing treatments to patients?

Answer. The FDA is committed to advancing cell and gene therapy development and making full use of the regulatory tools Congress has provided, particularly for rare diseases where traditional trial designs may not be feasible.

The FDA is actively implementing several key initiatives to support cell and gene therapy advancement. The Agency has established the Support for Clinical Trials

[1] https://www.acquisition.gov/far-overhaul

Advancing Rare Disease Therapeutics (START) Pilot Program for CBER and CDER, which provides enhanced communication between sponsors and FDA staff to address product-specific development issues more efficiently. This program specifically targets gene and cellular therapies for serious rare diseases, offering frequent advice and regular informal communication to help move development programs forward more quickly. Additionally, FDA has launched the Rare Disease Innovation Hub that will leverage expertise across the Agency to advance regulatory science on critical issues including novel endpoints, biomarker development, and innovative trial designs.

Regarding the use of regulatory flexibilities that Congress has provided, FDA explicitly confirms its commitment to applying these tools appropriately. These flexibilities include accelerated approval based on surrogate endpoints that are reasonably likely to predict clinical benefit, reliance on a single adequate and well-controlled trial with confirmatory evidence instead of requiring two trials, use of natural history study data as external control data, use of novel trial designs, and use of novel statistical methodologies.

The FDA also continues to support the Rare Disease Endpoint Advancement (RDEA) Pilot Program, a joint CBER and CDER initiative designed to support novel endpoint efficacy development for drugs that treat rare diseases by providing a mechanism for sponsors to collaborate with FDA throughout the efficacy endpoint development process. The Agency emphasizes that it considers all relevant statutory authorities and available flexibilities when making decisions appropriate to each particular rare disease and therapeutic product, and ensuring that the tools Congress has provided are being utilized effectively to benefit patients with serious rare diseases who have limited treatment options.

RARE DISEASES REQUIRE INNOVATIVE APPROACHES TO DRUG DEVELOPMENT AND REGULATION

Question. Dr. Makary, you have previously articulated the challenges in rare disease drug development, stating that for debilitating, life-threatening rare conditions, "you can't expect companies to do a randomized controlled trial" because it would "kill investment in those innovative ideas." You also spoke about the need to "customize the approval process to the condition" and uphold "gold standard science." I was encouraged by your statements because Congress has provided FDA with a wide array of regulatory tools to do just that, and these tools are especially important for rare diseases that are complex and challenge traditional approaches to drug development.

As you work towards building a more modern, efficient FDA, how will you ensure that your vision for customized approaches to regulation and gold standard science is implemented at the review level? Can we count on FDA under your leadership to fully leverage all the tools Congress has provided to apply innovative regulatory approaches beyond just focusing on randomized controlled trials—especially in rare diseases where such traditional approaches may not be possible?

Answer. FDA currently has numerous programs (e.g., accelerated approval, breakthrough therapy designation, fast track designation, and priority review) to help speed the availability of drugs intended to treat patients with serious and life-threatening diseases, while at the same time meeting appropriate safety and effectiveness standards and facilitating the collection of scientific data that is relevant and reliable.

FDA also focuses significant resources on rare disease drug development and initiatives to help bring safe and effective treatments to rare disease patients. These initiatives include:

—Rare Disease Innovation Hub[2]: In July 2024, FDA announced the creation of the Hub to serve as a point of collaboration and connectivity between CBER and CDER with the goal of ultimately improving outcomes for patients with rare diseases.

—CDER's Accelerating Rare disease Cures (ARC) Program[3]: In May 2022, CDER launched the ARC Program with a vision to speed and increase the development of safe and effective treatment options to address the unmet needs of patients with rare diseases.

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[2] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/fda-rare-disease-innovation-hub

[3] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/accelerating-rare-disease-cures-arc-program

—CBER/CDER START Pilot Program [4]: FDA's CBER and CDER initiated the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program to help further accelerate the development of novel drug and biological products for rare diseases.
—Rare Disease Endpoint Advancement (RDEA) Pilot Program [5]: This pilot is a PDUFA VII commitment designed to support novel efficacy endpoint development for drugs that treat rare diseases.
—The Oncology Center of Excellence (OCE) Rare Cancers Program [6]: This program is intended to promote the development of safe and effective new drugs and biologics totreat patients with rare cancers by engaging with multiple internal and external groups involved in rare cancer drug development, including patient groups, academia, industry, etc., and holding various workshops for pediatric cancers, rare cancers and ultra-rare cancer tumor indications. Importantly, the OCE has applied regulatory flexibility in many rare cancer drug approvals, including acceptance of the use of single arm trials where appropriate, one adequate and well controlled trial under accelerated approval, use of master protocols and seamless trial designs, etc.

THREATS TO US BIOTECH'S FUTURE INVESTMENT AND GLOBAL COMPETITIVENESS

Question. The National Security Commission on Emerging Biotechnology recently issued a report on the impact of emerging biotechnology on national security. The Commission's conclusion was a clear warning—the U.S. risks permanently forfeiting its position as the global leader in biotechnology if supportive action is not taken in the next few years. I am concerned that the US can fall behind competitors like China, which has been investing in biotech for the last two decades in an attempt to overtake the U.S. in this area.

What actions can the Administration take to restore the confidence and predictability needed in the regulatory process to ensure the viability of U.S. biotech, and what is this Administration's broader plan to preserve and defend our standing as the global leader in biotech and ensure that Americans have access to innovative, lifesaving treatments?

Answer. To preserve America's competitive edge in biotechnology, FDA is taking action across our product areas, including some notable examples below, to increase regulatory predictability, accelerate review timelines, and foster greater industry collaboration.

The FDA recognizes that drug developers and capital markets alike want predictability. To that end, FDA published more than 200 complete response letters (CRLs) to provide significantly greater insight into the FDA's decision-making and the most common deficiencies cited that sponsors must address before their application is approved. The Agency plans to publish additional CRLs from our archives.

The Agency also recently announced its Commissioner's National Priority Voucher (CNPV) program. The new voucher may be redeemed by drug developers to participate in a novel priority program by the FDA that shortens its review time from approximately 10–12 months to 1–2 months following a sponsor's final drug application submission.

Additionally, the Commissioner recently launched a six-city listening tour to gather direct input from biotechnology and pharmaceutical leaders on how FDA can modernize its regulatory framework to better support innovation and patient access to safe and effective therapies.

Lastly, FDA has streamlined its procedures for oversight of foods and animals developed using biotechnology and recently implemented a Voluntary Premarket Meeting process to help certain foods from genome edited plants reach the market much more quickly. This approach continues to protect public health and promote transparency while reducing FDA's regulatory timeline from months to weeks for these kinds of products.

Taken together, the US system generally, and FDA procedures in particular, have enabled the marketing of more biotechnology-derived food and animal products in the US than anywhere else in the world.

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[4] https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/support-clinical-trials-advancing-rare-disease-therapeutics-start-pilot-program

[5] https://www.fda.gov/drugs/development-resources/rare-disease-endpoint-advancement-pilot-program

[6] https://www.fda.gov/about-fda/oncology-center-excellence/oce-rare-cancers-program

STAFFING AT FDA

Question. Can you confirm the number of current FDA staff and how that compares to 2024?

—Have these staff losses affected certain offices, centers, or divisions more than others? If so, which?

—How many of these staff reductions were funded by user fees versus annual appropriations?

—Is the agency currently meeting its PDUFA-mandated review timelines, including for applications granted priority review or for those targeting rare diseases?

—What steps are you taking to ensure that the FDA has the staff it needs to review applications within the statutorily mandated timeline?

Answer. The table below shows the staff on board as of December 31, 2024, and May 22, 2025. The May 22, 2025, numbers exclude individuals that remain on administrative leave with anticipated departures due to DRP and pending RIF actions.

As Of	CBER	CDER	CDRH	CTP	CVM	HFP	OC	OII	Grand Total
12/31/2024	1373	5655	2192	1183	698	1966	3148	2983	19198
5/22/2025	1304	5388	2017	1078	634	1801	2769	2825	17816
Change (%)	5.03%	-4.72%	-8.12%	-8.88%	-9.17%	-8.39%	-12.04%	-5.30%	-7.20%

As demonstrated in the table above, the reductions range from approximately 18% to 23% by Center. The Office of the Commissioner is an outlier at 27.54%, reflective of the focus of the RIF actions on administrative, non-scientific positions without direct roles in the reviews, inspections, and investigations.

52% of FTEs who left the FDA during the time frame above were funded by user fees.

FDA continues to meet all of its user fee-related timelines, and therapeutics for rare diseases is a significant priority for the Agency. As in the past, FDA is monitoring and assessing organizational hiring needs to respond according to hiring authority guidelines, so that the Agency can continue to review applications within the statutorily mandated timelines.

VACCINE REGULATORY FRAMEWORK

Question. The Advisory Committee on Immunization Practices (ACIP) is an independent body of clinical experts that provides guidance with regard to vaccines Last month, the ACIP met and made several recommendations that are still pending review by HHS. Can you provide any timeline or update as to when HHS will consider the ACIP recommendations?

Answer. The Advisory Committee on Immunization Practices is an advisory committee of the Centers for Disease Control and Prevention (CDC). FDA recommends reaching out to CDC for further information.

BENZODIAZEPINES

Question. Commissioner Makary, recent media investigations have underscored the severe risks of the benzo (benzodiazepines) class of drugs-including dependency, cognitive decline, and fatal withdrawal complications-prompting many patients and providers to seek safer alternatives. In the last 2 years the Committee has asked FDA to report back on this topic.

Given that the FDA and DEA are currently collaborating on an analysis to determine whether to deschedule or reschedule newer DORA class insomnia medications, will you prioritize this analysis?

Answer. Under the Controlled Substances Act (CSA), drug scheduling is an effort coordinated between the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS), where a final scheduling action is taken by DEA. Generally, FDA, on behalf of the Secretary of HHS, performs the medical and scientific evaluation of substances for control under the CSA, pursuant to provisions under 21 U.S.C. 811(a-c). According to an April 11, 2024, opinion from the Department of Justice Office of Legal Counsel, such scientific and medical deter-

minations from HHS "must be binding [on DEA] until issuance of a notice of proposed rulemaking"; once formal rulemaking has commenced, DEA must continue to accord "significant deference" to those determinations. As such, we acknowledge our significant and important role in evaluating the science to support the scheduling process. However, the Agency notes that DEA is the Federal agency that takes final scheduling actions under the CSA, including any potential descheduling or rescheduling of DORA class substances (suvorexant, lemborexant, and daridorexant).

ALTERNATIVE METHODS FOR TESTING

Question. As you know, the FDA issued a Roadmap to reduce animal testing.

Please provide an update on the agency's plans and timeline regarding this initiative?

Answer. Our Roadmap, released before the hearing on April 10, 2025, outlines an approach for FDA to reduce toxicity testing in animals in the next 3 years:

1. Explore Pre-existing International Data.

2. Encourage sponsors to submit new approach methodologies (NAM) data in parallel with animal data to build a repository of experience.

3. Develop an open-access repository with a comprehensive collection of international drug toxicity data from animals and humans.

4. Reduce the routine 6-month primate toxicology testing for monoclonal antibodies (mAbs) that show no concerning signals in 1-month studies plus NAM tests to 3 months.

5. Reduction in animal toxicity testing timeframes for other drug categories.

6. Changes in toxicity testing will be tracked and quantified on a bi-annual basis.

Following the release of the roadmap, FDA and NIH held workshop on July 7 titled, "FDA & NIH Workshop on Reducing Animal Testing". The workshop discussed how the FDA and NIH can collaborate to reduce the animal testing currently performed for new drugs and other products.

In addition, over the coming year, the FDA aims to launch a pilot program allowing select monoclonal antibody developers to use a primarily non-animal-based testing strategy, under close FDA consultation. Findings from an accompanying pilot study will inform broader policy changes and guidance updates expected to roll out in phases.

FOREIGN INSPECTIONS

Question. Commissioner Makary, as you know many generic drugs used in the U.S. are manufactured overseas, particularly in India and China. I'm hopeful we can onshore more of this activity. In the interim, we still have to ensure those who depend on these medications can trust that they are safe and effective when they are imported.

How will the FDA ensure that it will be able to sustain its foreign inspection schedule?

Answer. FDA has resumed the recruitment and hiring of new investigators. Training our new and existing workforce of Investigators who conduct inspections remains a priority. FDA is committed to the continuous assessment and implementation of various training improvements, standardization efforts, and evaluations in efforts to support the development of the inspectorate and contribute to the completion of planned foreign inspections. Emerging training focusing on unique aspects of foreign inspections will help ensure that the time to prepare for foreign inspection work is minimized, thereby facilitating an aggressive foreign inspection schedule.

REGULATORY REVIEW TIMELINES

Question. Commissioner Makary, many small biotech firms have stressed that the predictability and speed of FDA regulatory engagement is critical to their investment decisions. Can you give us your assurance that regulatory review times and processes will not be significantly impacted by any staffing changes at the agency?

Answer. One of my highest priorities is to ensure that the U.S. continues to be at the leader in biotechnology innovation and to get these cutting-edge therapies to the American public quickly. For this reason, we made sure that there were no RIFs of reviewers of medical products and others serving in critical roles to support FDA's mission and operations. The Agency continues to meet its review goals under the user fee agreements and we anticipate continuing to do so. In fact, we have recently undertaken a number of new initiatives to make reviews more efficient in an effort

to further reduce current review times, including for products targeting rare diseases.

Dr. Makary, you have previously stated, "our number one goal is delivering cures and meaningful treatment and healthier foods for Americans." Smoking cessation therapies have been approved for decades but it has been almost 20 years since a new smoking cessation therapy has been approved.

Question. Under your leadership, how can the Center for Drug Evaluation and Research (CDER) help Americans be more effective in their efforts to quit smoking with new, safe and more effective smoking cessation therapies?

Answer. FDA recognizes there is an unmet need for novel therapies particularly for individuals who have not been able to quit smoking despite available therapies.

We are encouraging development of novel smoking cessation drug therapies that show benefit over existing products by providing recommendations on 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. The NRT Guidance provides recommendations for applicants to make NRT development easier, efficient, and streamlined:

—Clarifying recommendations 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 the abbreviated review pathways available 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 can be 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 held a joint public meeting with NIH to discuss innovations in development of smoking cessation products. The overall goal of the meeting was to stimulate novel product development to reduce rates of smoking and related chronic illnesses. Input gathered from that meeting will help inform future guidance for industry on development of non-nicotine containing drug products for smoking cessation.

Question. A recent study published in JAMA Oncology looked at the impact of smoking after a cancer diagnosis and concluded that evidence-based smoking cessation treatment within 6 months following a cancer diagnosis maximizes survival benefit, supporting smoking cessation as an important early clinical intervention for patients after being diagnosed with cancer, yet, the current smoking cessation toolkit hasn't changed in nearly two decades. Under your leadership, how will you ensure that all patients, including cancer patients, have the best chance for the most optimal treatment outcomes, including for patients for whom it is critical they are more effective in their attempts to quit smoking?

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. Although many national oncology organizations have emphasized the importance of smoking cessation treatment in comprehensive cancer care, use of FDA-approved smoking cessation products remains low in cancer patients as well. Among cancer patients, lack of access to smoking cessation therapies has been identified as a barrier to use. 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, making these products accessible to consumers without the need to see a healthcare provider.

Specifically, FDA has issued a final guidance intended to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products intended to help cigarette smokers stop smoking. That guidance, Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products, provides recommendations to assist sponsors in getting novel therapies directly in the hands of consumers, in the nonprescription setting, without going through development as a prescription product first. This pathway could be especially meaningful for cancer patients who seek timely access to supportive care treatments and who wish to reduce the burden of additional physician visits. In the guidance, we provide recommendations for developing over-the-counter (OTC) NRT products, which can reduce potential hurdles for access, and recommendations for sponsors to help get novel products over the goal line for approval. It also describes potential abbreviated pathways available 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 recommendations on how to qualify for this review.

Question. What opportunities do you see for innovation in smoking cessation therapies to be part of the administration's work to Make America Healthy Again?

Answer. As part of broader national efforts to reduce the burden of chronic conditions, such as Chronic Obstructive Pulmonary Disease (COPD), heart disease, and cancer, there is growing interest in advancing innovative approaches to smoking cessation. FDA's 2023 NRT guidance, discussed in the response to Question 16A encourages development of novel nicotine replacement therapies by providing recommendations for applicants to make NRT development easier, efficient, and streamlined.

Question. In October 2024, the Food and Drug Administration and the National Institutes of Health held a joint public meeting on smoking cessation, at which several patient and public health organizations underscored the detrimental impact smoking continues to have on the health of Americans and the importance of prioritizing innovations in smoking cessation therapies. What opportunities do you see to ensure FDA does not accept the status quo and the Center for Drug Evaluation and Research (CDER) approaches the risk-benefit considerations for nicotine replacement therapies in a manner that reflects the realities of how hard it is to quit and the unmet need for patients who continue to fail in their quit attempts?

Answer. Please see FDA's response to previously question.

Question. Cigarette smoking and secondhand smoke exposure account for nearly half a million deaths in the United States each year. Smoking-related death and disease cost the United States $600 billion each year and contribute to significant health challenges. Reducing smoking is not only an urgent public health challenge for Americans, but also an economic challenge for the health care system and American taxpayers. What is the administration doing to advance innovation in smoking cessation in order to offer Americans access to new therapies that can help them succeed in their quit attempts and limit the toll smoking-related health conditions take on the Medicare and Medicaid programs, and most importantly, the patients served by these health programs?

Answer. 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. Please see FDA's response to Question 16A for information about how FDA is attempting to encourage development novel smoking cessation drug therapies.

COMPOUNDING DRUGS

Question. In the Drug Quality and Security Act, Congress authorized the FDA to identify drug formulations that are "demonstrably difficult to compound (DDC)," to protect patients when the scientific evidence demonstrates that the risks of compounding a particular drug outweigh the benefits. Once added to the DDC list, it becomes unlawful to compound.

Commissioner Makary, as you know, the FDA is authorized to limit 503A compounding of specific drug products and 503B compounding of drugs and categories of drugs. In a March 2024 proposed rule, the FDA described six criteria for evaluating whether a drug should be added to the DDC list. I have heard concerns from constituents that the agency may seek to use those criteria to ban entire categories of drugs from 503A compounding. This could negatively impact patients who rely on compounded medications for a wide range of conditions, including when drugs are on shortage.

Will you commit that you will not finalize any rule that exceeds the agency's statutory authority under section 503A, including that only individual drug products may be added to the 503A DDC list?

Answer. As you note, FDA issued a proposed rule, "Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the FD&C Act," in March 2024.

The Agency is currently reviewing public comments on the proposed rule, including comments regarding the scope of the Agency's authorities regarding the development of the DDC lists.

FDA plans to finalize the rule consistent with our authorities under the FD&C Act.

REGULATORY REVIEW TIMELINES

Question. Many individuals are accessing health information through the use of digital tools, in addition to health care providers who are using such tools to make treatment decisions. Prescription Drug-Use-Related Software continues to play an increasing role in patient care and it is important to have a consistent framework in place that takes a modern approach to digital regulation. During the first Trump Administration, FDA issued guidance to advance such a framework.

Dr. Makary, do you plan to advance and/or update the guidance released during the first Trump Administration regarding the regulation of Prescription Drug-Use-Related Software?

Answer. FDA is considering whether to prepare a final version or issue another draft of the Regulatory Considerations for Prescription Drug Use-Related Software (PDURS) draft guidance document. FDA will continue to engage with stakeholders who are exploring PDURS and will consider whether to issue or revise guidance based on stakeholder feedback as appropriate and evolving regulatory considerations.

Phenobarbital—Phenobarbital, a schedule IV controlled substance, is a barbiturate that can slow the activity of a user's brain and nervous system. It is my understanding that phenobarbital in tablet form is primarily for veterinary use, and the only use approved by FDA is for the control of seizures associated with idiopathic epilepsy in dogs. Despite FDA's approval in 2023, many animals are being treated with unapproved phenobarbital drugs intended for human use.

I understand the FDA is aware of this issue and announced earlier this year that in November, 2024 warning letters were issued to six firms that were selling unapproved drugs that do not contain phenobarbital and that claim to treat and control seizures in dogs.

Question. In addition, has the FDA considered sending letters to companies prescribing or dispensing unapproved phenobarbital human drugs in lieu of an approved veterinarian phenobarbital drug?

Answer. CVM published a CVM Update following the conditional approval of Fidoquel-CA1 (phenobarbital tablets) for dogs on September 6, 2023, that included the statement, "Unapproved phenobarbital tablets from the human drug marketplace have historically been used in veterinary medicine to help control seizures in dogs. Fidoquel-CA1 are the only phenobarbital tablets that have received the agency's conditional approval for safety, quality manufacturing and reasonable expectation of effectiveness." CVM Updates are posted on our website and are also sent to various stakeholders.

Question. Given that "Dear Veterinarian Letters" and "Dear Pharmacy Professional Letters," are issued by the FDA, has the agency considered appropriately notifying veterinarians and pharmacists of the availability of the FDA-approved phenobarbital drug for treatment of their animal patients in lieu of unapproved phenobarbital preparations intended for human use?

*Answer.*When CVM conditionally approved Fidoquel-CA1 (phenobarbital tablets), a CVM Update was issued (FDA Conditionally Approves Phenobarbital Tablets to Control Seizures in Dogs with Idiopathic Epilepsy FDA). This CVM Update explains that Fidoquel-CA1 tablets are the only phenobarbital tablets that have received the agency's conditional approval for safety, quality manufacturing, and reasonable ex-

pectation of effectiveness. The CVM Update further explains that conditional approval allows an animal drug sponsor to legally market its product after demonstrating that the drug is safe and manufactured in accordance with full approval standards, and that there is a reasonable expectation of effectiveness for use. At this time, CVM does not intend to issue a "Dear Veterinarian Letter" or "Dear Pharmacy Professional Letter" about Fidoquel-CA1, as this information is already captured in the CVM Update. The sponsor of Fidoquel-CA1 was encouraged to share the CVM update with veterinarians and pharmacy professionals.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

Question. The Prescription Drug User Fee Act (PDUFA) was established in 1992 to address concerns regarding delays in the FDA's regulatory review of new medications for patients. Congress enacted PDUFA as a bipartisan approach to ensure that the American public receives the high-standard regulatory authority it deserves. PDUFA performance goals are designed to enhance the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles required for approval. Compared to its inception in 1992, significant progress has been made. However, despite the shared commitment between the U.S. FDA and the regulated industry, recent performance signals have raised concerns: 1) inconsistent first cycle approval rates, 2) fewer priority reviews granted in 2024 compared to the past 5 years, and 3) delayed responsiveness to meeting requests from companies developing medications for patients. What specific measures will be implemented to improve FDA performance?

Answer. FDA has worked and will continue to work diligently to meet its PDUFA performance goals. The FDA responds to each of the performance signals identified in this question:

The rate of first cycle approval is not a PDUFA performance goal; however, PDUFA commitments negotiated between FDA and regulated industry can contribute to greater first cycle approvals of marketing applications. As published in CDER's New Drugs Approval Reports, approvals of novel therapies in the first review cycle have consistently been well above 50% for the past 4 years: 86% in 2021 (43 out of 50); 76% in 2022 (28 out of 37); 84% in 2023 (46 out of 55); and 74% in 2024 (37 out of 50). For 2025, CDER has approved 19 novel therapies as of July 3, 2025, and 15 (79%) of these are first cycle approvals. CBER's first cycle approvals were 89% in 2021 (8 out of 9); 100% in 2022 (12 total); 82% in 2023 (9 out of 11); and 90% in 2024 (9 out of 10).

The number of priority reviews granted is also not a PDUFA commitment and instead reflects the type of marketing applications submitted to the FDA. Priority review is granted only if the marketing application meets the criteria for this expedited review program. Similar to the data for first cycle reviews, this information is provided in CDER's New Drugs Approval Reports, and the percentage of novel drugs approved that were designated priority review has consistently been above 50% for the past 4 years: 68% in 2021; 57% in 2022; 56% in 2023; and 56% in 2024. Of the 19 novel therapies approved in 2025 thus far, 10 (53%) were priority reviews. Of CBER approved products, there were high percentages of priority designated products: 78% in 2021; 75% in 2022; 73% in 2023; 70% in 2024.

Although neither of these above metrics is a PDUFA performance goal, FDA's ability to consistently deliver in both of these areas is a reflection of the extensive engagement between FDA and regulated industry throughout drug development.

In regard to your third concern, providing a timely response to meeting requests by either granting or denying the request is a PDUFA performance goal. FDA has historically met or exceeded this goal for most meeting types. To continue to maintain our PDUFA performance, FDA is committed to hiring, training, and retaining quality scientific staff across multiple disciplines.

Question. Complete Response Letters (CRLs) from the FDA for all approved products have remained relatively constant since 2018, but the proportion of those CRLs that can be attributed to manufacturing and quality-related issues has increased substantially. CRLs can arise for a wide range of issues, but with good, prompt communication between the FDA and sponsors there can be opportunities to avoid CRL and achieve a First Cycle Approval.

Given the increasing proportion of CRLs for manufacturing and quality-related issues, what steps will FDA take to improve communication with sponsors during the review and adjust the timing of manufacturing inspections to reduce unnecessary CRLs and accelerate patient access to innovative medicines?

Answer. Timely interactive communication with sponsors during drug development is a core Agency activity and helps achieve the Agency's mission to facilitate efficient and effective drug development programs.

FDA publishes policy documents such as guidance documents, compliance programs, and manuals of policies and procedures to facilitate an applicant or manufacturer's understanding of requirements and recommendations, and FDA business processes. This information enables applicants and manufacturers to proactively understand and meet pharmaceutical quality standards before submitting an application for review.

After FDA receives an application, FDA'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. 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.

In addition, we have initiated a new program for Post-Warning Letter Meetings (PWLM) regarding a facility's ongoing efforts to remediate current good manufacturing practice (CGMP) deficiencies.

Beyond the User Fee Commitments on facility inspections/evaluations, FDA has enhanced existing practices to provide earlier communication to a sponsor or applicant when any facility inspection, not just preapproval, may impact approvability to promote interaction between sponsor/applicant and their manufacturing facility to attempt to remediate the inspection observations prior to the application goal dates.

To avoid first-cycle CRLs due to manufacturing and quality issues, FDA continues to recommend that applicants/sponsors conduct due diligence to audit their manufacturing facilities, ensure they are meeting CGMP requirements that help protect patients and to provide access to high quality, safe, and effective medicines. Leveraging pre-submission meetings with the FDA and applying current FDA guidance and advice to their submissions, can help alleviate challenges that occur when a submission is of poor quality or does not incorporate recommendations found in publicly available guidance.

FDA works with all sponsors to resolve issues and help speed development of new products, while maintaining high, scientifically based safety and efficacy standards.

Question. Considering the decrease in the percentage of novel drugs approved first in the US from 86% in 2016 to 64% in 2023, what actions will be taken to ensure the FDA has adequate resources to uphold its high standards for regulatory review and enhance transparency in the review process to accelerate American access to innovative, safe and effective treatments?

Answer. The decrease in novel drugs approved first in the US is likely attributable to multiple factors. Pharmaceutical companies' decisions of where to first bring a novel drug to the market is likely based on a variety of business considerations, most of which would be beyond FDA's expertise and ability to opine on. It's also worth noting that the proportion of first-in-class drugs has increased from 2023 (36%) to 2024 (48%), indicating that drugs with novel mechanisms of action may be starting to represent a larger proportion of novel drug approvals in the US.

FDA cannot comment publicly on specific drug development programs or existing or potential applications of unapproved products. However, FDA recognizes that drug developers and capital markets alike want predictability. To that end, FDA published more than 200 letters, known as complete response letters (CRLs). Many were issued in response to applications submitted to the FDA for approval of novel drug or biological products between 2020 and 2025. By making the CRLs available, the public now has significantly greater insight into the FDA's decision-making and the most common deficiencies cited that sponsors must address before their application is approved. The Agency is in the process of publishing additional CRLs from its archives and is continuously exploring ways of providing the public with greater transparency into its decision-making process.

Commissioner Makary, you should know that Kansas is home to part of the Animal Health Corridor, which has more than 300 animal health companies—the largest concentration in the world. The animal health industry works with farmers and ranchers, government agencies, and veterinarians to ensure the health and safety of animals, humans, and the food supply. The Center for Veterinary Medicine (CVM) at FDA has long been an agency operating independently with the unique mission to review food, food additives, and drugs for animals to ensure they are safe and effective for the market.

Question. How will FDA ensure the animal product review functions at CVM can not only continue, but be improved?

Answer. CVM will continue to recruit scientific reviewers to maintain essential staffing levels and specialized expertise to ensure compliance with statutory and user fee goals. Integration of artificial intelligence tools will help streamline current review processes, furthering efficient review determinations for new animal drugs.

Question. What changes are needed at CVM to improve the review process and allow more innovation to come to the market?

Answer. FDA believes that facilitating increased innovation is critical to supporting the agriculture industry and others working to support both human and animal health. The Agency has begun modernizing its approaches, including through the use of artificial intelligence, and it welcomes the opportunity to work with Congress on any approaches that may be useful in improving these efforts.

Question. In March, HHS Secretary Kennedy directed the FDA to explore rulemaking to revise the Substances Generally Recognized as SAFE (GRAS) Final Rule to eliminate the self-affirmed GRAS pathway.

What is the current status of this directive?

Answer. We are pursuing the Secretary's directive and exploring potential rulemaking to eliminate the self-affirmed GRAS pathway.

In the Spring 2025 Unified Agenda, FDA announced intent to publish a proposed rule, that if finalized would amend the Generally Recognized as Safe (GRAS) regulations in 21 CFR parts 170 and 570 to require the mandatory submission of GRAS notices for the use of human and animal food substances that are purported to be GRAS.

Question. If FDA were to eliminate this pathway, in part or whole, what does the FDA view as an adequate replacement or alternative that will not force food companies into a pipeline process that could be subject to excessive delays?

Answer. To give a sense of the current baseline of FDA GRAS reviews, the program currently completes review of an average of 85 human and animal foods GRAS notices per year. FDA's FY26 President's Budget request proposes investing additional resources to support FDA's capacity to assess the safety of exposure to chemicals in the food supply, including meaningfully exploring closing the Generally Recognized as Safe (GRAS) loophole and more quickly implementing a framework for proactive, systematic, and risk-based reassessment of chemicals used in food.

Further, the accessibility of certain information made available to the public on FDA's website through the GRAS Notice Inventory as well as publishing the Agency's determinations when a substance is deemed not GRAS will continue to provide transparency to the industry to help support GRAS submissions to the agency.

Question. How will FDA engage food producers, especially small manufacturers, as they look for regulatory certainty?

Answer. FDA values transparency and public engagement and will continue to engage with industry as we consider regulatory options for improving the GRAS program. FDA is initiating rulemaking regarding the voluntary GRAS notification program, and will issue a notice of proposed rulemaking and invite public comment as part of that process.

Industry members looking to consult with FDA on pre-market submissions can contact FDA's Office of Premarket and Additive Safety, which operates the Voluntary GRAS Notification Program, at premarkt@fda.hhs.gov for human foods and animalfood-premarket@fda.hhs.gov. for animal foods.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Makary, you have discussed the importance of medical innovation to improving the health of our Nation and made the comment that drug development takes too long for many patients who are suffering from diseases that have no current treatment.

During a recent media interview, you advocated for new regulatory pathways for rare disease drugs, allowing for their conditional approval based on a "scientifically plausible mechanism." You stated that in some instances, "You can't expect the companies to do a randomized, controlled trial; you'll kill innovation. You'll kill investment in those innovative ideas," Makary said.

Can you give us examples of what you are doing to ensure that the FDA under your leadership is moving quickly to advance new pathways for rare disease?

Answer. FDA exercises appropriate regulatory discretion for rare diseases to help safe and effective products come to market as quickly as possible in accordance with the approval standards established by law. We leverage numerous programs, tools, and resources, that serve to speed the availability of products intended to treat patients with serious and life-threatening diseases, while at the same time meeting

appropriate safety and effectiveness standards and facilitating the collection of scientific data that is relevant and reliable. An example of a new initiative we've launched that is intended in part to address unmet medical needs, including drugs to treat or prevent rare diseases is the Commissioner's National Priority Voucher (CNPV) Pilot Program.

Additional details can be found at the following website: https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program

We know that there are pending applications for rare diseases that have either missed their PDUFA dates or have recently extended their PDUFA dates.

Question. What are you doing to ensure your staff applies maximum regulatory flexibility as required by the law and works urgently to complete their reviews of rare disease applications on time, or even early, to meet the urgent medical needs of patients who are waiting for life-altering treatments).

Answer. See response to previously question.

Question. It's my understanding that FDA has an ongoing Unapproved Drugs Initiative to remove and replace drugs that do not have the required regulatory approval from the market. The Agency's website States, "FDA has taken hundreds of unapproved prescription drugs off the market since 2006 and has executed multiple class actions announced through Federal Register Notices". FDA's guidance to industry encourages manufacturers to seek FDA approval of these drugs and in return, the Agency uses a risk-based approach to remove unapproved drugs from the market that pose a risk to public health.

I am aware of a company who received approval for a phenobarbital sodium product in November 2022, which marked the first, and only, approval of phenobarbital for human use, yet thirty months later, the Agency has not utilized its enforcement authority to remove the unapproved drugs from the market. As explained to me, phenobarbital is a controlled substance and many of the unapproved drugs contain preservatives that the Agency has prohibited from use in products administered to neonates because of known toxicity.

I am concerned the Agency's lack of action threatens the integrity of the Agency's regulatory mission, discourages manufacturers from making the significant investment to seek FDA approval, and poses health risks to these patients. I am hopeful that under your leadership the Agency will prioritize this important initiative.

Will you commit to reviewing this issue in a timely manner to ensure patients are receiving the safest, and most effective drugs?

Answer. FDA approved Sezaby (phenobarbital sodium) in November 2022 solely for the treatment of neonatal seizures in term and pre-term infants. Sezaby is the first 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.

There are a number of unapproved phenobarbital sodium injection products currently on the market. These products generally are indicated 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.

FDA exercises a risk-based approach to prioritizing enforcement action regarding unapproved drugs. This involves considering all the facts of a given circumstance and focusing on enforcement priorities for drugs that pose the highest risk to public health without imposing undue burden on patients or unnecessarily disrupting the availability of medically necessary drugs on the market.

The Agency is currently reviewing a Citizen Petition regarding unapproved phenobarbital sodium injection drugs, and will respond to the Petition as soon as possible and post the response to the public petition docket.

Question. A new study presented on Capitol Hill yesterday highlights a critical gap: most healthcare professionals misunderstand the risks of nicotine and remain unaware of the FDA's role in authorizing smoke-free alternatives. They continue to equate nicotine with cancer, despite evidence that it's the smoke- not nicotine-causing disease. These misperceptions are preventing pivotal informed patient counseling. This same study showed the overwhelming majority of healthcare providers want clear, accurate guidance from FDA on authorized smoke-free products so they can share this information with their patients.

Will you commit to immediately prioritize educating the medical community on the continuum of risk and the public health potential of authorized smoke-free products?

Answer. FDA agrees that the medical community has a unique and important role to play in the education of adults who use tobacco products. FDA's CTP currently disseminates educational content explaining that tobacco products exist on a continuum of risk, with combustible products such as cigarettes being the most harm-

ful. CTP's "The Relative Risks of Tobacco Products" webpage [7] informs consumers and stakeholders about tobacco product relative risk. CTP has also published commentaries [8] discussing evidence-based opportunities for addressing misperceptions about tobacco product relative risks, including the role of medical providers as trusted messengers of relative risk messaging for adults.

Question. Commissioner Makary, FDA places all tobacco and nicotine products on a continuum of risk, with smoking being the most harmful. Recent data shows that most medical professionals do not understand the continuum of risk across nicotine products and often misperceive nicotine- not smoke- as the main cause of tobacco related diseases.

Will you commit to educating the medical community on the relative risks of tobacco and nicotine products, including FDA-authorized smoke free alternatives?

Answer. See response to previously question.

Question. Skin cancer is the most common cancer in the United States, affecting over five million Americans annually and resulting in significant healthcare costs. Despite its prevalence, four out of five cases of skin cancer can be prevented through sun-safe practices, including the use of effective sunscreens. The United States has not approved a new sunscreen active ingredient since the 1990s while our peer countries have moved several generations ahead of the U.S. in terms of sunscreen technologies.

Considering the preventable nature of skin cancer and the importance of effective sunscreens, do you commit to utilizing your budget to improve the approval process for new sunscreen active ingredients to ensure that Americans have access to the most advanced and effective sun protection products?

Answer. FDA is strongly committed to timely evaluation of any industry submission requesting that FDA determine conditions under which a new active ingredient is generally recognized as safe and effective (GRASE) for use in sunscreens to enable that ingredient's use in OTC monograph sunscreen products marketed in the U.S. Once an active ingredient is included in the OTC sunscreen monograph (subject to an exclusivity period afforded by section 505G of the FD&C Act, if applicable), each sunscreen product that uses that ingredient can be marketed without first being reviewed by FDA, so long as that product conforms to the sunscreen monograph conditions and other general requirements. This can make it easier for firms to introduce individual sunscreen products to the market. The Agency has taken significant steps to help advance the development of submissions that could support a positive GRASE determination for use of new sunscreen active ingredients. We will continue to dedicate resources to this goal as well as to evaluation of any submissions industry makes.

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

Question. I am concerned about the workforce reductions at the FDA and the impact they will have on the FDA's ability to complete statutorily mandated functions of the Agency. Please provide responses to the following questions:

—How many people are employed by the FDA as of May 29, 2025?

—How many people were employed by the FDA on January 19, 2025?

Answer.

Position Type	As of Jan 19, 2025	As of May 29, 2025
Advisory Committee	1785	1667
Civilian	19166	17821
Commissioned Corps	954	945
Total	21905	20433

[7] https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products

[8] https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-director-co-authors-new-journal-commentary-relative-risks-tobacco-products

PROBATIONARY FIRINGS

Question. How many probationary staff were let go from the FDA since January 20th, 2025? Please provide a total and breakdown by Center.

—Of the probationary staff fired, how many were brought back?

—What were the factors used to determine which staff to bring back?

Answer. On 2/15/2025, the following probationary employees were placed on administrative leave:

Center/Office/Program	Employees
CDER	13
CDRH	229
CTP	108
CVM	41
HFP	89
OC	202
OII	12
Total	694

On 5/8/2025, the following probationary employees were terminated:

Center/Office/Program	Employees
CDER	1
CDRH	28
CTP	74
CVM	18
HFP	20
OC	93
OII	1
Total	235

The following probationary employees were not terminated at the time for the following reasons:

Reason Not Terminated	CDER	CDRH	CTP	CVM	HFP	OC	OII	Total
Probationary Period Completed	0	71	7	12	18	14	0	122
Data Correction—Not Probationary	0	2	13	0	2	18	0	35
Leadership Determination	0	108	4	36	22	11	181	
Resigned	0	3	2	1	4	5	0	15
Remained on Admin Leave Pending RIF	12	17	12	6	9	50	0	106
Total	12	201	34	23	69	109	11	459

Probationary employees restored due to leadership determination were based upon mission requirements and the needs of the agency.

REDUCTIONS IN FORCE (RIF)

Question. How many people were let go because of the RIFs that occurred on April 1, 2025? Please provide a total and breakdown the RIFs by Center.

—Of the employees who were a part of the RIF, how many have been brought back? Please breakdown by Center.

—What were the factors used to determine which staff to bring back?
Answer.

Data	CBER	CDER	CDRH	CTP	CVM	HFP	OC	OII	Total
Positions impacted by RIF as of 4/1/2025	193	825	233	220	148	256	415	170	2460
Positions impacted by RIF Rescissions as of 7/14/2025	55	214	73	109	89	94	103	24	761
Positions impacted by RIF as of 7/14/2025	133	593	167	165	113	65	333	144	1713

Rescission decisions were based upon impact analysis and impact to mission.

DEFERRED RESIGNATION PROGRAM

Question. How many people at the FDA took the offer for the Deferred Resignation Program? Please provide a total and breakdown by Center.
—Were there staff at the FDA who sought to participate in the Deferred Resignation Program but were not allowed to? If so, what factors were used to determine which staff at the FDA could participate in the Deferred Resignation Program?
Answer. Please see the below table. No eligible staff were disallowed from participating in the deferred resignation program if they indicated their interest to participate by the program deadline.

COP	DRP Participants
CBER	24
CDER	85
CDRH	55
CTP	21
CVM	18
HFP	51
OC	102
OII	100
Total	456

EARLY RETIREMENTS

Question. How many people at the FDA have opted into the Voluntary Early Retirement Authority or Voluntary Separation Incentive Program since January 20, 2025? Please provide a total and a breakdown by Center.
—How many people at the FDA combined early retirement authorities with the Deferred Resignation Program?
Answer. See the below table for the number of individuals signed up for the VERA and/or VSIP program after the DRP program was closed. As part of the DRP program, 91 people indicated they were participating under the VERA retirement authority.

COP	DRP Participants
CBER	47
CDER	112
CDRH	72
CTP	30
CVM	34
HFP	107

COP	DRP Participants
OC	209
OII	110
Total	721

HIRING

Question. You stated in your testimony that you are currently hiring scientists and other staff. How many people and which positions are you actively hiring for across the agency? Please provide a total and breakdown by center or office as well as a complete list of positions for which the agency has sought and received an exemption from the Office of Personnel Management to the ongoing hiring freeze. Please also share the links to positions the FDA is hiring for on USA Jobs.

Answer. FDA has sought and received an exemption from OPM for 1,000 positions for reviewers, inspectors, and criminal investigators. FDA plans to move forward with this hiring throughout the course of the summer and fall. FDA will continue to provide updates to the Committee, requested.

Question. What are you doing to ensure that all inspections move ahead as planned and to improve the rate of attrition among inspectors? How will that be reflected in the Fiscal Year 2026 budget request?

Answer. FDA continues to identify the highest priority inspectional work and is taking steps to improve efficiencies in conducting inspections. This includes using feedback mechanisms and working to centralize and enhance key operational functions across the Agency, empowering the Office of Inspections and Investigations (OII) to focus more directly on its core mission-related work.

FDA has also resumed the recruitment and hiring of new investigators. FDA is addressing attrition through various means, including the use of hiring authorities and through improved training processes.

OII and the Centers have ongoing collaborations to improve the efficiency and effectiveness of investigator training, with the goal of lessening the time for new investigators to begin conducting independent inspections, while ensuring the FDA maintains its gold standard for the quality of our inspection programs to protect public health and safety. Through this training modernization effort, which includes experiential learning and on the job training, early engagement and meeting staff training needs will also lessen the risk of attrition.

The FY 2026 President's Budget proposes funding levels for OII to support all of these efforts.

Question. One known way to cure type 1 diabetes (T1D) is through cell therapies, which replace destroyed beta cells with external cells that make insulin and protect them so that they maintain function long-term. The advancement of cell therapies holds immense promise for transforming the lives of those with T1D and other diseases. However, challenges and uncertainty in the therapy pipeline, including review timeliness and insufficient patient and expert input, are causing delays. What steps will you take to ensure cell therapies can reach the T1D populations that need them without unnecessary delay?

Answer. FDA works with all sponsors to resolve issues and speed development of new products, while maintaining high standards for safety and efficacy that are based on science. Clinical holds for Investigational New Drug applications (INDs) investigating Cell and Gene Therapy (CGT) products for treating various diseases, including Type 1 diabetes, have markedly decreased in the past few years. The decline results from many 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.

FDA also works with patients and their advocates to ensure that the patient voice is included in the regulatory process, and that reviewers have access to the latest science. For example, to advance Type 1 diabetes products, CBER works with Breakthrough T1D (formerly the Juvenile Diabetes Research Foundation) on an annual Cell Therapies Educational Seminar series, where outside experts provide science-based lectures on emerging technologies for the treatment of diabetes. Prior to the 2023 approval of LANTIDRA (donislecel-jujn), a cellular therapy product composed of purified allogeneic deceased donor pancreas derived islets of Langerhans for the treatment of certain adults with Type I diabetes, an FDA advisory committee

meeting was held where the committee and FDA reviewers considered testimony from patients who participated in clinical studies for the product.

FDA remains committed to advancing the development of safe and effective CGT products to treat serious or life-threatening conditions, including various rare diseases, forms of cancer, and Type 1 diabetes. When combined, FDA's scientific and patient-focused efforts increase predictability in the regulatory process to support a robust CGT product development pipeline.

Question. FDA participation in external scientific efforts that advance development and review of new therapies is critical. Such pre-competitive engagement guides the research to align with FDA expectations in real time, keeps the FDA informed on the current state of science, and makes future reviews more efficient. We've heard recent reports that FDA staff have declined invitations to participate in such external scientific efforts, citing bandwidth and the need to focus on PDUFA activities. We've also heard that previously planned and recurring events between the FDA and non-governmental organizations have been cancelled by the agency. When will external engagement at these types of events resume? What is the agency's policy on external engagement?

Answer. For more than 100 years, the FDA has been working to carry out our mission of promoting and protecting public health, and engaging with the public and the scientific community is a key part of that work. While there was a brief pause for certain types of engagements and communications at the agency at the beginning of the new administration, external engagements have resumed and remain a priority. The commissioner also recently began a series of Expert Panels to engage the public, media, and the scientific community on important public health topics, which have been open to the public and livestreamed. This initiative is part of the FDA's broader efforts to apply rigorous, evidence-based standards to ingredient safety and modernize regulatory oversight, thoroughly considering evolving science and consumer health.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

Question. In 2022, Congress passed the bipartisan Modernization of Cosmetics Regulation Act (Moca) which finally empowered the FDA with the tools it needs to better ensure cosmetic products are safe. MoCRA passed over 2 years ago, and the FDA has not put out any Good Manufacturing Practices for any cosmetic products. When does FDA expect those to be finalized?

Answer. FDA has listed a proposed rule, "Good Manufacturing Practice for Cosmetic Product Facilities," on the Unified Agenda as a long-term action.

Question. Do you have a timeline for finalization?

Answer. MoCRA established timeframes requiring the Secretary to publish a proposed rule not later than 2 years after December 29, 2022, which was on December 29, 2024, and to publish a final rule not later than 3 years after December 29, 2022, which is on December 29, 2025. Although the statutory date for publishing the proposed rule has passed, FDA is prioritizing this rulemaking.

The Long-Term National Strategy to Increase the Resiliency of the Infant Formula Market outlines several actions the FDA should be taking to protect the integrity of the infant formula supply chain, including taking measures to prevent contamination, and incentivizing new infant formula manufacturers to enter the U.S. market.

Question. What are you doing to implement the recommendations within the National Strategy to improve the integrity of infant formula supply chain in the U.S.?

Answer. FDA has taken numerous steps to implement recommendations in the Long-Term National Strategy to Increase the Resiliency of the U.S. Infant Formula Market:

—In October 2024, FDA established the Office of Critical Foods to oversee the regulation of critical foods (i.e., infant formula and medical foods) and continues prioritizing staff hiring, including having dedicated investigators to conduct infant formula inspections. The FY 2026 President's Budget proposes increased funding for infant formula work.

—FDA has worked to enhance infant formula supply diversity by providing a pathway for domestic and foreign infant formula manufacturers that were provided enforcement discretion to continue marketing their products while they worked to meet all FDA requirements. All the manufacturers participating in the enforcement discretion transition pathway submitted their new infant for-

mula submissions, for a total of 12 new infant formula products, consistent with FDA's timing expectations.

—FDA is enhancing post-market surveillance by taking the following steps:

—Released draft guidance in December 2024 for infant formula manufacturers on notifying the FDA of permanent discontinuances or interruptions that are likely to lead to a meaningful disruption in the U.S. supply.

—Engaging with infant formula manufacturers to monitor and assess production levels, ingredient supply chains, and final product distribution. FDA also monitors in-stock rates to track product volume and variety, as well as sales data to identify early signals of potential disruption.

—Working with industry to establish a system for voluntary reporting of product samples that test positive for Cronobacter or Salmonella.

—FDA collaborates with USDA's Special Supplemental Nutrition Program for Woman, Infants, and Children (WIC) to help ensure infant formula manufacturers meet evidence-based standards while exploring enhanced contract flexibilities during supply disruptions.

Question. How are you ensuring this work remains ongoing in light of agency reorganization efforts, probationary firings, deferred resignations, and RIFs?

Answer. FDA's Human Food Program is dedicated to and continues to prioritize the work contained in the Long-Term National Strategy and Operation Stork Speed. Overall, the functions outlined in the strategy are all related to critical foods work and, therefore, were not substantively affected by staff reductions. Additionally, despite the Federal hiring freeze, we have been able to post some high-priority job vacancies, one of which is the Director of the Office of Critical Foods, who will be directly responsible for the oversight of infant formula.

I am concerned that there was not a public search for the Director of the Center for Biologics and that Title 21 hiring authority may have been used. Title 21 was part of the landmark 21st Century Cures Act that I championed, was intended to help the FDA bring experts on board quickly and at relatively competitive salaries. Title 21 hiring authorities were drafted as such to prevent the hiring of political appointees.

Question. Can you confirm whether Dr. Prasad was hired under Title 21 and, if so, explain why a public search was not conducted, as has been done for all of the other recent senior leadership positions at the centers?

Answer. Following a nationwide search, Dr. Prasad was hired under the Title 21 hiring authority as the best candidate available. Dr. Prasad's extensive background as a medical practitioner, an author, and in academia made him uniquely qualified for the critical position as Director of the Center for Biologics Evaluation and Research. Given the importance of this position, it was not in the public interest to leave it vacant for many months. Title 21 allowed FDA to expedite the recruitment process and more efficiently onboard Dr. Prasad, as the Agency has done with other highly qualified experts in the past.

This approach aligns with the legislative intent of the 21st Century Cures Act to help the FDA attract top talent quickly with competitive salaries.

Question. If not hired under Title 21, what authority was used to hire Dr. Prasad?

Answer. Dr. Prasad was hired under Title 21 hiring authority.

Question. Do you commit to doing public searches for the Center for Drug Evaluation and Research and the Human Foods Program, who currently have acting directors?

Answer. As of December 3, 2025, Dr. Tracey Beth Hoeg is the acting Director of the Center for Drug Evaluation and Research. FDA has made a permanent hire of Kyle Diamantes as the Deputy Commissioner for Human Foods. Both are extremely qualified and have already provided great contributions in support of public health.

Question. The FDA is now requiring Pfizer and Moderna to expand warning labels of their COVID–19 vaccines to include risk of heart inflammation in adolescents and young men ages 18 to 24. This was determined after FDA's own analysis of insurance claims indicated an increased incidence from the 2023–2024 formulations. Will FDA be releasing this report and the data you used to determine this new practice?

Answer. In a post-approval U.S. study[9] funded and co-authored by FDA, study authors noted that myocarditis and pericarditis is a known complication of mRNA 9 vaccines, most frequently seen in adolescent and young adult males 1 to 7 days following vaccination.

Using data in a separate analysis, the estimated incidence rate of myocarditis and pericarditis during the 1–7 days following administration of the 2023–2024 formula

[9] https://www.sciencedirect.com/science/article/pii/S2589537024003882?via%3Dihub

of mRNA COVID–19 vaccines was approximately 8 cases per million doses in individuals 6 months through 64 years of age, with the highest rate among males aged 12–24 years at approximately 27 cases per million doses. These estimates do not provide an analysis of or evidence of an increased risk over time in any age group, but a standalone estimates of risk in the 1 to 7 days following the 2023–2024 Formula of mRNA COVID–19 vaccines.

The BEST initiative conducts continuous monitoring and assessment of the safety of vaccines, including the mRNA COVID–19 vaccines. These safety studies include prespecified analyses that assess whether the risk of an outcome is elevated and associated with vaccination, and results can be found on the BEST. Results of the 2023–2024 formula mRNA COVID–19 vaccine safety studies have been submitted for peer-reviewed publication and are currently under review.

Question. As FDA Commissioner, you have talked about increasing the transparency of the agency. Did you share the data mentioned in Question 4 with outside experts to help the FDA make a decision about including this risk on vaccine labels?

Answer. Information about myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) following vaccination with these mRNA COVID–19 vaccines has been included in the labeling since 2021. FDA has considered presenting the updated myocarditis/pericarditis data at a future Advisory Committee on Immunization Practices meeting if the opportunity arises. FDA is also evaluating the best way to disseminate these results.

Question. The FDA is essentially limiting COVID–19 vaccine approvals to people 65 and older and those with underlying conditions, because pharmaceutical companies are unlikely to conduct randomized control trials of updated vaccine formulations each year, as your new policy States they need to do. In alignment with your goal of transparency, will you please share which outside experts reviewed FDA recommendations on this policy change?

Answer. FDA notes that vaccine manufacturers have agreed to conduct additional randomized controlled studies in individuals 50 to 65 years of age without high-risk conditions and the Agency plans to review and take appropriate action on applications for vaccines with 2025–26 COVID–19 vaccine formulations. Further, it has not been established that updated vaccine formulations will be necessary each year in perpetuity. Please refer to "An Evidence-Based Approach to Covid-19 Vaccination" in New England Journal of Medicine which was published after discussion with the expert editorial staff of NEJM.

Question. Did any of the outside experts feel that this policy change was unwarranted?

Answer. Please reference previously question.

Question. What ethical concerns about this policy change were expressed?

Answer. Please reference previously question.

Question. What data did you present to outside experts to determine that this policy was evidence-based?

Answer. Please reference previously question.

Question. The Make American Healthy Again Commission is recommending that pesticides be reduced, as they are a driver of chronic health conditions in American children. What process will you create to start broad conversations with experts outside of the FDA to determine next steps regarding pesticide use?

Answer. FDA will take the following steps regarding appropriate pesticide use, including by engaging experts outside of the FDA as appropriate: 1) monitor pesticide residues in the American diet through compliance surveys and the FDA Total Diet Study while also providing transparent reporting of that data to all applicable stakeholders, including those in the US government; 2) coordinate with USDA and States to inform data-driven policies; 3) as appropriate, provide technical support to EPA in their role to reduce unnecessary or harmful pesticide use; and 4) as appropriate, engage in any reforms to Federal programs that favor traditional field crops over organic foods when and if FDA is the appropriate agency to be engaged.

Question. How will you identify best practices for improving childhood nutrition as a driver of childhood chronic disease?

Answer. Improving nutrition is one of the most effective public health interventions for reducing diet-related chronic illnesses and premature death. The vast majority of Americans, including children, do not eat enough fruits, vegetables, dairy, seafood, whole grains, and healthy oils. Researchers have estimated that more than half of calories consumed by adults and children in the U.S. are from foods considered to be ultra-processed, which are linked to increased risk of negative health outcomes. There are many best practices that can and are being implemented across the Federal Government to support Americans in meeting recommendations for a healthy eating pattern. For example, FDA is encouraging industry to make healthier foods and helping provide nutrition information so that consumers can

make informed choices. Further, FDA recently updated the definition of the "healthy" content claim to help consumers identify foods that are particularly useful as the foundation of a diet that is consistent with dietary recommendations. We will continue to work with Federal partners to research and identify best practices, including through FDA and the National Institutes of Health's recently announced Nutrition Regulatory Science Program.

Question. Will you work with USDA to ensure that the SNAP, WIC, and the National School Lunch Program is fully funded so that children and families have access to healthy food?

Answer. Reducing childhood chronic diseases is a priority for this Administration and FDA. The U.S. Department of Agriculture (USDA) is responsible for administering these programs and FDA regularly collaborates with USDA and other Federal agencies on a variety of nutrition programs and issues.

Question. What do you see as the biggest barrier to improving childhood nutrition in the U.S. and what steps will you take to address this?

Answer. While there are numerous factors that impact children's health, improving nutrition is one of the most effective public health interventions for reducing diet-related chronic illnesses. FDA is committed to addressing the root causes of chronic disease through its authorities, including by helping provide people with information and tools to help support healthy food choices while improving the nutritional quality of the food supply.

FDA is already moving forward with helping provide Americans with 'at-a-glance' information they can use to make better informed nutritional decisions, including with its front-of-package nutrition labeling work. FDA is also working with USDA and other Federal partners to develop a definition for ultra-processed foods to support uniform research and policies and provide increased transparency to consumers about the food they eat. The FY 2026 President's Budget includes a request to increase funding for FDA's nutrition work, including expanding a new pilot program to help schools research nutrition and transition to healthier foods to help ensure children in our Nation are served nutritious, wholesome food that will set them up for a healthy future.

Question. You recently held a virtual FDA Expert Panel on Talc. Could you please share the takeaways from that panel, and what FDA's next steps are related to address talc exposure?

Answer. As part of the Trump Administration's commitment to transforming the future of American health care and restoring trust in public health, the U.S. Food and Drug Administration held an independent panel of scientific experts for a roundtable discussion in a public forum on Tuesday, May 20, 2025. Using gold-standard science and a transparent process, this historic roundtable set the public standard for future roundtables, evaluating the safety and necessity of talc as an additive in food, drug, and cosmetic products. The expert panel, comprised of leaders in their respective fields, reviewed the latest scientific evidence, evaluated potential health risks, explored alternatives, and offered their recommendations for action. The Agency will take a close look at the literature shared by the panel and re-engage with stakeholders as questions emerge. Regarding additional steps, FDA continues to prioritize this issue and is working toward rulemaking.

Question. What process did the FDA use to determine who should be on the Expert Panel?

Answer. The panel was designed to bring together experts with a broad representation of perspectives to discuss the issue.

Question. You have indicated that you will soon hold an FDA roundtable on menopause hormone replacement therapy. Could you please share more details about these plans?

Answer. FDA will host the "FDA Expert Panel on Menopause and Hormone Replacement Therapy for Women" on July 17, 2025, from 1:00—3:00 ET. Panelists include Marty A. Makary, M.D., M.P.H., FDA Commissioner and Sara Brenner M.D., M.P.H., FDA Principal Deputy Commissioner. Additional panelists include those with expertise in various aspects of menopausal health, including gynecological, urological, cognitive, bone, and cardiovascular care. The purpose of the meeting is to discuss the latest understanding of the benefits and safety of menopause hormone therapy. The event will be live streamed and can be viewed over the FDA's YouTube channel.[10]

Question. Is the FDA going to be reviewing only hormonal treatments for menopause, or will you also consider non-hormonal treatments?

Answer. The FDA Expert Panel discussion will focus on hormonal treatments for conditions related to menopause. Regarding drugs to treat menopausal symptoms

[10] https://www.youtube.com/user/USFoodandDrugAdmin

more broadly, FDA considers development programs and applications for hormonal and non-hormonal medications.

Question. What is the FDA currently doing to ensure that the accelerated approval pathway is available for rare disease treatments?

Answer. FDA supports drug development through the accelerated approval pathway in many ways. Sponsors are encouraged to communicate with the Agency early in the drug development process concerning (1) the potential eligibility of a drug for accelerated approval, (2) proposed surrogate endpoints or intermediate clinical endpoints, (3) clinical trial designs, and (4) the planning and conduct of confirmatory trials. In addition, the Rare Disease Endpoint Advancement Pilot Program is a PDUFA VII commitment designed to support novel efficacy endpoint development for drugs that treat rare diseases.

FDA's recent initiatives also help facilitate the use of the accelerated approval pathway for rare disease therapies. For example, the Rare Disease Innovation Hub launched in 2024 serves as a point of collaboration and connectivity between CBER and CDER with the goal of ultimately improving outcomes for patients with rare diseases. The Hub program is intended to support both internal alignment and communication with the rare disease community on a variety of topics, including guidance on surrogate endpoints and accelerated approval. Communication with rare disease stakeholders is an important aspect of facilitating rare disease product development.

Approximately 60–70% of drugs approved under the accelerated approval pathway are oncology drugs, including drugs to treat rare cancers. Quite often the appropriate regulatory pathway (e.g., traditional approval or accelerated approval) for drugs intended to treat rare cancers is discussed early on in pivotal trial design.

QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

Question. When Congress gave FDA the authority to oversee tobacco products, it established an appropriately high bar for a new tobacco product to enter the market. Under the standard established in the Family Smoking Prevention and Tobacco Control Act, manufacturers must provide strong evidence that the benefits of introducing a new tobacco product to the market will outweigh the risks.

In reviewing applications for e-cigarettes in recent years, FDA has determined that flavors pose an additional level of risk because they are much more appealing to youth than tobacco-flavored products. Because of this higher level of risk, FDA has required e-cigarette manufacturers to show that a flavored e-cigarette will be more effective at helping a smoker to stop smoking cigarettes than a tobacco-flavored e-cigarette. A unanimous Supreme Court recently upheld this requirement. The vast majority of e-cigarette applications for flavored products have not been able to provide the evidence of a benefit to smokers that outweighs the risk to kids.

Under your leadership, will FDA continue to require robust evidence that the benefit of a flavored product in helping smokers quit is sufficient to outweigh the demonstrated risk of the flavor to youth?

Answer. The Federal Food, Drug and Cosmetic Act (FD&C Act) requires that FDA deny a premarket tobacco application (PMTA) where it finds "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." FDA is committed to its responsibility to protect public health, follow the law, and carefully review the science presented in each premarket application when determining if a product meets the standard for marketing.

Flavors are an important consideration in the review of a PMTA because of their impact on potential toxicity, consumer perceptions, and health risks-especially to youth. The burden is on the applicant to provide evidence to meet the public health standard provided by Congress. FDA will continue to consider whether PMTAs for flavored e-cigarette products contain evidence of an added benefit to adult smokers, as compared to tobacco-flavored e-cigarette products, that could outweigh the known and substantial risk of flavored e-cigarette products to youth.

Question. Do you think the premarket review process is an important way to keep e-cigarettes that are particularly appealing to young people off the market?

Answer. Ensuring new tobacco products undergo premarket evaluation by FDA is a critical part of the Agency's mission to protect the public health, particularly for the youth, and to reduce tobacco-related disease and death. As part of the evaluation of e-cigarettes, FDA determines whether to authorize the marketing of a new product under the "appropriate for the protection of the public health" standard and

will not authorize marketing if the applicant does not demonstrate that the public health benefit outweighs the risk to non-users, including youth.

Question. Earlier this year, dozens of staffers at the FDA's Center for Tobacco Products (CTP) were placed on administrative leave, including the Center's director. How many total FDA CTP employees have lost their jobs? How many have lost their jobs as a result of:

—The recent reductions in force announced by the Department on March 27, 2025 (including transfers to other Federal agencies)?
—The termination of probationary employees?
—Other Administration efforts to reduce the Federal workforce (e.g., early retirement and Fork in the Road)?

Answer. Thus far, no CTP employees have been removed as a result of the reduction in force, as they remain pending. 73 CTP probationary employees were terminated. A total of 51 employees voluntarily left their positions and made use of one of the incentive programs.

Question. For each office within FDA CTP (e.g., Office of the Director, Office of Management, Office of Regulations, Office of Science, Office of Health Communications and Education, and Office of Compliance and Enforcement), how many people have been removed from their positions and how many remain?

Answer.

Row Labels	Terminated (Probationary)	Other Termination	Retain
CTP	73	3	924
OFFICE OF THE CENTER DIRECTOR			27
OFFICE OF MANAGEMENT		2	19
OFFICE OF REGULATIONS			25
OFFICE OF SCIENCE	67	1	558
OFFICE OF HEALTH COMM & EDUCATION	3		55
OFFICE OF COMPLIANCE & ENFORCEMEN	4		240

Question. Which directors of offices within FDA CTP have been removed from their positions, placed on administrative leave, or transferred to other Federal agencies?

Answer. As of 7/26/2025, the Director for the Office of Science within FDA CTP is on administrative leave pending reassignment to IHS. In addition, the Director of the Center for Tobacco Products was initially placed on administrative leave pending reassignment to IHS but has since resigned.

Question. Does FDA CTP intend to spend the $712 million in tobacco user fees authorized under the Family Smoking Prevention and Tobacco Control Act and included in the FY 2025 Full-Year Continuing Appropriations and Extensions Act (Public Law 119–4)? Please indicate how CTP intends to spend its tobacco user fees for FY 2025, including, but not limited to, dollars spent on premarket review, enforcement of marketing and sales of illegal products, and Tobacco Centers of Regulatory Science.

Answer. In FY 2025, CTP plans to spend $680M in the following program areas:

Program Area	FY Planned Spending
Product Review, Scientific Research, and Research Infrastructure	$277M
Compliance and Enforcement	$164M
Public Education Campaigns and Communications	$80M
Leadership, Management Oversigt, and Administrative Services	$37M
Related Overheard Activities	$122M
Total Obligations:	$680M

Please note that because most of CTP's tobacco regulatory activities cut across product classes and programs, we do not track spending by tobacco product class or for specific programs such as premarket review or enforcement against illegally

marketed products. However, both PMTA review and Tobacco Centers of Regulatory Science spending is captured in the Product Review, Scientific Research, and Research and Research Infrastructure program area.

The Center's FY 2025 planned spending level is lower than its annual user fee collection amount for the following reasons.

—As a result of litigation, CTP no longer has the statutory authority to collect user fees from manufacturers and importers of premium cigars. For FY25, this means that about $16M in user fees will not be collected. When the litigation concludes, FDA intends to consider what options are feasible and statutorily authorized for reallocating the fees.

—Additionally, through the HHS cost efficiency initiative, CTP has reduced planned acquisitions spending in FY 2025 by the required $78.5 million. However, any unspent user fees in FY 2025 will be carried over and available to spend in FY 2026.

Question. What functions of CTP have been transferred to other offices at FDA or to other agencies? To which offices or agencies were they transferred?

Answer. None of CTP's functions have been transferred.

Question. What functions of CTP have been eliminated?

Answer. None of CTP's mission areas have been eliminated. The Center continues to perform all of its programmatic functions.

QUESTIONS SUBMITTED BY SENATOR GARY PETERS

Question. In response to questioning about FDA's suspension of programs to improve testing for potential H5N1 contamination in consumer products, including testing of milk, cheese and pet food, due to mass layoffs, you testified that a Washington Post article "debunked" these concerns.

Please provide a copy of the Washington Post article you referenced in your testimony.

Answer. As requested, the Washington Post article, titled "FDA's milk testing program pause is not cause for alarm, experts say", can be found at the following: https://www.washingtonpost.com/food/2025/04/23/fda-milk-testing-program-paused/

Question. Has FDA suspended, scaled back, or changed any of its programs to monitor and test for H5N1 since January 20, 2025? If so, please explain FDA's actions and its reasoning for suspending, scaling back, or changing any of these programs.

Answer. FDA programs to test for H5N1 in animal and human food have not changed since January 20, 2025. A combination of FDA internal laboratories, USDA's National Veterinary Services Laboratory, and FDA's Veterinary Laboratory Investigation and Response Network are supporting testing of animal and human food products for H5N1 virus.

You also testified that FDA suspending milk testing was due to a "normally scheduled pause" to "recalibrate the equipment" and that it is "back up and running."

Question. Please provide the full schedule for the Interlaboratory Comparison Exercise as it stood on April 1, 2025.

Answer. As of April 1, 2025, the HPAI Interlaboratory Comparison Exercise (ICE) schedule was as follows:

Completed work:

Planning began in November 2024. Sample testing, including stability, was completed in March 2025.

Scheduled work from April 1:

April 2025: Finalize instruction documents and training materials for participating laboratories
April 28th 2025: Ship sample sets to laboratories
May 12th 2025: Laboratory results due
June 2nd 2025: Send preliminary report to laboratories
August 2025: Complete final report

Question. Please list all the entities that have or were scheduled to participate in the Interlaboratory Comparison Exercise as of January 20, 2025, or later, including those from FDA's Veterinary Laboratory Investigation and Response Network and food laboratories, the USDA's National Animal Health Laboratory Network, and private industry.

*Answer.*43 laboratories have participated in the HPAI Interlaboratory Comparison Exercise, as of January 20, 2025:

—21 state laboratories
—13 university laboratories
—2 private industry laboratories
—2 other government laboratories
—5 FDA Laboratories:
  —FDA Arkansas Human and Animal Food Laboratory
  —FDA San Francisco Human and Animal Food Laboratory
  —FDA Denver Laboratory
  —FDA New York Human and Animal Foods Laboratory
  —FDA Atlanta Human and Animal Food Laboratory

Question. Please describe all quality assurance programs FDA is currently carrying out with regards to identifying potential H5N1 virus contamination in human or pet food.

Answer. FDA testing is performed in accordance with the "FDA Regulatory Testing Laboratory Manual of Quality Policies," which was prepared to meet the requirements for the laboratories' accreditation to the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC 17025:2017). FDA HPAI RT-qPCR detection methodology incorporates internal amplification controls in the qPCR reactions in addition to surrogate virus extraction controls to establish confidence in laboratory results.

Question. Please list all staff positions within FDA's Human Food Program as of January 20, 2025 and a corresponding description of each position, including:

—The job or function the position relates to.
—Whether the position was filled on January 20, 2025.
—Whether there have been any changes to the staffing of the position since January 20, 2025, and if so, describe the specific change(s).
—Whether FDA has any plans to reduce or eliminate the position within the next 24 months, and if so, what it may or will be replaced with.

Answer. Below is a table noting each job function within HFP and the number of positions within that function. Because staffing is fluid and employees are hired, leave FDA, or move to other parts of the Agency, staffing levels may change on a day-to-day basis. FDA currently does not have plans to reduce or eliminate such positions within the next 24 months.

As of January 20, 2025, HFP had the following 1,965 employees:

Position Title	Positions
Acquisition Program Specialist	5
Acquisition Program Specialist Assistant Commissioner For Par	1
Acquisition Program Specialist Audiovisual Production Special	2
Acquisition Program Specialist Bio (Sensory-Organoleptic)	1
Acquisition Program Specialist Biological Science Lab Technic	1
Acquisition Program Specialist Biological Science Technician	2
Acquisition Program Specialist Biologist	176
Acquisition Program Specialist Biologist (Molecular)	1
Acquisition Program Specialist Biologist (Senior Science Advisor)	1
Acquisition Program Specialist Biologist (Reg Prog Expert)	1
Acquisition Program Specialist Branch Chief	7
Acquisition Program Specialist Branch Chief For Budget Formulation	1
Acquisition Program Specialist Branch Chief, Chemical Contami	1
Acquisition Program Specialist Branch Chief, Exposure Assessm	1
Acquisition Program Specialist Branch Chief, Supervisory Phar	1
Acquisition Program Specialist Budget Analyst	10
Acquisition Program Specialist Business Analyst	1
Acquisition Program Specialist Business Information Management	1
Acquisition Program Specialist Certification Control Assistant	1
Acquisition Program Specialist Chemist	240
Chemist (Industrial)	1
Chemist (Investigative Analyst)	1
Chemist (Quality Assurance Man)	1
Chemist (Color Spec)	1

Position Title	Positions
Chemist (QA Manager)	1
Chemist (Residue Testing)	1
Chemist (Technology)	1
Chemistry	1
Chief Critical Foods Officer	1
Computer Scientist	2
Consumer Complaint Coordinator	7
Consumer Complaints Coordinator	2
Consumer Safety Officer	238
Consumer Safety Officer (Compl)	1
Consumer Safety Officer (Milk)	1
Consumer Safety Officer (Nation)	1
Consumer Safety Officer (Program)	1
Consumer Safety Officer (Retail	21
Consumer Safety Officer (Shell)	15
Consumer Safety Officer Product	1
Consumer Safety Technician	1
CSO (National Standardization)	1
Data Scientist	2
Dep Dir For Animal Der Foods	1
Dep Dir For Scientific Operation	1
Deputy Commissioner For Human	1
Deputy Director	1
Deputy Director For Plant Deri	1
Deputy Director ODSP	1
Deputy Director, Office Of Par	1
Deputy Director, Office Of Reg	1
Deputy Office Director	2
Deputy Office Director, Office	1
Dietitian/Nutritionist	1
Dir, Ne Regional Lab	1
Director Of The Office Of Diet	1
Director, DBP	1
Director, OARSA	1
Director, Office Of Core	1
Director, Office Of Executive	1
Director, Office Of Management	1
Director, Office Of Nutrition	1
Director, Office Of Regulatory	1
Director, Southeast Food And F	1
Division Director, Analytical	1
Division Director, DITM	1
Division Director, DWM	1
Electronic Engineer	1
Electronics Technician	1
Emergency Response Specialist	1
Entomologist	14
Epidemiologist	16
Ethics Management Specialist	1
Executive Assistant	2
FDA Liaison To CDC	1
Food Defense Science Program C	1
Food Technologist	9
Food Technologist	1
General Health Scientist	4
Geneticist	2
Geneticist (Research)	1
Government Information Special	4
Health Communication Specialist	3
Health Communications Spec.	5
Health Communications Specialist	2
Health Communications Specialist	15
Health Informaticist	2

Position Title	Positions
Health Science Policy Advisor	1
Health Scientist	6
Health Scientist (Quality)	1
Horticulturist	3
Hydrologist	1
Industrial Hygienist	1
Industrial Property Management	1
Information Technology Special	2
Instructional Systems Specialist	4
Interdisciplinary Scientist	1
Interdisciplinary Scientist (B	1
International Policy Analyst	6
Laboratory Support Assistant	9
Laboratory Technician (Oa)	1
Laboratory Worker	2
Lead Biologist	13
Lead Chemist	19
Lead Consumer Safety Officer	8
Lead Government Information Sp	2
Lead Management Analyst	1
Lead Management And Program An	2
Lead Microbiologist	16
Lead Toxicologist	1
Legal Instruments Exam (Oa)	2
Legal Instruments Examiner	1
Legal Technician (Oa)	1
Management And Program Analyst	1
Management & Program Analyst	1
Management Analyst	45
Management And Program Analysi	3
Management And Program Analyst	30
Management/Program Analyst	1
Management And Program Analyst	2
Mathematical Statistician	10
Mathematician Statistician	2
Medical Officer	2
Mgt And Prog Analysis Officer	1
Microbiologist	1
Microbiologist	156
Microbiologist (QSS)	1
Microbiologist (Spec Asst To Lb	1
Microbiologist	2
Miscellaneous Administration A	1
Ntnl Food Sfty Edc Advisor	1
Nutritionist	8
Office Director	1
Office Director, Office Of Pri	1
Office Support Assistant	1
Operations Research Analyst	2
Pharmacologist	1
Physical Science Technician	3
Physical Scientist	1
Physician	3
Policy Advisor	1
Policy Analyst	29
Policy Analyst (International)	3
Program Analyst	79
Program Analyst (International)	2
Program Manager (Communication)	1
Program Manager (Diversity, Eq)	1
Program Specialist	9
Program Support Specialist	13
Project Coordinator	1

Position Title	Positions
Project Manager	31
Project Officer	2
Project Specialist	8
Public Affairs Specialist	9
Public Health Advisor	4
Public Health Analyst	2
Public Health Educator	5
Public Information Specialist	1
Quality Assurance Manager	1
Quality Assurance Specialist	3
Quality Systems Specialist	2
Records & Info Management Spec	2
Regulations Analyst	1
Regulatory Counsel	14
Regulatory Health Information	1
Regulatory Information Special	2
Regulatory Policy Analyst	3
Research Biologist	28
Research Biologist (Bioinformatic)	1
Research Chemical Engineer	2
Research Chemist	22
Research Entomologist	1
Research Food Technologist	2
Research Microbiologist	31
Research Microbiology	1
Research Pharmacologist	2
Safety And Occupational Health	1
Sample Evidence Specialist	13
SBRBPAS Expert	5
SBRBPAS Expert (Parasitologist)	1
SBRBPAS Expert (Microbiologist)	1
Science Policy Analyst	1
Senior Advisor	2
Senior Advisor For Compliance	1
Senior Advisor For Intentional	1
Senior Advisor For Policy	1
Senior Consumer Safety Officer	1
Senior Dietician	1
Senior Health Communication Sp	1
Senior Physician	3
Senior Policy Advisor	8
Senior Policy Analyst	5
Senior Project Manager	3
Senior Project Officer	1
Senior Regulatory Advisor	1
Senior Regulatory Counsel	3
Senior Regulatory Counsel For	1
Senior Science Advisor	2
Senior Science Advisor For Bio	1
Senior Science Advisor For Eco	1
Senior Science Advisor For Foo	3
Senior Science Advisor For Glo	1
Senior Science Advisor For Int	1
Senior Science Advisor For Mil	1
Senior Science Advisor For Nut	2
Senior Science Advisor For Pro	1
Senior Science Advisor For Ris	1
Senior Science Advisor For Tox	2
Senior Staff Fellow	1
Senior Staff Fellow (Biologist)	1
Sensory Expert Organoleptic	1
Social Science Analyst	5
Social Scientist	2

Position Title	Positions
Special Assistant	4
Staff Assistant	5
Staff Director	4
Staff Fellow	24
Staff Fellow (Biologist)	3
Staff Fellow (Consumer Safety	1
Staff Fellow-Pharmacologist	1
Statistician	1
Statistician	1
Strategic Communications Specialist	1
Student Trainee	1
Supervisory Government Info Special	1
Supervisory Consumer Safety O	3
Supervisory Program Analyst	1
Supervisory Project Specialist	2
Supervisory Biologist	11
Supervisory Biologist (Integra)	1
Supervisory Budget Analyst	3
Supervisory Chemist	43
Supervisory Consumer Safety Of	54
Supervisory Consumer Safety Off	1
Supervisory Data Scientist	2
Supervisory Entomologist	1
Supervisory Food Technologist	2
Supervisory General Health Sci	2
Supervisory Geneticist	1
Supervisory Health Communication	1
Supervisory Health Scientist	1
Supervisory Information Commun	1
Supervisory Information Techno	2
Supervisory Management Analyst	6
Supervisory Management And Pro	7
Supervisory Management Liaison	1
Supervisory Management Officer	1
Supervisory Microbiologist	29
Supervisory Physician	1
Supervisory Policy Advisor	1
Supervisory Project Specialist	1
Supervisory Public Health Educ	2
Supervisory Quality Assurance	1
Supervisory Regulatory Counsel	3
Supervisory Regulatory Special	1
Supervisory Safety And Occupational	1
Supervisory SBRBPAS Expert	1
Supervisory SBRBPAS Expert (Ch)	1
Supervisory Science/Regulatory	1
Supervisory Toxicologist	4
Supply Management Specialist	1
Support Services Specialist	4
Supervisory Facilities Res Specialist	1
Supervisory Consumer Safety Officer	3
Supervisory Health Communications Spe	1
Supervisory Mathematical Statistician	1
Supervisory Mgmt And Prog Analyst	2
Supervisory Microbiologist	2
Supervisory Program Manager	1
Supervisory SBRBPAS Expert (Chemist)	3
Supervisory SBRBPAS Expert (Nutrition)	1
Supervisory Social Scientist	1
Supervisory Training Specialist	1
Supervisory Public Affairs Specialist	1
Survey Statistician	1
Technical Information Specialist	6

Position Title	Positions
Toxicologist	21
Training Administrator	1
Training Specialist	7
Vet Medical Officer (Pathology)	1
Visiting Associate (Biologist)	1
Visiting Scientist	1
Visual Information Specialist	3
Writer-Editor	1
Total	1965

Question. You testified that staffing cuts at FDA have not increased the risks related to bird flu. Has FDA cut any staffing positions or responsibilities related to bird flu since January 20, 2025?

—As of January 20, 2025, please list every position at FDA that has responsibilities regarding H5N1/bird flu and, for each, describe:

—The specific responsibilities related to H5N1/bird flu carried out by the person in the position.

—Whether the position was filled on January 20, 2025.

—Whether there have been any changes to the staffing of the position since January 20, 2025, and if so, describe the specific change(s).

—Whether FDA has any plans to reduce or eliminate the position within the next 24 months, and if so, what it may or will be replaced with.

Answer. The reduction in force (RIF) has not had an impact on FDA's activities related to H5N1. Upon my arrival at FDA, the Agency undertook an evaluation of all positions to ensure that any jobs critical to FDA's mission or operations were either not part of the RIF or had the RIF rescinded. FDA currently does not have plans to reduce or eliminate such within the next 24 months.

You testified that a potential future H5N1/bird flu vaccine should be based on a strain showing an "antigenic shift that represents a[n] epidemic threat, when there is human-to-human transmission."

Question. What evidence has FDA collected, obtained, or received to date demonstrating that such an antigenic shift has occurred for H5N1?

Answer. In the United States, the Centers for Disease Control and Prevention (CDC) is the lead for monitoring H5 avian influenza (bird flu) activity in people. As of July 7, 2025, the CDC reported publicly that there is no known person-to-person spread at this time in the United States and the risk is low for the general public.

Question. Is FDA at any stage of evaluation for potential H5N1 vaccine candidates for humans? If so, please describe what vaccines are being evaluated and which H5N1 strain(s) are being targeted.

Answer. FDA has approved three H5N1 vaccines for use in the U.S. [Sanofi Pasteur Inc (2007), ID Biomedical Corporation of Quebec (2013), and Seqirus, Inc. (2020). The vaccines manufactured by ID Biomedical and Seqirus are approved for use in individuals 6 months of age and older.

The vaccine manufactured by Sanofi is approved for use in individuals 18 through 64 years of age.

As discussed during FDA's October 2024 Vaccines and Related Biological Products Advisory Committee meeting,[11] licensed vaccine manufacturers have prepared candidate H5 influenza vaccines for A/Astrakhan/3212/2020, which has a hemagglutinin that is closely related antigenically to the HA of currently circulating H5 clade 2.3.4.4b viruses. Clinical trials to evaluate immunogenicity and safety have been initiated and FDA is working closely with these manufacturers to evaluate the results. Information about these vaccines is available on clinicaltrials.gov at https://clinicaltrials.gov/study/NCT05975840?id=NCT05975840&rank=1 and https://clinicaltrials.gov/study/NCT05874713?id=NCT05874713&rank=1.

Question. Please provide any evidence FDA has that demonstrates a "universal flu shot" would be effective against H5N1 infection or transmission in or among mammals. For the "current strain of bird flu" you cited that such a universal vaccine may protect against, please provide the specific H5N1 strain information.

[11] https://www.fda.gov/media/182543/download

Answer. The goal of developing a "universal" influenza vaccine would be to provide protection against many or most clades and strains of influenza and several experimental approaches are being actively pursued by researchers and vaccine manufacturers. Some vaccine candidates have demonstrated their potential for broad immunity in animal models, but all are still in development.

In May, doctors at the Children's Hospital of Philadelphia announced an incredible medical breakthrough—a baby born with a rare genetic disorder appears to be largely cured thanks to personalized gene therapy that uses CRISPR gene-editing technology. It took just 6 months from the time the baby was born to the doctors giving him the first treatments—a speed only made possible by rapid FDA approval of the novel therapy and knowledge learned from decades of robust Federal funding for science. Please describe what FDA is currently or planning on doing to ensure it has enough skilled personnel to help Americans benefit from remarkable advancements in personalized medicine.

Question. How many FDA personnel (irrespective of hiring mechanism) were assigned to reviewing, or consulting with outside stakeholders (such as academia and industry) on, applications for novel gene/personalized medicine therapies on January 20, 2025, and how many personnel are so assigned as of May 22, 2025?

Answer. The Office of Therapeutic Products (OTP) within FDA's Center for Biologics Evaluation and Research leads and oversees the development of CGT products and other products. It should be noted that many staff split their time between reviewing novel cell and gene therapy (CGT) products and other products regulated by CBER. As such, it is difficult to give a precise answer to the personnel assigned to reviewing or consulting on such applications. However, as an approximation, 366 employees were assigned to OTP on January 20, 2025, and 349 employees were assigned to the office on May 22, 2025.

Question. Please list all FDA positions responsible for reviewing, or consulting with outside stakeholders on, applications for novel gene/personalized medicine therapies that are or will be impacted as part of a reduction in force, deferred resignation, or early retirement program.

Answer. As noted in Question 6A it is difficult to give a precise answer to the personnel assigned to reviewing or consulting on such applications. As of September 16, 2025, 4 OTP employees were part of the deferred resignation program and 10 OTP employees took part in early retirement programs. No OTP staff members involved in review of CGT applications were subject to reduction in force.

Question. Please list all FDA positions responsible for reviewing, or consulting with outside stakeholders on, applications for novel gene/personalized medicine therapies that are or will be considered for elimination. For each position, please describe whether the position will be replaced by something else (for example, an AI tool) or combined with another position(s).

Answer. FDA is working to retain and recruit reviewers for CGT products and is not considering these positions for elimination or replacement.

Question. Please describe the specific artificial intelligence (AI) tools FDA is or will deploy as part of its regulatory and research processes, including the entity or entities that developed or have some level of ownership of the tool. For each AI tool:

—Please list which specific FDA components, programs, or offices will be deploying it.

—Please describe what cybersecurity and information security measures are or will be in place to safeguard intellectual property and other proprietary information, confidential or other privacy-related data, and any other sensitive information or data.

—Please describe the training that FDA personnel have or will receive before and while using the tool.

—Please describe what oversight FDA personnel will perform over the output produced by the tool, to include ensuring quality control, regulatory compliance, protection of privacy, protection of intellectual property, etc.

Answer. In June 2025, FDA deployed the generative AI Tool, Elsa, across the entire Agency. Elsa's development team was comprised of experts from every Center. Currently, we have approximately 11,400 users of Elsa, with 6,000–7,000 weekly active users, making it one of our most utilized applications. Elsa is an FDA-wide solution that can be employed to help with tasks in every Center/Office. The system supports diverse functions, from administrative tasks to Freedom of Information Act requests and human resources needs. We also expanded accessibility by developing mobile capabilities specifically for field investigators. In addition to Elsa, FDA is currently compiling the 2025 annual HHS AI use case inventory in accordance with Executive Order 13960, "Promoting the Use of Trustworthy Artificial Intelligence in

the Federal Government." FDA's 2024 use case list may be found here: AI Use Cases Inventory HHS.gov.

Regarding cybersecurity and information security measures, Elsa operates within the most robust security framework available to Federal agencies. The system is deployed in a FedRAMP/FISMA High environment, which represents the highest level of Federal cybersecurity standards. Our key security measures include comprehensive data protection protocols. The system is also not connected to the internet and operates securely behind the FDA firewall, allowing our staff to input FDA confidential information safely while maintaining the highest security standards. We maintain strict access controls, including user profile restrictions and the ability to create locked-down, user-specific document libraries. Staff can upload documents and data during individual chat sessions, and this information remains within that specific session and user context, preventing unauthorized access or data sharing. Additionally, we maintain rigorous vendor management protocols with our cloud solution providers and AI vendors, ensuring they meet all Federal security requirements while providing us with access to the latest modeling capabilities within our secure environment.

Our training approach is deliberately structured and progressive. We have conducted extensive trainings, paired with multiple office hours and video recordings. Our approach focuses heavily on prompt engineering—teaching users to craft specific, effective queries rather than relying on generic interactions. As new features and models are released, staff will be required to attend trainings to unlock such additional AI models and features. This ensures we have a process to continually train and reinforce the proper use of these tools as they advance.

FDA maintains rigorous mechanisms to ensure regulatory compliance and protection of sensitive information. All users are trained that Elsa is a supportive tool, not a decision-maker, and that they must verify all outputs through our established multiple levels of review. We maintain structured processes with extensive oversight, ensuring that AI-assisted work still meets our rigorous scientific and regulatory standards. Users learn to utilize feedback mechanisms, including rating systems that help our development team understand usage patterns and improve the system. Finally, we have implemented features in our system such that when users are interacting with Document Libraries, Elsa is forced to read prompts in the context of those documents and cite relevant documents, significantly limiting the likelihood that Elsa hallucinates information or references. Regardless, FDA staff are required to validate sources and information in every instance.

We also plan to provide Center leadership with information about usage patterns, enabling them to understand how their teams are utilizing the tools and ensure appropriate application within their specific regulatory contexts. Finally, we maintain currency with the latest AI capabilities, while ensuring all updates meet our security and functionality requirements. We recently upgraded from Claude 3.5 to Claude 4.0 within our secure environment, demonstrating our commitment to providing staff with cutting-edge tools while maintaining the highest security standards.

Question. Were algorithms used to make decisions about FDA's staffing cuts? If so:

—Who created the algorithms FDA used to execute these staffing cuts? Please identify the name, title, and affiliation of each individual involved.

—Who at FDA reviewed the algorithm decisions about staffing cuts prior to their execution?

—Who executed the staffing cuts and rehiring decisions at FDA?

Answer. FDA is not aware of algorithms used to make staffing decisions. Decisions were made by the Principal Deputy Commissioner and executed by the Chief Operating Officer.

An April 21, 2025, Brookings report raised concerns regarding the lack of quality standards for active ingredient manufacturers of semaglutide used in bulk compounding. The report found that a "large share" of these manufacturers were based "almost exclusively" in China, most had never been inspected by FDA, and many of those who had been inspected "had drug quality assurance violations." Reports also raised concerns that FDA's staffing cuts may impact its ability to conduct foreign drug inspections.

Question. What is FDA doing to ensure quality standards for bulk semiglutide and that all drug products entering the U.S. are safe and effective?

Answer. FDA reviews shipments of drugs offered for import to determine whether they appear to comply with applicable standards and are admissible into the U.S. FDA may detain and refuse products that appear to be compliant products. The

Agency's risk-based oversight has enabled us to effectively identify potential violations and take action, ultimately contributing to a more secure supply chain. Surveillance inspections for registered active pharmaceutical ingredient (API) and finished dosage form drug manufacturers are prioritized by the CDER risk-based Site Selection Model (SSM). The SSM uses risk factors, based on statutory requirements and emerging risks to prioritize inspectional assignments from CDER-regulated sites.

On September 5, 2025, FDA established a "green list" import alert to help stop potentially dangerous GLP–1 (glucagon-like peptide-1) API, including semaglutide, from unverified foreign sources from entering the U.S. market. This is part of the agency's steps to safeguard consumers from GLP–1 active ingredients imported from overseas that fail to meet applicable quality standards or are otherwise unlawful to help ensure patient safety and a secure drug supply chain. The green list includes GLP–1 API from suppliers the agency has evaluated (e.g., through establishment inspections or review of records requests) that appear to be in compliance with the FDA's rigorous standards—standards applicable to all API manufactured within or outside the U.S. The agency will continue to work with state regulators, monitor the market, and take enforcement actions as necessary to prevent unsafe or fraudulent GLP–1 drugs from reaching U.S. consumers.

FDA actively monitors the internet to identify unsafe online pharmacies and websites offering misbranded and/or illegally marketed unapproved drugs for sale to U.S. consumers and has issued warning letters seeking to stop and prevent the distribution of illegally marketed GLP–1 drugs. For instance, FDA has issued warning letters to companies, including compounding pharmacies and suppliers of active pharmaceutical ingredients used in compounding, that have illegally sold semaglutide, tirzepatide, or retatrutide drugs. FDA has urged consumers not to purchase these products, which are of unknown quality and may be harmful to their health. FDA's Office of Criminal Investigations has also worked with the Department of Justice to bring actions against parties for introducing unapproved and misbranded drugs into interstate commerce, including GLP–1 drugs.

In the President's FY 2026 proposed Budget, FDA proposed that Congress amend the FD&C Act to clearly require that the label and any accompanying certificate of analysis for an API for use in drug manufacturing, including human drug compounding, identify the name, address, and unique facility identifier of the API's original manufacturer. The original manufacturers of API are not always readily identified in labeling, such as when the label only indicates the repackager or distributor. This supply chain information is critical to investigate quality and safety problems.

Question. Has FDA made any staffing cuts that would impact its ability to carry out domestic and foreign drug manufacturing inspections?

Answer. FDA's investigator positions were not included in the RIF and the Agency continues to carry out inspections of both domestic and foreign drug facilities. Notably, FDA has recently embarked on an effort to increase the number of unannounced foreign facility inspections.

Question. In addition to FDA's announcement that it will be conducting unannounced foreign drug inspections, what specifically is FDA doing to ensure its inspection workforce is sufficiently staffed with experienced investigators to carry out quality inspections of both active pharmaceutical ingredient (API) and finished dosage form (FDF) manufacturing facilities to ensure products entering the U.S. meet FDA's quality standards and Current Good Manufacturing Practices (CGMPs)?

Answer. FDA notes that it has been conducting unannounced and short-notice inspections of foreign drug manufacturing facilities for several years and that we are now building on and significantly expanding those efforts. In terms of staffing, the Agency has resumed the recruitment and hiring of new investigators, including having announced multiple vacancies for investigator positions in efforts to hire additional inspectional staff.

Training our new and existing investigator workforce remains a priority. In support of the Agency's mission to have the workforce trained and operationally ready more quickly, the Office of Inspections and Investigations (OII) Office of Training, Education, and Development recently updated new Investigator training (aka Operational Foundations) to support basic inspection training across all commodities, and is exploring options for more effectively leveraging technology (e.g., AI) and immersive learning to improve efficiency and reduce the time to achieve the Independent Work qualification.

OII and the Center for Drug Evaluation and Research are collaborating to continually enhance and improve the training content and delivery to ensure that any staff conducting inspections on behalf of the Agency are consistently trained and

prepared to conduct high quality inspections of both API and FDF drug manufacturing facilities.

QUESTIONS SUBMITTED BY SENATOR KIRSTEN GILLIBRAND

Question. In February, FDA announced the recall of Lyons ReadyCare and Sysco Imperial frozen supplemental shakes. The recall is connected with an outbreak of Listeria that has infected 42 people from 21 States, including New York, and has led to 41 hospitalizations and 14 deaths. As Ranking Member of the Special Committee on Aging, I am concerned about this outbreak because the shakes were sold to congregate care settings, such as nursing homes.

Although FDA closed its investigation into the Listeria outbreak, I am concerned about how HHS cutbacks and efforts by the so-called "Department of Government Efficiency" may have impacted the investigation. My Aging Committee staff reached out to FDA with a series of questions on March 17, 2025. On March 27, HHS Secretary Kennedy announced his "reorganization" of the Department of Health and Human Services. On April 1, FDA informed my staff that the individuals working on a response to my staff's questions "are no longer at FDA as of this morning" and suggested that I reach out to HHS directly for a response. Given this turn of events, I ask that you answer the following questions:

How did staffing on the FDA team responding to the Listeria outbreak change between January 20, 2025 and the conclusion of FDA's investigation into the outbreak? Please provide information detailing:

Answer. HFP's Coordinated Outbreak Response and Evaluation team did not experience any staffing changes during this time-period.

Question. The number of staff on the FDA team on January 20, 2025.

Answer. The response team is a multidisciplinary group composed of six members.

Question. The number of staff on the FDA team when the Listeria investigation was closed.

Answer. The response team consisted of six members when this investigation was closed.

Question. The number of staff on the FDA team who accepted the "deferred resignation" scheme e-mailed by OPM to Federal employees on January 28, 2025, or who accepted any subsequent buyout or deferred resignation offers.

Answer. No members of the response team accepted the deferred resignation program.

Question. The number of staff on the FDA team who were laid off or fired between January 20, 2025 and the date when the Listeria investigation was closed.

Answer. No members of the outbreak response team were laid off or fired during the course of the investigation.

Question. What were the specific roles and duties of the staff on the FDA team that responded to the Listeria outbreak who accepted the January 28, 2025 deferred resignation scheme, or any subsequent buyout or deferred resignation offers? Please also detail:

Answer. As stated above, no members of the response team left the Agency during that time period.

Question. How those staff were involved in supporting the investigation into the Listeria outbreak connected to frozen shakes.

Answer. As stated above, no members of the response team left the Agency during that time period.

Question. What were the specific roles and duties of the staff on the FDA team who responded to the Listeria outbreak who were laid off or fired between January 20, 2025 and the date that FDA closed the investigation into the Listeria outbreak? Please also detail:

Answer. As stated above, no members of the response team left the Agency during that time period.

Question. How those staff were involved in supporting the investigation into the Listeria outbreak connected to frozen shakes.

Answer. As stated above, no members of the response team left the Agency during that time period.

Question. Please describe the role and duties of the FDA team that responded to the Listeria outbreak in responding to other outbreaks of foodborne illnesses.

Answer. FDA's Office of Coordinated Outbreak Response, Prevention, & Emergency Preparedness (CORE+EP) has several specialized teams to support outbreak detection and response. Once it is determined that a multi-State outbreak of foodborne illnesses or series of adverse events is likely due to an FDA-regulated

human food, CORE+EP's Response Teams lead the coordination of stopping the outbreak and preventing additional illnesses.

Response Teams work directly with FDA field offices, FDA subject-matter experts, CDC, and state partners on a response strategy. The team coordinates investigations, inspections, sampling, and traces product distribution. Close coordination among FDA, CDC, and State and local regulatory, public health and agriculture departments is crucial to stopping an outbreak.

Investigations coordinated by CORE+EP also inform follow-up activities carried out by other offices and divisions of FDA. These include, but are not limited to, follow-up inspections, continued risk assessments, and development of prevention strategies.[12]

Question. How many staff on the FDA team does FDA anticipate laying off or firing over the next year?

Answer. FDA does not anticipate any additional reductions in force.

During a March 14, 2025, call between my Aging Committee staff and subject matter experts at FDA and CDC, it was noted that the Federal Government supports State and local public health infrastructure that plays a critical role in responding to outbreaks of foodborne illnesses. That infrastructure includes State and local health departments and laboratories that the Federal Government assists with training and equipment. Please:

Question. Describe this State and local network in greater detail, including how the network assists CDC and FDA as they investigate and respond to outbreaks of foodborne illnesses.

Answer. FDA staff work in conjunction with CDC, State, and local partners during foodborne illness investigations to leverage regulatory authorities to effectuate the best public health outcome. This enables all parties to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of a safe national food supply.

State and local epidemiologists help track illnesses, interview patients, identify outbreak sources and collect samples. State and local health laboratories help analyze food, environmental, and clinical samples. State and local partner agencies also help conduct retail food inspections, produce inspections, manufactured food inspections, and surveil the food supply for a variety of hazards. They assist in finding the food that caused illnesses (traceback) and help conduct root cause assessments to find the cause of food contamination; or if they discover a hazard before an outbreak is detected or occurs, they work with FDA to help prevent illnesses.

Question. Describe in specific detail how the Federal Government supported this State and local network prior to January 20, 2025, including through Federal funding and grants, technical assistance, and training.

Answer. Prior to January 20, 2025, FDA provided support to State, local, Tribal, and territorial (SLTT) agencies, universities, and nonprofit organizations by routinely working directly with these partners and funding cooperative agreement programs—federal awards with substantial FDA involvement—that support personnel, supplies, training, technical assistance, and equipment to support these integrated response efforts. Further, FDA's Program Standards and Rapid Response Team Technical Experts also support state partners with technical assistance and training by participating in state-hosted meetings, capturing and sharing best practices amongst program participants, and facilitating national level training courses.

Question. Describe how Federal support for this network has changed between January 20, 2025, and present, including:

—Any grants to State or local governments, public health agencies, or laboratories that have been reduced or cancelled.

—Any Federal technical assistance or training for State or local governments, public health agencies, or laboratories that have been reduced in frequency or cancelled.

—Any other assistance, including with technology or equipment, to State and local governments, public health agencies, or laboratories that has been reduced or cancelled.

Answer. Since 2022, FDA allocated unspent dollars to increase annual state partnerships funding from the $83 million appropriated by Congress to $116 million. Given increasing inflationary costs and changes implemented as part of the FDA's 2024 Agency-wide reorganization, the Agency was no longer able to allocate this level of additional funding beginning in FY 2025. FDA is in the process of finalizing awards for FY 2025 and ensuring that resources are prioritized to the highest public

[12] https://www.fda.gov/food/outbreaks-foodborne-illness/post-outbreak-response-and-prevention-strategies-enhance-food-safety-updated-january-17–2025

health priorities using the Integrated Food Safety System (IFSS) Prioritization Model.

The FY 2026 President's Budget includes $33 million to restore the previous level of enhanced state funding to $116 million. If appropriated, this funding will support the expansion of current state agreements for routine inspections of domestic food facilities to cover all applicable domestic facilities, to the extent feasible. This paradigm shift streamlines routine inspections through a transformative oversight model that fosters enhanced collaboration between Federal and State agencies and reduces redundancy.

QUESTIONS SUBMITTED BY SENATOR JON OSSOFF

Question. What is the total number of probationary and non-probationary employees terminated from FDA's Human Foods Program since Thursday, February 13, 2025? Please include the following information:

—The job titles of employees who have had their termination finalized,

—The job titles of employees who have been scheduled to be terminated and their pending termination date, and

—The number of probationary and non-probationary terminated workers, from each office and center within the division, in raw numbers, and as a percentage of each office's, center's, and the division's total workforce.

Answer. All anticipated terminations within HFP have been finalized as of 7/26/2025. There are no pending or scheduled terminations within Human Foods Program (HFP).

Probationary and Non-Probationary Employee Terminations by COP

HFP Office	Terminations	% of HFP	% of FDA
Human Foods Program	0	0.00%	0.00%
Nutrition Center of Excellence	0	0.00%	0.00%
Office of Communications, Education, and Engagement	38	56.72%	0.18%
Office of Compliance and Enforcement	5	3.29%	0.02%
Office of Coordinated Outbreak Response, Evaluation, and Emergency Preparedness	1	1.61%	0.00%
Office of Executive Programs	16	43.24%	0.08%
Office of Food Chemical Safety, Dietary Supplements, and Innovation	7	3.74%	0.03%
Office of Integrated Food Safety System Partnerships	3	2.63%	0.01%
Office of Laboratory Operations and Applied Science	15	1.93%	0.07%
Office of Microbiological Food Safety	14	8.97%	0.07%
Office of Policy and International Engagement	0	0.00%	0.00%
Office of Quality Assessment and Management	1	4.55%	0.00%
Office of Resource Management	64	46.04%	0.31%
Office of Strategic Programs	12	85.71%	0.06%
Office of Surveillance Strategy and Risk Prioritization	8	8.42%	0.04%
Office of the Deputy Commissioner for Human Foods	6	35.29%	0.03%
Total	190		0.91%

Question. On April 17th, you told Megyn Kelly "there were no cuts to scientists, reviewers or inspectors or law enforcement" at FDA. On April 23rd, you told Dana Bash "there were no cuts to scientists or inspectors."

—Did you make those statements?

—Were those statements accurate?

Answer. There were no reductions in force (RIFs) for any reviewers, investigators, or law enforcement personnel. In addition, following the initial RIF decisions-which were made prior to my arrival at FDA-we took a close look at mission impacts and rescinded RIF notices for any employees who were in critical positions to the Agency's mission or operations.

Question. A fact sheet circulated by HHS States that the elimination of roles at FDA "will not affect drug, medical device, or food reviewers, nor will it impact inspectors." Please specify what is meant by the elimination of 3,500 roles at FDA not "affect[ing] reviewers" or "impact[ing] reviewers."

Answer. Please see the response to the above question.

Question. According to AgencyIQ reporting, over 200 employees supporting the critical work of the Human Foods Program no longer have active files in the U.S. Health and Human Services' (HHS) employee database. Many of them had job titles listing occupations such as Chemist, Biologist, and Microbiologist. On April 25, 2025, the New York Times reported an HHS spokesperson reinstated employee who had been "inadvertently fired because of inaccurate job classification codes."

—Will you conduct a full evaluation of these positions to ensure employees critical to safeguarding our Nation's food and preventing food-related illness and death were not "inadvertently" fired or scheduled for termination? Will you include each employee's duties, expertise, and past performance in such analysis?

—If after such analysis, you determine certain employees should not be reinstated or de-scheduled for termination, please provide your rationale.

—If after such analysis, you determine certain employees were critical for ensuring food safety, will you reinstate them?

Answer. After the HHS RIF, FDA reviewed impacts to FDA's mission and rescinded RIF notices of positions critical to the Agency's operations and mission areas.

Question. The FDA coordinates food surveillance activities with the Centers for Disease Control and Prevention. How has this coordination been impacted by the Reduction in Force and layoffs that have occurred within both agencies since February 13, 2025?

Answer. FDA's Human Food Program is dedicated to-and continues to prioritize-our foodborne illness surveillance work with CDC. These functions were not significantly affected by the reduction in force. For example, foodborne outbreak communications and the Outbreak Investigation Table continue to be published to provide relevant, timely, and actionable information to consumers and stakeholders.

Question. How has FDA evaluated the impact of the closure of the food safety labs?

Answer. No food safety labs have been subjected to closure.

SUBCOMMITTEE RECESS

Senator HOEVEN. Again, thank you. Appreciate it. Have a great day.

Dr. MAKARY. Thank you, Senator.

Senator HOEVEN. We are adjourned.

[Whereupon, at 12:06 p.m., Thursday, May 22, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

SUBJECT INDEX

DEPARTMENT OF AGRICULTURE

DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION