

**AGRICULTURE, RURAL DEVELOPMENT, FOOD AND
DRUG ADMINISTRATION, AND RELATED AGEN-
CIES APPROPRIATIONS FOR FISCAL YEAR 2024**

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

ON

H.R. 4368/S. 2131

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2024, 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 RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2024**

WEDNESDAY, MARCH 29, 2023

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

The subcommittee met at 10:01 a.m. in Room SD-192, Dirksen Senate Office Building, Hon. Martin Heinrich (chairman) presiding.
Present: Senators Heinrich, Murray, Tester, Merkley, Baldwin, Manchin, Hoeven, Collins, Moran, Hyde-Smith, and Fischer.

DEPARTMENT OF AGRICULTURE

STATEMENT OF HON. THOMAS J. VILSACK, SECRETARY

ACCOMPANIED BY:

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

OPENING STATEMENT OF SENATOR MARTIN HEINRICH

Senator HEINRICH. Good morning. This hearing of the Agriculture Appropriations Subcommittee is now called to order.

And I would like to start by welcoming Secretary Vilsack. Joining the Secretary is Mr. John Rapp, Budget Director for the Department of Agriculture. And we welcome both of you here today.

This is my first hearing as chairman of this subcommittee, and I am looking forward to a good discussion on the fiscal year 2024 Budget Request for the Department of Agriculture.

The programs and activities of this Department affect every single American, from farmers, and rural communities, to children and families who depend on healthy and nutritious food.

This subcommittee must ensure that USDA has the resources you need to fulfill your broad and absolutely critical mission. The budget request for United States Department of Agriculture (USDA) is ambitious, and it includes significant increases across the board. The request totals \$24.5 billion, which is an increase of \$2 billion.

I am pleased that the budget focuses on providing tools to producers in rural communities to address the climate crisis, and it calls for coordination of climate solutions across the entire Department. I look forward to discussing some of these initiatives and how this subcommittee can play a role in this critical issue.

We also know that affordable housing is a major challenge, not just in my home State of New Mexico, but really across the Nation, and particularly in rural areas. The budget includes much needed increases and innovative policy proposals to grow, our affordable housing stock in rural communities, and ensure that all Americans can access a safe and affordable place to call home.

Another issue of great importance to both of us is ensuring that our children can receive healthy and nutritious food, without this our children simply do not learn as effectively; do not thrive, so I am pleased to see increases to vital nutrition programs.

It is clear that USDA has much work to do. And I look forward to a robust discussion today. I am looking forward to starting the appropriations process and working with all the members of this subcommittee to draft an Agriculture Bill that supports these vital programs.

I want to briefly reiterate the importance of reaching a bipartisan top line agreement. We must invest in nondefense programs if we want to move this country forward. We have important work to do, and we need to come together to bring back regular order. That will not be easy, but I stand ready to work with every member as we continue to move this process forward.

And with that, I will turn to our ranking member, Ranking Member Hoeven, for any statement that he may have. And I would just quickly add that I am looking forward to working with you, and continuing the bipartisan tradition of this subcommittee.

STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Thanks Chairman Heinrich. Appreciate it. I look forward to working with you as well.

Welcome back, Secretary Vilsack. I appreciate you being here. We saw you on the Hill here a week or so ago, and appreciate your diligence, and certainly respect your knowledge of the Department of Agriculture having, you know, served 8 years prior, and back in the role. And of course I have had opportunity to work with you through the years both in that role and as governors.

The Department of Agriculture (Ag) affects every American every day, our farmers and ranchers produce the highest quality, low-cost food supply in the world that benefits every single American, every single day. So what you do is incredibly important, what we do here in Ag Appropriations is incredibly important. And of course writing a good Farm Bill this year is incredibly important.

There are always challenges, we have seen that, obviously, with trade relations, with Coronavirus (COVID), with weather, the supply chain issues, energy costs, all those things, are challenges that our farmers and ranchers face every day, and that is why it is so, so important that we have a good farm policy.

Because when you look at our AG industry I think it is absolutely remarkable. It is a remarkable industry where we have been able to maintain a network of small businesses across this country, unlike so many other industries where you have seen incredible concentration, but we have got those small businesses, family farms, and ranches, in many cases that have been operating for, you know, decades and generations of families. And we can't take that for granted.

Like I said, benefits every American because of this system we have, and we can't treat it like when we walk in the room and flip on the light that it is always going to be there for us just the way it is. So I think it is incredibly important we keep that in mind as we craft farm policy. And I know, Secretary, you do.

This subcommittee has provided substantial support for our farmers, ranchers, producers, and rural communities. Last year, we provided critical base funding increase of 4 percent for USDA research programs, 2.7 percent for Rural Development programs, 5.6 for the Animal and Plant Health Inspection Service (APHIS).

And you know, programs like that, again, are so important. I think sometimes people don't even realize they are out there. But we keep them healthy because of those inspection services that make sure that that food gets to people and they can count on it being, you know, healthy, and free of disease, and other problems.

Again, things that, you know, the consumer takes for granted. But food doesn't come just from the grocery store, it comes from the farm and ranch, and there is a lot that goes into making all that happen.

At the same time as we have provided more funds for these programs, we have got to be careful because of the cost of the overall farm program, the Farm Bill in total, the Supplemental Nutrition Assistance Program (SNAP), all the different components that go into this outstanding network of farming, and ranching, and food supply that we have, we have got to recognize that we have a real problem, overall, with the budget, and we have got to be part of helping find solutions that work. That has got to be an important part of what we do.

What I would submit to you, and I will be intrigued to hear your comments on it, Secretary, when we get into the Q&A, is that by doing a good job on crop insurance and the countercyclical safety net, we make sure those farmers can produce more food of the highest quality, with incredible variety that keeps the food costs for the consumer as one of the lowest percentage of their budgets of any country in the world.

That is not only important to every American every day, but when we look at the nutrition programs, it reduces the cost of those nutrition programs, because more supply not only means, you know, more availability of food, but lower costs.

So getting crop insurance and that safety net right benefits every aspect of what we do, and it is critically important, not only for this appropriations process, but as we go into writing the Farm Bill.

Again, Chairman, thank you; I look forward to working with you. And Secretary, thanks for joining us today.

Senator HEINRICH. Mr. Secretary.

SUMMARY STATEMENT OF HON. THOMAS J. VILSACK

Secretary VILSACK. Mr. Chairman, thank you very much for the opportunity; and Senator Hoeven, thank you for the opportunity, to appear before the committee today. And to the Members of Committee, thank you for this opportunity.

This is an unusual budget, perhaps one that you have never faced before, because you have to put it in the context of everything else that is surrounding the Department of Agriculture today.

Whether it is the investments that are being made in the American Rescue Plan (ARP), or the Bipartisan Infrastructure Law (BIL), or the Inflation Reduction Act (IRA), these are resources that complement and supplement, if you will, the budget that we are presenting to you.

And the goal of this budget, frankly, is to invest in a stronger America, and to expand our middle class, as the President likes to say, from the bottom up and the middle out. And there is no better opportunity to do that than within the agricultural budget.

I would make one observation and one request of this committee, that you take a look at the percentage increases of this committee over time, and compare it to the percentage increases of other Departments of Government. I think what you are going to find, even in the nondiscretionary—nondefense discretionary budget, the increases in this Department's budget have been modest compared to other agencies.

So as you look at choices that have to be made, I hope that that factor is taken into consideration, given the importance of this Department, and the work of this Department, as both the Chair and the Ranking Member have indicated.

When we look at making a stronger America and expanding the middle class, there are things like the investments that we are proposing in research surrounding clean energy and climate that will help to create that middle class. Whether it is developing a new industry, sustainable aviation fuel, or other bio-based products, the idea here is to create not just better energy sources, but also income sources for our farmers.

As Senator Hoeven knows, having listened to this before during the Farm Bill Hearing at the Senate Ag Committee, that we have had a record year in farm income in the last 2 years; however, that that bounty has not been fully shared by all farmers, nearly 50 percent of farmers during those record years did not make any money, another 40 percent, or so, made money, but the majority of money they made came from off-farm income.

So we had some farmers, those who sell more than \$1,000,000 in product do very, very well in this economy, but I think we still have a job to do for the other 90 percent. So investments in research that create new opportunities; new income opportunities, is a way of maintaining those small- and mid-sized farming operations.

We are asking for increases in investment and staff at Natural Resources Conservation Service (NRCS). Why? Because we want to provide more technical assistance to farmers who are embracing climate-smart practices, and we know that when they do they can qualify for ecosystem service market opportunities, which create another revenue source that is not currently available to many farmers.

It is not just about asking for more money, it is also about asking for legislative changes. We would like to be able to open up more credit opportunities for beginning farmers. We would like to take a look at the time and the number of times farmers can come back to the Farm Service Agency (FSA) for assistance and help so they can stay on the farm, extending the number of years that they can borrow from the USDA.

It is proposed legislative changes in the Rural Development to preserve rental assistance, we are facing a circumstance in situation where a number of rental units could be lost as mortgages get paid off, rental assistance units are lost, the amount of vouchers that we provided, basically, take care of about 35 projects each year. The circumstances today are that we are losing about 80 projects per year. So we are losing literally, potentially, tens of thousands of rental assistance units in rural America at a time when we need affordable housing.

It is protecting farmers from unfair practices in the marketplace, which is why we are asking for continued support for our packers and stockyards. There is a competing view, obviously, to this budget that we have proposed. And that competing view has suggested significant reductions across the board, and I wanted you all to have an understanding of the degree to which those budget cuts would impact and affect this Department.

If those budget cuts, even the most conservative budget cut, that is to say, putting it back to levels of several years ago, would result, not in an increase in Special Supplemental Nutrition Program for Women, Infants and Children (WIC) participation, but perhaps as many as 250,000 participants in WIC not being able to be provided that opportunity.

It would likely mean a loss of 40,000 rental assistance units in rural America. It would mean 84,000 farmers couldn't access the technical assistance they need to embrace conservation practices. It would mean 6,600 farmers wouldn't get the credit they need to continue farming operations. There are real impacts to these reductions.

So that is the reason why I am here today, is to talk to the committee about the importance of this Department's budget relative to all other budgets, and to basically make the case that in the context of what we are trying to do to create new opportunities for farmers, new income sources for farmers which, in turn, will create more job opportunities as well, in rural America, and create a revival of the economy, this budget is at a critical point, at a transformational point, in my view, in rural America, and in agriculture.

And I look forward to the opportunity to respond to any questions that the committee may have.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS J. VILSACK

Thank you, Chair Heinrich, Ranking Member Hoeven, and distinguished members of this subcommittee, for the opportunity to come before you today to discuss the Administration's priorities for the Department of Agriculture (USDA) and to provide you an overview of the 2024 President's Budget.

We are at a pivotal moment for American agriculture and rural communities with a decision to make about if, and how, agriculture will meet the challenges of our time. One option is to maintain the status quo. This path leads towards even more producers struggling to cover their costs and often turning to off-farm income to support their families; it leads to far too many rural communities languishing and demonstrates the outdatedness of agricultural policies designed to address challenges of the 1930s and 1970s, ones that reinforce systemic inequities. This path works for a few who have done what American agricultural economics has required of them: get big or get out. But there is another path, one that prompts us to recognize the undeniable challenges of climate change, the need for greater equity in our food system, and that there are opportunities to seize as we seek to adapt to a new course. This path draws on lessons from the COVID-19 pandemic, which exposed

vulnerabilities at every point in our food supply chain—from the field to the factory to the grocery store—and compels us to take transformative action so that this vital system is more resilient, secure, and accessible to all. This path also draws strength from the Interim Recommendations of the USDA Equity Commission¹, because they are a roadmap for ensuring USDA lives up to its name as the People’s Department for everyone. There is nothing more foundational to a country’s security and stability than its food supply; an inclusive agriculture and rural life must be part of a shift to a bottom-up, middle-out system if we want to create more opportunity in this country.

Through the fiscal Year 2024 Budget, the Biden-Harris Administration and USDA have embraced a path where the future of American agriculture is secure and where there is greater equity and economic opportunity for agricultural and rural communities.

The 2024 USDA President’s Budget also recognizes the historic investments that Congress has made through the American Rescue Plan, the Infrastructure Investment and Jobs Act, and the Inflation Reduction Act. USDA is delivering on these investments, and the 2024 Budget continues to confront challenges, rebuild the rural economy, and support a new, innovative approach to the future of agriculture. Agriculture is the foundation for fuel, fiber, and food; the agricultural economy is more than just growing crops and selling them, or raising livestock and selling them, or the products from them. The food and agriculture industry contributes nearly \$8 trillion to the global economy, about a fifth of the economic activity of our country. A strong agriculture sector is key to strong rural communities, supporting over 21 million people and 11 percent of jobs in the economy, providing access to essential services like housing, health facilities, and fast reliable internet; it’s how we ensure there’s safe, nutritious, affordable food on the table for everyone, supporting the more than 10.2 percent of Americans that experience food insecurity²; it’s how we support and protect forests, grasslands, and farms—nearly 50 percent of this nation’s total land mass; and it’s how we provide for the communities that depend on them. The proposals in this budget will address these challenges and spur new job creation and opportunities in rural America; build resilience in the food supply chain and restore America’s advantage in agriculture; leverage USDA’s expertise to address climate change; and support a stronger nutrition safety net. To make demonstrable progress toward addressing these real issues, the 2024 President’s Budget proposes \$213.2 billion for USDA programs, of which approximately \$180.6 billion is mandatory funding and \$32.6 billion is discretionary funding.

RESEARCH AND INNOVATION

This pivotal moment calls for additional investment in research and innovation that influence every program we implement at USDA. Agricultural research has a return on investment of \$17 for every \$1 invested. Between 1948 and 2019, total agricultural output in the United States grew by 142 percent. This rise was not due to increases in agricultural land or labor; in fact, both inputs declined over the period. The productivity stemmed from the adoption of a whole suite of innovations and technology transfer in crop and livestock breeding, nutrient use, pest management, farm practices, and farm equipment and structures. These innovations are the fruits of publicly funded agricultural R&D that often have a less-told story, but we live and reap the benefits of these investments every single day. Production agriculture requires constant innovation and adaptation as farmers and ranchers pursue climate-smart solutions to extreme weather, rural businesses seek new markets, and underserved communities seek trusted partners to tackle systemic concerns.

The budget proposes a \$4.2 billion investment in our research, education, and economics programs. The budget includes discretionary funding of \$1.9 billion for the National Institute of Food and Agriculture (NIFA) of which \$550 million is for the Agriculture and Food Research Initiative (AFRI). Demand for AFRI’s competitive funds grows annually and the awards focus on promoting enhanced profitability and productivity in U.S. agriculture, food and nutrition security, and boosting rural prosperity through a circular economy with support for clean energy technologies, climate-smart agriculture and forestry, and education and workforce development. An additional \$2 billion for the Agricultural Research Service (ARS) includes increases of \$20 million in support of the Cancer Moonshot, \$13 million for the operations and

¹ USDA Equity Commission. (2023). Interim Report 2023: Recommendations made to the U.S. Department of Agriculture to Advance equity for all. <https://www.usda.gov/equity-commission/reports>

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

maintenance of the new National Bio and Agro-Defense Facility, \$83 million for clean energy, \$88.5 million for climate science, \$10 million for Climate Hubs and Climate Hub Fellows, and \$14 million for additional high priority investments. These funds enable ARS to find solutions to agricultural problems that affect Americans every day from field to table. This is done through the delivery of cutting-edge, scientific tools and innovative solutions for American farmers, producers, industry, and communities to support the nourishment and well-being of all people; sustain our Nation's agroecosystems and natural resources; and ensure the economic competitiveness and excellence of our agriculture.

Science and research are the best defenses we have to protect our resources against the climate crisis. The changes in our environment have allowed invasive plants, pests, and diseases to move around the world more easily and become established in new areas. Without the tools and sufficient resources to protect ourselves against invasive species and safeguard the health, welfare, and value of American agriculture and natural resources, our farmers and our economy will suffer. The budget calls for an investment of \$6 million for the Civilian Climate Corps within our Animal Plant Health Inspection Service (APHIS) to identifying emerging invasive species threats and expand efforts to develop and implement new surveillance methods to detect incursions of invasive pests more quickly as well as develop new mitigation methods to address those already present causing economic and environmental damages.

TACKLING THE CLIMATE CRISIS

Producers and land managers across the country are experiencing real and increasing threats from climate change that have serious implications-not just for farmers, ranchers, and forest landowners- but also for surrounding communities and all Americans. In 2022, nearly 80 percent of the western region experienced extreme drought, wildfires burned over 7.6 million acres of our forestland, and communities across the country are dealing with the impacts of severe flooding and record snow fall exacerbated by climate change. Agriculture has a critical role in delivering climate change solutions and our Nations farmers, ranchers, and foresters are already leading the way through the adoption of voluntary and farmer friendly incentive-based climate-smart agricultural and forestry practices. The budget proposes over \$7 billion across the department in finding solutions to the climate crisis through science, clean energy innovation, minimizing emissions and greenhouse gases, building resilience, and supporting farmers and producers as they adapt to the changing environment. Farmers, ranchers, and forest landowners are ready, but they need USDA resources to help mitigate their risk as they adopt these solutions.

The budget includes \$904 million for Conservation Operations to work with landowners and managers to develop conservation plans that outline the specific practices needed to improve farm operations and enhance farm environmental sustainability. The request includes an increase of \$23 million for Climate Smart Agriculture Implementation to improve greenhouse gas monitoring, establish a soil health monitoring network, and better understand the interrelationship between conservation planning, practice implementation, and adaptation and resilience to climate change. The budget proposes to enhance the Conservation Technical Assistance Equity Conservation Cooperative Agreements, begun in 2021, with an additional \$50 million, bringing total funding for this initiative to \$100 million. The agreements are 2-year projects that expand the delivery of conservation assistance for climate-smart agriculture and forestry to farmers and ranchers who are beginning, limited resource, historically underserved and/or veterans. The budget also proposes \$20 million for the Healthy Forests Reserve Program to enroll private lands and acreage owned by Indian Tribes for the purpose of restoring, enhancing, and protecting forestland to enhance carbon sequestration, improve plant and animal biodiversity, and promote recovery of endangered and threatened species under the Endangered Species Act. These efforts will allow for important outreach and promotion of inclusive outcomes in farming practices, addressing some of the historical inequities and working to build new levels of trust with the People's Department.

The budget supports climate resiliency in a myriad of other ways because the approach to the addressing the climate crisis must be taken on multiple fronts. For example, USDA proposes to permanently authorize the pandemic Cover Crop Incentive Program and apply the successful model implemented with supplemental funding that provides a \$5 per acre premium subsidy for acres planted with cover crop. Cover cropping systems benefit the environment by reducing soil erosion and compaction, increase soil organic matter, and limit nutrient runoff. Given the demand

for this program in 2021 and 2022, USDA estimates a 15-million-acre enrollment in 2024 and that the program will grow 5 percent annually.

The budget provides \$255 million in new funding to support clean energy innovation, which includes an additional \$155 million for emissions mitigation deployment to help meet the Administration's goal of zero carbon electricity by 2035. Specifically, grants and loans will be used to expand rural clean energy, transform rural power production, and create jobs. The budget requests an additional \$30 million in annual grant funding for the Rural Energy for America Program (REAP) and will assist agricultural producers and rural small businesses to purchase or install renewable energy systems or make energy efficiency improvements. These increases will build tens of thousands of new renewable energy systems and support small business owners in every State.

CREATING MORE AND BETTER MARKETS

While our policies and programs have ensured an increasingly abundant food supply, growth in farm size and consolidation has put extreme economic pressure on small and medium sized farms and our rural communities. Most recently, the COVID-19 pandemic and the Russian invasion of Ukraine, have roiled the supply chain, and exacerbated the impacts of climate change, droughts, wildfires, other natural disasters, and an especially widespread highly pathogenic avian influenza (HPAI) outbreak. American agriculture has proven itself to be extraordinarily efficient, but these crises have further revealed hidden weaknesses in our production-optimized system. The challenges presented today to our farms and rural communities requires a whole systems approach to stay competitive and innovate the food and agricultural system so that it works for everyone. In recent history, there have been record setting farm income levels, but noting approximately 80 percent of the value of agricultural production is produced on farms that are mid-sized or larger. But nearly 50 percent of our farmers have had negative farm income. Our data shows that 40 percent of farms are small and midsize farms where the primary occupation of the household is farming, but most of their income that was supporting their families came from off-farm sources. It's obvious that the system needs to be revisited to find a way that the system benefits the small and medium farms, expands opportunity, and values their products. USDA currently has 141 Partnerships for Climate Smart Commodities projects that are helping to make it less risky for farmers to embrace climate-smart practices and link them to new markets that value and reward them for their commitment to sustainability. These opportunities for our farmers need Congress' support to build the markets and show value to their customers.

The budget requests \$80 million to support new supply chains and markets that uplift small and mid-sized farmers through programs such as the Local Agriculture Market Program, Dairy Business Innovation, Farmers Market and Local Food Production, and Transportation and Market Development. USDA is also expanding local food systems through urban agriculture, supporting communities' capacity to gather, process, move and store food in different geographic areas of the country. Urban agriculture provides more options for producers to create value-added products and sell locally to create new economic opportunities and job creation in underserved communities. In 2024, USDA will invest over \$157 million in urban agriculture and innovation production initiatives across the department, of which \$13.5 million will go towards the Urban Agriculture and Innovative Production Program, creating more grant opportunities with a priority on supporting historically underserved communities.

REBUILDING RURAL AMERICA

It has been said that Rural Development can build a town from the ground up. The essence of that statement is that USDA Rural Development, when well-resourced and well-staffed, provides support that is critical to improving quality of life in rural America—whether it is through more affordable housing in underserved communities, increased access to broadband service, or resilient wastewater infrastructure. These are problems we can and must solve, and USDA is committed to ensuring rural America has equitable access to essential resources. To do so, we must have sufficient Rural Development staff to deliver these vital programs. Over the last decade, RD's portfolio has increased 85 percent, but its staffing levels decreased by 30 percent. Increased staffing resources are desperately needed to ensure that we meet the growing priorities in critical areas that have a direct effect on our ability to be sustainable, relevant, and results-oriented in delivering much-needed programs and services across rural America. The budget proposal increases funding for Rural Development by \$801 million and includes critical increases for combat-

ting climate change, and improvements to rural communities' quality of life; these investments attract new businesses, create greater sense of pride in communities, and allow rural America to prosper.

In 2022 alone, USDA provided \$548 million to the ReConnect program and expanded access for 109,000 households, 14,520 farms, 5,900 businesses, 435 essential community facilities, 396 educational facilities, and 51 health care facilities. The fiscal Year 2024 Budget requests \$400 million to reach even more communities, homes, and businesses with reliable internet access which builds upon the \$2 billion of funding provided by Congress in the Bipartisan Infrastructure Law so that every community in America has access to affordable, high-speed Internet.

It's estimated that 2.2 million people in America still lack indoor plumbing and around 10 million homes still have poisonous lead pipes. The President's Budget proposes \$2.38 billion in the Water and Wastewater program to provide additional grants and loans that will improve water and waste disposal systems in rural areas and provide for lead pipe replacement. This is an increase of \$324 million over the 2023 enacted level and is a key investment in safe drinking water and sanitary waste disposal systems, which are vital to achieving a high quality of life for rural residents. Specifically, the budget provides \$1.6 billion in direct loans and \$872 million in BA for water and wastewater grants and loan subsidy. Within this funding, the Budget targets \$100M in grants for lead pipe replacement. In addition, the Budget includes an increased loan level of \$110 million for the 1 percent loan risk category, that targets the most rural and poor communities.

Affordable housing has been a long-standing problem for low-income residents in rural communities, one that is exacerbated by low energy efficiency of the aging housing stock which means higher costs to families. To help address this, the Budget includes a new proposal to eliminate the existing low-income borrower penalty that requires individuals to repay subsidy costs for Single-Family Direct loans—a requirement that only exists for rural housing. Ending the “recapture” penalty promotes equity in rural communities, with particular attention to those suffering from systemic racism and other forms of discrimination. In addition, the budget includes the authority to decouple rental assistance from USDA financed properties to help ensure low-income rural tenants in USDA financed properties continue to have access to affordable rents when projects reach loan maturity and leave the portfolio. This proposal would allow vouchers when we lose rental assisted properties, but these would be processed by HUD to ensure that USDA is not funding vouchers that can leave rural areas. The Budget also continues the 2023 Budget proposal to require climate smart construction in USDA's rural housing programs. There are also several new legislative changes designed to improve the disposal of Real Estate Owned (REO) properties in shorter time frames and reduce the costs associated with maintaining REO for longer periods; and provide authority to standardize multifamily housing foreclosures across States. The funding in the budget for these housing programs is \$2.2 billion, an increase of \$459 million over 2023 Enacted.

To ensure that all rural communities are made aware of and are encouraged to participate in USDA programs, this budget proposes \$32 million to sustain and expand the Rural Partners Network (RPN) authority. RPN provides targeted training, technical assistance, and outreach to distressed communities in rural America through an all-of-government approach to help rural and Tribal communities access Federal funding and resources. This support is allowing for more strategic community engagement, facilitating regional coordination among Federal agencies to share best practices, braid Federal resources, and foster collaboration with local and State partners. This work follows through a commitment the President made when he came to office—we must invest in America's heartland in a meaningful way. It is critical that we ensure that our rural and Tribal communities can benefit from Federal investments as the Biden-Harris Administration delivers unprecedented resources through the American Rescue Plan, Bipartisan Infrastructure Law, and Inflation Reduction Act. We can only expand this innovative work of RPN into more rural communities and additional States if Congress builds on the progress made over the last year and provides additional funding for RPN.

SUPPORTING NUTRITION FOR THE NATION

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

We know that the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) drives better health for infants and more nutritious diets for children, and it is a key tool for addressing disparities in maternal and child health outcomes. WIC serves about half of all babies in the United States. After many years of decreasing participation, WIC participation is now rising across all eligible categories—women, children and infants. Continuing the bipartisan commitment to full funding, the Budget requests \$6.3 billion for WIC to serve an estimated 6.5 million moms, infants, and young children per month in 2024. It also proposes to continue the enhanced Cash Value Benefits through 2024 to provide participants with increased benefits to buy fresh fruits and vegetables which ensures that participating women and children have access to scientific-based recommended levels of fruits and vegetables.

The Supplemental Nutrition Assistance Program (SNAP) stretches the food budget for many low-income people and research shows that participation in SNAP reduces food insecurity and allows families to have healthier diets. The budget request \$122.1 billion for SNAP, a \$32 billion decrease from 2023 primarily due to the expiration of emergency allotment payments that were provided during fiscal years 2020 through 2022 and the 1.3 million participant decrease projected in enrollment because of a recovering economy. As SNAP monthly benefits decline, USDA anticipates that more eligible Tribal members will choose to participate in the Food Distribution Program on Indian Reservations (FDPIR) over SNAP, as it provides food packages to Indian Tribal Organizations to improve nutrition and provide culturally appropriate sustenance. The budget requests \$165 million in 2024 to fund FDPIR food and administrative costs, which supports participation at pre-pandemic levels.

Child nutrition programs, such as the National School Lunch Program, School Breakfast Program, Summer Food Service Program, and Fresh Fruit and Vegetable Program, play a crucial role in ensuring that children receive nutritious meals and snacks that promote health and educational readiness. The meals children receive prepare them for learning, foster healthy eating habits, and safeguard their health with a goal of reducing the number of overweight and obese children. Thanks to the 2023 Omnibus Appropriations Bill, a series of landmark expansions for Child Nutrition Programs are now permanent. This includes establishing a permanent Summer Electronic Benefit Transfer Program for Children (Summer EBT) and adding a rural non-congregate option in the Summer Food Service Program. Thanks to these changes by Congress we know that we will see a permanent and positive impact on how we meet the nutritional needs of children during the summer, greatly improving equitable access to safe, healthy, and nutritious food. The 2024 budget request expands on those important expansions of child nutrition with a legislative proposal that would advance a pathway to free school meals for an additional 9 million school children through increased take up of the Community Eligibility Provision among schools and States. This proposal is expected to cost \$234 million in 2024 and \$15 billion over 10 years. During the COVID-19 pandemic, children had access to free meals resulting from temporary flexibilities provided in the Families First Coronavirus Response Act, and now many States are seeking ways to continue offering free school meals for all students. Offering free meals to all children reduces administrative burden, increases equitable access, reduces the stigma associated with school meal participation, and allows schools to focus on providing the highest quality meals.

The budget funds the child nutrition programs at a level that will allow for the anticipated increases in participation, food cost inflation, and implementation of new legislation. The budget projects serving 5 billion lunches and snacks and 2.6 billion breakfasts in schools, 1.9 billion meals in child and adult care programs, and 182 million meals through the Summer Food Service Program. The increases will strengthen integrity controls, modernize food ordering and inventory management systems, and provide critical staffing to enhance FNS's ability to provide technical assistance and oversight of child nutrition programs.

REBUILDING USDA THROUGH DIVERSITY, EQUITY, AND INCLUSION

Building a better USDA means bringing people of all backgrounds and lived experiences to be a part of a healthy, safe, and inclusive workplace. This includes ensuring we are recruiting the best and the brightest across our great country, and investing in our employees through recognition, wellness programs, and support to our employees. Building a better America is about ensuring all have equal access to USDA opportunities, which demands that we design and implement our policies and programs with our diverse customers at the center. The 2024 budget focuses on building a USDA that is a model employer and great place to work, proposes invest-

ments that remove barriers to accessing USDA programs, and addresses historic gaps with respect to who benefits from USDA programming.

It's an honor and a privilege to have the dedicated and talented staff of over 100,000 employees supporting USDA. However, the historic lack of investment throughout the Department over the years has resulted in a decline in staffing that we still struggle to recover from and has meant that we have not had the necessary resources to modernize critical IT systems or make other improvements to the way we do business here in USDA in support of rural Americans. Rebuilding our workplace and workforce right will take time and focus over the course of multiple years, but it couldn't be more important. In addition to the programs that the public relies on and subcommittee and Congress generously fund, I implore you to also concentrate on the critical needs of organizational abilities and operations management that ensure our staff are properly supported and our programs are delivered efficiently, effectively, and with integrity.

There is currently 13 percent of the USDA workforce that is eligible for retirement and in the next 4 years, another 13 percent will become eligible for retirement. We need to focus on the future of agriculture when rebuilding our workplace. Our workplace needs to remain competitive, and the future of agriculture needs to reflect the diversity across America and fight against historic inequities. USDA is fostering collaboration between State, federal, and Tribal partners, land-grant universities, Hispanic-serving institutions, Tribal colleges, historically black colleges and universities, and other strategic partners, to connect USDA programs and opportunities with the communities they are intended to serve. Within this budget request, over \$370 million is dedicated to 1890 historically black land-grant colleges and universities, 1994 Tribal land grant colleges and universities, and Hispanic-serving institutions. These partnerships with minority serving institutions support capacity building initiatives that bolster education and pathways to employment for students and faculty and help develop a strong pipeline of talented individuals for USDA and USDA partner jobs. These investments in future agricultural leaders will help USDA attract the best and brightest to face the growing challenges of the agricultural economy.

CONCLUSION

This budget is not a wish list; rather, it is a to do list to fulfill the items that Congress and USDA have been talking about fixing for decades. Moreover, this budget seeks to build the foundation for innovation during this pivotal moment. It gives USDA the set of tools to add to existing capabilities and develop new ways to address the urgent challenges of our time-rebuild from the pandemic, respond to the nutrition insecurity crisis, address the impacts of climate change, invest in research and innovation, strengthen and build new markets and opportunities for farmers and producers, rebuild the rural economy that benefits all Americans, and ensure our services and programs are accessible to everyone. It is a plan for what we need to do to continue to get USDA back on track and to help the U.S. outcompete the rest of the world. USDA needs the support of this subcommittee and of Congress to make the much-needed investments called for in the President's fiscal year 2024 Budget. I look forward to working with this subcommittee and to answering any questions you may have about our budget proposals.

Senator HEINRICH. Thank you for that opening statement, Secretary. We will start with five-minute rounds, or seven-minute rounds of questions, I guess. Are we doing five or seven? It keeps changing in front of me, sorry. We will just get into the questions. How about that?

USDA programs are just playing an absolutely indispensable role in the recovery from the Hermits Peak/Calf Canyon Fire in New Mexico. The Emergency Watershed Protection Program, the Emergency Forest Restoration Program, the Emergency Conservation Programs are lifelines for families who are working to get their properties back in condition, timberland back in working condition, ranches, et cetera.

At the end of last year we passed nearly \$1 billion dollars in supplemental funding for these USDA emergency programs. And I was just hoping you could give me a little bit of a progress update on how you feel the implementation is going?

Secretary VILSACK. I am pleased with the fact that Chief Cosby at NRCS has allocated \$133 million from the conservation programs, in a direct effort to try to address the nine projects that are of significance and importance. And obviously the Forest Service has been quite diligent in making sure that resources are being provided to communities.

So I think the effort is underway. There is still more work to be done, for sure. We are not going to forget about this, we know we have an obligation to folks. I would say that I was pleased with the opportunity that the Governor provided for us to have kind of a—the equivalent of a job fair in New Mexico, where we basically brought all of the various departments, for all of the various entities, together in a gymnasium, and basically gave people an opportunity to apply for various programs.

So if there is something more that we need to do, obviously, Mr. Chairman, I am more than happy to hear from you, and from your staff, but we have certainly focused on this, and understand the importance of it.

Senator HEINRICH. I think it is important for people to realize that these are not one-time emergencies. Because you have the emergency, and in this case that fire lasted a really long time people were out of their homes. And then you have the floods that come afterwards.

Every year we have, you know, about half of our precipitation in the late summer in what we call, the monsoon season, and then you are just right back in emergency situations once again. And so the coordination between all the departments that are really helping with this recovery is much appreciated, and we will continue that dialogue.

CHRONIC WASTING DISEASE

Chronic Wasting Disease (CWD) is an issue of particular importance to both the Ranking Member and myself. We passed some new authorities last year with the Chronic Wasting Disease and Research Management Act. As you know, CWD is a fatal disease that affects deer, elk, and moose.

Secretary, could you provide just a little bit of an update on the Department's implementation of this legislation?

Secretary VILSACK. We are using the resources that you all have provided, and the direction you have provided to enter into cooperative agreements with states and tribes, in an effort to try to focus on both wild and domestic herds. Basically, we are splitting the resources between those two, I think it is important.

We also are looking at the role of research trying to determine exactly that—how this is transmitted from wild to domestic, and domestic to wild, so that we get a better understanding and appreciation for what we can do to mitigate the consequences of this. And ultimately, potentially hopefully, at some point in time, eradicate it, but we are working on cooperative agreements right now.

Senator HEINRICH. Do you think the Herd Certification Program is working?

Secretary VILSACK. Well, we are in the process of seeking public input to make sure that as we implement this, that we do it in the right way, and that we do it consistent with what people believe

the certification program should provide. I would say that I would be in a better position to respond to your question in a month or two, after we have had that public input, and we have given a sense of how to design this program.

PRESERVATION OF MULTI-FAMILY HOUSING

Senator HEINRICH. Well, we will circle back on that for sure. Rural housing I want to focus on your preservation strategy for multi-family rental housing for a moment. For the second year, the budget proposes decoupling two really important programs financial assistance for affordable housing rehabilitation, and construction and project-based rental assistance.

These changes will help maintain and improve access to safe, affordable housing for low-income Americans. And I was really pleased that the fiscal year 2023 Senate Bill supported this crucial policy solution absent this fix. More than 500 family in New Mexico alone, and 65,000 families across the Nation, could lose access to affordable housing over the next 10 years.

So Secretary, can you tell us how USDA will implement those changes if they are enacted?

Secretary VILSACK. Well, this is obviously a process which will require us to go through a rule-making process, Senator, but it is really critically important that we get this done. Because as I said earlier, we have got a circumstance where there are more mortgages getting paid off, as they get paid off we lose those rental units unless there is a mechanism for continuing them. And we have a voucher program, but the voucher program is only providing resources to cover a portion of the rental units that are lost.

And the reality in rural America is those rental units are absolutely essential for small towns and communities. They are just simply, they are necessary. So unless we decouple, unless we figure out ways in which we can encourage reinvestment back in these facilities, and continue to provide housing that is affordable for folks, we are going to have a serious problem in communities, which is why we continue to ask for the decoupling, and ask for the assistance in making this happen.

Senator HEINRICH. Yeah. I want to ask you as well, about single-family housing recapture, and that proposal around the balloon payments. But I am over my time. So I am going to turn things over to the Ranking Member.

And then we will hear from the Chair of the entire committee.

Senator HOEVEN. Chairman, our Ranking Member is here, which I appreciate very much. So I am going to defer to her for the first round, if that is okay.

Senator COLLINS. Thank you very much. That is very gracious of you, Senator Hoeven.

I am really pleased to see the leadership of this subcommittee, as I know Chair Murray is, because I know that you will work very well together.

SCHOOL MEALS PROPOSED RULE

Mr. Secretary, welcome. I very much appreciated your call earlier this year to discuss with me, and to preview USDA's proposed rule

that would significantly change the nutritional standards for foods that are served in the school lunch and breakfast programs.

I think we can all agree on the need to have healthy, nutritious foods served at school lunches and breakfasts. I recently met with the Maine School Nutrition Association, and they expressed some concerns about the proposed rule. I have forwarded their letter to you, but I want to talk about them here today.

First, let me point out that these are nutrition professionals, many of them are registered dietitians, and their concern is that students may simply refuse to eat foods that have been reformulated to meet the standards in the proposed rule. They point out that there are already sodium and sugar requirements, and that they are already serving low-sodium and low-sugar products.

So they say that with these additional requirements, to further lower the sugar and sodium in these foods, that the food begins to taste less and less like anything the students have ever eaten, and that it will likely end up filling our garbage cans.

Erin Dow, the school nutrition director from Freeport, Durham, Maine, summed it up perfectly in our meeting when she said, “An uneaten meal, is not nutritious.”

My questions to you are this: First, has the Department consulted with the frontline school nutrition directors about this proposed rule? And second, how will USDA ensure that these additional requirements do not result in fewer students eating school meals?

Secretary VILSACK. Those are very good questions, Senator, and I appreciate you asking them. First of all, we absolutely have reached out to those who are the professionals, those who were the heroes during the pandemic, who fed so many children and families during the pandemic, and we are certainly respectful of the role that they have played, and understand the importance of the role they play now.

For that reason we have reached out to them, and we have received input from them, and one of the things we attempted to do with these rules was to provide a longer transition period. The reality is these requirements don't go into effect immediately, they are spaced in over a period of time, which I think is important to note, because it gives people an opportunity to make those adjustments, it gives the food industry an opportunity to make those adjustments.

I would also point out that many of the reduced sugar products that we are talking about, are already in the marketplace, they are already available, and in fact they are being used in schools today, especially when the adult and child care program it is embracing, and with some degree of success.

I would say that we are also providing grants, particularly for rural schools, to make it a little bit easier for them to respond. And we are understanding that there is a great deal of interest in this, and so we are announcing this week a transition or an expansion of, rather, an extension of the comment period, so we are going to provide additional time for people to comment.

And I would also point out, I am pretty proud of this, that we actually made a \$10 million award to the Full Plates and Full Potential Program in Maine.

Senator COLLINS. A great program.

Secretary VILSACK. Yes. The purpose of that is to provide help and assistance. So we are doing a lot in this space, and we understand, at the end of the day I think we all as you say, we have the same purpose which is to make sure our kids are fed well.

POLYFLOUORINATED SUBSTANCES

Senator COLLINS. Thank you, in my little time remaining, I also want to point out that we have had very good discussions on Per- and Polyfluorinated Substances (PFAS). I know this is of great interest to the Chairman as well, of that class of forever chemicals that are being found in our soil, our water, our animal feed, our crops, and our livestock.

In Maine, the presence of PFAS, and wastewater sludge spread decades ago as fertilizer is preventing some of our family farmers from being able to sell their products, causing them significant financial harm, as we have discussed.

Well, Maine state agencies, agricultural service providers, and academic researchers, are already undertaking research relevant to the presence of PFAS, and the agricultural landscape. Far more research is needed. I noticed in the budget that this year your Department is requesting \$20 million for PFAS-related activities? How do you propose to use these funds? And more broadly, what role do you see, for the Department, in supporting research relevant to the PFAS challenge?

Secretary VILSACK. We needed to have a better understanding, Senator, of the full extent of this challenge that we face, and a better understanding of the impact of PFAS, when it is found in soil, when it is found in anything that impacts and affects our food supply. So first and foremost we need to have better research to know precisely the extent of what the challenge we are faced with.

Secondly, we need resources to be able to begin raising awareness on the part of producers, now your producers in Maine and those in New Mexico are fully aware of this, but I am not sure that all of the producers around the country are aware of it. So Natural Resources Conservation Service (NRCS), I think, has a responsibility to raise awareness, to fill the knowledge gaps, and to begin figuring out soil health practices that can make a difference, potentially, in remediation.

We also need to take a look, creatively, at programs like Conservation Reserve Program (CRP) and Conservation Reserve Enhancement Program (CREP), just to determine whether or not they can be a response to whatever we need to do to remediate the soil. We need more research in terms of its impact on animals and crops, and we also need to make sure that our food safety folks are fully embracing and understanding of the need to test, to make sure that as we are inspecting meat, poultry, and processed eggs, that we know the impact, if any, of PFAS.

So there is a lot of work to do. \$20 million is probably not enough, but it is a start, and it is certainly more than the \$5 million we got last year.

Senator COLLINS. Thank you. Thank you, very much.

Senator HEINRICH. Chair Murray.

Senator MURRAY. Well, thank you very much, Chair Heinrich, and Ranking Member Hoeven, I do look forward to working with both of you, and Vice Chair Collins, and everyone on this subcommittee, as we return to regular order for the first time in years.

And I will keep saying it, it is not going to be easy, but we have to live up to our responsibility to pass these funding bills in a timely, bipartisan way to keep our families strong, and our economy strong, and our country competitive on the world stage. And as this hearing should remind all of us that requires a good deal more than just defense spending, after all, at the most basic level we can't have strong communities if people can't put food on the table.

RESEARCH INVESTMENTS IN FOOD SUPPLY

And that is as important as it is obvious. We have to make sure that our food supply is secure, and that means protecting our families from unsafe food. It means protecting them from shortages, so avoiding, and mitigating supply chain disruptions, addressing the climate crisis, like droughts, which can threaten crops that all of us rely on.

And it also means addressing food insecurity, so the food families need to stay safe and healthy, is available, and accessible, and affordable. This is essential to keeping our nation strong, not to mention competitive.

For one thing, and speaking as a grandmother and a former preschool teacher, our kids cannot grow and thrive in body and mind if they are not getting the nutrition they need. Which is why the school lunch programs are so important, and why fighting food insecurity, and getting family support, is a priority of mine, as we negotiate the Farm Bill as well, this year.

And as my colleagues know, agriculture is also a huge part of our economy. In my state, every day, apples, and cherries, and wheat, and potatoes, and pulse crops, and so many other commodities, from Washington State, are shipped across the world for people to enjoy. But we need to make sure that our farmers, and our growers, are getting the support they need to compete across the world as well, including through the research happening at institutions like my alma mater, Washington State University, and across the country, to address our water shortages, and our improved yields, and reduce inputs, and a lot more.

So I am really glad we have the opportunity now to assess what we need to do to support our communities through the important programs here at the Department of Agriculture. And look forward to working with this committee as we put this bill together.

So Mr. Secretary, I have a few questions for you, starting with: The growers in Washington State and across the country face a lot of challenges, extreme heat, wildfires, invasive pests, plant diseases. And USDA's research has supported American farmers and ranchers in adapting and responding to these challenges so they can continue to produce a safe and abundant food supply.

This research is often carried out in partnership with our universities, like Washington State University, where students and faculty work together on solutions to these challenges. Can you speak to the importance of strong research investments in our Nation's food supply?

Secretary VILSACK. Well, they are essential, Madam Chair. And I would say that that this budget that we have proposed is suggesting an increase in the Agriculture and Food Research Initiative (AFRI) Program, which is the program that provides that partnership between our land-grant universities, historic Black colleges, minority serving institutions, to be able to conduct that research.

I would say, frankly, that as a Nation we have underfunded research in agriculture for far too long. When you compare it to some of the other areas of our economy agriculture research has been underfunded for a substantial amount of time. And I am hopeful that we get the increase that we are seeking, because it does bear fruit it does provide increased productivity, greater resilience, adaptation and mitigation to climate, new opportunities to use agricultural waste product to produce a whole array of bio-based products that can improve job growth and farm income. So it is essential, and we would certainly be willing to talk to you in more detail about precisely where those resources should be.

Senator MURRAY. So bottom line is, research saves money in the future, and helps produce more food, and all the things we need for our economy?

Secretary VILSACK. Every dollar of research generates twenty dollars, or more, of economic opportunity.

CUTS TO FEDERAL FOOD ASSISTANCE

Senator MURRAY. Yes. Mr. Secretary, I am very concerned about the House GOP calling for steep cuts to critical programs like our Federal Food Assistance. My family relied on food stamps when I was growing up, and my dad lost his job because he got sick. And so I really understand how important this is for people, and I am focused on making sure that we support SNAP and the families who rely on it, in our Farm Bill this year.

As appropriators, we also have a role to play in making sure we have full funding for nutrition programs, WIC, school meals, fresh fruit and vegetable program. Can you talk to us about why it is so important that we fully fund the nutrition programs?

Secretary VILSACK. Well, the research has shown that the SNAP Program has a positive impact on reducing poverty, and for children it also improves children's health if, in fact, the benefits are meaningful. I think it is important for people to know who is actually receiving SNAP. More than 80 percent of SNAP recipients are either people with disabilities, senior citizens who worked all their life, but are living on a fixed income, or working moms and dads with children.

There is a lot of conversation about able-bodied adults without dependents, but you need to know who those folks are. There was a survey done in nine states, I think Washington might have been one of those nine states, taking a look at who those able-bodied folks were, and what they found was that they were mostly men, and mostly homeless, mainly homeless. And I suspect that many of them were probably homeless veterans.

And so I think as we look at the circumstances and situations to try to assist, I think we should be spending more time focusing on state's efforts with employment and training.

Your state, by the way, has one of the premier employment and training efforts in terms of trying to connect people. If you think about it, and Senator Hoeven, he knows this. States know who the recipients are because they administer the SNAP Program, and they also know where the jobs are, and they also operate workforce development.

And the question is: Why we can't do a better job of spending \$100 million on employment and training, to basically allow those things to connect so that the jobs that are available, are linked to the people that need and can actually do them?

CUTS TO CONSERVATION PROGRAMS

Senator MURRAY. Thank you very much for that. And finally, in Washington State I have a lot of constituents working on regionally important water storage projects in the Yakima and Columbia basins. Those projects require ongoing technical assistance, and support from local staff at the National Resources Conservation Service. I often hear about how long it takes to work with NRCS, or to get assistance.

Underfunded local staff are stretched really thin and it would be an enormous mistake, I believe, to make things worse by gutting these agencies working to conserve our vital watersheds. Can you speak to what the risks are to our folks who are working on these projects if we cut these budgets?

Secretary VILSACK. Well, the reality is that you will have 84,000—even the most—if you take not the most draconian reduction that people are talking about, but the less draconian version, it is 84,000 farmers who won't get the technical assistance that they need in order to complete the planning, in order to get the conservation benefit that they seek for their operation.

So it is a very real impact, and we have made a concerted effort to try to rebuild the workforce at NRCS, because when I came back to this job there were 6,500 fewer people working at USDA than before, and the morale was incredibly low. So we have had a process of trying to rebuild both the workforce and the morale.

Senator MURRAY. Thank you very much. I absolutely agree.

Thank you, Mr. Chairman.

Senator HEINRICH. Ranking Member Hoeven.

Senator HOEVEN. Thank you, Mr. Chairman.

CONCENTRATION OF SLAUGHTER INDUSTRY

Secretary, we have to do more to address the concentration and the slaughter industry, particularly as regards to the cattle industry, I know you share that belief and concern, and there is a variety of things that we are doing, obviously we have to continue to press on the practices of the large four slaughterhouses, the processors, also, I think you are making progress with alternatives, we are working hard on that, and I am seeing that in our state and across, the country.

And I think that is very important and very beneficial, but another thing that we have worked on—excuse me—is a cattle contract library. And we allocated \$2 million out of this committee, and the authorization moved forward with a pilot program. I think this is very valuable in terms of providing more information to pro-

ducers in regard to Agricultural Marketing Agreement (AMA), and trying to promote more transparency and competition. I know you got your rule out, tell me where you are with it? How you think it is going? What we need to do?

Secretary VILSACK. We put the rule out in January, and began the process of putting stuff online. It is interesting, our team believes, by virtue of what we knew before the rule was proposed, and what we are seeing being provided by the industry that adjustments have already been made to some contracts in a positive way for producers.

Senator HOEVEN. Good.

Secretary VILSACK. So I think the transparency, the sunlight is an incredibly important tool. We are obviously going to continue to do that, and to provide as much information so people can make a comparative reaction, and a comparative study of the contract that they are being offered, versus what others have been.

Senator HOEVEN. That program is important. The work you are doing right now is really important, we will look to make it a permanent program in the Farm Bill, and so we are learning—you know, as you put it into play the experience that you gather here is going to be really important, as we set up a permanent authorization and funding for the program.

So we will be looking to that and drawing on the input, the experience, and so forth that you pick up from the producers. And it is really important because of the challenge of getting the various associations to work together in cases like this it—you know, is very beneficial that we are getting that done, and that that experience you draw on is going to be very valuable to us, how to have a good—the most effective program going forward.

CATTLE IDENTIFICATION TAGS

Cattle identification tags, you have got your rule out for public comment, I guess my concerns would be cost and any mandatory nature of that, and how that is going to be handled vis-&-vis our producers, it is like what, 30 bucks an animal, roughly. And so that, you know, there is a cost, so I think your original estimate is about \$26 million, how are you going to handle that, so that we are not putting a burden on our producers out there?

Secretary VILSACK. Well, the benefit of this program is for producers themselves, because if we have an incident and the chances are that something will occur, the ability to be able to identify where that incident occurs, and to be able to contain it to a particular region, or a particular farm, is going to be beneficial to trade.

Senator HOEVEN. I agree on the benefit, I am just wondering how you are going to handle the cost, and the mandatory nature, you know, how our cowboys react to that stuff, so we want them to see it as the beneficial tool it is.

Secretary VILSACK. Well, that is why we have been working with the Cattlemen's Association, and other organizations, who are in favor of this mandatory effort. I don't know that we have, necessarily, had a conversation specifically. I haven't had a conversation specifically about cost, but I am happy to take that back to our team, and see what—

Senator HOEVEN. Yeah. I hope you are working with the associations on how you are going to handle that aspect of it. And I do recognize the benefit of the tool, as do they.

CHRONIC WASTING DISEASE

Chronic Wasting Disease, the Chairman is an avid hunter, I actually do enjoy hunting myself, and so we worked together on the legislation for Chronic Wasting Disease, and he did a tremendous job leading that effort. But really, one of the most important aspects of it is, for the first time we actually have domestic producers and the outdoorsmen working together rather than jockeying against each other trying to get the funding, and trying to get the research done that they want.

We finally brought them together in this initiative, and that is critical, and we will, you know, obviously it is authorized at \$70 million, will work to increase funding, we are already doing that, what is going to be most effective here to advance the research in your opinion? And is there something else we should be doing?

Secretary VILSACK. I think continuing to make sure that there isn't appropriate division of those resources between domestic and wild, that we don't seem to be favoring one or the other recognizing, as you just mentioned, the need for these folks to work together, and making sure that they see that this program is benefiting all sides in a fairly appropriate way, I think this is very important.

And then secondly, I think making sure that we have the resources on the research side, to be able to really begin a process of understanding, how does this get transmitted, and what can we do from a domestic perspective to prevent transmission. And we have got that issue frankly, and a lot of other species as well.

Senator HOEVEN. That is the breakthrough, that we have got them working together, and then USDA working with the local—or with the State Department of Ag, and their outdoor resources people, I think can really help keep that cooperation going.

Secretary VILSACK. Absolutely.

Senator HOEVEN. Thank you.

Senator HEINRICH. Senator Manchin.

Senator MANCHIN. Thank you, Mr. Chairman.

Mr. Secretary, thank you, so much for all your service, and feeding America, especially the children. I appreciate it more than you know.

DEFINITION OF RURAL

I am going to switch gears just a little bit based on rural America, and what we deal with. You and all of your staff and everything, you do an awful lot more than just feed us. There is an awful lot of economic activity that goes on, that sometimes people aren't aware of, and myself, has not been, until you and I spoke about what opportunities were out there.

Here is the problem we have, sir. The Economic Research Service, I think was in your all, bailiwick, develops various codes and criteria to help define rural America. The way I look at it is about 66 million people living what I would consider rural America. And currently, there is no code accurately that captures the moun-

tainous rural areas, which much difference; the mountainous rural, versus agriculture rural, two different things.

That is something we have not been able to see and it is difficult for us to do anything as far as the building towers to Internet, and all this, and delivering those services, are so much more expensive. So the project was started in 2021, and as of today we have not seen the Phase I published report. If you could give us any update on that, if you have it? If not, get back to me on that.

Secretary VILSACK. Well, I will have to get back to you on it, Senator. But I would say this is an ongoing problem in terms of the definition of “rural”. There are multiple definitions which creates a lot of confusion and a lot of uncertainty.

Senator MANCHIN. Oh, I know.

Secretary VILSACK. So I will be happy to work with you on that.

Senator MANCHIN. As a former Governor in serving, and yourself, and I, we serve together. But as a former Governor you have a lot of rule, at least in Iowa, you know—the problem that happens, I have seen it since I have been here 12 years, is when money is disbursed, whether it is in education, whether it is in health care, whether it is in agriculture, whatever it is, the rural areas do not get their proportion of shares.

So if there is 20 percent of the population that is classified “living in a rural area”, in my state, I don’t have one town, I don’t have one city bigger than 50,000 people. So I am a state of towns; 1.8 million people in a state of towns, but it is as rural as it gets. And it is as wonderful, it is just wild and wonderful, it is as wonderful as it gets, but they get left out. When we look at the national money that goes to rural America, it is only about 7-, 8-, 9 percent of Federal funding.

Because I guess showing the biggest bang for your buck, it is better if you have the 1,000,000 people, versus 50,000 people, but the services are just as needed. That is the problem we are running into.

Secretary VILSACK. They are, but there is also a contribution that rural America makes, a disproportionate contribution that speaks to our military.

Senator MANCHIN. Oh.

Secretary VILSACK. People often forget that disproportionate number of our military come from those small towns in West Virginia and Iowa.

RECONNECT

Senator MANCHIN. And Appalachia, I mean Appalachia especially. Let me go into this one here. President Biden requested another 400 million of the ReConnect Program, in his fiscal year 2024 Budget that he just put out. That is in addition to the \$348 million we had in the last budget, and that is on top of the \$2 billion in the Bipartisan Infrastructure Law (BIL).

So have we put billions of dollars out there, and what we are concerned about is, it is mammoth for you all I know that, but coordinating that effort to be able to administer working with Federal Communications Commission (FCC), National Telecommunications and Information Administration (NTIA), and Treasury. How is that going or where is the stumbling block?

Secretary VILSACK. I am pleased to tell you that by this summer we will have all of the BIL money, the Infrastructure money obligated, and the reason for that we really have spent a lot of time trying to do this, so that it will complement the work that will come next by NTIA and the Commerce Department, and the FCC, because we want to basically use our resources to upgrade, as best we can, the unserved and underserved areas so that they have meaningful broadband.

And then as the mapping gets completed, we will then know where the real serious gaps are which then will provide the resources under the infrastructure law for commerce, and so forth, to be able to invest through states. So we are coordinating. We are making sure they know where we are investing the money so that we are not overbuilding, and not duplicating.

Senator MANCHIN. Well, let me just say, in closing, I sincerely—in my lifetime I have never seen anyone has as much knowledge as you, and as much experience in this job, coming from where you came from, and also the states you represented, to being in this position, and the amount of years you were before, and one and done was not enough for the public service you are giving, and I just thank you, because you can help us so much, every one of you all.

I call him Tom, but I call him Governor, and I call him my friend, he knows more about how to help your areas as far as in getting other, than just the feeding of America, but basically economic development. There is so much that they can offer in that office, that we are not—we are just not accessing. So thank you. Thank you, my friend.

Secretary VILSACK. I appreciate it.

Senator HEINRICH. Well said, Senator Manchin.

Senator Hyde-Smith.

DISASTER ASSISTANCE

Senator HYDE-SMITH. Thank you, Mr. Chairman, and I certainly appreciate the opportunity to do this, and thank you for being here. But first of all, I want to tell you how much I appreciate your staff reaching out to us over the weekend with the Mississippi tornadoes. Within hours after the storm they were reaching out to the Mississippi delegation. And I certainly appreciate that.

And seeing the devastation first-hand, you know, we have just gone into that mode of trying to help these people as much as we can. Most of this area is farming area, the Mississippi Delta, and other areas as well. But you know, I just was up there after the storm, and the day after that. And seeing the devastation, you know, as resilient as we are, before we dive into the details of the funding, I was just hoping that you could kind of offer some information for the rural communities that were affected.

For instance USDA's recent press release following these tornadoes stated: Food Safety and Inspection Services (FSIS) helping affected residents reduce their risk of food-borne illnesses. Due to the power outages that we are looking at, the Risk Management Agency offers several risk protection tools to offset crop production and tree losses for certain crop insurance products.

But the Farm Service Agency offers the Livestock Indemnity Program, and the Tree Assistance Program, and the Emergency Con-

ervation Program, several things there, and NRCS can help address natural resources concern, by providing the cost assistance for work such as debris removal. But would you, please, elaborate a little bit on the areas of assistance offered, and how they can access this?

Secretary VILSACK. Well, first of all, I would encourage you to take a look at the Farmers.gov website, which has this document on it, which basically contains many of the programs that you just mentioned but more than the ones that you mentioned, and basically the kind of disaster they cover, and the kind of assistance that they can provide, and the information necessary. That would be the first order of business.

The second order of business is making sure that state officials and your staff reach out to the State Rural Development Director for the State of Mississippi. I mean our heart goes out. As a former governor, I have toured many tornado damaged sites, and it is absolutely devastating to people. They lose their home in a matter of seconds, and unfortunately, in your state, loss of life as well.

But the Rural Development folks can be there to begin the process of figuring out: How do we rebuild? How do we create the opportunities for housing for the community facilities that have been damaged or destroyed? What kind of resources could be available?

And the Farm Service folks are there, obviously, to begin the process of assessing the level of damage, so that crop insurance and any risk management tools, as you well know from your experience as commissioner down there, agriculture; that we provide as quickly, a response to the loss of production as possible.

So Farmers.gov, State Rural Development Director, and working with the local FSA Office, I think would be where I would start.

Senator HYDE-SMITH. Well, I certainly appreciate that because so much equipment got destroyed. You know, we are in the middle of planting corn, and the equipment is just gone.

Secretary VILSACK. There is also a Disaster SNAP Program that basically makes it a little bit easy for people who may have lost their SNAP Card, because the tornado destroyed their home.

Senator HYDE-SMITH. Yeah. They don't even have vehicles.

Secretary VILSACK. Right.

Senator HYDE-SMITH. You know, they have no way—no mode of transportation right now to even—to get somewhere, but we are going to recover, there is no doubt. We have some great folks there. But I just wanted to tell you how much I appreciated that.

HIGHLY PATHOGENIC AVIAN INFLUENZA

One thing I want to mention, I only have a little time left. The 2022–2023 Highly Pathogenic Avian Influenza (HPAI), the outbreak is the worst health crisis emergency in U.S. history. As Ag Commissioner, this kept me awake at night, no doubt. But paired with critical shortages of veterinarians in rural, food, animal, and public practice, this outbreak has been devastating for the poultry, turkey, and egg industries, which we are a huge poultry state and egg state.

But it has also directly affected millions of families who are struggling to keep up with the resulting rising cost of poultry and eggs. But I recognize and appreciate that the Animal and Plant

Health Inspection Service, APHIS, is working tirelessly to control Avian Influenza. But it seems as though having more food animal veterinarians, and more vets in APHIS would be helpful for current and future mitigation efforts.

But I also noticed that your budget includes \$3 million for incentives to recruit and retain public health veterinarians for food, and safety, and inspection, services. So clearly USDA understands the great need for veterinarians working in areas besides small, animal practice, which is great, we all love, and we have to have but, you know, it is just so much more attractive and lucrative.

But the Veterinary Medicine Loan Repayment Program, which your budget includes, helps alleviate veterinary shortages in rural, and Food Animal Practice Government agencies like APHIS and FSIS, by providing money towards the educational loans.

So you know, this subcommittee allocates the funds to this program, and a major portion of those funds go right back to the Federal Government because of the 39 percent Federal withholding tax, which is just incredible on that program, at its tax, 39 percent.

So only \$6.1 million of the \$10 million provided by Congress for this program, in fiscal 2023, will actually be put toward the educational loans of the veterinarians, and to address these critical veterinary shortages.

Can you respond to that to help prevent animal health emergencies, and what actions we can take to address this—shortages in both private Food Animal Practice, and in state, Federal Government, that 39 percent just blows me away.

Secretary VILSACK. Well, I am happy to take a look at that, Senator. But I will tell you, the biggest problem we have is retaining folks that we actually do get. They actually end up starting at APHIS, they are excited about their job, they do an amazing job for a year or two, and then someone basically says to them: Hey, in the private sector you can make 10-, 20-, 25,000, \$50,000 more, why don't you come over to the private practice? And that, that is the challenge.

Our compensation system has got to be looked at from—and when I say “our” I mean the Federal compensation system—so it is competitive. And we have to have more flexibility in terms of the ability to use retention resources to be able to retain these folks, because we can get them in the door we just, we are having a hard time keeping them.

The loan repayment is one aspect of it, but there are many, many other aspects in terms of lack of competitive nature of our compensation system.

Senator HYDE-SMITH. I would really appreciate some help with trying to offset that system.

I am sorry for going over my time, Mr. Chairman.

Senator HEINRICH. Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman.

DROUGHT IN THE WEST

And Mr. Secretary, good to see you; and I want to talk a little bit about drought in the west.

And in the eastern part and southern part of my state we have had droughts that have gone on year-after-year, it is also associ-

ated with the lower snowpack we have in the Cascades. I was just up at Crater Lake where they showed that they have lost 240 inches of average snowpack over the last 90 years, complicating the lack of rainfall during the spring and summer.

And the irrigation districts are responding by, one, changing their practices on the farm to get more crop with less water, but then also by piping their canals. And this piping has been essential because of the massive amount of water that is lost in open ditches, through evaporation and groundwater.

And that effort has been explored in an article, The Washington Post, "The Future of the American West is in Central Oregon", which is about that vast effort to pipe to save our agriculture and I want to submit it for the record

Senator HEINRICH. Without objection.

[The website link for the article follows:]

<https://www.bloomberg.com/opinion/articles/2022-08-28/central-oregon-is-the-future-of-the-american-west?embedded-checkout=true>

Senator MERKLEY. Thank you. So this effort has been recognized in the Western Water and Working Lands Framework, and that NRCS philosophy notes that water management is essential or we lose agriculture across a broad swath of the West. Are you familiar with that NRCS Framework, and do you support that?

Secretary VILSACK. I am very familiar. The six challenges and thirteen strategies, and the \$25 million that we have allocated to the Department of Interior WaterSMART Project?

Senator MERKLEY. Thank you.

Secretary VILSACK. Yes, I am.

Senator MERKLEY. I knew you would know every nuance of it. But I asked that simply because there is a tool that was incredibly effective that I worked to revitalize, with Senator Cochran, the 566 Program which had basically gone out of existence. And that program was being used to help with the piping of the irrigation districts in the West.

And over the last couple years the Administration has shifted that 566 money away from helping with piping in the West, and I am basically here to say: Can we recognize that this is an incredibly powerful tool to help address the goals in the Western Water and Working Lands Framework, and can we move some of that funding back into the direction of helping the Western Irrigation projects with their piping challenges?

Secretary VILSACK. It seems as if that would be consistent with one or more of the strategies to modernize the water infrastructure and the complete watershed projects; and also to do a better job of water management. So it would seem to fit within the strategies that the framework has called for.

Senator MERKLEY. It definitely fits. And I would appreciate any help that we can get. We have been able, through our community initiated projects, to direct a small amount of money. This is, if you will, the congressionally directed spending, which in Oregon we call "community initiated". And I can tell you the irrigation districts are all completing watershed plans to be eligible for this program.

And well, I am doing all I can to help them survive a very difficult changing climate where water efficiency will help save them,

but piping is essential, and for that piping 566, is essential so I ask for your help in shifting some of those resources.

Secretary VILSACK. So I will take a look at it, Senator.

Senator MERKLEY. Thank you very much.

Senator HEINRICH. Senator Moran.

Senator MORAN. Chairman, thank you.

Mr. Secretary, thank you, for being here. Thank you for your service to farmers and ranchers across the country, and in Kansas, in particular. You and I are about to have a high-five moment.

Secretary VILSACK. Yeah.

NATIONAL BIO AGRO-SCIENCE FACILITY

Senator MORAN. Thank you for working with me to pick a date for you to be in Kansas, and I want to take several moments, but want to give you a moment to highlight a development that began a long time ago as a result of the 9/11 Commission.

The Secretary will be in Kansas to cut a ribbon on, the National Bio Agro-Science Facility (NBAF), designed to protect public health and our food safety, managed by USDA, Agricultural Research Service (ARS), and APHIS, and it will contain the BL-4 Bio-containment Laboratory.

You were there, Mr. Secretary, in May of 2015, now 8 years ago, a long time coming, but a very important facility and asset for the Department of Agriculture, American farmers and ranchers, and in fact every American citizen, and around the globe.

I would be glad to have you highlight why you think this—if you do, why you think this is a benefit to the American people?

Secretary VILSACK. Well, Senator, it absolutely is. It modernizes our process and our ability to investigate and to research some of the major challenges and threats to American agriculture, whether it is African Swine Fever, or Foot-and-Mouth Disease, or some of the other seven critical diseases that could cripple our livestock industry which, obviously, would impact and affect our entire economy and our food security.

In addition, this facility will also be where the Vaccine Bank is housed, and as we develop vaccines to try to deal with some of these threats, obviously being able to stockpile appropriately and safely, those vaccines are incredibly important. There are also, a great deal of research is going to be done on the countermeasures, the biosecurity initiatives that are a part of protecting our livestock industry.

So this is critically important. And the fact it has taken as long as it has, is because of the minute nature of the protections and security that is required as we move from Plum Island to Manhattan, Kansas.

So I am looking forward to welcoming, and to cutting that ribbon. And I am sure that you will have a pair of scissors, and I am pretty sure Senator Roberts will have a pair of scissors.

Senator MORAN. I appreciate you being there, and I look forward to seeing you in Kansas on May the 24th. Thank you.

Secretary VILSACK. Looking forward to it.

GENETICALLY MODIFIED ORGANISM CORN

Senator MORAN. Mr. Secretary, I was in Mexico City, I met with President Obrador may be a week ago Sunday. Maybe in your answer to my question you can explain your smile. I raised my concerns about the efforts to ban genetically modified organism (GMO) corn, I was encouraged to hear what I thought was said, which was that the matter could be resolved in the consultation stage, rather than reach dispute settlement.

That was then followed by the suggestion that the United States and Mexico ought to do an additional study about the safety of GMO. Does the USDA continue to believe that the science on this matter is conclusive, and will it continue to fight to ensure full and fair access to the Mexican market?

Secretary VILSACK. Senator, and the reason I smiled is because I have had two such meetings with President Obrador, and I am fairly certain that what he told me on those occasions is exactly what he told you. And the reality is that we don't need another study, there are literally hundreds of studies about the safety of this technology, and that has been explained to the President. It has also been explained to the President that 66 percent of his feed needs for his livestock industry come from biotech corn that is grown and raised in the United States.

The challenge is that he is very—as you probably found out—very proud of the white corn that is produced, the maize that is produced in Mexico. And I think he has put himself in a situation, a political situation that is very hard for him to move out of.

At the same time, by virtue of banning the ability to have white corn from Nebraska, or other states come into Mexico we are—he is asking us to acknowledge a non-scientific basis for such a ban, and we can't do that. It is fundamental to our trade strategy and philosophy, and our approach to the rest of the world that we want a science-based system, and we believe in the safety of biotech products, we believe in the science behind it, and that has been explained to the President, politely, on a number of occasions.

Senator MORAN. Is there any question about what our trade agreement is between Canada, and Mexico, and the United States.

Secretary VILSACK. Not in our view.

Senator MORAN. Thank you. Mr. Chairman, I would conclude just by telling that—I would feel guilty if I didn't say this.

Mr. Secretary, you and I have worked in your previous time at USDA on trying to export and increase trade around the world, I would encourage you and the administration that you work in, to look for opportunities to reach agreements with other nations, singular and then collectively, trade is hugely important, and while we face challenges in making sure that we do trade agreements right and they are enforced, farmers in Kansas, and across the country depend upon the ability to export what they do, around the globe.

Secretary VILSACK. Well, the good news is that we have had over \$15 billion of additional opportunities in market access created in the last 2 years. So we will continue to do that.

Senator MORAN. Thank you.

Senator HEINRICH. Senator Fischer.

Senator FISCHER. Thank you, Mr. Chairman.

PRECISION AGRICULTURE

Mr. Secretary, so nice to see you again. A couple of weeks ago we had the opportunity to talk about the importance of precision agriculture, and I would like to talk about an exciting opportunity from USDA AG Research Service.

As you know, over the past couple of years Congress has appropriated \$31.2 million to begin construction on a new USDA-ARS National Center for Resilient and Regenerative Precision Agriculture, co-located at the University of Nebraska-Lincoln. Those already-appropriated funds are going to allow construction of a research greenhouse to begin on that project. And I was glad to see in the fiscal year 2024 request for an additional 60 USDA-ARS employees to Lincoln.

Can you discuss the need for those additional ARS employees, and the vital research that the National Center for Resilient and Regenerative Precision Agriculture will perform?

Secretary VILSACK. This is a process of rebuilding the workforce at ARS, and providing a complement to the research it has done through the AFRI Program, which is the grant program to land-grant universities.

We are very proud of the work that we do at ARS, but we just need more people, we need more bodies, and we need the ability to recruit bright young people to make sure that we have a constant stream of bright people. We have proposed this because we like working with the University of Nebraska. We think that they have a concept and a vision that is incredibly important to the future of agriculture as it relates to our response to climate.

We are going to have to produce more with less, and the only way you can do that is by better understanding how to use the inputs that you have in the most effective way, how you can have seed technologies that are more beneficial and more efficient in how they use the inputs. And then be able to provide the information to farmers so that they can utilize that information in the best possible way to improve their productivity and their profitability.

So this is an important enterprise, which is why we proposed additional investments, not only of people, but also money.

Senator FISCHER. And I hope that Congress is going to quickly provide Appropriations so we can see the construction of the facility as well.

IRA CONSERVATION FUNDING

In the Inflation Reduction Act it provided an addition of \$19.5 billion to several USDA conservation programs, text of the IRA departed from the resource concerns agreed to in the Bipartisan 2018 Farm Bill, and it restricted how these funds could be used to improving soil carbon, reducing nitrogen losses, or to reduce capture, avoid or sequester carbon dioxide, methane, or nitrous oxide emissions associated with agricultural production.

How is the USDA interpreting that restriction placed on IRA conservation funds? For example, how will you look at a producer who wants to use Environmental Quality Incentives Programs (EQIP) cost-share funding to upgrade their irrigation pivot, for ex-

ample, so they can optimize their water usage? Would that, or would they be at a disadvantage under the IRA funding?

Secretary VILSACK. What I can tell you, Senator, and I will get a specific answer to that hypothetical. I can tell you that the NRCS is focused on utilizing the climate-smart practices that we have identified that we are currently funding under the EQIP Program and using the IRA resources to basically ensure that those practices are targeted or benefited. I mean, the reality is, I think it is—there are 45 of them, so there is quite a broad range and the goal here is to try to encourage more of that. But I will ask our team to get back to you on the specific hypothetical you have provided.

Senator FISCHER. Yeah. That would be great. I am new on this committee, and I am excited to be on this committee because I want to be able to make sure that we are funding programs that work, and the producers use, where they are able to have fewer inputs, and also be more profitable. And I have I think if we can make those determinations that really work on the ground, it is going to help not just rural America, it is going to help our conservation methods as well.

Last question: The livestock is the biggest sector in Nebraska, we always talk about that. It is a huge economic engine. We have a Meat Animal Research Center in Clay Center. And I was glad to see the budget request included an addition of 15 employees at U.S. Meat Animal Research Center (MARC), as well as an increase in ARS funding for their Livestock Production Program. How would increased staff at MARC help carry out research related to critical livestock industry priorities, including increased environmental sustainability, improved production efficiencies, and really optimize the use of our natural resources?

Secretary VILSACK. Well, I think we are going to learn quite a bit, not only for the work that is specifically done at that Center, but also as we institute our partnership for climate-smart commodities there is going to be a significant amount of measurement, monitoring, verification, and accumulation of data.

Senator FISCHER. Mm-hmm.

Secretary VILSACK. That in turn can be provided to ARS facilities, into other facilities, in terms of being able to educate them about what we know works, and frankly we are going to find out stuff that doesn't work. And we want to make sure that we are not funding that, or we are not targeting resources to what doesn't work.

So I think it is a combination of the research that they would normally do, but it is also learning from the experience in virtually every commodity including livestock, there are a number of livestock projects in that Climate-Smart. So I think you are going to learn a lot from that.

Senator FISCHER. Okay. Great. I know specifically of one Ph.D. student who is doing research at the University of Nebraska, who has been conducting it, she has for over 5 years, to look at livestock emissions. And I think that is going to change the perception out there greatly, by the public, and really look at the benefits of livestock to the environment.

Secretary VILSACK. We need to reduce methane, and we can. There are strategies, and we also need to capture it and convert it.

Senator FISCHER. Yeah, thanks.

Senator HEINRICH. Senator Tester.

Senator TESTER. Thank you, Mr. Chair. I want to thank you and the Ranking Member for having this hearing.

FARM SERVICE AGENCY STAFFING

I want to thank you for being here, Secretary Vilsack, I appreciate it. You know, I have had a number of Farm Bill listening sessions since this is a Farm Bill year, and these haven't been invitation, this has been opening the doors and let folks in to speak their mind. And we have heard things that you have heard, like the reference price needs to go up because of inflation. We have heard things like conservation programs, like EQIP, need more flexibility, because we don't have enough well drillers or dirt movers to get these jobs done within timeframes.

We have heard things like the Crop Insurance Program, especially with the push of cover crops needs to be increased to cover a lot of those. We have heard a lot about food security because we both know that democracies don't work very well when you have a population that is hungry.

One of the things that I have heard about that I didn't expect to hear about, but I have heard it at every one of them, is that it is really hard to hire people in our FSA offices. We have got 236 total FSA positions in Montana, roughly 40 of them are vacant on any given day. Part of the problem is competitive salaries. The starting salary in Montana is \$33,700 if you don't have a degree, \$37,700 if you do.

I can tell you. And you know this, you know this, Mr. Secretary, you can probably make money doing damn near anything else but being a school teacher. Okay, that is probably the only thing you couldn't do. We do not have locality pay in Montana, and so a place like Bozeman, which is where our state office is, where the cost of a house is equivalent to a house in San Francisco, you are just not going to get people to work, you just aren't going to get people to work at those wages.

So my question is, in your budget do you have adequate dollars so that we can recruit some people; because it truly is a crisis situation? I use our office in Chouteau County and they felt the turnover, but in some of these offices it has been devastating. And you know very well, we can do the best job putting a Farm Bill up, and you can do the best job implementing it, if you don't have people on the ground we are screwed.

Secretary VILSACK. Senator, I couldn't agree with you more. And this isn't just your FSA office issue, it is an issue across FSA, it is not just an FSA issue, it is an issue across all of our mission areas. And it is, in part, a result of the overall Federal system that is in place, and we are trying to work with the Office of Personnel Management (OPM) to get a better understanding of how we might be able to reclassify people, and figure out ways in which we can provide more resources, and more incentives for people to work at USDA.

Senator TESTER. So I am willing to work with you at the OPM. You are right. It is a system-wide problem within Ag, within the Veterans Affairs (VA), a number of other agencies, if not every other agency. But let us say we get OPM to do that reclassification, will this budget support it?

Secretary VILSACK. I believe it will. I mean, we are we are asking for more resources so that we can hire more people. So I think we have the capacity. The challenge isn't just simply getting people, Senator, it is also retaining them.

Senator TESTER. Yes. That is correct.

Secretary VILSACK. That is actually, to a certain extent, that is an even greater problem, because as soon as they start working somebody—here is what happens in these FSA offices, the loan officers in particular, they get trained by us, get trained well.

Senator TESTER. Go to the bank.

Secretary VILSACK. And then a bank comes in and says: Hey, you can we can make \$5,000 more. And off they go. So we have the capacity I think in our budget to do some retention stuff, but we need, we need more permission.

Senator TESTER. Well, I think it is a problem, and I would have heard about it, at every group I went to. I mean these folks, they didn't get together and plan this, I didn't give them talking points. They came in, it came up organically. It is an important problem.

Secretary VILSACK. Yes.

BRAZILIAN BEEF

Senator TESTER. I want to talk about something else that isn't nearly as pleasant as not being able to hire or keep employees, believe it or not. And that is Brazilian beef. So I have just got to tell you, I have had bills to ban it, I think it is a bipartisan concern. Earlier this year Brazil had another case of bovine spongiform encephalopathy (BSE) it took them, it took them 35 days to report it. I would hope it doesn't take us 35 days to report if we have it here, although we don't, which is an issue that if we get it here it raises hell with our beef industry.

My question is, does it take an act of Congress to ban Brazilian beef, or can you do it? And if you can, why not do it?

Secretary VILSACK. This was an atypical case, Senator, and it is sort of like: Do you do you believe in the Golden Rule? Because if you do it to Brazil, Brazil can do it to us; we actually have had atypical BSE cases. And if you want the rest of the world to ban our beef, for an atypical case, which is not recognized as a bankable event by the World Health Organization (WHO), and the animal health organizations, that is the challenge, all right.

We have communicated to Brazil our unhappiness about the tardiness and the lateness with which they have identified this. We are happy to help them with their testing to make sure that they get information to us quickly as possible. But I think for an atypical case I think you are going down a road that is pretty slippery, and I don't think we have the authority to do it.

Senator TESTER. And I am over time. So here is the issue. I don't think you would disagree with the fact, that we raise the best beef in the world, we raise the best Ag products in the world. And that is not brag. I believe that is absolute unequivocal fact. When we

have a situation where we are having a generation of ranchers go broke because of an issue that you and I agree on, the amount of consolidation in the industry, and the processing industry, and one of those processors is JBS, which is a Brazilian company, I think we ought to do our level best not only to hold them accountable to make sure they are following the Packers and Stockyards Act, but hold them to extremely high standards, when it comes to bringing in Brazilian beef, because I think that is where most of it is coming through.

Secretary VILSACK. It is certainly fair, that they should be held to a high standard in terms of the safety of the product.

Senator TESTER. Okay. Thank you.

Senator HEINRICH. Secretary, we are going to try to do a quick second round, if you are amenable to that?

Secretary VILSACK. I didn't know I had a choice.

Senator HEINRICH. You seem to be doing fine so far, so we are not letting you off the hook just yet.

SINGLE-FAMILY HOUSING RECAPTURE

I mentioned the single-family housing recapture proposal and, you know, the challenge with those balloon payments. Can you just talk a little bit about how important this initiative is, and how it would improve access to affordable housing in rural America?

Secretary VILSACK. If you want to create distrust in government, continue this process. People, basically, they sign a loan document, they don't quite understand you are getting a loan, interest subsidy, and you know, interest rates going to be lower but, boy, you know, 20 years from now when you sell it, or when your heirs sell it, you are going to have a—you know, you are going to have a bill that you are going to have to pay, and it is going to be pretty substantial.

Senator HEINRICH. Yeah.

Secretary VILSACK. It is an outrage—I mean, to me, it is an outrageous process because it comes as a tremendous surprise, especially when “mom” and “dad” are gone, and the kids are selling the house, and then they are set—good news is you sold the house, the bad news is, you owe the Government \$27,000, and they go—that is not what we should be doing.

Senator HEINRICH. I don't know how we got here, but we need to fix it.

Secretary VILSACK. I don't know either, I don't know, and there may have been a rationale behind it, but it undercuts trust in government and to me that is the principal reason for getting rid of it, and to do it retroactively so that we don't surprise any more folks.

PROCESSING OPPORTUNITIES FOR BISON

Senator HEINRICH. Thank you. Both the Ranking Member and I have a special interest in bison. We actually designated bison the “National Mammal” a few years ago.

We have a lot of interest in bison production in New Mexico, particularly with some of our tribes, and Pueblo producers. What do you see as the USDA's role in aiding producers, and in particular

like expanding access to processing opportunities for those producers?

Secretary VILSACK. Well, we have had two initiatives, one basically taking a look at existing processing facilities, and giving them resources to be able to expand their market capacity, and market reach, two bison operations have received those Meat and Poultry Inspection Readiness Grants.

I think—if you are patient with us—within the next month or two you will see there will be a specific effort to provide additional resources for tribal processing, which obviously will be focused a great deal on bison. We have also, as part of our effort on food sovereignty, with tribes we have tried to integrate more bison purchasing, and more bison in some of our feeding programs.

And also I am pleased to note that the Partnership for Climate-Smart Agriculture Commodities included several bison projects as well, so there is a great deal of effort, both in terms of creating market opportunities, expanding processing capacity, and being able to incorporate bison into any climate-smart initiatives that we are developing.

Senator HEINRICH. And I appreciate your focus on it. I would mention, as you are looking at that production side, the concept of shared resources for mobile processing is something there is an awful lot of interest in and something to bear some focus.

Secretary VILSACK. There is a loan guarantee program that we have that is basically providing resources for mobile slaughter and processing, it is a loan program, but it is a guaranteed program with lower interest rates. That is something that folks could look at as well.

POLLINATORS

Senator HEINRICH. Great. Thank you. We have had a lot of challenges with pollinators in recent years, and an enormous amount of our agricultural production is directly dependent on pollinators, what are we doing in this budget around ensuring the long-term success of a whole range of pollinators that agriculture depends on?

Secretary VILSACK. Well, we have a specific CRP aspect to pollinator, which isn't necessarily specific to this budget, but it is obviously specific to the Department. There are research initiatives that are also focused on pollinator health, Utah State. For example, has a fairly significant initiative when it comes to pollinators.

I didn't know that there were like, you know, 4,000 different kinds of bees in the United States, and 20,000 internationally, but now I do know that, in part, because of their program. So we fund research, and we provide habitat, expanded investment in habitat.

Senator HEINRICH. Great. I am going to pass things off to the Ranking Member.

Senator HOEVEN. Thanks, Mr. Chairman.

DISASTER ASSISTANCE

A number of things that Senator Tester mentioned, I think are really important. I won't go back into them, but the FSA staffing is very important obviously. We want to work with you to address that. He also emphasized the importance of crop insurance and safety net as I did in my opening comment. Do you agree that

those have to be absolute priorities in the in the upcoming Farm Bill?

Secretary VILSACK. Yes.

Senator HOEVEN. Updating those?

Secretary VILSACK. Yes.

Senator HOEVEN. Okay. The emergency—we put together the Wildfires Hurricanes Indemnity Program+ (WHIP+), and then utilized it, and then came back, and utilized it again. You brought it out and called it Emergency Relief Program (ERP). Phase I worked very well, we are very pleased with that. Phase II, as you know, we weren't quite as pleased with, in terms of how you formulated it. My request to you, going forward, is that you would work with us if we utilized that WHIP+ Program, or as you call it, ERP, and the Livestock Risk Protection (LRP), again, I think you did a lot of good, but we would like to coordinate with you on how it is implemented, if utilized going forward.

Secretary VILSACK. Do you want me to respond to that, Senator?

Senator HOEVEN. Yes.

Secretary VILSACK. There are three groups of people that we are dealing with when it comes to ERP. There is the group that has Crop insurance or Noninsured Crop Disaster Assistance Program (NAP) coverage, where they have information and data that was provided to us and we pre-populated the application, tried to reduce the time to get resources satisfied.

Senator HOEVEN. Yeah. Mm-hmm.

Secretary VILSACK. That is Phase I. Phase II was focused on the people that did not have. That there are people that are greatest at risk, that don't have any of those protections. Try to get them into that system. If there is money left over from Phase II, our expectation is to take a look at the other group, which is the group that, because of their losses were pretty—didn't trigger an indemnity under crop insurance, that they would then be in a position to be able to receive resources.

And we are learning from this experience, and I would expect and anticipate that we need to look at that in terms of this year's ERP Program.

Senator HOEVEN. Yes.

Secretary VILSACK. Having said that, Senator, there is not enough money in that program.

Senator HOEVEN. I know. And that was part of it, which is why I registered concerns but left it at that.

Secretary VILSACK. Okay.

Senator HOEVEN. But no, that is what I hope you would say, and that is good. We will work with you going forward. Also I think again, as far as that countercyclical safety net that, you know, getting that right and crop insurance right, updating it like we are talking about, will help diminish the need for some of these other disaster assistance programs, so again, incredibly important.

And one of the areas, also, I want to ask about, is the Pest Management policies, you know, some of the issues we have seen with glyphosate, chlorpyrifos, some of those products that our farmers and ranchers have been using for years, and years, and years now are being taken off the market. Not necessarily through your ac-

tions, but through court actions, that can be kind of state by state. It is creating a difficult patchwork for our producers out there.

What can we do about that? And it is also creating a lot of uncertainty for them. I mean they are they are buying these products, and then they can't use them. I mean, it really is getting to be an issue that USDA needs to take the leadership role in terms of helping our farmers and ranchers from the standpoint of understanding what they do, and the certainty they need as they run their operations?

Secretary VILSACK. Well, I would say a couple things on that. I think, first of all, you are right. We need to be making sure that as other agencies of government make decisions that could impact and affect producers, that we have done a good enough job of educating them about the impact on producers. And I am fairly confident that our Pest Management folks are doing that at USDA. That they are providing the technical, and scientific, and detailed information about the impact and effect of what Environmental Protection Agency (EPA) may be considering.

Then secondly, to the extent that we can work with the industry to make sure that as things are restricted in some way, that the labeling is what it needs to be, to be able to provide clear understanding of when, and under what circumstances certain things can, in fact, be used.

And then third, if there is a way in which our NRCS capacities can be used in a way to mitigate the consequences of some of this, we ought to be, obviously, directing our resources to do so. And I think our research folks also have a responsibility to ask the question: Are there ways in which we can, if we can't use this, what is the alternative; and we need to provide that alternative to our producers through extension?

TRANSITIONING NEXT GENERATION FARMERS

Senator HOEVEN. Like-kind exchanges. The average age of a farmer nowadays is about 60 years old, which of course I think is remarkably young, but for most people 60 years old is, you know—we have got to get this next generation into farming. One of the tools they use is 1031 like-kind exchanges, and the administration has come out proposing limitations on 1031 like-kind exchanges. But you know the capital barriers to getting into production agriculture. We have got to help this next generation get into farming; that is an important tool.

Secretary VILSACK. Well, I would say that that is one of the reasons why we have asked for greater flexibility on our loan programs, so that we are in a position to help.

Senator HOEVEN. Agreed. Yeah, we need to do more with the beginning farmer, and the other loan programs as well. But you would agree, those are important tools that our—and that it is an important part of transitioning this next generation into agriculture.

Secretary VILSACK. It is Senator, but the reality is that there are so many needs, I mean we have to take a look at: Where does the resource come from to do all the stuff that we want done, that we have all talked about here in this committee? And that we are talking about in our budget? I mean, it is a balance.

Senator HOEVEN. Yeah. No, I understand. We have to we have to figure out good commonsense ways to accomplish it.
 Again, thank you, for being here today; and for your work.
 Secretary VILSACK. You bet.
 Senator HEINRICH. Senator Baldwin.
 Senator BALDWIN. Thank you, Mr. Chairman.

DAIRY BUSINESS INNOVATION INITIATIVE

Secretary Vilsack, it is great to have you back before the committee today. Before I get to my questions, I would like to just thank you for prioritizing the Dairy Business Innovation Initiative in your budget. In the time since its inclusion in the 2018 Farm Bill, millions of have gone to Dairy Producers including those in Wisconsin, enabling businesses to expand their product lines, and increase their market share.

These small dollar grants have been incredibly meaningful to my state's world-renowned dairy and cheese industry. So we appreciate that prioritization.

Wisconsin dairy farmers have also led the way in implementing managed grazing to sustain herds. This practice, when done right, can go a long way in improving soil health, plant diversity, and water quality. For years, Wisconsin grazers and those interested in pursuing managed grazing have made it clear to me that the success of their operation is significantly improved when they are able to consult a grazing expert.

Specifically a knowledgeable technician who can help address the unique needs of their operation, and can save farmers valuable time and get them on an expedited path to profitability, improved water quality, and climate resilience.

GRAZING LANDS CONSERVATION INITIATIVE

I was able to secure funding for the Grazing Lands Conservation Initiative in the fiscal years 2022 and 2023. And this funding was intended to begin meeting the needs for grazing technical assistance for the first time in over a decade.

So Secretary Vilsack, could you share with me the Agency's plan to allocate these funds so that technical assistance can be made available? But additionally, I would note that funds were not included in the fiscal year 2024 Budget, and so I am curious to know how the USDA plans to sustain this operation?

Secretary VILSACK. Senator, I may stand to be corrected in the answer I am about to give you. So bear with me if I am misstating something. NRCS has basically outlined a variety of factors that we want to, basically, invest our conservation resources in. And one of them has to do with grazing, and one of them has to do with rotational grazing and proper management, as part of their climate-smart practices.

And so I think, from a standpoint of NRCS, we see this as kind of already included in the suite of 45 practices that we have identified, that we want to target our resources, we want to direct IRA resources towards, based on the requests from farmers that we get. There is a significant backlog. I suspect that there are some producers in Wisconsin that are waiting for, they have a plan they are waiting for the resources from NRCS. And we are really trying to

focus on reducing that backlog, and then basically making sure that the EQIP, Conservation Stewardship Program (CSP), all of those resources are effectively invested in climate-smart practices.

CLIMATE-SMART COMMODITY PARTNERSHIP INITIATIVE

That is in addition to the fact that many Wisconsin producers will also be engaged and involved in the Climate-Smart Commodity Partnership Initiative, and I know that there are management practices included in many of the projects that we sponsor, and will be sponsoring in Wisconsin. So you will also have opportunities within that partnership initiative to also see significant investment in those practices.

Senator BALDWIN. Okay. I will certainly want to follow up, and be able to track this with some granularity.

I would like to next ask about Avian Influenza, which has contributed to major increases in egg prices this year; the Animal and Plant Health Inspection Service Line for the Emergency Preparedness and Response Initiatives, so a minor increase in your budget.

How will this budget proposal ensure that needs are met to fully address the spread of Avian Influenza, including providing quarantine and inspection services to producers, and funding for state agencies and universities that are conducting Avian Influenza testing?

Secretary VILSACK. This is a great question, and I appreciate you raising it. Because it basically allows me to indicate that there are a number of tools that we are bringing to the HPAI fight, and one of those tools is the Commodity Credit Corporation (CCC). So APHIS is receiving additional resources from the CCC Fund, which is essentially providing resources to allow us to help farmers deal with the detection, eradication, and restoration of their facilities.

And so there is a complement there, as you just can't look at the four corners of the budget, you have to look at also the additional resources that we are providing.

In addition, when we basically create resources for research there are a number of research projects that involve this that are underway at universities at are getting—they aren't specifically on a line item, but they are involved, potentially, in an AFRI effort.

We are also meeting with the industry and, you know, I think there is more work to be done here in terms of encouraging, not just the development of biosecurity plans, but the implementation of those plans, our producers, our commercial operations have done a much, much, much better job than they did in 2014/2015, because we didn't see quite the spread from commercial operations that we did.

But we need to continue to be very vigilant about that, we need to take a look at the design of these facilities in terms of the transmission, airflow which can potentially complicate things. We need to make sure that we continue our research on vaccines, with the understanding that we are not there yet, we are not even close to being there yet. We don't have a commercial operation willing to produce the vaccine, we haven't matched it identically to the issue that we have got right now, and there are trade complications as a result of the use of vaccine.

So it is really complicated. Some people like to simplify it, but it is very, very complicated. So all of that is in the budget in various pieces, it may not be specifically identified as such, but it is all in the budget.

Senator BALDWIN. Thank you. I yield back.

Senator HEINRICH. I want to thank you, Secretary Vilsack; and you Mr. Rapp, for being here today.

ADDITIONAL COMMITTEE QUESTIONS

Questions for the record are due by next Wednesday, April 5th, and we would appreciate responses back from USDA within the next 30 days.

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

DEFERRED MAINTENANCE FOR RESEARCH FACILITIES

Question. Secretary Vilsack, as you may know, a March 2021 study found that there is at least \$11.5 billion of deferred maintenance for university agricultural research facilities nationwide, and that 69 percent of infrastructure at these facilities is more than 25 years old. In Fiscal Year 2023, Congress provided \$2 million towards Research Facilities Act competitive grants. Absent a sustained Federal effort to upgrade aging or obsolete infrastructure, I am concerned that the United States' ability to conduct world-leading research will suffer.

Secretary Vilsack, what actions is the U.S. Department of Agriculture (USDA) currently taking to improve research infrastructure and support the next generation of agricultural researchers? How is USDA utilizing the \$2 million provided by Congress for Research Facilities Act grants in Fiscal Year 2023? How should USDA's efforts be scaled to better meet the needs of research institutions across the country?

Answer. USDA currently provides research facilities funding through multiple programs including the 1890 Facilities Grants Program, the Agriculture and Food Sciences Facilities and Equipment Program for Insular Areas and, most recently in fiscal year 2023, the Research Facilities Act Grant Program (RFAP). Through RFAP, USDA National Institute of Food and Agriculture (NIFA) will provide funding to assist in the construction, alteration, acquisition, modernization, renovation, or remodeling of agricultural research facilities. RFAP prioritizes facilities that are located at or primarily benefit minority-serving institutions in accordance with the Joint Explanatory Statement, which accompanied the Consolidated Appropriations Act, 2023. NIFA will host a virtual listening session on April 13, 2023, to receive input from stakeholders, customers, and partners that will facilitate the development of the Research Facilities Act Program Request for Applications (RFA). Once the publication date for the RFA is finalized, NIFA will host a technical assistance webinar to provide information and assist stakeholders in applying to RFAP.

NIFA's current research infrastructure programs support both fundamental and applied research across diverse institutions serving different communities. This investment in research infrastructure allows for more institutions, including minority-serving institutions, to improve their agricultural research facilities with multiple benefits including greater output of cutting-edge research that addresses current and future priority issues, improved training of a more diverse and well-trained workforce, and enhanced competition with global competitors. Among the multiple beneficiaries of investments in research facilities are limited resource farmers and ranchers since it can help them access new technologies, methods, and knowledge that will improve productivity, efficiency, and profitability. Consumers also benefit because improved and advanced research facilities can lead to the development of new and better products, such as healthier, safer, and more sustainable food choices. Finally, investments in research facilities can improve opportunities for students to gain firsthand experience leading to a better trained workforce in food and agricultural sciences. USDA stands ready to scale such efforts to better meet the needs of research institutions across the country.

LABOR COSTS

Question. Secretary Vilsack, labor costs account for 39 percent of the total cash expenses for specialty crop producers, three times more than other types of farms. In a report required by the 2018 Farm Bill on automation research efforts, USDA

found that specialty crop automation and mechanization research at Agricultural Marketing Service, Agricultural Research Service, and National Institute of Food and Agriculture represented 2 percent, 1 percent, and 3 percent of specialty crop research funding, respectively, from 2008 through 2018.

Secretary Vilsack, how can USDA better utilize existing programs to support automation and mechanization for specialty crops? Would USDA support a new stand-alone grant program to facilitate the development of labor-saving tools and support training and retraining of impacted workers?

Answer. Despite tremendous progress and advances made by existing USDA programs to support automation and mechanization for specialty crops, there remains a huge unmet need for USDA to expand and accelerate its support for the research, development, and use of next generation automation, sensors, robotics, and AI-powered (artificial intelligence) analytics in the production, harvesting, and processing of specialty crops that will result in new labor- and cost- saving tools, high-paying technical jobs, and support the training and retraining of impacted workers.

Based on the 2020 report to Congress, “Developing Automation and Mechanization for Specialty Crops: A Review of U.S. Department of Agriculture Programs” prepared by the Economic Research Service, USDA has six programs in the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), and the National Institute of Food and Agriculture (NIFA) that, among other objectives, support the development and use of automation or mechanization in the production and processing of U.S. specialty crops. The programs are: 1) AMS Specialty Crop Block Grant Program; 2) ARS Crop Production National Program and Product Quality and New Uses National Program; and 3) NIFA Specialty Crops Research Initiative (SCRI), Small Business Innovation Research (SBIR), and Agriculture and Food Research Initiative (AFRI). From 2008 to 2018, these programs funded \$288 million (\$28 million per year) toward 213 projects to develop and enhance the use of automation or mechanization in specialty crop production and processing. The projects included job aid/machinery automation, machine learning/data analysis, mechanical harvesting/processing, precision agriculture, remote sensing/drones, and sensors, and covered a variety of specialty crops (almonds, apples, avocados, beets, blueberries, broccoli, cabbage, carrots, cauliflower, celery, cherries, chestnuts, chickpeas, chili peppers, citrus, cranberries, currants, elderberry, table and wine grapes, hazelnuts, hops, lettuce, maple syrup, mushrooms, nursery crops, olives, onions, ornamentals, pecans, peaches, pears, peas, peonies, pistachios, potatoes, pumpkin seeds, raspberries, sod, strawberries, sweet corn, sweet potatoes, tea, tomatoes, and walnuts).

As more data is collected and USDA becomes more informed, resources could be used to address climate-smart agriculture of the future, in respect to novel scalable implementation of workforce development and in leveraging of resilient food systems transitions for broadening agricultural workforce participation across all sectors of society and ages.

There is a need for continued support regarding long-term data curation and sustainability of automation and mechanization projects, databases, and software. However, the focus of many new proposals center on novel ideas and tools, rather than continued maintenance and update of systems which is needed. USDA’s support of open-source projects helps encourage collaboration, reduces costs and time associated with project initiation and database development, and may decrease barriers associated with farmer concerns regarding for-profit data collection and use.

USDA stands ready to implement and support all existing and any new programs intended to support the development of labor-saving tools and support training and retraining of impacted workers.

CROP LOSS FROM NATURAL DISASTERS

Question. Since 2018, Congress has appropriated funds four times to support producers that experienced crop loss and damage due to natural disasters. These supplemental appropriations have included shifting requirements for USDA and producers, leading to the creation of several programs at USDA—the Wildfires and Hurricanes Indemnity Program in 2017, the Wildfire and Hurricane Indemnity Program Plus in 2018 and 2019, and the Emergency Relief Program in 2020 and 2021. Although, these programs provided much-needed assistance, the changing regulations confused producers and delayed payments. Beyond that, the impact of disasters can extend beyond the farm and into agricultural support industries-like processors—which may be devastated if there are no crops planted or harvested.

Secretary Vilsack, would a permanently authorized disaster program modeled on the Emergency Relief Program (ERP) improve USDA’s ability to quickly disseminate funds to disaster-affected producers following supplemental appropriations? How

could assistance be extended to agribusinesses that also experience significant loss after natural disasters?

Answer. USDA offers subsidized crop insurance, has permanent disaster programs, and is working to implement the current ad-hoc disaster program that Congress has authorized as a \$3.74B disaster assistance funding in the Consolidated Appropriations Act, 2023 (Div. N), which supplemented and extended provisions in the Emergency Relief Program/Emergency Livestock Relief Program from the Extending Government Funding and Delivering Emergency Assistance Act (Public Law 117-43). A permanently authorized disaster program may improve USDA's ability to quickly disseminate funds to eligible producers, although the full costs and benefits of a permanently authorized disaster program are unknown at this time. There is time needed after legislation is passed to develop policy and software for program implementation; however, after initial program implementation, future years can be close to seamless and allow USDA to respond to disasters in real-time, when funded.

Current and past ad-hoc disaster programs are tied to the loss of crops; with a 2-year linkage requirement to purchase crop insurance where crop insurance is available or Noninsured Crop Disaster Assistance Program (NAP) coverage for those commodities for which crop insurance is not available.

Agribusinesses are not eligible for current and past ad-hoc disaster programs, nor are they part of the permanent disaster programs, as agribusinesses are not the owners or shareholders of the crops. However, there are commercial insurance products that agribusinesses could choose to option as part of their risk management strategies. If Congress were to consider inclusion of agribusinesses it would require legislative guidance to change or further clarify the definition of loss and/or eligible producer.

CROP INSURANCE FOR SPECIALTY GROWERS

Question. Secretary Vilsack, I appreciate USDA's efforts to expand access to crop insurance for specialty crop growers, but I remain concerned that many growers have inadequate insurance options and are forced to rely on policies that only cover catastrophic loss or leave significant acreage uncovered.

Secretary Vilsack, how can USDA improve crop insurance options for specialty crop producers, especially those who have historically not purchased insurance policies or relied solely on coverage for catastrophic losses?

Answer. Expanding crop insurance to specialty crops and smaller farmers is a priority for this Administration. The USDA Risk Management Agency (RMA) made tremendous progress on expanding options for specialty crop growers, and we know there is still more work to be done. We've doubled the eligibility for Whole Farm and tripled the eligibility for Micro Farm, which helps smaller farmers.

We undertook an effort last winter to meet farmers and insurance professionals throughout the country to promote Whole Farm and Micro Farm. To date, we've had over 8,000 attendees. We've learned a great deal and so have the attendees. We hope to use this as a model to promote and educate about new products. RMA has a specialty crop liaison in every regional office and a national employee devoted to this effort. We would be glad to engage and discuss any specific ideas your office has on enhancing coverage.

On the outreach and education front, since 2021, the RMA has invested more than \$6.4 million in partnerships with 27 entities to expand outreach and education on crop insurance, which embodies the diversity of agriculture including Hispanic/Latino, Native Americans, African American, Beginning, Women, Veteran and Historically Underserved farmers, with additional emphasis on those producers who are growing and producing specialty crops, livestock, organic-certified or transitioning, sustainable/regenerative crops and/or small farms and ranches.

CAPTIVE MARINE MAMMAL CARE

Question. Secretary Vilsack, the USDA last updated key elements of its standards for the handling and care of captive marine mammals in 1984, nearly 40 years ago. Since that time, significant progress has been made in marine mammal biology and ecology research. You were also the Secretary of Agriculture in 2016 under President Obama, when a proposed rule was released that would have finally updated these standards. Unfortunately, that rule was never finalized, and it was withdrawn in 2021 because it was outdated.

Secretary Vilsack, do you agree that the captive marine mammal standards of care are outdated? What efforts is USDA undertaking to examine the standards and space requirements of marine mammals?

Answer. USDA takes the health and welfare of every animal covered under the Animal Welfare Act seriously, including marine mammal populations. The Animal

Welfare Act sets basic standards for humane care and treatment that must be provided for certain animals used in certain activities. USDA's focus is specific to those marine mammals used for public exhibition or biomedical research. Research surrounding captive marine mammals continues to evolve, including since the 2016 proposed rule was drafted. We will review the newly available research, as well as consider opportunities to engage with members of the marine mammal community, as we consider options for future rule making.

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

REGIONAL CONSERVATION PARTNERSHIP PROGRAM

Question. The Regional Conservation Partnership Program (RCPP) has shown significant promise as a flexible and partner driven conservation program but has had a troubled implementation and rollout since the 2018 Farm Bill. Given the U.S. Department of Agriculture's wide discretion in implementing this program, what steps has the agency taken to improve RCPP implementation? In particular, how is the agency: reducing paperwork burdens; ensuring efficient easement appraisal processes; streamlining easement and land management project implementation; and ensuring sufficient and consistent agency staffing—both at NRCS Headquarters and in State offices—to guarantee that Federal funds and partner resources are effectively delivered to America's farmers?

Answer. The USDA National Resource Conservation Service (NRCS) is evaluating the flexibilities to ensure appropriate use of RCPP funding, while listening to the challenges of our customers. We are leaning in on certified entities for easement transactions and internal training of our RCPP coordinators to ensure consistent interpretations of policies and procedures for success. We expect to make an initial public announcement in Spring of 2023 on the first set of flexibilities and are working towards additional improvements and efficiencies.

CONSERVATION TECHNICAL ASSISTANCE

Question. The Natural Resource Conservation Service (NRCS) has the ability to use Conservation Technical Assistance (CTA) funding to hire grazing technicians across the country, both within NRCS and at third party organizations, via the Grazing Lands Conservation Initiative (GLCI). With the passage of the Inflation Reduction Act (IRA), more CTA funding is available to NRCS than ever before, making now an ideal time to ensure dedicated funding for GCLI. Yet the recent President's Budget Request notes USDA's intention to spend \$0 through GLCI in FY24. Why is USDA opting to withhold funding that could support access to grazing technicians for producers across the country?

Answer. NRCS continues to prioritize hiring and focus on recruitment and retention of qualified technical staff. We are increasing staffing numbers and working with Land Grant Universities and other institutions to produce USDA qualified applicants, including grazing technicians. We are also seeking opportunities to partner with other technical organizations and agencies to onboard staff.

CONSERVATION STEWARDSHIP PROGRAM

Question. Secretary Vilsack noted during the March 29th Senate Appropriations subcommittee hearing on Agriculture, Rural Development, food and Drug Administration, and Related Agencies, that IRA spending within the Conservation Stewardship Program (CSP) and the Environmental Stewardship Program (EQIP) will be used to contract with producers implementing sustainable grazing practices already available within each program. However, contracting with a producer to implement a practice does not guarantee that that practices will create an overall benefit for farm, and targeted technical assistance is often needed to ensure practices have both an environmental benefit and an agronomic benefit. When both are realized, producers are more likely to maintain and improve upon practices over the long term. Given the importance of technical assistance in ensuring the success of sustainable grazing practices on farms, why hasn't USDA committed to ensuring that increased GLCI funding accompanies IRA spending in CSP and EQIP, helping to provide increased grazing TA simultaneously with increased funding for practice implementation?

Answer. The USDA National Resource Conservation Service (NRCS) is committed to this work and continues to seek out qualified applicants to join the technical teams across the country in our field offices. Grazing lands are a key component of soil health and climate solutions. Using a systems approach to addressing climate

smart resource concerns and the co-benefits of a grazing system are a primary focus of the Inflation Reduction Act (IRA) implementation.

BUSINESS AND INDUSTRY PROGRAM

Question. Last year, USDA proposed—and the Committees accepted—an interchange in budget authority that increased the lending authority of the Business and Industry Program. The program, again, faces a shortage of loan authority. Of the loans that have currently been obligated and the dollar value of those in the pipeline, there will be a deficit in the program in excess of \$250 million. To avoid the denial of qualified loans, would the agency consider supporting another interchange of unobligated funds to enable lending in the Business and Industry Program?

Answer. The Department is exploring options for continuing support of the Business and Industry Guaranteed Loan program above the level that Congress provided in order to meet demand. An interchange of unobligated funds is one of the options but in the interim the Department continues making any funding available from this program's recoveries.

QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN

USDA STAFFING NEEDS

Question. Is the Department of Agriculture able to adequately meet its staffing needs and is the agency able to fill key positions with qualified employees?

Answer. The Department is working diligently to maximize the effectiveness of the funding provided by Congress to meet our staffing needs across the country. At this time, yes, the Department believes that we are able to adequately meet our staffing needs. Our leadership team continues to look closely at staffing needs as they arise, whether within a headquarters unit or in a field office, to ensure that our staffing resources are ultimately aligned to address the needs of USDA's customers.

Question. Related, what percentage of USDA employees are back in the office full time nationwide?

Answer. Throughout the public health emergency, tens of thousands of USDA employees continued to work in-person to meet the Nation's needs for critical public services such as meat and poultry inspections and wildland firefighting. As the Department continues to analyze the data and evidence, we are focused on ensuring that our customers continue to get the support necessary from our workforce to meet their expectations and to meet their daily needs for support from USDA. When the Department concludes its analysis and finalizes its plans for maximizing the customer experience, we will share that information with you and the Committee.

DIFFICULT TERRAIN AND ACCESS TO URBAN AREA PROJECT

Question. The USDA Economic Research Service (ERS) has been working on the "Difficult Terrain and Access to Urban Area" project. This project was started in 2021, and as of 2023 my office has not seen the Phase I published report, due to "unanticipated delays". Can you provide an update on the status and publication of this project? Will the ERS commit to visiting West Virginia to better understand our mountainous and difficult terrain areas?

Answer. Yes, USDA is committed to visiting West Virginia to gain greater insights into the mountainous and difficult terrain areas. The ERS researchers are in the process of incorporating comments and conducting additional analysis of the data based on the comments on the peer review manuscript. In addition, ERS met with the Federal Office of Rural Health Policy in February to discuss the progress of this project. ERS plans on providing the office with the data needed for the next cycle of grant announcements. USDA is on track to publish the report by this summer.

BROADBAND COORDINATION

Question. With tens of billions in Federal funding directed to broadband in the last 5 years, how is USDA coordinating with other broadband deployment programs—such as those administered by the FCC, NTIA, and Treasury?

Answer. USDA meets regularly and on an ad hoc basis with the Federal Communications Commission (FCC), the National Telecommunications and Information Administration (NTIA) and the U.S. Treasury to ensure that Federal dollars are spent in the most efficient way possible. Additionally, USDA shares information with our Federal partners regarding the awards made under our programs to enable other

agencies to take those awards into consideration to ensure projects do not overlap or overbuild existing services already made available.

QUESTIONS SUBMITTED BY SENATOR SUSAN M. COLLINS

REMOTE WORK AND UPGRADES TO USDA HEADQUARTERS

Question. During the COVID-19 pandemic, many Federal employees were given the opportunity to work from home. While most have returned to the office, it is my understanding that many USDA employees are now permanently working from home with no intention to return. What is your plan for the South Building and to return staffing in the building to pre-pandemic levels so that taxpayers aren't asked to fund refurbishment of empty workspace?

The FY2024 budget proposes an increase of \$84 M for Agriculture Buildings and Facilities, \$46.8 M of which is specifically designated for modernization of the USDA South Building. The USDA South Building modification has been an ongoing endeavor since well before the pandemic. The Committee has requested a plan for how these funds will be used and prioritized, and we have yet to see one.

Answer. The Department recently submitted its response to OMB-M-23-15, the next step in reviewing USDA's Future of Work policies while maintaining laser focus on service delivery. USDA has been on a journey to modernize and transform our culture and workplace to become one of the "Best Places to Work in the Federal Government." A core value of our Future of Work approach is the importance of making data-driven decisions and ensuring our employees have a voice in the policies that impact their lives. We are committed to continuing to refine performance measures and benchmarks, use data to ensure we have a warning system in place to alert us if performance starts to wane under the current policies, and have data that will give the Department a better chance to make any telework policy changes without causing any drastic short-term performance and morale losses.

The South Building is a critical component of the Department's real property portfolio in the National Capital Region (NCR) and is home to the headquarters for many of the Department's program agencies and staff offices. The building, originally built in the 1930s, still includes many original systems which have been well maintained but the building has only been partially upgraded in recent years. A continued investment in the renovation of the South Building will enable the Department to address significant life and health safety challenges that exist throughout the facility due to the relative age of the structure and systems. These renovations will also create opportunities for the Department to make strategic decisions on the continued use of leased facilities throughout the NCR. Without continued investments in building modernization, the Department will likely need to maintain a significant portfolio of leased facilities in the NCR that cost over \$10 million per year in rental payments.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

INTERNATIONAL MARKET ACCESS

Question. As major exporters of beef, wheat, and oil seed, Kansas farmers know how crucial international market access is to their prosperity. The Department's budget request also recognizes foreign trade as essential for the vitality of the U.S. agricultural industry.

However, I'm increasingly concerned that the Biden Administration is instead opting out of free trade agreements that facilitate agricultural exports in favor of loosely-defined frameworks that do not benefit our farmers.

How does USDA reconcile the importance of agricultural trade with the administration's opposition to pursuing free trade agreements?

Answer. USDA is working alongside the United States Trade Representative (USTR) within the parameters of the Biden Administration to advance trade policy. One challenge that USDA and USTR currently face is to build trust in this country on trade. USDA and USTR must, therefore, work to secure wins by creating new or expanded market access, enforcing existing agreements, and restoring trust in trade. There are a multitude of ways in which USDA is making a difference in terms of trade without necessarily focusing solely on free trade agreements. We must continue to expand trade missions, provide support to foreign market develop-

ment programs that help drive exports, and always look for opportunities to break down barriers to trade.

We will therefore continue to work with USTR, the Department of Commerce, and other U.S. government partners on the U.S.-Kenya Strategic Trade and Investment Partnership (STIP), the 21st Century Taiwan Trade Initiative, and the Indo-Pacific Economic Framework for Prosperity (IPEF). The IPEF, for instance, can serve to increase U.S. agricultural exports to an area of the world where both the middle class and the demand for high-quality, trusted, sustainably produced agricultural products are growing. The IPEF Trade Pillar seeks to emphasize agricultural sustainability and agricultural biotechnology, enhancing agricultural supply chain resilience, improving transparency on regulatory measures, and promoting science-based decision-making to protect human, animal, and plant life. In doing so, markets can be created or opened to the type of high-quality, high-value products our farmers, ranchers, and producers are already producing.

USDA has also sponsored numerous Agribusiness Trade Missions (ATMs). In calendar year (CY) 2022, ATMs provided small and medium-sized U.S. exporters opportunities in markets including the United Arab Emirates, United Kingdom, Philippines, Kenya, Tanzania, Spain, and Portugal. During these missions, participants engaged directly with potential buyers, resulting in a total of 125 U.S. agribusinesses participating in 1,310 business-to-business meetings reporting \$42.2 million in 12-month projected sales. Our work to expand ATMs provides U.S. exporters with additional opportunities to increase their market presence overseas and generate sales, while providing senior-level USDA officials with a platform to advance U.S. agricultural trade priorities directly with foreign counterparts. Regarding CY 2023, USDA has executed or is in the process of executing trade missions to Panama, the Netherlands, Japan, Chile, Malaysia, and Angola.

The United States continues to implement agricultural trade policies in a manner consistent with its free trade agreement obligations and expects our trading partners to do the same while working to maintain open and predictable markets for American farmers and producers. Policy discussions with the European Union (EU) on several agricultural trade issues are ongoing to address market access issues such as overly restrictive maximum residue levels (MRL), unpredictable animal health certificate policies, lack of recognition of common food names, and deforestation-free supply chain regulations, to name a few.

Additionally, USDA continues to work in close coordination with USTR on dispute settlement efforts regarding Canada's tariff-rate quota allocation measures for dairy products under the U.S.-Mexico-Canada Agreement (USMCA). The United States' priority remains ensuring that U.S. workers, processors, farmers, and exporters benefit from the market access Canada committed to through the USMCA. USDA and USTR also continue to engage with Mexican officials at all levels to convey our serious concerns about Mexico's treatment of agricultural biotechnology. It is critical that Mexico fully complies with its USMCA commitments and that it returns to a science- and risk-based regulatory approach for all biotech products. Mexico is a valued trading partner, and USDA is committed to working with it to resolve these biotech issues and avoid any disruption of trade in corn or other agricultural products.

Specifically for beef, tariff reductions that came about under the U.S.-Japan Trade Agreement that went into effect in 2020 have helped the United States become Japan's top beef supplier for the first time in more than two decades. The revision of the beef safeguard, negotiated in 2022, will ensure that U.S. beef exports to Japan can continue to grow. For soybeans, the U.S. exported a record \$33.3 billion in product in 2022, and we will continue to fight any barriers that impede their export to global markets.

USDA advocates for U.S. agriculture around the world through diverse mechanisms to secure tariff reductions, improve the environment for exporting U.S. agricultural products, and increase predictability and transparency in trade regulation. Under this administration, USDA engagement was critical to delivering roughly \$15 billion in new or preserved market access through active policy intervention with foreign governments. By leveraging creative trade policy tools, and working in concert with USTR, USDA remains committed to making significant gains and expanding market access for farmers and ranchers throughout the United States.

RECONNECT DEPLOYMENT

Question. Secretary Vilsack, the FY2024 budget requests another \$400 million for the ReConnect broadband deployment program. With more than \$175 billion in Federal funding directed to broadband in the last 5 years, I am concerned about keep-

ing this program focused on unserved areas in rural America and ensuring Federal broadband deployment resources are efficiently utilized.

Does the Memorandum of Understanding (MOU) that USDA, NTIA, FCC, and Treasury signed in May 2022 ensure that ReConnect funds will not duplicate other Federal broadband deployment investments?

Answer. USDA meets regularly and on an ad hoc basis with the Federal Communications Commission (FCC), the National Telecommunications and Information Administration (NTIA), and the U.S. Treasury to ensure that Federal dollars are spent in the most efficient way possible. Under the Memorandum of Understanding that is in place, USDA shares information with our Federal partners regarding the awards made under our programs to enable other agencies to take those awards into consideration to ensure projects do not overlap or overbuild existing services already made available.

Question. If not, what more needs to be done to ensure Federal funds are not being duplicated, while unserved areas still exist?

Answer. The MOU signed in May 2022 is helping to ensure that duplication will not occur.

FARM SERVICE AGENCY LOAN OFFICERS

Question. Secretary Vilsack, as you are aware, USDA Farm Service Agency staff performs a crucial role in facilitating the investments in our agricultural communities and the rural towns they support we advocate for. My understanding is that about 40 percent of the FSA loan officers are retirement eligible in the next 5 years and that it takes 2 years to train a new loan officer.

What steps is the department taking to recruit and retain loan officers?

Answer. The USDA Farm Service Agency (FSA) continues to be challenged in the recruitment and retention of employees. In Farm Loan Programs, for example, 42 percent of loan officers and supervisors are eligible for retirement between now and fiscal year 2027. In addition to attrition through retirements, challenges include hiring and retaining new staff due to Federal pay scales that are not competitive with the private sector, high workload demands, and business processes that are manual and paper based compared to other financial industry employers.

FSA has taken several steps to address these challenges and to recruit and retain Loan Officers. Over the last couple of years, FSA has increased use of the Pathways Program to bring college students and recent graduates into the Agency, as well as increasing use of the 1890 Scholars Program and other internship programs. FSA has modified the required experience for the Loan Officer positions to include not only FSA loan approval authority but also private sector agricultural loan experience, thus expanding the Agency's recruitment reach. FSA is also encouraging States to make more use of the Loan Analyst position; loan analysts complete the first year of the Farm Loan Officer Training program, building a workforce that is readily available to step into the Loan Officer role more quickly.

FSA has also increased utilization of recruitment, relocation, and retention incentives for farm loan employees. In fiscal Year 2022, FSA issued over \$620,000 in student loan repayments to 69 farm loan employees. In exchange for receiving loan repayments, employees signed a 3-year service agreement. FSA plans to utilize student loan repayments for these series again in fiscal Year 2023. In addition, since February 2022, FSA has approved 38 relocation and recruitment incentives in these series. FSA continues to explore all options to improve recruitment and retention.

Question. For example, will you be seeking direct hiring authority from the Office of Personnel Management for these critical positions?

Answer. The FSA is looking at leveraging various authorities that exist including OPM waivers for direct hire authority.

SELECT AGENT REGISTRATION

Question. Can you please provide an update on the status of the select agent registration activities including a program schedule, it is my understanding that this is currently running slightly behind the initial planned schedule.

Answer. Delays in facility construction, commissioning schedule, and receipt of commissioning documents have impacted our initial Select Agent Registration schedule, yet personnel at the National Bio and Agro-Defense Facility (NBAF) have been proactive in the registration process and have been working with the Federal Select Agent Program (FSAP) on registration and approval for all activities with Select Agents necessary to transfer the mission from the Plum Island Animal Disease Center (PIADC) to NBAF.

NBAF personnel are in constant contact with FSAP regarding document submission and are coordinating with FSAP on planning inspection dates, with the goal of having a first inspection in Fall 2023.

NBAF and USDA leadership have developed a tiered science transition strategy, to begin laboratory work with non-infectious materials, progressing to low risk agents, and then eventual work with Select Agents after full FSAP approval is received. They will not work with any Select Agents until approved by the FSAP. The goal of completing full registration of the facility by Fall 2024, pending any unforeseen circumstances, remains the same.

Question. Please provide a crosswalk of the funds in the budget request for NBAF and related science at both ARS and APHIS.

Answer. The fiscal year 2024 President's budget requested an increase of \$23.9 million over the fiscal Year 2023 enacted level. This proposed increase consists of \$13 million in operations for contracts (facilities, security, supplies, and services), an additional \$10.6 million for capital improvements in the USDA Agricultural Research Service (ARS) Buildings and facilities account, and an increase of \$300 thousand to cover the anticipated increase in pay costs. There is no change in the proposed research and science budgets at ARS or the Animal and Plant Health Inspection Service (APHIS).

Question. Please explain USDA's plan to obtain sufficient BSL-2 space needed to house animals prior to the beginning of a specific experiment. If additional funds were provided in FY24 to address these needs, please provide budget details for funds would be executed.

Answer. While we recognize that BSL-2 space at NBAF is limited, there are no current plans for expanding animal holding capacity.

COLLABORATION WITH UNIVERSITY PARTNERS

Question. If additional funds were available in FY24 to enhance collaboration with university partners, what would be most helpful in either equipment or curriculum development to make enduring progress on the important educating and training students for the future workforce?

Answer. The partnership and workforce development funds provided have enabled considerable education and training initiatives for USDA ARS and APHIS to meet their specific mission needs. Additional investment in the NBAF Agrosecurity Partnerships for Innovative Research (ASPIRE) program would further strengthen the framework by which NBAF will enhance America's agricultural biosecurity by forming strategic partnerships with universities, industry, and other Federal agencies to support the NBAF Strategic Plan and National Biodefense Strategy.

Through ASPIRE, USDA is partnering with the Research Corporation for Science Advancement (RCSA) to launch a Scialog, pairing "science and dialogue" around fundamental scientific challenges, on Mitigating Zoonotic Threats. The Scialog fellows include around 50 early career faculty and scientists from across the U.S. with varied disciplinary expertise who work together for over 3 years to innovate around current best ideas and build an innovation network that will extend over the next 30+ years of their careers. ARS and APHIS have several of their early career scientists within this cohort.

Other key partnerships include the Research Alliance for Veterinary Science and Biodefense BSL-3 Network 'RAV3N' funded by USDA, which is a collaborative community of 18 U.S. academic and Federal institutions. The Network aims to establish strategic and coordinated approaches for collective large-animal biocontainment infrastructure and science capacity to improve bio-surveillance, diagnostics, and countermeasure developments against high-consequence pathogens of veterinary importance.

Recognizing the competitiveness of the workplace for research, diagnostic, and operational staff for high containment facilities, USDA has developed programs to help supply the scientific and operational pipeline and provide awareness of career opportunities at NBAF. For example, ARS has trained more than 20 students from 5 different universities and trained an additional 18 post-docs. In fiscal Year 2022, a new partnership was established with Indiana University of Pennsylvania to create a biosafety certificate program to increase the workforce pipeline for work in high containment facilities. APHIS is developing the next generation of subject matter experts and laboratory staff at NBAF through its NBAF Scientist Training Program (NSTP) and the NBAF Laboratorian Training Program (NLTP). The NSTP has supported 26 students from 15 universities with 10 now transferred to permanent Federal positions at NBAF and already contributing to science transition planning. The NLTP has trained 39 undergraduate students between programs at Kansas State University and Texas Tech University and will continue to do so.

Question. If additional funds were available in FY24, what activities and in what amount would be useful to the Department's future plan to house a Biologics Development Module at NBAF? Are there opportunities for university partners to contribute to the production of standardized biological reagents?

Answer. The Biologics Development Module (BDM) has filled several key positions and is developing a prioritization of projects to begin as the facility comes online. USDA will hold a BDM Stakeholder meeting on June 21–22, 2023, in Manhattan, Kansas. A primary goal for this meeting is to identify key contacts among industry, academia, and other Federal agencies who will be instrumental in successfully establishing collaborations and partnerships with the BDM. In addition, USDA will introduce stakeholders to the BDM personnel and describe its capabilities and solicit feedback from stakeholders regarding past experience with public private partnerships and lessons learned, and the potential to partner with universities on the production of standardized biological reagents.

QUESTIONS SUBMITTED BY SENATOR DEB FISCHER

UNOBLIGATED COVID FUNDING

Question. The President has stated that the pandemic is over, and the National emergency is set to end in May. Since 2020, USDA has received billions of dollars through the CARES Act, the Consolidated Appropriations of '21, and the American Rescue Plan Act to administer as emergency assistance, to help farmers and ranchers, consumers and rural communities withstand the impacts of the pandemic.

Can you provide to this subcommittee an accounting of the funds that remain unobligated and unspent under these authorities?

Answer. USDA submits a monthly accounting of the funds that remain unobligated and unspent under funding received through the CARES Act, the Consolidated Appropriations of 2021, and the American Rescue Plan Act to administer as emergency assistance, to help farmers and ranchers, consumers, and rural communities withstand the impacts of the pandemic. The latest report was sent March 14, 2023.

RECONNECT

Question. Can you provide the subcommittee with the latest outlays for ReConnect from the funding included in the Bipartisan Infrastructure Law?

Answer. USDA is working diligently to expedite all funding made available under the Bipartisan Infrastructure Law. The agency has already awarded over \$540 million in funds under our 3rd funding window and we are on-track to obligate the remaining ReConnect funding under our 4th window and expect to obligate approximately \$1.9 billion in awards by leveraging both loan and grant funding. As of today, there have not been any outlays, but Rural Development expects that outlays will begin this fiscal year and continue in the next 7 years, in line with the normal outlay patterns for the program.

Question. Would you be able to clarify your position about the program's goal, and whether you feel it should help unserved Americans without any broadband access in rural America?

Answer. The ReConnect Program is focused on extending affordable, reliable high-speed broadband service in rural unserved and underserved communities. Priority is given to unserved communities, but the program does make funding available to eligible underserved communities as well.

WATER QUALITY AND QUANTITY

Question. The legislative text of IRA departed from the resource concerns agreed to in the bipartisan 2018 Farm Bill and restricted those funds use to address "improving soil carbon, reducing nitrogen losses or to reduce, capture, avoid, or sequester carbon dioxide, methane, or nitrous oxide emissions, associated with agricultural production." Water quantity and water quality remain top local resource concerns in Nebraska. How will USDA interpret the restriction placed on IRA conservation funds?

For example, how will USDA look at a producer wanting to use EQIP cost share funding to upgrade their irrigation pivot to optimize water use? Would they be at a disadvantage with IRA funding?

Answer. Investments from the Inflation Reduction Act (IRA) are investments to help farmers, ranchers, and forest owners implement new or additional conservation activities on their lands, with a focus on Climate-Smart mitigation activities that

can increase storage of carbon and reduce greenhouse gas emissions and may also help to address drought and other climate-related stressors. We realize that conservation practices build upon each other, and the solutions include co-benefits. Applicants who want to address resource concerns related to climate smart agriculture and forestry are able to apply for all conservation programs regardless of funding source. State Technical Committees provide the guidance to the State Conservationist for funding priorities. In addition, NRCS recently announced the Western Water and Working Land Framework, of which Nebraska is included in the 17 States. In the Framework, NRCS identifies six major water and land resource management challenges, guidelines for identifying vulnerable agricultural landscapes and 13 strategies for NRCS leaders in western States to use now to collaborate with partners, water resource managers and producers. The goal is to help secure clean and available water supplies, healthy soils, resilient landscapes, and thriving agricultural communities, now and in the future.

Question. The IRA also removed a Farm Bill requirement that 50 percent of EQIP funds are used for livestock production. Without that requirement, does USDA anticipate a significant shift in the distribution of EQIP funds?

Answer. Livestock production will continue to be a significant piece of NRCS Farm Bill Environmental Quality Incentives Program (EQIP) distribution based on locally driven priority resource concerns. While IRA does not require a minimum, we continue to use EQIP Farm Bill funds with the 50 percent requirement.

PRECISION AGRICULTURE

Question. As you know our Nation is at a critical juncture in advancing precision agriculture technology and related artificial intelligence. To ensure producers have access to safe digital tools to guide and enhance management and production options, Congress provided US Department of Agriculture (USDA) Agriculture Research Service with the initial planning funding to co-locate and establish a national center for resilient and regenerative precision agriculture in Lincoln at the Nebraska Innovation Campus. This facility is envisioned to serve as the anchor of a national network comprised of USDA and land-grant universities and their Cooperative Extension arms to equip America's farmers and ranchers with 21st century precision technologies to meet present-day and future challenges.

Can you provide the Committee with an update on steps USDA taken to help expedite planning surrounding the implementation of initial funding provided by Congress and support moving forward?

Answer. The strategic plan for the new National Center for Resilient and Regenerative Precision Agriculture (NCRPA) will more than double ARS personnel at the location, expand research capacity, catalyze collaborations with University of Nebraska-Lincoln (UNL), and add new Agricultural Research Service (ARS) buildings to the existing ARS presence in Lincoln. The project is progressing. There will be two construction projects: one is a new headhouse and greenhouse (HH/GH) and one is a new lab/office building (LOB). ARS currently has \$11.2 million appropriated for planning and design and \$20 million for construction. ARS is actively planning and designing both buildings and will build the HH/GH first with funds already appropriated. The Architect and Engineering firm submitted the Program of Requirement for ARS review in December 2022. In March 2023, the 35 percent design for the LOB was provided to ARS. USDA ARS will adapt the HH/GH space into a Plant Growth Facility that will be a hybrid HH/GH plus grow house. Integrating a climate-controlled grow house reduces overall operating costs to meet current and future research mission needs. The hybrid Plant Growth Facility will still occupy 25,140 square feet and follows the Nebraska Innovation Campus building guidelines.

Question. What research and technology gaps has USDA identified that could be addressed by a National Center for Regenerative Precision Agriculture for the development of enhanced digital tools to meet present day and future challenges?

Answer. A key priority for the National Center for Regenerative Precision Agriculture (NCRPA) will be to develop and enable precision agriculture for producers of all sizes, of all crop and livestock systems, and in all parts of the U.S. Since data drives precision agriculture, this will require Big Data and High-Performance Computing capacity as well as data capture, integration and standardization efficiencies. USDA Agricultural Research Service (ARS) has worked to identify key data, infrastructure and technology gaps that are bottlenecks to providing all producers with meaningful and helpful precision agriculture tools and capacity.

As part of this, ARS has allocated most of the funding appropriated in fiscal year 2023 for Measurement and Monitoring Innovation to strategically catalyze innovation in sensors, Internet of Things (IoT) technologies and data capture, automation,

standardization and integration. In deploying these funds to a new project in Lincoln, ARS has directed the team there to establish collaborations with UNL around data integration and with North Dakota State University around sensor, electronics and computer engineering and design. In addition to these strategic new collaborations, the project will seek to link well aligned sensor, IoT and data integration research efforts at other ARS research locations (including Clay Center, Nebraska; Stillwater, Oklahoma; Mandan, North Dakota; Fort Collins, Colorado; Beltsville, Maryland; Mississippi State, Mississippi; Columbia, Missouri; and others) and university collaborators (including University of Nebraska-Lincoln, North Dakota State University, Colorado State University, Oklahoma State University, University of Missouri, North Carolina State University, and others).

Additionally, the fiscal Year 2024 President's Budget includes, as part of the ARS Climate Science request, the creation of a focused and coordinated climate change adaptation and mitigation modeling, data management and tool development project that serves as an ARS center of excellence to strengthen and support research across ARS and regional engagement of the Climate Hubs. If funded, this new Climate Science center of excellence will likely be located at NCRPPA and will increase the impact of ARS climate change mitigation and adaptation research efforts such as Long-Term Agroecosystem Research (LTAR), Breeding Insights, ARS Grand Challenges Synergies, and others. This new project will catalyze a data-driven and precision agriculture focus on climate change adaptation and mitigation. It will support and enhance other precision agriculture efforts already underway at ARS as well as the new precision livestock management effort at nearby Clay Center, University of Nebraska-Lincoln and other locations. Building on the current collaborations and common research framework of LTAR, the Climate Hubs, and others, these funds will increase focus specifically on climate smart practices, data, tools, and technologies that are relevant both regionally and nationally, and that can lead to greenhouse gas mitigation, producer participation in carbon and ecosystem markets, resilience to weather extremes, and adaptation to regional expected climatic conditions of the future. The effort will leverage ARS's Partnerships for Data Innovations, SciNet infrastructure for Big Data, Artificial Intelligence and Machine Learning processing and analytics, Life Cycle Analysis and strengthen data and modeling collaborations with other Agencies and Departments such as the National Oceanic and Atmospheric Administration, the National Aeronautics and Space Administration, and the Department of the Interior.

Question. Outside of funding, are there any barriers that would hinder the construction and establishment of the proposed ARS co-located facility?

Answer. ARS notes that significant progress is being made and no other significant barriers have been identified at this time.

EXTREME DROUGHT

Question. The extreme drought that persists across the western U.S. and shows signs of intensifying has wreaked havoc on farming communities, towns, and municipalities across the Western U.S. and some areas east of the Mississippi. One essential tool that USDA and U.S. agriculture producers have benefited from since 1999 is the U.S. Drought Monitor (USDM), produced weekly by the National Drought Mitigation Center (NDMC) at the University of Nebraska Lincoln. Can USDA provide the Committee with the current USDA programs and other Federal and State agencies that use the USDM and early warning science-based NDMC products to inform drought-related decisions?

Answer. While USDA cannot speak to USDM usage by other Federal agencies, several States have official drought plans incorporating information provided by the NDMC, including the weekly USDM map and associated statistics. These plans can be found here: <https://drought.unl.edu/planning/DroughtPlans/StatePlans.aspx>.

Congress has also mandated its use as a trigger for the Livestock Forage Disaster Program in the Food, Conservation, and Energy Act of 2008. Other USDA programs that use the USDM as a determinant of eligibility are:

- The Emergency Assistance for Livestock, Honeybees, and Farm Raised Fish Program;
- Fast Track USDA Disaster Designations;
- Emergency Farm Loans; and
- Emergency Haying and Grazing under the Conservation Reserve Program.

A summary of these and other programs providing relief from drought and other natural disasters is here: <https://www.farmers.gov/sites/default/files/2021-10/fsa-usdroughtmonitor-factsheet-21-101521.pdf>.

PORK PROCESSING CAPACITY

Question. I am glad the Department avoided a lapse in the NSIS time-limited trial and subsequent loss in pork processing capacity this spring. I appreciate the efforts you have taken to make gains in meat and poultry processing capacity. I'd urge you to establish the NSIS which allows plants to process hogs at the higher line speed permanently. These plants have been operating in this way for decades now, safely and efficiently. Do you agree we need a permanent solution to ensuring pork line speed? Can you share with us the timing and process for re-establishing this program permanently?

Answer. FSIS has contracted with a team of worker safety experts to study the impact of increased line speeds on worker safety at poultry establishments. The agency was able to expand the contract to include swine establishments. In early March 2023, FSIS announced that it was extending the duration of the swine "Time-Limited Trials" (TLT's) until November 30, 2023. This extension will allow the contractors to finalize their report on the swine establishments data, enable the agency to assess the report's findings and conclusions, and to determine future actions, including a potential rulemaking on line speed.

Question. Are there funding needs from the Department to ensure a permanent program?

Answer. There are no additional funding needs at this time.

SUBCOMMITTEE RECESS

Senator HEINRICH. And thank you. Thank you both.

And with that, this hearing is adjourned.

[Whereupon, at 11:35 a.m., Wednesday, March 29, the hearing was adjourned, and the subcommittee was recessed, to reconvene at a time subject to the call of the Chair.]

**AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2024**

WEDNESDAY, APRIL 19, 2023

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

The subcommittee met at 2:15 p.m. in Room SD-124, Dirksen Senate Office Building, Hon. Martin Heinrich (chairman) presiding.
Present: Senators Heinrich, Murray, Tester, Manchin, Peters, Hoeven, Collins, and Hyde-Smith.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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

OPENING STATEMENT OF SENATOR MARTIN HEINRICH

Senator HEINRICH. Good afternoon. This hearing of the Agricultural Appropriations Subcommittee is now called to order, and I'd like to begin by welcoming FDA Commissioner Dr. Robert Califf to this hearing. Thank you for being here today. Very much looking forward to discussing the fiscal year 2024 Budget Request for the Food and Drug Administration.

The responsibilities of the FDA are extensive and they impact every single American. Last year this committee provided historic funding for this agency but there is much more work that needs to be done and that begins with the budget request in front of us today.

This request for FDA includes the discretionary increase of \$372 million. This increase touches on a wide array of activities at the FDA, from enhancing food safety to advancing safe and effective medical products as well as continuing to address the ongoing Opioid crisis.

We must ensure that the vast number of products FDA regulates are safe while also not slowing down important advancements in research and technology. These are not easy tasks, but this committee stands ready to work to support the FDA and the critical work that is done there.

The decisions the FDA makes, whether approving a medical device or approving a new drug, must be guided by science and data, not by political pressure.

Dr. Califf, with your long and distinguished career in science, I suspect you must feel the same way and that precisely is why a recent decision by a Federal judge in Texas is so disturbing to me.

This judge has replaced his political agenda for the data-driven process used by the FDA. He has undermined the FDA's safety and efficacy determination of Mifepristone and with it he has undermined the FDA's authority to determine the safety and efficacy of all medications, from insulin to cancer treatments.

I know we're going to discuss this shortly and I'm interested to hear your thoughts, Dr. Califf, but first I look forward to hearing your testimony and having a robust discussion on this year's budget request, and I'll now turn the time over to Ranking Member Hoeven for any opening statements that he may have.

Thank you, Member Hoeven.

STATEMENT OF SENATOR JOHN HOEVEN

Senator HOEVEN. Thank you, Chairman Heinrich, appreciate it.

I'm also pleased that our Ranking Member for the Full Appropriations Committee, Senator Collins, is here. Thanks for joining us, appreciate it very much, and, Dr. Califf, thanks for being here, appreciate it very much.

Last year when you returned to reprise your role as Commissioner, we were at the beginning stages of the infant formula crisis. During both the budget hearing and subsequent food safety hearing, we had frank discussions on the need for sustained leadership in the agency, and I expressed to you at that time, you know, that we had seven commissioners in the past decade and that we need some stability in the FDA. I'm pleased that you're back and I know you're working hard to try to provide that stability. I think it's important and I appreciate your efforts.

Obviously FDA plays a critical role in the safety and prosperity of our nation. Your agency actually has some aspect of authority over approximately 20 cents of every dollar spent in America. You knew that, right? Pretty remarkable.

Americans expect the food that they eat and the drugs they take will be safe and effective. So your reach is vast. You have authority over more than a 160,000 foreign establishments and a 135,000 domestic establishments, ranging from food processing plants to facilities that manufacture life-saving medications.

In addition, FDA's tasked with the regulatory responsibility not only for the facilities but the individual products. So obviously that role is incredibly important, one that we can't take for granted, one that FDA has to get right.

In delivering these regulatory responsibilities, it's very important that you have transparency and certainty and particularly when we look at small businesses as well as ag producers, like we have in my state of North Dakota, you know, their overwhelming concern is that the Federal Government in terms of that regulatory burden is reasonable, that common sense is applied, transparent and predictable, and so all of these things are vitally important to encourage the type of innovation and so forth that we need to continue to advance our economy and do it safely and well.

So again I think as we pursue these solutions and I know you're involved in this and rightly so, this reorganization effort, we've got

to avoid a one size fits all and we've got to use common sense. We've got to appreciate and understand the incredible role that small business plays in our economy, truly the back bone of our economy, and make sure that as you do these things that we don't get overly bureaucratic burdensome and so forth but in fact find ways to do things as effectively as possible and in a way that provides certainty to people across this country in all different aspects of the things that you do which are so critically important to our nation.

Thank you for being here today with us, appreciate it.
Senator HEINRICH. Dr. Califf.

SUMMARY STATEMENT OF DR. ROBERT CALIFF

Dr. CALIFF. Thank you, Chair Heinrich, Ranking Member Hoeven, and Members of the Subcommittee. Thanks for the chance to be here today.

I'd like to start by thanking the Subcommittee for your continued support of FDA, especially over the last few years, as the agency has worked tirelessly to turn the corner on COVID-19, ensure a safe and nutritious food supply, and prepare for the emerging challenges of an expanding and changing landscape of food, medical, and tobacco products.

This has been possible due to the vital and never-ending work of our dedicated FDA staff across the country and the world. To continue supporting their work, the budget I present to you today requests a total of \$7.2 billion, a 7.8 percent increase in funding for the FDA.

This significant increase in funding will have an immediate impact on optimizing the health benefits of safe and nutritious food, reducing harm from tobacco products, and ensuring the availability of safe and effective medical products.

This funding will also enable the agency to continue to leverage new and emerging technologies, improve the recruitment and support of a highly skilled workforce, and adapt to new production and business models in the industries that we regulate.

I want all of you to know as well as the American people that I, along with the leadership at FDA, will continue to make the long- and short-term strategic organizational changes and investments to ensure this agency is best positioned for future public health and regulatory challenges and opportunities.

Since rejoining the agency I have consistently heard from industry, Congress, and other stakeholders that the Human Foods Program needed more attention and support. I don't have to tell you that the infant formula shortage highlighted many of these issues.

We've begun the exciting process of implementing a revitalized and forward-looking FDA Human Foods Program, including a new model for the Office of Regulatory Affairs. We've announced a search for a Deputy Commissioner of Human Foods who will report directly to the Commissioner and will have clear authority over the organization's strategy and resource allocation of the Human Foods Program.

As we embark on these changes, I want to be clear, our food is already the safest it has ever been and no other country has safer food, but that doesn't mean we can't improve; and while most pub-

lic discussion has been about preventing food contamination, America has a critical need to improve its nutritional status and better understand and reduce the chemicals that put our food supply at risk.

In addition to our focus on food, tobacco product regulation and enforcement remains one of our greatest opportunities to save lives.

Although tobacco use is declining and vaping has been modestly declining in youth, we will lose almost 500,000 Americans this year and millions of teenagers are already addicted to nicotine with many new users each day.

That's why our budget requests an additional \$100 million in user fees and authority to include manufacturers and importers of all deemed products, including electronic nicotine delivery systems or vaping products, among the tobacco product classes for which FDA assesses tobacco user fees.

No one anticipated we'd be inundated with almost 27 million applications for vaping products. It's time for this industry to pay its fair share as we grapple with the ongoing ravages of tobacco and nicotine addiction.

The U.S. continues to lead the world in medical product innovation but additional resources are needed to focus on key areas presenting new challenges. The ongoing Opioid overdose crisis, supply chain issues leading to a host of critical product shortages, increasing needs for post-market evaluation, and opportunities for amazing progress in battling cancer and neurodegenerative diseases.

Finally, we also need to ensure continuity of the agency's modernization of our IT infrastructure and data processes. This isn't just making sure our computers are the latest model or that the Wi-Fi works consistently, although that is important.

We need the ability to create systems that allow us to keep up with the complexities of the industries and products we regulate with the immense consequences for the health of all Americans.

Finally, we need to be prepared for the next pandemic threat. We've learned a lot over the course of the COVID pandemic and need to assure the public that we're ready for the next event.

I'd like to close by thanking the Subcommittee again for your continued support of the agency. As the gold standard for protecting health, FDA is trusted by Americans and relied upon around the world for our work, ensuring the safety, efficacy, and security of our nation's medical products and food supply.

Once again, thanks for inviting me to testify before you today and I look forward to answering your questions.

[The statement follows:]

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

Chairman Heinrich, Ranking Member Hoenes, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the President's Fiscal Year 2024 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 funding increases provided by the Subcommittee in the FY 2023 omnibus, as well as the expanded and new regulatory authorities included in the legislation to address cosmetics and medical device cybersecurity. Your continued partnership is critical as we further our mission to protect and promote the public health. FDA's talented and dedicated workforce has worked around the clock for the past three-plus years to respond to the COVID-

19 pandemic, confront related challenges, and ultimately strengthen our nation's response to future outbreaks. We appreciate your ongoing support on a variety of programs and initiatives, including the dedicated resources in several critical areas that support our personnel and efforts, including employee pay costs, infrastructure, and data-modernization to ensure continuity of our vital work.

The COVID-19 pandemic has underscored the need for a swift, unified governmental response with collaboration across Federal agencies, state, local, tribal, and territorial governments, industry, and the private sector. As we collectively work together as a nation to turn the corner on COVID, the Agency is using the lessons learned to continue our core mission while we pursue new ways to better prepare for future threats and confront new challenges posed from an ever-expanding marketplace of food, tobacco products, and medical products.

For example, in the foods area, the Agency has remained laser-focused on a variety of critical efforts, including stabilizing the supply chain for critical products such as infant formula, mitigating the risk of potential exposure to certain chemicals, toxic elements, and allergens, and facilitating consumer education regarding healthy foods through the development of updated and more accessible food labeling. Furthermore, with a Human Foods Program that regulates approximately 80% of foods consumed by Americans, including those bought in grocery stores, restaurants, and cafeterias, we are actively working towards a new, transformative vision for the program that is forward-thinking, proactive, and adaptive to an ever-changing and evolving landscape. FDA is taking steps, in line with the recommendations of the external evaluation conducted by the Reagan-Udall Foundation, to ensure that our customers, the American public, can remain as fully confident in the food they eat as they are in the medical products they rely on to support their health; our FY 2024 Budget places us firmly on the steps towards this path.

The funding requested in the President's FY 2024 Budget request builds upon funding provided in the FY 2023 omnibus for foods and other product areas, while also acknowledging additional future needs and challenges. Our FY 2024 program level request totals \$7.2 billion, which represents an overall increase of approximately \$521.4 million in annual funding above the FY 2023 Enacted level. Of this total, \$3.3 billion is for user fees, which is an increase of approximately \$149.5 million above the FY 2023 Enacted level. As part of the total program level, the Budget also requests \$3.96 billion in budget authority, which is an increase of approximately \$372 million above the FY 2023 Enacted level. These increases are organized into five critical areas that advance the Agency's activities in support of protecting and promoting human and animal health: (1) enhancing food safety, nutrition, and cosmetics oversight; (2) advancing medical product safety; (3) investing in core operations; (4) modernizing infrastructure, buildings and facilities; and (5) tobacco user fees. The Budget also provides \$670 million of mandatory funding to advance the goals of HHS's Pandemic Preparedness Plan.

ENHANCING FOOD SAFETY, NUTRITION, AND COSMETICS OVERSIGHT

FDA's Budget request provides a historic investment in FDA's Foods Program with \$1.7 billion for food safety, nutrition, and cosmetics, an increase of \$210.6 million above FY 2023 levels, to support our continual efforts and commitment to strengthening FDA's food safety and nutrition capacity. This funding will help to ensure our human and animal food supply is safe, sanitary, wholesome, and accurately labeled, as well as ensure that FDA can start to implement new authorities given by Congress to provide oversight of the safety and proper labeling of cosmetic products. Additionally, this Budget will increase FDA's inspectional capabilities, which include the risk-based oversight of food facilities subject to FDA's food safety regulations and help ensure a reliable and safe food supply chain.

New Era of Smarter Food Safety

As a nation, our food supply is the safest it has ever been—but that does not mean we can't improve upon it. Specifically, as part of the total \$1.7 billion request for FDA's Foods Program, the FY 2024 Budget includes an increase of \$37 million for our New Era of Smarter Food Safety initiative. This approach aims to bend the curve of foodborne illness by strengthening data access and analysis capabilities, as well as bolstering capacity and food safety inspectional efforts.

Healthy and Safe Food for All

Within these requested Foods Program investments, FDA is also seeking resources for our ongoing efforts to provide safe food to the American public, with a renewed emphasis on the availability of healthy food options. The infant formula shortage from the last year serves as a stark example of the need for continued attention to the critical issues of food safety and security, the importance of quality

nutrition, and the need for a safe and accessible supply of food products. To meet this goal, FDA is requesting an increase of \$64 million to modernize oversight of infant formula, empower consumers to make healthier food choices, and reduce exposure to toxic elements in the food supply. We are further requesting an increase of \$5 million in order to improve FDA's ability to assess and track certain elements of the food supply chain and industry capacity in order to help minimize supply chain disruptions and enable a more resilient food system.

White House Commitment to Nutrition and Food Labeling

Finally, I would note that as a cardiologist, I've seen firsthand the result of poor nutrition and diet, often stemming from childhood, and the long-term impacts from diet-related chronic disease that can occur. One of the first steps to addressing this often-neglected issue is to ensure consumers have adequate and necessary information on the food they eat. To advance these efforts, our budget also requests an increase of \$12 million to strengthen nutrition and labeling work in alignment with the White House's National Strategy on Hunger, Nutrition, and Health.

ADVANCING MEDICAL PRODUCT SAFETY

In addition to ensuring a safe and healthy food supply, FDA's FY 2024 Budget request includes \$4.6 billion for strengthening human and animal health efforts across FDA's medical product centers, an increase of \$199.9 million above the FY 2023 Enacted level.

Device Shortages and Supply Chain

For example, as part of FDA's total medical product safety investments, this budget requests an increase of \$11.6 million, for a total of \$21.6 million, to continue building capabilities for FDA's Resilient Supply Chain and Shortages Program for medical devices, and for recruiting data science, supply chain, and medical device experts to properly staff the program. These resources support our efforts to help prevent and mitigate shortages of critical medical devices, improve our ability to work proactively with medical device stakeholders to assess vulnerabilities and enhance resiliency, and ultimately safeguard the availability of life-saving technologies that are most often needed by vulnerable populations.

ALS (ACT for ALS)

In addition to maintaining access to current devices and other existing medical products, FDA also continues its focus on promoting the innovation and scientific advancement of new medical products, including products to address critical and rare diseases. Our medical products request therefore includes an increase of \$2.5 million for staffing to implement the ACT for ALS Act and to help facilitate access to therapies for neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS). Additionally, this funding will help to expand the related development of new scientific approaches and tools that are available for the development of effective new medical products to prevent, diagnose, mitigate, and treat rare neurodegenerative diseases.

Combating the Overdose Crisis

Finally, in addition to the ongoing efforts at the Agency to promote medical product access and innovation, I also remain deeply involved in efforts to address an issue that has devastated countless families across our country, the overdose crisis. FDA's Budget request includes a proposed increase of \$23 million, for a total of \$102.5 million, to support the continued development of overdose reversal treatments, as well as treatments for Opioid Use Disorder (OUD). This funding will also support preventative methods and tools which involve establishing satellite labs at International Mail Facilities with permanent staffing of scientists and investigators, along with expanding FDA's use of analytical tools for screening entries of potentially illicit products before they can enter our country. In addition, this funding will help advance the development, evaluation, and market authorization of digital health medical devices for further monitoring and addressing OUD inclusive of the patient perspective. Addressing this crisis is largely dependent on collaboration across the country, and utilizing real-time data to take effective and evidence-based approaches on this issue remains crucial to our next steps to turning the corner on this epidemic.

Cancer Moonshot

Further, FDA's Budget provides \$50 million for FDA to advance the President's Cancer Moonshot goals. These funds will enhance Agency-wide efforts to improve evidence generation for underrepresented subgroups in oncology clinical trials, as well as to support pragmatic, decentralized trials and the development of sources

of evidence that incorporate patient-generated data and real-world evidence. Additionally, these resources will assist in the expansion of FDA's efforts to facilitate the approvals of innovative and new cancer treatments by international regulatory authorities at the time of FDA approval and will foster collaboration on cancer treatments with other countries with standards comparable to the U.S. standard of care.

INVESTING IN CORE OPERATIONS

As highlighted in earlier portions of this testimony, our nation relies on FDA to provide rigorous and transparent scientific review, a predictable and responsive regulatory structure, a strong inspectorate, and expert staff to provide support for these activities. To meet these needs, as part of our total program level, our FY 2024 Budget requests \$131.1 million above FY 2023 levels to continue to strengthen and support FDA's core operations and pursue new areas of improvement and innovation. In order to support further efforts, the Agency needs a strong framework for our programs, and for us that begins with data. Core operations also include initiatives such as advancing lab safety, information technology, and support services to help ensure FDA's ability to carry out its programmatic responsibilities.

Data Modernization and Enhanced Technologies

FDA's core operations request includes an increase of \$10 million for Data and IT Modernization to build new tools and greater capacity to analyze real-time information. To meet the challenges of emerging threats and the need for real-time evaluation, FDA relies on the ability to rapidly and continuously access, analyze, and aggregate multiple sources of information. From the COVID-19 pandemic to import alerts and domestic recalls, continual modernization of FDA's IT infrastructure has become increasingly more vital in order to keep pace with the evolution of outbreaks and disease. With these resources, FDA will continue to further build our centralized enterprise data modernization capabilities and strengthen the Agency's common data infrastructure, data exchange, and IT analytic services, talent, and tools. Investments in these critical areas will enable FDA to directly meet the challenges of our modern data-driven world, and continue to operate as the gold standard for product regulation and oversight.

MODERNIZING INFRASTRUCTURE, BUILDINGS & FACILITIES

In addition to necessary investments in our core operations, including digital infrastructure, the continuity of the Agency's critical work also requires funding to complete projects that will improve the condition of FDA's owned buildings and physical site infrastructure. As part of our overarching FY 2024 Budget, FDA's request provides a total of \$395.9 million for infrastructure, buildings, and facilities. This funding will help to ensure that FDA's offices and labs across the country are optimally functioning. This funding will also directly support the Agency's priorities across the country by providing secure, modern, reliable, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of American families. By investing resources in FDA's facilities, the Agency will be able to continue to provide the high-quality infrastructure and facilities needed for FDA employees to work to ensure FDA can achieve its strategic priorities across the country and the world.

TOBACCO REGULATION

As one of these strategic priorities, tobacco product regulation represents one of FDA's greatest opportunities to save lives. The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. FDA finalized the Deeming rule in 2016, which extended FDA's tobacco authorities to all tobacco products, including cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, and electronic nicotine delivery systems (ENDS) such as e-cigarettes. In 2022, a new Federal law went into effect clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic or non-tobacco nicotine (NTN). FDA regulates the manufacture, marketing, and distribution of tobacco products. Key areas of focus include policy and rulemaking, compliance and enforcement, premarket review, research support, and public education campaigns.

In addition to the priorities mentioned earlier across foods, medical products, core operations, and infrastructure, the Budget also requests an additional \$100 million in user fees and requests authority to include manufacturers and importers of all deemed products—including ENDS—among the tobacco product classes for which FDA assesses tobacco user fees. These products represent an increasing share of FDA's tobacco regulatory activities. The additional funding will support hiring more

staff, help FDA bolster compliance and enforcement efforts for all tobacco products, and expand public education campaigns and science and research programs, as we work to mitigate harms and to protect consumers from the dangers of tobacco use. To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation. This proposal would ensure that FDA has the resources to address all regulated tobacco products, including ENDS, which currently have high rates of youth use, as well as future novel products.

PANDEMIC PREPAREDNESS

Finally, as we advance towards regular operations across our product centers, FDA remains aware that there is work yet to be done in our response to COVID-19, and it is critical that we learn from both our successes and the challenges we experienced to best improve our operations moving forward. Lessons learned from the COVID-19 pandemic have reiterated the need to proactively plan for the next public health emergency by ensuring FDA has the resources and capacity in place to fully respond. FDA plays a unique and central role to the whole-of-government response to protect and promote the public health, and in turn, we are requesting funding to improve FDA's core capabilities to help ensure there is the appropriate level of regulatory capacity to respond rapidly and effectively to any future pandemic or high consequence biological threat.

Separate from our aforementioned requests for discretionary budget authority, FDA's Budget includes a request for \$670 million in new mandatory resources available over 5 years to advance activities to better prepare FDA for the next pandemic. These funds would support the Agency's biodefense efforts, domestic and globally, by bolstering FDA's cadre of medical product reviewers and strengthening foundational processes. It would also increase FDA's capacity to leverage a One Health approach to respond to emerging threats. And lastly, these resources would help strengthen underlying technology platforms to improve electronic information exchange among stakeholders and bolster central coordinating capacity within the Office of the Commissioner. With these resources, FDA will have the opportunity now to build on lessons learned from previous responses and provide transformational investments to help ensure that FDA can respond quickly and effectively in times of a public health crisis.

CONCLUSION

This last year has presented some defining moments for the Agency and ample opportunities to bring the Agency into a new chapter. This Budget will help FDA maintain and expand on our current efforts, pursue new innovative strategies and methods, and provide a renewed focus on, and investment in, a variety of endeavors in the interest of public health for both humans and animals. I would like to close by thanking the Subcommittee again for your continued support of the Agency. I look forward to answering your questions today, and FDA looks forward to our collaboration and work together.

Senator HEINRICH. Thank you for your testimony this morning, Doctor.

As you know and I mentioned in my introduction earlier this month, U.S. District Judge in Texas ruled that FDA's approval of Mifepristone more than 20 years ago was improper and issued a nationwide injunction to halt it.

This sets an incredibly dangerous precedent in terms of both women's reproductive rights but also the FDA's review of drugs.

Doctor, I'd like to give you the opportunity to speak about what impact this ruling could have on other FDA-approved drugs.

Dr. CALIFF. Well, as you know, Senator, that matter's currently pending before the Supreme Court. So, I have to be brief and concise, but I will say that we are concerned about the potential future impacts of this case as reflected in the extensive briefs that have been filed by the Department of Justice on our behalf.

This includes a wide range of concerns ranging from the well-being of patients, including women who need access to this drug, the pharmaceutical industry, and our ability to implement our statutory authority. So, the considerations are extensive.

Senator HEINRICH. Switching gears just a little bit, Opioid and fentanyl use is having dire impacts in communities across the country, including my home state where two-thirds of drug overdose deaths involve an Opioid.

With Naloxone approved by the FDA and now available over the counter, what else is the FDA doing to continue addressing the Opioid epidemic broadly?

Dr. CALIFF. Really appreciate the chance to address this and we should all be concerned because the nature of the epidemic is changing significantly from just the prescription misuse to now cartels driving fentanyl being delivered by mail to American homes with unsuspecting parents finding teenagers dead, in addition to the other problems that we've seen.

Having said that, we have a major report that's out with a whole host of things that we're doing, but just to name a few. We recently are requiring now a mail-back system to be employed by all the manufacturers of opioids so that when people finish their supplies rather than having them sit in the medicine cabinet, they can be mailed back to the pharmacy. We also just changed the labeling of long-acting opioids just last week, taking into account that we still don't have the data we need about long-term benefits. In fact, there's a hearing going—I mean, an advisory committee going on today to talk about that.

We have a number of other things that we think are important in the future. One that I'll mention that's very important to us is we'd like to have the authority to require that any new opioid company attempting to bring an opioid to the market must show that the new one has superiority to the old ones in terms of safety.

Right now, by law we don't have the authority to make that decision. It would really help us if we had that authority. This is a carve-out, an exception. It's not pertinent. A lot of times the second drug along in a class turns out to have advantages that were unanticipated, but this is a case where for opioids we really need help.

I can go on much longer, but I know we have limited time.

Senator HEINRICH. Do you want to touch on—there's a \$23 million increase in the budget specific to this. Do you want to touch on your plans for that increased funding?

Dr. CALIFF. Sure. A lot of it has to do with the data systems that we need and the testing that we need to do in proximity to where the opioids are coming into the market.

If you ever want to have an interesting field trip, go to our International Mail Facility at JFK and see the Labrador retrievers. Senator Baldwin made that trip, but it's just an enormous amount of stuff coming in that Americans are getting over the Internet, I think not realizing that often they're getting really bad stuff.

So, we've got to invest in the testing to intercept this right at the border, have the data systems and the artificial intelligence to screen just as we do when people come into our airports to sort the bad guys from the good guys, and then we're hoping that there's going to be development of non-addictive pain medicines. It's a place where, in my view, the industry has let us down.

I say that having been on the industry side in part of my career. It's a tough job, but we're not succeeding in seeing non-addictive pain medicines coming through the pipeline. So, we need to do ev-

everything we can to push the industry and work with the NIH to make this happen.

Senator HEINRICH. The accelerated drug approval process at FDA can often be a game-changer for patients with serious medical conditions. It's a process that's important to myself, many advocates actually, yet many of these drugs approved through that process are not then reimbursed by the Centers for Medicare and Medicaid Services (CMS).

Doctor, what is the FDA doing to coordinate with CMS on drugs that are approved specifically through the accelerated process?

Dr. CALIFF. Well, you may remember when I came in this time, you know, I likened it to a relay race where we run the first lap and then we hand off the baton to the payers, the private payers and CMS. What we're doing is try to make sure the information is much more seamless, that we have the clinical trials that are relevant to what they need, but it's also abundantly critical CMS does not influence our decisions about safety and effectiveness and we don't have any authority to influence CMS's decisions about the reasonable and necessary criteria and what we want to do is to make sure people have the right information so that CMS can make the best decisions it can, that it understands what we were looking at when we made our decisions.

I think this is an area in American medicine where there's a lot more work to be done and we can maybe later in the session we can talk about.

Senator HEINRICH. Okay. Ranking Member Hoeven.

Senator HOEVEN. Mr. Chairman, I'm going to defer to our Appropriations Ranking Member Senator Collins for the first round. I always appreciate when she joins us.

Senator COLLINS. Thank you very much.

Dr. Califf, I have a series of questions that go to the heart of the recent court decision in Texas on Mifepristone.

First, are FDA's regulatory decisions based on sound science?

Dr. CALIFF. Yes, the latest available science with the best methods that we can find by civil servants who have no financial conflicts.

Senator COLLINS. Second, are political or economic considerations weighed in your drug approval process?

Dr. CALIFF. No. Of course, we're all human beings. We're aware of the discussions that go on, but that decisionmaking process is protected. Political appointees, even the Commissioner, me, I'm a political appointee, I think of myself as a doctor, but I'm politically appointed, we don't influence those decisions or intercede, except in very rare circumstances.

Senator COLLINS. Third, has this abortion drug been on the market for more than two decades?

Dr. CALIFF. Yes, 23 years, I think.

Senator COLLINS. And has it been used by millions of women during that period?

Dr. CALIFF. Many millions.

Senator COLLINS. Let me read you a quote that was included in a filing by some physicians who were challenging the process by which the FDA approved this drug. These doctors say, "For nearly a quarter century the FDA and the manufacturer have brazenly

flouted the law and applicable regulations, disregarded holes and red flags and their own safety data, intentionally evaded judicial review, and continually placed politics above women's health."

Could you comment on that statement?

Dr. CALIFF. Well, as I've said, we use the latest science, the best data to make our decisions, and these sorts of influences you're describing are protected within the FDA by the system for all drugs, not just this one.

Senator COLLINS. And I appreciate those answers. I consider the FDA to be the gold standard globally in approving drugs and I find this court ruling to be more reflective of the judge's personal views rather than a fair and impartial analysis of the facts of the case.

I do want to pick up on the issue that the Chairman raised because just as I question the court's decision in this case, I also question CMS's decision to deny Medicare patients access to two Alzheimer's drugs that have been approved by the FDA.

My view is CMS should stay in its lane, the FDA should stay in its lane, and we've talked about that. So I'm not going to ask you to comment today because I want to quickly get in one other issue, and it has to do with cell and gene therapy approvals.

Almost 5 years ago the FDA issued a forward-looking statement on the future of cell and gene therapy approvals and new policies to advance their development. The FDA stated its intent to maximize use of expedited programs, including accelerated approval to review gene therapies for serious life-threatening diseases, and this subcommittee's bill included language last year to further encourage FDA to bring urgency to the gene therapy.

In 2021 you stated that you are a fan of accelerated approval for the right conditions and as we've also talked, I believe that you are sincere in your belief that there's great promise here.

However, what I am frequently hearing is that the FDA's Center on Biologics has put clinical holds without explanation on some promising cell therapy developments.

Do you agree that there is a problem there?

Dr. CALIFF. I want to acknowledge that I think there are some issues there that need to be worked out. This was recognized in the User Fee Agreements that were just concluded and you all passed just last year which are now going into effect.

We're going to be hiring 150 to 200 people in this area under the leadership of Dr. Marks, who I think you'd agree has done a remarkable job with vaccines and now this is going to be a big focus of attention.

I would emphasize when it comes to clinical holds, it's not just it's something that's going wrong with a patient. Often it has to do with the integration of manufacturing and a lot of the companies are start-ups without robust manufacturing facilities. So, there's a lot of work to go on, but we agree that this is an area we've got to move along more quickly.

I know like everyone else you all talk about FDA approvals. I always feel like I need to emphasize we also don't approve a lot of things if they aren't safe and effective. If the risks outweigh the benefits, it's our job to stop those, but I do acknowledge that there's an issue here that we're addressing.

Senator COLLINS. Thank you. Thank you, Mr. Chairman.

Senator HEINRICH. Senator Peters.

Senator PETERS. Thank you, Mr. Chairman.

Dr. Califf, last month, as the Chair of the Senate Homeland Security and Government Affairs Committee, I released an investigative report that found that there were major blind spots in our ability to accurately assess vulnerabilities in our drug supply chain.

From both a national and a homeland security standpoint, I'm particularly concerned about shortfalls in the FDA's ability to use data analytics to effectively assess our reliance on foreign sources, especially in countries with rising geopolitical risk, like China.

The Defense Department, of course, relies on the same international market to provide drugs for our service members.

So my question for you, sir, do you agree that the FDA does not have sufficient visibility to identify some of the risks that could lead to supply shortages and if that is the case what are some of your top challenges to assess this risk?

Dr. CALIFF. Thanks for raising this issue. It's taking up a large amount of my time right now and just a couple of preface statements.

We're seeing shortages in every commodity we regulate, including food, devices, drugs, and biologics. The only one we're not seeing it in is tobacco, oddly enough, the one I might prefer there was a shortage, it's not occurring. They seem to have figured it out.

The second preface point that I would make is that I was on the National Academy of Medicine's Supply Chain Committee just before being nominated and spent a lot of time working on it then and the report that you put out is very consistent. I think there are five different reports now that make this point.

If FDA is looking through a windshield, we got mud on our windshield because we can see some things but there's a lot that we can't see because we don't have requirements of the industry to give us the data that we need and we don't have funding for the data systems and analytics that we need, and, if you wish, I'm glad to go into any amount of detail.

The one other point I want to make in general is that there's an element of this, that is clearly in FDA's lane, and there's an element which is more of an all of government; that is, when we see a problem, many of the levers that are really important to pull exist outside the FDA when it comes to things like tariffs or investments in manufacturing facilities in the U.S. with funding which are two of the areas I think we've got to look at.

Senator PETERS. Well, great. Well, I guess in further conversations we've had a follow-up report, two reports now, one we did prior to the pandemic and since then it's gotten worse, not better, and we've got a number of ideas how to address it but love to have your thoughts and meet with you at some point in the near future.

Dr. CALIFF. I'd like to, and your point about insecure countries that we're dependent on is really critical right now.

Senator PETERS. Right, absolutely. Thank you.

Sir, I'd also like to follow up with you on the FDA's work to restore confidence in our nation's infant formula supply.

As you're well aware, in Michigan we witnessed the devastating harm that can come from bacterial contamination of infant formula that families rely on, and it's clear, absolutely clear that we have

a lot more work to do. In the most recent Michigan case, once again contaminated formula was recalled only long after it was already distributed, sold, and consumed. This put vulnerable infants at risk and once again in response the FDA asked manufacturers to voluntarily notify the FDA of any time a product sample is found to be positive for Cronobacter or Salmonella, even if the affected lots have not yet been distributed.

So my question is are you confident the industry will consistently volunteer accurate and verifiable information to the FDA or do you think we're going to need to be thinking of legislative change to require earlier industry reporting, if necessary?

Dr. CALIFF. I am confident the majority of the industry will comply, but I would prefer it if the things that are really needed are written into law. It's a lesson I've learned this year.

You know, it's like anything in America. Most people want to do the right thing and they do it but you have outliers. In the case of the infant formula situation, it's a concentrated industry. So one entity not doing the right thing can create a problem.

I do want to point out the recent case you talk about, we changed the standards and this particular entity got caught in the middle of it, didn't meet what we expected them to do. I think the whole industry is moving to the standard of notification and better bracketing of products, but still I think having the authority is so much better.

I've been on the industry side and when the industry is told you must do something, it actually does it because the penalties are very different than in a voluntary situation.

Senator PETERS. Right. Well, thank you. Thank you, Mr. Chairman.

Senator HEINRICH. Thank you.

Ranking Member Hoeven.

Senator HOEVEN. Dr. Califf, as you and I have discussed, I am concerned about FDA decisions to allow Mifepristone to be distributed by mail and without physician supervision.

So my question to you is will you commit to following the decision of the courts with respect to the drug and how it's handled?

Dr. CALIFF. I'll just say the FDA intends to comply with any court orders.

Senator HOEVEN. Thank you.

And I would like to follow up on the infant formula supply. Talk about supply—we're still getting reports in some cases of supply of certain types of brands. Where are we at with the supply of infant formula and what else are you doing to make sure it's available?

Dr. CALIFF. You know, I've tried to stay understated on this because, you know, the day of the Abbott recall was the day I was confirmed and I discovered all these problems inside the FDA that needed to be fixed. We could have a long discussion about how much those problems actually affected infant formulas specifically I don't think as much as people think, but that doesn't change the fact that we needed to fix our own house internally.

But, I am pleased to say today we're over 90 percent in stock which is higher than it was before the recall. So there's plenty of formula out there and March 28th we put out our Stability Report with a whole host of things that we've done, but I also want to say

that while we're stable at this point and probably a little better off than we were before the recall, there are four or five key things that are beyond the FDA that need to be fixed.

It's a concentrated industry. We don't have enough variation in the suppliers. Putting up a new infant formula plant takes years and, in fact, Abbott has decided to put up a new one. It's going to take a couple years for them to do it and they have the most capacity in the industry already, but you've got to get 30 ingredients right, the quality has to be there. So, this is not a trivial thing for start-ups to begin to do.

So, there's a lot of work to do to diversify the industry to assure that if there's a bad lot event like the major flood that occurred in Michigan, you know, one in a hundred-year flood, that the whole thing doesn't become short again. So, I don't want to appear complacent. We still have work to do. It's very much there in our report.

Senator HOEVEN. So I think that answer is helpful. I think it reassures people that supply is out there and that you're working on it and I think in your leadership role that's the kind of thing that both in terms of the information and action that can help address this type of situation. So I appreciate that.

Dr. CALIFF. If I may mention, I know you're particularly concerned about rural areas, I'll just say in everything that we're currently regulating, rural areas are in need of better support.

Now, you know, FDA can measure these things but we can't necessarily fix it, but in infant formula I know that's still a bit of an issue as the supply's up overall but it tends to be centrally distributed to start with. So, we're very much working on that every day. I just wanted to make sure that was noted.

Senator HOEVEN. Right. Particularly when you're looking for certain size and certain brands, certain types, you know, obviously it's there in the urban center and the big store but that's exactly right and so I appreciate that.

In regard to the traceability rule, this goes back to my opening comments, and I'm concerned about the size and scope of the traceability rule and, you know, the workability.

So, I mean, do you have a comprehensive list of the products that you're going to cover under the rule? Who's going to have the burden of maintaining records, the entity, the business, or the industry, or FDA, or both, and then are you going to allow exceptions again for small business, family-owned business kind of thing?

Dr. CALIFF. Sure. As we've discussed before, we've got to be sensitive to the needs of small organizations and we already have exceptions for, for example, family farms and for retail establishments that are small. There are exceptions, but, you know, there's a phrase used in the industry "educate before you regulate" and what we want to do, if we look 10 years ahead, we hope the entire supply chain will be digitized, right, so that we can distribute the right stuff to the right place regardless of where it is in America, but for smaller companies to get there, they're going to need help and support.

We recognize that and it'll be shown in our adaptive approach to regulation.

Senator HOEVEN. The exception is very important and that rule can get away from you. So I'm glad you're watching it closely.

My last question is regarding the Medicare and Medicaid coverage of Alzheimer's drugs. I joined with 19 of my colleagues, including Senator Collins, in sending a letter to CMS expressing our dismay for the agency's coverage termination on Alzheimer's drug.

AS Commissioner and a physician, are you concerned with CMS choosing not to cover some of those FDA-approved Alzheimer's drugs?

Dr. CALIFF. Senator, you know I can't comment on CMS's decision.

Senator HOEVEN. Sure you can.

Dr. CALIFF. All I can say is we evaluated and considered it safe and effective.

I'll just point this is an amazing area of biology that is still a problem.

Senator HOEVEN. That's the good comment for a non-comment.

Dr. CALIFF. Okay.

Senator HOEVEN. You determined them to be safe and effective.

Dr. CALIFF. But that's different than reasonable and necessary which is the CMS standard. I just got—you know, we have family involvement with this disease. It affects my family greatly. So, I'm very much hoping the biology works out.

There's a whole bunch of new clinical trials about to come in. I think this will—I'm actually very confident having talked with CMS we'll get this resolved in a positive way and let's see the data as it comes in.

Senator HOEVEN. I appreciate that.

Senator HEINRICH. Chair Murray.

Senator MURRAY. Well, thank you very much, Chair Heinrich and Ranking Member Hoeven.

You know, families back home are really counting on us to work in this committee and across the Appropriations in a timely bipartisan way so we can pass our funding bills that keep them safe and our country strong. So I'm really glad this committee is continuing full steam ahead with return to regular order and talking about making sure that FDA has the resources it needs to live up to its really critical mission because make no mistake protecting our families is not just about how strong our military is, it is about how safe our food or drugs or our medical devices are, not to mention how smooth our supply chains are to ensure that families get what they need.

We've had some tough reminders of that over the years, whether it's the medical supply shortages during the pandemic or the agency's important work to quickly, safely review COVID treatments and vaccines, or, as we've talked about here, the inexcusable baby formula shortage.

That is really why I pressed very hard to make sure our end of the year package last year included some really important reforms to FDA, but we have more work to do, including on this subcommittee, to make sure we provide the resources for all this, as well, because there is a direct line between FDA having the resources it needs and the safety of American families.

Every time families back in Washington State go to the grocery store or gather around the dinner table or fill a prescription or rely on a medical device, they're really putting their trust in FDA and their experts to uphold the gold standard of safety and effectiveness, and let me just say once again, especially in light of recent events, the determination about whether drugs are safe and effective needs to be left to the experts at FDA, not politicians and certainly not judges.

We got a stark reminder of this in the recent weeks when extreme, poorly reasoned, and dangerous rulings of judges undermined FDA's authority to review and approve drugs by declaring themselves to know better than FDA's experts about medication abortion.

FDA has an enormous responsibility and some hard work ahead to make sure it is living up to that responsibility. The last thing our families need at this critical moment is for politicians to undermine its authority or shortchange its efforts.

So I'm really glad today, Dr. Califf, to have you before this committee to talk about what the agency is doing and what it requires to tackle the challenges you have ahead, and I do want to start out with the Mifepristone issue.

As you know, the Supreme Court is going to decide a case that really threatens access to medication abortion nationwide and seeks to undermine the FDA's authorities to approve and regulate medicine.

Let me ask the question this way. Commissioner Califf, would you speak to the implications of this case on the drug approval process and the scientific rigor with which the agency approaches drug applications?

Dr. CALIFF. As we discussed already today, our decisions are based on the latest science, the best data we can find, the weighing of risks and benefits by our professionals who are full-time civil servants without financial conflict, and there is concern in this case about the impact on a wide variety of things, including patients, women in need of access to a drug which is approved, the pharmaceutical industry itself because of the threat to the separation of this decision about what's approval and what's not sequestered away from political influence. So, these are all concerns that we have.

Senator MURRAY. So I take from your answer that this, of course, could have an implication on Mifepristone but also on the process that all of the drugs and tools that are going through the FDA?

Dr. CALIFF. This is well reflected in the extensive briefs that the Justice Department has filed on our behalf and are publicly available.

Senator MURRAY. Thank you very much.

Dr. Califf, at the end of last year, as you know, I negotiated and passed the Modernization of Cosmetics Regulation Act of 2022 which Senator Collins, who just left, was a critical part of. It provided new authority to your agency to make sure that cosmetics are safe for the people who use them.

The FDA finally, after many years, will know who is making and marketing what products and where and what ingredients are being used and when there is an adverse event, like severe rashes

or hair falling out or worse. This is the first time and I'm very excited that you now have the authority to regulate this. I can't tell you how many people I've talked to didn't even know they weren't regulated before. So very important step. You will now have the power to take products off the shelves if they're not safe.

Can you provide us with an update about how you're moving forward with this new authority and, importantly for this committee, what resources you will need to implement them?

Dr. CALIFF. Sure. I'm still stunned by the average of 12 cosmetics a day for women and six cosmetics a day for men, something I hadn't really considered before, but I am pleased to say that we're on track and I'm really excited that we've moved this under the auspices of Dr. Namandje' N. Bumpus, who's our Chief Scientist.

If you all have not met her, I would urge you to meet with her. She was the Chair of a Department of Pharmacology at Hopkins and I tried to talk her out of coming to FDA because she had a good life as an endowed professor, but she's a great civil servant, a preeminent scientist in that role.

We're moving along well with the registration issues that are part of this, developing the adverse event system. We've asked for \$5 million for next year which is a very important part of the budget. Our estimate for the overall dealing with this \$70 billion a year industry is about \$40 million to get us where we need to be over time and we'll phase that in so that we can show progress.

I know I've learned we need to show that in order to get people interested, but there are real safety issues that we're encountering. So, I'm glad we have that opportunity.

Senator MURRAY. Okay. Thank you very much. Thank you, Mr. Chairman.

Senator HEINRICH. Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman, and thank you, Dr. Califf, for being here today before the committee because I certainly look forward to your questions.

I just find it extremely concerning that under your watch the FDA allowed the dangerous life-ending, because they do kill the baby, chemical abortion drugs to be ordered by consumers through mail or purchased in retail pharmacies without ever seeing a doctor in person, I think that's the concern of many, many people. In 2016, as you know, the risk evaluation and mitigation strategies were changed to eliminate the requirements that non-fatal adverse events would even have to be reported to FDA.

So that's been 7 years that if the woman almost died, it was not reported. It was only reported if there were fatal cases. The FDA that claimed this drug to be safe in part based on the lack of reports of non-fatal adverse events. I agree with the fifth circuit's description of this deeply disturbing this of really-not-looking-at-it or the head-in-the-sand approach. Because of the lackluster approach to safety, women seeking to use these drugs do so without the chance to be screened by an ultrasound for complications. My main concern is an ectopic pregnancy that if the baby is not positioned which is deadly, or if she's further along that she's saying that she is, I'm truly grateful that the two Federal courts have ruled that the FDA's most recent action failed to meet its legal obligation.

So that's what the lawsuit is about, not judging if the drug is safe or unsafe but that the FDA failed to meet its legal obligation to protect the safety of women and girls and that it also directly violated longstanding Federal criminal laws that expressly prohibited the mailing and interstate shipping of abortion drugs.

So the FDA, it's more of a legal issue of the procedure that happened than a safety issue of determining what drug is safe. If the Supreme Court allows the lower court rulings to go into effect, will the FDA fully comply with the decision without delay and not attempt to flout the ruling under the guise of some kind of enforcement discretion? Would you apply immediately?

Dr. CALIFF. First, let me just reply to one small thing that you said, not such a small thing, but I do want to offer a different viewpoint on the adverse event reporting.

Adverse event reporting is required of all drugs, including this one. The reporting of adverse events is not being ignored in this case. It's required just like with all drugs. What was done was to take away a separate form that's different from all the rest of the drugs.

But with regard to your question, we're confident the law's on our side. We've appealed the District Court's decision to the Supreme Court and have sought a stay pending that appeal, but FDA, as I've said already, does intend to comply with any court orders.

Senator HYDE-SMITH. Okay. In making its decision to eliminate the in-person dispensing requirement, none of the studies the FDA cited, which were largely conducted by abortion activists, studied the drugs under the new no-test tele-abortion regime.

Despite this, the FDA concluded that it was safe, but even the FDA admitted that this decision would increase emergency room visits for pregnant women taking the drugs.

How comfortable is the FDA in recommending practices that have not yet been fully tested for safety?

Dr. CALIFF. Senator, since that's before the Supreme Court, I have to refer you to the briefs that have been filed by the Justice Department on our behalf. The answers to these questions are discussed in detail there.

Senator HYDE-SMITH. Okay. And how many studies has FDA considered that studied the effects of abortion drugs on young girls as required by law?

Dr. CALIFF. Again, I'd have to refer you to the briefs that have been filed by the Justice Department.

Senator HYDE-SMITH. Okay. And the law also requires the FDA to respond to petitions within a 180 days, but the FDA waited roughly 14 years and nearly 3 years to respond to citizens' petitions challenging FDA approval and deregulation of chemical abortion drugs.

Can you speak to that?

Dr. CALIFF. I'll just say again this is discussed in the briefs that are filed by the Justice Department and it would take a long answer.

Senator HYDE-SMITH. Okay. My time is up.

Senator HEINRICH. Senator Tester.

Senator TESTER. Thank you, Mr. Chairman, Ranking Member, for having this hearing.

I want to thank you for being here, Dr. Califf. I think you guys have been the gold standard. I appreciate the fact that you're in the position that you're in and I want to thank you for your work.

I'm not going to get into the activist judges. I'm not going to get into any of that stuff. The fact of the matter is, is that the FDA has done a great job and have done it for a long time and it continues under your watch.

I come from Rural America. You touched on it a little bit with the Ranking Member, but when we spoke last year we talked about the importance of ensuring good health outcomes in Rural America.

Given your background as a clinical researcher, we can talk about the clinical trials for new and innovative medical treatments and how they work for Rural America.

So clinical trials are critical, you know that, for drug development. Montana's rural population face many challenges in assessing and accessing clinical trials for innovative pharmaceuticals.

So the question is this. Can you explain how the FDA's budget allocation supports the expansion of clinical trials to rural areas, including efforts to increase diversity in clinical research participants and ensuring safety and efficacy of the drugs for all Americans, regardless of geographic location?

Dr. CALIFF. Sure. Thanks for the question.

I think it's critically important. I can't resist making one comment which is that we can't ask clinical trials to fix a structural issue with our health care system in general, but having said that, we got to do everything we can for the clinical trials.

We have an office essentially charged with dealing with diversity across the board, including clinical trials. There's a cross-agency task force working on this. We have several guidance that have come out and, of course, our increasing encouragement of adoption of the use of telehealth in clinical trials is a big part of this.

Here, I'd also emphasize that we've got to get broadband out to the rural communities. The money allocated for that as I understand it. So we can't use that technology unless someone is wired up in order to be able to use it, and I can't emphasize enough let's say you have a significant cancer driving three hours to get your experimental treatment, something a lot of people just can't do, and so we've got to set up these systems that can efficiently get the clinical trials done.

Finally, I'd just say the real-world evidence which has been a big part of my career that is using data that's all part of the health care system and then doing the trials more virtually is a rapidly growing method that we're very much in favor of.

So, all these things are in play, but I'm not going to argue we're there yet. We've got a ways to go in this regard.

Senator TESTER. So in that regard of broadband, I can tell you the gentleman to my right, Senator Manchin and myself worked on a bill called The Bipartisan Infrastructure Package. It'll get these folks wired up as soon as we get that money out the door and get the cable in the ground.

Dr. CALIFF. I had a flat tire in West Virginia and I couldn't even use my cell phone. It was not a pleasant night.

Senator TESTER. That's Manchin's fault.

[Laughter.]

Senator TESTER. Let me get you his phone number.

Dr. CALIFF. There was no way to call. I had to wait for a pass-erby to come by.

Senator TESTER. I want to talk a little bit not because I have an agenda on this, I'm just curious. You talked about approvals and you also talked about disapprovals.

Can you give me a number of the drugs that you guys take a look at? Is it a fairly static number that you disapprove compared to what you approve?

Dr. CALIFF. I would say it's really hard, Senator, because this all starts when a scientist has an idea and it's like one out of a thousand ideas get into human clinical trials because to get to human clinical trial, you got to have the money invested, an IRB has to be approved, the FDA has to approve it.

Out of those that get into the first human clinical trial, about 90 percent don't make it to the market.

Senator TESTER. Okay.

Dr. CALIFF. Now the big change that's happened is we meet with the companies all the time. It used to be there were a lot of applications submitted that had no hope. Now the only applications that go in are the ones that have gotten all the way to the end of the game. We get rid of all the others. Very efficient financially but also protects patients who are being enrolled in clinical trials for drugs that aren't going to work.

Senator TESTER. So you just talked about the lengths, so that gets into timeliness.

As a doctor, how do you think the FDA's doing on timeliness, and this is being somewhat self-critical or pat yourself on the back?

Dr. CALIFF. I think we're the fastest in the world at high quality. Now there's some countries that don't have much of a regulatory system at all. That's different. We're the fastest in the world, but we're also the most thorough and we're the only regulatory entity that does an independent analysis of the data.

I'm pleased to say as of today we're meeting a hundred percent of our user fee agreement requirements. Remember industry comes in and the user fees negotiates with us and the primary thing that they measure is whether we're meeting our timeframes that are required and even in the midst of this recovering from the pandemic we're now meeting all of our requirements for timeliness.

We just discussed earlier in the area of biologics with gene editing. That's an area that we're emphasizing where we've got to do some work.

Senator TESTER. Thank you, Dr. Califf. Keep up the good work.

Senator HEINRICH. Thank you, Senator Tester.

Senator Manchin, did you want to share yourself on with the Doctor?

Senator MANCHIN. As soon as we get that tower up, you'll be in good shape.

You and I talked briefly and I want to go over some of the things we talked about. The FDA is holding an advisory committee meeting on opiates today in particular on the questionable clinical trial practice known as enriched enrollment. The agenda today has a majority of the speakers who attended the very questionable IMPACT Meetings that we spoke about and I previously expressed

concerns and I think most of you all know about the IMPACT meetings. That was the questionable pay to play where they would pay to present themselves before the FDA advisory committees.

The speakers today have not been disclosed, have not even, I don't think, disclosed their involvement with IMPACT if they had been partaking in those before. I find it imperative that this advisory committee has non-ideological presenters to avoid the appearance of industry influence on the agency's decisionmaking. As it stands, this very much appears there will be heavy influence on today's advisory committee.

Let me tell you what I'm speaking about. We got more and more opiates coming on the market. My state is ground zero. All of you all have—every state has problems and you and I talked about this. So there shouldn't be—to put a new opiate on the market, some manufacturer coming to you, there has to be something that it's replacing, something that's not doing—and this is a better, more improved.

We take nothing off. Everything stays on the market as you bring more on, and if you can explain that to me and what we can do to make sure we're passing legislation that allows you to remove when you find approving drug, if you can explain that to us, it'd be appreciated.

Dr. CALIFF. Yes. So, first, we'll get back to you on the advisory committee meeting, but the issue that you raise, we discussed this earlier before you came in, but to be clear about it, the most important thing I think you can do is give us the statutory authority in the area of opioids to require that anything new that attempts to come on the market has to demonstrate clear superiority in terms of safety to the all drug.

Now whatever else you want to attach to that, we talked a bit yesterday, it was pretty much the same conversation we had in 2016, as I recall. So it could really help us move more quickly and accomplish the common goals that we have.

Senator MANCHIN. Are your staff, are they aware of the EFFEC-TIVE Act?

Dr. CALIFF. Yes.

Senator MANCHIN. Okay. Is there some ways that you think we could improve that to give you more authority?

Dr. CALIFF. We'd like to work with you on that.

Senator MANCHIN. Okay.

Dr. CALIFF. And inviting your staff to come out to FDA and we'll come to you.

Senator MANCHIN. We'll do that. I think she's working with your staff to make an appearance there and sit down and work with you all.

Let me ask this. With today's meeting, what additional stakeholders have you invited? Did you make any adjustments so it'll be more of a—

Dr. CALIFF. We only had that conversation last night. So there wasn't time to adjust the meeting, but there was an open session. The gentleman you brought up, Dr. Kolodney, was the second public speaker and I think, you know, as you pointed out, it wasn't two—he got five minutes but I know you'd like for him to get more time.

Senator MANCHIN. Well, the person that I'm saying was basically important to the IMPACT before is the person who got all the time, you know, and he was definitely tied to the industry.

If the pharmaceutical—I mean, you talk about the fox in the henhouse, that's our problem. It's just killing our state. It just has done irreparable damage.

Let me ask you this. On the recommendation of external review of the FDA Regulations of Opiates Report that you ordered was to ensure the FDA be as transparent as possible regarding decision-making. Advisory committees present complex scientific reviews of safety and efficacy of medicines most patients and general public really don't have a background to fully understand the scientific studies discussed in these settings.

Dr. CALIFF, you recently have been pushing to reduce voting in the FDA's advisory committees, even stating in a Med page Today interview that "voting doesn't matter," but they're the ones that do have the expertise, the public does not, and how does ending voting for the advisory committee meetings improve the transparency and the public trust that you advocated for?

Dr. CALIFF. To be clear about what I said and what I believe,—

Senator MANCHIN. It wasn't taken out of content, was it, sir, because we never would do that.

Dr. CALIFF. A little bit, but generally—so what I'd say, we're pushing to have advisory committees, not less.

Senator MANCHIN. Yeah.

Dr. CALIFF. The point I was making is that people focus on the vote, but it's the FDA that has to make the decision, not the advisory committee. What the FDA employees and leaders want out of the advisory committee is deep knowledge about the thinking from multiple points of view.

What is it that is driving their thinking and because it is advisory, people tend to focus on like if it's an eight to five vote—

Senator MANCHIN. Well, here is the thing. You know, you know the one I'm talking about. It's 11 to two.

Dr. CALIFF. Yeah.

Senator MANCHIN. Please don't put this drug on the market. They overrule and you all put it on the market. You weren't there. They put it on the market anyway. We begged them not to. Then they had the—finally the company pulled it off themselves but it was just horrific. I mean, I'm saying these are the people that have knowledge thinking it was dangerous to put it on the market.

Dr. CALIFF. I hear you. What I want is much more public discussion about the issues, less focus on like a cage match of who's voting for what and rushing out the door.

Senator MANCHIN. Just a number of states have been affected beyond anybody's imagination.

Dr. CALIFF. Senator, as I told you yesterday, I helped start a not-for-profit in Dayton, Ohio, which is right there with West Virginia, as you know, in terms of death rates and other problems. I have a deep sense of what this is about and we're going to work on it as hard as we can. I'm not pretending we got everything right. So, I appreciate your concern.

Senator MANCHIN. We need help on that. I was alarmed to see that the meeting that was going on today and how it was put to-

gether and the presenters and who had the time to do that. It just didn't seem like it was very balanced.

Dr. CALIFF. I hear you.

Senator MANCHIN. Thank you, sir.

Senator HEINRICH. I want to thank Commissioner Califf for being here today.

ADDITIONAL COMMITTEE QUESTIONS

Questions for the record are due by next Wednesday, April 26th and we'd certainly appreciate responses back from FDA within 30 days.

QUESTIONS SUBMITTED BY SENATOR MARTIN HEINRICH

Question. Last December, the Reagan-Udall Foundation released its evaluation of the FDA's human foods program and highlighted serious organizational challenges within the agency.

Since that report was issued, several senior staff within FDA announced their departure from the agency. How will FDA continue to move forward and address the challenges identified within the Foundation report with such a significant change in senior leadership?

Answer. Following the release of Reagan-Udall Foundation's Operational Evaluation of FDA's Human Foods Program, Commissioner Califf announced a proposal for a unified Human Foods Program (HFP) and a new model for the Office of Regulatory Affairs (ORA). Since the announcement, the Agency has made significant progress to implement the vision, including initiating a competitive national search for a new Deputy Commissioner for Human Foods who will report directly to the Commissioner and provide leadership and expertise for FDA's entire nutrition and food safety programs. The Commissioner has identified competent and capable FDA senior leaders to fill the leadership roles in ORA, the Center for Food Safety and Applied Nutrition (CFSAN), and the Office of Food Policy and Response (OFPR) during the transition, while the Agency is also working to address the challenges identified in the Reagan-Udall report through an Agency-wide approach. FDA has created an internal Implementation and Change Management Group—comprising current and future leaders from all components of the Human Foods Program and from other Centers—to develop a detailed plan to ensure the successful execution of a unified Human Foods Program and to restructure ORA into an enterprise-wide organization supporting the priorities of the Human Foods Program and the Centers, while focusing on the core functions of inspections, import operations, sampling, laboratory analysis, and investigations.

Question. Where is the agency on hiring a Deputy Commissioner for Human Foods?

Answer. The Agency's search for a Deputy Commissioner for Human Foods commenced in late February through a vacancy announcement under our Title 21 hiring authority (granted to us by the 21st Century Cures Act). FDA is currently in the process of interviewing several qualified candidates and hopes to make a selection for this important position as soon as possible. This is a critical role and the Agency is moving as quickly as possible, although we need to follow the necessary legal processes. The Agency looks forward to keeping you apprised of our progress.

Question. Your budget requests an additional \$11.6 million to continue building capabilities for FDA's Resilient Supply Chain and Shortages Program for medical devices. With supplemental funding ending in 2025, how does the FDA plan to manage this program for the long term?

Answer. FDA appreciates the funds Congress has provided thus far—the \$10 million total provided across FY 2022 and FY 2023 were the first funds provided to FDA's base for medical device supply chain efforts, and we have been able to transition some staff and capabilities funded by the COVID-19 supplementals to start building a permanent, serviceable program. The Agency is still in a building stage, however—having essentially started building from scratch during the pandemic, FDA has had to develop infrastructure where it did not exist, recruit expertise it did not have, and start building capabilities and a program where none had existed.

What FDA has today remains a largely reactive program. It is making a huge difference for the domestic supply chain, but major vulnerabilities continue to put the nation's supply chain and the

U.S. healthcare system as a whole, at risk. Medical device shortages most often impact vulnerable and underserved populations, such as children, rural communities, and veterans. The Agency is also aware that China accounts for approximately 45% of finished medical devices imported into the U.S., and that the U.S. remains heavily dependent on China for raw materials and components that are used to make medical devices. Patient safety and national security depend on having preventative capabilities. FDA seeks to get out of “response mode” by focusing on what is needed for a serviceable, sustainable program where the Agency can intervene and help prevent shortages from happening in the first place.

The request for an additional \$11.6 million is the difference between a such a reactive program and transitioning to a proactive program that is preventive—so regardless of the situation, whether it is a massive pandemic or a spot shortage in one part of the country, FDA is not left scrambling and playing catch up. Without these additional funds in FY 2024, FDA will need to start scaling back the existing program capabilities as COVID supplemental funding runs out.

Question. How does FDA view shortages in medical devices from a national security perspective?

Answer. Medical product supply chains are critical to U.S. national security, and preventing shortages and interruptions depend, in part, on FDA having the resources and the authorities to establish a proactive supply chain program to prevent these problems from happening before they occur, particularly in the face of global threats and cybersecurity attacks. Simply stated, health security is national security.

The nation’s continued dependence on China for critical devices and the raw materials and components used to manufacture them is one of the largest threats to health security and infrastructure. This was evident during the early phases of the pandemic, China held products hostage and did not allow the U.S. to get them out of that country. There also continue to be cybersecurity threats that could force manufacturers to go offline.

In order to build a strong healthcare structure that is resilient to these national security challenges, FDA needs the resources to have visibility into the supply chain and get information as early as possible. The Agency also needs critical authorities, including the removal of the temporal limitation of “during, or in advance of” a public health emergency for notifications of manufacturing disruptions to the FDA. Additionally, FDA needs the authority to require manufacturers to maintain and share Risk Management Plans.

Having a proactive system and information to help better understand vulnerabilities and risks, and to work with manufacturers to prevent potential supply chain shortages before harm comes to patients and healthcare providers strengthens national security.

Question. The infant formula crisis the country experienced highlighted the importance of moving away from a few large manufacturers to allowing smaller facilities more capacity. How is FDA working with smaller infant formula companies to expand their capacity?

Answer. Recognizing the importance of a resilient and diversified supply chain, FDA has taken numerous steps to help all producers, regardless of size, have the ability to access and support the U.S. market for infant formula. In May 2022, to help address the infant formula shortage, FDA issued the “Guidance for Industry: Infant Formula Enforcement Discretion Policy”¹ to describe considerations for firms and formulas entering the market temporarily under FDA’s exercise of enforcement discretion. During the initial period of enforcement discretion, when supply chain concerns were at their peak, FDA developed webpages about the new formulas that were entering the market under FDA’s exercise of enforcement discretion, with information about how to safely switch to those formulas, if needed. Subsequently, in September 2022, FDA issued the “Guidance for Industry: Infant Formula Transition Plan for Exercise of Enforcement Discretion”² to outline a path for interested firms marketing products in the U.S. under the exercise of enforcement discretion to bring those products into compliance with all U.S. requirements to facilitate longer-term availability of those products in the market.

Additionally, FDA hosted multiple webinars in autumn 2022 to support infant formula firms interested in marketing their products in the U.S., including those marketing as part of the transition plan and new market entrants more generally. Topics of the webinars included: the Infant Formula Transition Plan guidance, FDA’s

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy>

² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-transition-plan-exercise-enforcement-discretion>

requirements and recommendations for new infant formula submissions, protein efficiency ratio (PER) studies, and growth monitoring studies (GMS). Following these webinars, in February 2023, FDA issued “Draft Guidance for Industry: Protein Efficiency Ratio (PER) Rat Bioassay Studies to Demonstrate that a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein,”³ with more information relating to a key component of a new infant formula submission. Most recently, FDA has announced two additional webinars to be held on Wednesday, May 24, 2023, and Wednesday, June 7, 2023, to provide stakeholders with information on regulatory requirements and considerations for infant formula ingredients and packaging.

More broadly, on March 28, 2023, FDA published the Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market.

³ERR14*³ The strategy describes immediate actions FDA took to address the shortage and details the Agency’s plans for improving the resiliency of the infant formula market, while noting multiple issues that are beyond the purview of FDA. The immediate strategy represents a first step toward issuing, with input from the National Academy of Science, Engineering and Medicine, a long-term national strategy in 2024 to improve preparedness against infant formula shortages by outlining methods to improve information-sharing, recommending measures for protecting the integrity of the infant formula supply chain, and preventing contamination. The longer-term strategy will explore new approaches to help facilitate entry of new infant formula manufacturers to increase supply and mitigate future shortages and assess whether additional regulatory authorities are needed to gain insight into the supply chain and risks for shortages.

⁴ <https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/immediate-national-strategy-increase-resiliency-us-infant-formula-market>

⁵ <https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/immediate-national-strategy-increase-resiliency-us-infant-formula-market>

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements>

¹⁴ April 19, 2023: Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Meeting Announcement and Materials

¹⁵ April 19, 2023: Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Meeting Announcement and Materials

¹⁶ <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework>

¹⁷ Development of Non-Opioid Analgesics for Acute Pain

⁷ <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/2022-meeting-announcement-science-board-fda-06142022>

⁹ <https://www.fda.gov/tobacco-products/ctp-newsroom/all-center-approach-ctps-response-reagan-udall-foundation-evaluation-report>

¹⁰ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp>

¹¹ Per section 919 of the Federal Food, Drug, and Cosmetic Act, these six classes are: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. FDA does not currently have authority to assess and collect user fees for ENDS products.

¹² Section 919 authorizes the total amount of user fees FDA must assess and collect each year. For the first 10 years of the FDA tobacco program, the total amount of user fee collections increased each year. Beginning in FY2019, the authorized amount is fixed at \$712 million.

¹³ <https://www.nationalacademies.org/our-work/clinical-utility-of-treating-patients-with-com>

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-protein-efficiency-ratio-rat-bioassay-studies-demonstrate-new-infant-formula>

*ERR14**Question*. Can you update the Committee on FDA’s efforts ensure such a crisis never happens again?

improve preparedness and explore new approaches to help facilitate entry of new manufacturers to increase supply and mitigate future potential shortages.

To specifically ensure the issues encountered at Abbott Nutrition's Sturgis, MI, facility will not be repeated, FDA negotiated a consent decree with Abbott Nutrition, which was entered by the U.S. District Court for the Western District of Michigan on May 16, 2022. This consent decree requires Abbott to take steps necessary to safely produce infant formula in close coordination with FDA and under our oversight of its manufacturing and food safety processes. More broadly, FDA is committed to conducting surveillance food safety inspections of all infant formula manufacturers at least annually and to use remote regulatory assessments, as needed. Work is also underway to significantly expand and improve infant formula training for investigators and other appropriate staff to ensure every infant formula inspection is robust, thorough, and focused on the most critical aspects of the infant formula manufacturing process.

FDA is also working to monitor the infant formula supply and supply chain to assess general market health and current and future demand, and identify potential signs of production and supply chain challenges by analyzing industry production data, in-stock rates, sales data, and information on key supply chain characteristics. Much of the work on infant formula will be coordinated through the creation of a new Office of Critical Foods responsible for oversight, coordination, and other activities related to critical foods, which is defined to include infant formula and medical foods. FDA will continue to build on these efforts throughout FY 2023 as a result of \$7.5 million in additional funding provided by Congress for infant formula-related activities. This is enabling the Agency to hire 16 new full-time equivalents (FTE) in the Center for Food Safety and Applied Nutrition. FDA's FY 2024 request contains an additional \$21 million to further expand its work in this area.

However, the infant formula industry needs to take its responsibility to produce safe food more seriously. FDA has reviewed conditions during recent inspections of powdered infant formula manufacturers and has identified numerous areas for improvement across the infant formula industry. The Agency outlined these areas for improvement in a March 8, 2023, letter, which was a call to action for all members of the infant formula industry to help protect our most vulnerable population by, among other things, evaluating established systems of production and in-process controls and ensuring that appropriate controls are implemented at any point, step, or stage in the production process where control is necessary to prevent adulteration of infant formula. In addition, the infant formula industry is now required to establish and implement risk redundancy plans to minimize the impact of any future disruptions in production. Industry must ensure they are producing formula consistent with high U.S. food safety standards and maintaining their facilities so recalls and shutdowns are minimized.

Question. The recent White House National Strategy on Hunger, Nutrition, and Health highlighted the need to empower consumers to make healthier food choices. The budget is requesting an additional \$12 million to strengthen the FDA's work on nutrition and labeling. Can you detail how this additional funding will be used?

Answer. The additional requested funding of \$12 million, which includes 19 FTE, will be used to enhance and strengthen the nutrition and labeling work performed by FDA. This includes the development of a standardized, science-based, front-of-package labeling scheme that would help consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that can help them build a healthy dietary pattern. Front-of-package labeling would complement the Nutrition Facts label by displaying simplified, at-a-glance nutrition information and giving consumers additional context to help them quickly make more informed food selections.

FDA will also continue to examine the use of the nutrient content claim, "healthy," in food labeling to ensure that it aligns with current nutrition science and the Dietary Guidelines for Americans. FDA will continue its rulemaking effort to update the nutrition criteria for when the "healthy" nutrient content claim can be put on a product, which will help to provide consumers with information to make more informed dietary choices. FDA will also continue its work to develop a symbol companies can use on food packages to depict the nutrient content claim, "healthy." In addition, FDA will work to finalize a guidance on using Dietary Guidance Statements on food labeling in order to help consumers understand how a particular food can contribute to a healthy eating pattern. Additional funding will also go towards advances in e-commerce, such as gathering additional public input to inform a possible guidance for the food industry on nutrition, ingredient, and allergen information that should be available for groceries sold online.

FDA will also assess progress in reducing sodium in processed packaged and prepared foods and begin the process to develop revised, voluntary sodium reduction

targets as part of the Agency's broad and continued approach to facilitating the reduction of sodium intake, as outlined in the White House National Strategy. In October 2021, the Agency issued voluntary, short-term (2.5 year) sodium reduction targets. The request will support FDA in finalizing a regulation that will provide companies with additional flexibility in the use of safe and suitable salt substitutes in standardized foods, for which salt is an optional or required ingredient, giving industry additional tools to produce foods lower in sodium content.

Question. The Drug Supply Chain Security Act (DSCSA) of 2013 established a uniform, interoperable framework for tracing pharmaceutical products throughout the supply chain. On the DSCSA's final implementation deadline of November 27, 2023, supply chain trading partners will be required to provide and receive serialized transaction data along with serialized product upon a change of ownership. The supply chain is at a critical point and it appears that industry may not be fully ready which could lead to supply chain challenges.

The pandemic brought to light many issues in the drug supply chain. To this day we still struggle with shortages of drugs including Adderall and Albuterol, among others. If the DSCSA is not properly implemented, it could cause more shortages. Is the FDA concerned about drug shortages if product is not able to move through the supply chain?

Answer. The DSCSA program is critical to improve the detection and removal of potentially dangerous drugs from the supply chain and help protect patients from receiving a drug that may be counterfeit, stolen, contaminated, or otherwise harmful. The Agency has heard from trading partners and other stakeholders about implementation challenges, particularly related to data and data exchange issues, and concerns that not everyone in the supply chain will have their systems and processes in place to meet the November 2023 requirements. FDA considers all stakeholder concerns and examines all available regulatory options to minimize the chance of supply chain disruptions.

Question. If manufacturers aren't ready, how will that affect pharmacies and patients?

Answer. FDA has heard that while there has been industry progress towards enhanced drug distribution security requirements, stakeholders are concerned about the current status of readiness of trading partners in the supply chain and implementation challenges. Stakeholders indicated that some of these challenges may lead to supply chain issues, potentially affecting the distribution and availability of certain prescription drugs. The Agency is actively continuing stakeholder outreach and engagement on these issues. In addition, FDA will be conducting a small dispenser assessment that will examine necessary software and hardware accessibility, and the cost to obtain, install, maintain, and integrate them into business practices. The assessment will help FDA identify and consider compliance challenges faced by small dispensers (i.e. small pharmacies).

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

Question. How is the agency considering the widespread concern from consumers, farmers and producers over FDA not enforcing dairy standards of identity?

Answer. FDA establishes food standards of identity to promote honesty and fair dealing in the interest of consumers, and this remains an Agency priority. The Agency recognizes that there has been significant development and commercial activity in the area of plant-based alternatives to traditional food products, including plant-based beverages labeled with names that include the terms of dairy standards of identity, such as "milk." In February 2023, FDA issued a draft guidance⁶ entitled "Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements." This draft guidance explains that, while plant-based milk alternatives are not permitted to be offered for sale as "milk," the use of the term "milk" as part of the name of plant-based milk alternatives does not mean that such products are represented as "milk" as defined in FDA regulations. The draft guidance also provides recommendations for labeling plant-based beverages with additional nutrition information to help consumers compare these products to milk and make informed dietary choices. Empowering consumers with nutrition information they can use to identify healthier choices more easily is a priority under FDA's Nutrition Initiatives.

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements>

FDA is interested in hearing from stakeholders and encourages all interested persons to submit comments to the draft guidance docket by July 31, 2023.

Question. How will these concerns be implemented into the final Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements?

Answer. On May 1, 2023, FDA reopened the public comment period for 90 more days to allow additional time for interested persons to develop and submit comments to the draft guidance. The deadline for comments is July 31, 2023. The Agency welcomes comments on any aspect of the draft guidance. This topic is of great interest to a variety of stakeholders with differing perspectives and FDA anticipates receiving useful information from comments. All comments, data, and research timely submitted to the docket will be reviewed and considered before beginning work on a final guidance.

Question. How does the FDA plan to evaluate animal feed additives with environmental claims, such as those intended to target enteric methane emissions, in a safe and timely manner?

Answer. FDA understands Congress's and stakeholders' interest in a robust and timely pathway for environmentally beneficial products to enter the market for use in animal food.

The Federal Food, Drug, and Cosmetic Act sets the regulatory paradigm to which products used in animal food are subject. Articles (other than food) intended to affect the structure or function of the body of an animal are drugs under the Act. Some products with environmental claims, such as those non-nutritive substances that affect an animal's function to reduce methane emissions, meet the definition of a drug.

FDA remains engaged with Congress and stakeholders to consider potential solutions. The Agency is also considering alternative approaches for the regulation of these products in the absence of legislation. In the interim, FDA is working with sponsors to identify alternative pathways to market, where appropriate, on a case-by-case basis.

Question. The FDA is now 19 months past a court ordered deadline to finish its review of e-cigarette applications, and 8 months past a deadline set by Congress to review applications of synthetic nicotine products. Unauthorized vaping products remain on the market. Why have these products been allowed to stay on the market, and what is the current backlog of applications?

Answer. FDA continues to make significant progress on reviewing applications despite their sheer volume and the rapidly evolving tobacco product landscape. To date, FDA has received premarket tobacco product applications for 26 million products, the vast majority of which are for e-cigarettes, and has successfully completed its review of 99 percent of them. This includes one million applications for non-tobacco nicotine products, including synthetic nicotine—for which FDA has successfully completed review of 99.5% of applications. FDA has been working diligently to ensure we are processing applications as quickly as possible while also ensuring the decisions are scientifically accurate, legally defensible, and aligned with the authorities granted by Congress.

FDA has been clear that all new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement by FDA. We will continue to closely monitor the marketplace and take compliance and enforcement actions on a case-by-case basis according to our enforcement priorities and the individual circumstances. Compliance and enforcement actions include: warning letters, civil money penalties, seizures, and injunctions, among others. Importantly, FDA does not have independent litigation authority. Therefore, we work with the U.S. Department of Justice (DOJ) to inform our enforcement actions. The DOJ must evaluate the legal risks of pursuing particular actions and decide whether to litigate cases on our behalf.

Question. On April 26, 2022, the Director of the Center of Drug Evaluation and Research testified under oath at a Senate HELP Committee hearing that "The Center for Drugs currently does not have a contract with McKinsey and across FDA. [W]e anticipate that further contracts will not be issued pending the outcome of the investigations." This followed a 2022 congressional investigation that found that at least 22 McKinsey consultants worked for both FDA and opioid manufacturers on related topics, including at the same time. Can you confirm that over the last year, McKinsey has not been hired by the FDA and will not be hired in the future?

Answer. FDA does not have any active contracts with McKinsey. Due to rules governing competition, it would be inappropriate to comment on future plans absent an explicit prohibition or debarment of McKinsey. The Federal Acquisition Regulation (FAR), particularly Part 6, prescribes policies and procedures to promote full and open competition in the acquisition process.

QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN

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

The External Report of FDA Regulations of Opioid Analgesics notes that “there are several limitations of EERW design that warrant additional consideration for opioid[s]”.

—Will the FDA commit to following the recommendations of the report and hold another Advisory Committee meeting focused on FDA’s use of enriched enrollment for opioid approvals?

Answer. The Agency understands your concern with enriched enrollment randomized withdrawal (EERW) trials. As you know, the Agency recently held an Advisory Committee meeting with the Drug Safety and Risk Management Advisory Committee to review EERW trial design.¹⁴

The Agency is reviewing the discussion from the Advisory Committee and if there is further need to obtain independent expert advice on scientific, technical, and policy matters related to EERW design FDA will at that time consider the need for an additional Advisory Committee meeting regarding EERW design.

Question. The Fiscal Year 2022 Consolidated Appropriations report included language directing the FDA to “conduct a study to review EERW study designs used in the approval of new prescription opioids for chronic pain.” This study is intended to specifically look at the use of EERWs use to approve new opioids. Will the FDA commit to completing this study?

Answer. As noted in Question 1, the Agency is conducting an ongoing review of the use of EERW trial design. An element of the review was the Advisory Committee held on April 19th, 2023.¹⁵

Question. I introduced the FDA Accountability for Public Safety Act to ensure Advisory Committees are properly used. Specifically, if a Committee votes against approval and you decide to go against this vote, you must submit a report to Congress that includes the medical and scientific evidence to justify its approval. How will the FDA ensure Advisory Committee discussions are clear and transparent?

Answer. FDA’s advisory committee meetings are conducted in accordance with the Federal Advisory Committee Act, which requires that timely notice of advisory committee meetings be published in the Federal Register, that the meetings generally be open to the public, and that records of all meetings be maintained and available to the public, subject to limited exceptions. To that end, and to be as transparent as possible, FDA maintains a public website for each of its advisory committees that includes agendas, presentation materials, minutes, and transcripts of all meetings of the committee. FDA’s advisory committee meetings can also be viewed live via webcast and when meetings are held on FDA’s campus or at other locations, members of the public and press are able to attend in person. Advisory committees make non-binding recommendations to the FDA, which generally follows the recommendations, but is not legally bound to do so. The available science and data guide the Agency’s decisionmaking.

Question. Between November 2021 and November 2022, the CDC reported that over 78,000 people died of an opioid related overdose. While we know opioids can be prescribed with legitimate prescriptions to treat pain, we also know that even with prescriptions, opioids can kill. These pills kill via respiratory depression, essentially, they make you go to sleep and forget to breathe. However, we do know of several non-opioid treatments to treat pain that don’t result in respiratory depression. What is the FDA doing to speed up approval of non-opioid treatments for pain?

Answer. Addressing the overdose crisis continues to be one of FDA’s top public health priorities, and the Agency agrees that there is still much work to do as deaths from drug overdoses remain at historically high levels. One of FDA’s four Overdose Prevention Priorities under our Overdose Prevention Framework¹⁶ is supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing. A key activity under this priority

¹⁴ April 19, 2023: Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Meeting Announcement and Materials

¹⁵ April 19, 2023: Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Meeting Announcement and Materials

¹⁶ <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework>

is the development of novel, non-opioid pain therapies, which the Agency believes will ultimately help prevent new cases of overdose and reduce deaths. FDA is committed to doing its part to help spur this development. To support such developments, the Agency recently published draft guidances titled “Development of Non-Opioid Analgesics for Acute Pain”¹⁷ (February 2022) and “Development of Local Anesthetic Drug Products With Prolonged Duration of Effect” (March 2023). These guidances are intended to assist sponsors in the development of alternatives to opioids for the management of pain. Additionally, FDA is developing a guidance for industry on the development of non-addictive medical products for the management of chronic pain, as stated on the 2023 CDER guidance agenda.

QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

Question. In fiscal year (FY) 2023, Congress provided \$5 million in new funding to implement an FDA-wide New Alternative Methods (NAMs) Program with the goal of advancing the development, qualification, and implementation of NAMs for product testing. It is important that the funds are used to provide regulatory clarity to sponsors and the community as to what constitutes a “regulatory-grade” NAM. Please provide an update on the implementation plan for the NAMs program.

Answer. FDA appreciates that Congress provided \$5 million in new funding in FY 2023 to implement an FDA-wide New Alternative Methods (NAMs) Program. With dedicated resources for alternative methods, FDA is beginning to implement a program to evaluate the suitability and validity of these methods to best inform the Agency’s regulatory decisionmaking process. Centrally coordinated and managed by FDA’s Office of the Chief Scientist, this core program focuses on establishing cohesive and comprehensive strategies to advance the development, qualification, and implementation of NAMs for regulatory use. The program broadens and complements longstanding work led by FDA Centers and Offices, including specific programmatic objectives such as expanding capacity to qualify alternative methods and filling information gaps with applied research to support new policy and guidance development.

The FY 2024 President’s Budget builds on the FY 2023 Budget by requesting an additional \$1.5 million in funding within the Office of the Chief Scientist to further support the NAMs Program by providing strategic coordination, implementation, and oversight, as well as to develop a qualification process to assess NAMs for regulatory use.

As follow up to a presentation for the Science Board to FDA at its June 2022 meeting,⁷ the Agency is working to establish a Science Board subcommittee that will be charged with continued discussion on the topic of NAMs and will look to consider the board’s recommendations as part of the overarching efforts for continued progress. The Agency is also assessing its current activities to identify capabilities, critical gaps, and potential actions that could be taken to continue and enhance ongoing efforts to advance development and adoption of alternative methods.

Question. It is my understanding that Canada just updated their Listeria monocytogenes (Lm) policy and continue to base their policy on whether foods support or do not support growth of the pathogen. Will FDA also incorporate a risk-based approach that is reflective of the current scientific evidence?

Answer. FDA is developing three guidance documents on the following topics:

- The Agency’s enforcement policy for Listeria monocytogenes (Lm) in foods.
- Classifying food as ready to eat (RTE) or not ready to eat (NRTE).
- Control of Listeria monocytogenes in RTE foods.

In the development of these documents, FDA is considering updated scientific information, including current thinking regarding the enforcement policy for foods based on whether foods support the growth of Lm. All three documents are a priority for FDA, and the CPG and guidance on classifying food as RTE or NRTE are on FDA’s 2023 “Foods Program Guidance Documents Under Development.”⁸ The Agency’s goal is to issue Listeria policies that are grounded in the best available science, protective of public health, and practical for industry to implement.

⁸ <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development>

Question. The Reagan-Udall Foundation evaluation on the tobacco program raised significant questions about the lack of a cohesive plan at the Center for Tobacco Products (CTP), finding, “the lack of clarity about CTP’s direction, its priorities and

¹⁷ Development of Non-Opioid Analgesics for Acute Pain

⁷ <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/2022-meeting-announcement-science-board-fda-06142022>

its near-term and longer-term goals and objectives, hinders CTP's ability to effectively carry out its mission establish efficient programs to accomplish its goals and objectives, and set appropriate metrics to assess outcomes."

For fiscal year (FY) 2024, the President's budget requests a \$100 million increase for tobacco user-fees. How would this additional funding be employed, and does the agency have a plan to address the issues raised in the Reagan-Udall Foundation's Evaluation Report?

Answer. FDA welcomed the opportunity for the independent external review by the Reagan-Udall Foundation and is committed to addressing all the recommendations outlined in its evaluation report as expeditiously as possible. In February 2023, FDA announced the Center for Tobacco Products' (CTP's) plans for addressing the recommendations.⁹ FDA also developed a new webpage¹⁰ describing CTP's activities to address the recommendations, by topic area, that will be updated routinely to reflect progress.

A key recommendation of the report was that CTP create and implement a new strategic plan that identifies the Center's strategic objectives and plots an operational roadmap of the steps CTP will take over the next 5 years to achieve those objectives. Development of the strategic plan commenced in February 2023, and will build upon prior strategic plans the Center has created and implemented since its inception. For the new strategic plan, CTP will engage with both internal and external stakeholders during development. We anticipate release of the plan no later than December 2023.

The Reagan-Udall Foundation report also specifically recommended that "additional resources should be sought, particularly to provide some parity among the tobacco sectors assessed under user fees for the Center's work." Currently, FDA is only authorized to assess user fees on tobacco products that fall within six product classes.¹¹ The authorized collection amount is fixed and is not indexed to inflation.¹² FDA believes that an additional \$100 million in user fees, indexed to inflation, represents an appropriate increase in resources to ensure comprehensive regulation of the changing tobacco product marketplace. An additional \$100 million will enable FDA to expand much-needed activities for the newly regulated products, with three-quarters of the additional resources being dedicated to compliance and enforcement and product review; the remaining resources would be allocated to scientific research, regulation and guidance development, and public education.

Question. The issue of access to compounded hormones remains a concern for millions of patients who rely on access to compounded therapies. In response to a question for the record I posed last year, the agency cited the National Academies of Sciences, Engineering, and Medicine's (NASEM) report stating, "FDA intends to consider the information in the NASEM report." The FDA did not mention any other scientific studies on this topic in its response.

Will FDA review all relevant stakeholder comments and consider additional peer-reviewed scientific studies as part of the agency's review of the NASEM report and its recommendations?

Answer. When developing Agency policies, FDA intends to consider all relevant information, including the NASEM report and stakeholder comments and submissions, while taking into account patient access concerns. Moreover, before implementing a new policy, the Agency generally provides an opportunity for public comment, whether the policy is announced through a draft guidance, Federal Register Notice, or proposed rulemaking.

As background, compounded "bioidentical hormone replacement therapy" (cBHRT) products are not FDA-approved, which means these products have not undergone an FDA assessment of safety, effectiveness, or quality prior to marketing.

To help inform the public and the FDA's policies regarding cBHRT, the Agency entered into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM) to convene an ad hoc committee to conduct a study on the clinical utility of cBHRT drug products. The committee also reviewed which populations may benefit from the use of these preparations and considered whether the available evidence supports their use to treat patients. The committee issued its re-

⁹ <https://www.fda.gov/tobacco-products/ctp-newsroom/all-center-approach-ctps-response-reagan-udall-foundation-evaluation-report>

¹⁰ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp>

¹¹ Per section 919 of the Federal Food, Drug, and Cosmetic Act, these six classes are: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. FDA does not currently have authority to assess and collect user fees for ENDS products.

¹² Section 919 authorizes the total amount of user fees FDA must assess and collect each year. For the first 10 years of the FDA tobacco program, the total amount of user fee collections increased each year. Beginning in FY2019, the authorized amount is fixed at \$712 million.

port, “The Clinical Utility of Compounded Bioidentical Hormone Therapy,” on July 1, 2020.¹³

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

The NASEM report discusses some of the uncertainties of the potential benefits and safety risks associated with the use of these compounded products. FDA believes the results of NASEM’s research provide important information that will increase public understanding regarding cBHRT products.

QUESTIONS SUBMITTED BY SENATOR SUSAN M. COLLINS

Question. Clinical Holds. I wanted to follow up on the issue of clinical holds, which I raised during the hearing. Clinical holds can be an important and appropriate tool for the Agency to utilize when a potential concern with an application has surfaced, but they are not a substitute for timely, constructive, and clear communication to sponsors. Further, when clinical holds are imposed for an ongoing development program, there should be urgency brought to resolving it.

The anecdotal evidence suggests that the review process for cell and gene therapy is becoming more protracted, and I am concerned that the lack of face-to-face meetings may be negatively affecting the FDA’s ability to keep pace and retain its scientific and regulatory stature as the gold standard.

How many clinical holds have been issued in the past year? What percentage of cell and gene therapy applications have been subject to a clinical hold? Please include whether the Agency either sought or granted live meetings to discuss and potentially resolve the Agency’s questions that led to the clinical hold.

Answer. Of the 262 cell and gene therapy Investigational New Drug applications (INDs) received in calendar year 2022, 54 (20.6%) were placed on clinical hold in the initial 30 days after receiving the application. The Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) began accepting requests for in-person, face-to-face industry meetings on February 13, 2023, for certain meeting types. As such, no in-person, face-to-face meetings were held for INDs put on clinical hold within CY 2022. However, throughout that time, FDA has continued to hold “live” meetings (e.g., via teleconference) when appropriate.

It is important to note that the likelihood an IND application will be allowed to proceed is related to the quality and completeness of each IND section (Chemistry, Manufacturing and Controls (CMC), Pharmacology and Toxicology (P/T), and Clinical), whether all the identified safety risks are adequately addressed, and whether the sponsor provides timely responses to Agency information requests. There may be additional challenges encountered by the review team during the review of an original IND, which may include:

- Grossly inadequate or missing sections of the IND for CMC, P/T or Clinical review.
- Inadequate donor eligibility information.
- Inclusion of a device (e.g., delivery device, companion diagnostic), human factors study, or combination product classification that requires a consultative review(s) from another Center. Based on our experience, oftentimes such inclusions are inadequately or poorly addressed in submissions.
- Requirement for clinical subspecialty review from another Center.
- Cross reference of a Master File or IND in another product Office within the Center or another Center, requiring a consultative review.

FDA remains committed to working with all sponsors to resolve issues and help speed development of new products, while maintaining high, scientifically based safety and efficacy standards.

Question. Written Responses. I remain interested in the Agency’s progress towards restoring face-to-face (FTF) meetings with sponsors and relying less on Written Response Only (WRO) communications. While I am pleased that FDA an-

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

nounced on January 30, 2023, that is was restoring some FTF meetings, the Agency has not expanded the FTF option for all types of meetings. The opportunity for critical discussion and meaningful scientific exchange are diminished under a WRO. FDA needs to preserve WRO as a tool for routine exchanges and clarifying responses to sponsors, but should otherwise be working to restore live options for most types of meetings and requests.

What is the current timeline for full restoration of FTF interactions across each meeting type?

Answer. The Agency understands the desire to conduct face-to-face (FTF) meetings. There are three formats for formal meetings with FDA, namely FTF (can be either in-person or virtual), Teleconference, and Written Response Only (WRO). As noted, WROs are one of these meeting formats and are an important and efficient tool under the appropriate circumstances. For each meeting request, the Agency carefully considers the specific questions posed by the drug developer, as well as the context (e.g., stage of development, product complexity, clinical indication and unmet need). When the Agency expects that our responses will be straightforward (e.g., referral to content of a specific guidance document) or will reiterate points made in previous discussions with the sponsor, then FDA has commonly provided written responses. When the questions are complex, for example with a product that raises new scientific questions, or an innovative trial design, the Agency has been more likely to offer a FTF meeting via videoconference or in-person.

While WROs have been and will continue to be an important tool, FDA has continued to hold “live” meetings (e.g., discussion via teleconference or virtual face-to-face) with sponsors and applicants over the past 3 years for any meeting type when appropriate. The announcement on January 30 provided new information about the reintroduction of in-person FTF meetings, which were precluded during the pandemic. The reintroduced in-person FTF meetings (which will include a hybrid component to allow broader participation) will continue to expand until all meeting types are included.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Over a million patients a day use medical gases under the supervision of healthcare professionals across the country. We congratulate the FDA for releasing a notice of proposed rulemaking for medical gases on May 23, 2022. However, the FY 2017 Consolidated Appropriations Act required a final rule to be issued by July 15, 2017—nearly 6 years ago. The public comment period ended on August 23, 2022 and FDA received a total of 4 public comments on the proposed rule. I was dismayed to see in the Fall 2022 Unified Agenda that FDA had put the rulemaking on the backburner, listing it as a long-term action with a projected publication date of October 2024. That means FDA is projecting it needs 29 months to respond to four public comments to finalize the medical gas rulemaking.

It is deeply frustrating that the subcommittee is being told—six years after a statutory deadline—that it will be another year before FDA issues a final rule on medical gases. The FY 2023 Joint Explanatory Statement requires the FDA to produce quarterly reports on progress until the final rule is published. We would rather have the final rule rather than make you produce more reports. Can you commit to this Committee that you will accelerate the final rule and publish it in 2023?

Answer. FDA is working in earnest to finalize and publish the medical gas final rule by the projected publication date, but we cannot guarantee publication on a given timeline because certain aspects of the rulemaking and clearance process are outside of FDA’s control. This rulemaking is large and complex because it is intended to address a wide range of topics and is anticipated to include changes to existing regulations as well as the addition of entirely new regulations. Developing this rule has also required coordination across numerous Agency components, given the range of subjects involved, including labeling, current good manufacturing practice, certification, and safety reporting. In making changes based on the comments we received to the proposed rule, we must also ensure that any revisions do not create issues for other regulatory areas. We would be happy to provide updates, as appropriate.

QUESTIONS SUBMITTED BY SENATOR DEB FISCHER

Question. Feed additives can include enzymes, vitamins, and minerals that help livestock to increase feed efficiencies and reduce environmental impact. However,

slow approvals prevent advancements in these additives and their benefits. Can you discuss how additional resources in the past few years have helped the Center for Veterinary Medicine speed up the review process?

Answer. FDA received an additional \$5 million in FY 2020 and an additional \$1 million in FY 2022 for animal food ingredient reviews, which allowed the Center for Veterinary Medicine (CVM) to successfully hire more staff and improve timeliness for pre-market review of multifaceted and innovative new animal food ingredients. The animal food ingredient industry is rapidly evolving and submissions of innovative new animal food ingredients have become more complex and contain more scientific data for CVM to analyze. Since receiving these increased resources, FDA has increased its on-time rate from 44% of reviews to 73% of reviews this past year, all while moving over twice as many reviews through the system. Additionally, CVM's Office of Surveillance and Compliance underwent a reorganization in 2022 to more fully align its resources and work, which included establishing the Division of Animal Food Ingredients (DAFI). All 36 FTEs in DAFI are focused on work related to the pre-market review of new animal food ingredients, which includes reviewing new submissions, developing policy, evaluating science, and administering functions associated with the pre-market animal food ingredient processes.

Question. I also understand the Center for Veterinary Medicine is working to update their policy manual to better address innovative new products in the feed industry. How is that going and are there other items that the Center for Veterinary Medicine is doing to improve the animal food ingredient review process?

Answer. CVM is reviewing its Policy and Procedures Manual (PPM) Guide 1240.3605, Regulating Animal Foods with Drug Claims, in part to keep pace with innovative uses of substances in food for animals. In October 2022, the Center held a public listening session to gain stakeholder input on potential changes resulting from this review. Substances that benefit animal production, the environment, human food safety, or the animal's microbiome, and positively impact animal agriculture are a part of the discussions as to the best way to regulate them to ensure safety, effectiveness, and provide innovative products to animal producers.

At this point in FDA's evaluation, the Agency believes it will issue an updated Guidance for Industry. However, it should be noted that evaluating claims about the effects of food ingredients will increase the workload for the ingredient review staff and new claims will also present the need for new expertise for their evaluation. To prepare for the anticipated additional workload, CVM continues to update and streamline operating processes and procedures. CVM is also engaging and training the animal food industry on effective ways to submit data to expedite the review process.

Question. In the FY24 Budget Request, you noted that FDA will develop a standardized system to help consumers quickly and easily identify foods that are part of a healthy eating pattern. FDA will also make sure "healthy" labeling aligns with current nutrition science and the Dietary Guidelines for Americans with a proposal to update the nutrition standards for when "healthy" claims can be put on products, and will also develop a symbol to be used to depict and easily communicate a food as "healthy." Can you discuss what coordination has been done with USDA in regards to the healthy label? Specifically, how would meat products under USDA labeling jurisdiction be treated by FDA's proposed rule?

Answer. The proposed rule developed by FDA was shared with USDA, which reviewed it and engaged with FDA throughout the clearance process. FDA carefully considered USDA's input before publishing the proposed rule. The proposed rule only applies to foods subject to FDA's labeling regulations. This includes the meat products that are regulated by FDA, specifically game meat and seafood. Meat and poultry products under USDA jurisdiction are subject to the regulations set forth by USDA. However, the definitions for nutrient content claims for FDA and USDA are typically identical or very similar due to our inter-departmental collaborative efforts.

Question. What assurances has the agency provided to food manufacturers to avoid potential lawsuits for being out of compliance with the updated "healthy" definition during the proposed compliance period after a new definition is updated?

Answer. Even after any new requirements for the definition of the nutrient content claim "healthy" are in effect, manufacturers may begin to comply with the new requirements or they may continue to use the old definition of "healthy" until the compliance date arrives. FDA notes that manufacturers would not be required to comply with requirements of the final rule until the compliance date. The Agency has proposed an effective date 60 days after the date of publication of the final rule in the Federal Register, with a proposed compliance date 3 years after the effective date. This timeframe would provide industry time to revise labeling to come into compliance with the new requirements.

SUBCOMMITTEE RECESS

Senator HEINRICH. With that, this hearing is adjourned.

Dr. CALIFF. Thank you.

Senator HEINRICH. [Whereupon, at 3:14 p.m., Wednesday, April 19, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

**AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2024**

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

NONDEPARTMENTAL WITNESSES

[The following testimonies were received by the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for inclusion in the record. The submitted materials relate to the fiscal year 2024 budget request for programs within the subcommittee's jurisdiction.]

PREPARED STATEMENT OF THE ALLIANCE FOR A STRONGER FDA

The Alliance for a Stronger FDA thanks the subcommittee for its continuing support of the Food and Drug Administration (FDA). The resources you have provided FDA serve the American people, assure a safe food supply and help deliver safe and effective medical products.

We support the Administration's request for \$3.914 billion in BA funding for FDA in fiscal Year 24. As you evaluate the merits of this request, we ask that you keep these three thoughts in mind:

FDA has a uniquely difficult mission while providing a core function of government:

—Few (if any) Federal agencies have a broader range of responsibilities than the FDA.

—No Federal agency's mission and responsibilities are more affected by changes in science, technology, innovation, commerce, and social trends than the FDA.

FDA needs more resources each year because of its expanding mission and growing responsibilities:

—Increased complexity and progress in science, technology, and innovation;

—Continued growth of FDA-regulated industries, including globalization;

—FDA's responsibilities regularly increase, including with unfunded mandates; and

—Likelihood of unexpected public health and scientific needs/challenges every year

FDA's mission and responsibilities are incredibly consequential and visible:

—Every day, thousands of tasks are completed successfully and uneventfully by the FDA.

—FDA's dedicated employees (largely unseen) devote millions of hours each year to successfully maintaining FDA's high standards for safe food and safe and effective medical products.

—Problems should be addressed; often that requires additional resources and authorities.

BACKGROUND

The Alliance for a Stronger FDA includes 150 stakeholder organizations that advocate for FDA resources commensurate with its growing responsibilities. Our members are consumer and patient groups, research advocates, health professional societies, trade groups, companies, and individuals.

We believe that the primary beneficiary of FDA's activities is the American public. Accordingly, it is critical that the public remains the largest source of FDA funding.

Our request for fiscal Year 24 funding focuses exclusively on appropriations that come from monies paid by taxpayers (BA) and intentionally does not include user fees and mandated funding (e.g., *Cures* monies transferred from the National Institutes of Health). However, we urge Congress to fully fund those programs, as well.

FDA's jurisdiction includes responsibility for more than 80 percent of the food supply and all drugs, medical devices, biologics, vaccines, veterinary food/medicine, dietary supplements, and cosmetics. Altogether, the agency oversees products that represent 20 percent of all consumer spending (\$2.8 trillion) and touch the American public multiple times each day.

Because the FDA's mission continues to grow and its vital activities have become more sophisticated and complex, the Alliance supports the Administration's budget authority (BA) request of \$3.914 billion for FY24. This provides for an increase of \$366 million in BA salary and expenses (S&E) and an increase of \$6 million in BA buildings and facilities (B&F).

The Alliance encourages FDA to increase transparency and accountability in its use of funding.

FDA NEEDS FUNDING TO MEET 21ST CENTURY CHALLENGES

We support strengthening the scientific capabilities of FDA throughout the five Centers, ORA, NCTR, and the Office of the Commissioner. This includes personnel capable of conducting FDA's ongoing responsibilities while looking for innovative ways to meet future demands. To support science-based decision-making and keep up with innovation in both food and medical products, the FDA needs more scientific and technical staff, and better analytical tools.

The growing complexity of science, interwoven with new advances in technology, is a challenge across the agency. In food safety, this means the use of artificial intelligence, whole genome sequencing, and enhanced electronic recordkeeping that will contribute to a safer food supply. In medical products, this means new tools to evaluate medical products that incorporate cell and gene therapy, digital health, artificial intelligence, and real-world evidence. Addressing cybersecurity concerns is a priority.

AREAS OF NEED AND OPPORTUNITY

The Administration's request, which the Alliance supports, has four components, to which we have added the Alliance's comments.

ENHANCING FOOD SAFETY, NUTRITION AND COSMETICS

—\$128.2 million in investments in food safety and nutrition modernization, including food labeling and animal food safety oversight. While the agency is in the process of defining its future vision for the Human Foods Program, there is significant need for additional resources to strengthen its foundational food safety and nutrition capacity.

Alliance comment: The fiscal Year 24 FDA budget request places a strong emphasis on strengthening food and nutrition programs. The request is based on needs-based assessments made last summer and represents steps that can and should be supported in fiscal Year 24.

Priorities should include: more robust and rapid implementation of the Food Safety Modernization Act (FSMA); a strong start on initiatives in the agency's New Era of Smarter Food Safety; finalization of guidances; a focus on produce safety, import safety, and training/education; enhanced funding of systems for surveillance of foodborne illnesses and outbreak response; and strengthening the scientific capabilities of CFSAN/CVM/NCTR.

FDA's BA appropriation should include increased support and predictability for the agency's extremely valuable cooperative relationships with State and local regulatory programs (including public health laboratories).

—\$5 million toward modernizing oversight of cosmetics. The budget includes new funding for the development of regulations, compliance policies, product registration and listing platforms, adverse event reporting and other activities.

Alliance comment: This past December, Congress passed The Modernization of Cosmetics Regulation Act of 2022, a major overhaul of the regulation of cosmetics, amending a law that was passed in 1938. There is no money in the fiscal Year 23 (current year) appropriation to pay for implementation. The President's request for \$5 million in fiscal Year 24 is a good start. Congress should recognize that more money will be needed.

ADVANCING ACCESS TO SAFE AND EFFECTIVE MEDICAL PRODUCTS

- \$23 million in additional funds to advance the goal of ending the opioid crisis. Funding will support broader development of treatments for substance use disorders and enhance regulatory oversight, expand compliance, enforcement, and laboratory support.
- \$11.6 million increase toward improving the medical device supply chain and shortage programs. The agency will continue to build its capabilities to ensure patients have access to medical devices at all times.
- \$2.5 million to implement ACT for ALS to foster development of treatments for ALS and other rare neurodegenerative diseases. To help the FDA implement the ACT for ALS Act.

Alliance comment: These proposed investments are responses to important problems, and we support the Administration's request for each. The medical device supply chain is especially pressing. The request for ACT for ALS responds to newly enacted legislation and reflects the particular difficulties in evaluating treatments for neurodegenerative diseases.

We expect that FDA will be continuing a number of similar medical products initiatives funded in prior fiscal years, including programs targeted at advanced manufacturing, outsourcing, real-world evidence, compounding, generics, and rare diseases.

REIGNITING CANCER MOONSHOT

- \$50 million to advance the President's Cancer Moonshot goals. This funding will advance the President's Cancer Moonshot.

Alliance comment: Our nation's investment in prevention, diagnosis, treatment, and cure of cancer has produced remarkable advances. FDA plays an essential role as the intermediary between research and clinical practice. With more funding, FDA will be able to do more to improve the outlook for cancer patients and their families.

STRENGTHENING PUBLIC HEALTH AND MISSION SUPPORT CAPACITY (AGENCY-WIDE IMPACT)

- \$10 million in further investments in enterprise data and IT modernization. The budget will expand data exchange capabilities and underlying technology platforms to better meet the challenges of the FDA's programs and mission-critical responsibilities.
- \$16 million for regulatory and mission support functions within the Office of the Commissioner. These resources will enable the FDA to provide the appropriate crosscutting strategic direction, policy coordination, and business services to ensure that the FDA's programs operate effectively, efficiently, and are well coordinated.
- \$9.4 million for FDA buildings, facilities, and infrastructure improvements. The budget includes additional funding to help ensure that the FDA's offices and laboratories across the country are secure, modern, reliable, and cost-effective.
- \$105.3 million for cost-of-living salary increases for fiscal Year 23 and fiscal Year 24.

Alliance comment: Science-based decision making requires infrastructure, integrated databases, and program coordination. Investments in these areas have not kept pace with the agency's needs. We earlier commented on the challenges of recruiting and maintaining a scientific workforce. Paying for the salary increases outright, rather than subtracting them from existing programs, is an important budgeting advance.

CONCLUSION

We urge Congress to recognize the multiple opportunities for FDA to be a more effective protector of public health, as well as a fair and efficient regulator. Addi-

tional investment in FDA will result in substantial added value to the American public.

The Alliance again thanks the subcommittee for its support of the agency and looks forward to working with Members of Congress and staff on fiscal Year 24 appropriations for FDA.

[This statement was submitted by Steven A. Grossmann, Executive Director, Alliance for a Stronger FDA.]

PREPARED STATEMENT OF AMERICAN BRAIN COALITION

Chair Heinrich and Ranking Member Hoeven, on behalf of the (ABC) thank you for the opportunity to submit testimony in support of our request for \$3 million in Fiscal Year 2024 funding for the Neurology Drug Program at the Food and Drug Administration (FDA).

My name is Dr. Matthew Rizzo, I am a physician, a researcher, a neurologist, and a professor. I am also a husband, son, father, and friend. I sincerely appreciate the opportunity to submit this testimony on an issue of great professional interest and great personal importance to me and so many other Americans.

I currently serve as the Frances & Edgar Reynolds Chair & Professor of the Department of Neurological Sciences, Director of Neurosciences Services, and Co-Director of the Center for Integrative and Translational Neuroscience at the University of Nebraska Medical Center, as well as Director of the National Institutes of Health/ National Institute of General Medical Sciences Great Plains IDEa-Clinical and Translational Research network. I received my medical training at Johns Hopkins University School of Medicine and completed my residency in Neurology and fellowship in Behavioral Neurology and Cognitive Neuroscience at the University of Iowa. Prior to joining the University of Nebraska Medical Center, I served as a Professor of Neurology at the University of Iowa College of Medicine; Vice Chair of Transitional and Clinical Research, Department of Neurology at the University of Iowa College of Medicine, and as the Director of the Aging Brain and Mind Initiative at the University of Iowa. They do research and provide care for patients with memory disorders, particularly focusing on addressing behavioral consequences of aging and neurological disorders.

I am also honored to serve as the Chair of the American Brain Coalition (ABC). The ABC is a nonprofit organization comprised of nearly 150 of the Nation's leading professional neurological, psychological, and psychiatric associations and patient organizations. Together, the ABC seeks to advance the understanding of the brain and reduce the burden of brain disorders for the millions of Americans who suffer from diseases affecting the brain and central nervous system (CNS).

We are grateful that Congress first funded the Neurology Drug Program in fiscal Year 2023. This initial funding will allow FDA to gain the expertise to develop policies and guidance that keep pace with emerging brain science. We look forward to the resulting advances from the Neurology Drug Program that encompass all areas of brain health including neurodevelopmental, neurodegenerative, psychiatric, brain injuries and more.

Brain diseases, including neurological, psychiatric, and CNS disorders, impose staggering personal and financial costs on Americans. Nearly one in five U.S. adults live with a mental illness. Neuropsychiatric disorders are also the leading cause of disability in the Nation, making up 18.7 percent of years lost to disability and premature death.¹ Neurological conditions are troublingly prevalent as well—twenty million Americans suffer from a neurological condition, with 16 percent of households including an individual with a brain impairment.² Brain and CNS diseases also harm older Americans, with more than one in nine people over age 65 having Alzheimer's dementia.³

The enormous personal costs of brain and CNS conditions also translate to financial hardship for patients and their families and burden the U.S. economy. Brain disorders and diseases cost the U.S. more than \$1.5 trillion per year,⁴ a significant

¹ Office of Disease Prevention and Health Promotion, Mental Health and Mental Disorders, at: <https://www.healthypeople.gov/2020/topics-objectives/topic/mental-health-and-mental-disorders>.

² S. Pal, Incidence and Prevalence of Major Neurologic Disorders. US Pharm, at: <https://www.uspharmacist.com/article/incidence-and-prevalence-of-major-neurologic-disorders>

³ Alzheimer's Association, Facts and Figures, at: <https://www.alz.org/alzheimers-dementia/facts-figures>.

⁴ Information Technology & Innovation Foundation, A Trillion-Dollar Opportunity: How Brain Research Can Drive Health and Prosperity, at: <http://www2.itif.org/2016-trillion-dollar-opportunity.pdf?—ga=2.209915987.77733799.1607703298-1777725734.1607703298>.

portion of which is borne by the Medicare program. Seven of the twenty-one chronic conditions tracked by the Centers for Medicare & Medicaid Services are related to the brain, representing an average annual cost of \$23,325 per Medicare beneficiary—higher than the average cost for all other chronic conditions.⁵

The high prevalence of these diseases means that nearly every family in the U.S. has either personally experienced a brain disease or watched a loved one struggle with the effects of diseases like substance use disorder, schizophrenia, multiple sclerosis, Alzheimer’s disease, and hundreds of other diseases that impact the brain.

Despite the prevalence and impact of these diseases, few effective treatments are available for many brain diseases and disorders. While product development is difficult for any condition, treatment development for brain disease is uniquely challenging. In particular:

- Clinical trials for brain and CNS conditions fail more often and are frequently more costly than clinical trials for other conditions.⁶
- Brain-targeting drugs, devices, and other therapeutics reviewed by the FDA are approved at a much lower rate than those for other disease areas, with one recent study finding that the mean approval phase time for CNS compared to non-CNS was an astonishing 57 percent longer.⁷
- A recent report indicated that the probability of a drug successfully making its way through a Phase 1 clinical trial to the point of approval is only 15 percent for brain and CNS treatments -compared to 32 percent for ophthalmology, 25 percent for cardiovascular problems, and 25 percent for infectious disease.⁸

These delays compound the fact that not enough treatments exist—every extra expense and every delay means more time that our families, friends, and neighbors suffer from the frequently debilitating effects of these diseases.

The lack of safe and effective treatments for brain disease is particularly frustrating given the incredible neuroscience discoveries made in the past decade. In addition to private investment, robust public investment in the National Institutes of Health (NIH) and the BRAIN Initiative, we are building the knowledge base that will allow us to finally deliver treatments to patients that need them.

Ambitious engineers hope to extract human consciousness and put it in artificial processors able to hold the experience and unique processing capacity that form our individuality. The sheer number of brain cells (about 200 billion, half of them neurons) and connections (up to 10,000 per neuron), and ignorance of relevant systems science and minimal requirements to generate any kind of consciousness, put this dream out of reach so far.⁹ Others hope to understand the restorative capacity of the brain and the potential to regenerate, replace and integrate elements as they die, or to delay the demise of neurons so that they last as long as our bodies last. These approaches include attempts to delay mental decline before it becomes clinically significant through increased mental and physical activity and caloric restriction.

For example, ongoing work aims to discern and delay different phases of Alzheimer’s disease (AD), associated with declines in vasculature, lipid metabolism, and neurotransmitters. Phases of decline preceding cell death in AD and related disorders are biochemical, cellular, and clinical, and may antedate diagnosis by decades. The biochemical phase begins decades before the cellular phase, which in turn begins years before clinical diagnosis. AD builds up slowly, long before it becomes clinically apparent and does not simply “happen” all at once, later in life. Understanding these early phases of a disease that devastates so many older Americans is critical. Early diagnosis could allow early intervention to halt disease progression in its tracks, before it is too late to matter.

To respond to the unique challenges in the discovery and development of treatments for brain disease, and allow more neuroscience discoveries to directly benefit patients, it is vital that the Federal Government prepare the brain-specific regu-

⁵Center for Medicare & Medicaid Services Chronic Conditions Utilization/Spending State Level: All Beneficiaries 2017. The average per capita spending for a chronic condition is \$22,099.

⁶J.A. Dimasi, CNS drugs take 20 percent longer to develop and to approve vs. non-CNS drugs. Tufts Center for the Study of Drug Development.

⁷See Bio, Clinical Development Success Rates and Contributing Factors 2011–2020, at: <https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011–2020>; J.A. Dimasi, CNS drugs take 20 percent longer to develop and to approve vs. non-CNS drugs. Tufts Center for the Study of Drug Development.

⁸C. Heem Wong, et al. Estimation of clinical trial success rates and related parameters. *Biostatistics*, kxx069.

⁹<https://www.nimh.nih.gov/news/science-news/2021/nih-brain-initiative-unveils-detailed-atlas-of-the-mammalian-primary-motor-cortex>

latory tools and guidelines needed for fast, well-structured, transparent, and predictable product review. To support this aim, ABC and the brain community are advocating for Congress to increase funding for the Neurology Drug Program at the FDA. This program would allow FDA to develop policies and guidance that keep pace with emerging brain science. By appropriating the necessary resources dedicated to meet the challenges I have outlined, FDA will be positioned to issue guidance and eventually bring safe and effective brain-targeting treatments to market.

A problem like brain disease requires a focused, urgent response that takes seriously the incredible burden borne by patients who often face poor prognoses and have access to too few treatments. Every day that a safe and effective treatment for a brain disease or disorder is delayed unnecessarily is another day that millions of patients suffer from potentially debilitating diseases. ABC urges the subcommittee to provide \$3 million in fiscal Year 2024 to for the Neurology Drug Program to provide better guidance to researchers and product developers for detection and treatment of neurological disorders.

Thank you for the opportunity to provide this testimony. The ABC looks forward to continuing this dialogue and identifying creative solutions to bring more treatments and cures to patients with neurological and psychiatric disease.

[This statement was submitted by Matthew Rizzo, MD, FAAN, Chair, American Brain Coalition.]

PREPARED STATEMENT OF AMERICAN COMMODITY DISTRIBUTION ASSOCIATION

On behalf of the American Commodity Distribution Association (ACDA), I respectfully submit this statement regarding the FY 2024 budget request of the Food and Nutrition Service for inclusion in the Subcommittee's official record. ACDA members appreciate the Subcommittee's support for these vital programs.

ACDA members involved in school food programs and household programs continue to do all that they can to provide USDA Foods in a variety of settings. We have dealt with supply chain challenges, different demands across different programs, and concerns about the potential for increased needs particularly in household programs in the coming year.

We continue to thank our partners at the Agricultural Marketing Service and the Food and Nutrition Service who have responded using the authorities available to them. We also continue to maintain the specific concerns we have regarding donated food support for both schools and food banks. While efforts are being made to return to "normal", it is a transition. Food prices have not returned to "normal", and are a significant problem. We continue to ask that you fully fund administrative expense funding for TEFAP at \$100 million; provide the requested \$390,000,000 for the Commodity Supplemental Food Program (CSFP) to maintain the current caseload and to allow for requested expansion; and to increase funding for the school food equipment grant program.

ACDA is a non-profit professional trade association, dedicated since 1974 to the growth and improvement of USDA's Commodity Food Distribution Program. ACDA members include state agencies that distribute USDA-purchased foods; agricultural organizations; industry; associate members; recipient agencies, such as schools and soup kitchens; and allied organizations, such as anti-hunger groups. ACDA members this past year distributed more than 3 billion pounds of domestically produced commodities this past year to programs including the National School Lunch and Breakfast Programs, the Emergency Food Assistance Program, the Summer Food Service Program, the Commodity Supplemental Food Program, and the Child and Adult Care Food Program.

USDA FOODS FACE CHALLENGES

ACDA supports the budget request of \$468,752,000 for the purchase of TEFAP commodities and supports the Secretary's ability to procure additional foods as needed using the authority of the Commodity Credit Corporation (CCC). The \$517,000,000 in FY 2022 bonus commodities was very helpful in meeting the needs faced by food banks, and we urge the Subcommittee to monitor available food supplies to recognize that both bonuses and supplemental funding may be needed to meet needs. We are anticipating a higher demand on food banks with the loss of higher SNAP benefits.

As we have done previously, we highlight section 4205 of the Agricultural Act of 2014 which established a multiagency task force to evaluate and monitor the commodity programs to ensure that they meet the mission of the Department. There has not been such a report in the past year, so we urge the Subcommittee to direct

the prompt provision of such a report, and to include both food vendors and recipient agencies to secure their views.

We also ask the Subcommittee to solicit a study on the impact of fees on USDA Foods utilization in the National School Lunch Program. We also urge the Subcommittee call for a study on the challenges faced by rural and remote schools face including the absence of distributors, the complexity of deliveries, and their smaller scale.

NUTRITION STANDARDS GOING FORWARD

In February FNS published its proposed rule establishing school meal nutrition standards for SY 2024–2025 and beyond. The public comment period is open through April 10, and ACDA has urged the Secretary to extend the comment period given the significance of this proposed rule. ACDA will submit comments reflecting our members' views, and will continue to work on this issue.

As we said last year, ACDA supports responsible meal standards that provide quality meals to students. Any such rule should meet standards of affordability, availability, acceptability, and administrative achievability. The ability to offer a quality school meal program is directly linked to the ability to pay the costs associated with the program's operation. Any more stringent nutrition standard needs to be both realistic and phased in over time. The Department should keep in mind the challenges that manufacturers face in developing new products, the costs associated with a schedule of revising products to meet standards, and the challenges that school food authorities face in providing nutritious meals that are desired by students. It is important that the dialogue encouraged by comments on the rule proceed so that meaningful and measured action can be achieved.

FULLY FUND TEFAP ADMINISTRATIVE FUNDS AT \$100 MILLION

ACDA strongly supports the President's proposal to fully fund TEFAP Administrative Funds at \$100 million. ACDA has consistently urged full funding and appreciates the level of support provided by the Subcommittee in the past. Food banks are making every effort to control costs, but operating expenses are increasing further demonstrating the justification for full funding.

As we have told the Subcommittee in the past, food banks, Community Action Agencies, and other TEFAP operators continue to find that they have had little choice but to convert food dollars to administrative expense funds to maintain their operations. Using food dollars, particularly when programs face higher food costs, for operating expenses reduces the ability of these operators to provide food assistance to more individuals and families who continue to face difficult times.

SCHOOL FOOD EQUIPMENT GRANTS

ACDA supports increasing School Food Equipment Grants to \$35 million, an increase of \$5 million over the budget request, and opposes the proposal to decrease School Breakfast Equipment Grants by \$3,000,000. The ability to provide quality meals is directly linked to school food equipment. Many more school food authorities need this type of assistance, meriting expanding these programs and not reducing them.

ACDA continues to support emphasizing the importance of fruits and vegetables in all forms—fresh, canned, dried, and frozen—as noted in the *2020–2025 Dietary Guidelines for Americans*. However, we remain concerned about mandating not just what children are offered in school meals but what they must take, whether they intend to eat it or not. Increasing flexibility to program sponsors in planning menus that meet high nutrition standards but still are within cost targets is of critical importance and will help reduce waste resulting from this mandate.

BUY AMERICAN

ACDA appreciates the efforts of America's farmers and ranchers to provide wholesome product for various feeding programs, in addition to the important role they make in supporting American consumers. Producers continue to see product coming into the United States that disrupt domestic sales and result in the need for Bonus Buys. Buy American provisions are included in the proposed school meals standard rule. ACDA continues to stand by the recommendations we made last year. First, ACDA urges FNS to work to reduce the administrative burden of repetitive exemption forms. State agencies need better guidance to permit longer-term exemptions when supply issues are well known. Second, help clarify what products should/should not be sold to School Food Authorities (SFAs) while supporting domestic suppliers that provide our most essential needs. Third, exemptions of commodity repro-

essed products sold in the National School Lunch Program (NSLP) and School Breakfast Program (SBP) would benefit both processors and Recipient Agencies by reducing audit paperwork while supporting domestic farmers and industry stakeholders. Fourth, FNS should provide guidance and best practices to vendors/distributors, particularly national and multi-state operations, as to how to identify the point of origin on products being offered for sale. Fifth, several SFAs have limited options when it comes to vendors who are willing to supply their programs. FNS should consider some type of incentive program for vendors to provide supplies to limited-service areas which could provide additional competition that would help both with price and product availability.

ACDA thanks the Subcommittee for its support over the years and looks forward to continuing to work with you as the FY 2024 Appropriation moves ahead.

[This statement was submitted by Noelle Sanchez, President, American Commodity Distribution Association]

PREPARED STATEMENT OF AMERICAN FARM BUREAU FEDERATION

Chairman Heinrich, Ranking Member Hoeven and members of the Committee:

On behalf of the American Farm Bureau Federation (AFBF), the Nation's largest general farm organization, I commend the committee's steadfast support of agriculture, our Nation's food supply, and the well-being of rural America. The funding priorities for our organization are outlined below.

AFBF supports increasing spending levels above FY23 enacted levels for the following programs:

Agricultural Research: USDA's Agricultural Research Service, National Institute of Food and Agriculture, including the Agriculture and Food Research Initiative, Economic Research Service, and National Agricultural Statistics Service which provide research, data, and statistical analysis critical for addressing challenges faced by the agriculture community.

Crop Protection: Office of Pesticide Management Policy, which promotes the development of new pest management approaches and is critical for crop protection. USDA's Minor Crop Pest Management Program (IR-4) ensures safe and effective agrichemicals and biopesticides are available for small, specialty crop markets.

Farm Programs: AFBF urges the committee to protect programs that ensure U.S. farmers and ranchers are able to continue to produce food, fiber and fuel as they battle high input prices, labor challenges, and natural disasters. AFBF supports increased funding for risk management tools, which include Federal crop insurance and commodity programs, as well as Federal conservation programs, which preserve environmental benefits. AFBF supports prioritizing working lands conservation programs over retirement land programs. Additionally, increased funding for the Farm Service Agency (FSA) loan guarantee programs will ensure availability to farmers eligible under current authorities and the FSA Agricultural Mediation Program.

In addition, adequate funding should be provided for personnel and technology upgrades to effectively serve farmers and ranchers utilizing these programs.

Food Safety: Increase funding for food protection at the Food and Drug Administration and Food Safety and Inspection Service (FSIS) directed to increase education and training of inspectors and other relevant staff.

International Programs: The Market Access Program and the Foreign Market Development Program to increase demand for U.S. agriculture and food products in foreign markets. The McGovern-Dole International Food for Education and Child Nutrition Program, which effectively delivers both food aid and educational assistance. Public Law 480 programs, which provide foreign food aid by purchasing U.S. commodities.

AFBF supports funding the following programs at the authorized spending level:

Agriculture Advanced Research and Development Authority (AgARDA): This pilot program was authorized in the 2018 Farm Bill to leverage successful public-private partnerships to improve efficiency and accelerate research and development in pursuit of overcoming long-term and high-risk agricultural and food-related research and development challenges.

ANIMAL HEALTH

—Animal and Plant Health Inspection Service (APHIS) Antimicrobial Resistance Action Plan.

—The Veterinary Medicine Loan Repayment Program and the Veterinary Services Grant Program, which allow veterinarians to ensure animal health and welfare while protecting the Nation's food supply.

- The National Animal Health Laboratory Network, which provides an early warning system for emerging animal diseases.
 - Section 1433 Continuing Animal Health and Disease, Food Security, and Stewardship Research, Education and Extension Programs to address critical priorities in food security, zoonotic disease and stewardship.
 - The FDA’s Center for Veterinary Medicine, which oversees the safety of animal drugs, feed, and biotechnology-derived products.
 - The availability of foot-and-mouth disease vaccines to meet emergency response requirements.
- Biotechnology Promotion: APHIS’ Biotechnology Regulatory Services, if there are appropriate levels of congressional oversight, to ensure APHIS’ regulatory considerations are science- and risk-based, transparent and predictable, while promoting innovation in plant breeding and facilitating trade.
- Expanding International Markets and Safeguarding U.S. Agriculture:
- The Foreign Agricultural Service, Emerging Markets Program and Technical Assistance for Specialty Crops Program, all of which increase demand for U.S. agriculture and food products abroad.
 - APHIS Plant Protection and Quarantine personnel and facilities.
 - APHIS trade issues resolution and management activities that are essential for an effective response when other countries raise sanitary and phytosanitary measures related to American products.
 - The U.S. Codex Office, which is essential to improving the harmonization of international science-based standards for the safety of food and agriculture products.

Farm and Ranch Stress Assistance Network (FRSAN): The Farm and Ranch Stress Assistance Network provides stress assistance programs that address the increasing financial and mental stress impacting farmers and ranchers.

Food Safety and Protection Funding for the Food & Drug Administration in the following areas:

- Implementation of the Food Safety Modernization Act;
- Additional science-based inspection, targeted according to risk;
- Effective inspection of imported food and feed products;
- Research and development of scientifically based rapid-testing procedures and tools;
- Accurate and timely response to outbreaks that identify contaminated products, remove them from the market and minimize disruption to producers; and
- Indemnification for producers who suffer marketing losses due to inaccurate government- advised recalls or warnings.
- Funding for USDA food protection programs in the following areas: The National Antimicrobial Residue Monitoring System to detect trends in antibiotic resistance in foodborne bacteria.
- The Food Animal Residue Avoidance Databank, through which veterinarians establish science-based recommendations for drug withdrawal intervals.

RENEWABLE ENERGY

- Renewable Energy for America Program, which offers a combination of grants and guaranteed loans for farmers to purchase renewable energy systems.
- USDA’s energy programs that improve the Nation’s energy security and economic development including: the Biobased Markets Program, Biorefinery Assistance Program, Biomass Crop Assistance Program, Biomass Research & Development Initiative, Bioenergy Program for Advanced Biofuels, Biodiesel Fuel Education Program, and Carbon Utilization and Biogas Education Program.

STRENGTHENING RURAL COMMUNITIES

- Rural Utilities Service telecommunications programs, including the ReConnect Loan and Grant Program the Distance Learning and Telemedicine Program, and Community Connect Program which seek to bring broadband to rural communities and improve access to distance learning and telemedicine opportunities for rural residents.

- Business and Industry Loan Program, Value-Added Producer Grant Program, and the Rural Innovation Stronger Economy Program which support business creation and growth in rural communities.
 - Community Facilities Direct Loan and Grant Program and Community Facilities Loan Guarantee Program, which fund the construction or improvement of essential community facilities.
 - Agriculture in the Classroom which helps students gain greater awareness of the role agriculture plays in the economy and society.
- Wildlife Services: Wildlife Services programs that prevent and minimize wildlife damage, while protecting human health and safety from conflicts with wildlife.
- Thank you for your continued support for American agriculture. We look forward to working with the subcommittee as the appropriations process moves forward. Contact: Emily Buckman, Director, Government Affairs, emilyb@fb.org.

[This statement was submitted by Zippy Duvall, President.]

PREPARED STATEMENT OF AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) appreciates the opportunity to submit outside witness testimony for the Fiscal Year 2024 Agriculture appropriations bill in support of increased funding for the Research, Education, and Economics research area.

ASM respectfully requests that Congress provide \$4 billion for research, education, and outreach at the U.S. Department of Agriculture in Fiscal Year 2024. Specifically, we recommend

- \$700 million for the Agriculture and Food Research Initiative (AFRI),
- \$1.9 billion for the Agricultural Research Service (ARS)
- \$112 million for the National Bio and Agro-Defense Facility (NBAF),
- \$100 million for the Advanced Agriculture Research and Development Authority (AgARDA), and
- an increase of \$85 million for antimicrobial resistance priorities at USDA.
- \$2.2 billion for the Animal and Plant Health Inspection Service (APHIS)

ASM is one of the oldest and largest life science societies with 30,000 members in the U.S. and around the world. Our mission is to promote and advance the microbial sciences, including programs and initiatives funded by Federal Government departments and agencies, by virtue of the integral role microorganisms play in human health and society. Microbial science is a cross-cutting endeavor, and our members' federally funded research is fundamental to advances in human health, agriculture, energy, and the environment.

A STRONG INVESTMENT IN MICROBIAL RESEARCH PAYS DIVIDENDS

We thank Congress for its bipartisan support of agriculture research and for its commitment to foundational microbiology research at USDA. For every dollar invested in agriculture research, there is a return on investment of \$17. At one point in time, agriculture research represented 4.3 percent of the overall non-defense research allocations and appropriations for the Federal Government. Today, it is nearly half that amount, which is concerning, considering Agricultural research is the underpinning of all Titles within the Farm Bill.

ASM appreciates USDA's commitment to environmentally sound and economically viable agricultural practices. As noted in the National Academies report *Science Breakthroughs to Advance Food and Agricultural Research by 2030*, further understanding of animal, soil, and plant microbiomes will provide opportunities to improve crop production, transform feed efficiency, and increase resilience to stress and disease. To support these innovative technologies and practices, USDA must increase investments in the microbial sciences.

Thanks to past investments in microbiology research through AFRI, scientists are:

- Developing a voluntary framework for antimicrobial stewardship in animals. This addresses a critical need, as widespread use of antibiotics in animals and humans has led to increased resistance and could render these medicines ineffective.
- Learning more about how soil and root microbiome can be altered to improve plant productivity and soil health. This knowledge will help ensure crop viability over the longer term.

- Studying the connection of the soil microbiome to human gut health and related outcomes. This promising area of research will become increasingly important as climate change alters crop production and food availability.
- Learning more about the role that the bovine gut microbiome plays in how cattle process feed. By deepening our understanding of this complex ecosystem, scientists hope that better strategies for sustainable beef production can be developed.

USDA-FUNDED RESEARCH IS NEEDED TO ADDRESS CLIMATE CHANGE, ANTIMICROBIAL RESISTANCE, AND FOOD SECURITY

The challenges facing our Nation's producers and consumers are growing. World food demand is expected to double in the next 25 years, increasing the stress on the U.S. food and agricultural enterprise. In addition, we continue to face a rapidly changing climate and antimicrobial resistance (AMR), while recovering from the ongoing pandemic and preparing for the next one. AMR is one of the most daunting public health challenges facing the U.S. and the world. ASM and its members are tackling AMR from a variety of angles—from health care and clinical laboratory settings to agricultural and environmental microbial research perspectives, in the U.S. and around the world. A problem as complex as AMR requires multi-faceted approaches consistent with the One Health model, recognizing that the health of people, animals, and the environment are interdependent. Likewise, policy solutions must be comprehensive and address AMR from multiple angles and, when possible, with integrated strategies.

To combat AMR, we recommend an increase of at least \$85 million for antimicrobial resistance priorities at USDA, including a \$25 million increase in funding for the Animal and Plant Health Inspection Service (APHIS) and the National Animal Health Laboratory Network (NAHLN). This funding allows the agency to continue to promote agricultural stewardship, including gathering and evaluating valuable information on antibiotic use practices and identifying and characterizing injudicious use on farms and other agricultural settings through the National Animal Health Monitoring System (NAHMS) and other initiatives.

Tackling AMR will require increased investment in basic and applied research into why microbes become resistant, how they persist in ecological niches, and to develop novel countermeasures, including continued support for Invasive Pest Emergencies and the National Animal and Disease Preparedness and Response programs. This work also will entail public-private partnerships through entities such as the Advanced Research Projects Agency for Health and ideally its USDA equivalent, AGARDA. Other policy approaches that are critical to success include those that bolster AMR surveillance and laboratory capacity, support programs dedicated to infection prevention and control in healthcare and non-healthcare settings, policies to promote access to AMR tools in low and middle resource countries that improve diagnostics, microbiome modulators and antibiotic stewardship, and broader application and integration of pathogen genomic sequencing technologies.

Expanded funding for agricultural research including the National Bio and Agro-Defense Facility through ARS will enable USDA investigators and scientists to better protect the Nation's agriculture, farmers and citizens against the threat and potential impact of serious animal diseases and to understand the factors driving the emergence of resistant pathogens, which are expected to become even more common due to climate change. If we are to seize the current, unparalleled scientific opportunities that exist in microbial research, Congress must also support the deployment and use of technology and practices to enhance microbial research data collection and utilization to make our food and agricultural systems more efficient, resilient, and sustainable.

As in human health, applications of the microbiome in animal health are expanding rapidly, with exciting prospects for application in domestic pets, farm animals, and conservation. Food production depends on healthy microbiomes, and microbiome innovation can support the agricultural sector as it works to meet the needs of a growing population. To date, many studies have identified associations between the microbiome, productivity, and management practices in various food animal species; however, the specific organisms and metabolic pathways involved remain to be determined. A coordinated effort to do so in the main food producing animals could propel the industry to the next level and support the pressing concerns of feeding the planet and combating antimicrobial resistance.

Our nation's ability to meet the 21st century challenges of human nutrition and food security, conservation of our Nation's resources, and antimicrobial resistance will only be possible if Congress continues its commitment to robust and sustained funding increases for microbial, food, and agricultural research through AFRI,

AgARDA, and other USDA-funded research, education, and extension programs. ASM recognizes the challenges facing our Nation and the difficult decisions that must be made to ensure our Nation's fiscal health, and we believe that funding cutting edge agricultural research will help our Nation's farmers and ranchers succeed in the 21st century. Targeted acceleration of innovative research through funding AgARDA, combined with meaningful increases for USDA-funded research and FDA budget authority in fiscal Year 2024 are essential for supporting microbial research to benefit animal, human, and environmental health.

[This statement was submitted by Allen Segal, Chief Advocacy Officer.]

PREPARED STATEMENT OF AMERICAN SOCIETY FOR NUTRITION

The American Society for Nutrition (ASN) respectfully requests that the U.S. Department of Agriculture (USDA)/National Institute of Food and Agriculture/Agriculture and Food Research Initiative receive \$550 million, and that the USDA/Agricultural Research Service receive \$1.95 billion in fiscal year 2024. ASN has more than 8,000 members working throughout academia, clinical practice, government, and industry, who conduct research to advance our knowledge and application of nutrition.

AGRICULTURE AND FOOD RESEARCH INITIATIVE

The USDA has been the lead nutrition agency and the most important Federal agency to influence U.S. policies on dietary intake and food patterns for years. Agricultural research is essential to address the ever-increasing demand for a healthy, affordable, nutritious and sustainable food supply. The Agriculture and Food Research Initiative (AFRI) competitive grants program is charged with funding fundamental and applied research, extension, and education in support of our Nation's interconnected food and agricultural systems, which includes human nutrition. AFRI has funded cutting-edge, nutrition research on key issues of timely importance on a competitive, peer-reviewed basis since its establishment in the 2008 Farm Bill.

ASN requests that AFRI be funded at \$550 million in fiscal Year 2024, the same amount requested in the President's budget proposal. \$550 million would allow AFRI to support more competitive grants that ensure a safe, sustainable, nutritious, affordable, adequate food supply and bring AFRI closer to its fully authorized funding level of \$700 million/year. This funding level for AFRI is needed to invest in crucial areas aimed at addressing our Nation's most urgent and pressing food, agriculture, and public health challenges. AFRI-funded research supports nutrition and wellness, equity across the food system, food safety and traceability, supply chain resiliency, and a diverse research workforce. Growing inflation and food insecurity have been felt throughout the food and agriculture sector. However, AFRI is uniquely suited to address many of these challenges through transdisciplinary research, which allows researchers across disciplines to examine issues in a systematic way rather than in silos. For example, a total of \$20 million is included in the AFRI budget proposal to support the Cancer Moonshot efforts with funding for the Precision Nutrition program at the National Institutes of Health (NIH). However, despite incremental increases in AFRI funding, roughly 70 percent of AFRI proposals that are deemed worthy by expert review panels are not funded, simply because of insufficient funding. Agricultural and food research funding at the USDA has unfortunately remained fairly flat over the last fifty years.

Funding AFRI at \$550 million in fiscal Year 2024 is critical to provide a safe and nutritious food supply for the world's population, to preserve the competitive position of U.S. agriculture in the global marketplace, and to provide jobs and revenue crucial to support the U.S. economy. Robust investment in USDA-supported research is also needed to attract, retain, and develop the next generation of scientists from diverse backgrounds to advance innovations benefiting all Americans. In order to achieve those benefits, AFRI must be able to support agricultural research and coordinate opportunities to build off of these discoveries.

AGRICULTURAL RESEARCH SERVICE

The Agricultural Research Service (ARS) ensures high-quality, safe food and other agricultural products; assesses the nutritional needs of Americans; sustains a competitive agricultural economy; enhances the natural resource base and the environment; and provides economic opportunities for rural citizens, communities, and society as a whole. ARS supports intramural and extramural research across four national program areas including Nutrition, Food Safety and Quality. The ARS Nutrition, Food Safety, and Quality National Program maintains a healthy and safe food

supply while improving the economic viability and competitiveness of American agriculture. ASN requests that ARS receive \$1.95 billion in fiscal Year 2024 to ensure that ARS can respond to food safety and nutrition security concerns, new plant and animal pests and diseases, and weather-related and environmental stresses.

ARS's human nutrition research program includes six Human Nutrition Research Centers (HNRCs) across the Nation that link producer and consumer interests and form the core for building knowledge about food and nutrition. HNRCs conduct unparalleled human nutrition research on the role of food and dietary components in human health from conception to advanced old age, and they provide authoritative, peer-reviewed, science-based evidence that forms the basis of our Federal nutrition policy and programs. HNRCs play an important role not only in generating knowledge, but also in translating it for stakeholders. Funding for ARS supports all of the USDA/HNRCs and ensures that these research facilities have adequate funding to continue their unique mission of improving the health of Americans through cutting-edge food, nutrition and agricultural research. The President's budget request seeks \$1.979 billion for ARS and includes \$41 to improve ARS buildings and facilities.

Nutrition monitoring conducted by the USDA/ARS in partnership with the Department of Health and Human Services (HHS) is a unique and critically important surveillance function in which dietary intake, nutritional status, and health status are evaluated in a rigorous and standardized manner. ARS is responsible for food and nutrient databases and the "What We Eat in America" dietary survey, while HHS tracks nutritional status and health parameters. Nutrition monitoring findings are essential for multiple government agencies, as well as the public and private sector to track what Americans are eating, inform nutrition and dietary guidance policy, evaluate the effectiveness and efficiency of nutrition assistance programs, and study nutrition-related disease outcomes. Because of past funding deficiencies, some food composition database entries do not reflect the realities of the current food supply, which may negatively impact programs and policies based on this information. It is imperative that ARS continue to receive increased support to update food and nutrient databases and to continue critical surveillance of the Nation's nutritional status and the many benefits it provides.

Thank you for the opportunity to submit testimony regarding fiscal Year 2024 appropriations for the U.S. Department of Agriculture/National Institute of Food and Agriculture/AFRI competitive grants program and Agricultural Research Service. Please contact John E. Courtney, Ph.D., Executive Officer, at jcourtney@nutrition.org or 240-428-3643, 9211 Corporate Boulevard, Suite 300, Rockville, MD 20850 if ASN may provide further assistance.

[This statement was submitted by Martha A. Belury, PhD, RDN, 2022-2023 President, American Society for Nutrition.]

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS (ASPCA)

On behalf of The American Society for the Prevention of Cruelty to Animals (ASPCA), the first humane organization in North America, and our over 2 million supporters nationwide, thank you for the opportunity to submit written testimony to the subcommittee. We ask that you please consider the following provisions to benefit animal welfare as you draft the FY2024 Agriculture Appropriations bill.

REQUIRE APHIS TO PROPERLY ENFORCE THE ANIMAL WELFARE ACT

The USDA's Animal and Plant Health Inspection Service (APHIS) continues to fail to enforce the Animal Welfare Act, despite having adequate resources to do so. Rather than request additional funds for the program to address problematic licenses and stop systemic animal cruelty, the agency has proposed a decrease of \$1.865 million and 32 FTEs for the program in FY2024. We are grateful that the enacted Consolidated Appropriations Act, 2023 (Public Law 117-328) included bill language preventing the use of funds for the non-recording of observed violations of the AWA on inspection reports, finally ending the agency's misguided "Teachable Moments" program, which allowed non-compliant facilities to avoid having their violations recorded. The House Agriculture Appropriations Report, which was incorporated into the Joint Explanatory Statement by reference, also included a strong directive to the agency to reform its licensing, inspection, and enforcement scheme. However, despite this language, the agency continues to fail to respond to violations of the law with appropriate action, even in the worst cases. In early March 2023, Reuters published a story revealing that high-ranking APHIS officials went to great lengths to

cover up ongoing AWA violations and animal suffering at the beagle breeding and testing facility operated by Envigo in Cumberland, Virginia—thwarting efforts by inspectors to intervene and alleviate the suffering of thousands of dogs. The article includes details about agency officials directing inspectors to delete content from their reports, denying support for inspections to build a case against this non-compliant licensee, and removing the team leader supervising the investigation without explanation. This disturbing series of events expose an agency that is more concerned about protecting licensed businesses from repercussions than protecting animals. The ASPCA requests that the subcommittee include the following bill language: “Sec. X: None of the funds made available by this act or any other act may be used to: (a) issue or renew the license of any licensed dealer or exhibitor where agency personnel have previously recorded or observed any violation of the Animal Welfare Act or its regulations, other than administrative or record-keeping violations on inspection reports; (b) conduct announced inspections (other than pre-license inspections) or any announced “courtesy” or “compliance” visit; (c) conduct any inspection of any dealer or exhibitor’s facility without the use of a body camera for all agency personnel present at the inspection. The Secretary shall ensure that each inspection report and all supporting records, including photographs and video recordings, reflecting any violation of the law or regulations, other than administrative or record keeping violations, are shared immediately, and no later than 24 hours after inspection, with State and local law enforcement authorities of appropriate jurisdiction; (d) conduct more than one pre-license inspection.” Additionally, we request an increase of \$4,000,000 above the President’s FY24 request for the Animal Welfare program to ensure the proper enforcement of Federal standards, as well as to cover the initial costs of body cameras for inspectors and the necessary software to enable APHIS to share photographs and videos with State and local law enforcement as necessary to assist with animal cruelty investigations.

CONTINUE THE CURRENT BAN ON FEDERAL FUNDING FOR HORSE SLAUGHTERHOUSE INSPECTIONS

The Consolidated Appropriations Act, 2023 continues the longstanding provision barring Federal funding for Food Safety and Inspection Service (FSIS) inspections at domestic horse slaughterhouses. Americans do not consume horse meat, we do not raise horses for food, and national polling from 2021¹ indicates that 83 percent of American voters oppose the slaughter of horses for human consumption. Cruelties associated with all stages of horse slaughter are well-documented. Horses are at risk of suffering for prolonged periods during transport to slaughter. Before this funding restriction was in place, horses slaughtered in FSIS regulated plants endured repeated blows, sometimes remaining conscious during dismemberment, because the equipment used to slaughter horses is not designed for their physiology.

In addition to these intrinsic welfare concerns, consumption of meat from American horses is a public safety gamble. A 2010 Food and Chemical Toxicology Journal article detailed the ubiquitous use of phenylbutazone in racehorses subsequently sent to auction and then to slaughter only days after medication.² Phenylbutazone is one of the anti-inflammatory drugs most frequently administered to horses in the United States regardless of discipline, and its use is prohibited for animals raised for human consumption. Taxpayer dollars should not be used to prop up an industry that disregards animal welfare and human health. President Biden’s FY24 Budget Proposal includes this longstanding provision blocking Federal funding for horse slaughterhouse inspections. The ASPCA requests that the subcommittee continue the prohibition on Federal funding for domestic horse slaughter by including the following bill language: “None of the funds made available by this or any other act in this or any fiscal year hereafter may be used to pay the salaries or expenses of personnel- (1) to inspect horses under section 3 of the Federal Meat Inspection Act (21 U.S.C. 603); (2) to inspect horses under section 903 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 1901 note; Public Law 104–127); or (3) to implement or enforce section 352.19 of title 9, Code of Federal Regulations (or a successor regulation).”

DIRECT USDA TO REPORT ON COSTS AND RISKS OF ANIMAL DEPOPULATION

Concentrated Animal Feeding Operations (CAFOs) operate using a “just in time” model, meaning that CAFOs run according to a strict timeline of animal rearing tied

¹ <https://www.aspc.org/about-us/press-releases/new-research-shows-overwhelming-majority-americans-oppose-horse-slaughter>

² Dodman, N., Blondeau, N., Marini, A.M., “Association of Phenylbutazone Usage with Horses Bought for Slaughter: A Public Health Risk.” Food and Chemical Toxicology: May 2010.

to specific slaughter dates at predetermined slaughter facilities. Once one herd or flock is transported off-site for slaughter, there is just enough time to prep for the arrival of the next batch of animals. When an emergency occurs and access to slaughter is reduced or eliminated, CAFOs are ill-equipped to adjust and care for “excess” animals who can quickly accumulate on farms. Without the space or resources to care for those animals, they resort to “intentional depopulation,” which requires killing entire flocks or herds of animals through various methods, rather than through the regular slaughter process or humane euthanasia. Some of the methods used to kill “excess” animals, like ventilation shutdown, are particularly inhumane. To kill chickens and pigs using ventilation shutdown, workers are forced to shut off barns’ ventilation systems—and often raise the heat—with animals sealed inside, where they slowly die from overheating and suffocation. At this time, there are no reporting requirements on the methods used to depopulate farm animals. The ASPCA requests that the subcommittee include the following bill language requesting a report on the current and future costs to taxpayers and risks to national security, animals, rural communities, and consumers associated with the mass depopulation of livestock and poultry in CAFOs: “Not later than 180 days after the date of enactment of this act, the Secretary of Agriculture shall submit to the Committee on Appropriations in both Houses of Congress a report detailing the future costs to taxpayers and the risks to national security, animals, rural communities, and consumers associated with the depopulation of livestock and poultry in concentrated animal feeding operations, as defined by 40 CFR 122.23.” Additionally, we request the following report language: “The Committee understands that, in response to the COVID pandemic, poultry and livestock producers that operate concentrated animal feeding operations engaged in large scale depopulation practices that included inhumane methods such as ventilation shutdowns and water-based foam, and received USDA COVID-19 relief funds, resources, and other forms of support to accomplish this depopulation. The Committee must fully understand the impact these depopulation practices have on animals, consumers, taxpayers, and the communities where these concentrated animal feeding operations exist.”

DIRECT THE GAO TO SUBMIT A REPORT EVALUATING THE 28-HOUR RULE

The regular feeding, watering, and rest required for animals under 49 USC § 80502 by animal carriers is not being effectively enforced or may be waived by USDA inspectors; lack of enforcement or waiver of the 28-hour rule causes undue stress on the animals being transported and is counter to the intent of underlying statute. To acquire more information about how the USDA is enforcing the 28-hour rule, the ASPCA requests the following bill language: “(a) Not later than 365 days after the date of enactment of this act, the Government Accountability Office (GAO) shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report evaluating the 28-hour rule, as defined in 49 USC § 80502, prohibiting the confinement of animals in a vehicle or vessel for more than 28 consecutive hours without unloading the animals for feeding, water, and rest. (b) The report shall include—(1) An examination of the enforcement and waivers of the 28-hour rule; and (2) An evaluation of: (a) The monitoring systems in place for enforcement; (b) The number of waivers issued on a yearly basis; (c) An evaluation of the roles of the Department of Agriculture, Department of Transportation, and the Department of Justice in enforcing the statute; (d) An evaluation of the funding of the agencies authorized to enforce the statute; (e) Any concerns or problems with the implementation of the statute; and (f) Any positive or negative impact on the welfare of animals in transport related to the enforcement, or lack thereof, and waiver process. (c) Reporting—Not later than 60 days after the release of the GAO report, the Secretary of Agriculture, the Secretary of Transportation and the Attorney General shall brief the committees on a plan to address issues raised by the report issued under this section.” Additionally, we request the following report language: “The Committee is concerned that the regular feeding, watering, and rest required under 49 USC § 80502 by animal carriers is not being effectively enforced or may be waived by USDA inspectors; lack of enforcement or waiver of the 28-hour rule causes undue stress on the animals being transported and is counter to the intent of underlying statute. The Committee recognizes that millions of animals that are regulated by this statute are transported every year, but the lack of coordination by government agencies may be leading to the lack of enforcement. The Committee is concerned that lack of enforcement and waiving is due to inadequate monitoring systems and enforcement authority for the three agencies involved in enforcement: the USDA, DOJ, and DOT. The Committee directs the Secretary of Agriculture, Secretary of

Transportation, and the Attorney General to provide a briefing to the Committee on a plan to address issues raised within 60 days of the release of the GAO report.”

REQUIRE FSIS TO STRENGTHEN ENFORCEMENT OF THE HUMANE METHODS OF
SLAUGHTER ACT

The Humane Methods of Slaughter Act (HMSA) is effectively the only Federal law protecting farm animals from cruelty. It is vitally important for animal welfare and food safety that FSIS enforce this law and ensure that slaughterhouses follow related humane slaughter and handling regulations. We urge the subcommittee to include the following bill language to ensure HMSA enforcement is strengthened: “No fewer than 165 full-time equivalent positions shall be employed during fiscal year 2024 for purposes dedicated solely to inspections and enforcement related to the Humane Methods of Slaughter Act. This number is in addition to the Humane Handling Enforcement Coordinator and District Veterinary Medical Specialist positions.” Additionally, we request the following report language: “The Food Safety and Inspection Service (FSIS) shall ensure that all inspection personnel conducting humane handling verification procedures receive robust initial training and periodic refresher training on the FSIS humane handling and slaughter regulations and directives. This includes handling of non-ambulatory disabled animals, as well as proper use of the Humane Activities Tracking System to ensure humane handling of animals as they arrive and are offloaded and handled in ante-mortem holding pens, suspect pens, chutes, stunning areas, and on the processing line. The Committee directs the agency to continue preparation and online publication of the Humane Handling Quarterly Reports, to include: (1) the number of humane handling verification procedures performed, (2) the number of administrative enforcement actions taken, (3) time spent on Humane Handling Activities Tracking System activities, and (4) comparisons of these measurements by plant size and FSIS district. The Committee recognizes that the humane handling of birds at slaughter according to Good Commercial Practices reduces the occurrence of adulterated poultry products in the marketplace and can improve the treatment of birds at slaughter. The Committee awaits the Department’s briefing requested in the fiscal year 2022 and 2023 reports on documented instances where establishments lost control of their processes for handling birds, and consequently were not operating in accordance with GCPs. Further, the Committee directs the USDA to track the number of inspector hours spent on GCP verification activities intended to reduce instances of adulteration using its existing Humane Activities Tracking System or other appropriate method.”

ALLOCATE FUNDING FOR THE VALUE-ADDED PRODUCER GRANT PROGRAM

The USDA’s Value-Added Producer Grant (VAPG) program helps farmers participate in value-added farming activities to generate new products, create and expand marketing opportunities and increase farmer income, including those produced using more humane farming methods, such as welfare-certified or pasture-raised products. The VAPG program is one of the only Federal grant programs available to farmers raising animals outside of the conventional confinement model and is a critical resource for building a more humane food system. The enacted Consolidated Appropriations Act, 2023 included \$13 million in discretionary funding for this program; the ASPCA requests the subcommittee to meet or exceed this funding level in the FY2024 bill.

ALLOCATE FUNDING FOR HORSE SORING ENFORCEMENT & URGE USDA TO ISSUE NEW
PROPOSED HPA RULE

APHIS is also charged with protecting horses through its enforcement of the Horse Protection Act (HPA). We appreciate that Congress provided \$4.096 million in fiscal year 2023 for USDA to strengthen enforcement of the HPA. The ASPCA requests no less than the fiscal year 2023 enacted level of \$4.096 million in the bill to support needed enforcement of the HPA. Additionally, we request the following report language: “The Committee provides \$4,096,000 for enforcement of the Horse Protection Act of 1970, as amended (15 U.S.C. 1831), and reminds the Secretary that Congress granted the agency primary responsibility to enforce this law. The Committee urges the Secretary to issue the new proposed HPA rule expeditiously, consistent with the agency’s announced intentions in December 2021, and to finalize and publish the new final rule by December 31, 2023. The Committee further urges the Secretary to ensure that the new rule includes at a minimum all the key elements of the final rule, “Horse Protection; Licensing of Designated Qualified Persons and Other Amendments” [Docket No. APHIS–2011–0009], that was finalized and displayed in advance public notice in the Federal Register on January 19, 2017.”

PROVIDE FUNDING FOR USDA TO IMPLEMENT THE PET AND WOMEN SAFETY ACT GRANT PROGRAM

We appreciate that Congress provided \$3 million in fiscal year 2023 to continue implementing Section 12502 of the 2018 Farm Bill (Public Law 115–334), which incorporated the language of the Pet and Women Safety (PAWS) Act to authorize a grant program to provide emergency and transitional shelter options for domestic violence survivors with companion animals. Research shows that abusers often threaten or inflict violence on pets to intimidate or exert control over their partners and prevent them from leaving. This program will ensure that more domestic violence service providers are able to accommodate pets or arrange for pet shelter. The ASPCA urges the subcommittee to include \$3,000,000 in the FY2024 Agriculture Appropriations Bill to continue implementing the PAWS grant program as authorized in Section 12502 of Public Law 115–334. The ASPCA also requests the subcommittee to include the following Report Language: “The Committee directs the Secretary of Agriculture to continue coordinating with the Departments of Justice, Housing and Urban Development, and Health and Human Services to efficiently implement the grant program for providing emergency and transitional shelter options for domestic violence survivors with companion animals.”

[This statement was submitted by Ingrid Seggerman, Senior Director of Federal Affairs, ASPCA.]

PREPARED STATEMENT OF ANIMAL HEALTH INSTITUTE

On behalf of the Animal Health Institute (AHI), I write today to request that you include funding for priorities important to human and animal health in the Fiscal Year 2024 Agriculture, Rural Development, Food and Drug Administrations and Related Agencies Appropriations Bill. Funding of these programs protects animal health and human health by providing safe and effective products to prevent and treat disease in animals.

AHI is appreciative to Congress for providing \$21.48 million for the Center for Veterinary Biologics (CVB) in last year’s spending bill. We request Congress maintain this funding level for the Center to continue to review and approve veterinary biologics in a timely manner, help compensate for the coming wave of retirements by experienced CVB staffers and continue to bring current vaccines and new and innovative technologies to market.

We request the user fees established by the Animal Drug User Fee Act (ADUFA) of \$33.500 million be included in the fiscal Year 2024 appropriations bill. ADUFA provides a system of performance standards and user fees to improve the new animal drug review process at the U.S. Food and Drug Administration’s (FDA) Center for Veterinary Medicine (CVM). Predictability of the review process has improved as FDA CVM has met the agreed-upon performance standards. To maintain this success, we request that the fees be integrated into this year’s appropriation bill. The appropriation is entirely budget neutral as the money will be provided by the animal health companies.

The FDA CVM issued final guidance #256, Compounding Animal Drugs from Bulk Drug Substances, in 2022, to provide regulatory certainty about animal drug compounding from bulk drug substances. The guidance alone will not end current abusive practices that threaten animal health unless vigorously enforced. We request Congress provide \$2 million to support the CVM in fully and properly enforcing guidance #256 to protect animal health.

Another area of importance within animal and public health is the control of ectoparasites in pets, livestock, and the environment. In order to ensure timely approval of new preventative medications for controlling fleas, ticks, and other ectoparasites in animals, AHI requests the Environmental Protection Agency’s (EPA) pesticide registration activities be appropriated \$166 million for the fiscal Year 2024. This will help ensure that much needed improvements to the EPA registration process are possible and the agency can decrease the time currently required for review and approval of new products.

AHI respectfully requests \$33 million for the USDA–APHIS Wildlife Services National Rabies Management Program (NRMP). The program is critical to decreasing the spread of rabies and is protective of human and animal health.

Thank you for your consideration. Please do not hesitate to contact me if you have any questions or need additional information.

Sincerely,



Ronald B. Phillips
Senior Vice President, Policy

PREPARED STATEMENT OF ANIMAL WELFARE INSTITUTE

The Animal Welfare Institute, a nonprofit national animal welfare advocacy organization, thanks the subcommittee for its ongoing and robust efforts to ensure strong enforcement of the Animal Welfare Act and to provide resources to assist domestic violence survivors and their pets. We respectfully ask the subcommittee to maintain these efforts in FY24 as its leadership and oversight continue to be urgently needed.

Meaningful animal welfare laws are essential both for humane and human reasons. These laws and the steps Congress takes to improve their enforcement—decrease the sale of sick pets by commercial breeders, improve the integrity of animal-based research, reduce risks of disease transmission and dangerous encounters involving animals and the public, protect pet owners from the theft of their companion animals by unscrupulous dealers, assure food safety for consumers, and improve slaughterhouse conditions for both workers and animals. Most importantly, they are intended to assure humane treatment of animals used in commercial activities throughout the country.

APHIS/ANIMAL CARE/ANIMAL WELFARE ACT ENFORCEMENT

Bill Language Request: “The Secretary shall ensure that appropriate enforcement action in the form of penalties or case referral to the Office of General Counsel or the Department of Justice, or both, is taken when a regulated facility violates the Animal Welfare Act (7 U.S.C. §§ 2131–2159), as documented on an inspection report, with due consideration to the appropriateness of the penalty with respect to the size of the business of the person involved, the gravity of the violation, the person’s good faith, and the history of previous violations, as provided in 7 U.S.C. § 2149(b).”

“The Secretary shall ensure that any interference with or failure to allow access for an inspection under the Animal Welfare Act, 7 U.S.C. §§ 2131–2159, is documented on an inspection report.

“The Secretary shall ensure that all dealers selling dogs, cats, and other covered animals online have the necessary license pursuant to Animal Welfare Act, 7 U.S.C. §§ 2131–2159, as required under 78 Fed. Reg. 57227.

“The Secretary of Agriculture shall enter into a memorandum of understanding with the U.S. Attorney General to encourage greater collaboration on Animal Welfare Act enforcement and ensure that the Department of Justice has access to evidence needed to initiate cases.”

Report Language Request: “Case Referrals for Animal Welfare Act (AWA) Violations.—The Committee is concerned that USDA is not fully utilizing its enforcement capabilities, particularly for chronic violators of the AWA. There has been an overall decline in AWA enforcement since 2010, when USDA initiated 874 cases and 74 stipulated penalties. By 2021, enforcement had dropped to 262 initiated cases, of which 18 resulted in settlements and 17 in administrative orders. The Committee directs USDA to use its full enforcement capabilities under the AWA, including referring cases to the Office of General Counsel, the Department of Justice, or both, when appropriate according to the factors the agency must consider under 7 U.S.C. § 2149(b).”

Justification: The AWA is the chief Federal law for the protection of animals. We are concerned about USDA’s oversight of regulated industries in recent years. While we acknowledge some improvements in 2021 compared to the previous 4 years, overall there has been a decline in AWA enforcement, with far fewer cases initiated, warnings issued, and official complaints filed in recent years. In fiscal Year 2021, APHIS opened 118 new enforcement cases, which was an improvement compared to 2020, but still a decline of more than 50 percent compared to the 252 cases opened in fiscal Year 2014. Lower-level actions like official warnings were also issued sparingly; in fiscal Year 2016, the agency issued almost 200 warnings, but in fiscal Year 2021, it issued only 58. It should be noted that this is improved from fiscal Year 2019, when it issued only two, and in fiscal Year 2020, when it did not issue a single one.

Problems are present throughout the system. In 2018, inspectors were issued guidance that allows ailing animals to be diagnosed over the phone without a physical veterinary examination or testing, which denies animals necessary care and puts the public at risk. These guidelines no longer require that euthanasia be carried out according to the American Veterinary Medical Association's Guidelines for Euthanasia of Animals, which can lead to horrific cases such as a Kansas breeder who fatally shot 24 dogs, resulting in a suspension of their state license but no penalty from USDA. We are also aware of licensees who have repeatedly denied access to their facilities for inspections (even before the pandemic) or interfered with USDA's collection of information, and have not been cited. There also continue to be cases where significant violations have been documented, but USDA has opted not to take any enforcement action. One look no further than the Envigo case in Virginia, where years of documented noncompliances went unaddressed until DOJ took the extraordinary step of seeking injunctive relief. At the same time as 4,000 dogs were being removed from horrendous conditions to be placed in loving homes, USDA was renewing the license of Envigo's parent company. While the scale is enormous, this is by no means an isolated case.

In 2013, USDA issued a rule intended to close loopholes that allowed dog breeders to sell puppies online without a USDA license, but enforcement with respect to online dealers has been lackluster. As a result, many online operations continue to sell puppies sight unseen to consumers without the necessary USDA licensing and oversight.

We are grateful to the Committee and Congress for directing Animal Care to document every observed AWA violation on official inspection reports and that, as a result, Animal Care finally put an end to its "Teachable Moments" program.

APHIS/ANIMAL CARE/PROTECTING ANIMALS WITH SHELTER (PAWS) FUNDING

Requested Funding: We request that Congress again provide the full authorized appropriation of \$3 million to continue implementing the PAWS grant program as authorized by Section 12502 of Public Law 115-334. (It should be noted that the program is set up as a pass-through, with funds going initially to USDA but the grants being administered by DOJ.)

Requested Report Language: "The Committee directs the Secretary of Agriculture to continue coordinating with the Departments of Justice, Housing and Urban Development, and Health and Human Services to efficiently implement the grant program for providing emergency and transitional shelter options for domestic violence survivors with companion animals."

Justification: We appreciate that Congress provided \$3 million in fiscal Year 2023 to continue implementing Section 12502 of the 2018 Farm Bill (Public Law 115-334), which authorized a new grant program to provide emergency and transitional housing options for domestic violence survivors with companion animals. Research shows that abusers often threaten or inflict violence on pets as a way to intimidate or exert control over their partners and prevent them from leaving. In fact, nearly half of domestic violence survivors report staying with their abuser for fear of what would happen to their pets if they leave. This program is successfully ensuring that more survivors feel they can leave because safekeeping for their pets is available. The programs that have been funded so far represent diversity in geographic areas and populations served, as well as in their solutions to the problem of how best to assist domestic violence survivors who have companion animals. The common thread through them all is the level of excitement at being able to reach this highly underserved population of survivors and to increase community awareness about this long-standing oversight, which would not have been possible with these grants. But there has been more demand for grants than the program has been able to meet: For FY20 through FY22, 23 grants were awarded, but 81 applications had been received. Continued funding is essential.

USDA/OFFICE OF INSPECTOR GENERAL/ANIMAL FIGHTING ENFORCEMENT

Requested Report Language: "The Committee is concerned about illegal animal fighting activity that subjects animals to cruel conditions and has the potential to spread illnesses such as virulent Newcastle disease and avian flu. The OIG is encouraged to increase its enforcement efforts in the States and territories and to pursue animal fighting cases even if related concerns, such as money laundering and illegal weapons, have not yet been determined to be at issue before an investigation is opened. OIG is also encouraged to work with USPS and DoJ to examine the prevalence of the illegal shipment of game-fowl used in cockfighting. The Committee also encourages the OIG to audit and investigate USDA enforcement of the Animal Welfare Act and the Horse Protection Act to help improve compliance with these impor-

tant laws. This should include finalizing the reopening of the audit of the Animal Care Program Oversight of Dog Breeders to allow completion of in-person visits. Additionally, the Committee is concerned about the lack of meaningful enforcement of the AWA and HPA and requests that these audits should also examine what barriers exist to full enforcement of both Acts, and what if any steps can be taken within APHIS' Animal Care and Investigative and Enforcement Services programs to ensure that the regulated community is held accountable for violations of these Acts."

APHIS/ANIMAL CARE/EMERGENCY PREPAREDNESS AND RESPONSE

Requested Funding: We request \$1.45 million for Animal Care under APHIS' Emergency Preparedness and Response line item.

Background: APHIS Emergency Preparedness and Response funds enable the Animal Care program to support a cooperative agreement on hazard preparedness and response for zoos and aquariums, facilitate networking efforts for state emergency agriculture officials, update Best Practices Documents for animal emergency management, conduct outreach, and implement the final rule issued in December 2021 following a directive in the fiscal Year 2021 omnibus (86 Fed Reg 68533), which requires emergency contingency plans for all facilities regulated under the Animal Welfare Act.

FOOD AND DRUG ADMINISTRATION/REDUCING ANIMAL TESTING AND ADVANCING NONANIMAL METHODS

Requested Funding: We request no less than the fiscal year 2023 level of \$5 million.

Requested Report Language: "The Committee directs FDA to efficiently and expeditiously utilize existing funds to reduce animal testing and advance alternative methods in a measurable and impactful way. The agency is further directed to provide a report to the Committee within 90 days of enactment that provides details on the status of forming the New Alternative Methods Program in the Commissioner's office, including but not limited to a description of program goals and staffing levels by position classification; FDA's priority areas for reducing animal use and advancing alternatives, including goals, timelines, and funding associated with each of these identified priorities; metrics the agency will use to measure impact, and how the agency will communicate information regarding acceptance of alternative methods to the regulated community. The agency should not use funding to carry out new animal testing, including to compare the use of animals to alternative methods, but instead use existing animal data."

APHIS/ANIMAL CARE/MARINE MAMMALS IN CAPTIVITY

Requested Report Language: "Last year, the Committee directed USDA to prioritize and reissue a proposed rulemaking to update regulations for the handling and care of marine mammals in captivity. This has not happened yet. The Committee continues to be concerned that USDA's handling, care, treatment, and transportation standards for marine mammals in captivity are seriously outdated. Marine mammal science has progressed significantly in the almost 40 years since the most important of these regulations were last updated, and the current standards do not adequately protect the welfare of captive marine mammals. An effort to modernize these standards that began in 2002 ended in 2021 when a proposed rule published in 2016 was withdrawn, recognizing it was now outdated. The Committee reminds APHIS that it expects it to prioritize developing and finalizing a humane and science-based rule to modernize its marine mammal regulations and directs the agency to report back within 6 months on its progress in achieving that goal."

Justification: It was 1984 when the USDA last updated key elements of the handling and care standards for marine mammals. In those nearly 40 years, significant progress has been made in marine mammal biology and ecology research, the results of which should inform Federal care regulations, such as increasing minimum space requirements, establishing species-specific ambient temperature ranges, and mitigating the effects of noise. An effort to modernize these standards that began in 2002 ended in 2021 when a proposed rule (81 FR 5629) published in 2016 was withdrawn "due to the age of the analyses on which it relies." Updating the minimum space requirements is especially critical to improve the welfare of captive marine mammals. Research within the past 20 years indicates that marine mammals in the wild move far more widely than was previously understood, including diving to astounding depths. For example, a 2015 study by researchers at the University of Alaska Fairbanks and University of Washington Seattle found that belugas routinely dive to 2,000 feet, yet the current minimum required depth for this species in captivity is only 7 feet (half the average body length of the species).

[This statement was submitted by Nancy Blaney, Director, Government Affairs.]

PREPARED STATEMENT OF ANIMAL WELFARE INSTITUTE

The Animal Welfare Institute appreciates the opportunity to submit testimony on FY2024 spending priorities for the U.S. Department of Agriculture's Animal and Plant Health Inspection Service's Wildlife Services program. AWI is grateful to Congress for the actions it has taken over the past several years to encourage Wildlife Services to invest in developing and transitioning to nonlethal methods of responding to human-wildlife conflict. While the agency has taken small steps towards implementing nonlethal methods, leadership from the Committee is still needed to ensure this remains a priority for the agency because it continues to use inhumane methods, such as M-44 sodium cyanide devices, that pose a risk to millions of animals, the environment, and the public.

CHEMICAL POISONS

Report language request: "No Federal funds shall be expended or committed for the manufacture, import, purchase, sale, distribution, preparation, placement, deployment, training in the use of, or authorization for use by third parties, of M-44 sodium cyanide ejector devices ('M-44s'), including any of the device's components or parts. This prohibition extends to use of Wildlife Services staff time and resources in connection with the use of M-44s, including where such actions are undertaken in connection with a cooperative agreement, except for activities directly related to the removal of M-44s that have been placed on federal, Tribal, State, and private land. Nor shall Federal funds be expended or committed for the manufacture, import, purchase, sale, distribution, preparation, placement, deployment, training in the use of, or authorization for use by third parties of sodium fluoroacetate ('Compound 1080'), including for livestock protection collars.

"Exposure to sodium cyanide and Compound 1080 can cause severe, unjustifiable suffering and often results in painful, protracted deaths for wildlife and family pets, including many non-target animals and even people. Use of M-44s and Compound 1080 for wildlife 'control' purposes is unsafe for people and animals alike and is an ineffective approach to sustainably reducing and preventing human-wildlife conflict and livestock losses. The Committee urges Wildlife Services to reallocate resources to the provision of technical assistance and education to promote, incentivize, implement, and sustain the use of nonlethal methods of predator control and coexistence, which can be less costly, more effective, and less dangerous to non-target species relative to M-44s and Compound 1080.

"Just as Federal funds may not be allocated to the use of M-44s or Compound 1080, Federal funds may not be used to develop, introduce, or reintroduce other chemical poisons, including but not limited to alternative delivery mechanisms for sodium cyanide, Compound 1080, and other pesticides, for purposes of lethal predator control. This prohibition extends to the use of Federal funds to initiate or continue research, development, testing, registration, manufacture, preparation, or investigation of any chemical poisons or pesticides that may be used for lethal predator control."

Justification: Lethal animal control devices such as M-44s or Compound 1080 cause severe, unnecessary pain and suffering and often result in painful deaths of wild animals and family pets. In 2022, Wildlife Services killed over 6,000 animals with M-44s, 152 of whom were killed unintentionally. These devices have killed family pets and have caused severe, irreparable harm to people who have been exposed. Sodium cyanide, used in M-44s, and Compound 1080 (sodium fluoroacetate), used in livestock collars, are two of the world's deadliest poisons and present threats to public health, the environment, and national security. With an assortment of safer and more effective nonlethal options available, Wildlife Services should no longer employ M-44s or Compound 1080 as a means of predator control.

NONLETHAL METHODS DEVELOPMENT

Report language request: "The Committee is aware that Wildlife Services, according to the program's informational materials, has worked with landowners to deploy nonlethal predator management strategies such as fladry, electric fencing, and livestock guardian dogs. However, these efforts have been insufficient, and millions of animals continue to be inhumanely killed each year, including thousands of nontarget animals. Wildlife Services must implement and prioritize nonlethal strategies through the following: (1) promoting and implementing nonlethal livestock-predator conflict deterrence and mitigation techniques, including but not limited to use of

barriers and fencing, fladry and turbo-fladry, visual and auditory deterrents, livestock protection animals, appropriate husbandry practices, night corralling, shed lambing, attractant and carcass removal, livestock herding, and human presence; (2) providing training in selection, implementation, monitoring, and adaptation of nonlethal techniques for agricultural producers, landowners, Federal and State agency personnel, and others; and (3) collaborating with the National Wildlife Research Center to advance and improve nonlethal predator coexistence methods, conduct research on monitoring methods for efficacy of nonlethal control methods implemented to reduce predation, and establish clear documentation protocols for nonlethal approaches implemented in advance of lethal control measures where applicable.

“The Committee directs Wildlife Services to fund nonlethal predator control activities from a percentage of the United States Department of Agriculture’s total budget. No less than \$5,000,000 of existing funds must be allocated towards nonlethal strategies. In FY23, the Committee allocated funding specific to nonlethal measures. Wildlife Services is directed to provide a report detailing how these additional funds were dispersed-including regional distribution, wild and domestic species affected, number and size of livestock/agricultural operations affected, nonlethal tools and methods implemented and supported, and efficacy evaluation methods and outcomes- within 45 days of the enactment of this act. Wildlife Services is also directed to document all work on nonlethal strategies development and submit a report demonstrating progress in this area within 180 days of the enactment of this act.”

Justification: It is estimated that USDA’s Wildlife Services has killed over 34 million animals over the last decade. In 2022, 383,731 native animals were killed by the agency-more than 2,600 of whom were killed unintentionally. The death toll included more than 56,000 coyotes, 26,000 beavers, 2,400 foxes, and hundreds of gray wolves, black bears, mountain lions, and badgers, among many other species. These animals were killed using a variety of inhumane methods, such as M-44 devices, snares, body-gripping traps, leghold traps, and firearms. Lethal predator control methods, often employed to benefit the agriculture industry, are proven to be ineffective and inhumane and to pose safety risks to both humans and pets, and are more costly than nonlethal methods. Predator species are a critical part of healthy ecosystems. Employing nonlethal predator control methods will establish sustainable coexistence and benefit both the agricultural community and the environment.

TRAPPING

Report language request: “The Committee directs the Secretary to allocate \$300,000 to institute a 3-year pilot program to replace the use of body-gripping traps by agency personnel with non-lethal methods and equipment, with the following exceptions:

- When the body-gripping trap is used to (i) control documented invasive species to achieve resource management objectives where alternative methods have failed; or (ii) protect a species that is (I) listed as an endangered species or threatened species under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); or (II) treated by the Forest Service as a sensitive species.
- Exception only applies when: (i) such use of a body-gripping trap is in accordance with applicable State and Federal law; (ii) prior to use of a body-gripping trap, all available and viable nonlethal methods for such control or protection, respectively, are attempted; and (iii) such attempts are documented in writing, and such documentation is maintained at the headquarters of the department that employs the individual engaging in such attempt.”

Justification: Body-gripping traps, such as snares, Conibear traps, and steel-jaw leghold traps, are inhumane and inherently nonselective. The nontarget animals caught in these traps include threatened and endangered species, as well as family pets. These traps do not belong on public lands where families go to enjoy spending time outdoors, and where anyone who trips a trap can become a victim.

Based on funding levels for other predator control programs, \$300,000 over 3 years would be a reasonable amount to fund a pilot program for replacing agency use of body-gripping traps with nonlethal methods. The Fish and Wildlife Service’s Endangered Species Conservation-Wolf Livestock Loss Compensation and Prevention fund tends to give \$50,000-\$100,000 to each recipient. The FWS Fish and Wildlife Coordination and Assistance fund was appropriated \$150,000 in FY16 (the most recent year with data) to award grants to conservation and/or environmental projects. Wildlife Services gave Colorado State University a \$50,028 grant to study nonlethal management of coyote predation. This paints a picture of \$50,000–150,000

per year for a small predator management program, and a 3-year program is advisable to obtain meaningful results.

Thank you for your consideration of our recommendations for how the Committee can ensure Wildlife Services prioritizes a transition to safer, effective nonlethal methods.

[This statement was submitted by Erica Gandolfo, Policy Advisor, Government Affairs, Animal Welfare Institute.]

PREPARED STATEMENT OF THE ANIMAL WELFARE INSTITUTE

Thank you for the opportunity to submit testimony on Fiscal Year 2024 funding priorities for the U.S. Department of Agriculture. Below are some of the Animal Welfare Institute's top priorities that fall under the Food Safety and Inspection Service, Farm Service Agency, and Animal and Plant Health Inspection Service pertaining to the humane treatment of farmed animals and equines.

FOOD SAFETY AND INSPECTION SERVICE—HUMANE METHODS OF SLAUGHTER ACT
ENFORCEMENT

Effective enforcement of the Humane Methods of Slaughter Act can prevent abuses like those documented in undercover investigations and reduce the chance of associated food safety risks and costly recalls of meat and egg products. The number of FTEs required under annual appropriations for enforcement of the HMSA has remained at 148 since FY12, despite the fact that actual staffing levels have consistently been above this number for the past decade. To more accurately reflect previous staffing levels that have proven to increase the number of humane handling verification procedures performed and align with the agency's staffing commitments, 165 FTEs should be appropriated. We also request that the agency continue publishing the Humane Handling Quarterly Reports—as previously directed by the FY21, FY22 and FY23 agriculture appropriations reports—to allow for timely and efficient access to information pertinent to monitoring HMSA enforcement. AWI greatly appreciates the Committee's attention to this matter given that Humane Handling Quarterly Reports provide critical information that promotes transparency and public trust in FSIS's oversight of the treatment of animals slaughtered at USDA inspected facilities.

Bill language request: No fewer than 165 full-time equivalent positions shall be employed during fiscal year 2024 for purposes dedicated solely to inspections and enforcement related to the Humane Methods of Slaughter Act. This number is in addition to the Humane Handling Enforcement Coordinator and District Veterinary Medical Specialist positions.

Report language request: FSIS shall ensure that all inspection personnel conducting humane handling verification procedures receive robust initial training and periodic refresher training on the FSIS humane handling and slaughter regulations and directives. This includes handling of non-ambulatory disabled animals, as well as proper use of the Humane Activities Tracking System to ensure humane handling of animals as they arrive and are offloaded and handled in ante-mortem holding pens, suspect pens, chutes, stunning areas, and on the processing line. The Committee directs the agency to continue preparation and online publication of the Humane Handling Quarterly Reports, to include: (1) the number of humane handling verification procedures performed, (2) the number of administrative enforcement actions taken, (3) time spent on Humane Handling Activities Tracking System activities, and (4) comparisons of these measurements by plant size and FSIS district.

FOOD SAFETY AND INSPECTION SERVICE—POULTRY SLAUGHTER GOOD COMMERCIAL
PRACTICES

USDA has documented a variety of serious humane handling problems at poultry slaughter plants, including birds drowning in scalding tanks, disposal of live birds under piles of dead birds, birds dying due to suffocation and/or prolonged exposure to extreme weather, and mechanical problems resulting in injury and death. In 2005, USDA issued a notice to slaughter establishments that acknowledged the link between inhumane treatment of birds and adulterated poultry products, and referenced industry "Good Commercial Practices" for bird handling. Subsequently, USDA inspectors began conducting verification of these requirements for live bird handling in every federally inspected plant. However, inspector oversight appears to vary widely at poultry slaughter establishments. According to USDA enforcement records, between 2018 and 2020, nearly one-half (42 percent) of federally inspected poultry plants were not issued any enforcement records documenting GCP compli-

ance. In order to determine why the reporting of GCP compliance varies so dramatically among inspection personnel, USDA should begin tracking the time inspectors spend on GCP-related activities. Information gained from this monitoring will also assist USDA and Congress in determining the level of inspector oversight needed to prevent repeated incidents of bird mistreatment that has the potential to result in poultry product adulteration.

Report language request: The Committee recognizes that the humane handling of birds at slaughter according to Good Commercial Practices (GCPs) reduces the occurrence of adulterated poultry products in the marketplace and can improve the treatment of birds at slaughter. The Committee awaits the Department's briefing requested in the fiscal year 2022 and 2023 reports on documented instances where establishments lost control of their processes for handling birds, and consequently were not operating in accordance with GCPs. Further, the Committee directs the USDA to track the number of inspector hours spent on GCP verification activities intended to reduce instances of adulteration using its existing Humane Activities Tracking System or other appropriate method.

FARM SERVICE AGENCY—LIVESTOCK INDEMNITY PROGRAM

The Livestock Indemnity Program compensates producers for farmed animal injuries and deaths caused by adverse weather and natural disasters. The number of farmed animals that die from adverse weather events is immense—as is the amount of Federal funds disbursed under LIP. According to data from the USDA Economic Research Service, USAspending.gov, and public records obtained via FOIA, LIP payments have totaled over \$500 million since 2008. However, producers are not required to demonstrate that they provide animals with basic protections from extreme weather or that they have disaster plans in place before receiving taxpayer dollars under LIP. Disaster preparedness plans are widely supported by agriculture industry groups and are recommended by both the American Veterinary Medical Association and the USDA. To save taxpayer dollars and mitigate losses, USDA should require that producers have disaster preparedness plans for the issuance of payments under LIP.

Bill language request: Livestock Indemnity Payments for Adverse Weather. For expenses involved in making indemnity payments to eligible livestock owners or contract growers, such sums as may be necessary: Provided, That the Secretary shall ensure that no funds are used for issuing payments under the program, unless the applicant offers 1) a disaster preparedness plan that is specific to the species of animal(s) and region of the country, and 2) a description of how the plan was executed to prevent livestock injuries or deaths.

Report language request: Disaster Preparedness.—The Committee recognizes that millions of farmed animals die each year due to the effects of adverse weather, and extreme weather events are occurring at increased frequency, putting additional livestock at risk of injury and death. The committee also is cognizant that veterinary and agricultural trade associations recognize the importance of disaster planning in preventing the extent of livestock deaths. Therefore, the Committee directs USDA to require written disaster preparedness plans for the issuance of payments under the Livestock Indemnity Program.

FOOD SAFETY AND INSPECTION SERVICE AND ANIMAL AND PLANT HEALTH INSPECTION SERVICE—ENFORCEMENT OF THE TWENTY-EIGHT HOUR LAW

The Twenty-Eight Hour Law is the only Federal law aimed at providing basic protections for farmed animals transported across the United States; unfortunately, oversight of compliance is virtually nonexistent even though available evidence and investigations have revealed numerous instances where animals were transported in excess of 28 hours without food, water, or rest. Given that the statute is not actively enforced by any of the agencies responsible for doing so, report language should direct USDA and DOT to develop a mechanism (e.g., through guidance, policies, or regulations) to monitor compliance (e.g., by integrating checks into routine roadside inspections that are already being conducted by DOT, during humane handling verifications conducted by FSIS at federally inspected livestock slaughter establishments, and/or during live animal export inspections conducted by APHIS). Transport can be very stressful for animals, as they are subjected to increased handling, exposure to temperature extremes, and long journeys involving overcrowding and food and water deprivation. At a bare minimum, ensuring that the Twenty-Eight Hour Law is being followed would vastly improve conditions. Moreover, better protecting the health and welfare of these animals helps to prevent the spread of disease and reduce incidences of injury, infection, and mortality due to the stresses associated with transport.

Report language request: Enforcement of the Twenty-Eight Hour Law.-Not later than 180 days after the date of enactment of this act, the Secretary of Agriculture, in consultation with the Secretary of Transportation, shall develop a mechanism for conducting investigations or inspections, including but not limited to inspection of any vehicle or vessel transporting animals or any written or electronic records associated with such transport of animals, to determine whether any rail carrier, express carrier, or common carrier, a receiver, trustee, or lessee of one of those carriers, or an owner or master of a vessel transporting animals has violated or is violating the Twenty-Eight Hour Law (Section 80502 of title 49, United States Code).

FOOD SAFETY AND INSPECTION SERVICE—HORSE SLAUGHTER FACILITY INSPECTIONS

Horse slaughter does not occur in the United States due to the inclusion of annual appropriations language blocking the use of Federal funds to inspect horse slaughter facilities, thereby preventing these facilities from legally operating on U.S. soil. Before horse slaughter facilities closed in the United States, USDA itself documented horrific incidents of cruelty. Horses—which serve as companion, working, and performance animals—have a strong fight-or-flight reflex and instinctively thrash their long necks when panicked. Rendering horses unconscious prior to slaughter can be extremely difficult as stunning them often requires repeated blows to the head. In addition to well-documented animal abuse within the predatory horse slaughter industry, the consumption of horse meat presents a significant food safety concern. Horses are not raised for human consumption in the United States and are regularly administered a wide range of drugs that are expressly prohibited by the Food and Drug Administration for use in food animals.

Bill language request: Hereafter, none of the funds made available by this act or any other act may be used to pay the salaries or expenses of personnel- 1) to inspect horses under section 3 of the Federal Meat Inspection Act (21 U.S.C 603); (2) to inspect horses under section 903 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 1901 note; Public Law 104–127); or (3) to implement or enforce section 352.19 of title 9, Code of Federal Regulations (or a successor regulation).

Report language request: Nearly every year since 2005, Congress has prohibited equines from being slaughtered for human consumption in the United States by restricting the USDA's use of funds for slaughter inspections. Despite Congressional intent to shutter the horse slaughter industry through this prohibition, thousands of equines continue to be exported to foreign abattoirs annually. The Committee is deeply concerned with the welfare of American horses caught in the slaughter pipeline and the economic impacts that this practice has on the American equine community. Therefore, the Committee directs the USDA to cease all activities that allow, facilitate, or otherwise support the horse slaughter industry, including the transport or export of American equines for human consumption.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE—HORSE PROTECTION ACT
ENFORCEMENT

We appreciate Congress providing \$4.096 million in FY23 for USDA to improve enforcement of the Horse Protection Act and combat the abusive practices associated with soring. A 2010 Office of Inspector report outlined serious conflicts of interest with the industry self-monitoring system by Horse Industry Organizations on which USDA still relies. In 2021, the National Academies of Sciences, Engineering, and Medicine issued a report that echoed OIG's findings and called for an end to the industry self-policing system. But although USDA announced final regulations in 2017 to eliminate industry self-policing and institute other reforms to end soring, these widely supported regulations were frozen by the last administration. We appreciate Congress's past inclusion of language directing USDA to finalize a long overdue rulemaking that would substantially improve HPA enforcement.

Report language request: The Committee provides \$4,096,000 for enforcement of the Horse Protection Act of 1970, as amended (15 U.S.C. 1831), and reminds the Secretary that Congress granted the agency primary responsibility to enforce this law, including the training of all inspectors. The Committee urges the Secretary to issue the new proposed HPA rule expeditiously, consistent with the agency's announced intentions in December 2021, and to finalize and publish the new final rule by December 31, 2023. The Committee further urges the Secretary to ensure that the new rule includes at a minimum all the key elements of the final rule, "Horse Protection; Licensing of Designated Qualified Persons and Other Amendments" [Docket No. APHIS–2011–0009], that was finalized and displayed in advance public notice in the Federal Register on January 19, 2017.

[This statement was submitted by Dena Jones, Director, Farm Animal Program and Joanna Grossman, PhD, Equine Program Director and Senior Advisor.]

PREPARED STATEMENT OF ANIMAL WELFARE INSTITUTE

The Animal Welfare Institute, a national nonprofit animal welfare advocacy organization, respectfully asks the Committee to allocate \$500,000 for the U.S. Department of Agriculture's National Agricultural Statistics Service to expand the scope of its annual mink survey to collect and publish additional data about mink farms, and to collect data about other types of fur farms. This will increase transparency regarding the total number of animals bred and killed for fur in the U.S., and whether public safety measures are enforced to curb disease transmission.

MINK FARMS POSE A PUBLIC HEALTH RISK

Mink on fur farms incubate and transmit diseases such as COVID-19 and avian influenza, creating circumstances that threaten to worsen the current pandemic and usher in the next one. Mink pose a high risk to humans because their upper respiratory tract is exceptionally well suited to be a conduit to ours, making them effective "mixing vessels" to create novel pandemic viruses.¹ Furthermore, fur farms house mink in crowded environments that create an ideal setting for pathogens to circulate among and across species.² Wire cages are packed together and may be stacked on top of each other so that urine and excrement falls on the animals below. Given the conditions of confinement, these animals are highly stressed and thus immunocompromised, making them more susceptible to infection. The absence of legal requirements for veterinary care only compounds the problem.

Mink are highly susceptible to COVID-19, which has infected tens of thousands of mink in the U.S.³ and millions more internationally. Even more alarmingly, they are capable of passing a mutated form of the virus back to humans. Mink to human transmission of the virus has been reported in the Netherlands, Denmark, and Poland, and the U.S. Four people in Michigan were infected with a unique COVID-19 strain traced back to mink.⁴ Spillover from mink farms to humans could introduce new variants, undermining the effectiveness of vaccines and jeopardizing efforts to contain the pandemic.⁵ Like humans, mink can become infected with COVID-19 without showing symptoms, thus potentially serving as an undetected reservoir of the disease. Escapees from these farms can also transmit the virus to wild populations, potentially fostering reservoirs of the virus off the farms. In December 2020, a wild mink captured near a mink farm in Utah tested positive for a variant of COVID-19 indistinguishable from the virus found in nearby infected farmed mink—demonstrating the broader dangers posed.⁶

In addition, a deadly avian influenza virus (H5N1) infected mink on a fur farm in Spain in October 2022. Before this outbreak, the virus spread primarily through contact with infected birds, not between mammals. However, in Spain it spread from mink to mink and gained at least one mutation that favors mammal-to-mammal spread.⁷ H5N1, which has spread swiftly among birds around the world since 2020, could infect other mink farms and mutate to become transmissible between humans.⁸ Scientists are sounding the alarm on this H5N1 outbreak in Spain, calling it a "clear mechanism for an H5 pandemic to start" and "a warning bell."⁹

ANNUAL MINK FARM SURVEY

It is vital that the USDA heed the recommendations of the World Health Organization,⁹ the Food and Agriculture Organization of the United Nations,¹⁰ and other global health and food safety organizations that recommend monitoring fur farms more closely. Implementing these recommendations will require the agency to collect more data than it currently does.

There is no way to know the total number of animals bred and killed on fur farms in the U.S. each year, and there are no Federal regulations governing the operation

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7993395/>

² https://www.hsvma.org/index.php?option=com_content&view=article&id=1179:fur_riskofinfection

³ <https://www.rochesterfirst.com/news/coronavirus-confirmed-in-mink-at-oregon-fur-farm/>

⁴ <https://www.freep.com/story/news/health/2022/04/17/michigan-covid-cases-tied-to-mink-human-spillover/7338784001/>

⁵ <https://www.who.int/news/item/07-03-2022-joint-statement-on-the-prioritization-of-monitoring-sars-cov-2-infection-in-wildlife-and-preventing-the-formation-of-animal-reservoirs>

⁶ <https://www.sciencenews.org/article/covid-19-coronavirus-mink-utah-first-wild-animal-test-positive>

⁷ <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2023.28.3.2300001>

⁸ <https://www.science.org/content/article/incredibly-concerning-bird-flu-outbreak-spanish-mink-farm-triggers-pandemic-fears>

⁹ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/origins-of-the-virus>

¹⁰ <https://www.fao.org/publications/card/en/c/CB3368EN/>

of fur farms. There is little transparency regarding what, if, or how public safety measures are implemented on these farms to curb disease transmission. A small amount of data on mink farms is compiled by the USDA in an annual market report as part of its reporting on agricultural commodities.¹¹ However, no data are collected on fox, lynx, bobcat, or other animals farmed for fur.

Not only does the lack of meaningful Federal or state oversight mean that animals can be bred, housed, and killed in inhumane ways, but it also means that it is impossible to easily monitor the potential infectious diseases incubated or spread at these farms.

Thus, AWI recommends an additional \$500,000 for the National Agricultural Statistics Service to expand the scope of its annual mink survey to collect and publish additional data about mink farms, and to collect data about other types of fur farms.

Accompanying this funding, AWI urges the inclusion of a directive outlining the information to be gathered and published in this survey, including at minimum: the full contact information for all fur farm owners and operators; the address for each place of business where a fur farm conducted business; the legal descriptions of any lands upon which the fur farm conducted business; all trade names under which the fur farm conducted business; the number of individuals who worked on each farm; the number and sex of individual animals raised for fur; the source of each individual animal raised for fur; a detailed description of how the animals were transported, including the route taken, if applicable; the number of individual animals purchased, transferred, or sold and the name of each person or entity to whom or from whom such animals were purchased, transferred, or sold; a description of the size, number, and type of the fur farm's pens, cages, or other such enclosures; a description of the barrier(s) used to contain the animals raised for fur on the farm, as well as the barriers used to prevent other animals from gaining access to the farm; a description of the procedures the fur farm uses to dispose of manure, carcasses and any parts thereof; a description of the practices and procedures used by the fur farm to ensure the health and safety of farm workers, the public, and animals on and around the farm; the number of animals raised for fur that died or were killed, the cause of death, and, if killed by humans, the reason each was killed and the method used; a description of the measures the fur farm adhered to in compliance with the current American Veterinary Medical Association guidelines relevant to fur farm operations, including euthanasia and depopulation; and a description of the measures the fur farm adhered to in compliance with the latest guidelines and recommendations developed by the USDA, the CDC, and any other Federal agencies, in order to prevent the transmission of COVID-19 or other diseases to other captive furbearing animals or to wildlife, fur farm workers, and the public.

To help curb the current pandemic and to prevent the next one—we must gain a better understanding of fur farms in the U.S. Thank you for your consideration of our recommendations for how the Committee can direct the USDA to provide this information to Congress and to the public.

[This statement was submitted by Kate Dylewsky, Assistant Director of Government Affairs.]

PREPARED STATEMENT OF THE CAMPAIGN FOR CONTRACT AGRICULTURE REFORM

I am submitting this testimony on behalf of the Campaign for Contract Agriculture Reform (CCAR) regarding our fiscal year 2024 funding requests for USDA programs.

The Campaign for Contract Agriculture Reform (CCAR) is a national alliance of organizations working to provide a voice for farmers and ranchers involved in contract agriculture, as well as the communities in which they live. The member organizations of CCAR include Farm Aid, Farm and Ranch Freedom Alliance, Food Integrity Campaign, National Family Farm Coalition, National Farmers Union, National Sustainable Agriculture Coalition, R-CALF USA, Rural Advancement Foundation International and Western Organization of Resource Councils.

USDA/AGRICULTURAL MARKETING SERVICE (AMS)

Packers and Stockyards Act Oversight and Enforcement
Packers and Stockyards Program—\$35 million

We commend the Subcommittee for its strong support for Packers and Stockyards Act oversight and enforcement in the Fiscal Year 2023 Omnibus Appropriations bill,

¹¹ https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Mink/index.php

and in the preliminary Agriculture Appropriations bill and report that informed the final bill.

The Packers and Stockyard Act is a strong statute that provides broad protections for farmers against unfair, deceptive, discriminatory, and unduly preferential or prejudicial practices of livestock and poultry companies. Unfortunately, the lack of clear regulations to define the terms of the statute and provide clarity about USDA interpretation of those protections has hindered enforcement, to the detriment of poultry growers and livestock farmers and ranchers.

When the Packers and Stockyards Act (PSA) was passed in 1921, it came at a time of great concern by Americans about the concentration and related market power of meatpackers and other agricultural processors. Congress passed the PSA because it realized that while existing antitrust laws (Sherman Act, Federal Trade Commission Act, and the Clayton Antitrust Act) address mergers, acquisition, and business practices that unlawfully harm competition in the marketplace, those statutes do not address harms to individual farmers and ranchers caused by unlawful practices of powerful meatpackers and poultry companies. Indeed, the primary focus of Congress in passing the PSA and its amendments was to ensure that USDA could address meatpacker and poultry company actions that harm farmers and ranchers individually. In fact, the primary farmer and rancher protection provisions of the Packers and Stockyards Act [Section 202(a) and (b)] focus on meatpacker and poultry company harms to farmers and ranchers, without establishing any requirement for farmers or USDA to prove that those practices have also harmed competition in the marketplace broadly.

While market consolidation and the power of meatpackers in 1921 was a major impetus for Congress to pass the Packers and Stockyards Act, it's important to note that meat and poultry markets are even more consolidated now than they were in 1921. In addition, more recent vertical integration structures through poultry and hog contracting practices, and certain cattle contracting practices, have allowed those firms to shift economic risks onto the backs of the farmers and ranchers with whom they contract. The current market conditions for livestock and poultry make PSA enforcement, and the regulatory updates to support that enforcement, more important now than ever.

Therefore, CCAR is supporting the request in the President's budget for \$35 million for the Packers and Stockyards program within the Agricultural Marketing Service. We would also strongly oppose any efforts by Congress to place limitations on USDA's authority to finalize Packers and Stockyards Act regulatory updates.

In addition, CCAR requests the inclusion of the following report language to address these issues:

The Committee recognizes that consolidation in agribusiness can be detrimental to farmers, consumers, workers, and the environment. The Committee considers enforcement of the Packers and Stockyards Act a top priority and directs the Department to continue enforcing the Act to the fullest extent of the law. Further, the Committee urges the USDA Agricultural Marketing Service (AMS) and other agencies and mission areas to fully incorporate fair and competitive markets priorities across relevant programs and operations.

Thank you for the opportunity to provide this testimony about the Fiscal Year 2024 Agriculture Appropriations process.

[This statement was submitted by Steven Etko, Policy Director, Campaign for Contract Agriculture Reform]

PREPARED STATEMENT OF THE CAMPAIGN FOR FAMILY FARMS AND THE ENVIRONMENT
U.S. DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE

The Campaign for Family Farms and the Environment (CFFE) is a coalition of State and national organizations, including Dakota Rural Action, Iowa Citizens for Community Improvement, Land Stewardship Project, Missouri Rural Crisis Center, Food & Water Watch and Institute for Agriculture and Trade Policy. Our organizations work together to change policies that promote consolidation in animal agriculture at the expense of independent family farms, rural and urban economies, workers and public health.

COMPETITIVE MARKETS FOR LIVESTOCK AND POULTRY

It has been clear for decades that lack of enforcement of the Packers and Stockyards Act (PSA), along with unchecked mergers of meat and poultry companies, has

allowed large buyers to exercise extreme market power at the expense of livestock producers and contract growers. This has led to devastating changes in the structure of livestock and poultry markets around the country, and removed any chance for economic viability for many independent producers.

CFFE members have lived through this transition, particularly in hog markets, which in the 1980s offered small independent producers in the Midwest flexibility and the potential for profitability by including livestock in their farming operations. But by the mid-1990's, Midwestern farmers saw the rise of buyer power by the largest packers shift the market away from cash sales and limit or eliminate market access for smaller sellers. Producers who lived through the upheaval of the hog market collapse in the late 1990's describe how the buying stations they depended on to purchase hogs disappeared, leaving them to deal directly with very large packers who openly stated that they would pay producers with smaller herds less per head. This drove out independent producers, to be replaced with large, industrialized operations raising contracted hogs, to devastating effect for rural communities. Now, there is essentially no cash market for hogs. As a recent USDA proposed rule points out, today, "in effect, the only production/marketing choice for a hog producer is to enter a contract."¹

While structural changes in cattle markets have not yet driven independent producers completely out of the market as happened in the hog sector, the same trends are developing on a longer timeline. The USDA notes that for cattle "there are commonly only one or two buyers in some local geographic markets, and few sellers have the option of selling fed cattle to more than three or four packers."² And that "since 2005, negotiated cash trades have declined from 65 percent to about 27 percent today."³ This transition replaced cash trades with contracts and alternative marketing arrangements that not only eliminate producers' access to cash markets, but also eliminate opportunities for price discovery and create another avenue for packers to advantage some producers over others.

There are many reforms needed to address the stranglehold that a handful of multinational corporations have on each step of the livestock and protein supply chain. CFFE appreciates the committee's recognition of these issues in the FY23 funding bill with the inclusion of report language and funding for enforcement of the PSA. We urge you to continue to include following report language in fiscal Year 2024:

The Committee recognizes that consolidation in agribusiness can be detrimental to farmers, consumers, workers, and the environment. The Committee considers enforcement of the Packers and Stockyards Act a top priority and directs the Department to continue enforcing the act to the fullest extent of the law. Further, the Committee urges the USDA Agricultural Marketing Service (AMS) and other agencies and mission areas to fully incorporate fair and competitive markets priorities across relevant programs and operations.

ENFORCEMENT OF THE PACKERS AND STOCKYARDS ACT

Livestock and poultry markets are based on asymmetric information, limited or nonexistent price discovery, extreme buyer power at the regional level, and widespread retaliation and deception in many forms. To address these systemic problems, producers need a comprehensive set of regulations, along with a strategy for robust enforcement by the USDA. CFFE supports the regulatory updates and clarifications to the PSA currently being promulgated by the Agricultural Marketing Service's Packers and Stockyards Division.

In addition to providing a long overdue update to improve enforcement of the PSA, these rules will serve as an important complement to the USDA's plans to invest significant resources into new and expanded meat and poultry processing infrastructure. If the USDA does not also prioritize robust enforcement of antitrust laws to level the playing field in these markets, these investments will not create processing capacity that is economically viable in the long-term.

We oppose any efforts to interfere with the USDA's rulemaking authority and the ongoing Packers and Stockyards Act rulemakings in the appropriations process or other legislation. Additionally, we request that the Committee provide AMS with ad-

¹Agricultural Marketing Service, U.S. Department of Agriculture. Proposed Rule. "Inclusive Competition and Market Integrity Under the Packers and Stockyards Act." October 23, 2022. Federal Register. Pg. 60040.

²Agricultural Marketing Service. Pg. 60011.

³Agricultural Marketing Service. Pg. 60012.

ditional funding for Packers and Stockyards Act enforcement at the \$35 million level.

CATTLE CONTRACTS LIBRARY

We encourage the Committee to renew the Cattle Contracts Library pilot program that was first appropriated in FY23. This pilot program has just begun to provide information to producers and others, and needs more time to provide desperately needed transparency about what types of contracts are being offered by large meatpackers to cattle producers.

[This statement was submitted by Patty Lovera, Policy Advisor, Campaign for Family Farms and the Environment.]

PREPARED STATEMENT OF CENTRAL ARIZONA WATER CONSERVATION DISTRICT

On behalf of the Central Arizona Water Conservation District (CAWCD), I am writing to ask that you include \$12.2 million in the U.S. Department of Agriculture's Environmental Quality Incentives Program Financial Assistance (EQIP FA) for the Colorado River Basin Salinity Control Program in the Fiscal Year 2024 Appropriation bill. The salinity control funding under EQIP FA will help protect the water quality of the Colorado River that is used by approximately 40 million people for municipal and industrial purposes and used to irrigate approximately 5.5 million acres in the United States.

The CAWCD manages the Central Arizona Project (CAP), a multi-purpose water resource development and management project that delivers Colorado River water into central and southern Arizona. The largest supplier of renewable water in Arizona, CAP delivers up to 1.5 million acre-feet of Arizona's 2.8-million-acre-foot Colorado River entitlement each year to municipal and industrial users, agricultural irrigation districts, and Indian communities.

Our goal at CAWCD is to provide an affordable, reliable and sustainable supply of Colorado River water to a service area that includes more than 80 percent of Arizona's population.

These renewable water supplies are critical to Arizona's economy and to the economies of Native American communities throughout the state. Nearly 90 percent of economic activity in the State of Arizona occurs within CAP's service area. The canal provides an economic benefit of \$100 billion annually, accounting for one-third of the entire Arizona gross state product. CAP also helps the State of Arizona meet its water management and regulatory objectives of reducing groundwater use and ensuring availability of groundwater as a supplemental water supply during future droughts. Achieving and maintaining these water management objectives is critical to the long-term sustainability of a State as arid as Arizona.

NEGATIVE IMPACTS OF CONCENTRATED SALTS

Natural and man-induced salt loading to the Colorado River creates environmental and economic damages. EPA has identified that more than 60 percent of the salt load of the Colorado River comes from natural sources. With the significant Federal ownership in the Basin, most of this comes from federally administered lands. Human activity, principally irrigation, adds to the salt load of the Colorado River. Further, natural and human activities concentrate the dissolved salts in the River.

The U.S. Bureau of Reclamation (Reclamation) has estimated quantifiable damages at about \$354 million per year. Modeling by Reclamation indicates that damages will rise to approximately \$671 million per year by 2040 without continuation of the Program. These damages include:

- A reduction in the ability to reclaim and reuse water for beneficial uses, including drinking water and irrigation water supplies, due to high salinities in the water delivered to water treatment and reclamation facilities;
- A reduction in the yield of salt sensitive crops and increased water use to meet the leaching requirements in the agricultural sector;
- Increased use of imported water and cost of desalination and brine disposal for recycling water in the municipal sector;
- An increase in the use of water and the cost of water treatment, and an increase in sewer fees in the industrial sector;
- An increase in the cost of cooling operations and the cost of water softening, and a decrease in equipment service life in the commercial sector;

- A reduction in the useful life of galvanized water pipe systems, water heaters, faucets, garbage disposals, clothes washers, and dishwashers, and increased use of bottled water and water softeners in the household sector;
- A decrease in the life of treatment facilities and pipelines in the utility sector, and
- Difficulty in meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit terms and conditions, and an increase in desalination and brine disposal costs due to accumulation of salts in groundwater basins.

The threat of salinity continues to be a concern between the United States and Mexico. Since the agreement of Minute 242 in 1973 to the 1944 Water Treaty, the United States has taken several actions to improve the quality of water delivered to Mexico, including operating and maintaining the Main Outlet Drain Extension (MODE). More recently, on November 20, 2012, a 5-year agreement, known as Minute 319, was signed between the U.S. and Mexico to guide future management of the Colorado River. Among the key issues addressed in Minute 319 included an agreement to maintain current salinity management and existing salinity standards. The United States, Mexico, and key water users, including CAWCD, worked since 2015 to develop a successor agreement, Minute 323, which was finalized on September 27, 2017. Minute 323 continues collaboration and cooperation among the United States and Mexico with respect to salinity control in the Colorado River system. The CAWCD and other key water providers are committed to meeting these goals.

Adequate funding for salinity control will prevent the water quality of the Colorado River from further degradation and avoid significant increases in economic damages to municipal, industrial and irrigation users.

CONCLUSION

Implementation of salinity control practices through EQIP has proven to be a very cost-effective method of controlling the salinity in the Colorado River. CAWCD urges the subcommittee to include \$12.2 million from the USDA's Environmental Quality Incentive Program Financial Assistance for the Colorado River Basin Salinity Control Program in the Fiscal Year 2024 Appropriation bill. Additionally, there is needed sufficient Technical Assistance dollars to adequately implement the program. The funding level will prevent the further degradation of water quality of the Colorado River, and significantly increased damages from the higher salt concentrations to municipal, industrial and irrigation users.

[This statement was submitted by Brenda Burman, General Manager.]

PREPARED STATEMENT OF THE CENTER FOR INVASIVE SPECIES PREVENTION

The Center for Invasive Species Prevention (CISP) and the Vermont Woodlands Association (VWA) urge continued support by the subcommittee on Agriculture and related agencies for a Federal program that is key to protecting America's urban and rural forests from pest-caused mortality: the USDA Animal and Plant Health Inspection Service (APHIS). APHIS is responsible for preventing introduction and spread of pests that harm agriculture, including forests. While most port inspections are carried out by the Department of Homeland Security Bureau of Customs and Border Protection, APHIS sets the policy guidance. APHIS also inspects imports of living plants.

Program	FY 2022 (millions)	FY 2023 (millions)	FY 2024 Pres' request (millions)	Our ask (millions)
Tree & Wood Pests	\$61	\$63	\$64	\$65
Specialty Crops	\$210	\$216	\$222	\$222
Pest Detection	\$28	\$29	\$30	\$30
Methods Development	\$21	\$23	\$23	\$25

We thank you for recent incremental funding increases for these programs. We welcome the additional increases proposed by the Administration. Unfortunately, more substantial investments are needed.

Introduced pests threaten many forest products and services benefitting all Americans. These include wood products; wildlife habitat; carbon sequestration; clean water and air; storm water management; lower energy costs; improved health; aesthetic enjoyment; and jobs. Already, the 15 most damaging non-native pests threaten at least 41 percent of forest biomass in the “lower 48” States. These 15 species have caused an additional annual conversion of live biomass to dead wood at a rate similar in magnitude to that attributed to fire (5.53 TgC per year for pests v. 5.4 to 14.2 TgC per year for fire).¹

These pests also impose significant costs that are borne principally by municipal governments and homeowners. As more pests have been accidentally introduced, these costs have risen. By 2050,² 1.4 million street trees in urban areas and communities will probably be killed by introduced insect pests. High costs will be seen in Milwaukee and Madison Wisconsin; the Chicago area; Cleveland; and Baltimore, Towson, and Salisbury, Maryland. Removing and replacing these trees is projected to cost cities \$30 million per year. Additional trees in parks, on homeowners’ properties, and in urban woodlands—will also die and require removal and replacement.

Tree-killing pests are linked to the international supply chain. Many pests—especially the highly damaging wood-borers—arrive in inadequately treated crates and pallets made of wood.

Imports from Asia transport the most damaging pests, e.g., Asian longhorned beetle, emerald ash borer, redbay ambrosia beetle, and the invasive shot hole borers. U.S. imports from Asia involve an estimated 20 million shipping containers annually. At least 33,000 of these containers, perhaps twice that number,³ probably carry a tree-killing pest. If an Asian wood-boring insect that attacks maples or oaks were introduced, it could kill 6.1 million trees and cost American cities \$4.9 billion over 30 years.⁴ The risk would be highest if this pest were introduced to the South—a growing likelihood given rising direct shipments from Asia following the expansion of the Panama Canal in 2016.

Since 2006, all countries shipping goods to North America must treat their wood packaging according to specified protocols in the International Standard for Phytosanitary Measures (ISPM) #15. However, as of 2020, 0.22 percent [1/5th of 1 percent] of the shipping containers entering the U.S. were infested by a tree-killing insect.⁵ This equates to tens of thousands of containers harboring tree-killing insects.

Worse, trade partners’ compliance with the rules has deteriorated; the “approach rate” of pest-infested wood packaging fell in 2005–2006, but has since gone back up. The most troubling of offenders is China. China has been required to treat its wood packaging since December 1998. Nevertheless, in the 2010–2020 period, 0.73 percent [or 3/4 of 1 percent] of its wood packaging contained a tree-killing pest. This is three times the global average for the period. China supplied 40.7 percent of U.S. imports in 2022,⁶ (5,655,000 containers), so it alone might be sending to our shores 30,000 containers infested with tree-killing insects. These pests threaten all our forests and the ecosystem services they provide.

We suggest that the subcommittee ask APHIS what steps it will take to end China’s noncompliance. (The Department of Homeland Security’s Bureau of Customs and Border Protection has twice strengthened its enforcement of wood packaging rules. In 2017 it began penalizing importers of non-compliant wood packaging under Title 19 of the United States Code. In 2021, it incorporated the wood packaging requirements into its voluntary C–TPAC program.)

ISPM#15 per se is falling short at the global level. The presence of the mark indicating that a crate or pallet complies with ISPM#15 is not reliable. Therefore we suggest further that the subcommittee ask APHIS what steps it is taking at the global level to improve the efficacy of ISPM#15—or to replace it if necessary to ensure that pests are not being introduced.

¹Fei, S., R.S. Morin, C.M. Oswalt, and A.M. 2019. Biomass losses resulting from insect and disease invasions in United States forests. PNAS August 27, 2019. Vol. 116 No. 35 17371–17376

²Hudgins, E.J., F.H. Koch, M.J. Ambrose, and B. Leung. 2022. Hotspots of pest-induced US urban tree death, 2020–2050. *Journal of Applied Ecology*

³Haack RA, Hardin JA, Caton BP and Petrice TR (2022) Wood borer detection rates on wood packaging materials entering the United States during different phases of ISPM#15 implementation and regulatory changes. *Front. For. Glob. Change* 5:1069117. doi: 10.3389/fgc.2022.1069117

⁴Hudgins, et al. op. cit.

⁵Haack et al. op cit.

⁶Szakonyi, M. 2023. Sourcing shift from China pulls US import share to more than a decade low.

Other pests—especially plant diseases and sap sucking insects—come on imported plants. The U.S. imported about 5 billion plants in 2021.⁷ Recent introductions probably via this pathway include several pathogens—e.g. rapid ‘ohi‘a death in Hawai‘i, beech leaf disease (established from Ohio to Maine), and boxwood blight. Insects have also been introduced on imported plants recently; one example is the elm zigzag sawfly (present in North Carolina, Virginia, and New York).

In 2009,⁸ approximately 12 percent of plant shipments were infested by a pest. This pest approach rate is more than 50 times higher than the 0.22 percent approach rate for wood packaging. APHIS has adopted several changes to its phytosanitary system for imported plants in the decade since 2009. The few analyses published have not considered pathogens. We suggest that the subcommittee ask APHIS to facilitate an independent analysis of the efficacy of the agency’s current phytosanitary programs to prevent introductions of pests on important plants, with an emphasis on introductions of plant pathogens.

Once introduced, invasive pests do not stay in the cities where they first arrived. Instead, they proliferate and spread—often facilitated by movement of firewood, plants, and outdoor household goods such as patio furniture.

APHIS is responsible for preventing spread of the sudden oak death pathogen, *Phytophthora ramorum*, through trade in nursery plants. In recent years California has had few detections in nurseries and little expansion in forests—probably because the drought suppressed the fungus. This year’s very wet winter will probably lead to a new disease outbreaks. In cooler, wetter conditions in Oregon and Washington, detections in nurseries and in the forest or plantings continue.

In 2022, *P. ramorum* was detected at 18 establishments, 12 of which were first-time detections. We believe reduced funding in support for the California nursery regulatory program are unwise given the increase in outbreaks likely to result from the wet 2022–2023 winter. Oregon and Washington continue to detect infestations in additional retailers brought in by plants bought from other nurseries. Washington responded to several “trace forward” incidents, one involving more than 160 residential sites. APHIS’ program is not succeeding in eradicating *P. ramorum* from nurseries. We suggest that the subcommittee ask APHIS what steps it is taking to improve the efficacy of the SOD program.

In the East, *P. ramorum* was found in three of 65 streams sampled in 10 primarily southeastern States. Most troubling is the first-time detection in South Carolina. *P. ramorum* has now been detected from eight streams in four States, Alabama, Mississippi, North Carolina, and now South Carolina. The pathogen has been present in some of these streams for more than 10 years. Is it established?

Oregon faces particularly high risks because three of the four known genetic strains of *Phytophthora ramorum* are established in the State’s forests. This proliferation is likely to promote more aggressive infections, so exacerbating the disease. How did these three strains enter the U.S.?

Beech trees so important to wildlife conservation in the Northeast are under attack by two pathogens and at risk to an insect. Most alarming is the rapid spread of beech leaf disease from Ohio to Maine. A leaf-feeding weevil is spreading south in eastern Canada. We suggest that the subcommittee ask APHIS what steps it is taking to prevent its introduction to the U.S.

‘Ohī‘a trees make up 80 percent of the biomass of forests across the Hawaiian archipelago. They are under attack by two introduced diseases first detected in 2010. How is APHIS helping to protect these forests—so important to biodiversity and other ecosystem services, including water supplies?

APHIS FUNDING LEVELS

To respond effectively to these pests and to the others that will be introduced in coming years, the key APHIS programs identified above must have adequate funds—even in this time of budgetary constraints. For this reason, we thank the Congress for increasing funding for APHIS’ Tree and Wood Pests program to \$64 million in fiscal year 2023 and ask that you raise it to \$65 million in FY2024.

The Tree and Wood Pests account supports eradication and control efforts targeting principally the Asian longhorned beetle (ALB) and spongy (formerly gypsy) moth. Eradicating the ALB normally receives about two-thirds of the funds. The

⁷MacLachlan, M.J., A. M. Liebhold, T. Yamanaka, M. R. Springborn. 2022. Hidden patterns of insect establishment risk revealed from two centuries of alien species discoveries. *Sci. Adv.* 7, eabj1012 (2021).

⁸Liebhold, A.M., E.G. Brockerhoff, L.J. Garrett, J.L. Parke, and K.O. Britton. 2012. Live Plant Imports: the Major Pathway for Forest Insect and Pathogen Invasions of the US. *Frontiers in Ecology*.

programs in Massachusetts, New York, Ohio, and South Carolina must continue until eradication succeeds.

Oregon detected the emerald ash borer (EAB) near Portland in 2022. More than 9,000 ash trees along Portland's streets and thousands more in parks will probably die. In wetlands of the Willamette Valley, ash constitutes almost 100 percent of the forest trees. Washington and California also face risks. Indeed, the Hudgins study identified Seattle and Takoma as likely to lose thousands of ash trees. The numerous ash in riparian forests, windbreaks, and towns of North Dakota are also at risk since EAB is established in South Dakota, Minnesota, and Manitoba. We suggest that the Committee ask APHIS what it has learned from the EAB program's failure and how it will apply that lesson to other programs.

We have described failures of the Specialty Crops program to prevent spread of the sudden oak death pathogen through the interstate trade in nursery plants. We support the Administration's request for \$222 million for this program. However, we ask that the Committee ensure that APHIS allots adequate funding under this budget line to management of sudden oak death, and such new invaders as rapid 'ohi'a death in Hawai'i, and beech leaf disease and elm zig-zag sawfly in the East.

We support the Administration's request for the Pest Detection program. This program is key to the prompt detection of newly introduced pests that is critical to successful pest eradication or containment. However, we ask for a small increase for the "Methods Development" program, which enables APHIS to improve development of essential detection and eradication tools.

We note that the current \$1 million emergency fund is far below the level needed to respond when a new pest is discovered. Funding constraints have hampered APHIS' response to past pest incursions.

[This statement was submitted by Faith T. Campbell, President, Center for Invasive Species Prevention.]

PREPARED STATEMENT OF THE COLORADO RIVER BOARD OF CALIFORNIA (BOARD)

This testimony is provided by the Colorado River Board of California (Board) and is in support of Fiscal-Year 2024 funding for the U.S. Department of Agriculture (USDA) associated with those activities that assist in the implementation of Title II of the Colorado River Basin Salinity Control Act of 1974 (Public Law 93-320), as amended. This long-standing and cost-effective salinity control program in the Colorado River Basin is being carried out pursuant to the Colorado River Basin Salinity Control Act and the Clean Water Act (Public Law 92-500). Congress authorized the Colorado River Basin Salinity Control Program (Program) in 1974 to offset increased damages caused by continued development and use of the waters of the Colorado River. The USDA portion of the Program, as authorized by Congress and funded and administered by the Natural Resources Conservation Service (NRCS) under the Environmental Quality Incentives Program (EQIP), is an essential part of the overall effort. A funding level of at least \$12.2 million in EQIP Financial Assistance (FA) is required annually to prevent further degradation of the quality of the Colorado River and increased downstream environmental and economic damages.

The Board is the state agency charged with protecting California's interests and rights in the water and power resources of the Colorado River system. In this capacity, California participates along with the other six Colorado River Basin States in the Colorado River Basin Salinity Control Forum (Forum), the interstate organization responsible for coordinating the Basin States' salinity control efforts. In close cooperation with the U. S. Environmental Protection Agency (EPA) and pursuant to requirements of the Clean Water Act, the Forum is charged with reviewing the Colorado River's water quality standards every 3 years. The Forum adopts a Plan of Implementation consistent with these water quality standards. The level of appropriation being supported in this testimony is consistent with the Forum's 2020 Plan of Implementation. The Forum's 2020 Plan of Implementation can be found on this website: <https://coloradoriversalinity.org/docs/2020%20REVIEW%20Final%20percent20w%20percent20appendices.pdf>. If adequate funds are not appropriated, significant damages associated with increasing salinity concentrations of Colorado River water would become more widespread in the United States and Mexico.

The Program benefits both the Upper Basin water users through more efficient water management and Lower Basin water users through reduced salinity concentration of Colorado River water. The salinity of Colorado River waters increases from about 50 mg/L at its headwaters to more than 700 mg/L in the Lower Basin. There are very significant economic damages caused downstream by high salt levels in the water. There are also local benefits in the Upper Colorado River Basin from

the Program in the form of soil and environmental benefits, improved agricultural production, improved water efficiencies, reduced fertilizer use and labor costs, and water distribution and infrastructure improvements. Local producers submit cost-effective applications under EQIP in Colorado, Utah, and Wyoming and offer to cost-share in the acquisition of new irrigation equipment. The mix of funding under EQIP, cost-share from the Basin States and efforts and cost-share brought forward by local producers has created a most remarkable and successful partnership.

At the urging of the States and directives from Congress, NRCS recognized that the Program is different than small watershed enhancement efforts common to EQIP. In the case of Colorado River salinity control efforts, the watershed being managed stretches more than 1,400 miles from the Colorado River's headwaters in the Rocky Mountains to the Colorado River's terminus in the Gulf of California in Mexico. Each year, NRCS State Conservationists in Colorado, Utah and Wyoming prepare a 3-year funding plan for the salinity control efforts under EQIP. The Board supports this funding plan which recognizes the need for \$12.2 million in EQIP Financial Assistance (FA) allocations in fiscal Year 2024. Additionally, there is still a need for sufficient Technical Assistance (TA) dollars to adequately implement the Program.

It has been over forty-nine years since the passage of the Colorado River Basin Salinity Control Act and much has been learned about the impact of salts in the Colorado River system. Currently, the salinity concentration of Colorado River water causes about \$354 million in quantifiable damages in the United States annually. Economic and hydrologic modeling by Reclamation indicates that the quantifiable damages could rise to nearly \$671 million by the year 2040 without the continuation of the Program. For example, damages can be incurred related to the following activities:

- A reduction in the ability and increased costs to re-claim and reuse water due to high salinities in the water delivered to water treatment and reclamation facilities;
- A reduction in the yield of salt sensitive crops and increased water use to meet the leaching requirements in the agricultural sector;
- Increases in the volumes of imported water required;
- Increased costs of desalination and brine disposal for recycling water in the municipal and industrial sectors;
- A reduction in the useful life of galvanized water pipe systems, water heaters, faucets, garbage disposals, clothes washers, and dishwashers, and increased use of bottled water and water softeners in the household sector;
- An increase in the cost of cooling operations and the cost of water softening, and a decrease in equipment service life in the commercial sectors;
- An increase in the use of water and the cost of water treatment, and an increase in sewer fees in the industrial sectors;
- A decrease in the life of treatment facilities and pipelines in the utility sectors;
- Difficulty in meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit terms and conditions; and
- An increase in desalination and brine disposal costs due to accumulation of salts in groundwater basins.

The Colorado River is, and will continue to be, a major and vital water resource to the nearly 20 million residents and 860,000 acres of irrigated agriculture within southern California, including municipal, industrial, and agricultural water users in Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Diego, and Ventura Counties. The protection and improvement of Colorado River water quality through the continuation and expansion of an effective salinity control program avoids additional economic and environmental damages to Mexico, California and the other States that rely on Colorado River water resources.

Thank you for your consideration of this testimony.

[This statement was submitted by Christopher S. Harris, Executive Director, Colorado River Board of California.]

PREPARED STATEMENT OF THE COLORADO RIVER BASIN SALINITY CONTROL PROGRAM

Congress authorized the Colorado River Basin Salinity Control Program (Program) through the Colorado River Basin Salinity Control Act (Act) in 1974 to offset increased damages caused by continued development and use of the waters of the

Colorado River. Congress has directed the Secretary of Agriculture to participate in the implementation of the Program. The USDA portion of the Program, as authorized by Congress and funded and administered by the Natural Resources Conservation Service (NRCS) under the Environmental Quality Incentives Program (EQIP), is an essential part of the overall effort. A funding level of \$12.2 Million in EQIP Financial Assistance (FA) in 2024 is consistent with the Program's Plan of Implementation and is required to prevent further degradation of the quality of the Colorado River and commensurate increases in economic damages to water users.

The Program is currently funded under NRCS's EQIP and under the Bureau of Reclamation's Basinwide Program. Recognizing that agricultural improvements are some of the most cost-effective strategies, Congress passed several Acts to authorize and fund the United States Departments of Agriculture and Interior to establish a voluntary, cooperative program with irrigators to improve water management and reduce watershed erosion:

- 1984 amendment of the Salinity Control Act
- 1996 Federal Agriculture Improvement and Reform Act
- 2002 Farm Security and Rural Investment Act (FSRIA)
- 2008 Food, Conservation and Energy Act (FCEA)
- 2018 Agricultural Improvement Act

The Program, as set forth in the act, is to reduce salinity levels for the benefit of Lower Basin water users hundreds of miles downstream from the sources of salinity in the Upper Basin. EQIP is used to improve upstream irrigation efficiencies, which in turn reduces leaching of salts to the Colorado River. The Upper Colorado River Basin also benefits from the Program as it provides soil and environmental benefits, improved agricultural production, improved water efficiencies, lower fertilizer and labor costs, and water distribution and infrastructure improvements. EQIP also fosters good collaboration between farmers and ranchers, States, and the Federal Government in complying with U.S. Environmental Protection Agency mandated water quality standards. Local producers submit cost-effective applications under EQIP in Colorado, Utah and Wyoming and offer to cost share in the acquisition of new irrigation equipment. The mix of funding under EQIP, cost share from the Basin States and efforts brought forward by local agricultural producers has created a successful partnership.

This Program is different from small watershed enhancement efforts common to EQIP. The watershed to be considered stretches more than 1,400 miles from the Colorado River's headwaters in the Rocky Mountains to the Colorado River's terminus in the Gulf of California in Mexico. Each year the NRCS State Conservationists for Colorado, Utah and Wyoming prepare a 3-year funding plan for the salinity efforts under EQIP.

The State of New Mexico supports this funding plan which recognizes the need for \$12.2 M in EQIP FA allocations in fiscal Year 2024. Additionally, there is a need for sufficient EQIP Technical Assistance (TA) dollars to adequately implement the program. State and local cost sharing is triggered by the Federal appropriation. New Mexico appreciates the efforts of NRCS leadership and the support of this subcommittee in implementing the Program.

Damages to water users in the United States and Mexico, caused by the concentration of salt in the Colorado River, include:

- reduced ability to reclaim and reuse water for beneficial uses,
- reduced yield of salt sensitive crops,
- increased use of imported water and cost of desalination,
- reduced useful life of galvanized water pipe systems and appliances,
- increased use of bottled water and water softeners,
- increased cost of cooling operations and water softening,
- increased cost of water treatment,
- increased sewer fees,
- decreased lifespan of treatment facilities and pipelines,
- difficulty meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit requirements,

The State of New Mexico is a member of the Colorado River Basin Salinity Control Forum (Forum) which is composed of gubernatorial appointees from Arizona, California, Colorado, Nevada, New Mexico, Utah, and Wyoming. Every third year, the Forum adopts a Plan of Implementation consistent with efforts to facilitate compliance with the Clean Water Act. The level of appropriation requested in this testi-

mony is in keeping with the adopted Plan of Implementation. If adequate funds are not appropriated, significant damages from higher salinity concentrations in the water will be more widespread in the United States and Mexico.

NRCS personnel have developed a productive working relationship with farmers within the Colorado River Basin. Additionally, technical assistance is required for planning, design and implementation of future projects. Continued funding for the monitoring and evaluation of existing projects is essential to maintaining the salinity reduction already achieved.

New Mexico stands in support of continuation of EQIP with adequate funding levels dedicated to the Program.

[This statement was submitted by Mike A. Hamman, P.E., State Engineer.]

PREPARED STATEMENT OF THE COLORADO RIVER BASIN SALINITY CONTROL FORUM

Waters from the Colorado River are used by approximately 40 million people for municipal and industrial purposes and used to irrigate approximately 5.5 million acres in the United States. Natural and human-induced salt loading to the Colorado River creates environmental and economic damages. In 2020 the Bureau of Reclamation (Reclamation) estimated the quantifiable damages to Lower Basin water users due to elevated salinity levels at about \$354 million per year (unquantifiable damages add to this amount). Congress authorized the Colorado River Basin Salinity Control Program (Program) through the Colorado River Basin Salinity Control Act (Act) (Public Law 93-320) in 1974 to offset increased damages caused by continued development and use of the waters of the Colorado River. Modeling by Reclamation indicates that the quantifiable damages will rise to approximately \$671 million annually by the year 2040 without continuation of the Program. Congress has directed the Secretary of Agriculture to participate in the implementation of the Program. The USDA portion of the Program, as authorized by Congress and funded and administered by the Natural Resources Conservation Service (NRCS) under the Environmental Quality Incentives Program (EQIP), is an essential part of the overall effort. A funding level of \$12.2 M in EQIP Financial Assistance (FA) in 2024 is consistent with the Program's Plan of Implementation and is required to prevent further degradation of the quality of the Colorado River and commensurate increases in downstream economic damages to water users.

In enacting the Colorado River Basin Salinity Control Act in 1974, Congress directed that the Colorado River Basin Salinity Control Program should be implemented in a cost-effective way. The Program is currently funded under EQIP through NRCS and under Reclamation's Basinwide Program. Recognizing that agricultural on-farm improvements are some of the most cost-effective strategies, Congress authorized the United States Department of Agriculture (USDA) to establish a voluntary, cooperative program with irrigators to improve on-farm water management and reduce watershed erosion through amendment of the act in 1984 (Public Law 98-569). With the enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA) (Public Law 104-127), Congress directed that the Program should continue to be implemented as part of the then newly created EQIP. Since the enactment of the Farm Security and Rural Investment Act (FSRIA) in 2002, and more recent EQIP funding levels, there have been, for the first time in a number of years, opportunities to adequately fund the Program within EQIP. In 2008, Congress passed the Food, Conservation and Energy Act (FCEA) (Public Law 110-234). The FCEA amended the act to address the cost sharing requirement and established the Basin States Program (BSP). The BSP provides the mechanism for expenditure of 30 percent of the total amount spent each year by the combined EQIP and BSP effort. With the passage of the Agricultural Improvement Act of 2018 (Public Law 115-334), the authority for USDA to implement salinity control activities in the Colorado River Basin was continued.

The Program, as set forth in the act, is to benefit Lower Basin water users hundreds of miles downstream from the sources of salinity in the Upper Basin. The salinity of Colorado River waters increases from about 50 mg/L at its headwaters to more than 700 mg/L in the Lower Basin. There are very significant economic damages caused downstream by high salt levels in the water. EQIP is used to improve upstream irrigation efficiencies, which in turn reduce leaching of salts to the Colorado River. There are also local benefits in the Upper Colorado River Basin from the Program in the form of soil and environmental benefits, improved agricultural production, improved water efficiencies, lower fertilizer and labor costs, and water distribution and infrastructure improvements. Also important is the collaboration that EQIP fosters between farmers and ranchers, States, and the Federal Government in complying with U.S. Environmental Protection Agency mandated water

quality standards and the attainment of multi-benefit economic and sustainability goals. Local producers submit cost-effective applications under EQIP in Colorado, Utah and Wyoming and offer to cost share in the acquisition of new irrigation equipment. The mix of funding under EQIP, cost share from the Basin States and efforts and cost share brought forward by local agricultural producers has created a most remarkable and successful partnership.

After longstanding urgings from the States and directives from Congress, NRCS recognized that this Program is different from small watershed enhancement efforts common to EQIP. In the case of the Colorado River salinity control effort, the watershed to be considered stretches more than 1,400 miles from the Colorado River's headwaters in the Rocky Mountains to the Colorado River's terminus in the Gulf of California in Mexico. Each year the NRCS State Conservationists for Colorado, Utah and Wyoming prepare a 3-year funding plan for the salinity efforts under EQIP. The Colorado River Basin Salinity Control Forum (Forum) supports this funding plan which recognizes the need for \$12.2 M in EQIP FA allocations in fiscal Year 2024. Additionally, there is a need for sufficient EQIP Technical Assistance (TA) dollars to adequately implement the program. State and local cost sharing is triggered by the Federal appropriation. The Forum appreciates the efforts of NRCS leadership and the support of this subcommittee in implementing the Program.

Damages to water users in the United States and Mexico, caused by the concentration of salt in the Colorado River, by water usage sector, include the following:

- a reduction in the ability to reclaim and reuse water for beneficial uses, including drinking water and irrigation water supplies, due to high salinities in the water delivered to water treatment and reclamation facilities,
- a reduction in the yield of salt sensitive crops, increased water use to meet leaching requirements and additional actions necessary to comply with the Clean Water Act within the agricultural sector,
- increased use of imported water and cost of desalination and brine disposal for recycling water in the municipal sector,
- a reduction in the useful life of galvanized water pipe systems, water heaters, faucets, garbage disposals, clothes washers and dishwashers, and increased use of bottled water and water softeners in the household sector,
- an increase in the cost of cooling operations and the cost of water softening, and a decrease in equipment service life in the commercial sector,
- an increase in the use of water and the cost of water treatment, and a corresponding increase in sewer fees in the industrial sector,
- a decrease in the lifespan of treatment facilities and pipelines in the utility sector, and
- difficulty in meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit terms and conditions, and an increase in desalination and brine disposal costs necessary to minimize accumulation of salts in groundwater basins.

The Colorado River Basin Salinity Control Forum (Forum) is composed of gubernatorial appointees from Arizona, California, Colorado, Nevada, New Mexico, Utah, and Wyoming. The Forum is charged with reviewing the Colorado River's water quality standards for salinity every 3 years to facilitate compliance with Section 303(c) of the Clean Water Act (Public Law 92-500). In so doing, it adopts a Plan of Implementation consistent with these standards. The level of appropriation requested in this testimony is in keeping with the adopted Plan of Implementation. If adequate funds are not appropriated, significant damages from higher salinity concentrations in the water will be more widespread in the United States and Mexico.

Over the years, NRCS personnel have developed a productive working relationship with farmers within the Colorado River Basin. Maintaining salinity control achieved by implementation of past practices requires continuing education and technical assistance from NRCS personnel. Additionally, technical assistance is required for planning, design and implementation of future projects. Lastly, the continued funding for the monitoring and evaluation of existing projects is essential to maintaining the salinity reduction already achieved.

In summary, implementation of salinity control practices through EQIP has proven to be a very cost-effective method of controlling the salinity of the Colorado River and is an essential component to the overall Colorado River Basin Salinity Control Program. Continuation of EQIP with adequate funding levels dedicated to the Program will prevent the water quality of the Colorado River from further degradation and significant increases in economic damages to municipal, industrial and irriga-

tion users. A modest investment in source control pays huge dividends in improved water quality for nearly 40 million Americans.

[This statement was submitted by Don A. Barnett, Executive Director, Colorado River Basin Salinity Control Forum.]

PREPARED STATEMENT OF ENTOMOLOGICAL SOCIETY OF AMERICA

The Entomological Society of America (ESA) respectfully submits this statement for the official record in support of funding for agricultural research at the U.S. Department of Agriculture (USDA). ESA joins the research community and requests discretionary appropriations of at least \$2.080 billion in fiscal year 2024 for USDA's National Institute of Food and Agriculture (NIFA), including at least \$500 million for the Agriculture and Food Research Initiative (AFRI). The Society also supports a topline funding level of at least \$1.95 billion for the Agricultural Research Service (ARS) including robust funding for the ARS Crop Protection budget as well as funding to preserve valuable pest management research, invasive species programs, and pollinator health in fiscal Year 2022. Additionally, ESA supports at least \$1.188 billion for Animal and Plant Health Inspection Service (APHIS) to carry out its mission of safeguarding domestic agriculture from foreign and invasive threats.

ESA requests at least \$2.080 billion in fiscal Year 2024 for USDA's NIFA. NIFA grants support research that aims to solve national challenges in agriculture, food, the environment, and communities. One example of important NIFA grants are those that support integrated pest management (IPM). IPM is the most sustainable long-term solution to pest problems, which are a constant threat to the agriculture in the United States. U.S. farmers lose approximately 10–35 percent of their crops to pests every year, and they spent \$9 billion on pesticides (including insecticides, fungicides, and herbicides) in 2019 alone. IPM integrates multiple pest management tactics to protect crops. This integration of multiple strategies and technologies helps to minimize overuse of any one strategy, specifically pesticides, which reduces the risk of resistance development, secondary pest outbreaks, and other unintended consequences.

NIFA supports several programs that fund IPM research, and IPM is most directly supported by the Federal Crop Protection and Pest Management grant program, which was established when several budget lines were consolidated in 2014. Funding for IPM took dramatic cuts in the amount of more than \$63 million during that consolidation and has remained static for many years. Continued investment in IPM Infrastructure is vital for protecting U.S. agricultural production to safeguard U.S. agricultural industry and food supply.

ESA requests at least \$500 million for AFRI in fiscal Year 2024. As NIFA's premier competitive research program, AFRI funds a wide range of agricultural research, education, and extension projects at universities and research institutions nationwide. To maximize its resources, AFRI supports projects that address key societal challenges and build foundational knowledge in high-priority areas of the food and agricultural sciences. For example, with AFRI funding, scientists based at Iowa State University tested how small strips of prairie grasses could be integrated into corn and soybean fields in the Midwest to advance ecosystem services with minimal impacts on crop production.¹ They found that the integration of prairie grass reduced nutrient runoff and soil erosion while increasing the abundance and diversity of bees, without significant loss in agricultural productivity. This work has been foundational across multiple disciplines, and the technique was included as a conservation practice supported by the Farm Bill in 2018.

Another critical function of the AFRI program is to fund timely research on human nutrition. For example, AFRI supported a study at Virginia Polytechnic Institute focused on determining the protein content and structure of black soldier fly larvae as a potential alternative protein source.² Continued funding of work like this can help clarify the potential role insects can play in food security for direct human consumption or for livestock feed.

ESA supports at least \$1.95 billion for ARS and maintaining strong funding levels for the Crop Protection and Crop Production accounts. As USDA's intramural research agency, ARS funds research with a direct impact on our Nation's agriculture enterprise, including in the areas of crop and livestock production and protection, human nutrition, food safety, and environmental stewardship. For example, the Brazilian peppertree is a highly invasive plant that obstructs restoration efforts in

¹ <https://app.dimensions.ai/details/grant/grant.8819440>

² <https://doi.org/10.3390/insects1112087>

Everglades National Park.³ Recently, ARS scientists collaborated with the University of Florida and Florida Department of Food and Consumer Services to test the potential of Brazilian peppertree thrips, natural predators, as a cost-effective and environmentally friendly method to control these invasive trees and found that these insects are a viable solution.⁴

ESA supports APHIS's mission to safeguard the Nation's agricultural enterprise and native ecosystems and requests support for APHIS in fiscal Year 2024 of at least \$1.188 billion in discretionary funding, in line with the fiscal Year 2024 President's Budget Request. APHIS plays a critical role in protecting domestic soils from foreign threats in the form of invasive species. Invasive insect pests are some of the most costly and troublesome challenges faced by farmers, homeowners, and others, and APHIS is tasked with preventing their entry into the country, an increasingly challenging task considering increasing rates of trade, human movement, and climate change. Only a tiny fraction of cargo coming in through ports and planes are screened. While data-driven methods for prioritizing shipment inspections based on statistical risk are improving the odds of intercepting invasive pests in international cargo, the capacity for international cooperation on pre-border, border, and post-border inspection and response must be expanded and improved. Furthermore, remote sensing could play a significant role in increasing early detection and rapid response (EDRR) to invasive pests, but it is virtually absent in insect pest management. APHIS would benefit from a program dedicated to EDRR for emerging threats. This would include an additional \$25 million on top of the \$75 million authorized in the 2018 Farm Bill for a program focused on responding to emerging invasive threats via EDRR at a high level, rather than a threat-specific line item, giving APHIS the flexibility and discretion to respond as new threats emerge.

In addition to responding to new threats, ESA supports APHIS's continued research on known and destructive invasive pests including the khapra beetle, which poses a threat to global food security and which is not easily controlled with conventional techniques.^{5,6} APHIS researchers identified a new attractant for use in traps for the monitoring and surveillance of the beetle, which led to the filing of a patent and an important public-private partnership to improve trapping and monitoring of the khapra beetle.⁷

ESA also supports increased funding for research on pollinator populations. Insects that play a role in pollination are vital to our Nation's agriculture industry. Honeybees alone pollinate more than 100 crops in the U.S. and are essential to produce an estimated one-third of all the food we eat or export. To ensure a healthy pollinator population, more research is needed to examine the diverse factors that endanger their health. ESA appreciates the establishment of the Honeybee and Pollinator Research Coordinator position in the 2018 Farm Bill. To this end, ESA supports USDA's coordination of multi-agency activities through the Office of the Chief Scientist to further investigate pollinator health and develop implementation plans to prevent pollinator population decline.

ESA, headquartered in Annapolis, MD, is the largest organization in the world serving the professional and scientific needs of entomologists and individuals in related disciplines. Founded in 1889, ESA is a non-partisan professional organization with over 7,000 members affiliated with educational institutions, health agencies, private industry, and government. Members are researchers, teachers, extension service personnel, administrators, marketing representatives, research technicians, consultants, students, pest management professionals, and hobbyists. Thank you for the opportunity to accept the Entomological Society of America's support for USDA research programs. For more information about the Entomological Society of America, please see <http://www.entsoc.org/>

[This statement was submitted by Marianne Alleyne, Ph.D., President, Entomological Society of America.]

PREPARED STATEMENT OF ENVIRONMENTAL AND ENERGY STUDY INSTITUTE

Thank you for the opportunity to submit written testimony for the record in support of programs under the subcommittee's jurisdiction that support climate change

³ <https://agris.fao.org/agris-search/search.do?recordID=US201600024952>.

⁴ <https://bioone.org/journals/florida-entomologist/volume-105/issue-3/024.105.0308/Release-and-Persistence-of-the-Brazilian-Peppertree-Biological-Control-Agent/10.1653/024.105.0308.full>.

⁵ <https://portals.iucn.org/library/sites/library/files/documents/2000-126.pdf>

⁶ https://fmipa.umri.ac.id/wp-content/uploads/2016/03/Amalendu_Chakraverty_Arun_S.-Mujumdar_HosahalliBookFi.org-.pdf.

⁷ <https://link.springer.com/article/10.1007/s10340-019-01171-z>.

mitigation and adaptation. Specifically, our testimony highlights the need for at least \$26 million for the Rural Energy Savings Program (RESP) in Fiscal Year 2024.

The Environmental and Energy Study Institute (EESI) is a non-profit organization founded in 1984 on a bipartisan basis by members of Congress to help educate and inform policymakers, their staff, stakeholders, and the American public about the benefits of a low-emissions economy that prioritizes energy efficiency, renewable energy, and new clean energy technologies.¹ In 1988, EESI declared that addressing climate change is a moral imperative, and that has since guided our work. More recently, we have also developed a program to provide technical assistance to rural utilities interested in on-bill financing programs for energy efficiency, renewable energy and storage, and beneficial electrification for their customers.

RESP, administered by the U.S. Department of Agriculture (USDA) Rural Utilities Service (RUS), was first authorized in the 2014 Farm Bill.² RESP provides zero-interest loans to electric cooperatives, state financing entities, green banks, and others to establish or expand residential and small business energy efficiency improvement programs. These programs offer rural households and small businesses no- or low-cost financing for cost-effective energy efficiency, renewable energy, and electrification improvements. These improvements are made at no upfront cost and repaid over time via a utility bill line-item.³ On average, these improvements cost between \$5,000 to \$15,000—an investment otherwise out of reach for many Americans, particularly in rural areas where families pay on average 40 percent more of their income for energy compared to their urban counterparts.

RESP loans are leveraged, so each dollar of Federal appropriations facilitates zero-interest loans worth much more. But higher interest rates mean the credit subsidy mechanism used by RUS results in less leverage than before. An increase in appropriations in FY2024 is necessary to keep RESP at a constant level of lending authority, which also sends a message of certainty and confidence to prospective borrowers.

The demand for RESP loans remains strong. RUS has awarded almost \$290 million in RESP loans.⁴ USDA plays a key role in efforts to help drive economic growth and create jobs in rural communities, and robust funding for RESP in FY2024 is critical to ensure low-income families can enjoy the benefits of energy efficiency and clean energy improvements.

The benefits of RESP are wide-ranging. For many families and small businesses that ultimately receive the funds, they immediately realize lower energy bills from insulation, air sealing, and new heating and cooling equipment. Some RESP-funded programs also finance distributed renewable energy generation, energy storage, electric vehicle supply equipment, irrigation improvements, and more—provided that improvements can be shown to be cost-effective to the end user.

These investments all have the added benefits of resource conservation and, by lowering consumption and replacing fossil fuel with renewable sources to generate electricity, greenhouse gas emissions reductions. RESP also helps finance the last stretch of broadband infrastructure from the main line, which increases the number of households able to benefit from smart thermostats and other grid-enabled devices. Many RESP-funded programs are designed so financing for cost-effective improvements is accessible to all end-users regardless of income or credit, which helps provide a more equitable distribution of benefits.

Moreover, when implementing RESP programs, electric cooperatives and other eligible entities support local jobs implementing these improvements. The energy efficiency sector by itself accounted for about 2.2 million jobs in 2021, according to the U.S. Energy and Employment Report.⁵ Clean energy businesses contribute to local economic development and provide workers with new training opportunities, which are often too few in rural communities that disproportionately suffer from persistent poverty and high energy burdens.

Thank you for your consideration.

[This statement was submitted by Daniel Bresette, President, Environmental and Energy Study Institute.]

¹ About Us, <https://www.eesi.org/about>.

² Rural Energy Savings Program, <https://www.rd.usda.gov/programs-services/electric-programs/rural-energy-savings-program>.

³ On-Bill Financing Project, <https://www.eesi.org/obf/main>.

⁴ Rural Investments in Program Areas, <https://www.rd.usda.gov/rural-data-gateway/rural-investments/program-areas>.

⁵ 2022 U.S. Energy and Employment Report Fact Sheet, https://www.energy.gov/sites/default/files/2022-06/USEER_percent202022_percent20Fact_percent20Sheet_0.pdf.

PREPARED STATEMENT OF FOOD INDUSTRY ASSOCIATION

FMI—The Food Industry Association works with and on behalf of the entire food industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain—from retailers who sell to consumers, to producers who supply the food, as well as the wide variety of companies providing critical services—to amplify the collective work of the industry. The reach and impact of our industry is extensive, ultimately touching the lives of over 100 million households in the United States and representing an \$800 billion industry with nearly 6 million employees.

In one of the final rulemaking actions to implement a relatively narrow provision of the *Food Safety Modernization Act (FSMA)* passed by Congress, the Food and Drug Administration (FDA) issued an incredibly complex final rule—the Food Traceability Rule—in November 2022, more than 10 years after FSMA passage (signed into Public Law on January 4, 2011). The legislation contained a much simpler and streamlined provision targeting a small number of “high-risk” foods. However, the rulemaking is 596 pages in length and the justification for determining which foods are designated as “high-risk” is over 100 pages in length—certainly challenging for any small business to confront and attempt to comply with. While the list of foods FDA determined should be included in this high-risk category, and thus subject to a 2-year recordkeeping requirement, is not yet defined at the food product level, the food and ingredient categories determined by an algorithm include foods like cream cheese that should never be on a high-risk list.

This action by FDA followed the publication of a proposed rule in 2021 seeking comments from stakeholders. FMI, along with other industry stakeholders, submitted substantial comments outlining concerns with the scope and magnitude of the proposed rule, along with the unrealistic product level tracking provisions and lengthy record keeping requirements being proposed. FMI also asked FDA to publish a supplemental rule (as was done with most other FDA rules to implement provisions of the Food Safety Modernization Act), yet FDA moved forward with the final rule.

Ultimately, FDA made very few modifications or changes from the proposed rule to address the concerns raised by FMI and other industry stakeholders. While the traceability rule was intended to focus on only “high risk” foods as authorized by a very narrow provision of the FSMA law, FDA has morphed this provision into an expansive “food traceability list” that now includes more than two dozen categories of foods and food ingredients. Thus, the list of food products subject to this new traceability requirement will number in the tens of thousands, and even FDA hasn’t been able to establish a comprehensive list of products they expect to be traced.

The original intent of the legislative provision was to target truly “high risk” food products that have experienced challenging food safety concerns and product recalls. The result of this final rule is to burden the entire food supply chain with an unworkable product tracing requirement, where no current technology is in practice to accomplish this. Furthermore, the rule will produce massive amounts of records that our industry members will have to maintain for 2 years, and that FDA likely cannot even effectively utilize in a timely manner.

This rule is entirely reactive rather than focusing on proactive, preventative food safety measures, which is the focus of the food industry and should be FDA’s focus. This rule will bring significant costs to the entire U.S. food supply and delivery system and does not include a single ingredient contained in the infant formula recall that demanded so many FDA and industry resources and caused so many consumer challenges this past year.

As a result of these issues and concerns surrounding the final Food Traceability rule, FMI is requesting the subcommittee’s consideration of bill and report language in the fiscal Year ‘24 Agriculture Appropriations bill to require FDA to take additional actions and steps before implementing or enforcing compliance with the final, 596-page rule. The proposed language below is needed to require FDA to identify what technology can feasibly be used by industry to meet the requirements of the rule, and to develop the complete list of the thousands of products they intend to be traced. Until FDA can take these steps, the Agency should not be allowed to implement or enforce the Food Traceability rule.

The requested bill language and report language are outlined below.

Proposed Bill Language:

No funds appropriated by this act may be used to implement, administer, or enforce the requirements of the Final Rule “Requirements for Additional Traceability Records for Certain Foods” (21 CFR Part 1 Subpart S) until the U.S. Food and Drug Administration provides a comprehensive, electroni-

cally downloadable list of each food product subject to the rule; and submits a report to this Committee identifying the low-cost technology available to maintain lot code information for foods subject to the rule.

Proposed Report Language:

The Committee directs the Food and Drug Administration, before implementing or enforcing the compliance requirements of the Final Rule "Requirements for Additional Traceability Records for Certain Foods" (21 CFR Part 1 Subpart S) to: develop a comprehensive, electronically downloadable list of each food product subject to the rule; submit a report to this Committee identifying the low-cost technology solutions currently available to maintain lot code information for foods subject to the rule; and publish a protocol detailing consistent investigation practices the Agency will use to respond to food borne illness and outbreak investigations.

On behalf of FMI, we appreciate your consideration of this important request for our industry members. Please let us know what additional information we can provide that would be helpful and any questions we can answer. We look forward to working with you and your colleagues on this and other important priorities for the U.S. food and agriculture industry.

Thank you,



Jennifer Hatcher
Chief Public Policy Officer &
Senior Vice President, Government Relations
FMI—The Food Industry Association

PREPARED STATEMENT OF HALEON

Haleon appreciates the opportunity to submit written testimony to the Senate Committee on Appropriations subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. Haleon is a world-leading consumer health company with a clear purpose to deliver better everyday health with humanity. Haleon is committed to developing over-the-counter solutions to assist those who seek to decrease or end their tobacco use. We respectfully request the subcommittee to support innovation in new tobacco cessation products through the inclusion of the report language provided below.

Smoking and other forms of tobacco use continue to be major risks to public health. According to the Centers for Disease Control and Prevention (CDC), cigarette smoking remains the leading cause of preventable disease, disability, and death in the United States, accounting for more than 480,000 deaths every year, or about 1 in 5 deaths. In 2020, nearly 13 of every 100 U.S. adults aged 18 years or older (12.5 percent) currently smoked cigarettes. This means an estimated 30.8 million adults in the United States currently smoke cigarettes. More than 16 million Americans live with a smoking-related disease. Although cigarette smoking has declined significantly since 1964, disparities in tobacco use remain across race, ethnicity, educational level, and socioeconomic status. In addition, the most recent Annual National Youth Tobacco Survey raises significant concerns that 14.1 percent (2.14 million) of high school students and 3.3 percent (380,000) of middle school students reported current e-cigarette use.

Given the inherent health risks from smoking and vaping, there is a need to promote and improve cessation among adults and adolescents. Fortunately, there are proven tools and methods for decreasing tobacco use, including nicotine replacement therapy (NRT) and counseling. Studies have shown that combining these two strategies is the best way to quit. Haleon is supportive of all efforts to reduce and prevent tobacco consumption and decrease dependence on nicotine.

Haleon maintains a steadfast commitment to provide safe and effective over-the-counter (OTC) solutions for consumers looking to live a healthier life. Millions of Americans rely on safe and effective NRT products, which can come in forms like lozenges, patches, gum, and inhalers. We are working to expand access to these products, including through State quitlines; many of which can provide NRT products for free.

Haleon recognizes the public health imperative for innovation in bringing new tobacco cessation products to market; however, we have concerns that the Food and Drug Administration's approach to OTC NRT products is hindering, rather than facilitating, their development and approval. We continue to develop—and are seeking to bring to the U.S. market—other options.

We respectfully request the subcommittee to include the following report language for the Food and Drug Administration regarding NRT products in the FY2024 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies spending bill:

Ensuring Innovation to combat youth smoking trends.—The Committee appreciates the Food and Drug Administration (FDA)'s efforts to combat youth smoking. The Committee, however, is alarmed by the findings from the most recent Annual National Youth Tobacco Survey, which indicate that 14.1 percent (2.14 million) of high school students and 3.3 percent (380,000) of middle school students reported current e-cigarette use. The same study also found that nearly 85 percent of current users preferred flavored e-cigarettes, with fruit flavors being the most popular, followed by candy, desserts, or other sweets. Given these concerning findings, coupled with the ongoing morbidity and mortality burden caused by tobacco use, the Committee directs the FDA, no later than March 2024, to report to the Committee on agency efforts undertaken within the last five calendar years to facilitate the development of new consumer-oriented smoking cessation products to help reduce tobacco and e-cigarette use. Further, the FDA is directed to convene the Nonprescription Drugs Advisory Committee, the Psychopharmacologic Drugs Advisory Committee, and the Tobacco Products Scientific Advisory Committee to discuss ways to expand over-the-counter and prescription options for tobacco cessation.

Haleon believes additional safe and effective over-the-counter NRT offerings are critical to help millions of Americans quit the harmful and costly impact of tobacco and nicotine use. We urge Congress and the FDA to make progress in the Nation's battle against the leading cause of preventable disease, disability, and death in the United States. We thank you for the opportunity to submit written testimony for the record.

[This statement was submitted by Elizabeth Brewer, MS, MPH, Head of U.S. Government Affairs.]

PREPARED STATEMENT OF THE HUMANE SOCIETY LEGISLATIVE FUND AND HUMANE SOCIETY

FDA/REDUCING ANIMAL TESTING AND ADVANCING NONANIMAL METHODS

We request no less than the fiscal Year 2023 level of \$5 million for the New Alternative Methods Program and report language: “The Committee directs FDA to efficiently and expeditiously utilize existing funds to reduce animal testing and advance alternative nonanimal methods in a measurable and impactful way. The agency is further directed to provide a report to the Committee within 90 days of enactment that provides details on the status of forming the New Alternative Methods Program in the Commissioner's office, including but not limited to a description of program goals and staffing levels by position classification; FDA's priority areas for reducing animal use and advancing nonanimal alternatives, including goals, timelines and funding associated with each of these identified priorities; the metrics the agency will use to measure impact; and how the agency will communicate information regarding acceptance of nonanimal alternative methods to the regulated community. The agency should not use funding to carry out new animal testing, including to evaluate the predictive capacity of the nonanimal alternative methods, but instead use human data or existing animal data. The Committee is also aware that the regulated community lacks certainty as to when nonanimal methods will be accepted in lieu of animal testing for safety and efficacy testing, which serves as a barrier to implementation of such alternative methods in the industry. To combat this, the Committee directs FDA to clarify the acceptance of new approach methodologies (NAMs) in its regulations and related guidance documents where appropriate, communicate up-to-date information about NAMs acceptance on the agency's website, remove outdated guidance, and proactively communicate with stakeholders on NAMs acceptance for regulatory use. Along with these updates, the Committee directs FDA to prioritize and incentivize the development, use and regulatory acceptance of NAMs.”

We seek to ensure FDA's judicious and impactful use of funding to reduce animal testing and advance alternative methods, and request details related to these efforts. Non-animal approaches include cell cultures, computer modeling, and other

methods that are often faster, cheaper and more predictive of human health than animal tests. In FY23 Congress directed FDA to report on its progress regarding reliability, reproducibility and development related to new alternative methods and the evaluation of the methods with which FDA is involved. FDA regulations and guidance documents acknowledge that FDA has the authority and flexibility to accept NAMs for safety and efficacy testing but in some areas emphasize animal testing that suggests it is mandatory for all new drug applications. This lack of clarity and internal consistency serves as a barrier to the adoption and use of NAMs. The FDA should clarify the acceptance of NAMs in the appropriate regulations and related guidance documents, communicate up-to-date information about NAMs acceptance on the agency's website, remove outdated guidance, and proactively communicate with stakeholders on NAMs acceptance for regulatory use.

FSIS/HORSE SLAUGHTER

We request bill language permanently barring USDA from expenditure of funds for horse slaughter inspections: "None of the funds made available by this or any other act in this or any fiscal year hereafter, may be used to pay the salaries or expenses of any person or personnel- (1) to inspect horses under section 3 of the Federal Meat Inspection Act (21 U.S.C. 603); (2) to inspect horses under section 903 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 1901 note; Public Law 104-127); or (3) to implement or enforce section 352.19 of title 9, Code of Federal Regulations, or any other regulation concerning the inspection of slaughter horses."

This provision is vital to prevent renewed horse slaughter activity in this country and wasting tax dollars on a practice that 83 percent of the American public opposes as inherently cruel and posing serious public health risks.

OFFICE OF THE SECRETARY/CAGE-FREE AND CRATE-FREE HOUSING CONVERSION

We request report language: "The cage-free egg and gestation crate-free pork market continues to expand due to demand by consumers and food corporations as well as state laws requiring in-state farmers to convert to cage-free or gestation crate-free facilities. Producers may increase their long-term income when they are able to convert to cage-free and crate-free facilities to better meet these demands. The Committee directs the Secretary to continue helping egg and pork farmers address the economic opportunities associated with cage-free and gestation crate-free housing. In order to meet the needs of this effort, the Secretary is encouraged to submit a reprogramming of funding to the Committee."

Due to an increase in consumer awareness surrounding animal welfare and food safety concerns in our agricultural systems, more than 200 companies are demanding a 100 percent cage-free egg supply including McDonald's, Walmart, Kroger, Denny's, and IHOP. Eleven States have passed laws banning cages for egg laying hens, and eight of those States require that eggs sold within their state borders are cage-free. There is also surging demand from major pork buyers like Kroger, Target, Burger King, Costco, and dozens of others for pork produced without the use of gestation crates that keep sows in space so tight they cannot turn around. Ten States have laws banning or restricting the use of gestation crates. Some producers, however, have been hesitant to make the switch to cage-free and crate-free systems because of the initial costs to convert to these systems. USDA data shows that more than 100 million hens are cage-free (36 percent of the U.S. egg flock), and according to the National Pork Producers Council, 38 percent of sows are raised in groups at least part of their pregnancy. Federal support on the upfront conversion costs would help producers make the shift, bolstering animal welfare and helping the egg and pork industries take advantage of the expanding cage-free and crate-free market. In addition to humane concerns, this is a food safety issue because studies have shown that cage egg operations are significantly more likely to harbor Salmonella than cage-free facilities. Meanwhile, leading food safety groups have identified serious concerns about pork from facilities that confine breeding sows in gestation crates.

APHIS/ANIMAL WELFARE ACT (AWA) ENFORCEMENT

We request bill language: "The Secretary shall ensure that appropriate enforcement action in the form of penalties or case referral to the Office of General Counsel or the Department of Justice or both is taken when a regulated facility violates the Animal Welfare Act (7 U.S.C. 2131-2159) as documented on an inspection report, with due consideration to the appropriateness of the penalty with respect to the size of the business of the person involved, the gravity of the violation, the person's good faith, and the history of previous violations, as provided in 7 U.S.C. Section 2149(b). The Secretary shall ensure that any interference with or failure to allow access for

an inspection under the Animal Welfare Act, 7 U.S.C. Sections 2131–2159, is documented on an inspection report. The Secretary shall ensure that all dealers selling dogs, cats, and other covered animals online have the necessary license pursuant to Animal Welfare Act, 7 U.S.C. Sections 2131–2159, as required under 78 Fed. Reg. 57227. The Secretary of Agriculture shall enter into a memorandum of understanding with the U.S. Attorney General to encourage greater collaboration on Animal Welfare Act enforcement and ensure that the Department of Justice has access to evidence needed to initiate cases.”

Report language: “Case Referrals for Animal Welfare Act (AWA) Violations.-The Committee is concerned that USDA is not fully utilizing its enforcement capabilities, particularly for chronic violators of the AWA. There has been an overall decline in AWA enforcement since 2010 when USDA initiated 874 cases and 74 stipulated penalties. By 2021, enforcement dropped to 262 initiated cases of which 18 resulted in settlements and 17 with administrative orders. The Committee directs USDA to use its full enforcement capabilities under the AWA including referring cases to the Office of General Counsel, the Department of Justice or both, when appropriate according to the factors the agency must consider under 7 U.S.C. Section 2149(b).”

USDA is responsible for ensuring compliance with AWA standards at 16,853 sites currently, including commercial breeding facilities, laboratories, zoos, circuses, and airlines. We are concerned with the agency’s inadequate enforcement in recent years. In fiscal Year 2022, USDA initiated 262 cases against AWA licensees, resulting in 204 warnings, 18 settlements, and 17 administrative orders. Seven licenses were suspended or revoked. While this was more than the previous 5 years, overall there has been a decline in AWA enforcement since 2010, when USDA initiated 874 cases, with 74 stipulated penalties. APHIS should improve enforcement activity, especially by initiating more significant penalties, and work more with local law enforcement and the Department of Justice.

APHIS/HORSE PROTECTION ACT (HPA) ENFORCEMENT

We request no less than \$4,096,000 (FY 2023 level) in the bill and report language: “The Committee provides \$4,096,000 for enforcement of the Horse Protection Act of 1970, as amended (15 U.S.C. 1831), and reminds the Secretary that Congress granted the agency primary responsibility to enforce this law, including the training of all inspectors. The Committee urges the Secretary to issue the new proposed HPA rule expeditiously, consistent with the agency’s announced intentions in December 2021, and to finalize and publish the new final rule by December 31, 2023. The Committee further urges the Secretary to ensure that the new rule includes at a minimum all the key elements of the final rule, “Horse Protection: Licensing of Designated Qualified Persons and Other Amendments” [Docket No. APHIS–2011–0009], that was finalized and displayed in advance public notice in the Federal Register on January 19, 2017.”

APHIS/PROTECTING ANIMALS WITH SHELTER (PAWS) IMPLEMENTATION

We request \$3,000,000 in the bill for PAWS grants and report language: “The Committee directs the Secretary of Agriculture to continue coordinating with the Departments of Justice, Housing and Urban Development, and Health and Human Services to efficiently implement the grant program for providing emergency and transitional shelter options for domestic violence survivors with companion animals.”

FSIS/HUMANE METHODS OF SLAUGHTER ACT (HMSA) ENFORCEMENT

We request language to strengthen HMSA enforcement. Bill: “No fewer than 165 full-time equivalent positions shall be employed during fiscal year 2024 for purposes dedicated solely to inspections and enforcement related to the Humane Methods of Slaughter Act. This number is in addition to the Humane Handling Enforcement Coordinator and District Veterinary Medical Specialist positions.” Report: “FSIS shall ensure that all inspection personnel conducting humane handling verification procedures receive robust initial training and periodic refresher training on the FSIS humane handling and slaughter regulations and directives. This includes handling of non-ambulatory disabled animals, as well as proper use of the Humane Activities Tracking System to ensure humane handling of animals as they arrive and are offloaded and handled in ante-mortem holding pens, suspect pens, chutes, stunning areas, and on the processing line. The Committee directs the agency to continue preparation and online publication of the Humane Handling Quarterly Reports, to include: (1) the number of humane handling verification procedures performed, (2) the number of administrative enforcement actions taken, (3) time spent on Humane Handling Activities Tracking System activities, and (4) comparisons of

these measurements by plant size and FSIS district. The Committee recognizes that the humane handling of birds at slaughter according to Good Commercial Practices (GCPs) reduces the occurrence of adulterated poultry products in the marketplace and can improve the treatment of birds at slaughter. The Committee awaits the Department's briefing requested in the fiscal year 2022 and 2023 reports on documented instances where establishments lost control of their processes for handling birds, and consequently were not operating in accordance with GCPs. Further, the Committee directs the USDA to track the number of inspector hours spent on GCP verification activities intended to reduce instances of adulteration using its existing Humane Activities Tracking System or other appropriate method."

OIG/ANIMAL FIGHTING ENFORCEMENT

We request report language: "The Committee is concerned about illegal animal fighting activity that subjects animals to cruel conditions and has the potential to spread illnesses such as virulent Newcastle disease and avian flu. The OIG is encouraged to increase its efforts to pursue animal fighting cases even if related concerns, such as money laundering and illegal weapons, have not yet been determined to be at issue before an investigation is opened. OIG is also encouraged to work with USPS and DOJ to examine the prevalence of the illegal shipment of game-fowl used in cockfighting. The Committee also encourages the OIG to audit and investigate USDA enforcement of the Animal Welfare Act and the Horse Protection Act to help improve compliance with these important laws. This should include finalizing the reopening of the audit on the Animal Care Program Oversight of Dog Breeders to allow completion of in-person visits. Additionally, the Committee is concerned about the lack of meaningful enforcement of the AWA and HPA and requests that these audits should also examine what barriers exist to full enforcement of both Acts, and what if any steps can be taken within APHIS' Animal Care and Investigative and Enforcement Services programs to ensure that the regulated community is held accountable for violations of these Acts."

NIFA/NATIONAL VETERINARY MEDICAL SERVICES ACT

We request \$10,500,000 for the Veterinary Medicine Loan Repayment Program (Public Law 108-161).

APHIS/EMERGENCY PREPAREDNESS AND RESPONSE/ANIMAL CARE

We request \$1,450,000 for Animal Care to assist in addressing animal issues in disasters.

We appreciate the Committee's prior support of animal welfare issues, and hope you are able to accommodate these requests to better address the critical issues that impact millions of animals.

[This statement was submitted by Mimi Brody, Director of Federal Affairs, Humane Society Legislative Fund.]

PREPARED STATEMENT OF HUMANE SOCIETY OF THE UNITED STATES

On behalf of the undersigned horse industry, veterinary, and animal welfare organizations, we submit the following testimony seeking funding of not less than \$4,096,000 and language for the USDA/APHIS Horse Protection Program, for fiscal Year 2024. We appreciate that Congress provided \$4,096,000 in fiscal Year 2023 for USDA to strengthen enforcement of the Horse Protection Act. An FY24 appropriation of no less than that amount is urgently needed as we seek to fulfill the intent of the Horse Protection Act—to eliminate the cruel practice of soring—by allowing the USDA to further strengthen its enforcement capabilities for this law.

We urge you to include the following report language: "The Committee provides \$4,096,000 for enforcement of the Horse Protection Act of 1970, as amended (15 U.S.C. 1831), and reminds the Secretary that Congress granted the agency primary responsibility to enforce this law, including the training of all inspectors. The Committee urges the Secretary to issue the new proposed HPA rule expeditiously, consistent with the agency's announced intentions in December 2021, and to finalize and publish the new final rule by December 31, 2023. The Committee further urges the Secretary to ensure that the new rule includes at a minimum all the key elements of the final rule, "Horse Protection; Licensing of Designated Qualified Persons and Other Amendments" [Docket No. APHIS-2011-0009], that was finalized and displayed in advance public notice in the Federal Register on January 19, 2017."

In January 2017, the USDA announced final regulations to eliminate industry self-policing and institute other reforms needed to end soring. These rules (Docket

No. APHIS–2011–0009) received over 100,000 public comments in support, including bipartisan letters signed by 182 Representatives and 42 Senators. Unfortunately, the regulations were withdrawn soon after.

In January 2021, the National Academies of Sciences, Engineering, and Medicine (NASEM) issued a report that criticized the industry self-policing system, urging that only veterinarians be allowed to inspect the horses and making recommendations consistent with the 2017 regulations. The report called for greater use of technologies such as thermography, prohibited substance testing, and blood testing, as well as urging that only veterinarians be allowed to inspect the horses. These recommendations depend on adequate agency resources. With current funding, Animal Care was only able to attend approximately 18 percent of the 229 HPA events held in fiscal Year 2022.

In December 2021, the USDA announced plans to propose a new and improved HPA rule to take into account the NASEM findings. We were pleased that the agency stated its intention to issue the new rule expeditiously and identified this as a top regulatory priority.

More than 50 years ago, Congress passed the Horse Protection Act in 1970 to end soring, the intentional infliction of pain on the hooves and legs of a horse to produce an exaggerated gait in the “Big Lick” segment of the Tennessee Walking Horse show industry. Caustic chemicals—such as mustard oil, diesel fuel, and kerosene—are painted on the horse’s lower front legs. Then the legs are wrapped for days in plastic wrap and bandages to “cook” the chemicals deep into the flesh, making the horse’s legs extremely painful and sensitive. When ridden, the horse is fitted with chains that slide up and down the sore legs, forcing the animal to produce an exaggerated, high-stepping gait in the show ring. Additional tactics include inserting foreign objects such as hard acrylic between a heavy stacked shoe and the horse’s hoof; pressure shoeing—cutting a horse’s hoof down to the sensitive live tissue to cause extreme pain every time the horse bears weight on the hoof; and applying painful chemicals such as salicylic acid to slough off scarred tissue or numbing agents, in an attempt to obscure evidence of soring.

The Horse Protection Act authorizes the USDA to inspect horses, including the three specific breeds known to be involved in soring—Tennessee Walking, Racking, and Spotted Saddle Horses—in transport to and at shows, exhibits, auctions and sales—for signs of soring, and to pursue penalties against violators. Unfortunately, since its inception, enforcement has been plagued by underfunding. As a result, the USDA has never been able to adequately enforce the act, allowing this extreme and deliberate cruelty to persist on a widespread basis.

To eliminate soring and meet the goals of the act, USDA officials must be present at more shows. Years ago, the Agency set up the industry-run system of certified HIO inspection programs, which are charged with inspecting horses for signs of soring at the majority of shows. These groups license examiners known as Designated Qualified Persons (DQPs) to conduct inspections. Several of these organizations hire industry insiders who have an obvious stake in preserving the status quo. Statistics clearly show that when USDA inspectors are in attendance to oversee shows affiliated with these organizations, the numbers of noted violations are many times higher than at shows where industry inspectors alone are conducting the inspections. By all measures, the overall DQP program as a whole has been a failure—the only remedy is to abolish the conflicted industry-run inspection programs charged with self-regulation and have USDA oversee a legitimate inspection program.

USDA appeared to have attempted to step up its enforcement efforts some years ago, and had begun to work with the Department of Justice in prosecuting criminal cases as provided for under the act. In 2011, a Federal prosecutor sought the first-ever criminal indictments under the act and as a result, a well-known, winning trainer in the Spotted Saddle Horse industry served a prison sentence of over 1 year. A former Walking Horse Trainers’ Association Trainer of the Year and winner of the Tennessee Walking Horse World Grand Championship, Jackie McConnell, was indicted in 2012 on 52 counts (18 of them felony) of violating the act and pleaded guilty to felony conspiracy to violate the act. He was sentenced to 3 years of probation and a \$75,000 fine in Federal court. In 2013, another Tennessee trainer, Larry Wheelon, and three of his employees were indicted on 19 counts of aggravated animal cruelty charges under state law in a case flowing from a USDA Office of Inspector General investigation. While Wheelon’s case was dismissed on a technicality, evidence of soring in his barn was plentiful and horrifying.

These were significant actions that should have had a deterrent effect, but there are many other violators who go undetected and many cases that go unprosecuted due to a lack of resources USDA needs to carry out its responsibilities under this act as Congress and the public expect. In years past, Agency inspections were lim-

ited to physical observation and palpation by the inspector. Protocols for the use of new technologies, such as chemical analysis of prohibited foreign substances used by violators on the legs of horses (either to sore them, or to mask underlying soring and evade detection by inspectors) have been implemented, which can help inspectors identify violations more effectively. The results of USDA's testing for prohibited foreign substances are staggering: 46 of the 66 random samples (70 percent) taken by the USDA (in 2019, the last year for which the agency has made this data available) at the industry's pinnacle event—the Tennessee Walking Horse National Celebration—tested positive for illegal foreign substances including soring, masking, and numbing agents.

Effective though this inspection protocol may be, due to budget constraints, USDA has been unable to put enough of this testing into use in the field, allowing industry players to continually evade detection. In 2019, USDA collected and tested only 268 samples at only 8 of the largest Big Lick shows; in 2018, 260 samples at only 20 shows; and in 2017, 316 samples at only 14 shows. With increased funding, the USDA could purchase more equipment and dispatch more inspectors to use it, greatly increasing the agency's ability to enforce the HPA.

Currently, when USDA inspectors arrive at shows affiliated with some industry organizations, many exhibitors leave to avoid being caught with sored horses. While USDA could stop these trailers, Agency officials have stated that inspectors are wary of going outside of their designated inspection area, for fear of harassment and physical violence from exhibitors. Armed security is frequently utilized in the designated area to allow such inspections, at additional expense to this program. That exhibitors feel they can intimidate government officials without penalty is a testament to the inherent shortcomings of the current system.

Lack of a consistent presence by USDA officials at events featuring Tennessee Walking, Racking, and Spotted Saddle Horses has fostered a cavalier attitude among industry insiders, who have not stopped their abuse, but have only become more clandestine in their soring methods. The continued use of soring to gain an advantage in the show ring has tainted this segment of the horse industry, and creates an unfair advantage for those who are willing to break the law in pursuit of victory. Besides the indefensible suffering of the animals themselves, the continued acceptance of sored horses in the show ring prevents those with sound horses from competing fairly for prizes, breeding fees and other financial incentives, while those horse owners whose horses are sored may unwittingly suffer property damage and be duped into believing that their now abused, damaged horses are naturally superior.

The egregious cruelty of soring is not only a concern for horse industry and animal protection organizations, but also for veterinarians. In 2008, the American Association of Equine Practitioners (AAEP) condemned soring, calling it “one of the most significant welfare issues faced by the equine industry.” It called for the abolition of the DQP Program, saying “the acknowledged conflicts of interest which involve many of them cannot be reasonably resolved, and these individuals should be excluded from the regulatory process.” The AAEP further stated, “The failure of the HPA to eliminate the practice of soring can be traced to the woefully inadequate annual budget... allocated to the USDA to enforce these rules and regulations.”

The USDA Office of Inspector General conducted a comprehensive audit of the Horse Protection Program, and issued its report in September 2010 documenting serious conflicts of interest and other significant problems with the industry self-monitoring system of HIOs on which the APHIS inspection program still relies. The report recommended the abolition of DQP inspections and an increase in funding for APHIS enforcement of the Horse Protection Act. The Agency concurred with the findings and recommendations in the report, pledging to abolish industry self-policing and agreeing with Recommendation 2: “Seeking the necessary funding from Congress to adequately oversee the Horse Protection Program,” indicating that it would develop a budgeting and staffing plan to phase in the resources needed to adequately oversee the Horse Protection Program. Unfortunately, in recent years, it has been reported that USDA officials have stated their view that Horse Industry Organizations (HIOs) have primary responsibility to enforce the HPA, not the Agency.

It is unacceptable that more than half a century after passage of the Horse Protection Act, the USDA still lacks the resources needed to end this extreme form of abuse. It is time for Congress to give our public servants charged with enforcing this act the support and resources they need to fulfill their duty to protect these horses as effectively and safely as possible.

We appreciate the opportunity to share our views, and your consideration of our request.

Sincerely,

Keith Dane, Senior Director, Equine Protection, Humane Society of the United States
 Robert P. Franklin, DVM, DACVIM, President, American Association of Equine Practitioners
 Barry Kipperman, DVM, DACVIM, President, Humane Society Veterinary Medical Association
 Cathy Liss, President, Animal Welfare Institute
 Sara Amundson, President, Humane Society Legislative Fund
 Nancy Perry, Senior Vice President, Government Relations, American Society for the Prevention of Cruelty to Animals (ASPCA)
 Teresa Bippin, President, Friends of Sound Horses, Inc.
 Robin Lohnes, Executive Director, American Horse Protection Association
 Neda DeMayo, President, Return to Freedom Wild Horse Conservation In Our Hands Action Fund
 Donna Benefield, Vice President, International Walking Horse Association
 Susan Crotty, President, Plantation Walking Horse Association of California
 Molly Lieberknecht, President, United Pleasure Walking Horse Association
 Gina Vehige, President, Gaitway Walking Horse Association, Inc.
 Lucy Rangel, President, Missouri Horse Shows Association
 Bonnie Yeager, President, International Pleasure Walking Horse Registry
 Penny Austin, President, One Horse At a Time, Inc. Horse Rescue
 Fran Cole, President, Northern California Walking Horse Association
 Linda Fey, President, New York State Plantation Walking Horse Club, LLC
 Libby Kurtz, San Francisco Bay Area Tennessee Walking Horse Club
 Nancy O'Dell Plunkett, President, Northwest Gaited Horse Association
 Jacquie Cowan, Chesapeake Plantation Walking Horse Club

[This statement was submitted by Keith Dane, Senior Director, Equine Protection, Humane Society of the United States.]

PREPARED STATEMENT OF JAZZ PHARMACEUTICALS

On behalf of Jazz Pharmaceuticals (Jazz), we respectfully submit this statement regarding the fiscal Year 2024 budget request for the Food and Drug Administration (FDA) for inclusion in the Committee's official record. Jazz appreciates the Committee's support for FDA's ongoing regulatory oversight of cannabis and cannabis-derived substances, including encouraging high caliber research, review of product applications, and robust inspections and enforcement. We appreciate the Committee's support in the 2023 appropriations cycle and ask for a continuation of that support so FDA's work may continue.

ABOUT OUR CANNABIS PHARMACEUTICAL DEVELOPMENT PROGRAM

Jazz, through GW Pharmaceuticals, is the first and only company to have brought a cannabis-derived pharmaceutical grade therapy through the drug review and approval process of the FDA. FDA approved Epidiolex(r) (cannabidiol) oral solution (Epidiolex) in 2018 for the treatment of seizures associated with two rare diseases, Lennox-Gastaut Syndrome (LGS) and Dravet Syndrome (Dravet); in 2020, FDA also approved Epidiolex for the treatment of seizures associated with tuberous sclerosis complex (TSC). In addition to continuing explore the therapeutic potential of Epidiolex for other serious medical conditions, we have other cannabis-based products in development, in both the United States and worldwide.

BACKGROUND ON CANNABIS AND FDA ACTIVITY

Cannabis is a complex plant containing more than eighty biologically active chemical compounds called "cannabinoids." The most commonly known cannabinoids are delta-9-tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD).

The 2018 Farm Bill¹ established that "hemp" (i.e., cannabis plants and plant material with less than 0.3 percent delta-9 THC) and hemp derivatives were no longer controlled substances. In the 2018 Farm Bill, Congress also specifically preserved FDA's authority and affirmed the agency's role in protecting consumers and patients from dangerous products and unproven therapies.

CBD is the active ingredient in Epidiolex, an FDA-approved prescription drug; therefore, it is illegal under the Federal Food, Drug & Cosmetic Act (FDCA) to add

¹The Agricultural Improvement Act of 2018, H.R. 2; Pub. L. 115-534.

CBD to food or to market it as a dietary supplement.² Yet, despite its illegality, CBD is widely available in consumables and personal care products. The global CBD market size was valued at \$5.18 billion in 2021; U.S. sales of CBD products could climb as high as \$11 billion by 2027.³

These unlawful, CBD-containing products are often marketed with claims of medical benefits, without FDA approval, or any scientific evidence.⁴ FDA has also identified numerous gaps in understanding how CBD affects human health, and what is known points to real risks to consuming CBD for any reason, and especially without a physician's oversight. CBD can cause liver injury, interact with other drugs, potentially causing serious side effects, and is associated with reproductive toxicity and damage to fertility. CBD is also associated with changes in alertness and mood, and gastrointestinal distress. Additional questions also remain regarding CBD consumption, such as if it is consumed daily, for sustained periods of time, and CBD's impacts upon children, pregnant and breastfeeding women, and fetal development.⁵

Based upon these concerns, FDA concluded in January 2023 "it is not apparent how CBD products could meet safety standards for dietary supplements or food additives."⁶ The agency has limited tools under the FDCA "for managing many of the risks associated with CBD products." As a consequence, the agency announced it would not initiate rulemaking to permit CBD in dietary supplements and foods. FDA offered to work with Congress "to develop a cross-agency strategy for the regulation of these CBD-containing products to protect the public's health and safety." This new regulatory pathway Congress might establish could include risk management tools for the agency to manage CBD risks to consumer health, including "clear labels, prevention of contaminants, CBD content limits, and measures, such as minimum purchase age, to mitigate the risk of ingestion by children."⁷ In the interim, FDA committed to continuing "to take action against CBD and other cannabis-derived products to protect the public."

While Congress and FDA continue to work together to develop an appropriate framework for CBD, we believe the following continuing concerns with cannabis-derived products merit inclusion of appropriations language:

—Cannabis-Derived Products Can Pose Significant Health Consequences. Cannabis-derived products are not approved by FDA and are often promoted to vulnerable populations without a prescription or healthcare professional oversight of dosing, side effects, and drug interactions. This poses potential dangers to patient and consumer health because some cannabis derivatives are known to interact with a variety of commonly used prescription drugs, cause liver complications, and have other adverse health effects.⁸ State-legal cannabis products are frequently contaminated with harmful substances, including mold, pesticides, heavy metals, and bacteria.⁹

²See FDA Regulation Of Dietary Supplement & Conventional Food Products Containing Cannabis And Cannabis-Derived Compounds (accessed March 9, 2023).

³Cannabinoids/Cannabis 101 (accessed March 9, 2023); CBD Sales Projected to Hit \$11 Billion (accessed March 9, 2023).

⁴Cannabidiol (CBD): Implicit, Unsubstantiated Therapeutic Claims through Academic Joint Ventures in an Unregulated Marketplace Could Risk Public Health (accessed March 9, 2023); FDA Warning Letters and Test Results for Cannabidiol-Related Products (accessed March 9, 2023).

⁵See, e.g., FDA, What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD (accessed March 9, 2023); Safety of CBD in Humans—A Literature Review (As of December 12, 2019) (accessed March 9, 2023); January 26, 2023 Statement by Dr. Janet Woodcock, FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward (accessed March 9, 2023) (hereinafter "Dr. Woodcock Statement").

⁶January 26, 2023 Dr. Woodcock Statement.

⁷January 26, 2023 Dr. Woodcock Statement.

⁸See, e.g., FDA, What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD (accessed March 9, 2023); Safety of CBD in Humans—A Literature Review (As of December 12, 2019) (accessed March 9, 2023); FDA, What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding (accessed March 9, 2023); FDA summarized the clinical and pre-clinical data (and the absence of such data) on CBD safety in responses to three Citizen Petitions and two New Dietary Ingredient Notifications for CBD in full spectrum hemp extracts. See FDA Issues Response to Three Citizen Petitions Related to CBD and Dietary Supplements (January 26, 2023) (accessed March 9, 2023); July 23, 2021 Letter from FDA to Mr. Tim Orr, Charlotte's Web (accessed March 9, 2023); July 23, 2021 Letter from FDA to Irwin Naturals (accessed March 9, 2023).

⁹Chicago Sun-Times, "What's in Illinois' legal weed?" See also Poison Alert! Quality Control is Often Lacking for Cannabis Products—Are your CBD and THC-rich consumables contami-

- Dietary Supplements And Foods Containing Cannabis Derivatives Must Be Differentiated From FDA-Approved Drugs To Preserve Research And Innovation. FDA-approved drugs are studied for efficacy and safety in the intended patient population and are manufactured to exacting standards, all of which ensure American patients have access to the safest and most advanced drugs in the world. Dietary supplements and foods containing cannabis-derived compounds need to be differentiated from FDA-approved drug products. If there is no distinction made between approved drugs and unapproved dietary supplements and foods, there is, similarly, no incentive to undertake costly clinical research to develop robust data on the therapeutic benefits of cannabis.
- Many Cannabis-Derived Products Are Marketed Deceptively And Misleading Claims May Harm Deceived Patients. Since January 1, 2020, FDA has sent over 60 warning letters to marketers of hemp cannabinoid products that were making unproven and false medical claims, including treatment claims for COVID-19, Parkinson’s, epilepsy, bi-polar disorder, and autism. The agency stated these marketing tactics put patients at risk because the products were not demonstrated to be safe or effective.¹⁰ While FDA and the Federal Trade Commission (FTC) have taken enforcement action against hemp manufacturers marketing CBD with unsubstantiated therapeutic claims, they have not taken similar action against medical cannabis businesses operating in State programs despite those companies utilizing the same unlawful marketing strategies. Numerous studies have documented how cannabis manufacturers make health and disease treatment claims about their products that are not substantiated by science-based research or rigorous testing.¹¹ Widespread false and misleading marketing spurred the American Medical Association (AMA) to urge FDA and FTC to do more to “protect consumers and combat marketing of unapproved medical claims for cannabis” when there is “currently little available evidence to demonstrate safe and effective use of these products for these purposes, and in some cases these claims are completely fabricated and with no supporting evidence at all.”¹² Further, as one study concluded, “Regulatory action against unsupported therapeutic claims by the medical cannabis industry has thus far been anemic” with at least one company that received a warning letter continuing to make unproven and false claims.¹³ As the AMA stated, permitting medical claims “outside of those validated through robust clinical trials has serious impacts for all patients who may use cannabis and cannabis-based products.” These deceptions may keep some patients from accessing appropriate, recognized therapies to treat serious or fatal diseases.

Based upon the foregoing public health and safety concerns, we ask for inclusion of the language below to ensure that FDA’s work continues. The proposed language is consistent with fiscal Year 2023 appropriations language.¹⁴

PROPOSED REPORT LANGUAGE

The Committee is concerned about the proliferation of products marketed in violation of the Federal Food, Drug & Cosmetic Act (the “FDCA”), including products containing derivatives of the cannabis plant. The Committee is aware that non-FDCA-compliant products pose potential health and safety risks to consumers through misleading, unsubstantiated, and false claims that cannabis and cannabis derivatives can treat serious and life-threatening diseases and conditions, including

nated by heavy metals, pesticides, and reproductive toxins? N. Seltenrich (Dec. 14, 2022). State cannabis authorities have issued numerous recalls and advisories regarding cannabis products contaminated with yeast, mold, pesticides, heavy metals, and bacteria, including in Vermont, Nevada, Oregon, Colorado, Oklahoma, and Arizona.

¹⁰See FDA Warning Letters and Test Results for Cannabidiol-Related Products (accessed March 9, 2023).

¹¹Caputi TL, The Use of Academic Research in Medical Cannabis Marketing: A Qualitative and Quantitative Review of Company Websites. *J Stud Alcohol Drugs*, 2022 Jan;83(1):5–17.; Shover CL, et al. Association of State Policies Allowing Medical Cannabis for Opioid Use Disorder With Dispensary Marketing for This Indication. *JAMA Netw Open*. 2020;3(7):e2010001; Cavazos-Rehg PA, et al., Marijuana Promotion Online: an Investigation of Dispensary Practices. *Prev Sci*. 2019 Feb;20(2):280–290.

¹²October 20, 2022 Letter from American Medical Association to FDA and FTC (accessed March 9, 2023).

¹³Shover CL, et al.

¹⁴See House Report 117–392 to Agriculture, Rural Development, Food And Drug Administration, And Related Agencies Appropriations Bill, 2023, H.R. 8239. The Committee’s Explanatory Statement adopting House Report 117–392 is available here. H.R. 8239 became Consolidated Appropriations Act, 2023, Public Law No: 117–328.

COVID-19 and cancer. Such products may also be contaminated with harmful substances.

The Committee recognizes that FDA intends to work with Congress on creating a regulatory framework that could permit one compound in cannabis, cannabidiol (“CBD”), in consumer products. FDA indicated that such a framework could safeguard consumers by providing risk management tools to the agency to manage CBD risks, including labeling requirements, prevention of contaminants, content limits, and other public health protections, such as minimum purchase age, to mitigate the risk of ingestion by children.

The Committee recognizes FDA’s use of its existing authorities to undertake cannabis-related efforts, including research, requests for data, consumer education, issuance of guidance and policy around cannabis-based drug product development, and some enforcement against wrongdoers.¹⁵ The Committee expects FDA to continue and to increase these efforts given the proliferation of non-FDCA-compliant, cannabis-containing products and the risks they pose to public health. The Committee also expects FDA to take enforcement action against the manufacturers of any cannabis products marketed with unlawful therapeutic claims to preserve the integrity of the drug development and approval processes, which ensures that products, including cannabis-containing products, that are marketed as drugs have undergone a rigorous scientific evaluation to assure that they are safe, pure, potent, and effective for the diseases and conditions they claim to treat. It is also imperative that FDA continue to exercise its existing authorities to preserve incentives to invest in robust clinical study of cannabis so its therapeutic value can be better understood.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE ENERGY OFFICIALS
(NASEO)

Chairman Heinrich and Ranking Member Hoeven, I am David Terry, President of the National Association of State Energy Officials (NASEO), and I am testifying in support of FY24 funding for the energy title of the Farm Bill. The mandatory levels of the energy title of the Farm Bill should be supported (2018 Farm Bill, Public Law 115–334). Specifically, we support funding of at least \$50 million mandatory and \$250 million in additional discretionary spending for the Rural Energy for America (REAP) program. Fifteen percent of the additional discretionary funds should be allocated to underutilized renewable energy technologies through a reserve fund. The REAP program was created in the 2002 Farm Bill and it has been a huge success. Over 15,000 energy efficiency and renewable energy projects have been implemented in every State since 2003. Since the 2014 Farm Bill, REAP has leveraged \$7 billion in private investments with the \$338 million in appropriations. We also support \$15 million in mandatory funding and \$30 million in discretionary funding; a total of \$45 million for the Rural Energy for America Loans program. “On-bill” energy efficiency financing programs for rural electric cooperatives is an important activity through USDA. Under the Rural Energy Savings Program (RESP), \$26 million should be provided for FY’24. The models in South Carolina, Arkansas, and Washington are very exciting. This program should be dramatically expanded. We also recommend that beneficial electrification initiatives should be funded with both the REAP and RESP programs. These recommendations are in addition to funding under the Inflation Reduction Act and the Infrastructure, Investment, and Jobs Act.

REAP has specifically benefitted farmers, ranchers and rural small businesses that are often underserved by other Federal energy efforts. NASEO’s State Energy Office members work directly with eligible entities, as well as state agricultural agencies and rural interests to promote this successful program. REAP focuses on facilitating private-sector led rural economic development.

NASEO represents the energy offices in the 56 States, territories and the District of Columbia. The REAP program, and the other critical programs in the energy title of the last multi-year Farm Bill (and RESP), helps the private sector create jobs, supports increased agricultural productivity and operational efficiency, reduces energy costs for farmers, ranchers and rural small businesses, generates home-grown energy, promotes use of alternative fuels produced by America’s farmers, and further reduces our dependence on imported petroleum. The cost is very low and the payback is very high.

¹⁵ See, e.g., Meeting of the Science Board of the U.S. FDA (June 14, 2022) at pages 9–18 (accessed March 9, 2023).

As noted above, NASEO also supports additional energy title programs. There are several of note that should be supported at mandatory funding levels and RESP. These include the Biomass Crop Assistance Program, Biorefinery Assistance, Renewable Chemical and Biobased Product Manufacturing Assistance Program, and the Biobased Markets Program (otherwise referred to as “Biopreferred”), the Biomass Research & Development Initiative, the Bioenergy Program for Advanced Biofuels, the Biodiesel Fuel Education Program, and the Carbon Utilization and Biogas Education Program.

The RESP zero-interest loans to rural electric cooperatives, state financing entities and others help on residential and small business energy efficiency measures. RUS has awarded almost \$290 million in RESP loans.

In FY24, we urge your support for the REAP program and the Rural Energy for America Loans program, and additional energy title programs as noted above. We also support expansion and support for “on-bill” financing programs (RESP) through USDA. For all these programs, we recommend streamlining the applications in order to reduce paperwork burdens for low-cost grants and loans. The REAP program’s small grant cap should be raised to \$75,000.

Contacts: David Terry, NASEO President (dterry@naseo.org); and Jeff Genzer, NASEO Counsel (jcg@dwgp.com).

[This statement was submitted by David Terry, President, National Association of State Energy Officials.]

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF WHEAT GROWERS

The National Association of Wheat Growers (NAWG) appreciates the opportunity to provide testimony about our priorities for the fiscal year 2024 Agriculture Appropriations bill. Before outlining our fiscal Year 2024 requests, we wanted to say “thank you” for continuing to fully fund the U.S. Wheat and Barley Scab Initiative (USWBSI) in fiscal Year 2023. For fiscal Year 2024, NAWG supports funding the following U.S. Department of Agriculture’s Agriculture Research Service programs:

As our leaders in Congress consider an fiscal Year 2024 Agriculture Appropriations bill, one of NAWG’s main priorities will be to ensure that no provisions are included that would cut Farm Bill programs, particularly mandatory programs like crop insurance, farm programs, conservation programs, or trade promotion programs. As the Appropriations Committee works to lay out goals for Fiscal Year 2024, we respectfully urge you to protect crop insurance from harmful cuts. Even in good years, farmers need access to a strong and secure Federal crop insurance program, a program that farmers have described time and again as a critical linchpin of the farm safety net. Given the ongoing drought throughout winter wheat country and severely wet spring in spring wheat country, mandatory programs like crop insurance, farm programs, conservation programs, and trade promotion programs mustn’t be cut or harmed. The 2018 Farm Bill passed through Congress with strong bipartisan, bicameral support and sent a clear message that these critical programs should not be harmed.

NAWG also strongly urges Congress to provide at least \$255 million for the Agricultural Trade Promotion and Facilitation Program with at least \$200 million for the Market Access Program (MAP) and \$34.5 million for the Foreign Market Development (FMD) program in fiscal Year 2024. We are asking that your subcommittee use discretionary funds to provide \$7 million—less than 3 percent of the program investment—for USDA administrative and operational costs to help reverse the diminished real dollar value of MAP and FMD from being funded at the same level for over 15 years. MAP/FMD funding is critical to help U.S. farmers, ranchers, and food exporters keep pace and help us make up for a lost time after two and half years of trade conflict and retaliatory tariffs.

Wheat is a vital crop and source of economic activity. In the United States, wheat ranks third in planted acreage, production, and gross farm receipts, according to the USDA’s Economic Research Service (ERS). According to the USDA, in the 2022/2023 crop year, total U.S. farmers produced a total of 1.6 billion bushels of wheat from a harvested area on 35.5 million acres. In any given year, wheat farmers must deal with a number of disease and pest challenges that can only be addressed through public and private research efforts. Federal funding for agriculture research has remained stagnant, threatening the future viability and competitiveness of U.S. food systems by being out invested by competitors such as China.

NAWG joins the National Wheat Improvement Committees (NWIC) and National Barley Improvement Committees in urging the Committee to maintain full funding for the UWSBSI. Fusarium Head Blight (Scab) is a plant disease attacking all wheat-producing regions of the U.S. that impacts not just growers but also millers

and bakers because of its impact on the quality of wheat. The 2018 Farm Bill increased authorization for the USWBSI from \$9.5 million to \$15 million to enhance food safety and supply by reducing the impact of Fusarium Head Blight (Scab) on wheat and barley. While the President's budget zeroed out funding for the USWBSI, we appreciate Congress's role in the appropriations process and for fully funding the initiative for the past several years. Continued full funding is vital in supporting the agricultural economy and food system.

Also, NAWG supports the NWIC's request to start funding a Wheat Resiliency Initiative (WRI) at \$1.6 million to address new and emerging challenges to wheat production. The key challenges are wheat stem sawfly, Hessian fly, bacterial leaf streak, and the rust diseases. Changing weather patterns combined with the migration of pest and disease problems to regions previously unfamiliar with these yield robbers are resulting in substantial economic losses at the farm gate. For example, losses caused by wheat stem sawfly are now estimated to exceed \$350 million annually for spring and winter wheat growers in Montana, Colorado, Nebraska, North and South Dakota, and Kansas. The Wheat Resiliency Initiative, over time, will require \$6.5 million in new funding—equally split between intramural and extramural funding—to meet its stated objectives and goals. Fully funded, the initiative will support multi-disciplinary research and involve scientists in 18 States. However, providing an initial \$1.6 million will help this initiative begin researching wheat stem sawfly and Hessian fly resistance.

Together, these various pests and pathogens affect every growing region and market class of wheat grown across the U.S. Wheat is grown, milled, and delivered as a dietary staple in every State. If funded, through this initiative, the community of U.S. wheat researchers will build a new genetic base in all wheat market classes for resiliency to these challenges posed by wheat rusts, stem sawfly, hessian fly, and bacterial leaf streak. The strength of local agricultural economies of every State will be supported through building resiliency in the face of these challenges to wheat production.

In addition to securing new resources for the WRI, NAWG encourages the subcommittee to provide an additional \$750,000 for strip rust screening nurseries. Currently, the wheat stripe rust initiative receives nearly \$200,000 annually to support public wheat research into stripe rust at facilities in Manhattan, KS; Raleigh, NC; Aberdeen, ID; and Pullman, WA. These additional resources would be used to support additional stripe rust screening nurseries in all wheat-producing regions.

NAWG urges the Committee to continue to fully fund the Small Grains Genomic Initiative (SGGI) at \$3.44 million. While the President's budget cut funding for the SGGI, the program provides critical resources to four research areas: Next Generation Genotyping, Next Generation Phenomics, ARS Uniform Small Grains Nurseries, and Doubled Haploid Research and Production. It is important to retain full funding for the SGGI in fiscal Year 2024.

Lastly, NAWG supports retaining language that provides \$1 million to support research focused on utilizing crop genetics research at public-private consortiums. NAWG applauds the funding of the National Predictive Modeling Tool Initiative (NPMTI) in fiscal Year 2022 at \$5 million, and we urge the committee to maintain or increase funding for the NPMTI as additional resources permit. NAWG continues to support maintaining at least the current level of funding for the NIFA Hatch Act, Smith-Lever Formula Grants, and the Agriculture and Food Research Initiative.

Wheat research at the Federal level is driven by funding to the ARS division of USDA, land grant universities via Hatch Act and Smith-Lever Act funds, and Agriculture and Food Research Initiative competitive grants. State governments support wheat research through funding of public universities and agriculture experiment stations. Wheat growers in many States directly support wheat research through checkoffs or assessments on their crop each year. This collaborative partnership has made the United States one of the premier countries for wheat research, with all segments sharing in its cost. The investment has resulted in wheat varieties with the end-use quality that meets or exceeds the demands of our customers, both domestic and international.

Agribusiness investment in wheat breeding and wheat improvement in the United States is minimal compared to other commodities. Private investment in wheat research has increased in recent years, but increased Federal investments must be made to provide solutions for problems affecting wheat productivity in the U.S. Wheat growers and the wheat industry depend on the USDA-ARS' public research efforts land grant universities to provide these solutions.

The National Association of Wheat Growers works with our 20 wheat state associations and industry partners to benefit wheat farmers. These requests will directly help find new markets to export our wheat, provide critical investments in research, and facilitate innovative wheat research to improve quality and protect against dis-

ease and pest challenges. We greatly appreciate your consideration of these requests.

[This statement was submitted by Brent Cheyne, President, National Association of Wheat Growers.]

PREPARED STATEMENT OF NATIONAL COALITION FOR FOOD AND AGRICULTURAL RESEARCH (NCFAR)

The undersigned organizations and institutions would first like to thank you for your collective efforts to complete the fiscal year 2023 appropriations. As Congress moves forward to develop a 2024 spending package, we encourage you to support increased investments to advance food and agricultural research at the U.S. Department of Agriculture (USDA) through the Research, Education, and Economics Mission Area.

Recent data from the U.S. Economic Research Service indicates that for every \$1 in public investment, U.S. food and agriculture R&D has returned \$20 to the American economy. However, the report further notes that “U.S. public agricultural R&D spending peaked in 2002, and by 2019 spending had declined to roughly where it was in 1970.”

The food and agriculture enterprise faces unprecedented challenges from extreme weather exacerbated by climate change, supply chain disruptions and rising food costs resulting from natural and geopolitical events, and adverse health outcomes related to nutrition insecurity and inequality. Fortunately, the key to addressing many of these challenges lies in strong Federal investments in the broad suite of research, education, and extension programs within USDA. We urge you to make the following investments in the final 2024 spending agreement.

Provide \$2.080 billion for the National Institute of Food and Agriculture Research (NIFA) as recommended in the House Agriculture Appropriations bill.

As USDA’s extramural funding arm, NIFA programs integrate research, education, and Extension to ensure that groundbreaking scientific discoveries are brought out of the laboratory and into the hands of those who can put them to work.

Provide increased support for all the capacity programs, which are fundamental to the extramural research, education, and Cooperative Extension system.

NIFA’s capacity programs provide an innovation network supporting our Nation’s Experiment Stations, research farms, and Cooperative Extension activities to keep the United States as the global leader of agricultural research.

- Request \$300 million in FY2024 for the Hatch Act account which supports 1862 land-grant university federal-state partnerships that employ science experts across each State at Experiment Stations respond to critical issues that affect production, profitability, invasive plant/animal species, biosecurity, land and water use, climate resilience, economic analysis, and farm safety. The multistate component of Hatch ensures coordination on key projects that advance agricultural production and processing, profitability, and sustainability.
- Requests \$108 million in FY2024 for the Evans-Allen account to provide capacity funding for food and agricultural research at the 1890 Historically Black land-grant universities and Tuskegee University. The Evans-Allen Program enables research for small farmer challenges, food security and nutrition, rural prosperity and economic sustainability, natural resources and the environment and workforce development. Most Black students majoring in agriculture graduate from 1890s universities.
- Request \$17.5 million for the Tribal College Research program for research funding that helps to protect reservation forests, woodlands, grasslands, and crops, and monitoring of the quality of soil, water, and other environmental factors.
- Requests \$46 million to support the McIntire-Stennis Cooperative Forestry research which investigates carbon sequestration, development of biobased products, prevention of forest fires, identification of biobased-energy sources, and training of forest and natural resource scientists.
- Requests \$420 million in Smith-Lever3(b) and 3(c) funds to support the Cooperative Extension System (CES), a unique network of on-farm researchers, specialists, agents, and educators who deliver vital, practical information to agricultural producers, small business owners, communities, youth, and families.
- Requests \$88 million for the Extension Services of 1890s land-grant universities. This program supports adoption of new farm production and management approaches through informal education via on-site demonstrations.

—Requests \$17.5 million in FY2024 for Tribal Colleges Extension, which supports community-based learning on topics such as farmer education, youth development, diet and nutrition, and rural entrepreneurship.

Provide \$500 million in funding for the Agriculture and Food Research Initiative (AFRI) as recommended in the House Agriculture Appropriations bill.

AFRI is USDA's premier competitive research program, supporting fundamental and applied research to address key problems of local, regional, national, and global importance in conventional, organic, and urban agricultural systems. This funding level for the program is needed to invest in crucial areas aimed at addressing our Nation's most urgent and pressing food, agriculture, and public health challenges. AFRI-funded research supports COVID-19 recovery, climate change adaptation and mitigation, equity across the food system, food safety and traceability, supply chain resiliency, bioenergy, nutrition and wellness, agricultural technology, rural economic prosperity, and a diverse research workforce. At its current funding level, AFRI can support fewer than a third of the projects recommended for funding. AFRI research programs support the development of new technologies and a workforce that will advance our National security, agricultural productivity, and the health of Americans.

Provide \$500 million in funding for the Research Facilities Act (RFA) as recommended in the House Appropriations Minibus bill.

Agricultural and food research solves global issues including preventing the next pandemic, addressing energy sustainability, limiting forest fires, and feeding global populations. Yet, the U.S. is at a hazardous crossroads and is rapidly losing ground as the global leader in agricultural science. 70 percent of the research facilities at U.S. public colleges of agriculture are at the end of their useful life. RFA funding will allow land-grant universities and non-land-grant colleges of agriculture to construct and modernize their research infrastructure to meet the needs of 21st century agricultural challenges.

A 2021 report determined 70 percent of research facilities at U.S. public colleges of agriculture are at the end of their useful life with \$11.5 billion in deferred maintenance. RFA allows for construction of modern facilities at colleges of agriculture that support agricultural research, that will increase pest and disease preparedness and use of advanced technologies, nation-wide.

Provide \$1.95 billion for the Agricultural Research Service (ARS) as recommended in the Senate Agriculture Appropriations bill.

As USDA's principal in-house research agency, ARS advances scientific knowledge through its four national program areas: nutrition, food safety and quality; animal production and protection; natural resources and sustainable agricultural systems; and crop production and protection. As one of the only funding sources available for long-term agricultural research, the ARS labs and research sites foster synergistic research collaborations across scientific disciplines and geographic locations. This funding would also help to address ARS infrastructure improvements critical to carrying out its research responsibilities.

Provide at least \$50 million in funding for the Agriculture Advanced Research and Development Authority (AgARDA) as recommended in the House Agriculture Appropriations bill.

The power of an advanced research program lies in its unique selection process to identify innovative ideas and technologies, allowing significant achievements to occur more rapidly than in a conventional research setting. By fully funding AgARDA, Congress can respond to our most pressing challenges: threats from plant and animal pests and diseases, rising costs and limited availability of inputs, inefficiencies in planting, harvesting and processing, and vulnerabilities to increasingly extreme weather.

Our food and agricultural system is vast, complex, and interconnected. Shocks from natural disasters, geopolitical instability, and labor and supply chain disruptions have shown us that now, more than ever, we need a radically different approach to achieving solutions. AgARDA can reach across the boundaries of traditional scientific disciplines and draw from industries of the future—nanotechnology, quantum computing, and machine learning—to sustainably increase the quantity and quality of our food supply.

The U.S. food and agricultural enterprise is at a crossroad: continue to underinvest in research and innovation or support a robust, diverse public agricultural research portfolio that will transform our agricultural system and maintain U.S. global leadership. AgARDA can be a key component of that future, but we can't wait, the time to invest is now.

Provide \$98 million for the Economic Research Service (ERS) as recommended in the FY2024 President's Budget U.S. agriculture benefits greatly from ERS and

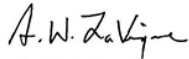
NASS data and modeling. This information not only helps the industry and academia but also guides sound policymaking.

Some of these datasets need to be developed from scratch and may lead to a better understanding of adaptation strategies to climatic change or improve our knowledge of mitigation strategies (e.g., the value of cover crops and why it is not widely adopted). These datasets can also help us better understand how to deal with disasters and reduce the cost of natural disasters. Data that can help understand the importance of capacity building in rural America. Finally, the datasets can also better inform us of the energy transition effect on underserved communities and the impact of climatic disasters on these communities.

Provide \$241 million for the National Agricultural Statistics Service (NASS) as recommended in the FY2024 President's Budget. The investments in USDA research, education, and extension programs made today will be responsible for developing the scientific outcomes and workforce urgently needed to meet identified and as-yet unknown challenges in the future. We urge you to do all you can to support a robust, diverse research, education, and extension portfolio within USDA.

We thank you for your continued support and look forward to working with you on this important effort.

Sincerely,



President, NCFAR

PREPARED STATEMENT OF NATIONAL COMMODITY SUPPLEMENTAL FOOD PROGRAM ASSOCIATION (NCSFPA)

Mister Chairman and subcommittee members, thank you for this opportunity to present information regarding the USDA/FNS Commodity Supplemental Food Program (CSFP). The National Commodity Supplemental Food Program Association (NCSFPA) requests that the Senate Agriculture Appropriations subcommittee fund CSFP for fiscal Year 2024 at \$390,000,000 subject to cost revisions to be submitted by the U. S. Department of Agriculture. NCSFPA would also like to thank the subcommittee for providing sufficient funding to support CSFP service in all 50 States, and sustained caseload as we continue to support the program to statewide levels in all 50 States.

CSFP is a unique program which brings together Federal and State agencies, along with public and private entities. CSFP currently provides services through over 150 non-profit community and faith-based organizations at 1,800 sites located in 50 States, the District of Columbia, Puerto Rico, and eight Indian Tribal Organizations (Red Lake, Minnesota, Oglala Sioux, South Dakota, the Seminole Nation in Oklahoma, the Spirit Lake Sioux Tribe in North Dakota, the Shingle Springs Band of Miwok Indians in California, Wichita and Affiliated Tribes), and most recently, the Mississippi Band of Choctaw Indians, and Winnebago Tribe of Nebraska. Each month up to 760,547 low-income seniors are authorized to receive a nutritionally balanced food box. The program has moved to serve exclusively elderly participants, as required by the Agricultural Act of 2014. Our Association thanks the subcommittee for funding that enables us to continue serving our vulnerable population.

The CSFP Local Agencies are committed grassroots operators with dedicated volunteers fulfilling a mission to provide quality nutrition assistance economically, efficiently, and responsibly. In cooperation with USDA, NCSFPA seeks to meet the current and emerging needs of CSFP participants. NCSFPA wishes to commend the Food Distribution Division of the Food and Nutrition Service (FNS) of the Department of Agriculture for their continued support of CSFP through the pandemic through efforts to address product shortages through substitute products and distribution flexibilities which we would like to continue, until production limitations subsided. At this time, CSFP agencies have been advised to return to distributing complete monthly boxes that will include all pre-pandemic items. Additional CSFP funding will continue to sustain national inventories and address the increased food costs.

As the Food and Nutrition Service notes in its Budget Explanatory Notes:

"According to the Census Bureau, the elderly population in the United States has been growing over the past several years and will continue to grow by an additional 27 percent by 2050. SNAP data shows that, of the proportion

of the elderly population who are eligible, only about 41 percent currently receive SNAP benefits; meaning that many low-income, elderly persons rely on other sources of food assistance through food banks and food pantries, and programs such as CSFP.”

“CSFP requests a total appropriation of \$390 million in 2024 to continue to serve the full caseload of 764,000. This increase is due to current and projected prices for commodities as well as the assumption that, as the pandemic wanes, participation will return to higher levels. Currently, the program is experiencing lower-than-normal participation levels during the pandemic, which is a reversal of the increased participation trend seen in 2019 and early 2020. However, by 2024, FNS expects that participation will return to the robust levels seen pre-pandemic. CSFP is currently able to support caseload due to an infusion of resources from supplemental spending bills in 2021. Those additional resources will be depleted during 2023.”

Equally encouraging are the comments from the Presidential Proclamation honoring May 2022 as Older Americans Month:

“Older adults have always been a vital source of strength and resilience in America. During the pandemic, many seniors came out of retirement to serve their communities in health care and education roles, filling job vacancies in critical shortage areas. Moving forward, we must ensure that older Americans have the appropriate resources to maintain their independence and stay connected to their communities.” The President went on to say “My Administration is committed to keeping older Americans safe and healthy as they age. The American Rescue Plan allocated \$1.4 billion to providing older adults with services for nutrition, health promotion, disease prevention, caregiver support, and long-term care.”

As a senior-based program, CSFP has a long-standing presence in providing healthy food to some of our most vulnerable citizens. Commitment to supporting CSFP in fiscal Year 2024 will build on that foundation at a time when our senior population continues to grow, and new distributions remain needed to reach unserved populations in States across the US.

CSFP continues to be a testimony to the power of community partnerships with faith-based organizations, farmers, private industry, and government agencies. The CSFP offers a unique combination of advantages unparalleled by any other food assistance program:

- The CSFP specifically targets one of our Nation’s most nutritionally vulnerable populations: low-income seniors.
- The CSFP provides a monthly selection of food packages tailored to specific nutritional needs.
- The CSFP involves the entire community. Tens of thousands of volunteers and private companies donate money, equipment, and most importantly time and effort to deliver food to needy and homebound seniors. These volunteers not only bring food but companionship and other assistance to seniors who might have limited support systems.
- The COVID–19 pandemic provided some powerful examples of the protective benefits of CSFP. While stores continued to see limitations for some food items, CSFP participants still had access to nutritious foods, provided through safe and socially distant practices implemented during the pandemic. No-contact distributions, including home deliveries, electronic intake practices, and drive-up food pick-ups streamlined efforts to protect staff, volunteers, and participants.
- With the aging of the Baby Boomers and the coming ‘Silver Tsunami’, CSFP is uniquely positioned to meet the nutritional needs of our Nation’s growing population of vulnerable seniors. Replenishing national food inventories and increasing caseload are vital as we work to keep up with this growing population.

NCSFPA senior participants across the country value their CSFP benefits for both the balanced meals that CSFP provides each month and the interaction between seniors and program staff. CSFP is a program that promotes healthy lifestyles and reduces any discomfort associated with participation in food support programs. The program allows seniors to live more stable, self-sufficient lives, whether homebound, living with limited income, or lacking access to other food and support options. It allows participant income to be put toward other costs of living, such as rent/mortgage, utilities, medical care.

America is aging and CSFP is an integral part of senior nutrition programming that is a cost effective and nutritionally sound way to ensure that today’s seniors

remain productive, healthy, and independent to maintain a good quality of life. It is of note that many seniors are now continuing to work at least part-time beyond retirement age to ensure that they can afford basic necessities. As such, CSFP is an important tool for them to remain healthy so that they may continue to be an active part of the work force.

The Agriculture Appropriations subcommittee has consistently supported CSFP, acknowledging it as a cost-effective way of providing nutritious supplemental foods. We urge the subcommittee to provide \$390,000,000 subject to cost revisions submitted by the U. S. Department of Agriculture for the Commodity Supplemental Food Program in order to allow us to provide needed services to a minimum of 760,547 vulnerable seniors each month.

Again, thank you for your continuing support. We look forward to working with you on behalf of CSFP participants.

[This statement was submitted by Christina Peretti, President, cperetti@gbfb.org, National Commodity Supplemental Food Program Association.]

PREPARED STATEMENT OF THE NATIONAL ENVIRONMENTAL HEALTH ASSOCIATION
(NEHA)

The National Environmental Health Association (NEHA) represents almost 7,000 environmental health professionals throughout the U.S. and around the world. NEHA is the profession's strongest advocate for excellence in the practice of environmental health. Our mission is the advancement of the environmental health professional and we serve to provide quality training, continuing education, and credentialing to our members and environmental health professionals.

As the committee reviews the fiscal year 2024 (FY 2024) budget, we would like to emphasize the following:

Program Name	FY 2023	FY 2024 Request
Food and Drug Administration Food Safety Program	\$1,519 million	\$1,730 million.
Federal and State Initiative	\$120 million	\$150 million.
New Era of Smarter Food Safety	\$3.5 million	\$40.5 million.
Integrated Food Safety System	\$115.6 million	\$128 million.

THE U.S. FOOD SAFETY SYSTEM

The U.S. has one of the safest, if not the safest, retail and manufactured food systems in the world. The rate of foodborne disease in our Nation, however, remains too high. The U.S. food industry is worth approximately \$1.5 trillion, accounting for one-fifth of the U.S. economy. FDA oversees 78 percent of the U.S. human food supply.

The programs highlighted above support efforts of the Food and Drug Administration (FDA) to provide resources to State, local, Tribal, and territorial (SLTT) food safety programs that protect this nation's food safety system through inspection, education, and enforcement.

Foodborne illness outbreaks can originate from any stage in the food production line. Restaurants are the most reported location of food preparation associated with outbreaks, accounting for 64 percent of the outbreaks for which a single location of preparation was reported; most of such outbreaks (48 percent) occur in sit-down establishments.

NEHA would like to highlight three points regarding this nation's food safety system:

Food Safety Is Performed by State, Local, Tribal, and Territorial Agencies.

The numerous Federal agencies regulating foods (primarily FDA) rely on their SLTT counterparts to implement their food safety programs. There are 70 State agencies alone that apply the FDA Food Code-mainly through their departments of agriculture, health, or environment-to protect the public from adverse food incidents. There are over 3,500 local health departments with food safety authorities, several Tribal jurisdictions with delegated authority from their States and the Federal Government, and U.S. territories that have food safety responsibilities.

SLTT programs implement the requirements of FDA food safety programs. The vast majority of food safety inspections, both retail and manufacturing, are per-

formed by SLTT inspectors. The majority of enforcement actions occur by SLTT agencies, under SLTT authorities.

FDA's Retail Flexible Funding Model (RFFM) provides the resources that SLTT food agencies need to meet the requirements of the Retail Food Standards and the Food Code, and has been very beneficial to the jurisdictions that have accepted the funding.

Food safety will only succeed if SLTT agencies are well-funded through programs like the RFFM and provided with resources necessary to implement and administer food safety measures.

The FDA Uniform Food Safety System promotes public health.

National uniform adherence with FDA retail food regulation best practices-such as the FDA Food Code and Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards)-decrease the occurrence of foodborne illness outbreaks. The FDA Federal and State Initiative and Integrated Food Safety System promote a uniform food safety system.

The Retail Program Standards provide a clear set of evidence-based guidelines for self-assessment and continuous improvement of regulatory agency programs and processes. SLTT enrollment with the Retail Program Standards aids in the reduction of foodborne illness incidence by providing standardized training, program evaluation, and technical support for SLTT jurisdictions.

Adoption of the FDA Food Code prevents foodborne illness. The FDA Food Code advances known practices for preventing foodborne illness. The code promotes the best advice from FDA to address the safety and protection of food offered at retail food and food service industries. FDA's purpose in maintaining an updated Food Code is to assist SLTT jurisdictions by providing them with a scientifically sound, technical, and legal basis for regulating the retail segment of the food industry.

The Retail Food Safety Association Collaborative, a cooperative agreement funded by FDA, promotes the adoption of the Food Code.

There are more than 3,500 SLTT government agencies that have the primary responsibility of regulating retail food and food service industries in the U.S., all of which follow some version of the Food Code. These agencies regulate food service operations in restaurants, retail food stores, food vendors, schools, hospitals, assisted-living facilities, nursing homes, and childcare centers.

Conformance with the Food Code and Retail Program Standards encourages STLL jurisdictions to follow a standardized set of guidelines for food safety that are known to lower the incidence of foodborne outbreaks.

A strong, qualified environmental health workforce is necessary to meet the public health mandate around food and human food needs.

Trained and credentialed personnel within SLTT food safety programs prevent adverse foodborne health outcomes through ensuring human food remains healthy and nutritious. This workforce is vital in FDA meeting its human food objectives.

Credentialed personnel within SLTT food safety programs improve the health and quality of life of people living in their communities. Their services prevent adverse health outcomes. FDA needs to improve its ability to recruit, hire and retain personnel with the skills necessary to meet its objectives, both at the Federal and STLL levels.

According to the Reagan-Udall report on human foods, FDA should move to a stronger, more cooperative relationship with States and other local authorities. Approximately half of the human food inspections are done by States through contracts and cooperative agreements, accounting for over 13,190 human food inspections in FY22. Funding for a strong, qualified SLTT workforce through FDA's Federal and State Initiative, the Integrated Food Safety System, and the Retail Flexible Funding Model is imperative in meeting FDA's goal of meeting public health mandate around food safety.

Food safety is a critical public health issue that affects individuals and communities across the U.S. and around the world.

We look forward to working with Congress and FDA in funding a system that improves the Nation's food safety system.

In health,

D. Gary Brown, DrPH, CIH, RS, DAAS
2022-2023 President
National Environmental Health Association
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[This statement was submitted by Doug Farquhar, JD, Director, Government Affairs, National Environmental Health Association.]

PREPARED STATEMENT OF NATIONAL FARMERS UNION

I write on behalf of National Farmers Union's (NFU) more than 220,000 family farmer, rancher, and rural members. Farmers and ranchers have faced many challenges over the past year, including high input costs and lingering supply chain disruptions caused by trade disputes, the COVID-19 pandemic, and Russia's war on Ukraine. Natural disasters and extreme weather events exacerbated by climate change continue to make the business of farming more difficult. Additionally, underlying market concentration across food and agricultural supply chains continues to squeeze family farmers and ranchers.

These challenges result in significant stress for farmers and their communities. As you draft and advance appropriations legislation, I urge you to provide funding for programs that alleviate the challenges facing rural and agricultural communities and that improve the resiliency of our food system.

FAIR, COMPETITIVE, AND RESILIENT MARKETS

Most sectors in American agriculture are dominated by a small handful of multinational corporations. Multiple waves of unfettered mergers and acquisitions over several decades have resulted in agriculture and food supply chains that are uncompetitive and that underpay farmers while overcharging consumers. This extreme concentration leaves food and agriculture supply chains less resilient and more vulnerable to shocks.

Concentration in the livestock and poultry industries has been on the rise for decades. Just four companies controlled 85 percent of beef slaughter and processing in 2019, and concentration is high in pork and poultry as well. Concentrated market structures increase opportunities for anticompetitive behavior. Thus, it is essential that the Packers and Stockyards Act (P&S Act) is enforced. The P&S Act is a law meant to protect farmers from discriminatory and monopolistic practices in the livestock, meat, and poultry industries.

NFU appreciates the committee's recognition of these issues in the FY23 funding bill by including our requested report language and by securing funding for enforcement of the Packers & Stockyards Act. NFU requests the continued inclusion of the following report language to address these issues:

The Committee recognizes that consolidation in agribusiness can be detrimental to farmers, consumers, workers, and the environment. The Committee considers enforcement of the Packers and Stockyards Act a top priority and directs the Department to continue enforcing the act to the fullest extent of the law. Further, the Committee urges the USDA Agricultural Marketing Service (AMS) and other agencies and mission areas to fully incorporate fair and competitive markets priorities across relevant programs and operations.

We also request that the Committee provide USDA AMS with additional funding for Packers and Stockyards Act enforcement at the \$35 million level in FY24.

Additionally, NFU supports the USDA Agricultural Marketing Service (AMS), Packers and Stockyards Division, being permitted to complete the P&S Act rulemakings the agency is currently promulgating. NFU opposes any efforts to interfere with USDA's rulemaking authority and the ongoing P&S Act rulemakings.

Furthermore, NFU supports strong funding for USDA's Food Safety and Inspection Service (FSIS) to help ensure the safety of the Nation's commercial supply of meat, poultry, and eggs, and to support building fairer and more competitive markets for producers. NFU supports FSIS continuing to fund the reduction in overtime and holiday inspection fees for small and very small establishments. NFU also strongly supports USDA FSIS's comprehensive review and ongoing rulemaking regarding the "Product of USA" voluntary labeling claim.

CLIMATE CHANGE AND CONSERVATION

America's family farmers and ranchers have been and will continue to help address climate change. But they need the support of voluntary, incentive-based conservation programs to implement effective practices on their land. On-the-ground capacity at the Natural Resources Conservation Service (NRCS) continues to be a limitation for farmers seeking to implement conservation practices. Funding for Conservation Technical Assistance (CTA) is needed for NRCS to hire more staff and

partner with organizations to do conservation planning on farms and assist with conservation program implementation.

We ask that you provide no less than \$1.2 billion in funding for Conservation Operations, including CTA, in FY24. The request for this funding should be in addition to any Congressionally Directed Spending used for Conservation Operations and CTA.

Improved pasture and grazing management can play a substantial role in carbon sequestration and improving soil health. NFU appreciates the committee's provision of \$14 million for the Grazing Lands Conservation Initiative (GLCI) in FY22 and FY23.

We ask the committee to build on these investments by providing at least \$30 million in FY24 for GLCI, administered by NRCS. The initiative should provide competitive grants or cooperative agreements for locally led efforts to provide technical assistance to help maintain and improve the management, productivity, and health of our Nation's grazing lands.

FARM AND RANCH STRESS ASSISTANCE NETWORK (FRSAN)

Farming can be a stressful and isolating occupation. There are multiple causes of stress among farmers and their families, including volatility in the farm economy, the financial risk involved in agriculture, weather unpredictability, and a changing climate. FRSAN funds regional service provider networks that connect individuals and their families engaged in farming, ranching, and other agriculture-related occupations to stress assistance programs. These regional networks help State and local governments, nonprofits, and other institutions share best practices, fill service gaps, and avoid duplicating efforts. FRSAN has also helped existing service providers reach more individuals and families in need.

We urge the committee to increase funding for FRSAN, administered by the National Institute of Food and Agriculture (NIFA), from \$10 million in FY23 to \$12 million in FY24 to address the urgent need to address farm stress and save lives.

RURAL COOPERATIVE DEVELOPMENT GRANT (RCDG) PROGRAM

The objective of the RCDG program, administered by USDA's Rural Business-Cooperative Service, is to improve the economic condition of rural areas by assisting individuals or entities in the startup, expansion, or operational improvement of rural cooperatives through Cooperative Development Centers. The RCDG program has received stagnant funding at \$5.8 million since FY12. Congress should increase the funding available for Cooperative Development Centers to ensure technical assistance is available in more communities to help spur economic growth and job creation.

NFU requests at least \$15 million for grants through RCDG for Cooperative Development Centers for FY24.

BROADBAND AND HIGH-SPEED INTERNET

Rural Americans are 10 times more likely than urban residents to lack access to quality broadband. Robust Federal investment in broadband internet connectivity is essential for advancing telehealth and distance learning in rural areas, and to ensure family farms and ranches can thrive. NFU supports the ReConnect Loan and Grant Program, which helps fund the construction, improvement, or acquisition of facilities and equipment needed to provide broadband service in eligible rural areas.

NFU urges the committee to provide full funding in FY24 to continue the ReConnect Loan and Grant Program, administered by USDA's Rural Development (RD) Rural Utilities Service (RUS).

FOOD SAFETY EDUCATION, OUTREACH AND TECHNICAL ASSISTANCE

The Food Safety Outreach Program (FSOP) provides outreach, education, and technical assistance to small- and mid-sized, beginning, and socially disadvantaged farmers and processors to help them comply with Food Safety Modernization Act (FSMA) regulations. FSMA regulations are complex, and it is essential that producers have access to assistance to help them understand how to comply with the law.

To help ensure a safe food supply for American families, and to help small- and mid-sized, beginning, and socially disadvantaged farmers comply with food safety regulations, we urge you to provide \$10 million for FSOP, administered by the National Institute of Food and Agriculture (NIFA), in FY24.

We also request robust funding for Food and Drug Administration (FDA) FSMA implementation that will allow FDA to continue their current outreach, education, and technical assistance efforts. We request the following report language:

The agreement directs the Food and Drug Administration (FDA) to provide outreach, training, and technical assistance to farmers for compliance with the Food Safety Modernization Act (FSMA) and directs FDA to provide funding at no less than the fiscal year 2023 level. The agreement also directs the FDA to continue working with small farms to clarify requirements for compliance with FSMA and directs FDA to provide funding at no less than the fiscal year 2023 level.

CONCLUSION

Thank you for your attention to these matters. If you have any questions or would like to further discuss NFU's requests, please contact Aaron Shier, NFU Government Relations Director, at ashier@nfudc.org.

[This statement was submitted by Rob Larew, President, National Farmers Union.]

PREPARED STATEMENT OF NATIONAL CENTER FOR APPROPRIATE TECHNOLOGY

Appropriations Bill: Agriculture
 Specific Agency: Rural Business—Cooperative Service
 Appropriations Account: Rural Cooperative Development Grants
 Program: Appropriate Technology Transfer for Rural Areas
 Amount requested for fiscal Year 2024: Appropriations: \$3.5 million
 Amount Provided in fiscal Year 2023: \$3.5 million

SUMMARY

ATTRA (Appropriate Technology Transfer for Rural Areas) provides trusted, practical, research-based information to tens of thousands of farmers, ranchers, extension agents, conservation professionals, on-farm energy specialists, and urban agriculture practitioners. ATTRA is a long-standing Farm Bill program with a current authorization for appropriations of \$5 million annually. ATTRA is a one-stop shop for sustainable agriculture information for farmers and ranchers, managed by the National Center for Appropriate Technology under a Cooperative Agreement with USDA Rural Development's Rural Business—Cooperative Service.

The program offers free technical assistance on sustainable agriculture production and farm energy issues via a toll-free hotline that is answered in English and Spanish for nine hours per day and through our websites www.ncat.attra.org and www.ncat.attra.org/espanol. Assistance is also available through email, texting, social media, and online chat. NCAT's agricultural specialists include 30+ highly qualified experts from diverse agricultural disciplines including horticulture, agronomy, animal science, economics, soil science, business planning, and marketing. Most staff also have experience in farming, ranching, Extension, and education. The In addition to answering specific producer questions, the ATTRA staff also produce workshops, webinars, and multi-media materials and meet with producers at conferences and during farm visits and field days.

In addition to technical assistance and educational materials, ATTRA also helps train military veterans with its Armed to Farm program and is accelerating the adoption of regenerative agriculture practices through NCAT's Soil for Water program, which combines peer-to-peer learning networks with rangeland monitoring, workshops, and direct producer technical support.

We appreciate the current year appropriation of \$3.5 million and for fiscal Year 2024, we again request \$3.5 million, level funding with fiscal Year 23, as we continue to expand ATTRA services for technical assistance to respond to the myriad farming needs of our clients, including improving soil health and water retention, increasing farm resilience, expanding market opportunities, adopting on-farm renewable energy programs including agrisolar, and expand training for beginning, socially disadvantaged, limited resource, and veteran farmers.

NCAT has also signed on in support of other appropriations requests when those requests are linked closely to ATTRA's mission and where ATTRA can provide resources and expertise to support other programs, including support for farm sustainability, climate resilience, soil and water conservation and quality, value-added marketing, on-farm renewable energy production, and farming opportunities for beginning socially disadvantaged, limited resource, and veteran farmers. These linkages are highlighted at the end of this testimony.

ATTRA HIGHLIGHTS AND INITIATIVES

Educational Materials and Outreach: ATTRA offers over 1,200 educational resources in print publications, webinars, databases, podcasts, videos, blogs, and tutorials directly related to sustainable agriculture, soil health, regenerative land management, climate solutions, business planning, and marketing. In its 2022 program year, ATTRA's digital resources were accessed over 2.5 million times. Fifty new podcast episodes were provided, along with 169 new videos and webinars. For example, ATTRA specialists presented a webinar to over 250 NRCS staff on tools and equipment for small and urban farms, and to 115 participants from various USDA agencies as part of the Southwest Drought Network on soil health and water resources.

Technical Assistance: ATTRA provides one-on-one assistance, small-group assistance, and peer-to-peer learning networks through workshops, conference presentations, farmer listening sessions, farm tours, and social media. In its 2022 program year, ATTRA provided TA to nearly 30,000 clients, including over 2,000 cases that required in-depth research. Topics included grazing management, soil health training, cover crops, land access, bio-solarization, financing for producer cooperatives, and crop insurance education, among many others.

Training: ATTRA has a strong reputation for providing practical training for farmers and ranchers, with a particular emphasis on beginning, socially disadvantaged, historically underserved, and military veteran farmers. More than 200 trainings are offered, virtually and in-person, each year.

Armed to Farm is a sustainable agriculture training program for military veterans. During the 2022 project year, more than 1,000 veterans have been trained, in-person and virtually, in week-long sessions through farm visits, hands-on activities, and classroom sessions on business planning, marketing, recordkeeping, access to USDA programs, and various production topics. In-person trainings in 2022 took place in MD, GA, NM, and CA. To date 80 percent of participants are farming or in the process of starting a farm; 94 percent say that the training improved their ability to farm; and 35 percent added new enterprises to their farm since attending the training. NCAT hosts a website, newsletter, listserv, and an Armed to Farm Facebook page to connect veterans to resources and to facilitate peer-to-peer learning.

Soil for Water is accelerating the adoption of regenerative agricultural practices that catch and hold more water in soils. Peer-to-peer learning networks are combined with, workshops, and support for producers who are trying new ways to improve health of their land and soils. ATTRA resources have been leveraged to expand these networks with support from NRCS, SARE, and private foundations. Soil for Water is a free, voluntary network available to all commercial agriculture producers in the U.S. Soil for Water has launched a new website, online forum, and the Regenerator's Atlas of America to strengthen peer-to-peer learning and networking opportunities.

The **AgriSolar Clearinghouse** is connecting businesses, land managers, and researchers with trusted resources to support the growth of co-located solar and sustainable agriculture. The AgriSolar Clearinghouse boasts more than 400 peer-reviewed articles and practical resources for farmers, land managers, and solar developers to maximize land and farm revenue. The hub includes a peer-to-peer forum, a bi-monthly newsletter, and one-on-one technical assistance from the NCAT energy and agriculture teams. ATTRA resources supporting farm energy solutions have been leveraged through the U.S. Department of Energy to develop the AgriSolar Clearinghouse.

To learn more about ATTRA's activities, please see our 2021–2022 Report to RBCS as well as the ATTRA website.

ATTRA REGIONAL OFFICES

Work carried out under ATTRA is accomplished among NCAT's 10 field offices, located in Butte, Montana (headquarters), Arkansas, California, Colorado, Idaho, Kentucky, Mississippi, New Hampshire, Pennsylvania, and Texas. Six of those offices provide support across an entire region of the U.S.: Montana covers the northern plains, Arkansas covers the southeast, California covers the west, Texas covers the southwest, New Hampshire covers the northeast, and Mississippi covers the Gulf States region

ATTRA AND NCAT CONTRIBUTIONS TO OTHER PROGRAMS IN THE ANNUAL
APPROPRIATIONS BILL

In addition to running a first-class education, training, and technical assistance program via a cooperative agreement with USDA with funds provided by this subcommittee, we also have a closely linked interest and make contributions to and help promote many other USDA programs and thus also have an interest in their annual funding level. We support of robust appropriations for the following:

- NIFA’s Sustainable Agriculture Research and Education (SARE)—\$60 million
- RBCS’ Rural Energy for American Program (REAP)—\$30 million
- RBCS’s Value-Added Producer Grants (VAPG)—\$15 million
- NRCS’ Grazing Lands Conservation Initiative (GLCI)—\$30 million from within the NRCS CTA account
- Farm and Ranch Stress Assistance Network (FRSAN)—\$10 million

NCAT is proud to be a long-term partner with USDA in support of sustainable agriculture, value-added production and marketing, local food systems, and training and technical assistance for beginning, socially disadvantaged, limited resource, and veteran farmers. We appreciate the subcommittee’s ongoing support for ATTRA as the Nation’s premier source of information on sustainable agriculture and for the range of other programs that help farmers thrive by producing healthy, fresh food to the American people while conserving natural resources and supporting rural communities.

[This statement was submitted by Ferd Hoefner, Consultant to NCAT.]

PREPARED STATEMENT OF NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

Founded in 1912, FASEB is a nonprofit which provides a forum for educational meetings, develops publications, and disseminates results of biological research. Now the Nation’s largest biomedical coalition, it represents 27 scientific societies and more than 115,000 researchers worldwide. Our mission is to advance health and well-being by promoting research and education in biological and biomedical sciences through collaborative advocacy and service to our member societies and their members.

FASEB’s fiscal Year 2024 Recommendation for the Agriculture and Food Research Initiative is \$700 million to fulfill its mission as the leading competitive grants program for agricultural sciences.

Federal investments in fundamental research have led to remarkable progress in the biological and biomedical sciences—an increasingly multidisciplinary team-based effort. These collaborative research efforts have enabled investigators to respond to pressing scientific challenges. Basic research was the groundwork for the speed-months instead of years—that led to the development of COVID–19 vaccines and also supports pre-clinical research involving the use of animal studies to achieve medical progress.

A major contributing factor to the success of team science is the mobilization of core facilities and shared research resources (SRRs), including the scientific technology and expertise infrastructure within research organizations. SRRs and cores work across different scientific disciplines and deliver unbiased research data in support of scientific rigor and transparency. They are essential training grounds for the next generation of skills-based scientists from diverse backgrounds.

Despite Congress’ bipartisan support for investing in science, Federal funding for research has not kept pace with scientific opportunity, posing a threat to our Nation’s competitiveness. We face a real threat of losing our edge in industries such as biotechnology if we do not continue to prioritize increasing investments in science, shared resource facilities, including core facilities, and building a diverse workforce.¹ The U.S. spends less on research and development (R&D) than many countries. If the U.S. is to be prepared to respond to future threats, our scientific leadership must progress. According to Science Is Us, more than 67 million workers in the U.S. are professionals in science, technology, engineering, and math (STEM) fields. STEM economic activity accounted for 40.5 percent of U.S. gross domestic product in 2021.²

Our agricultural system faces unprecedented challenges, including global food and fuel demand, water availability, and training a diverse agricultural workforce. The

¹ The State of U.S. Science and Engineering 2020—NSF—National Science Foundation

² People-of-Science-Economic-Impact-Analysis-FINAL—March—2023.pdf (scienceisus.org)

U.S. Department of Agriculture's National Institute of Food and Agriculture (NIFA) is the lead Federal agency providing extramural funding for food and agricultural sciences. NIFA funds an interdisciplinary research portfolio that brings pioneering science to address complex problems through the Agriculture and Food Research Initiative (AFRI), our Nation's leading competitive grants program for agriculture that supports education, research, extension, and integrated projects. AFRI funds agricultural and food sciences research at colleges, universities, and other institutions nationwide. Established by the Farm Bill in 2008, AFRI funding, while not keeping pace with the cost of doing research, has resulted in numerous advances, including new wheat cultivars and novel ways to combat invasive species.^{3 4}

AFRI funds agricultural and food sciences research at colleges, universities, and other institutions nationwide. Established by the Farm Bill in 2008, AFRI funding, while not keeping pace with the cost of doing research, has resulted in numerous advancements, including new wheat cultivars and novel ways to combat invasive species.

Despite AFRI's progress-and the need for scientifically informed solutions-the program is appropriated at about 65 percent of its authorization, leaving hundreds of innovative proposals unfunded. According to the latest AFRI 2020 annual report, of the total 2,783 competitive grant applications for fiscal Year 2020, awards totaling \$377,748,316 were made to 715 high-ranked applications across AFRI with a success rate of 24 percent. There were an additional 895 proposals that were highly ranked (Outstanding, High Priority, or Medium Priority) which were unsupported due to a lack of Federal funding.

AFRI should be funded at its full \$700 million authorization, which is \$245 million above fiscal Year 2023 enacted (53 percent increase), to fulfill its mission as the leading competitive grants program for agricultural sciences.

[This statement was submitted by National Institute of Food and Agriculture.]

PREPARED STATEMENT OF NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

Thank you for your continued support of the U.S. Department of Agriculture's (USDA) extramural research, Cooperative Extension, and education programs funded through the National Institute of Food and Agriculture (NIFA). The APLU Board on Agriculture Assembly (BAA) requests bold Federal investment in our Nation's colleges of agriculture and forestry by advancing funding increases for core accounts that underpin the strength of our Nation's public research, Extension, and education system serving U.S. food and agriculture.

The return on investment of U.S. agriculture research and Cooperative Extension is \$20 for every public \$1 invested. Yet Federal support for NIFA agricultural research, education, and Extension has been flat in real dollars, resulting in destabilization of the very system the U.S. relies on to cultivate agricultural leaders, reinforce domestic preparedness against pests and diseases, and ensure the U.S. leadership in global food security and technology. We request investment that rebuilds U.S. preeminence across public university research, Cooperative Extension System, education programs, and research facilities.

RESEARCH

We respectfully request robust funding for the following programs that provide capacity and competitive funds to support faculty, students, and technicians solving climate, production, nutrition, and agricultural resilience challenges:

- Hatch Act-\$300 million: Agricultural Experiment Stations located in every State provide research capacity for critical issues and innovations that affect agricultural production, profitability, and sustainability, such as climate resilience strategies, conservation, economic analysis, food safety, invasive species, biosecurity, and precision agriculture. Geographically relevant research occurs across national, regional, State, and local contexts.
- Evans-Allen-\$108 million: Agricultural research at 1890s colleges of agriculture takes place due to Evans-Allen capacity funds that enable research for small farmer challenges, food security and nutrition, and workforce development. Most Black students majoring in agriculture graduate from 1890s institutions.

³The Agriculture and Food Research Initiative (AFRI), National Institute of Food and Agriculture (usda.gov)

- 1994 Institution Research Program-\$17.5 million: The Tribal College Research Program supports research that protect reservation forests, woodlands, grasslands, and crops, as well monitor soil and water quality.
- McIntire-Stennis-\$46 million: Forestry research capacity addresses development of biobased products, prevention of forest fires, identification of new energy sources, expansion of outdoor recreational activity, and mitigation techniques for invasive species. It is a direct source of funds for resource science graduates.
- Agriculture and Food Research Initiative (AFRI)-\$500 million: The flagship competitive grants program for Federal priorities that improves rural economies, increases food production, stimulates the bioeconomy, mitigates the impacts of climate variability, addresses water availability issues, ensures food safety, enhances human nutrition, and trains the next generation of agricultural professionals.

COOPERATIVE EXTENSION

We respectfully request increased investments for the following programs that support the Cooperative Extension System (CES):

- Smith-Lever Section 3(b) and (c)-\$425 million: Capacity for 1862 Extension that supports a network of land-grant-university-connected state, Tribal, and local educators who deliver vital, timely, practical information to agricultural producers, small business owners, communities, youth, and families.
- Extension services at 1890 institutions-\$88 million: Capacity that assists 1890s in working with diverse communities with research-based, non-formal education about market development, acquisition of capital and technology, eState planning, and profitability. Stakeholders include small to medium size farmers or other underserved populations.
- Extension services at 1994 institutions-\$17.5 million: Enables 1994 institutions to deliver science-based, culturally relevant extension education programs to address biobased energy, production, and food safety needs, improving quality of life on reservations.
- Smith Lever 3(d) Programs-\$95 million: Includes the following important programs-Expanded Food and Nutrition Education Program (EFNEP); Farm Safety and Youth Farm Safety Education; New Technologies for Agricultural Extension; Children, Youth, and Families at Risk; and Federally Recognized Tribes Extension Programs.

EDUCATION

The agricultural sector will face severe workforce shortages in the near future. Robust funding in the following NIFA education programs for food, agriculture, and natural resources are critical to address the Nation's diverse talent needs:

- Women and Minorities in STEM (WAMS)-\$10 million: Increases student success for rural women and minorities in agricultural research, education, and Extension.
- 1994 Institutions Equity Payment-\$17.5 million: Focuses on Tribal college undergraduate and graduate studies in the food and agricultural sciences by supporting curricula design, faculty development, experiential learning, equipment, and student retention.

INFRASTRUCTURE

Our country is facing unprecedented challenges, from extreme droughts and floods to invasive species and new plant and animal diseases. What's more, a 2022 Economic Research Service (ERS) report, found that U.S. public agricultural R&D spending in 2019 was 1/3 of that in 2002 (constant dollars) and the U.S. is falling behind international trade partners including China and the European Union.¹

However, our agricultural research infrastructure dates to the 1950s and 1960s and cannot meaningfully address 21st century challenges. A 2021 report estimated that nearly 70 percent of these buildings are at the end of their useful lives, and the cost of upgrading deferred maintenance is \$11.5 billion.² With outdated and di-

⁴ AFRI Project Types (usda.gov)

¹ <https://www.ers.usda.gov/amber-waves/2022/june/investment-in-u-s-public-agricultural-research-and-development-has-fallen-by-a-third-over-past-two-decades-lags-major-trade>

lapidated facilities, scientists cannot be expected to keep pace with international competitors.

To address this urgent need we request \$500 million for agricultural research facilities at public colleges of agriculture, as authorized through the Research Facilities Act (RFA) in Section 7503 of the Agricultural Improvement Act of 2018 (P.L. 115-334). RFA will support competitive grants to land-grant universities and non-land-grant colleges of agriculture for facility construction, alteration, acquisition, modernization, renovation, or remodeling.

GLOBAL AGRICULTURE RESEARCH AND EXTENSION PARTNERSHIPS

Support critical international grants that foster international collaborations:

—International Capacity and Competitive Grants—\$15 million: Partnerships to Build Capacity in International Agricultural Research, Extension, and Teaching program strengthens international collaboration and the exchange of research results that promote teaching and Extension. Competitive Grants for International Agricultural Science and Education program strengthens U.S. economic competitiveness and promotes international market development.

The challenges our agricultural sector faces are significant and have broad, nationwide impacts. Our Cooperative Extension specialists are being asked to do more with less and our research facilities are falling down—not only hindering innovation, but our ability to recruit the best and brightest to the agricultural sciences, repercussions that will ripple throughout the ag sector for years to come. However, with bold investments across NIFA's extramural programs, there is an opportunity to transform the face of modern agriculture and ensure the United States remains a leader in agricultural innovation. We hope you will support us in these efforts.

[This statement was submitted by Douglas Steele, Ph.D., Vice President, Food, Agriculture, & Natural Resources (FANR).]

PREPARED STATEMENT OF NATIONAL MULTIPLE SCLEROSIS SOCIETY

Chairman Heinrich, Ranking Member Hoeven and Members of the Committee, thank you for this opportunity to provide testimony on behalf of the National Multiple Sclerosis Society (Society) regarding fiscal year 2023 (FY23) appropriations for the Food and Drug Administration (FDA). The Society urges the Committee to fund the FDA's budget authority at the Administration's request of \$372 million increase in BA (taxpayer) funding, including \$3 million to fund the Neurology Drug Program.

MS is an unpredictable disease of the central nervous system. Currently, there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. Early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS. The Society, founded in 1946, is the global leader of a growing movement dedicated to creating a world free of MS. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

The Society sees itself as a partner to Federal agencies under the Committee's jurisdiction and partner with many of the programs that provide services across the country, particularly the FDA. While we advocate for the government's involvement in accelerating the discovery, development, and delivery of new treatments, we do it as an organization whose research investment exceeds \$1 billion to date.

THE ROLE OF THE FDA

The FDA is the Nation's pre-eminent public health agency, responsible for oversight of more than \$2.6 trillion in medical products, food, and other consumer goods. It oversees the entirety of new drugs and therapies, vaccines, medical devices, and personal care products and 70 percent of our Nation's food supply. Altogether, the products and industries regulated by FDA account for about 20 percent of all consumer spending in the United States, approximately \$2.4 trillion per year.

No Federal agency's mission and responsibilities are more affected by changes in science, technology, innovation, and social trends than the FDA. People with MS not only rely on the FDA to approve safe and effective therapies to help manage their disease, but also to ensure a safe food supply, regulate tobacco (smoking may increase the risk of developing in MS and can worsen MS symptoms), help expedite the approval generic medications are approved to help address prescription drug af-

fordability. Further, MS healthcare providers rely on the accurate, science-based information from the agency to utilize in conversations with people with MS, their families, and care partners around health care and treatment decisions.

FDA's core mission should receive robust and sustained funding to meet the challenges of advances in science and technology that make regulatory decisions more complex and require greater sophistication and expertise to complete. The agency should have additional resources, more scientific and technical staff, and better analytical tools that support scientific-based decision-making and keep up with innovation in both food and medical products and we believe the Administration's request allows for FDA to invest in these key areas.

THE NEUROLOGY DRUG PROGRAM

The FDA has been instrumental in approving and regulating MS disease modifying therapies (DMTs), as well as other treatments that aid with symptom management. In 1992, there were no FDA approved therapies for MS. Today, we have more than 20 disease-modifying therapies approved by the FDA; however, more work remains to help people with MS access needed DMTs, novel therapies, medications to aid in symptom management and ultimately to find a cure for MS. MS presents and progresses differently in every individual, and there are multiple variables that go into decision-making for the use of DMTs. DMTs are generally not interchangeable and do not work in every person with MS.

The Society is grateful that Congress provided funding for the establishment of a Neurology Drug Program in FY23. We have long been concerned that the Agency does not have the personnel and expertise needed to develop policy and guidance that keep pace with emerging research in brain disease and neuroscience, as well as ensure that the Agency has a comprehensive approach to patient engagement as a core component of the regulatory process.

Stakeholders report uncertainty and inconsistency in which types of data will be acceptable to individual review divisions regarding patient experience-informed endpoints. We believe that the initial investment in the Neurology Drug Program will allow FDA to gain the expertise to develop policies and guidance that keep pace with emerging brain science. We look forward to working with FDA personnel to ensure this investment results in advances that encompass all areas of brain health including neurodevelopmental, neurodegenerative, psychiatric, brain injuries and more.

We believe that people with MS and patients in all disease States would be best served if the agency had consistent processes for engagement with all stakeholders and that these processes should be a core part of the agency's mission. The Society urges the subcommittee to ensure that these efforts are appropriately funded and prioritized within the agency's base funding, as this is an area of regulatory science that requires training and specific staffing throughout the agency and within review divisions.

CONCLUSION

In conclusion, we hope that the Committee continues to invest in the Agency and fund the FDA's budget authority at the Administration's request of \$372 billion for FY24.

[This statement was submitted by Leslie Ritter, Associate Vice President, Federal Government Affairs.]

PREPARED STATEMENT OF THE NATIONAL ORGANIC COALITION

I am submitting this testimony on behalf of the National Organic Coalition (NOC) to detail our fiscal year 2024 funding requests for USDA programs of importance to the organic sector.

USDA/AGRICULTURAL MARKETING SERVICE (AMS)

National Organic Program Request: \$26.4 million

Organic agriculture is one of the fastest growing sectors of agriculture, fueled by strong consumer demand. The organic sector now exceeds \$66 billion in annual sales with over 27,000 certified organic family farmers and other businesses represented.

The National Organic Program (NOP) is the agency charged with regulating and enforcing the USDA organic label. NOP was funded at \$18 million for FY 2021, \$20 million for FY2022, and \$22 million for FY2023. We are requesting \$26.4 million

for the NOP for FY 2024 in recognition of the need for enhanced oversight, enforcement, and rulemaking for the rapidly growing sector.

In addition, we are requesting the following report language to encourage NOP to increase enforcement efforts regarding the soil health requirements of existing organic standards:

USDA organic standards require organic farmers to use farming practices that improve soil health, such as crop rotations, cover cropping, and pasture-based livestock practices. By improving soil health, these farming practices also increase the carbon sequestration potential of the soil and improve the farm's resilience to extreme weather events and patterns. To maximize the climate benefits of organic agriculture, the Committee urges the National Organic Program to continue to increase enforcement efforts to ensure full compliance with the soil health and pasture requirements of USDA organic standards.

USDA (AMS, NASS, ERS)

Organic Data Initiative

Request: \$1 million for organic data collection and analysis

Authorized by Section 7407 of the 2002 Farm Bill, the Organic Production and Marketing Data Initiative states that the "Secretary shall ensure that segregated data on the production and marketing of organic agricultural products is included in the ongoing baseline of data collection regarding agricultural production and marketing." In addition to mandatory funding, Section 10103 of the 2018 Farm Bill authorizes \$5 million annually in discretionary funding.

As the organic industry matures and grows at a rapid rate, the lack of data for the production, pricing, and marketing of organic products has impeded further development of the industry and limited the functioning of USDA organic programs. Organic data collection and analysis at USDA has made significant strides in recent years but remains in its infancy.

We request \$1 million for FY 2024 for organic data collection at AMS, NASS, and ERS.

USDA/NATIONAL INSTITUTE OF FOOD AND AGRICULTURE (NIFA)

Organic Transitions Program

Request: \$10 million

The Organic Transitions Program, authorized by Section 406 of the Agricultural Research, Education and Extension Reform Act (AREERA) for Integrated Research Programs, is a research grant program to help farmers address challenges of organic production and marketing. As the organic industry grows, the demand for research on organic agriculture is experiencing significant growth as well. This research has broad applications to all sectors of agriculture, even beyond the organic sector.

Many organic research needs go unmet because of lack of adequate funding. As demand for organic products continues to grow at a fast rate, domestic production of organic food has not kept pace, requiring a greater percentage of organic product to be imported to meet the consumer demand. Funding for organic research has not kept pace with the growth in the industry either.

The Organic Transition Program was funded at \$7 million for FY 2021, and \$7.5 million for FY 2022 and FY 2023. We are seeking \$10 million for FY 2024, with report language to specify that the increase in funding should be used for fund research regarding climate change and organic agriculture.

Agriculture and Food Research Initiative (AFRI)

Request: Report language on public cultivar development

In recent decades, public resources for the development of improved plant varieties and cultivars have dwindled, while resources have shifted toward genomics and biotechnology, with a focus on a limited set of major crops and regions.

In Section 7406 of the Food, Conservation, and Energy Act of 2008, the National Research Initiative was merged with the Initiative for Future Agriculture and Food Systems to become the Agriculture and Food Research Initiative (AFRI). Congress included language within AFRI to make "conventional" plant and animal breeding a priority for AFRI grants, consistent with concerns expressed by the Appropriations Committee in past appropriations cycles.

In the last several years, USDA has made regionally adapted cultivar development using conventional breeding techniques a higher priority within the plant breeding funding area.

In response to direction from the Senate Agriculture Appropriations Subcommittee report language, a “Conventional Plant Breeding for Cultivar Development” program area was created within the Plant Health and Production and Plant Products (PHPPP) priority area with the Foundational and Applied Science RFA of AFRI. While this development represents progress, there are several areas where further improvement is needed: 1) the amount of funding overall remains extremely low relative to the need; 2) the AFRI practice of awarding three-to-five-year grants conflicts with the longer-term breeding cycles required for public cultivar development projects 3) the “Conventional Plant Breeding for Cultivar Development” RFA does not specify that the cultivars developed with these grants should remain publicly available for farmers and for plant breeders for future breeding efforts; and 4) the maximum grant in this new program area priority is \$500,000, whereas the grant limit within the other PHPPP program area priorities range from \$650,000 for standard grants up to \$800,000 for partnerships.

Therefore, we request the following AFRI report language to address these concerns:

Section 7406 of the Food, Conservation, and Energy Act of 2008 specifies priority areas within the Agriculture and Food Research Initiative [AFRI], including an emphasis on conventional (classical) plant and animal breeding. The Committee strongly concurs with the intent of this section and appreciates the agency’s progress in creating a distinct Conventional Plant Breeding for Cultivar Development program area priority within the AFRI program for development of locally and regionally adapted cultivars, as the Committee previously directed. While noting this progress, the Committee expects the agency to significantly increase funding for this AFRI priority area, to increase the timeframe for grants made in this area to be more in keeping with classical plant breeding timeframes, to increase grant funding limits to be parallel with the other AFRI Plant Health and Production and Plant Health program areas, and to require that cultivars developed using these grants be publicly available for farmers and for plant breeders for future breeding efforts. In addition, the agency should take steps to improve its tracking of public cultivar development projects within AFRI. The Committee further directs the agency to report its progress in meeting these requirements.

Sustainable Agriculture Research and Education (SARE)

Request: \$60 million

The SARE program has successfully funded on-farm research on environmentally sound and profitable practices and systems, including organic production. The reliable information developed and distributed through SARE grants is very helpful to organic farmers. SARE was funded at \$40 million in FY2021, \$45 million in FY2022, and \$50 million in FY2023. The President’s FY2024 Budget requests \$60 million for SARE. We are also requesting \$60 million for SARE for FY 2024.

USDA/NATIONAL AGRICULTURAL STATISTICS SERVICE (NASS)

Tenure, Ownership, and Transition of Agricultural Land (TOTAL) Survey

Request: \$15 million

Land access is a major challenge facing beginning, socially disadvantaged, and young farmers, including organic farmers. Sec. 12607 of the 2018 Farm Bill tasked the National Agricultural Statistics Service with completing an updated TOTAL Survey to provide data on farmland ownership, tenure, transition, and entry of beginning and socially disadvantaged farmers. NOC is requesting \$15 million for the TOTAL survey for FY2024.

USDA/AGRICULTURAL RESEARCH SERVICE (ARS)

Organic Research within the Agricultural Research Service (ARS)

Request: \$35 million

Organic farmers across the country lack research on basic agronomic challenges. ARS organic funding has declined from over \$15 million in FY2007 to just \$12 million in FY2020. This is less than 1 percent of the ARS research budget. If ARS were to invest 6 percent of its total research budget on organic, commensurate with organic’s market share, that would equate to over \$120 million. To start addressing this inequity, we are requesting FY2024 report language to require not less than \$35 million for ARS organic research.

Thank you for your consideration of these requests.

[This statement was submitted by Steven Etka, Policy Director, National Organic Coalition.]

PREPARED STATEMENT OF THE NATIONAL TREASURY EMPLOYEES UNION

FOOD & DRUG ADMINISTRATION

NTEU is grateful to have this opportunity to submit this statement of our views on Fiscal Year 2024 appropriations for the Food & Drug Administration (FDA) where our union represents the bargaining unit employees.

The Administration has requested a 10 percent increase (\$372 million above the FY23 enacted level) for the Food & Drug Administration (FDA). The total FDA budget request is for \$7.2 billion of which \$3.93 billion would come from funds appropriated by Congress, \$2.5 billion from medical products user fees, and \$700 million from tobacco user fees. NTEU strongly endorses the Administration's request and urges Congress to fully fund the requested amounts.

The FDA workload is constantly growing and must grow as private sector growth continues in medical, pharmaceutical, veterinary and food production marketing. To hold back FDA would mean to hold back the innovations of the private sector in these critical and necessary products. That would not be in the interests of the health and safety of the American public.

FDA is a staff-intensive organization, with more than 80 percent of its budget devoted to personnel costs. FDA employees are among the most highly skilled and dedicated employees that will be found anywhere in the public or private sector. The agency needs to be able to recruit and retain skilled scientists, inspectors, chemists and other professionals. FDA certainly does not match the superior pay offered by the private sector, where these skills are very much in demand, but it does have a workforce committed to public service and public health.

However, FDA has a turnover rate two times the government wide average and 70 percent of the staff are retirement eligible. According to a recent Government Accountability Office (GAO) report, the crafts with the greatest pay and benefits differential from the private sector are scientists, physicians and regulatory attorneys. More broadly, there are hiring and retention problems with the professional and technical staff as well as those who work in medical product review. And of constantly growing importance is FDA's foreign inspection program. As we have told the Members of this Committee before, FDA has a hiring and retention crisis. Failure to overcome this crisis will mean a failure in the mission of FDA.

NTEU applauds the steps FDA has been taking to address this crisis. In listening to the employees at FDA, we find that the most effective initiatives are improved student loan repayment benefits, an expanded child care subsidy and telework. These initiatives can help retain skilled professionals while attracting new employees to service at FDA. Assuming robust implementation, these initiatives will achieve great strides in addressing the staffing crisis. We believe that the President's budget submission includes the resources needed to fully implement these initiatives and that the funding allocated in the request should be directed there. In addition, each of these initiatives also create cost savings that help to mitigate their costs, particularly in decreasing new employee training.

Telework and remote work provide the greatest opportunity for recruiting and retaining the best employees. While not all positions at FDA lend themselves to telework—chemists need to be in their laboratories and inspectors have always worked remotely as they move from facility to facility for their inspections—there are at FDA those who analyze text rather than substances or perform administrative or grants management tasks that are well suited for telework. In the coming years, FDA should re-evaluate the amount of space it leases at taxpayer expense and significantly reduce its footprint, savings tens of millions of dollars. Further savings are likely to be achieved when full time remote workers re-locate away from the FDA offices which are often in urban areas with high Federal locality pay to rural and small town areas where the employee accepts a lower locality pay while at the same time bringing jobs and their paycheck to rural and small town America.

However, there are three issues where FDA needs attention:

Among the least desirable tasks of FDA Consumer Safety Officers (CSO) is carrying out overseas inspections. It has been very difficult to fully staff these positions even though it is essential that overseas pharmaceutical, medical and food producers be held to the same high standards that domestic firms are held to. To hold importers to a more lenient standard than American producers not only harms the health and food safety of American consumers, it is also unfair to American businesses.

Let me be clear. These inspection trips are not a vacation. They are typically three week trips overseas visiting multiple facilities in remote industrial zones in countries like China. All Grade 12 or above CSOs are required to be available for these inspections. It is hard work, where inspectors spend this time away from their families in a foreign country where both the facility and the government may be less than welcoming and not committed to the transparency the inspector seeks. Employees also have concerns about their personal safety. FDA needs additional funding to make these jobs more desirable. NTEU supports new funding for bonuses for inspectors and reduction of trips from three weeks to two weeks. Congress should also fund positions at FDA to serve as translators for the inspectors. Currently the translators are provided by the facility or maybe even the Chinese government. While this has been a much criticized arrangement, to date, Congress has not provided the needed funding for FDA to hire its own translators.

Recruiting and retaining the best and most highly skilled employees is not just a matter of compensation and worklife issues and FDA management needs to better recruit from parts of our society that have not been well included in the FDA staff. In our call for improved diversity, equity and inclusion at FDA, this year, I would like to particularly highlight the missed potential of many high skilled military veterans. The Department of Health & Human Services, which FDA is part, has one of the lowest percentage of military veterans on staff of any Federal agency. HHS is at 8 percent while 30 percent of Federal civilian employees overall are veterans. NTEU believes that while FDA suffers significant staffing shortages, there are significant numbers of qualified veterans who would make superior employees at FDA. More robust affirmative steps should be taken to notify veterans of employment opportunities at FDA, recruit them and retain them.

Lastly, FDA is currently undergoing a reorganization of its food safety function. It would be useful for management to meaningfully consult with the union as it implements this re-organization.

Thank you for your consideration. NTEU appreciates the opportunity to present this statement.

[This statement was submitted by Anthony M. Reardon, National President.]

PREPARED STATEMENT OF ORGANIC FARMERS ASSOCIATION

The Organic Farmers Association is a nonprofit membership organization that represents U.S. certified organic farmers. We appreciate the opportunity to share these requests related to fiscal Year 2024 appropriations for agencies within the U.S. Department of Agriculture.

NATIONAL ORGANIC PROGRAM

*Account: Agricultural Marketing Service
OFA fiscal Year 2024 request: \$26.4 million*

The integrity of the organic label is organic farmers' top priority. If the National Organic Program is not able to enforce the organic standards, consumers will lose trust in the integrity of the label, putting the economic viability of organic farmers at risk. The NOP has oversight of the standards that define the USDA certified organic label as well as the accredited certifying agencies that inspect organic farms and food companies. The NOP must be able to grow to provide proper oversight of certifiers and enforcement in an industry that is rapidly expanding to create complex new supply chains that present numerous opportunities for fraud. Enforcement priorities for OFA include compliance with the Pasture Rule, finishing the Strengthening Organic Enforcement rulemaking, clarifying standards and certification interpretation of hydroponic and container operations, and reducing opportunities for fraud in the organic supply chain.

Despite the explosive growth of the organic industry into a global industry and repeated instances of failures by USDA to keep up with oversight and enforcement, the NOP was level funded at \$9 million from fiscal years 2014 to 2017. The NOP was funded at \$16 million in 2020, \$18 million in 2021, \$20 million in 2022, and \$22 million for FY23. We request \$26.4 million for the NOP for fiscal Year 2024, and report language continuing to urge NOP to increase enforcement of soil health requirements critical to organic's role in addressing climate change, including use of cover crops, crop rotation and enforcement of pasture standards.

ORGANIC DATA INITIATIVE

Account: Agriculture Marketing Service, National Agricultural Statistics Service, and Economic Research Service
OFA fiscal Year 2023 request: \$1 million (authorized level)

As the organic industry has grown, we have struggled to represent that growth to policy makers and regulators, in part because USDA has been slow to develop systems to track the growth of organic. Increasing USDA's capacity to conduct the Certified Organic Production Survey and other organic data collection will not only help us show the public and policy makers that organic is a growth industry for U.S. farmers, having accurate data on the amount of organic acreage around the world will also help the National Organic Program and organic certifiers to better enforce organic standards. Accurate information about the amount of organic production that is happening can help provide a way to identify potential fraud in the supply chain.

As the organic industry grows, the lack of good organic data has been an impediment. We request \$1 million for the Organic Data Initiative for AMS, NASS, and ERS to expand organic data collection and analysis efforts.

ORGANIC TRANSITIONS PROGRAM

Account: National Institute of Food and Agriculture
OFA fiscal Year 2024 request: \$10 million

Many of the challenges facing the organic sector can be addressed with increased research. Organic research often investigates practices and challenges that are also relevant to farmers who are not certified organic or who farm conventionally. An increased focus on soil health, alternatives to chemical pest management and cover crops across all sectors of agriculture show that this kind of research can serve an audience that is wider than certified organic. The Organic Transitions Program focuses on these types of topics and addresses the historic backlog of research needs in this sector.

The growth in demand for organic products means that there is potential for more organic farms and operations in the U.S., but obstacles such as research to address and promote organic farming solutions to production problems has lagged historically. Many of the debates about specific materials that can or cannot be used in organic production boil down to a lack of research on organic materials or practices that can be used as an alternative to the conventional approach of using a synthetic material. The backlog of research needs for organic farmers can begin to be addressed if the Organic Transitions Program continues to grow.

OFA is requesting \$10 million for fiscal Year 2024, with a focus on using the increase to fund climate change research related to organic agriculture.

SUSTAINABLE AGRICULTURE RESEARCH AND EDUCATION PROGRAM

Account: National Institute of Food and Agriculture
OFA fiscal Year 2023 Request: \$60 million

Another critical research program for organic farmers is the SARE program. SARE has been a leader in addressing key sustainability challenges facing agriculture for over 30 years and remains USDA's only farmer-driven research program. It has helped create more innovative organic and conservation farm practices that are adopted by farmers on the ground than any other competitive agricultural research program. Yet despite SARE's long-standing record of helping farmers and ranchers develop and adopt innovative practices and systems, the program has yet to reach its full authorized amount of \$60 million. Without increased investments, farmers will not be able to meet future productivity challenges and remain competitive, and they will lack the easily accessible and regionally appropriate research that they need to develop sustainable and climate resilient farming systems. In light of this, we support full funding for SARE at its authorized level of \$60 million for fiscal Year 2024.

ORGANIC RESEARCH WITHIN THE AGRICULTURAL RESEARCH SERVICE (ARS)—\$35 MILLION

Organic farmers across the country lack research on basic agronomic challenges. ARS organic funding has declined from over \$15 million in FY07 to just \$12 million in FY20. This is less than 1 percent of the ARS research budget, versus organic's market share of 6 percent. If ARS were to invest 6 percent of its total research budget on organic, it would equate to over \$120 million. To start addressing this inequity, we are requesting \$35 million for ARS organic research in FY24.

USDA RESPONSE TO PFAS CONTAMINATION OF FARMS

OFA urges the Committee to instruct USDA to assist state agriculture departments in a robust response to the emerging issue of per- and polyfluoroalkyl substances (PFAS) contamination of farms and livestock. The widespread use of PFAS chemicals in a variety of industries makes it likely that the PFAS-contamination of farmland and livestock being discovered in some States is likely to be repeated around the country. The USDA could assist States in responding to this emerging crisis for farms in several ways:

- 1) creating an indemnity or disaster response program for farms (other than dairy farms) with PFAS contamination;
- 2) conducting and disseminating research on the fate and transport of PFAS in soils to various types of crops and foods;
- 3) conducting and disseminating research on methods for remediating PFAS contaminated farm soils or livestock;
- 4) providing grants, equipment and technical assistance to States to increase capacity for testing farm soils and water supplies.

FUNDING FOR REGIONALLY ADAPTED, PUBLIC CULTIVAR DEVELOPMENT PROGRAMS—
AFRI REPORT LANGUAGE

Farmers need access to seeds and animal breeds adapted to their farming systems, soils and climates. USDA recently responded to the request by the Senate Appropriations Committee for a separate AFRI funding stream for regionally adapted cultivars, by establishing an AFRI “cultivar development” program priority area. The FY2024 appropriations bill should call for increased funding for this AFRI priority area.

Thank you for the opportunity to present this testimony on fiscal Year 24 funding levels for programs that serve organic farmers.

[This statement was submitted by Lily Hawkins, Policy Director, Organic Farmers Association.]

PREPARED STATEMENT OF ORGANIC FARMING RESEARCH FOUNDATION

I am submitting this testimony on behalf of the Organic Farming Research Foundation (OFRF) to detail our fiscal year 2024 funding requests for USDA-REE agency programs important to the maintenance and growth of the organic sector.

USDA—AGRICULTURAL RESEARCH SERVICE

Research into organic agriculture topics at ARS facilities
Request: \$35 million and report language

Organic farming is a bright spot in the agriculture economy, yet organic producers across the country remain disadvantaged by the lack of research on basic agronomic and economic challenges. Funding from the USDA ARS for organic farming research is not commensurate with the continued rapid growth of the organic market. In fact, according to ARS data, current organic farming research funding within the agency represents less than one percent, or about \$15 million, of the total ARS research budget. Meanwhile, the organic sector’s market share is six percent, which should reflect over \$120 million in ARS research funding. This funding gap must be closed to provide equity and address barriers to wider adoption of organic production practices. Investments in organic agriculture research will advance the substantial contributions of the organic sector’s efforts to address pressing environmental, climate, and human health concerns. The ARS research facility located in Salinas, California conducts the sole organic focused research project in the country, and continues to produce high quality, action-oriented research products but continues to face budget constraints and is at risk.

The ARS recently released its Organic Research Priorities and roadmap for organic research to the Appropriations Committees. These priorities highlight the need for continued and expanded investments into researching organic crop and livestock production necessary to provide organic farmers cutting edge, usable research and technologies. Putting this plan into action is critical to meet the needs of organic and transitioning to organic and transitioning to organic producers.

ARS works at the forefront to find solutions to agricultural problems. The long-term research carried out at the agency is and will continue to be critical in preparing farmers and ranchers, organic and non-organic, to adapt to and mitigate the climate crisis. ARS National Programs and LTAR sites support long-term basic and

applied research vital to the understanding of phenomena such as soil carbon sequestration, nutrient cycling, plant-soil-microbe interactions, and climate resilience in different farming systems. We believe that increasing funding for organic research, building on the just-released ARS strategic plan for organic research, will help the agency address the historical lack of investment in organic agriculture research and help organic and non-organic producers alike overcome challenges to realize their potential to mitigate and adapt to the impacts of the climate crisis.

In conjunction with that agency plan, we believe that appropriators should act to ensure organic agriculture receives its share of the ARS research budget to reverse the chronic underinvestment in organic research at the agency. A \$20 million increase in Fiscal Year 2024 would put the ARS research budget on a path toward an equitable distribution of research funding for organic agriculture over the course of the next several fiscal years. ARS looks to the Appropriations Committee for their direction, and providing clear support for expanding organic agriculture research is necessary for ARS to act.

Therefore, we request the following ARS report language:

The Agricultural Research Service (ARS) currently invests \$15 million, or less than one percent of their budget, into organic farming research. Meanwhile, the organic sector's market share is six percent and growing. Organic's fair share of the total budget should reflect over \$120 million in ARS research funding; this \$35 million request in FY24 is a down payment toward meeting the need. This funding gap must be closed to provide equity and address barriers to wider adoption of organic production practices. Investments in organic agriculture research will advance the substantial contributions of the organic sector's efforts to address pressing environmental, climate, and human health concerns.

Previous report language:

FY 23 House report <https://www.congress.gov/117/crpt/hrpt392/CRPT-117hrpt392.pdf>—page 19

Organic Research.—The Committee looks forward to receiving the 5 year plan requested in House Report 117–82.

FY 22 House report <https://www.congress.gov/117/crpt/hrpt82/CRPT-117hrpt82.pdf>—page 23

Organic Research.—The Committee directs ARS to develop a 5-year plan for organic food and agriculture research encompassing all relevant crop, animal, nutrition, and natural resource national programs.

USDA—NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

Organic Transitions Program

Request: \$10 million

This is a key competitive grants program that supports organic agriculture research at universities around the country, including many research programs that benefit farmers and consumers across the United States. The overall goal of the Organic Transition Research Program (ORG) is to support the development and implementation of research, extension and higher education programs to improve the competitiveness of organic livestock and crop producers, as well as those who are adopting organic practices and transitioning to organic certification. Investing in organic systems research is an effective way to invest in developing tools to support both climate mitigation and adaptation through land management. Practices and systems addressed by ORG include those associated with organic crops, organic animal production, and organic systems integrating plant and animal production. ORG consistently receives more funding requests than can be accommodated as consumer demand for organic products outpaces domestic production. For example, in 2020 there were 34 applications and only 12 awards distributed. Without continued funding of ORG as an organic-specific research grant program, this gap will only increase.

The program should be funded at \$10 million in FY2024, to ensure that U.S. farmers and ranchers have the information and technology necessary to meet the high demand for organic products in the marketplace.

Sustainable Agriculture Research and Education Program

Request: \$60 million

The Sustainable Agriculture Research and Education (SARE) program has a clear and consistent focus on sustainability and farmer-driven research. For over 30 years, SARE has been at the forefront of research and extension activities for farm-

ing systems based on profitable and environmentally sound practices developed with farmer and business input. Despite SARE's popularity and demonstrated administrative efficiency, after more than 30 years of proven on-the-ground results, the program has yet to reach its full authorized amount of \$60 million. As a result, USDA can only fund roughly 10 percent out of all eligible research and education pre-proposals submitted to the program each year. We urge Congress to provide full funding at \$60 million for SARE in fiscal Year 2024.

USDA—ECONOMIC RESEARCH SERVICE, AGRICULTURAL MARKETING SERVICE, AND
NATIONAL AGRICULTURAL STATISTICS SERVICE

Organic Data Initiative
Request: \$1 million

The Organic Data Initiative (ODI) collects and disseminates data regarding organic agriculture through the Agricultural Marketing Service (AMS), Economic Research Service (ERS), and National Agricultural Statistics Service (NASS). This program has been successful in providing valuable information to Congress, government agencies, and the organic sector. Funding specifically designated to the Organic Data Initiative is used for economic analysis, organic risk assessments, survey and statistical analysis, and market data collection and analysis. We urge strong funding for this small but valuable program, this increase in funds would allow for stronger intra-agency cooperation and be used to modernize systems and provide high-value, accurate organic price reporting and organic data collection.

Organic farms, both certified and non-certified, throughout the United States, representing an over \$52 billion industry, will benefit from an increase in organic farming data tools and functions.

Thank you for the consideration of these requests, and I look forward to discussing them with you.

[This statement was submitted by Gordon N. Merrick, Policy & Programs Manager, Organic Farming Research Foundation.]

PREPARED STATEMENT OF THE ORGANIC TRADE ASSOCIATION (OTA)

On behalf of the Organic Trade Association (OTA) and membership, I respectfully request appropriate and adequate funding levels and oversight for programs whose mandate is to support the growth of the organic industry. OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for organic in the United States, representing over 10,000 organic farms and businesses across all 50 States through direct membership and our farmer's advisory council. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, consultants, retailers, and others. OTA believes increasing appropriations for U.S. Department of Agriculture (USDA) programs and initiatives which regulate current operations or benefit new farmers entering organic is important as the industry continues to experience growth on a year-to-year basis.

Despite the many challenges facing the food and agriculture sector, U.S. organic soared to new highs in 2022, growing to \$66 billion in annual sales. As one of the fastest-growing food and farming sectors in the U.S. and global marketplace, organic is an increasingly essential part of American agriculture. Organic provides economic opportunities for farmers, creating jobs, and lifting rural economies, while also utilizing sustainable farming practices which benefit the environment. Organic provides a safe, healthy choice to consumers, who are increasingly seeking out the trusted USDA Organic seal on the food and products they purchase for their families.

Therefore, in order to continue this growth, we request the Committee consider the following appropriations requests for USDA programs most impactful on organic production in the United States:

- USDA (AMS) National Organic Program (NOP)—\$26.4 million;
- USDA (FSA) Organic Certification Cost-Share Program (OCCSP)—\$5 million;
- USDA (NIFA) Organic Agriculture Research and Extension Initiative (OREI)—\$10 million;
- USDA (AMS) Organic Data Initiative—\$1 million; and,
- USDA (NIFA) Organic Transition Research Program—\$10 million.

NATIONAL ORGANIC PROGRAM (NOP)

The National Organic Program (NOP) is the regulatory program within the USDA Agricultural Marketing Service responsible for developing and enforcing national standards for certified organic agricultural products. These standards assure consumers that products with the USDA organic seal meet consistent, uniform standards. The NOP is vital to meeting growing consumer demand for organic products. Recognizing the continued growth of the industry, we ask for \$26.4 million, the full amount of the last authorization plus an additional 10 percent to accommodate growth. Moreover, this would give NOP the resources it needs to enforce the organic regulations globally, to continue to develop international equivalency agreements to expand the market for American organic products worldwide, and to develop new organic standards for emerging sectors. Increased funding will allow NOP to update existing standards to address developing new developments in best practices, scientific evidence, and consumer demands. Therefore, OTA requests \$26.4M for continued operations of the NOP.

Additionally, non-foods represent 10 percent of the organic marketplace. OTA requests the subcommittee consider the inclusion of report language addressing the ability of NOP to enforce standards “The committee requests that the National Organic Program apply its authority to the maximum extent possible and exercise oversight and enforcement of organic claims made on agricultural products which are non-food, including but not limited to textiles (processed fiber products), dietary supplements, pet food, personal care products (including cosmetics), household items (e.g. cleaners, detergents), and flowers, and assist any other agencies that might have some authority over these final products with a definition of organic production and handling and rules for the use of organic label claims. Additionally, the Committee requests the National Organic Program to take steps to ensure any certifying agents acting on the behalf of the USDA are applying the organic standards for non-foods in a uniform and consistent manner.”

ORGANIC CERTIFICATION COST-SHARE PROGRAM (OCCSP)

The Organic Certification Cost Share program is important to attracting new, young farmers to organic. Farms can receive up to \$750 each year (75 percent of the certification fee) through the Farm Bill to help defray the annual costs of organic certification. However, despite the commitment of Congress to assist organic farmers, the last 2 years USDA announced reimbursement rates for certification costs would be cut to 50 percent of the certified organic operation’s eligible expenses, up to a maximum of \$500 per scope due to funding shortfalls. We urge the inclusion of this additional funding to ensure that organic farms and businesses can continue to count on this long-standing program to help offset their certification requirements as the producers continue to experience increasing costs. In order to accommodate the growing need and actions of the USDA in previous fiscal years, OTA requests \$5M for the program.

ORGANIC AGRICULTURE RESEARCH AND EXTENSION INITIATIVE (OREI)

OREI is the flagship research program for organic agriculture within USDA. Research is necessary to measure and optimize the outcomes of organic agriculture systems and develop new ecological technology—which benefits both organic and conventional producers, as conventional producers often adopt ecological agricultural practices developed from this research. Organic makes up six percent of U.S. food sales and should be equally represented in Federal research funding. OREI receives mandatory funds through the Commodity Credit Corporation, but OTA requests an additional \$10 million of discretionary funding to ensure the benefits of organic research reach farmers in the field through increased extension and outreach activities.

ORGANIC [TC1][PM2]DATA INITIATIVE (ODI)

The organic industry has grown at a tremendous rate over the past several years, and accurate data for the production, pricing and marketing of organic products is essential to maintaining stable markets, identifying fraud, creating risk management tools, tracking production trends, and increasing exports. ODI collects and disseminates data regarding organic agriculture through the Agricultural Marketing Service (AMS), the National Agricultural Statistics Service (NASS) and the Economic Research Service (ERS). This program has been successful in providing valuable information to Congress, government agencies, and the organic industry at a low cost. The necessity of this data is evidenced by the difficulty in obtaining the data to properly roll out the Organic Dairy Marketing Assistance Program, which

would deliver needed relief to organic dairy farmers as a result from rising costs due to the war in Ukraine and supply chain issues. OTA asks for \$1 million in discretionary funding for the agencies tasked with data collection and analysis to continue collecting organic pricing information and conducting surveys and expand collections to levels comparable to conventional agriculture. Increased data collection will empower Congress and USDA to better modify existing programs so organic farmers can fully participate.

ORGANIC TRANSITION RESEARCH PROGRAM (ORG)

The overall goal of the Organic Transition Research Program (ORG) is to support the development and implementation of research, extension, and higher education programs to improve the competitiveness of organic livestock and crop producers, as well as those who are adopting organic practices and transitioning to organic certification. Practices and systems addressed include those associated with organic crops, organic animal production, and organic systems integrating plant and animal production. ORG consistently receives more funding requests than can be accommodated as consumer demand for organic products outpaces domestic production. Without continued funding of ORG as an organic-specific research grant program, this gap will only increase. OTA requests Committee fund the program at \$10 million, to facilitate growth of this important research.

In conclusion, organic food and farming are built on a commitment to shape our collective future for the better. The organic industry is creating jobs, stimulating our rural economy, creating domestic capacity, and delivering quality products in high demand to consumers. OTA requests the subcommittee continue to work towards providing the necessary support to achieve even greater success.

I thank the members of this subcommittee for their consideration and look forward to working with you to advance the organic industry.

Sincerely,



CEO
Organic Trade Association

PREPARED STATEMENT OF THE OREGON WATER RESOURCES CONGRESS

The Oregon Water Resources Congress (OWRC) strongly supports increased funding for the U.S. Department of Agriculture's (USDA) Natural Resources Conservation Service (NRCS) programs for fiscal Year 2024. A minimum of \$4 billion is needed to support watershed protection and irrigation modernization efforts across the Nation, split between the PL-566 programs, the Regional Conservation Partnership Program (RCPP), and the Environmental Quality Incentives Program (EQIP). Within the PL-566 programs, a minimum of \$1 billion is needed to support ongoing irrigation modernization efforts under the Watershed Protection and Flood Prevention Operations (WFPO) Program and \$500 million is needed for coordinated Federal agency watershed planning and assistance with dam rehabilitation under the Small Watershed Rehabilitation Program (SWRP).

OWRC was established in 1912 as a trade association to support the protection and use of water rights and promote the wise stewardship of water resources in Oregon. Our members are local governmental entities, including irrigation districts, water control districts, drainage districts, water improvement districts, and other agricultural water suppliers that deliver water to one-third of all irrigated land in Oregon. These water stewards operate complex water management systems, including water supply reservoirs, canals, pipelines, fish screens, and hydropower facilities.

PL-566 PROGRAM NEEDS & BENEFITS

Our members in Oregon face many challenges related to irrigation water supply reliability, including recurring drought, aging infrastructure, climate change, and issues related to the Endangered Species Act (ESA) and the Clean Water Act (CWA). While there are common concerns and interests throughout irrigated agri-

culture, each basin is unique, and necessitates local communities' work collaboratively to identify needs and develop tailored solutions. NRCS's programs support multi-benefit projects that help improve water quality, restore habitat, and more efficiently deliver water to users, without placing the entire burden on the backs of the agricultural economy that produces food and fiber for our Nation.

These programs also leverage scarce State and local resources and incentivize phased-in strategic approaches to meet the myriad of watershed needs, allowing for irrigation districts and other partners to plan and implement projects incrementally. NRCS-funded irrigation modernization projects go through a robust public outreach and scoping process which leads to the development of a Draft Watershed Plan and Environmental Assessment. Once the watershed plan is completed and approved by NRCS, the project is eligible for implementation funding through the PL-566 WFPO program. While the 2021 Bipartisan Infrastructure Law provided \$500 million for WFPO, this amount is still woefully insufficient in comparison to the multitude of funding needs in Oregon and across the Nation. Given the high interest in planning or implementing projects using NRCS PL-566 funding, we anticipate a sustained demand for additional funding to support projects like the examples below.

EXAMPLES OF WFPO PROJECTS IN OREGON

The irrigation modernization projects below are in various stages of developing and implementing Watershed Plans through the WFPO program. More projects like these could be developed and implemented in Oregon and throughout the Nation with additional Federal support.

Arnold Irrigation District, Deschutes County—The District recently received approval for its NRCS Watershed Plan and is moving forward with its first phase of project implementation in Fall of 2023. The overall project will convert 11.9 miles of open canals into pipe and install two SCADA systems to improve operational efficiency over the course of 6 years. Additionally, 88 turnouts will be upgraded to pressurized delivery systems. The project will save 32.5 cfs of water, conserve 80.8K kWh/year in energy, improve water quality, and improve 52 miles of the Deschutes River. The District is seeking funding for the subsequent phases of its Watershed Plan.

Hermiston Irrigation District, Umatilla County—The District is proposing to modernize aging infrastructure to conserve water, improve operational efficiencies, improve water quality, enhance fish and wildlife habitat in the Umatilla River, reduce public safety risks, and increase recreation opportunities. By converting open-ditch irrigation canals into underground, closed-pipe systems or lining the District's remaining open canals, the proposed Hermiston Irrigation District Modernization Project could reduce conveyance and operational losses over the entire irrigation season and improve the District's ability to efficiently provide water to its patrons.

Klamath Drainage District, Klamath County—The District is in process of developing a Watershed Plan to modernize district irrigation infrastructure and improve watershed protection. Proposed projects include install fish screens at the district's diversions on the Klamath River, extend and re-engineer sections of canals to increase flows to the Lower Klamath National Wildlife Refuge (LKNWR), and improve the district's use and control over water throughout the district. The proposed project would enable the district to improve water management within the district's conveyance system and benefit fish populations by preventing fish from getting trapped in the district's canals. By reducing water use inefficiencies, the proposed project would improve water quality. The project would also allow the district to supply additional water to the LKNWR, which would increase critically needed habitat for wildlife.

North Unit Irrigation District, Jefferson County—The District is moving forward with implementing initial projects from its Watershed Plan, which will install 27.5 miles of gravity-pressurized, buried pipe; upgrade 153 turnouts; and construct four 1,000 cubic-yard retention ponds, each approximately 0.5 acres in size. The project will improve water conservation on District-operated laterals; improve water delivery reliability and drought resilience to NUID irrigators; reduce NUID's operation and maintenance costs; reduce operational spills into natural waterbodies; and improve streamflow, water quality, and habitat in the Deschutes River. Following project completion, 4,567 acre-feet of the water saved annually by the project would augment water supplies for NUID's existing patrons, helping to fulfill existing water rights, and alleviate water supply shortages across the District. The remaining 1,522 acre-feet of water saved annually would be allocated for instream purposes and released into the upper Deschutes River during the non-irrigation season.

Tumalo Irrigation District, Deschutes County—The District was among the first in the Nation to receive funding for an Irrigation Modernization Project through

WFPO and has been implementing identified projects in phases over the past 5 years. The project includes modernizing up to 1.9 miles of the District's canals and 66.9 miles of laterals to improve water conservation, water delivery reliability, and public safety. The project will occur in phases over 11 years. By converting open irrigation ditches into a closed piped system, the project will reduce water loss from canals by up to 48 cubic feet per second (cfs). Water saved from the project will be protected in the Deschutes River and Tumalo Creek, benefiting fish and wildlife habitat. The project also will deliver water to irrigators in a safer, more efficient manner and reduce energy consumption from pumping. The District is reaching the final phases of funding eligibility based on current program caps but still has several project phases to implement.

Owyhee Irrigation District, Malheur County—In recent years, the District has faced droughts that limit water supply to irrigators and the design and age of the District's conveyance system no longer meets its obligations. To address these concerns, funds will be used to implement ag-water management and conservation practices and rehabilitate the conveyance system to improve water delivery reliability and water conservation throughout the District. Modernizing the conveyance infrastructure will enable opportunities to benefit the local agricultural community by improving drought resilience and reducing inefficiencies associated with the current system.

SMALL WATERSHED REHABILITATION PROGRAM NEEDS

OWRC also strongly supports funding for projects under the Small Watershed Rehabilitation Program. Two of our members, Sutherlin Water Control District (SWCD) and Middle Fork Irrigation District (MFID) have dams that were built under the original PL-566. SWCD and MFID have received funds to begin the long and expensive process of updating their 50-year-old dams to today's standards for safety, however; both districts will need continued funding from the Watershed Rehabilitation Program and other NRCS funding programs to fully update their infrastructure.

SWCD operates two dams built under PL-566, Plat I and Cooper Creek, located in the Umpqua River watershed in Douglas County. While they were built to seismic standards 55 years ago, they do not meet today's standards for earthquakes. SWCD's dams serve as multi-purpose storage for the community: providing flood control, irrigation water for farmland, municipal water for the city of Sutherlin, and recreation. To date, SWCD has been authorized to receive funding for planning, design, and construction of one of their dams and planning and design for the other. However, SWCD will still need considerable funding dollars to complete necessary work on both dams. Current estimates for Cooper Creek are 2.4 million for construction and a minimum of \$7 million for Plat I, primarily for dredging, sediment removal.

MFID is responsible for the management and maintenance of Clear Branch Dam, a PL-566 dam within the Hood River watershed, which provides a clean, dependable water supply and distribution system for the irrigation of pears, apples, cherries, and other high value crops. Rehabilitation of the dam is needed to protect the public from flooding, for access to a clean and dependable water supply, and to maintain agricultural productivity. In the past year, MFID has continued the dam rehabilitation planning process with its Federal partners (NRCS as the lead Federal agency and USDA Forest Service as a cooperating agency), which has included analysis of elements to include in an updated watershed workplan and EIS document. Planned rehabilitation project elements that support dam stability include seismic upgrade, seepage mitigation, fish passage and water quality improvements that support ESA listed species while maintaining the project purpose and the need to support irrigated agriculture with a clean and dependable water supply. Considering the high costs to fix just three of the PL-566 dams in Oregon, and the immense price tag of modernizing infrastructure to increase water conservation, preserve wildlife habitat, and increase water reliability for farmers and ranchers, a minimum of \$500 million is needed to fund this important program in fiscal Year 2024.

RCPP & EQIP BENEFITS & NEEDS

OWRC strongly supports robust funding for RCPP and EQIP, which are critical tools for districts and other agricultural water suppliers in developing and implementing water and energy conservation projects in Oregon. RCPP currently has over 2,000 partners engaged in locally led conservation efforts that help implement collaborative basin-level solutions and reduce detrimental legal action, resulting in better outcomes for all. Since 2014, RCPP has invested over \$1 billion in over 375 projects across all fifty States and Puerto Rico. That \$1 billion investment has lever-

aged an additional \$2 billion from State and local partners for a total of \$3 billion invested in RCPP related water conservation projects. Federal support of water conservation activities funded through NRCS programs, including the RCPP, is essential to the conservation of our natural resources and critical to protecting our food, energy, and water supply. Irrigation districts in Oregon are the model of successful RCPP projects that “innovate, leverage additional contributions, offer impactful solutions and engage more participants.”

Ongoing RCPP Projects in Oregon—East Fork Irrigation District, Hood River County—This project brings together a diverse set of partners in the Hood River watershed to focus on a top-priority water conservation and fish habitat project. The project will construct Phase 1 of a pipeline project, assist agricultural producers with approximately 400 acres of on-farm water conservation practices, educate producers and farm workers on the latest irrigation water management techniques, and restore one mile of spawning and rearing habitat for threatened fish species. NRCS programs that will support these efforts include EQIP, CSP, and PL566. Together, these projects will increase irrigation water reliability for high value food crops, improve resilience to drought, and restore instream habitat for ESA-listed species.

Additional funding for PL-566, RCPP, and EQIP programs will ensure NRCS can continue to provide critical technical and financial assistance to project partners and build upon momentum from successful projects to accelerate innovative solutions to some of our most vexing water management challenges. Increasing the budget for NRCS programs is a strategic investment that will pay both environmental and economic dividends for current and future generations in Oregon and nationally.

Thank you for the opportunity to provide testimony on fiscal Year 2024 Budget for the U.S. Department of Agriculture’s (USDA) Natural Resources Conservation Service (NRCS) programs.

Sincerely,
April Snell, Executive Director
Address: 795 Winter St. NE, Salem, OR 97301

[This statement was submitted by April Snell, Executive Director, Oregon Water Resources Congress.]

PREPARED STATEMENT OF THE PERSONALIZED MEDICINE COALITION (PMC)

Chairman Heinrich, Ranking Member Hoeven and distinguished members of the subcommittee, the Personalized Medicine Coalition (PMC) appreciates the opportunity to submit testimony on the U.S. Food and Drug Administration (FDA)’s fiscal year 2024 appropriations. PMC is a nonprofit education and advocacy organization comprised of more than 220 member institutions across the health care spectrum who are working together to advance personalized medicine in ways that benefit patients and health systems. We appreciate that the subcommittee provided an increased budget for FDA in fiscal Year 2023 to allow the agency to continue carrying out its public health mission. However, the agency’s responsibilities increase in complexity each year. For this reason, the agency requires a budget that grows each year. Thus, as the subcommittee begins work on the fiscal Year 2024 Agriculture, Rural Development, FDA, & Related Agencies Appropriations bill, we respectfully ask that you continue to invest in FDA by appropriating \$3.914 billion to FDA’s budget authority as requested by the Administration. Such an increase will position FDA to provide access to safe and effective medical products, including advances in technologies that are the foundation for the future personalized medicine.

Personalized medicine, also called precision or individualized medicine, is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual’s medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine promises to help us detect the onset of disease, pre-empt its progression, and improve the quality, accessibility, and affordability of health care.¹

Budget authority provides FDA with the broadest and most flexible means of meeting all its responsibilities.² Previous increases in budget authority enabled the agency to implement multiple programs facilitating the development of personalized medicine products, which require greater sophistication and expertise to review. Ad-

¹ <http://www.personalizedmedicinecoalition.org/pdf>

² <https://acrobat.adobe.com/link/track?uri=urn:aaid:scds:US:fbda0765-44c4-47d2-aa11-71a4721a4d3f#pageNum=2>

ditional increases in fiscal Year 2024 budget authority would allow FDA to expand these initiatives and launch new ones with a highly skilled and technically empowered workforce equipped with modernized analytical tools that support science-based decision-making. By increasing Federal investment in FDA activities fostering the development of innovative medical products, real-world evidence (RWE), and digital health, Congress can help usher in a new era of personalized medicine at a pivotal moment, promising a brighter future for health systems and patients with unmet medical needs.

THE ROLE OF FDA IN PERSONALIZED MEDICINE

Thanks in part to a responsive regulatory agency, personalized medicine is progressing steadily. As of 2022, more than 300 personalized treatments are available for patients. That number has continued to grow, with personalized medicines accounting for more than a quarter of all new drugs approved by FDA for each of the past 8 years, including 34 percent of the new drugs approved by FDA last year.³ These new approvals are helping to transform care for molecularly selected subsets of patients with cancer, where 53 percent of newly approved personalized medicines are indicated, as well as rare, common, and infectious diseases, which account for the rest. In 2022, FDA also approved five gene and cell-based therapies and new diagnostic indications for 12 testing platforms.

FDA is the gateway for many personalized medicine breakthroughs entering the market. FDA's Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER) each have responsibilities for evaluating the safety and efficacy of breakthrough medical products. As personalized approaches to treatment and prevention have grown, new types of drugs, tools, and technologies leveraging complex and sophisticated data, like RWE, have challenged existing regulatory frameworks and processes.

FACILITATING THE DEVELOPMENT OF PERSONALIZED MEDICINE PRODUCTS

FDA is taking a number of steps to modernize its regulatory processes, such as streamlining its technical and data infrastructure to shorten review times, improving clinical trials to address unmet medical needs, integrating RWE into medical product reviews, and building partnerships to foster digital health and artificial intelligence (AI) technologies. In future years, robust funding from Congress will help FDA continue to build upon this work and bring personalized medicine products to patients as efficiently as possible.

EXPEDITING PRODUCT DEVELOPMENT

As a byproduct of scientific breakthroughs, the amount and variety of data that FDA generates, needs and uses is rapidly increasing. Even though FDA has taken action across the agency in recent years to make more rapid decisions and improve communications with medical product developers, the agency's technical infrastructure remains fragmented. In 2021, FDA announced a new Office of Digital Transformation to advance the agency's information technology transformation, which began in 2019. The \$10 million included in the Administration's proposed budget for fiscal Year 2024 would allow further investments in enterprise data and IT modernization to streamline data practices across centers and help translate FDA's wealth of information into knowledge supporting progress in personalized medicine.

The agency must also bolster its workforce to build in flexibilities across each of its centers and to keep pace with the growing pipeline of cell and gene therapies. Cell and gene therapy holds considerable potential for the treatment of hereditary genetic disorders, including rare, neurodegenerative, and infectious diseases. The number of cell and gene therapy submissions FDA receives is rising sharply. More than 200 new gene therapy Investigational New Drug applications are coming to FDA's CBER annually, up sharply from just over 100 in fiscal Year 2017.⁴ CBER provides extensive scientific and regulatory advice to product manufacturers throughout the medical product lifecycle. The center also develops policy and guidance on novel clinical, scientific, and manufacturing challenges for these products. An increase in FDA's budget authority would allow the agency to continue working with stakeholders to facilitate end-to-end solutions addressing key issues limiting the development and application of gene therapies, like manufacturing challenges,

³ <https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/report.pdf>

⁴ <https://www.fda.gov/media/166182/download>

that make these therapies cost-prohibitive and in some cases not commercially viable.

MODERNIZING CLINICAL TRIALS

More rare diseases and cancers are being defined by biological markers, creating smaller groups of patients who are more likely to respond to targeted treatments and are candidates for participation in trials. Trials that rely on identification of patients by biological markers, such as enriched trials, trials with master protocols, and in silico trials using computer modeling, present opportunities to streamline clinical research, especially in cases where a scarcity of patients makes a randomized control infeasible and where important personalized medicines may be delayed or discarded because FDA cannot afford to run the trials needed to validate them.

For many rare diseases, treatments are now within reach. Incentives and regulatory pathways, however, must be maintained for all rare diseases to make development financially viable. FDA's Orphan Products Grant Program supports the development of products to treat orphan or rare diseases including programs to support clinical trials, natural history studies, and new authority to fund grants addressing regulatory science challenges.⁵ Advances in the understanding of rare diseases and novel technology platforms have transformed many disease pipelines. By providing \$30 million for the Orphan Products Grant Program, this subcommittee can respond to the documented economic burden rare diseases present to families and the country.⁶

To help expand the development of new scientific approaches and tools available for advancing effective medical products that can prevent, diagnose, mitigate, and treat rare neurodegenerative diseases, Congress passed the act for ALS Act. This bill authorized \$2.5 million in funding for staffing to support implementation.⁷ To allow FDA to facilitate access to therapies for neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS) while continuing to focus on innovation and scientific advancement of new medical products to address other critical and rare diseases, the subcommittee should provide the agency with the full authorized funding level.

The Administration's fiscal Year 2024 budget proposal also calls for \$50 million for FDA to advance the President's Cancer Moonshot goals. These funds would enhance agency-wide efforts to improve evidence generation for underrepresented subgroups in oncology clinical trials. They would also support pragmatic, decentralized trials and the development of sources of evidence that incorporate patient-generated data and RWE.⁸ If appropriated, these resources will assist in the expansion of FDA's efforts to facilitate the approvals of innovative new cancer treatments by international regulatory authorities at the time of FDA approval, thus fostering collaboration on cancer treatments with other countries with standards comparable to those prevailing in the U.S.

ADVANCING THE USE OF REAL-WORLD EVIDENCE (RWE)

Traditional post-market studies require years to design and complete and cost millions of dollars. The use of data collected outside of a clinical trial plays a vital role in answering key questions about therapeutics, diagnostics, and other healthcare interventions. The proliferation and widespread adoption of electronic health records, as well as other emerging digital health solutions, have made real-world data (RWD) an attractive source of data for clinical and translational research. FDA has a long history of using RWD and RWE to monitor and evaluate the post-market safety of approved medical products. Advances in the availability and analysis of RWD have increased the potential for generating robust RWE to support FDA regulatory decisions.⁹ FDA continues to work to expand the use of fit-for-purpose RWD to generate RWE in regulatory decision-making regarding medical product effectiveness. RWE has even supported some approvals of applications meeting evidentiary standards. FDA has also published a series of foundational guidances regarding the use of RWD, including assessing whether RWD, such as registries, are fit for use. These foundational guidances will be followed by further guidance on clinical trial and other study designs using RWD. For this type of infor-

⁵ <https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/orphan-products-grants-program>

⁶ https://everylifefoundation.org/wp-content/uploads/2022/04/Orphanet_Journal_of_Rare_Diseases.pdf

⁷ <http://docs.house.gov/meetings/AP/AP01/20230329/115588/HHRG-118-AP01-Wstate-CaliffR-20230329.pdf>

⁸ <https://www.whitehouse.gov/ostp/news-updates/2023/03/09/fact-sheet-cancer-fy24/>

⁹ <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

mation to be useful in achieving the goal of generating and using RWE and RWD for personalized medicine, the data must be of high quality. Increased budget authority for FDA would create a more reliable source of funding for FDA's activities that strengthen programs focused on improving the quality of RWE and RWD.

FOSTERING DIGITAL HEALTH TECHNOLOGIES AND ARTIFICIAL INTELLIGENCE (AI)

CDRH launched the Digital Health Center of Excellence (DHCoE) to help both FDA staff and external stakeholders advance the development and FDA review of digital health technologies.¹⁰ The DHCoE is focused in multiple areas including AI and machine learning (ML). AI/ML technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day.¹¹ Digital health and AI are becoming increasingly important for personalized medicine as patients assume a larger role in managing their own health care and are more informed by their ability to access data about their unique biology. Additional appropriated resources would enable FDA to continue developing training programs to clarify regulatory pathways for internal FDA and external digital health stakeholders through the DHCoE. They would also strengthen the agency's partnerships focused on AI/ML and wearable technology, software, and patient-generated health data. Activities in these areas will help patients achieve their goals of getting high quality digital health technologies to patients.

CONCLUSION

PMC appreciates the opportunity to highlight FDA's importance to the continued success of personalized medicine. A budget authority appropriation for FDA in fiscal Year 2024 of \$3.914 billion will help the agency chart an efficient path for advancing innovative medical product development and bring us closer to a future in which every patient benefits from a personalized approach to health care.

[This statement was submitted by Cynthia A. Bens, Senior Vice President, Public Policy, Personalized Medicine Coalition.]

PREPARED STATEMENT OF PET AND WOMEN SAFETY ACT (PAWS)

The Pet and Women Safety Act (PAWS) Coalition, a group of organizations working together in support of domestic violence survivors and their pets, strongly supports continued appropriations for the Emergency and Transitional Pet Shelter and Housing Assistance Grant Program. Together, we call on Congress to fund the program at the fully authorized amount of \$3,000,000.

PAWS Act legislation was included in the 2018 Farm Bill (Section 12502), establishing this important grant program to support domestic violence shelters as they help survivors and their pets safely seek shelter when leaving an abuser. These grants provide emergency and transitional shelter and housing assistance or short-term shelter and housing assistance. Grants awarded may also be used for programs that enable a survivor to locate and secure safe housing with their pet, safe boarding for their pet, or related services such as transportation and other assistance. In 2023, funding will provide training and technical assistance to existing grantees from fiscal Year 2020–2022. The U.S. Department of Justice (DOJ) Office of Victims of Crime (OVC) is now in its third year of administering this program, and demand for this funding is high.

The \$3.3 million appropriated for 2023 follows the success of the fiscal Year 2020, fiscal Year 2021, and fiscal Year 2022 Emergency Transitional Pet Shelter Housing and Assistance Grant Programs, which awarded approximately \$2 million to six organizations in six States across the Nation in 2020, a total of \$2.42 million to five organizations in 2021, and a total of \$2.7 million to 12 organizations in 2022. Grants have enabled shelters to expand housing and supportive service resources for domestic violence survivors, provide assistance including rent, pet deposits, and pet supplies to those seeking transitional housing with their pet, and more. Each year, the PAWS Act Coalition has worked to raise awareness among the domestic violence shelter community of the availability of this important funding.

PAWS Act Coalition members are also contributing funds and volunteer hours to the cause of making more domestic violence shelters pet-friendly. For example, in 2022 alone, Purina and RedRover awarded nine additional Purple Leash Project

¹⁰ <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-center-excellence-services>

¹¹ <https://www.fda.gov/media/166182/download>

grants to domestic violence shelters across the country in need. These grants provide funding and resources to transform domestic violence emergency shelters into safe spaces for survivors and their pets. Shelters can use the grant money to complete renovations and upgrades to their survivor services offerings that will allow people and pets to escape abuse and heal together. The success of this program demonstrates that smaller-size grants can still have a big impact. Purple Leash Project grants typically range between \$20,000 and \$50,000 each. Since founding the Purple Leash Project, Purina and RedRover have provided 34 grants totaling more than \$700,000 in funding to domestic violence shelters across the United States. Since 2012, RedRover has awarded 185 Safe Housing grants to domestic violence shelters in 46 States to help them become pet-friendly, and the majority of these grants are less than \$20,000. Purina and RedRover are working towards the goal of helping 25 percent of U.S. domestic violence shelters to become pet-friendly by the end of 2025. While these public-private partnerships are hugely important, fully funding the PAWS Act grant program will help to address the widespread need for funding to support similar programs across the country.

The PAWS Act Coalition is grateful to have had the opportunity to meet with the DOJ OVC and the U.S. Department of Agriculture (USDA) to discuss the grant program and offer constructive feedback. Specifically, the Coalition encouraged the USDA and the DOJ to consider providing a greater number of grants at lesser dollar amounts in 2021, with the intention of filling a gap in funding resources and helping more shelters become pet-friendly, especially those that are smaller and more rural. In response, the fiscal Year 2022 and fiscal Year 2023 Grant Programs include small awards designed for shelters and other transitional housing services for DV survivors and their pets that may only be seeking funding for smaller purchases such as kennels, crates, pet supplies, beds and other items that may be necessary to housing survivors and pets together.

Funding the Emergency and Transitional Pet Shelter and Housing Assistance Grant Program at \$3 million is essential to saving the lives of people and pets. According to the Centers for Disease Control, about 1 in 3 women and 1 in 4 men have experienced physical violence by an intimate partner within their lifetime and over 61 million women and 53 million men have experienced psychological aggression by an intimate partner in their lifetime.¹ More than 10 million U.S. adults experience domestic violence annually. On a typical day, there are more than 19,000 phone calls placed to domestic violence hotlines nationwide.²

There remains a critical need for shelter options that accommodate pets. According to a recent nationwide survey of 2,500 domestic violence survivors commissioned by the Urban Resource Institute (URI) and the National Domestic Violence Hotline, 50 percent of respondents reported that they would not consider shelter for themselves if they could not take their pets with them. Ninety-seven percent of respondents said that keeping their pets with them is an important factor in deciding whether or not to seek shelter. Ninety-one percent of respondents indicated that their pets' emotional support and physical protection are significant in their ability to survive and heal. Further, 48 percent reported the threat of harm to pets was a worry and 37 percent reported their abuser had threatened to harm or kill a pet.³

A growing body of science has demonstrated a link between domestic violence and animal cruelty⁴. An outlet of emotional support for survivors, the family pet often becomes a target for physical abuse.⁵ In studies that have explored the role of companion animals in an abusive relationship, companion animals are used by abusers to control, hurt, and intimidate their partners.⁶

Research demonstrates the link between pets and improvements in mental health, particularly for those who have experienced trauma. Companion animals often serve as a much needed and effective outlet for overcoming abuse, and have also been

¹Centers for Disease Control (2022). IPV Factsheet. Retrieved from https://www.cdc.gov/violenceprevention/pdf/ipv/IPV-factsheet_2022.pdf

²National Coalition Against Domestic Violence (2020). Domestic violence. Retrieved from https://assets.speakcdn.com/assets/2497/domestic_violence-2020080709350855.pdf?1596811079991.

³Urban Resource Institute (URI) and The National Domestic Violence Hotline (2019). National Survey on Domestic Violence and Pets: Breaking Barriers to Safety and Healing. Retrieved from <https://urinc.org/wp-content/uploads/2021/05/PALS-Report-Exec-Summary.pdf>

⁴Faver, Catherine A., and Elizabeth B. Strand. "Domestic violence and animal cruelty: Untangling the web of abuse." *Journal of Social Work Education* 39.2 (2003): 237–253.

⁵Matthews, Kevin, and Kelly McConkey. "Examining the nexus between domestic violence and animal abuse in a national sample of service providers." *Violence and victims* 27.2 (2012): 280.

⁶Flynn, Clifton P. "Battered women and their animal companions: Symbolic interaction between human and nonhuman animals." *Society & Animals* 8.2 (2000): 99–127.

shown to improve mental health conditions such as depression, stress and anxiety, all of which can manifest from intimate partner violence.⁷ The pervasiveness of domestic violence during the COVID-19 pandemic and the incidence of violence towards pets in the United States shows the urgency of providing safe shelter for survivors and their pets.

The need for additional pet-friendly options for domestic violence survivors remains an under-addressed, critical issue facing our country. The continuation of the Emergency and Transitional Pet Shelter Housing and Assistance Grant Program funding is an important step to meet this need. Please support Federal funding in fiscal Year 2024 for the PAWS Act grant program to the fully authorized amount of \$3 million so that no survivor of domestic violence will have to choose between their own safety or the safety of their pets.

The PAWS Act Coalition is counting on your strong support for the Emergency and Transitional Pet Shelter Housing and Assistance Grant Program. Together, we can protect survivors of domestic violence by protecting the animals they rely on for comfort and healing.

Respectfully submitted,

Steven Feldman
Human Animal Bond Research Institute (HABRI)
On behalf of the Pet and Women Safety Act Coalition Members:
Nestlé Purina Petcare
Human Animal Bond Research Institute
Pet Partners
RedRover
Urban Resource Institute

[This statement was submitted by Steven Feldman, Human Animal Bond Research Institute (HABRI).]

PREPARED STATEMENT OF RESEARCH!AMERICA

On behalf of Research!America, thank you for this opportunity to submit testimony on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations for Fiscal Year 2024 (FY24). Research!America is a non-profit, non-partisan advocacy alliance. Our more than 300 organizational members work to elevate the priority assigned to speeding the pace of medical and public health progress.

The FDA plays a critical role in ensuring public health and safety through oversight of drugs, biologics, medical devices, food, and cosmetics. In the interest of the continued protection and advancement of our Nation's health, we request that the Committee allocate \$3.963 billion for the FDA in FY24, an increase of \$420 million over FY23.

THE FOOD AND DRUG ADMINISTRATION

The FDA is the oldest consumer protection agency in the U.S. and has overseen an extensive catalog of consumer products for over a century. An estimated \$2.7 trillion in food, medical, and tobacco products are currently regulated under the purview of the FDA, constituting nearly 20 percent of every dollar spent by U.S. consumers. The FDA oversees more than \$360 billion in imports and \$245 billion in exports annually, and monitors more than 270,000 facilities producing drugs, food, biologics, and devices. Furthermore, the FDA regulates nearly 80 percent of the U.S. food supply.

Robust funding for the FDA is critical to ensuring the agency can perform its critical responsibilities with rigor and efficiency. In FY21, over \$3 billion of the FDA's \$6.1 billion budget was spent in programs evaluating the safety and effectiveness of human drugs, biologics, medical devices, and radiological technology. An additional \$1.1 billion was spent in programs that regulate foods. Considering the expansive scope of FDA oversight, it is not a reach to say that every household in the U.S. contains food, medical, and/or cosmetic products that were evaluated for safety and efficacy by the agency.

The need for increased funding reflects both the growing demands on the agency and the growing complexity of those demands. We are in a period of unimagined

⁷ World Health Organization. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. World Health Organization, 2013.

medical progress, epitomized by gene therapy, immunology, the expanding use of digital technologies, and artificial intelligence applications. FDA clearly needs additional funding to fulfill its key role in assuring these developments translate into safe and effective advances benefiting the American people, while assuring ongoing rigor and effectiveness across its other responsibilities.

Given the pivotal role the FDA plays in our public health system and economy, and the increasing scope and complexity of its oversight responsibilities, we believe it is vastly in the Nation's best interests to increase its budget by at least \$420 million in FY24. Thank you for considering our testimony, and for your efforts, and those of your respective staff members, on behalf of us all.

[This statement was submitted by Ellie Dehoney, Senior Vice President of Policy and Advocacy, Research!America.]

PREPARED STATEMENT OF THE SUSTAINABLE AGRICULTURE RESEARCH AND
EDUCATION

Thank you for the opportunity to present our fiscal year 2024 funding requests. We appreciate your work on the Consolidated Appropriations Act, 2023, which addressed many of our priorities for FY23. On behalf of our member organizations from around the country, we submit the following requests for the Department of Agriculture. These requests are listed in the order they typically appear in the appropriations bill.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE
SUSTAINABLE AGRICULTURE RESEARCH AND EDUCATION PROGRAM

For over 30 years, the Sustainable Agriculture Research and Education (SARE) program has been a leader in addressing key sustainability and profitability challenges facing agriculture. As USDA's only farmer-driven research program, SARE has helped create more innovative farm practices that are actually adopted by farmers on the ground than any other competitive research program. SARE is also expanding outreach to historically underserved farmers and ranchers by providing funds to support education and training. Investing in agriculture research is a win for taxpayers too: every dollar invested in public research generates \$20 in economic activity.

Since the program launched, SARE has awarded over \$377 million to over 8,300 initiatives focused on farmer-driven research and education efforts in every State across the country. Despite SARE's long-standing record of helping farmers and ranchers develop and adopt innovative practices and systems, the program has not reached its full authorized amount of \$60 million. As a result, USDA can only fund a fraction of eligible proposals submitted each year. To meet future challenges, farmers need research that is accessible and relevant to their farms. We therefore urge Congress to provide full funding for SARE at its authorized level of \$60 million, mirroring the President's Budget Request for FY24. This funding will allow SARE to continue supporting research at land grant universities, accessible and practical information for farmers, resources tailored to underserved farmers, farm-based resilience to climate change, and thriving rural communities.

ORGANIC TRANSITIONS INITIATIVE (ORG)

The Organic Transitions Research, Education, and Extension program (ORG) helps farmers fill knowledge gaps and overcome barriers in successfully transitioning to organic farming. For nearly 20 years, ORG has invested \$44 million in over 90 projects to develop and implement research and education programs to improve the competitiveness of organic and transitioning-to-organic livestock and crop producers. By providing critical funding to colleges and universities conducting organic farming research, ORG also helps farmers better understand the economic and environmental benefits of organic farming.

Since the 1990s, the organic market has grown into a multi-billion-dollar industry. Despite this growth, total USDA investment in organic research remains below 2 percent of its annual research budget, far short of the 6 percent market share of organic products in the US. Given the growth of the organic sector and the continued demand for support to organic farmers, investment in the ORG program must increase to keep pace with this need. We therefore urge Congress to provide \$10 million in discretionary funding in FY24 for the Organic Transitions Program.

AGRICULTURAL MARKETING SERVICE AND RURAL BUSINESS—COOPERATIVE SERVICE

LOCAL AGRICULTURE MARKET PROGRAM

The Local Agriculture Market Program (LAMP) serves as an umbrella program for the Farmers Market and Local Food Promotion Program (FMLFPP) and the Value-Added Producers Grant Program (VAPG). Through these programs, USDA has invested in the physical infrastructure, training, and relationship development necessary to expand local and regional supply chains. These investments provided significant return when the pandemic and other recent supply chain disruptions upended our food system. LAMP helped ensure that infrastructure and relationships were in place to enable local and regional food distribution networks to fill critical supply chain gaps and provide for the most vulnerable in our communities.

VAPG offers grants to farmers and ranchers who are developing farm and food businesses to manage risk and boost income, create jobs, and support regional supply chains in rural America. A recent Economic Research Service report shows that businesses that received VAPGs were 89 percent less likely to fail 2 years after the grant compared to similar businesses that did not receive support through the program.

FMLFPP is a competitive grants program that funds direct-to-consumer marketing and local businesses that act as intermediaries between producers and consumers by aggregating, storing, processing, and distributing local or regional food. Since 2006, FMLFPP and its predecessor program have invested over \$250 million in strengthening local and regional food systems in every State in the country. Despite a long and successful track record and interest in local and regional markets and value-added products, funding for both of these programs is only a fraction of what is needed to meet demand. Therefore, we support the President's Budget Request of \$16 million in discretionary funding for VAPG and \$7.5 million in discretionary funding for FMLFPP for FY24.

NATURAL RESOURCES CONSERVATION SERVICE (NRCS)

CONSERVATION TECHNICAL ASSISTANCE AND THE GRAZING LANDS CONSERVATION INITIATIVE

Conservation Technical Assistance (CTA), a subset of Conservation Operations, is the backbone of USDA's conservation programs. Through CTA, NRCS field staff work with farmers to develop and implement conservation plans to steward resources, assess conservation practices on farms, fulfill conservation compliance requirements, and collect and disseminate data on the Nation's natural resources. This funding is critical to help producers develop site-specific plans to conserve water, prepare for extreme weather, and address natural resource concerns on their land. CTA funding can also support NRCS efforts to provide technical assistance to farmers and ranchers interested in improving their grazing operations.

Grazing-based farm and ranch operations improve profitability for producers across the Nation. Grass-based agriculture is an important strategy for introducing new farmers and ranchers into livestock management because they can be low up-front-capital operations that nonetheless generate good income. Well managed grazing of livestock can help new and established farmers and ranchers alike thrive and stay in their rural communities. Effectively managed grasslands also protect water quality, improve soil health, and provide a good habitat for pollinators and wildlife.

Whether it is one-to-one technical assistance focused on grazing or the development of conservation plans for an individual farm, on-the-ground capacity at NRCS continues to be a limiting factor for conservation implementation, and an increased investment in CTA (including GLCI) will give NRCS the ability to truly build local capacity, leading to improved conservation and resource management. To ensure that CTA has the resources needed to help producers implement the conservation practices that are essential to mitigating climate change, we urge Congress to provide \$1.1 billion for CTA, with \$30 million of that specifically dedicated to GLCI.

OFFICE OF URBAN AGRICULTURE AND INNOVATIVE PRODUCTION

The 2018 Farm Bill authorized the creation of the Office of Urban Agriculture and Innovative Production (the Office), whose mission is to encourage and promote urban, indoor, and other innovative agricultural practices. While the name implies a restriction to urban areas, urban agriculture broadly covers a variety of growing techniques that lend themselves to urban environments but have been adopted in both suburban and rural areas. The Office promotes a wide variety of practices including community gardens, outdoor vertical production, greenhouses, indoor farms, and hydroponic facilities.

The Office received funding for the first time in FY20 to implement its authorities. Since FY20, funding has been utilized to pilot an advisory committee for the Office and USDA, a competitive grants program, a Community Compost and Food Waste Reduction cooperative agreement program, and 17 urban and suburban Farm Service Agency (FSA) County Committees. Both the competitive grants and food waste reduction cooperative agreements have garnered interest far beyond available funding. In fiscal year 2021 alone, the Office awarded \$6.6 million in grants and cooperative agreements, \$4.75 million for 10 Planning Projects and 11 Implementation Projects, and \$1.92 million in 24 compost cooperative agreements.

Due to overwhelming interest, especially from farmers of color frequently operating in urban areas, we urge Congress to fully fund the Office of Urban Agriculture at the authorized level of \$25 million in FY24 so that it has sufficient resources to meet the demand of a growing farming sector and expand beyond initial pilot States.

OFFICE OF PARTNERSHIPS AND PUBLIC ENGAGEMENT AND NATIONAL INSTITUTE OF
FOOD AND AGRICULTURE

FARMING OPPORTUNITIES TRAINING AND OUTREACH PROGRAM

The 2018 Farm Bill created the Farming Opportunities Training and Outreach (FOTO) program to strengthen USDA's efforts to train and assist beginning, veteran, Tribal and other underserved farmers. FOTO combines two of USDA's flagship training and technical assistance programs: the Beginning Farmer and Rancher Development Program (BFRDP) and the Outreach and Assistance to Socially Disadvantaged and Veteran Farmers and Ranchers Program (aka "Section 2501").

Since 1990, the 2501 Program has been the only program investing millions of dollars to reverse disadvantages and disparities that have faced our Nation's military veterans and minority farmers by providing tools they need to thrive in today's agricultural economy. For over a decade, BFRDP has been the only Federal program exclusively dedicated to training new farmers and ranchers and has invested over \$176 million in grants to ensure they have the skills to start successful farms. Both programs have funded academic institutions, extension services, and community organizations to support and train farmers and ranchers. Ensuring the success of minority farmers, veteran farmers, and new and beginning farmers through technical assistance and other resources is critical to the continued success of a new generation of American agriculture. Therefore, we urge Congress to provide \$10 million in discretionary funding in FY24 for the Farming Opportunities Training and Outreach Program, split equally between BFRDP and 2501.

GENERAL PROVISIONS

PACKERS AND STOCKYARDS ACT RULEMAKING RIDERS

The Packers and Stockyards Act (PSA) was passed a century ago to combat anti-competitive practices in the livestock and poultry industries as corporate meatpackers and processors consolidated and amassed power over producers. From authority given in the 2008 Farm Bill, USDA published a set of proposed regulations to strengthen PSA enforcement and received over 61,000 comments largely in support of the rules. However, livestock and poultry companies lobbied Congress to use the annual appropriations process to block USDA from finalizing the rules, known as "GIPSA" rules. As a result, the annual agriculture appropriations bill for FY2012–2015 included "GIPSA riders" to block USDA from implementing the rules and, in some cases, to require USDA to rescind rules that had been finalized.

Since June 2022, USDA has released two rules to strengthen PSA: the Transparency in Poultry Growing Contracts and Tournaments rule, and the Inclusive Competition and Market Integrity rule—while a third rule is still anticipated. It is critical that USDA is allowed to implement these pro-competition rules to protect producers and consumers alike from unfair and anticompetitive practices in agricultural markets. These reforms cannot happen if appropriations riders block them. As such, we urge appropriators to not include any general provision blocking the USDA from finalizing the PSA fair competition rules.

[This statement was submitted by Mike Lavender, Policy Director:
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PREPARED STATEMENT OF SPARK CLIMATE SOLUTIONS

In this testimony, Spark Climate Solutions, a nonprofit organization, urges the Senate to invest in research and development to increase livestock productivity and significantly reduce livestock enteric methane emissions. We must also modernize regulatory processes to evaluate, and where appropriate, approve, new solutions that will keep American producers globally competitive while working towards climate goals. Near-term action is needed to achieve this goal by funding research and development of new solutions, producer education, regulatory innovation, and targeted incentives.

In 2023 the USDA's Agriculture Food & Research Institute is funding \$5,000,000 in competitive grants for livestock enteric methane emissions research. We recommend increasing USDA-AFRI's funding in 2024 to expand this program. We also recommend that Hatch funding, NIFA Animal Health and Disease, USDA Equipment Grants, USDA-ARS and other competitive and capacity funding be appropriated towards achieving this goal.

Agriculture emits 36 percent of United States methane emissions, more than that leaked from U.S. fossil fuel infrastructure.¹ While a significant amount of these emissions come from manure, 70 percent of agriculture methane comes from cattle as methane exhaled from cattle from a process called "enteric fermentation."² Remediating livestock enteric methane emissions represents an opportunity to reduce the US greenhouse gas footprint by 3 percent. Because the enteric methane comes from the calories in the feed being used inefficiently, this could simultaneously potentially improve cattle productivity by up to 6 percent. Currently available solutions can address, at most, about 10 percent of US enteric emissions, and not all of those solutions are yet approved to be used by American producers, while they have been approved for major livestock competitors in Brazil, Australia, Europe and other agricultural export nations.³ And we need to find new solutions for the remaining majority of emissions. As methane is an unproductive byproduct of ruminant digestion, research and development should prioritize enhanced productivity that simultaneously reduces emissions. Yet over the last 5 years, the US Federal Government has spent less than estimated \$5,000,000 per year on research and development in this area, very low in light of the high potential climate and productivity impact, compared to other agricultural research areas.⁴

Lowering enteric methane emissions would help bolster U.S. agricultural leadership and export competitiveness. To that end, we recommend investing in building regulatory pathways that are ready to make informed decisions about new solutions coming on the market and authorizing and appropriating \$82,000,000 per year to a US Department of Agriculture enteric emissions research and innovation program which would advance solutions that could easily drop into existing farm practices and convert avoided methane into increased milk and meat production. We set out the justification for this amount below, which can be addressed by a combination of authorizations and appropriations.

CHALLENGE & OPPORTUNITY

Cattle and other ruminants digest their food via anaerobic (oxygen-free) fermentation. This allows them to digest roughage such as grasses and other forage and transform it into meat and milk. But it also generates methane. Cattle release on average 6 percent of the calories they eat as methane, a substantial loss in their potential meat and milk productivity. This methane is in addition to the methane emitted by their manure.

An invisible and odorless gas, methane is a powerful greenhouse gas that is responsible for 0.5°C of the 1°C of modern global warming (based on the 2010–2019 average).⁵ One-third of U.S. anthropogenic methane emissions come from cattle and other ruminants. Solutions may be able to be developed that both disrupt enteric methane production while also increasing cattle productivity. That would help reduce global temperatures and provide benefits for both producers and consumers. Currently, there are a few tested and marketable solutions that use chemicals to disrupt methane-creating microbes in the cattle's first stomach (the rumen). These are important solutions that need to be evaluated for regulatory approval. However,

¹ <https://cfpub.epa.gov/ghgdata/inventoryexplorer/#allsectors/allsectors/allgas/gas/all>

² <https://www.epa.gov/system/files/documents/2022-04/us-ghg-inventory-2022-chapter-5-agriculture.pdf>

³ <https://globalresearchalliance.org/wp-content/uploads/2021/12/An-evaluation-of-evidence-for-efficacy-and-applicability-of-methane-inhibiting-feed-additives-for-livestock-FINAL.pdf>

⁴ <https://thebreakthrough.org/issues/food-agriculture-environment/from-lab-to-farm>

⁵ <https://www.ipcc.ch/report/ar6/wg1/figures/summary-for-policymakers/figure-spm-2>

additional research and development must also be done, to help address the majority of emissions that don't yet have available solutions, particularly from cattle grazing in pastures. Additional work is also needed to continue developing solutions that consistently lead to a productivity benefit. Focused scientific research could deepen our understanding of cattle metabolism, and advance new solutions for reducing enteric methane further.

Progress on this front also requires improved research tools to measure how much methane cattle breathe out burp and relate these methane emissions to their productivity and intake of feed and forage. Access to such research tools enables researchers and innovators to develop and evaluate new solutions. We know that methane emissions rates vary widely between cattle on the same farm of the same breed, as well as across breeds. Currently these tools are expensive and not widely available, for example the primary tool available measures thirty cattle per day, costs \$100,000, and can be found at only a handful of research institutions. That presents a practical problem of access not only for producers but also for non-specialist scientific innovators. Making those tools more accessible, for example via fee-for-service centers at leading US Land Grant institutes, would make them more affordable for producers and researchers. That would help unlock the creativity of US innovators, and provide evidence that their solutions really work for producers, and are having positive climate impact.

Even when new solutions are found and proven, innovators still face a 10-year FDA approval process. This is uncompetitive and restrictive compared to other countries. Since much faster approval is possible in Australia, Brazil, and Europe, innovators have an incentive to launch their products and build their businesses there rather than in the USA. And as climate-aware export markets develop, slow FDA approval will cost US producers market share and market opportunity. We therefore recommend that the FDA be given authority and direction to evaluate new methane-reducing products for safety on an accelerated timeline, while maintaining critical human and animal safety standards. This would help the US position itself as a global leader in a potential multi-billion dollar market while upholding its climate commitments.

To achieve these goals, we propose the following steps:

FUND BASIC & APPLIED LIVESTOCK ENTERIC METHANE RESEARCH

Developing science-based, effective livestock enteric methane solution depends on a detailed understanding of cattle microbiology as well as practical understanding of what makes solutions easy to adopt. Increasing funding for basic and applied research could accelerate development of new methods, and rapidly build a portfolio of scalable potential solutions. We recommend that within USDA-NIFA, that AFRI, Hatch, Animal Health and Disease, and other competitive and capacity funding be appropriated to:

- Basic research in livestock methane microbiology, to create a knowledge base that will support development of new win-win solutions.
- Applied livestock methane solutions research, simultaneously prioritizing productivity and methane reduction solutions, that could be administered in a long-duration (e.g. once per year) product formulation compatible with grazing cattle. Such technology already exists for cattle nutrition and disease prevention⁶.
- Surveys and other social science research to understand barriers and opportunities for implementation, with the goal of finding simple, inexpensive ways American producers and ranchers can implement new solutions.

Funds Needed: \$50,000,000 per year

Congress should also include report language urging USDA to increase funding for enteric methane within the Division of Animal Systems, for example:

Enteric Methane Innovation.—The Committee recognizes the innovations that increased public research on enteric methane could make possible. The Committee encourages AFRI to make the advancement of enteric fermentation solutions, such as cattle feed additives, methane-inhibiting vaccines, and breeding for low-methane cattle, a distinct research priority.

CREATE PUBLIC FEE-FOR-SERVICE TESTING FACILITIES FOR LIVESTOCK METHANE

Access to methane test facilities, from the laboratory to the dairy barn, is a bottleneck. It limits how many innovative ideas for solutions can be tested. Only a small number of institutions worldwide have the tools needed to test methane, and outside

⁶<https://www.natural-techna.com/en/bolus-bovine-ovine-goat>

access to those tools is limited. We recommend funding be appropriated for innovation-enabling research infrastructure to USDA-ARS and USDA-NIFA, through USDA Equipment Grants and USDA-AFRI. This funding would:

- Establish a nationwide network of fee-for-access livestock methane research facilities, equipped with research measurement equipment and technical staff. US Land Grant universities already possess the necessary research cattle management expertise. Joint investment with them and partial support from research users would quickly resolve access issues and help make the US an international leader in livestock methane research.
- Develop a USDA-ARS national center for pre-livestock testing and screening of potential products, which would serve as a user facility, accessible to scientists in many fields. Specialized cattle researchers shouldn't be the only ones who can test new ideas for reducing livestock enteric methane. Accessible facilities could unlock innovation from the leading U.S. biology researchers.

US Department of Energy national labs have successful user facilities which could serve as a model. For example, the National Renewable Energy Lab leads standard-setting and validation for high-efficiency solar energy technology. New Zealand's AgResearch is another model. It has a grant-accessible anti-methane rapid testing facility and it recently developed a breed of sheep with 10 percent reduced methane emissions and higher productivity.

Funds Needed: \$15,000,000 per year

FUND DEVELOPMENT OF LOW-COST CATTLE METHANE MEASUREMENT TECHNOLOGY

What can be measured can guide innovation and management, and what we measure easily and consistently, we improve. Producers measure milk production on every cow every day and we've seen this lead to a 300 percent productivity increase since 1950. But producers and most researchers do not measure livestock methane production. Livestock methane measurement equipment currently costs about \$100,000 for a system that measures 30-40 cattle a day. We recommend that within USDA-NIFA, that AFRI, Hatch, Animal Health and Disease, and other competitive and capacity funding be appropriated to:

- Develop lower-cost measurement systems, so every research barn can afford to measure livestock methane. US Land Grant universities have over 10,000 research cattle. Equipped with measurement systems, they could all provide livestock methane research data.
- Develop farm-integrable measurement systems that make methane emissions visible to US producers, enabling them to experiment and innovate. Methane is a loss for livestock production. If producers can see it, they'll work to decrease methane and improve their bottom line.

A \$15 million annual budget for technological development might lead to rapid improvements in measuring equipment systems. A portion of this could fund interdisciplinary projects that bring engineers from across industry and livestock experts together. Another portion could be framed as a grand challenge to achieve cost and performance targets connected to a government procurement market-shaping program.

Funds Needed: \$15,000,000 per year

DIRECT THE FDA TO CREATE A NEW REGULATORY CATEGORY AND TEAM FOR CLIMATE-POSITIVE LIVESTOCK PRODUCTS

Current anti-methane feed additives are regulated as drugs, requiring a ten-year approval process. As European export markets increasingly regulate emissions, this may lead to a lack of competitiveness for US products. To address this, Congress should create a special FDA category with a dedicated team for climate-positive livestock products, with appropriate funding to resource the team and infrastructure necessary to achieve the goals of robustly evaluating new anti-methane solutions for safety and efficacy, and making new solutions available to US farmers if safe and effective.

[This statement was submitted by Spark Climate Solutions, Sparkclimate.org.]

PREPARED STATEMENT OF SPARK CLIMATE SOLUTIONS

In this testimony, which I am submitting on behalf of Spark Climate Solutions, a non-profit organization, I urge the Senate to invest in research, development and best management practice adoption to modernize soil management and fertilizer

usage, leading to improved crop productivity, further climate resilience, and increased resilience to global fertilizer shortages.

Building and maintaining soil organic matter is widely viewed as beneficial for multiple reasons, including provisioning of nutrients for crop productivity, improving soil aeration and water holding capacity, maintaining habitat for beneficial soil microorganisms, sequestering carbon, and retaining nitrogen and phosphorus. Proper soil management that retains nutrients not only improves crop productivity, but also reduces harmful soil erosion and nutrient runoff and reduces emissions of the potent greenhouse gas, nitrous oxide (N₂O). Here we present recommendations to address the multiple goals of improving soil quality for crop production, sequestering carbon, retaining nitrogen, and reducing N₂O emissions.

Spark would recommend the following guidelines for investments in advancing these objectives regarding carbon gains and avoiding nitrogen losses, including nitrous oxide (N₂O), whether applied to spending authorization of activities indicated in the IRA and other existing programs, or new authorizations under the 2023 Farm Bill:

1. Both carbon sequestration and nitrogen retention (resulting in lower nitrogen losses and lower N₂O emissions) should be promoted with incentives for farmers to adopt best management practices (BMPs). Increased funding for programs such as USDA's Environmental Quality Incentives Program (EQIP) and Conservation Innovation Grants (CIG) would promote adoption of BMPs including:

- Developing and updating nutrient management plans
- Planting cover crops for the non-growing season
- Spring rather than fall application of fertilizers
- Split application of smaller doses of fertilizers during the growing season
- Conservation tillage practices that are appropriate for each region's crops, soils, and climate
- Using enhanced efficiency fertilizers and inhibitors of urease and nitrification
- Experimenting with multi-cropping
- Experimenting with re-integrating livestock and crop production systems

2. Incentive programs should focus on adoption of these BMPs rather than verification of the specific effects at the farm scale. BMP adoption is relatively easy to verify with a combination of satellite imagery, drone overflights, brief on-site visits, and farmer self-reporting. While verifying the benefits of these BMPs for carbon sequestration, reduced nitrate runoff, and reduced N₂O emissions may not be feasible or affordable at the individual farm scale, in the aggregate, widespread BMP adoption will yield these benefits at larger scales. Unless and until monitoring, reporting, and validation (MRV) of soil carbon credits at the farm scale can meet more rigorous standards, incentives and outreach to encourage BMP adoption will be a more effective policy approach to increasing soil carbon sequestration and reducing nitrogen losses and N₂O emissions. Additional research should be funded to quantify average environmental benefits of BMPs by soil type, climate, and crop. The Long-Term Agricultural Research (LTAR) network within USDA-ARS would be well suited to conduct this research. It should be authorized and its annual funding increased to \$42m. This research will enable BMP impacts on environmental outcomes to be evaluated at the regional scale.

3. USDA should be tasked and funded to harmonize and coordinate MRV requirements for the rapidly emerging markets for carbon credits in agricultural soils. These markets already have considerable momentum but lack rigor and consistency-guidance that USDA could help provide. Regional Climate Hubs should be authorized and the budget increased to \$30M annually to develop and share resources related to MRV requirements and tools.

4. Funding should be increased for social science studies to better understand why farmers choose to accept or decline incentive programs to adopt BMPs or to participate in soil carbon credit programs. Farmer decision making is not confined only to the influences of agronomic advice and economic benefits, but is also influenced by numerous social factors, such as education, tradition, trusted sources of information from family or crop advisors, risk aversion, etc. These factors are poorly understood due to insufficient funding of social science research in agronomy. It's urgent to close this research gap. The Economic Research Service (ERS) currently hosts most of USDA's economic research, but we believe that basic social science research should be added to the remit of the National Institute of Food and Agriculture (NIFA), with funding of \$10M per year for basic socio-economic research on farmer decision making regarding adoption of BMPs. Funding for R&D, including agronomic, economic, or social science research, should emphasize farmer participation

and follow emerging principles of stakeholder engagement in convergent science. Farmers have knowledge and experience that can help inform the design, implementation, and analysis of research. Their participation in all stages of research also improves the probability they will buy into the resulting recommendations.

5. Additional R&D funding is needed for medium-to-long-term efforts toward decoupling food production from intensive use of nitrogen amendments. This will require significant advanced research and transformative innovation of our food production system, which is the objective of the Agriculture Advanced Research and Development Authority (AgARDA; a “DARPA-style” approach to transformative technological innovation). The current suite of BMPs promoting the “4Rs” of nutrient stewardship (the right form, right time, right amount, and right place of fertilizers applications) are helpful and worthy of continued support. But their incremental improvements in nitrogen use efficiency have been insufficient to reduce total nitrogen pollution as agricultural productivity increases in response to growing food demand. Therefore, longer-term, innovative and transformative solutions should be promoted through funding appropriation to AGARDA at the currently authorized level of \$50M/yr, with increases in both authorization and appropriations to at least \$200M/yr, to pursue innovations in the topics listed below, among many other important agricultural innovation priorities. In addition, USDA should establish new centers of excellence for research on each of these topics:

- Developing decentralized green ammonia production (using renewable energy to produce the hydrogen used for ammonia synthesis). This would provide farmers with reliable, year-round access to fertilizers so that applications could be more closely matched and optimized with crop growth.
- Expanding direct feeding of livestock with synthetic nitrogen, including urea, nitrate, and synthetic amino acids, so that less cropland and less fertilizer are needed to nourish livestock (e.g., less soybean and alfalfa and lower nitrogen concentrations in grains like corn)
- New efforts in crop breeding to enable crops to grow further into cold seasons (thus remaining sinks for soil nitrogen for a longer period), internal recycling of nitrogen within crop plants, nitrogen concentrations of grain that are optimized for specific markets, production of natural nitrification inhibitors, and perennialization of grain crops.

[This statement was submitted by Eric A. Davidson, Ph.D., Spark Climate Solutions Sparkclimate.org.]

PREPARED STATEMENT OF SQUAXIN ISLAND TRIBE

On behalf of the Tribal Leadership and citizens of the Squaxin Island Tribe, I am honored to submit written testimony on our annual budget priorities for the fiscal Year 2024 Appropriations for the Department of Agriculture funding for Tribal Programs in Rural Development and the Food and Nutrition Service. The Squaxin Island Tribe requests that all Tribal program funding throughout the Federal Government be exempt from future sequestrations, rescissions, and disproportionate cuts.

TRIBAL SPECIAL REQUEST

1. Food Distribution Program on Indian Reservations (FDPIR) Demonstration Project—Increase funding to expand the number of Tribes participating—Squaxin Island Tribe requests to participate—Food Nutrition Service

NATIONAL AND REGIONAL REQUESTS

1. Permanent authority for the 638 FDPIR Demonstration Project
2. Support efforts to Fulfill U.S. Trust Responsibility to Indian Tribes in the Stewardship of Federal Lands and Waters
3. \$2.0 Million—Rural Development Technical Assistance Program
4. Support the requests of the National Congress of American Indians (NCAI) and the Affiliated Tribes of Northwest Indians (ATNI)

SQUAXIN ISLAND TRIBE BACKGROUND

We are native people of South Puget Sound and descendants of the maritime people who lived and prospered along these shores for untold centuries. We are known as the People of the Water because of our strong cultural connection to the natural beauty and bounty of Puget Sound going back hundreds of years. The Squaxin Indian Reservation is in southeastern Mason County, Washington and the Tribe is a signatory to the 1854 Medicine Creek Treaty. Our treaty-designated reservation, Squaxin Island, is approximately 2.2 square miles of uninhabited forested

land, surrounded by the bays and inlets of southern Puget Sound. Because the Island lacks fresh water, the Tribe has built its community on roughly 26 acres at Kamilche, Washington purchased and placed into trust. The Tribe also owns 6 acres across Pickering Passage from Squaxin Island and a plot of 36 acres on Harstine Island, across Peale Passage. The total land area including off-reservation trust lands is 1,715.46 acres. In addition, the Tribe manages roughly 500 acres of Puget Sound tidelands.

Our Tribal governance combines our sovereign powers as well as U.S. Congressional acts related to treaties, statutes, and public law. Squaxin Island Tribe, like all Tribal Nations, continue to work through the impacts of the pandemic. Prior to COVID-19, the Tribal government and our economic enterprises constituted the largest employer in Mason County with over 1,250 employees. The Tribe has a current enrollment of 1,040 and an on-reservation population of 426 living in 141 homes. Squaxin has an estimated service area population of 2,747; a growth rate of about 10 percent, and an unemployment rate of about 30 percent (according to the BIA Labor Force Report). We continue to need the assistance of Congressional relief funds to mitigate the ongoing challenges to recovery. We are grateful for the support we have received so far.

SQUAXIN ISLAND TRIBE SPECIFIC REQUEST/JUSTIFICATION:

THE FARM BILL REAUTHORIZATION

The 2018 Farm Bill was a major bipartisan achievement that included an impressive Tribal agenda. It has been a catalyst for Tribal rural communities to advance food sovereignty and security, economic and workforce development initiatives, public health priorities, and rural broadband internet deployment just to name a few. The Squaxin Island Tribe is a self-determining, self-governing sovereign nation and for more than 35 years, we have administered programs, functions, services and activities that were previously assumed to be performed for our benefit by the Federal Government. We enjoy our autonomy but are limited by Self-Governance authority only in the Department of the Interior, Department of Health and Human Services and Department of Transportation. While the 2018 Farm Bill provided Tribes with unprecedented opportunities, the next version should build on the progress made to date and advance a Federal agricultural policy that incorporates our priorities and expands Self-Governance authority.

FOOD DISTRIBUTION PROGRAM ON INDIAN RESERVATIONS (FDPIR) DEMONSTRATION PROJECT—INCREASE FUNDING TO EXPAND THE NUMBER OF TRIBES PARTICIPATING AND ALLOW ADDITIONAL TRIBAL GOODS ON PRODUCTS LIST

The Squaxin Island Tribe has been successfully operating programs, services, functions and activities previously performed by both the Department of Interior's Bureau of Indian Affairs and the Department of Health and Human Services' Indian Health Service under 638 contracts and Self-Governance compacts for more than thirty-five years. We will be exploring options in the Department of Transportation under Self-Governance soon.

The USDA Indigenous Food Sovereignty Initiative has been operating since 2021. The "Food Distribution Program on Indian Reservations (FDPIR)" demonstration project, is an initiative that allows Tribes to promote Traditional foods, agriculture markets and indigenous healthy foods tailored to American Indian and Alaska Native dietary needs. Tribes also market Tribal foods, support seed saving centers along with other traditional food practices. We are excited to see the FDPIR demonstration project in USDA and are anxious to explore how to expand the FDPIR products and get more seafood on the products list. Squaxin Island has many other seafood products, such as clams, oysters, salmon and geoducks, and we would like to have an opportunity to offer these additional products to the FDPIR products list.

We ask this subcommittee to continue to invest in this initiative and increase the funding that will allow additional Tribes to participate in the 639 FDPIR demonstration project and allow for other Tribal practices to be showcased and support self-determination and self-government.

NATIONAL AND REGIONAL REQUESTS:

1. Permanent authority for the 638 FDPIR Demonstration Project—For nearly 35 years Tribes have operated programs under the Self-Governance authority in the Indian Self-Determination and Education Assistance Act (ISDEAA), that were previously performed by Federal personnel. Tribes have improved program administration, management and operations efficiently and effectively for better delivery of services to our Tribal citizens

and within our communities. We ask that the Committee continues to provide funding for the expansion of the demonstration. With documented success, permanent authority should be imminent in the 2023 Farm Bill Reauthorization.

2. Support efforts to Fulfill U.S. Trust Responsibility to Indian Tribes in the Stewardship of Federal Lands and Waters—The Secretaries of Agriculture and Interior issued a Joint Secretarial Order 3403 to ensure that their departments and component bureaus and offices are fulfilling the Trust Responsibility in the stewardship of Federal lands and waters. Even though there have been more than 20 new co-stewardship agreements with Tribes to further stewardship goals, in the past, Tribes have been made many promises and as we move into another chapter of American Indian and Alaska Native history with the United States, we ask that such fulfillment of the U.S. Trust Responsibility be codified to protect the progress made under this Joint Secretarial Order.

3. Include \$2 Million for USDA Rural Development Tribal Technical Assistance Program—The 2018 Farm Bill mandated the establishment of a Tribal Technical Assistance Program within USDA-Rural Development (RD) designed to address the unique challenges Indian Country faces when seeking infrastructure, cooperative development, housing, and other development opportunities funded by USDA–RD. Funding for this newly established area is especially critical due to the unique circumstances surrounding lending and infrastructure deployment in Tribal communities, which often leads to either misinformation provided to Tribal nations or misinterpretation of Tribal applications. Appropriating \$2 million to this program will help to eliminate these unnecessary barriers to development in Indian Country.

4. Support the fiscal Year 2024 Budgets Requests of the National Congress of American Indians (NCAI) and the Affiliated Tribes of Northwest Indians (ATNI)

Thank you for this opportunity to present written testimony and considering these requests.

[This statement was submitted by Hon. Kristopher Peters, Chairman.]

PREPARED STATEMENT OF THE TRANSFORMATION PROJECT

Thank you for the opportunity to present The Transformation Project's fiscal Year 2024 funding requests. The Transformation Project works with farmers, local technical consultants, and research universities across the country to model agricultural systems that demonstrate the feasibility of transitioning contract poultry and livestock operations to more lucrative and resilient farming methods that center farmer autonomy and more sustainable production practices. We match enrolled farmers with local technical consultants and industry experts to design individualized farm transition plans, document those transitions, and create public-facing resources and economic models to serve as guides for other farmers to easily replicate. The Transformation Project aims to facilitate alternative business opportunities to farmers who would like to feed our Nation outside of the industrialized model. These alternatives offer farmers autonomy to make decisions for their business needs and promote competition by supporting local food systems.

On behalf of the farmers, technical consultants, and supporters we serve, we submit the following requests for the Department of Agriculture:

GENERAL PROVISIONS

Create a Climate-Smart Transition Initiative. USDA's conservation programs provide significant cost-share dollars for farmers implementing practices that protect water, soil, and wildlife; preserve ecosystems; and help farmers impacted by natural disasters. Federal programs like the Environmental Quality Incentives Program, should be leveraged to more actively support climate-smart farm transitions that restore value to stranded farm assets and support beginning and socially disadvantaged farmers, in a larger effort to increase the resiliency of our entire agricultural system.

Utilizing existing funding authorized under the Inflation Reduction Act (Section 21001(a)(1) of Public Law 117–169) to create a Federal climate-smart transition initiative would create a more just, equitable, and sustainable food system by transitioning high-emission animal confinement operations, such as contract poultry and hog farmers and dairy farmers, to growing lower-emission crops in a more resilient manner. These transitions level the playing field between foreign competition,

and create a more secure domestic food system, by increasing year-round specialty crop production. This initiative will give farmers the freedom to respond to market changes, be competitive in emerging markets, create new jobs in rural communities, and leverage funding for the dual purpose of protecting environmental resources and increasing farm values.

Proposed Bill Language. Climate-Smart Transition Initiative.-Of the funds authorized under Section 21001(a)(1) of Public Law 117-169, the Secretary shall provide grants and cooperative agreements that will facilitate the adoption of more resilient and climate-smart agricultural practices by livestock and poultry producers through infrastructure improvements related to (1) providing animals with access to the outdoors or pasture, and (2) converting to specialty and organic crop production.

Proposed Accompany Report language: Section 21001(a)(1) of Public Law 117-169 appropriates \$1.75 billion for Fiscal Year 2024 to support conservation activities under the environmental quality incentives program that directly improve soil carbon, reduce nitrogen losses, or reduce, capture, avoid, or sequester carbon dioxide, methane, or nitrous oxide emissions, associated with agricultural production. The committee directs the USDA to include in these efforts, support for farmers who wish to transition from high-emission animal production systems to lower-emission farming methods that utilize specialty crops and organic production methods. Further, the committee directs the USDA to monitor these climate-smart transition efforts, including but not limited to: the costs associated with transitions including any necessary upgrades, debt-relief, the viability and the profitability of plant-focused farming using existing infrastructure from animal agriculture operations. The Committee directs the Secretary to report back to this Committee with his findings no later than 180 days after the enactment of this legislation.

Additional Background:

The uncertainty faced by our Nation’s farmers due to the unbalanced influence of large agribusiness companies is an overlooked social and economic danger in the United States. The widely utilized contractor model that is especially prevalent in animal agriculture, combined with extreme weather events and the increasing unpredictability of market forces, have resulted in the bankruptcy and foreclosure of thousands of small American farmers, or the abandonment of farming altogether.

To evaluate the economic viability of converting contract poultry and livestock facilities to specialty crop production, we worked with Virginia Tech to create proposed infrastructure conversion recommendations and with an agricultural economics firm to study the potential return on investment of these recommendations. We analyzed four crops to assess their potential to service the debt of these recommended infrastructure conversion. This data will help farmers interested in exiting the contract poultry or swine industry to select transition crops.

The four crops we analyzed were cucumbers, tomatoes, microgreens, and strawberries. For each analysis, we created a projected enterprise budget that assumed an infrastructure conversion cost of \$87,520 to \$148,730 (depending on the crop analyzed); used a labor rate of \$17.58 per hour; and included a sensitivity analysis for factors such as price received, yield, and labor rate, as well as packaging, natural gas use, soil, and other relevant variable costs. The conversion costs in these analyses were based on the recommendations we received from Virginia Tech and independent greenhouse consultants for converting a 16,000-square-foot space.

The table below summarizes crop-specific gross returns, operating income, debt obligations, and debt-service coverage ratios for both 10-year and 20-year financing. A debt-service coverage ratio (DSCR) is a measurement of an operation’s available cash flow to pay current debt obligations, calculated as net income divided by debt obligations (principal and interest payments). A DSCR of less than 1.0 poses potential solvency problems, while a ratio of at least 2.0 is generally considered very strong.

	Tomatoes	Cucumbers	Microgreens	Strawberries
Estimated cost to convert	\$147,820	\$148,730	\$87,520	\$87,520
Gross returns	\$228,000	\$180,000	\$611,604	\$140,000

	Tomatoes	Cucumbers	Microgreens	Strawberries
Operating income	\$55,294	\$26,046	\$284,578	\$52,944
10-year debt obligation	\$18,506	\$18,620	\$45,072	\$18,888
10-year (6.5 percent interest) DSCR	2.99	1.39	6.31	2.80
20-year debt obligation	\$11,599	\$11,670	\$28,250	\$11,838
20-year (6 percent interest) DSCR	4.77	2.23	10.07	4.47

As you can see from the table above, each crop analyzed has the potential to service the debt necessary to convert contract poultry and livestock operations, and provide substantial income to farmers. As this is a new use of these facilities and a new market for farmers who choose to enter this field, support from the Federal Government in the forms of grants and cooperative agreements would dramatically reduce the barriers to entry for farmers wanting to diversify their farming operations. In addition to reducing their environmental footprint, these transitioned operations will support the growth of rural jobs by diversifying their local economy.

In the face of many complex challenges, such as food security, increased droughts, inflation, collapsing supply chains and global pandemics, investments are needed in American farmers, who stand at the very core of rural America, in a way that allows them to restore profitability and ensure their legacy of farming lives on for future generations. As small business owners who are integral to local economies and rural communities, farmers are stewards who remain driven by financial and production-oriented concerns. The costly and time-consuming work of repurposing farmers' unused, stranded assets into active, resilient, and diversified farming operations has the potential to revitalize rural economies but only if producers have the ability to shift their production to readily respond to market conditions and capitalize on growing trends. Without action by policymakers, the current trends of dwindling farmers will further intensify and increase rural flight.

[This statement was submitted by Frances Chrzan, The Transformation Project, francesc@thetransformationproject.org]

PREPARED STATEMENT OF THE WESTERN GOVERNORS' ASSOCIATION (WGA)

Chair Heinrich, Ranking Member Hoeven, and Members of the subcommittee, the Western Governors' Association (WGA) appreciates the opportunity to provide written testimony on the appropriations and activities of the U.S. Department of Agriculture (USDA). WGA is an independent organization representing the Governors of the 22 westernmost States and territories. The Association is an instrument of the Governors for bipartisan policy development, information sharing and collective action on issues of critical importance to the western United States.

USDA programs have a significant effect on the American West and the economic viability of its rural communities. Western Governors recognize the importance of a close and productive working relationship between States and the Federal Government and understand that more effective cooperation depends on Federal recognition of States as co-sovereigns and partners. The promotion of greater partnership between States and the Federal Government is central to the mission of WGA and is reflected in the Governors' Policy Resolution 2021-01, Strengthening the State-Federal Relationship. WGA also commends your attention to other Western Governors' resolutions that articulate policy positions relevant to the subcommittee's work. These include Policy Resolutions 2020-06, Western Agriculture; 2021-03, National Forest and Rangeland Management; 2022-11; Biosecurity and Invasive Species Management; 2021-08, Water Resource Management in the West; 2021-04, Species Conservation and the Endangered Species Act; 2020-07, Rural Development; and 2020-08, Broadband Connectivity.

Agriculture in western States faces a variety of challenges, including extreme variations in soil, climate, terrain, commodity and specialty crops, production practices, and water availability. Amid these difficult conditions, the western agricultural sector provides a vast array of high-demand, high-quality food products for American and foreign markets. Western agricultural lands also serve as primary sources of crucial ecosystem services, including open space, wildlife habitat, and water supplies, and support a diverse suite of rural economic opportunities in the recreation, food, fiber, energy, and bio-based product industries.

USDA conservation programs promote responsible land management in western States and are of crucial importance to the agricultural sector, including livestock producers dependent on using Federal allotments through permits and fees to sustain their operations. Western Governors support targeted, voluntary, and collaborative conservation to address locally identified natural resource issues affecting farms, rangelands, and forests on private and public lands. These issues include soil health, air and water quality, drought and wildfire resilience, wildlife habitat conservation, and invasive species. WGA supports the role of conservation title programs under the Agriculture Improvement Act of 2018 (Pub. L. 115–334) in promoting voluntary solutions to the challenges of threatened and endangered species, water quality impairments, and groundwater recharge. Western Governors encourage the subcommittee to support appropriate funding levels for programs addressing these critical concerns.

The work of the Natural Resources Conservation Service (NRCS) is especially important to western States, and WGA encourages the subcommittee to provide adequate funding for conservation programs administered by the agency. NRCS empowers private landowners to work with States and the Federal Government on large-scale management priorities across landscapes with different land ownerships. NRCS programs provide multiple benefits to western communities:

- Stimulating economic activity and creating jobs in local communities;
- Conserving habitat for the greater sage-grouse, lesser prairie chicken, and other species;
- Mitigating wildland fire potential in western States;
- Improving water quality;
- Reducing the threat of invasive species on western lands; and
- Responding to imminent hazards caused by floods, wildfire, windstorms, and other natural disasters through the Emergency Watershed Protection Program.

Western Governors also support adequate funding of NRCS' Snow Survey and Water Supply Forecasting (SSWSF) program. Sufficient funding is required to ensure the long-term viability of the program's continued and uninterrupted collection of snowpack and water data, the full operation and maintenance of all snow survey sites, the hiring of needed program staff, and technological and software upgrades. The SSWSF program provides integral information for water supply management decisions in agricultural production, hydroelectric power generation, reservoir operations, industry, recreation and economic development, and international treaties. The program's predictive capabilities are critically useful throughout the arid West, where snowpack accounts for the vast majority of the region's annual water supply.

Western Governors support adequate funding for the National Institute of Food and Agriculture (NIFA). Western Governors recognize the valuable role NIFA plays in research on biosecurity and invasive species and support further research to understand the potential spread of invasive species and to develop geographically appropriate control measures.

The West's network of land grant universities and colleges, including Cooperative Extension Service programs and Agricultural Experiment Stations, provides national leadership in research to develop more resilient seeds and crops, manage soil health, advance technology deployment in the bio-based economy, and conduct on-farm research experiments that help farmers and ranchers be more effective and efficient. Western Governors support efforts to expand research funding to address drought, a changing climate, and extreme weather risks facing western producers. WGA also encourages the effective use of Extension to deliver practical tools, technologies, and information to farmers, ranchers and forest landowners and to respond to the changing needs of rural communities.

Healthy, vibrant, and prosperous rural communities are critical to western States. Rural communities, however, face a variety of challenges with respect to economic development, infrastructure, and quality of life. Western Governors support USDA's Rural Development programs, which address those challenges, and request an increased emphasis on rural capacity-building efforts. Building local capacity through training, technical assistance, and consistent support for institutions that serve rural communities is fundamental to economic and community development and maximizes the effect of State and Federal resources. It will be especially important to maximize the benefits of the Infrastructure Investment and Jobs Act (Pub. L. 117–58) for rural communities. At the same time, Western Governors urge USDA to evaluate rural development programs, identify barriers for rural applicants, and revise onerous requirements in a manner that recognizes the limited resources and capacity of rural applicants.

Western Governors support rural development programs aimed at fostering small businesses, entrepreneurs, and cooperative business models, and appreciate the increase in funding for the Rural Business-Cooperative Service in fiscal Year 2023. Western agricultural cooperatives perform many important functions for their members and rural communities. These include provision of seed, feed, and fertilizer to growers; product storage, processing, and transportation; trade and market promotion; supply chain solutions; and education and technical assistance. Cooperative business models can also help meet rural community needs for childcare, homecare, main street businesses, and more. Western Governors recognize the need for substantial technical assistance and education in developing new cooperative businesses and support funding to promote these efforts, including USDA Rural Cooperative Development Grants and Value-Added Producer Grants, and programs administered by USDA's Agricultural Marketing Service and NIFA.

Western Governors also remain committed to creating new opportunities for rural job seekers and for young people to pursue careers in their rural communities. WGA supports solutions that leverage public universities, community colleges, and the business community to provide the appropriate training and skills for the jobs that are available in rural communities.

Western Governors support funding for the Market Access and Foreign Market Development Programs to promote opportunities for western producers to increase export revenues and encourage trade agreements that maximize benefits for the West's farmers, ranchers, and forest landowners. WGA also supports adequate funding for the Specialty Crop Block Grant Program, which provides critical research, education, and promotion tools to fruit and vegetable producers.

Western Governors support the continued efforts of the Rural Utilities Service to provide financial assistance for drinking water and wastewater facilities, renewable energy projects on agricultural lands, and broadband connectivity in rural and remote areas, particularly in communities that have minimal or no such infrastructure. Western Governors support dedicated funding to develop innovative solutions for communities and Tribes that cannot be served by traditional drinking water and wastewater systems. Governors also remain concerned by the Nationwide shortage of certified water system operators. Ongoing and coordinated efforts to develop these skilled workers are necessary to ensure that existing water access in rural communities can be maintained.

Expanding broadband access to rural America empowers citizens to compete in a global market and access electronic information and telecommunications technologies to support and promote telehealth and distance learning. Western Governors note the significance of programs such as the Distance Learning and Telemedicine Program and the ReConnect Program, which support broadband deployment to underserved or wholly unserved rural communities, and appreciate the subcommittee's continued commitment to the ReConnect Program and rural broadband. Consistent funding for these programs is critical to closing the digital divide. In addition, Western Governors are pleased that the minimum speed for ReConnect eligibility remains at 100/20 Mbps, as 25/3 Mbps does not correspond with the requisite download and upload speeds necessary to support modern internet needs.

Given the numerous Federal agency programs, policies, and regulations directly affecting the collective States, agency coordination with States and the integration of state data into Federal programs for policymaking is paramount to their success. Western Governors support full and consistent Federal funding for agencies to carry out the requirements of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. 115-435) and encourage the subcommittee to direct Federal agencies to improve their internal processes and coordinate with States on Federal data policies and procedures, as required in the act.

Western Governors recognize that nutrition assistance programs can help meet the needs of children and the most vulnerable, while creating economic opportunity across the agriculture supply chain from the store where food is purchased all the way back to the farm. Nutrition assistance programs should continue to provide flexibility for States to respond to unique economic conditions, serve all eligible participants without drastically reducing benefits, and pursue transparency and accountability in program administration.

Western States and Federal agencies deal with a complex web of interrelated agriculture, conservation, and economic development priorities. It is an enormous challenge to judiciously balance competing needs in this environment, and Western Governors appreciate the difficulty of the decisions the subcommittee must make. The foregoing recommendations are offered in a spirit of cooperation and respect, and WGA is prepared to assist you in discharging these critical and challenging responsibilities.

[This statement was submitted by Jack Waldorf, Executive Director, Western Governors' Association.]

PREPARED STATEMENT OF THE WILDLIFE SOCIETY

The Wildlife Society (TWS; wildlife.org) inspires, empowers, and enables wildlife professionals to sustain wildlife populations and their habitat through science-based management and conservation. Founded in 1937, TWS and our network of affiliated chapters and sections represents more than 15,000 professional wildlife biologists, managers, and educators dedicated to excellence in wildlife stewardship. As leaders in wildlife science, management, and conservation, TWS promotes the use of science in all aspects of policy and decision-making and is also committed to the identification and removal of barriers to recruitment, effective mentoring, and retention of a diverse workforce.

The Wildlife Society appreciates the opportunity to submit testimony concerning the Fiscal Year 2024 budgets for the Animal and Plant Health Inspection Service (APHIS), National Institute of Food and Agriculture (NIFA), and the Natural Resources Conservation Service (NRCS). We respectfully request the following programmatic funding in fiscal Year 2024. Thank you in advance for considering the views of The Wildlife Society.

Agency	Program	Fiscal year 2023 Enacted	FY2024 TWS Recommendation
APHIS/Wildlife Services	Wildlife Damage Management	\$122 M	\$123 M
	Methods Development	\$26.2 M	\$27 M
NIFA/Formula Grants	RREA	\$4 M	\$10 M
	McIntire-Stennis	\$38 M	\$43 M
NIFA/Minority-Serving Institution programs	Hispanic Serving Institutions Education Partnerships Grants Program.	\$16 M	\$20 M
	Alaska Native Serving and Native Hawaiian-Serving Institutions Education Grants.	\$5 M	\$6 M
	1890 Institutions Centers of Excellence.	\$10 M	\$11 M
NRCS	Private Lands Conservation Operations.	\$827 M	\$904 M

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

APHIS Wildlife Services resolves human-wildlife conflicts and protects wildlife, agriculture, and human health and safety from wildlife damage and wildlife-borne diseases. The Wildlife Damage Management program provides frontline assistance to cooperators to protect natural and human-made resources. We appreciate the increase for this program in fiscal Year 2023 and encourage Congress to provide another small increase in funding in fiscal Year 2024 to \$123 million as requested by the Administration. Maintaining inflation-adjusted funding levels will allow Wildlife Services to carry out programs identified by Congress as key focus areas, including the National Rabies Management Program, which distributes oral rabies vaccines to wildlife within targeted areas with the goal of disease elimination, and the feral swine management program, which works with cooperators to protect natural and human-made resources against this highly destructive non-native species.

Methods Development, also within Wildlife Services, funds the vitally important National Wildlife Research Center (NWRC), which provides tools that the Damage Management program, as well as federal, State, and local partners need to deter

human-wildlife conflict in the field setting. TWS thanks Congress for increased funding in fiscal Year 2023 and requests another small increase in fiscal Year 2024 to allow the NWRC to continue to deliver new research critical to state wildlife agencies, Federal agencies, and municipalities, including novel deterrents to prevent predator conflict with livestock, the development of new humane toxicants against feral swine, and research into the efficacy of fertility control applications in free-roaming horses.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

The Renewable Resources Extension Act (RREA) provides resources to state extension programs that share with landowners and managers the latest management tools applicable to forest and rangeland resources, including wildlife management. RREA funds private landowner outreach and effectively leverages cooperative partnerships at an average ratio of four to one. These extension programs improve management practices on over 43 million acres. Authorized at \$30 million, RREA has seen flat funding at only \$4 million annually for over a decade. TWS requests an increase in RREA funding to at least \$10 million in fiscal Year 2024.

The McIntire-Stennis Cooperative Forestry Program also has a long history of effectively leveraging outside dollars that benefit private land management practices. This program requires a 1:1 non-federal match for research projects related to producing, using, and protecting natural resources based on identified private landowner needs. The funds are targeted at public and land grant university research, which in turn fosters the next generation of natural resources professionals. Private landowners own approximately 300 million acres (over 35 percent) of the Nation's forests and woodlands. Funding of \$43 million in fiscal Year 2024 will allow NIFA to make continued investments in conservation and management techniques on the Nation's private lands.

The USDA's budget request includes \$370 million for Minority-Serving Institution programs, which support capacity-building initiatives, education, and pathways to employment at minority-serving institutions. TWS strongly support policies, programs, and practices that advance efforts to recruit, mentor, and retain professionals from a broad spectrum of identities, including individuals from historically underrepresented backgrounds.

The Hispanic Serving Institutions Education Partnerships Grants Program expands and strengthens academic programs in the agricultural sciences, natural resources, forestry, and other disciplines tied to the food and agriculture production and delivery systems at Hispanic-serving colleges and universities. TWS supports the administration's request for a \$4 million increase for this program and encourages funding at \$20 million in fiscal Year 2024.

The Alaska Native Serving and Native Hawaiian-Serving Institutions Education Grants are aimed at recruiting, supporting and educating minority scientists and professionals, and advancing the educational capacity of Native-serving institutions. TWS appreciates the recent increases in funding for this program and encourages funding at \$6 million in fiscal Year 2024.

The 1890 Institutions Centers of Excellence are designed to supply the country with a globally diverse workforce and support critical global development needs, thereby addressing trans-boundary research and education challenges including climate change, biodiversity conservation and development. We encourage Congress to provide a small increase for this important program in fiscal Year 2024, bringing funding to \$11 million.

We also encourage Congress to support other USDA Minority-Serving Institution programs administered by NIFA, such as the National Scholars Program, which is intended to increase the number of minority students enrolling in agriculture, food, natural resource sciences, and other related programs in pursuit of a bachelor's degree at Land Grant Universities, and the Tribal Scholars Program, which seeks to increase the number of American Indian and Alaska Native students studying agriculture, food, natural resources, and related disciplines.

NATURAL RESOURCES CONSERVATION SERVICE

The Natural Resources Conservation Service (NRCS) is the primary Federal agency working with private land and farm owners to help them conserve, maintain, and improve natural resources on their lands, including soil, water, air, plants, fish, and wildlife. In fiscal Year 2024, TWS requests that Congress provide full funding to the conservation programs authorized by the 2018 Farm Bill, which work with landowners to provide measurable benefits for fish and wildlife.

TWS also urges Congress to provide critical discretionary funding for Private Lands Conservation Operations administered by NRCS, including Conservation

Technical Assistance (CTA). The CTA program provides landowners with site-specific solutions needed to implement conservation programs, while also providing for public accountability to ensure funds are spent as intended. As Congress turns its attention to constructing and modifying private lands programs in the 2023 Farm Bill, demand for technical assistance will continue to grow. TWS requests Congress fund this vital program at the Administration-requested \$904 million in fiscal Year 2024.

Thank you for considering the views of wildlife professionals. Please reach out to Caroline Murphy, AWB(r), TWS government relations manager (cmurphy@wildlife.org), with any questions regarding these recommendations.

[This statement was submitted by Don Yasuda, CWB(r), President, The Wildlife Society.]

PREPARED STATEMENT OF NATIONAL CENTER FOR APPROPRIATE TECHNOLOGY

Request: An increase of \$2.5 million fiscal Year 2024 appropriation for biochar research by the USDA Agricultural Research Service (ARS) for new research at the Sidney, Montana Northern Plains Agricultural Research Laboratory, the Prosser, Washington ARS site, and the ARS National Laboratory for Agriculture and the Environment at Ames, Iowa to be undertaken in conjunction with ongoing ARS biochar research at other sites. This request is for ongoing appropriations for permanent positions to conduct long-term research.

Background: The proposed research would test a common set of biochar types across multiple sites to advance understanding of the impact of diverse types of biochar in varying soils and circumstances on soil health, productivity, and carbon sequestration. This multisite research will inform farmers and ranchers on which types of biochar have positive impacts in their soils and circumstances.

Findings would be used to develop and refine decision-support tools for use by producers and provide the basis for expanding applied research on integration of biochar in local production systems. The research would also provide the knowledge to design and certify different types and treatments of biochar for use in different soils and circumstances.

Rationale: Research suggests that appropriately designed biochar can increase soil health, plant available water, soil fertility and plant growth and yields, thereby enhancing agricultural productivity and resilience as well as food security. Research results are inconsistent, however, because different types of biochar are being tested in varying soils and circumstances.

Biochar is highly effective in addressing the challenge of building and maintaining soil carbon/organic matter. Planting cover crops can add carbon to soil and no-till farming can in some instances slow breakdown of crop residue. But under either practice, organic matter is largely decomposed in a few years and released back to the atmosphere as CO₂.

The unique promise of biochar is that it provides “recalcitrant” soil carbon that lasts for hundreds to thousands of years. In addition, appropriately designed biochar can slow the breakdown of other soil carbon. Thus, biochar integrated with other soil building practices may add more to soil carbon and organic matter than the sum of each alone.

But to realize biochar’s full potential, we need coordinated research to determine which types of biochar are beneficial in varying soils and circumstances. This request meets that need and reflects the recommendations of leading biochar researchers and the 2022 Convening on Biochar Research and Commercialization which included agency and industry stakeholders. The cross-site research that would be supported by this research is far more efficient way to close critical knowledge gaps on biochar than funding uncoordinated individual research projects.

The Biochar Policy Project has discussed this proposal with, and received favorable responses from, the relevant ARS National Program Leaders and with staff at the three proposed locations.

[This statement was submitted by Chuck Hassebrook, Director of the Biochar Policy Project of the National Center for Appropriate Technology.]

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