S. HRG. 114–696

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2017

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

ON

H.R. 5054/S. 2956

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES PROGRAMS FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2017, AND FOR OTHER PURPOSES

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

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HEARINGS

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2017

WEDNESDAY, MARCH 2, 2016

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

The subcommittee met at 1:58 p.m., in room SD–124, Dirksen Senate Office Building, Hon. Jerry Moran (chairman) presiding.

Present: Senators Moran, Daines, and Merkley.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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

ACCOMPANIED BY JAY TYLER, CHIEF FINANCIAL OFFICER

OPENING STATEMENT OF SENATOR JERRY MORAN

Senator MORAN. Good afternoon, everyone. We are having an abbreviated hearing today as a result of four votes being announced at 2:30.

Dr. Califf, congratulations on your confirmation. Welcome to the Food and Drug Administration (FDA). Senator Merkley and I have agreed to withhold our opening statements, which should be to the benefit of all in the audience.

[Laughter.]

Senator MORAN. And we will submit those for the record.

And we are going to start with your testimony, then we will have a round of questions for as long as we are able until the votes are called. We will go a little bit until that time.

So, Dr. Califf, we welcome your testimony as we begin the appropriations process for this year.

SUMMARY STATEMENT OF HON. DR. ROBERT CALIFF

Dr. CALIFF. Thank you, Chairman Moran and Ranking Member Merkley. I was advised that my testimony could be sidelined, too, but I am happy to give it if you would like. I know your time is limited.

Senator MORAN. We would welcome you perhaps highlighting the things you want to make certain we know, and perhaps if you can

do that rather than reading your statement, that is to all of our benefit.

Dr. CALIFF. Great. Well, I will try to do this in one minute instead of five, and I appreciate being here. I also want to acknowledge Dr. Ostroff sitting behind me, who has just finished his term as Acting Commissioner, and I think he has done a wonderful job. We all owe him a debt of gratitude for stepping in with such equanimity and grace.

You have got the budget in front of you. We think it is a very responsible budget, and several of the main priorities that I have in this, as you well know, are, first of all, the workforce at the FDA. Due to the increasing intensity of biological, agricultural, and engineering advances, we need a topnotch workforce, and much of our activity is devoted to that. And the second is shoring up the science base, which includes a heavy emphasis on quantitative analytics. One of our biggest priorities for this year is implementation of the Food Safety Modernization Act (FSMA).

At the core of that is a quality system, which you have all participated in helping us develop. We appreciate the funding increase that we got last year. It has made a big difference, but we still have work to do there. And at the core of it is a quality system built on high-level analytics so that we can deploy FDA forces in the most efficient and effective manner.

So at the core of it for me is that we are in a continuing evolution of the FDA as a science-based public health organization with a very broad scope of activities. There is an amazing array of details that we can talk about. They are specified in my testimony that we have submitted, and I look forward to taking your questions.

[The statement follows:]

PREPARED STATEMENT OF HON. DR. ROBERT CALIFF

I. INTRODUCTION

Good afternoon Chairman Moran, Ranking Member Merkley, and Members of the Subcommittee, I am Dr. Robert Califf, Commissioner of the Food and Drug Administration (FDA). Thank you for the opportunity to appear before you today to discuss the President's fiscal year (FY) 2017 Budget Request for FDA. I would like to thank the Subcommittee for its past investments in FDA, most recently for fiscal year 2016 funding, which have helped us meet the demands of our increasingly complex and diverse mission at home and abroad. For fiscal year 2017, FDA is requesting $5.1 billion to support our essential functions and priority needs.

I am honored to have been chosen by the President and confirmed by Congress to lead the FDA. Thank you all for your willingness to share with me and my predecessor, Dr. Ostroff, your perspectives on ways the FDA can better serve the American people. My first priority as Commissioner is to strengthen and better support the FDA's talented and dedicated workforce. I will focus on the need to carry our critical priorities over the finish line. FDA's ambitious agenda currently includes implementation of the Food Safety Modernization Act, finalizing the Tobacco Deeming Rule, facilitating the development of medical counter measures, and making progress on the Combating Antibiotic Resistant Bacteria (CARB) initiative, and the Precision Medicine Initiative. I also want to further development of the FDA's science base that informs decisionmaking across drugs, medical devices, food safety, and more. FDA's work on the groundbreaking Sentinel system, supported by your mandate, demonstrates the power of the use of our new national digital infrastructure. We are increasingly able to rapidly develop evidence to inform FDA's decisionmaking, and giving us the ability to act quickly on safety issues, rather than having to wait for a new study every time a safety issue arises. I look forward to continued dialogue with you to gain support for FDA's important public health mission.

II. FDA PLAYS A CRITICAL ROLE IN AMERICA'S PUBLIC HEALTH SYSTEM

FDA is a science-based regulatory agency charged with an enormous and significant responsibility: to promote and protect public health. Our goal in carrying out our mission is to ensure the safety, effectiveness, and quality of human and veterinary drugs, biological products and medical devices; the safety of dietary supplements; as well as the safety and security of the vast majority of our nation's food supply. Additionally, the Agency regulates the manufacturing, marketing, and distribution of tobacco products, and seeks to reduce the use of tobacco products by minors and the detrimental effects of tobacco on the general population. FDA's relatively new authority to oversee tobacco products, as well as the Agency's heightened role in the food supply, has tremendously increased FDA's responsibilities and opportunities to promote and protect public health.

FDA plays a unique and vital role in facilitating the availability of safe and effective products and treatments, while also protecting people from products that are promoted using false claims or may cause harm. FDA works with a broad array of stakeholders including industry, other government agencies, and the public, in order to achieve the best possible outcomes.

Congress has recognized the dynamic role that FDA plays and the increasingly complex and inter-connected global environment in which we operate. As a result, FDA has been tasked with a multitude of new responsibilities and authorities in the public health arena, including the Drug Quality and Security Act (DQSA); the FDA Safety and Innovation Act (FDASIA); the FDA Food Safety Modernization Act (FSMA); and the Family Smoking Prevention and Tobacco Control Act (TCA). While FDA has stepped up to meet these essential public health responsibilities under current funding levels, successful implementation of these new authorities requires additional resources.

III. FDA Has a Proven Track Record of Success

FDA's accomplishments over the past year have been as substantial as any in the Agency's recent history. Across the areas of food safety and nutrition, medical product safety and innovation, tobacco control, and other areas of our work, our accomplishments demonstrate our ability to respond to evolving needs and opportunities—including the embrace of new approval pathways, innovative technologies, and cutting-edge science.

Moreover, given the importance of our work, FDA's budget is a bargain for American taxpayers. The products regulated by FDA account for more than 20 percent of every consumer dollar spent on products in the U.S.; individual Americans only pay about 2 cents per day to support oversight to help ensure that those products are safe and effective. This is a small price for life-saving medicines and treatments approved as fast as or faster than anywhere in the world, confidence in medical products that are relied on daily, and a food supply that is among the safest in the world.

IV. FDA'S INNOVATIONS IMPROVE AND PROTECT AMERICA'S FOOD SUPPLY

Food Safety Modernization. Congress enacted FSMA in response to dramatic changes over the last 25 years in the global food system and in our understanding of foodborne illness and its consequences, including the realization that foodborne illness is a significant public health problem, is preventable, and is costly. FDA is modernizing our food-safety system, using quality systems and analytics to prevent foodborne illness before it occurs. These food system changes and the new FSMA mandates require transformative change in how FDA does its work.

FDA published seven major proposed rules in 2013 and, after much stakeholder input, five of those became final in 2015: the preventive controls rules for human and animal food, the produce safety rule, the foreign supplier verification program rule and the third-party accreditation rule. These groundbreaking final rules will help food manufacturers, produce farmers, and food importers take steps to prevent food safety problems. The produce safety and foreign supplier verification rules, for the first time, establish enforceable science-based safety standards for the growing and harvesting of produce and make importers accountable for conducting risk-based verification to determine that imported food meets U.S. safety standards. In addition, as part of these rulemakings we are establishing a program for the accreditation of third-party certification bodies to conduct food safety audits of foreign food facilities.

Nutrition. Americans eat and drink about one-third of their calories away from home. To this end, on December 1, 2014, FDA carried out a congressional mandate to publish rules requiring that calorie information be listed on menus and menu boards in chain restaurants and similar retail food establishments, and on signs for vending machines. In 2015, FDA issued two guidances to help affected industries

implement the menu labeling rule, one aimed at small businesses, and the second providing more detailed advice on how the rule works in the context of a diverse industry. FDA also listened to stakeholders and extended the compliance date for menu labeling.

V. PROMOTING INNOVATIVE MEDICAL PRODUCT DEVELOPMENT

Medical Product Application Review. This year, through application of our efficient and flexible approval process, we again were able to approve a broad range of innovative medical products and treatments with the potential to make a positive difference in the lives of patients. These products included a new generation of targeted therapies that will be used to treat or prevent diseases that affect only a few individuals and additional products that will be used to treat diseases that affect large portions of the population. They involve novel approaches to therapy developed from the rapidly accelerating science of genomics and even new product categories, such as our approval of the first biosimilar biological product.

We also enhanced engagement of patients in the development, approval and evaluation process. And we continued to make progress in our application of some of the most cutting edge areas of science and technology, such as precision medicine, which is helping us to advance biomedical understanding and provide targeted therapies that will allow us to better treat individual patients and diseases.

FDA's rapid drug reviews and use of expedited programs for certain categories of drugs haves helped provide meaningful new products to U.S. patients quickly without compromising our safety and efficacy standards. In 2015, FDA approved 56 novel new drugs. These approvals included four new treatments for patients with multiple myeloma, two new drugs for patients with heart failure, and another robust year of approvals of drugs for rare or "orphan" diseases.

In 2015, we also approved several important vaccines, including one for serogroup B meningococcal disease, the first seasonal influenza vaccine to contain an adjuvant (intended for people 65 years and older), and a new indication for anthrax vaccine to prevent disease following exposure to anthrax—the first vaccine to receive an approved indication based on the Animal Rule, which allows efficacy data generated in animal models to serve as the basis for the approval of medical countermeasures against chemical, biological, radiological or nuclear threats when human efficacy studies aren't ethical or feasible. We also saw the approval of several innovative devices that will make a positive difference in the lives of patients, including a device that extends the survival time of patients with brain cancer, and a transcatheter pulmonary valve that can be placed in certain patients with congenital heart disease, without requiring open heart surgery.

We have also seen important progress in our device review program. Our average time to reach decisions on premarket approvals (PMAs) has dropped 36 percent since 2009. And in 2015, FDA approved 79 novel devices, the most since the start of the Medical Device User Fee Program. Most importantly, enhanced flexibility and an efficient approval process have come without lowering our standards for safety and efficacy.

An important component of all of the medical product reviews is the use of interaction between product developers and our expert staff at FDA at critical points in product development. Our expert review teams "see it all" and therefore play an important role in providing guidance and feedback to companies that is enabling more effective product development. The enhanced communication and growing expertise within FDA promotes earlier exit of products that will not pass muster and a much higher rate of approval on first review for products that do meet our rigorous criteria for safety and efficacy. The success of this approach highlights the need for talented people at the FDA—as medical products become more sophisticated the need for talented reviewers at FDA will grow.

Opioid Medications. Prescription opioid analgesics are an important part of modern pain management; however, misuse and abuse of these products contribute to a serious and growing public health epidemic. After extensive internal review, the Agency has issued a detailed action plan that includes a new framework for considering the consequences of addiction, abuse and misuse not only on the individuals for whom the treatment is intended, but also upon the larger society that is affected by abuse and misuse. Additional post-market requirements for studies have been added. FDA continues to support development of antidotes to treat overdose, abuse deterrent formulations, non-addictive pain relievers, and medication-assisted treatments for dependence.

Biosimilars. FDA has been developing its biosimilar program, an effort which led to the approval of the first biosimilar biological product in March 2015. And there are more applications in the pipeline. To prepare, FDA has produced a variety of

guidancesin this area. FDA remains committed to strengthening the biosimilars pathway by continuing to work diligently to provide development phase advice to sponsors and evaluate applications submitted under this abbreviated pathway, and issue additional guidance as needed to provide clarity to stakeholders.

Next Generation Sequencing and Precision Medicine. Our strengthened focus on regulatory science is helping to drive innovation. One illuminating example is our growing ability to apply the sophisticated technologies of next generation sequencing and precision medicine. FDA today is better prepared for and more engaged than ever in facilitating the development of these new technologies (as well as new uses for older technologies), with reasonable assurance of safety and effectiveness. These efforts help to achieve more precise diagnosis or treatment, through the development and review of state of the art diagnostics and drugs that are targeted to an individual's genetic blueprint. We continue to move forward on the White House's Precision Medicine Initiative to advance biomedical understanding by leveraging genomic advances, health information technologies, and new methods of analyzing large volumes of data. Recently, we launched FDA's precisionFDA web platform, a cloud-based portal that has already succeeded in enabling scientists from industry, academia, government and other partners to come together to foster innovation and develop the science behind next-generation sequencing. PrecisionFDA provides a clear example of regulatory science stimulating innovation.

We are also working to refine clinical trial design and statistical methods of analysis to create more efficient studies that take advantage of advances in genomics and information technology to provide more rapid, less expensive and more reliable answers about medical products. For instance, we continue to support collaborative efforts in clinical trials, such as the NIH's Lung-MAP protocol for lung cancer.

Drug Quality and Security Act. FDA is implementing the DQSA and working diligently to reduce the risks of compounded drug products in the U.S. Since enactment of the DQSA, FDA has conducted over 230 inspections of compounders, many in response to reports of serious adverse events, product quality problems, or other complaints. FDA continues to identify serious problems during these inspections, including contamination in purportedly sterile drugs and in the sterile compounding environment, and other insanitary conditions that put patients at risk. FDA has also investigated serious adverse events associated with non-sterile drugs that were superpotent, as much as 1000 times the labeled strength. As a result of these inspections, FDA has taken aggressive action to protect the American public from compounded drugs that could cause harm. Since enactment of the DQSA, FDA has issued over 75 warning letters to compounders and has worked closely with the Department of Justice on civil and criminal enforcement actions. Many compounders have recalled all of their sterile drugs and ceased sterile operations at FDA's recommendation. FDA has also been working diligently to implement sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (as added by DQSA) by publishing draft and final policy documents while taking into consideration stakeholder input. FDA has issued 12 draft guidance documents, five of which were finalized, a proposed rule, and a draft memorandum of understanding related to interstate distribution of drugs compounded by state-licensed pharmacies and Federal facilities. FDA has consulted with the Pharmacy Compounding Advisory Committee, convened three intergovernmental working meetings with state representatives, and has actively engaged with more than 50 stakeholder groups during listening sessions. FDA will continue to work diligently on draft and final policy documents to implement the DQSA, and to engage with stakeholders on our proposed policies. We have also put out a draft guidance on the appropriate use of compounded products for animals. Even though not specifically included in the legislation, stakeholders have asked us to clarify our policy on animal drug compounding for years, which we are now doing.

VI. FDA WORKS TO REDUCE THE IMPACT OF TOBACCO ON THE PUBLIC HEALTH

Family Smoking Prevention and Tobacco Control Act.

FDA closely monitors retailers' compliance with restrictions on tobacco product marketing and sales to youth—and takes strong corrective action when violations occur. In late 2015, FDA issued its first ever no-tobacco-sale-orders to retailers who continually violate the law. In addition, the Agency launched a second major public education campaign, "Fresh Empire," targeting multicultural youth with powerful messaging about the dangers of tobacco products, all as part of the effort to reduce the number of young people who use tobacco products.

Also for the first time, in 2015, FDA authorized the marketing of eight new tobacco products under the premarket tobacco application pathway. We have made significant progress and have taken many steps to improve timeframes in reviewing

marketing applications. Our actions include increasing scientific staffing; providing feedback to industry; issuing multiple guidance documents; holding meetings with industry; hosting webinars; sending letters and other communications to clarify expectations for industry; and, finally, establishing performance goals that include timeframes for review of Substantial Equivalence (SE) reports for products that are not on the market.

VII. FDA TACKLES EMERGING, UNIQUE, AND COMPLEX CHALLENGES

Combating Antibiotic-Resistant Bacteria (CARB). FDA has made progress on each of the five goals of the President's National Action Plan for CARB. These goals are to slow the emergence of resistant bacteria and prevent the spread of infections caused by resistant bacteria; strengthen national one-health surveillance efforts to combat resistance; advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria; accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines; and improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control and antibiotic research and development.

On June 2, 2015, both human and animal health stakeholders came together in support of a one-health antibiotic stewardship forum hosted by the White House. Additionally, CDC and FDA launched the antimicrobial-resistant isolate bank of over 160 isolates composed of collections of carbapenem-resistant Enterobacteriaceae and other multi-drug resistant bacteria of antibiotics that are approved for use in food- producing animals. FDA also is working closely with CDC and USDA on a data collection plan to verify the changes in on-farm antibiotic use that are expected to result from FDA's initiative to eliminate animal production uses (e.g., growth promotion) of medically important antibiotics in food-producing animals and to require veterinaryoversight for therapeutic uses of these drugs for the treatment, control or prevention of a specifically-identified disease. In support of this effort, FDA finalized changes to the Veterinary Feed Directive (VFD) regulation in June 2015 which took effect in October 2015. FDA also published a proposed rule in May 2015 that includes additional reporting requirements regarding the sale and distribution of antibiotics that are approved for use in food-producing animals.

Responding to Ebola. In a world where disease knows no borders, FDA's response to the Ebola outbreak in West Africa demonstrated how we used our scientific expertise and regulatory authorities to the fullest extent possible to address a tragic public health crisis of global impact. Our response involved collaborating with partners across government, pharmaceutical and diagnostic companies, international organizations like the World Health Organization, and our international regulatory counterparts. We played a key role in encouraging the appropriate study of and expediting the availability of diagnostic tests, investigational therapeutics, and vaccines, as well as investigating fraudulent products marketed to diagnose, prevent and treat Ebola. And many FDA commissioned corps officers of the U.S. Public Health Service served on the front lines, deployed in a humanitarian mission to provide care to patients at the Monrovia Medical Unit in Liberia, one of the West African nations that were hard hit by the outbreak.

Medical Countermeasures. FDA's Medical Countermeasures mission is to promote national health and security by facilitating the development and availability of medical countermeasures (MCMs) such as drugs, biologics, vaccines, devices, and diagnostic tests. These products are used to diagnose, prevent, or treat conditions stemming from an attack with a chemical, biological, radiological, or nuclear material, or a naturally occurring emerging infectious disease, such as Ebola or the most recent outbreak of Zika virus in the Americas. Sixteen diagnostic tests have been authorized under FDA's Emergency Use Authorization authority in response to emerging infectious disease threats. MCMs have been approved for anthrax, plague, botulism, Acute Radiation Syndrome, and pandemic influenza, and several others are on an acceleratedevelopment track. FDA finalized the guidance "Product Development Under the AnimalRule"; to date, eleven drug and biologic products have been approved under thisregulation. We also established a publicly available microbial DNA reference database to help advance diagnostic test development.

VIII. FDA'S FISCAL YEAR 2017 PRESIDENT'S BUDGET REQUEST

The fiscal year 2017 Budget Request for FDA is $5.1 billion, an increase of 8 percent or $358.3 million compared to the fiscal year 2016 enacted level. The budget includes $2.7 billion for budget authority—an increase of one-half of 1 percent or

$14.6 million compared to fiscal year 2016; $2.3 billion for user fees [1] an increase of twelve percent or $268.7 million compared to fiscal year 2016. Mindful of the larger pressures on the Federal budget, we have focused our request on the most urgent needs for fiscal year 2017.

Food Safety. The fiscal year 2017 Budget provides $1.5 billion for food safety, an increase of $211.6 million above the fiscal year 2016 level. The budget includes $1.3 billion for budget authority—an increase of 1 percent or $18.4 million compared to the fiscal year 2016Enacted budget—and $209.8 million for user fees—an increase of $193.2 million compared to the fiscal year 2016 Enacted budget. The budget includes an increase of $25.3 million to improve food and feed safety through continued FSMA implementation.

FDA's fiscal year 2017 budget will build on the fiscal year 2016 investments and focus on two strategic areas of investment that are essential to the success of FSMA: state capacity to partner with FDA and the safety of imported food. The fiscal year 2017 budget request for state capacity building will be used primarily to fund state cooperative agreements and grants that support the essential state role in implementing FSMA's new produce safety rule requirements.

Additionally, the fiscal year 2017 request will enable FDA to continue progress toward implementing the multifaceted new import safety system mandated by Congress, including the Foreign Supplier Verification Program (FSVP) rule, foreign food facility and produce inspections, and partnerships with foreign governments. Under the FSVP rule, importers must verify that imported food has been produced in a manner consistent with FSMA's new standards for produce safety and preventive controls.

The user fee request for food safety includes $105.3 million in new resources to support the new import safety system and $61.3 million in new resources to further modernize the FDA inspection program.

Medical Product Safety and Innovation. The fiscal year 2017 Budget request for FDA for Medical Product Safety and Availability is $2.8 billion, an increase of $116.2 million above the fiscal year 2016 Enacted level. The request includes $1.3 billion for budget authority—an increase of 0.2 percent or $3.2 million compared to the fiscal year 2016 Enacted level, $1.4 billion for user fees—an increase of 3 percent or $38.0 million compared to the fiscal year 2016 Enacted level, and $75.0 million in new mandatory funding for the Vice President's Cancer Moonshot. With this request, FDA will improve medical product safety and innovation in five key areas: evaluating Precision Medicine-based diagnostics, improving the safety of compounded drugs, combating antibiotic resistant bacteria, supporting animal drug and medical device review, and improving cancer diagnostics and treatments.

FDA requests $4 million in fiscal year 2017, an increase of $2.0 million above fiscal year 2016 for Precision Medicine. With the majority of the increase, FDA will help advance Precision Medicine by establishing the National Medical Device Evaluation System (NMDES) to identify patients who benefit most or do not benefit from specific types of devices. FDA will also continue to invest in precisionFDA, which provides a crowd- sourced, cloud-based platform to advance regulatory science around NGS-based analytical tools and datasets.

FDA requests $18 million, an increase of $1 million above fiscal year 2016, to enhance oversight of human drug compounding through increased inspection and enforcement activities, policy development and implementation, and state collaboration and coordination.

For CARB, FDA requests $42 million to support continued work to address public health concerns associated with antimicrobial drug use in animals and to better protect antibiotic effectiveness for both human and animal populations. FDA will work in collaboration with USDA to support efforts to monitor antimicrobial drug use in food- producing animals.

FDA requests an additional $2.9 million to support ongoing activities within the Animal Drugs Review Program and the Devices Program to achieve enhanced and predictable review performance that meets industry, congressional, and public expectations. The increased funding requested will enable FDA to continue to meet premarket animal drug review requirements by having the necessary review staff to carry out these activities. The request will also support ongoing review activities in theDevices Program to meet statutory requirements for the review of medical device applications.

In fiscal year 2017, FDA requests $75.0 million in mandatory resources as part of the Vice President's Cancer Moonshot in order to accelerate progress in cancer—

[1] Includes proposed Food Facility Registration and Inspection, Food Import, International Courier, Cosmetics, and Food Contact Substance Notification fees and proposed increase to the Export Certification fee.

to reduce the number of people who develop cancer and to improve the outcome for those who do. In order to support the dramatic increase in the number, complexity, and strength of cancer diagnostics and therapeutics, FDA will establish an Oncology Center of Excellence to streamline collaboration across FDA's Human Drugs, Biologics, and Devices and Radiological Health Programs and to interface more effectively with the NIH and the clinical environment. A highly effective interface will be needed to deal with the proliferation of highly effective but complex combinations of targeted drug and biological therapies and immunotherapy, driven by sophisticated diagnostic testing and monitoring devices. There is hope that many forms of cancer will be cured or changed to chronic diseases.

Infrastructure, Rent and Facilities. The fiscal year 2017 Budget Request provides an increase of $3 million over the fiscal year 2016 Enacted level, for a total of $12 million, for urgent facility investments that will provide functioning offices and labs across the country to ensure FDA can execute its Food Safety and Medical Product Safety mission. This $3.0 million increase will be used to address repairs, improvements and mission support needs at FDA's owned laboratories and other critical owned facilities across the U.S.

IX. CONCLUSION

FDA's public-health mission is indispensable to the health and well-being of every American. We carry out our broad and expanding public health responsibilities effectively and with relatively few taxpayer dollars, despite dramatic expansions in our responsibilities as a result of new legislation, scientific and technological advances, and a globalized marketplace. The fiscal year 2017 Budget Request plans for efficient spending on programs that are essential to providing Americans with the safe foods and safe and effective medical products they expect. We look forward to answering your questions today and to working with you in the coming year.

Senator MORAN. Commissioner, thank you very much. Let me, first of all, agree with you and express my appreciation for the relationship and the work by Dr. Ostroff at FDA. I very much value his service to the Agency and to the American people, who, in my view, are safer because of his work. And so, thank you for that service, and we look forward to it continuing.

Let me start with a complaint, however.

[Laughter.]

Senator MORAN. And one of the things that I have, at least in my view when I became chairman of this committee, we have worked at developing a relationship with FDA, and I appreciate that we have that. But I am concerned that the FDA is often slow in communicating with us and with our staff, that many times, in fact today was a perfect example. I would guess that many questions will be submitted to the FDA in writing for the record. A timely response is not always the case, and specificity of answering those questions is often lacking.

And so, in an attempt to suit you up today on your first hearing before this subcommittee, Dr. Califf, I would ask if you would assure me that you will do everything as the commissioner to see that our subcommittee, its members, get appropriate, full, complete, and timely responses to inquiries we make to the FDA.

Dr. CALIFF. In my consideration of joining the FDA and taking this job, outspokenness was one of the criteria that was said about me, and it is the case that I do think the FDA can do a better job of explaining what it is doing and of communicating. I have also had a hard lesson coming to the FDA in learning about issues with regard to trade secrets, and I will just call them social mores that exist about how things roll out that you are well aware of.

But taking all that into account, we are going to step up our communications. I can promise you that we will do that. I am an old intensive care unit doctor. I carry a cell phone. I am used to being

called 24 by 7, and if you feel that communication is slow, just call me. I am here.

ARSENIC IN RICE

Senator MORAN. Thank you very much. Let me ask a specific question about rice and arsenic. Last week during the budget meeting in the House, Dr. Ostroff noted that the FDA was making the risk assessment for arsenic in rice a priority. When do you plan to move, and what exactly are you planning to release in that regard?

Dr. CALIFF. Well, as you well know, the issue here is estimating the risk associated with arsenic that is in rice, and estimating the benefits of rice, which has been a staple of the American diet. My ancestors down between Charleston and Hilton Head actually farmed rice for a living, so I have a little history here.

The assessment is complicated because the data are imperfect. It is in a multiagency review. I think you are well aware of that. It is a very high priority for us to get this out. We know that people are waiting. I am not able to give you the specifics of what will be in it, but we are working on it very hard with other Federal agencies.

Senator MORAN. This decision potentially has significant consequence to a lot of people, from producers to consumers, and I would ask that you initiate a broad discussion among those affected by this decision before a conclusion is reached. Is that something you intend to do?

Dr. CALIFF. Yes, I would say there has already been a good bit of discussion, but there certainly will be a lot of discussion about it.

Senator MORAN. Are there other foods that are involved in this topic besides rice?

Dr. CALIFF. This particular decision is a rice decision, which, of course, comes in many preparations, including infant formulas and nutritional aspects, so, you know, it is an important decision. We are well aware of that. It will affect people, and we want to make sure we take that into account.

Senator MORAN. Thank you very much. Let me now turn to the ranking member, Senator Merkley.

TOBACCO RELATED ISSUES

Senator MERKLEY. Thank you, Mr. Chairman, and congratulations, Dr. Califf. There are plenty of fascinating and really important issues that the FDA deals with, and the one I wanted to start off with is related to the tobacco deeming regulation. That regulation has now been in the Office of Management and Budget (OMB) since October 2015. The basic rules are that it is not supposed to be there more than 90 days with one 30-day extension. That would be 120 days. As of today we are at 134 and counting.

So it has been a mystery year after year after year that this deeming regulation has not been finished because while essentially we have been not acting, the addiction rate for e-cigarettes has increased dramatically. They are targeted at kids with all kinds of flavors—Scooby Doo, Double Dutch Chocolate. You name it, you can find it. And to have a product targeted to children that is that effective is troublesome since it means the likelihood of a lifetime

of nicotine addiction with related health consequences, and certainly a lot of expenses for our healthcare system as well.

So what is going on? Is this ever going to emerge from OMB?

Dr. CALIFF. I can assure that it will emerge, and just—as I think you know, I am a cardiologist. I had a very busy clinical practice and intensive care units, so I have probably seen as many people die or have strokes, or heart attacks, or renal failure due to tobacco-related issues as almost anyone on earth at this point. So I am strongly committed to get this out. You are also well aware of the complexity. We had 135,000 comments. There are many views about the details that were aired that we have been working through.

But I do not think you will find anybody more committed to getting this out than I am. I have seen the consequences of tobacco-related illnesses, and we need to take care of this.

Senator MERKLEY. Well, I do appreciate that your personal background gives you that direct insight because some type of special change is needed here because for 2011, 2012, 2013, 2014, 2015, now we are in 2016, very responsible individuals who have said they care a lot about this issue, that they care a lot about kids, they care a lot about people, say we are doing everything we can, we will have it in a short period of time. And it just never happens. So I am hoping the new energy you bring and your perspective can say let us get this done.

Let me just note that between 2013 and 2014, e-cigarette use tripled among middle and high school students in 1 year. And so, obviously the targeting of children is very effective, and it is hurting a lot of people, and this is something where we can actually make a difference for the good. So I do hope you take your personal experiences and pry this out into the public space, and hopefully it will include a ban on all of these kid targeting flavors, and hopefully it will include caps that are difficult for children to take off so that we do not have as many poison cases as we have had with children. That is my hope, my hope and my prayer.

Dr. CALIFF. Well, I mean, as you know, we are instructed by law to take care of the children with the Tobacco Act, and we plan to do it. Chairman Upton this morning in a meeting—I was with him—pointed out that we can all understand the FDA better if we think about our own families. And I have a son, a brilliant rocket scientist son, who became addicted to nicotine at age 12 in North Carolina, so this is not a matter of intelligence or willpower. It is something that we need to protect children from. And 400,000 people a year are dying from tobacco-related illnesses even now, so we have work to do here.

Senator MERKLEY. Thank you, doctor.

AGRICULTURE AND BIOTECHNOLOGY

Senator MORAN. The Senator from Montana.

Senator DAINES. Thank you, Mr. Chairman. Thank you for the efficiency with which you run this committee. I greatly appreciate it.

Dr. Califf, congratulations to you as well on your recent confirmation, and thank you for coming before this committee.

As you know, the United States is a world leader in food production, in food safety, and the FDA plays a critical role in maintaining our global leadership in those fields. In my home State of Montana, agriculture is our number one industry, and our farmers, our ranchers, whether they produce wheat, cattle, sugar, beets, pulse crops, or other products, play a critical role in not only feeding the United States, but also the world.

And one important way Montana is able to do that is by having a world-class research facility at the land grant university, Montana State University (MSU). In fact, I was particularly proud when I heard that MSU was able to endow its first Montana plant sciences chair who is a world leader in cereal genetics and started earlier this year.

Moving forward, it is critical that Washington not get in the way and push policies that have the potential to hinder or even discriminate against ag research and technology that has proven to be effective, proven to be safe, and proven to be productive. In particular, the prospects for biotechnology continue to be bright. Whether it is enhancing production by increasing crop yields or helping protect the environment by requiring fewer pesticides, or reducing demand for water, for example, or even lower food costs for families, I view biotech as essential to the future of our food supply.

So with that as background, my question is, there was a decision made in November of 2015 by the FDA to deny a petition to require mandatory labeling of biotech in food products. Do you agree with that decision?

Dr. CALIFF. Well, this is a decision that was really mandated by law in the opinion of the FDA because in order for the FDA to mandate a label, it would be required that there be a material difference, for example, as measured by a change in the nutritional composition of what you eat for a genetically engineered product versus a non-genetically engineered product. And we have been unable to detect such differences at this point, which explains our decision.

Senator DAINES. So as a food safety agency, it sounds like you would believe, and I do not want to put words in your mouth, but do you believe the FDA should make its decisions based on sound science rather than unsubstantiated claims that might not be supported by evidence?

Dr. CALIFF. We are firmly committed at the FDA to base our decisions and policies on the best science that we can possibly get.

Senator DAINES. Yeah, it is good to have a doctor running it. Thank you, and I agree with you. And to bring this issue home, for example, in Montana on the eastern side of our State, sugar beets are a major crop. They are an economic driver for our State, and, in fact, the source of hundreds of jobs, and most sugar beets are grown utilizing biotechnology. But the sugar that results from the processing of a conventional sugar beet versus a biotech sugar beet is identical in both nutritional value and composition, I think to the point that were just describing there.

If a biotech food product, like sugar beets in the example provided, is deemed by the FDA to be safe for human consumption, meet the same quality standards as a non-biotech, and is nutrition-

ally and essentially the same as a non-biotech counterpart, should it be regulated by the FDA any differently?

Dr. CALIFF. Well, the law tells us it should not be labeled specifically for that if the quality is as you described. But I also want to take the chance here to stress something that you said. This is vitally dependent on a robust agricultural, biomedical research enterprise, which is not predominantly located at the FDA. We have great people, and Susan Main is here today who leads that.

But it is very important to have first-rate universities that are doing the kind of research that you described where you are. In my previous career at Duke University, we had great biology and botany, but NC State, you know, is world class in the broader agricultural sciences, and I had the chance to do a lot of work with those folks. So what we are really dependent on is a first-rate research enterprise that delivers the science that we need to make good decisions, so any decision would depend on the specifics of what was measured about the plant that you are discussing.

Senator DAINES. Well, I am out of time, but I want to thank you, Commissioner Califf, for the thoughtful remarks. And moving forward, I do believe it is important that the FDA remains focused on its mission to helping ensure the United States has a safe food supply and abstains from marketing or labeling mandates that would have no bearing on food safety. So thanks for your remarks.

Dr. CALIFF. I would like to add, Senator, that we did issue a guidance on voluntary labeling so those who wish to do so have a specified way to do that for those. Who think it should be labeled as such.

Senator DAINES. Thank you.

FOOD SAFETY MODERIZATION ACT CFSMA

Senator MORAN. Thank you, Senator. Commissioner, let me turn my attention, our attention, to FSMA and the topic of guidance documents. How many guidance documents is FDA working on, and does FDA anticipate releasing—how many do they intend to release in regard to FSMA implementation?

Dr. CALIFF. Well, Senator Moran, this has been a fascinating issue for me because essentially thanks to Congress, we are implementing an entire new structure to prevent food-borne illness and problems, rather than reacting to it. So this means an entire system is having to be put into place.

As you know, five out of the seven major rules have already been issued. We have two more rules to come out shortly, and then emanating from those rules will be a whole series of guidance documents. And what I have come to understand about this particular area that is really fascinating and of emblematic of where America should be, is a system that starts at the farm, works at the county, works at the State, and includes the Federal Government.

And as guidance documents are put out, and I cannot give you an exact number because it will depend somewhat on how things go. It is really the interpretation of the rules that gives people the information they need to for implementation. And since this is not the Federal Government saying here is exactly how you have to do it, it is really a discussion occurring among multiple parties. There has to be some flexibility in here so that we get it right.

And you might even imagine the exact way things are implemented could vary depending on the circumstances in particular regions or with particular issues. So we are committed to issuing the guidance documents that are needed so that this is done right and it prevents food-borne illness.

Senator MORAN. And something you just said is a reminder to me to remind you and FDA, when your inspectors are reviewing practices and making a determination whether compliance is occurring, the guidance documents are just guidance. And the entity being reviewed can perform compliance in a different way than the guidance documents. That is true?

Dr. CALIFF. Yes. So let me tell you why—I am actually excited about this topic. A lot of my career was built on doing multinational human clinical trials, and the first one we did was so big about 20 years ago, the FDA was not prepared for the inspection. So we ended up with meat inspectors looking at our electrocardiograms out in hospitals around the world, and it just was not ideal.

And so, you know, before I got here, wise people figured out that our inspectors need to be aligned with a particular center so that there is a continuity between the expertise and the center and what the inspectors are doing. And when you have that expertise, it gives you the flexibility for the inspectors to look at the built-in quality as opposed to just reading a document and saying you have to do it this way.

And, you know, I am really pleased to say this is well under way. It is a critical part of FSMA, so people inspecting farms and food places will have expertise in that area, and they will be connected to the center so that if there are issues rather than just relying on rote memory, they will be able to deal with it. Now, you know, whenever you have a complex system it is never perfect. People will need to let us know so we can adjust if there are problems.

Senator MORAN. You are making the point that I wanted to make sure was clear because even though a producer or a processor may not follow the guidelines, they still could be in compliance. And I want to make sure that your inspector would know that.

Dr. CALIFF. Yeah, so——

Senator MORAN. It is about the result. It is not about—I mean, FSMA is designed in a way to create safe food, not a regulatory checklist. And I think that is what you just told me that you agree with.

Dr. CALIFF. I agree with that, but I do want to pick a little finer point here——

Senator MORAN. Okay.

Dr. CALIFF. [continuing]. Because in general, I can speak to this from hospital quality which has similar issues. The process typically is closely related to the outcome that you want. So when you deviate from a standard process that has been proven to be effective, then you need to have a good reason for doing it, and there often are good reasons. And I have been on the other side of the inspection, so I feel like I understand when a good reason may be in play.

But I would not want anybody to believe that we can throw the process out the window here. I mean, the whole reason to have FSMA is so that we can share knowledge, and people on the farms

and in the food processing places can know what the best standard for quality is. And our inspectors should know that quite well, too, because if we did not have that, we would have total chaos and no standard.

So we are going to be flexible, but, you know, we have got to have people understand that process leads to the quality. Does that make sense?

Senator MORAN. It does. Related topic, what is the status of the personnel necessary to pursue compliance of FSMA? Are you in hiring mode?

Dr. CALIFF. We have done a lot of hiring. We are still in hiring mode, and again, thanks for the funding because it is has made a huge difference. We are having to increase the workforce and the realignment. Remember previously it was geographically organized. Now we are saying, you know, you have got a particular job to do with a particular industry. And so, it is not just hiring people. It is also a tremendous amount of team building, and the things that you would do if you are building a first rate in a company.

Senator MORAN. Education and training.

Dr. CALIFF. Yeah, and, you know it is a complex process. We have States and counties involved in doing a lot of the work. It is well underway, and I think it is going really well. We are excited about it.

Senator MORAN. Thank you, doctor. Senator Merkley.

OPIODS AND ADDICTION

Senator MERKLEY. I want to turn to the current Senate conversation about opioids and opioid addiction and the overdoses that are occurring. The FDA has come under criticism for not always using an advisory panel on opioids. With Zohydro approved back in 2013, the FDA did have an advisory panel. It recommended 12–2 against approval, but FDA approved it anyway. And then the following year the FDA approved two additional opioids, but decided not to convene an advisory panel. What was the reason? Was it that FDA did not want to hear about the concerns from medical professionals, or why would on such an important issue—with so many addiction-related issues, why would the FDA have wanted to trash their advisory panel system?

Dr. CALIFF. Well, let me be clear. There is no interest at the FDA in trashing the advisory panel system. As you know, we have recently taken a very deep look at opioids. It is right that people are upset. I know you are dealing with it today on the Senate floor. It is a national epidemic, more people dying from overdoses than from auto accidents, which is a startling statistic.

So we have a very deep eight-point plan that was just published in the New England Journal with everything from having advisory panels on almost everything to reframing the whole issue. You know, the question is how do you consider a situation where maybe half of opioids that are prescribed are actually diverted to someone for whom the prescription was not written. How do you consider the societal effects in addition to the effects on the person for whom the treatment is prescribed?

So this is a major point of emphasis. We are changing our tactic on this. And I guess the way I like to describe it is we are fighting

a battle here against a very tough opponent. I think the FDA has always tried to do the best job it could, but the opponents have gotten tough very quickly, and we are having to change our tact here. We are going to do that.

Senator MERKLEY. So I know you were not at the FDA last year when the FDA approved OxyContin for children without an advisory panel. It just kind of defies logic, and so I want to ask the question again. Why did the FDA decide to do away with advisory panels on these dangerous drugs?

Dr. CALIFF. Let me address the two that you brought up specifically, Zohydro and pediatric OxyContin. And it will take just a minute, if it is okay. I know we are pressed for time.

This Zohydro issue, it is true the panel took a vote that you have recited, but it also specified that there were criteria that might make it okay. Their problem was they were concerned about the post-market system that was in place. And I have learned there was a feeling at the FDA that the requirements of the advisory panel were met, so it was not felt that it was really disagreeing with the advisory panel. It was listening to the advisory panel and making the changes.

But on that one, we are in complete agreement. If had we to do it over again, we would have met with the advisory panel again and reviewed the issues.

And on the pediatric OxyContin, this is a very important one, and I think technically I do not think it is correct to simply call it an approval. OxyContin has been available for children. There are about 10,000 children a year, and if you have ever seen a child with sickle cell disease, for example, which is one of the serious illnesses for which chronic opioids are needed for very severe pain, or a child dying of cancer, the drugs are being prescribed, and we think for children, mostly appropriately so. Pediatricians would not use these drugs ad hoc.

So the only change that was made was to make proper dosing available in the label as opposed to changing fundamentally the way the drug was used. And it was associated with a very profound post-market commitment to make sure we are able to track what is done with OxyContin. Having said that, we learned a lot by seeing what happened, and I should note that I was at the FDA when this happened because I was at Medical Products and Tobacco. So I do not want to be shirking responsibility here.

But seeing the public reaction to this, we are going to have two consecutive pediatric advisory panels to review all of our approaches to opioids and children. They are already scheduled. They will be very intensive, and we will certainly listen to the advice.

Finally, if I could just note one other thing about this, we do have a letter that was recently in the Boston Globe from the American Academy of Pediatrics and from the chair of the Standing Pediatric Advisory Committee of the FDA saying that they thought our decision was the correct decision to give doctors dosing information so they would know the right doses to use when these drugs are indicated. But, you know, having said that, we are going to use advisory panels to review these things.

Senator MERKLEY. Mr. Chairman, could I ask one more question here?

Senator MORAN. Yes.

OPIOD LABELS

Senator MERKLEY. So I am glad to hear the commitment to advisory panels going forward. Did you require on the label warnings about the addiction properties? Is that on all the opioids now?

Dr. CALIFF. Yes.

Senator MERKLEY. And if not, is that something that can be done right away?

Dr. CALIFF. It is on all the opioids, but we are going to strengthen the labels, which is part of the plan that you see. And one thing that happened is there were a whole series of things done for long-acting opioids, so-called ER/LA, extended-release and long-acting. And we are just updating this information to put out sterner warnings.

So I think if you read what is in the label, it is pretty clear what the problems are, but we have learned that it has not gotten through, and we need to get to prescribers because the prescribing really needs to be brought under control.

Senator MERKLEY. Well, I can tell you it does not get through because just recently, for example, my daughter had her wisdom teeth extracted, and so when she came home and she had her prescription, I said to her, you know, we have to be very careful of these because of the dangers of addiction, and it was one of those, "oh, Dad" moments. Now, if the dentist had talked to her about the dangers of addiction that would have carried some weight, if the pharmacist had talked with her about the dangers of addiction.

But it was crazy to her. What is this crazy idea that she is hearing from her dad. And as I have talked to people, very few get any sort of education from their doctors about the substantial risks involved. And just think in Oregon, four million people last year, 100 million opioid pills prescribed. One hundred million.

Dr. CALIFF. Well, if I may, I feel qualified to talk about this because up until 10 months I was a pretty busy practicing doc. I started in intensive care, and then had an outpatient practice. So, you know, recently it was not so big because I had administrator responsibilities, but still saw it all.

The medical practice issue here is profound, and I know you all are going to be dealing with it actually today. It is our stated position in the New England Journal there should be mandatory education. And a really critical thing as you talk about this, to back up one second, we spent all day yesterday with our science board in a public meeting. One of your colleagues actually came out to the FDA to give some public testimony.

A really critical thing here is mandatory education, but not just about opioids because, you know, the pain that people have is real. There are 10 to 12 million Americans with severe chronic pain, and we also heard from them. And so, the doctors need to be trained about how to deal with pain and then how to deal with the opioid part of pain.

We have a voluntary program which is part of the RIMS commitment that companies have to pay for it, but independent CME providers do it. But one problem with voluntary education is that people most likely to volunteer to take it are the ones who probably

need it the least. So we are officially in favor of mandatory education, and we think it is one of the most important things that could be done.

Senator MERKLEY. Thank you.

CENTER FOR VETERINARY MEDICINE

Senator MORAN. Commissioner, I saw recently that the Director of the Center for Veterinary Medicine announced that she was leaving the agency. And I would ask you and encourage you to consider the appointment of a veterinary medicine practitioner, a doctor of veterinary medicine, to that position. Have you thought about what is next in this regard?

Dr. CALIFF. I have. We will do a national search, and, you know, by standard we need to have it open to all types of people who might apply. I will note that I have a proclivity towards veterinarians right now. My future daughter-in-law, we have a family wedding coming up in Colorado. She is actually a Wyoming native, has just graduated from the Cornell Veterinary School. So I have heard the veterinarians' perspective on this, and personally I have sort of a love of veterinarians because of that, but we have to open it up to everyone.

Being a medical doctor and now in charge of the FDA, I understand what you are saying, the concerns, the deep science concerns, you know. It would mean that someone from that background could be very helpful and someone with experience out in the field.

BIOSIMILARS

Senator MORAN. Thank you. Let me talk a moment about biosimilars and highlight language that was included in the omnibus spending bill directing the commission to respond, the FDA to respond. And what the language says is—first of all, I would preface this by saying there are lots of folks in the industry who would like to have input, understanding analysis as the biosimilar program is developed, naming labeling, interchangeability, and indication extrapolation. And our language in the appropriation bill that you are now operating under directed that the committee be provided with an estimated timeline by which the Agency will finalize all pending draft biosimilar guidance documents and regulations.

The committee expects to receive this report no later than 60 days after enactment. Enactment occurred in December, and we have not had a response to that directive. What is the status, and what can we expect?

Dr. CALIFF. Well, it sounds lame to say I am going to have to get back with you on the details of the timing, but we will get back with you. I will just point out, I was in charge of the clinical trial for the first biologic in cardiology, and ended up working a lot with biologics. So I am well aware of the issues. They are complex, but I think we are very close.

I will give a shout out to Janet Woodcock and her team who have been working on this. They are not only regulators. They are world authorities on the chemistry and biology of biologic drugs.

So we are going to get this as quickly as we can. I mean, after all, we have 59 compounds in the pipeline now for the biosimilar

program. So if we do not get this out soon, it is going to be difficult for people to navigate and know what they need to do.

So I hear you, and we will get back with you.

[The information follows:]

Report to the Committee on Appropriations

Draft Biosimilar Guidance

Report in Response to

Senate Report 114-82

And

Explanatory Statement Accompanying the

Consolidated Appropriations Act, 2016

Food and Drug Administration

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Table of Contents

I. Introduction

This report is prepared in response to the following language:

A. Senate Report 114-82:

Biosimilars- The Committee is concerned that FDA has failed to provide the public adequate opportunity to review and comment on regulatory standards for the approval and oversight of biosimilar drugs. Therefore. FDA is directed to provide the Commitlee with an estimated limeline by which the agency will: finalize all pending draft biosimilars guidance documents, publish draft biosimilar guidance documents included in its 2015 regulatmy agenda, and finalize those drqft guidance documents. The Commiltee expects to receive this report no later than 2 weeks qfier the Committee reports this legislation.

B. Explanatory Statement accompanying the Consolidated Appropriations Act, 2016:

The agreement acknowledges some progress in FDA's effort to address issues with products that are biosimilar to and interchangeable with FDA-licensed biological drug products. In August of this year, the FDA issued drqft guidance and a proposed rule regarding naming of these products. However, the agreement remains concerned that FDA needs to provide the public with a greater opportunity to review and comment on ail regulatory standards for the approval and oversight ofbiosimilar drugs. Ther fore, FDA is directed to provide the Committees with an estimated timeline by which the agency will finalize all pending draft biosimilars guidance documents and regulations. The Commillees expect to receive this report no later than 60 days after enactment.

II. Food and Drug Administration Response

The Food and Drug Administration (FDA) has worked diligently to issue multiple guidances on biosimilar products since enactment of the Biologics Price Competition and IJmovation Act of 2009 (BPCI Act). While FDA will continue to work on drafting guidances, reviewing submitted comments, and finalizing guidances in fiscal year 2016, the release of guidances is dependent on factors such as ongoing work, competing priorities, and the timing of interagency clearance.

FDA anticipates issuing the following biosimilar final guidances in the next 12 months:

1. Final Guidance: Nonproprietary Naming of Biological Products
2. Final Guidance: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and IImovation Act of2009
3. Final Guidance: Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product
4. Final Guidance: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act

FDA anticipates issuing the following biosimilar draft guidances in the next 12 months:

1. Draft Guidance: Considerations in Demonstrating Interchangeability With a Reference Product

2. Draft Guidance: Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity

Please keep in mind that while these are our best estimates, they are subject to change and factors such as workload and a shift in priorities could influence the list.

4

GAO REPORT ON FDA'S IT INFRASTRUCTURE

Senator MORAN. Let me highlight a Government Accountability Office (GAO) report that was released in December of 2015 on FDA's information technology infrastructure. That report made a recommendation that FDA define schedules and milestones for incorporating into its IT plan elements that align the Agency's mission and business strategies, and fully implement the plan.

I have gotten interested in IT. We have seen lots of problems in Federal agencies and their use of IT, and I would highlight the GAO report for your consideration and information, and encourage the FDA to take an active role in meeting the recommendations of

the GAO report. This matters a lot to efficiency and good government.

Dr. CALIFF. Well, let me just say it was an interesting experience to come from a major university with a lot of Federal funds and then to step inside of the Federal system on IT, so I appreciate your concerns. And what I would say is that in the past, the primary issue at the FDA has been considered to be protecting all of the highly protected trade secret information that is under constant attack, and that has gone well. We have done that well.

But I am pleased to say we hired a new CIO just as I came on board. He is a great guy. He has experience in the Federal Government and the private sector. We read the GAO report and we are complying with it. Not only that, we are working closely with the GAO to close the gaps.

And what it pointed out was there was a plan for IT inside the FDA, but not a marriage of the IT plan with the overall strategic plan of the organization. And I can assure you in a science-based organization, if you do not have good knowledge management infrastructure, and the way the FDA works it is a lot of transactions, a lot like a business. People put in applications, and they have to be dealt with. If you do not have those systems working, you have got a real deficit that is going to hurt you, so we are very focused on it. And I am confident we will comply.

Senator MORAN. We have just a few more minutes. The vote has been called, but let me ask Senator Merkley if he has any brief, short follow-up questions that he would like to make sure he asks.

OPIODS

Senator MERKLEY. Thank you, Mr. Chairman. I want to go back to the opioid situation, and I mentioned the number of pills in Oregon, the 100 million pills prescribed for the population in 1 year of 4 million. It seems like there must be ways to take this on. So many people say, hey, I needed eight pills, and I had 30 left over or whatever. And not only are they not getting from their doctors about the addiction risk, they are also not being told, and these represent a significant problem, these leftover pills, so this is what I want you to do. This is how you get rid of those pills. This is how you return them to me, or this is how you——

So is it worth thinking about a smaller number of prescribed initially? And the way, I was shocked to read that the number—the percent—that virtually everyone who suffered an opioid overdose—I think it was 90 percent of those who suffered an overdose, were able to go back and easily fulfill—get a prescription filled again even after their overdose. In other words, there is something—maybe we do not have a tracking database, people are getting prescriptions in various places.

What can we do? It is crazy, 100 million pills in the State of Oregon?

Dr. CALIFF. There is no doubt about this, and I should reveal that in my academic career just before coming to FDA, I was involved in the National Institute on Drug Abuse (NIDA) network to deal with opioid abuse, the National Institutes of Health (NIH)-funded network. We oversaw a project Kaiser was doing to organize its health system to offer alternative team-based approaches to

pain to reduce opioid prescription. And we had a grant from NIDA together with the CMS Innovation Center to develop electronic health record systems to identify and intervene people who were high risk in rural southern counties in West Virginia, Mississippi, and North Carolina. So I have done a lot of work on this topic.

You are fair to call it crazy, and if I could take 1 minute. I know you have got to go vote. Ten years ago there was a call for America's doctors to stamp out pain. It was a quality measure in hospitals. Doctors were taught that you had to get the pain level down to zero, and that was the goal. There obviously was an overreaction. It is extreme. It has created a national epidemic. We have got to rein it in.

The FDA has a role. We are not going to shirk our responsibility. I believe our directions are currently clear, but if you talk to doctors, none of them read medical drug labels. I did not either. It is the derivative instructions that go to the doctor and the education.

So we are one of multiple Federal agencies, and the Congress, and the States that need to work together. Remember that medicine is regulated mostly at the State level. We are prohibited from regulating the practice of medicine. We are going to be very outspoken about this along with you, and we have got to put practical things in place.

One just quick comment about arbitrary restrictions on numbers of days. It is complicated because many of the people actually do need opioids for chronic pain. We had amazing testimony by someone from Walter Reed yesterday who was involved with tens of thousands of veterans that have had amputations. And many of them are in extended living facilities or other places where they cannot easily get back to the doctor to get their prescriptions refilled.

So I would urge against an arbitrary restriction, but we have got to work together to convince doctors that they need to exert the most care with the fewest possible pills prescribed. And there are clear instructions for disposal of the medication if you do not need everything that is in your bottle.

CONCLUSION

Senator MORAN. Dr. Califf, thank you very much. Thank you for your testimony today. I was impressed with your level of knowledge and expertise, and I wish you well as you lead the Food and Drug Administration. My intention, as I indicated when we visited in my office, that I would have expected to have a conversation today about Zika, about opioids, which Senator Merkley clearly was interested in, and about cancer—the cure of cancer, and the moonshot effort. I welcome those conversations to continue. We can do that one-on-one.

But my hope is that a few months into your job as we get through the appropriations process, that we would invite you back, that you would accept that invitation, and we would give not only Senator Merkley and I, but other members of this subcommittee the chance to have a more in-depth conversation about a variety of issues facing the FDA.

Dr. CALIFF. I would really appreciate that opportunity. As my testimony submitted for the record says, we need the interchange

and the guidance to get it right because we base everything we do on science, and we must insist that we get better and better at the science. But policy obviously involves an intersection of culture and science, and you are the intersection. So we look forward to working with you.

Senator MORAN. Thank you very much. And, Mr. Tyler, thank you for joining us. You have been very good at handing notes to the Commissioner.

[Laughter.]

ADDITIONAL COMMITTEE QUESTIONS

Senator MORAN. I would take the opportunity to formally conclude this hearing as soon as I find the magic words.

For members of the subcommittee, any questions that you would like to submit for the record should be turned into the subcommittee staff within 1 week, which is Wednesday, March the 9th. We would appreciate if we could have responses from the FDA within 4 weeks of that time.

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

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

CANCER MOONSHOT

Question. The budget requests $755 million in mandatory funds for new cancer-related research activities, of which $75 million would be transferred from NIH to FDA to develop a virtual Oncology Center of Excellence.

It is my understanding that the $75 million in mandatory funding for the Cancer Moonshot would be available for 5 years. How does that work? Would this funding only be used for infrastructure/IT, or would it be used for staffing? Would the mandatory funding need to be reauthorized, or is it a one-time cost?

Answer. FDA is conducting a needs assessment to ensure a successful implementation of the Oncology Center of Excellence. Until business and systems requirements are fully documented, funding should be distributed equally across all 5 years, allocating $15 million per year.

Preliminary budget estimates for fiscal year 2017 include a mix of:

—IT funding to support system enhancements and innovation for oncology related activities and improve analytic capabilities in CBER, CDER and CDRH (each Center has multiple IT systems that may need major or minor enhancements to support oncology efforts)

—Funding for executive recruitment search efforts to hire a dedicated Oncology Center of Excellence Program Director and senior staff

—Funding for FTEs to support oncology activities across medical product areas: drugs, biologics, and devices

—Funding for FTEs to document business and systems requirements: business project managers, information technology specialists, systems engineers and other support disciplines.

After the first 5 years, FDA will assess whether additional funding is necessary for the Oncology Center of Excellence.

Question. Should Congress not move forward with the mandatory funding for the Cancer Moonshot, how much money would you need in fiscal year 17 to begin moving forward with the virtual Oncology Center of Excellence?

Answer. Mandates such as the Oncology Center of Excellence can be challenging to implement without appropriate funding. Based on the magnitude of establishing a new structure to support the Oncology Center of Excellence, the minimum funding needed in fiscal year 2017 would be $15million in budget authority, consistent with the distribution methodology over 5 years as described above. FDA regulates multiple product areas for drugs, biologics and devices, in addition to building, enhancing and maintaining various IT systems needed to automate the regulatory review processes.

FSMA—PRODUCE

Question. The produce industry has expressed concerns about the possibility of having some of their packinghouses subject to the preventive controls rule while other packinghouses would be subject to the produce rule. The produce industry has worked closely with FDA to ensure that there are commodity specific, risk based standards put in place under the produce rule.

Would you agree that it makes no sense for produce facilities, because of ownership structure, to not be handled under the produce rule and instead under the preventive controls rule?

Answer. In September, 2015 FDA launched a FSMA Technical Assistance Network (TAN) to provide technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. FDA is using information specialists and subject matter experts to respond to questions related to the FSMA rules and programs. These questions are being tracked and trended to assist FDA in prioritizing FSMA guidance and training. FDA is also establishing a technical assistance network to support FDA food safety staff (FDA and State) performing inspections and compliance activities. FDA is identifying a cadre of experts to be available to assist inspectors and compliance staff with technical and policy questions including queries about regulation requirements and applicability.

Question. Don't you think this would create added complexity, confusion, and cost when the real focus should be on food safety?

Answer. Under FSMA, farms packing and holding covered produce are subject to the produce safety rule, and facilities required to register are subject to the preventive controls for human food rule. Our preventive controls and produce safety regulations adhere to the statutory framework. Accordingly, produce packing houses that fall under the new farm definition and pack covered produce are covered by the produce safety rule. Produce packing houses that do not fall under the new farm definition are facilities covered by the preventive controls for human food rule.

We acknowledge the circumstances that result from the framework and have used our authority to minimize the practical effect of this dichotomy to the extent possible. First, we expanded our definition of "farm" to include more packinghouses than before. However, it was important to us for the definition to reflect what farms are in the real world. As a result, we did not include all packinghouses, such as those businesses with a limited relationship to a farm, within that definition.

Second, we expect that the specific steps necessary to ensure the safety of produce would generally be the same for on-farm and off-farm produce packing houses. For example, several of the CGMP requirements in the preventive controls rule that would apply to an off-farm produce packing facility (like provisions for employee health and hygiene, the plant and its grounds, sanitary operations and facilities, and equipment and utensils) have analogous counterparts in the produce safety rule. In addition, although an off-farm produce packing facility would be required to establish and implement a food safety plan and establish preventive controls food safety management components, we expect that, in general, off-farm produce packing houses can look toward the produce safety rule for guidance. We expect that an off-farm produce packing facility's food safety plan would focus on a few key preventive controls, which reflect similar measures in the produce safety rule. For example, we expect that the food safety plan for an off-farm produce packing facility would include preventive controls such as maintaining and monitoring the temperature of water used during packing. We also expect that an off-farm produce packing facility would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces. These preventive controls are also reflected in the produce safety rule.

FSMA—SUPPLIER VERIFICATION

Question. There is a great deal of concern and confusion regarding the provisions in the final rule for Human Consumption dealing with situations when a facility is not required to implement a preventive control specifically with respect to the requirement for written assurances from customers.

Does FDA intend to issue additional guidance on this section and if so when? With the final rule effective in close to 6 months, would FDA exercise enforcement discretion for this provision?

Answer. FDA understands there is some concern about written assurances from customers required under certain provisions of the regulations on preventive controls for human and animal food as well as the regulation on foreign supplier verification programs, and we continue to have dialogue with industry to better un-

derstand their concerns and identify areas of confusion. We are considering guidance in this area, as well as other options for addressing the written assurance provisions before the first facilities have to comply with the preventive controls regulations on September 19, 2016.

FSMA—TECHNICAL ASSISTANCE NETWORK

Question. FDA has developed a Technical Assistance Network (TAN) to share information among consumers, industry, regulators and other stakeholders working to implement FSMA.

Are the questions and answers submitted to TAN made public? If not, what is FDA's rationale for not making the questions and answers public?

Answer. The individual questions and answers submitted to FDA's Technical Assistance Network (TAN) are not currently posted on FDA's web site. The TAN process is intended to address questions from individuals and firms. The posting of questions and answers FDA provides through the TAN process is not a substitute for FDA following the good guidance practice requirements (21 USC 371(h); 21 CFR 10.115) for communicating its current thinking on regulatory issues to a wider audience. In addition, FDA is in the process of developing answers to frequently asked questions for posting on the web site. Further, FDA is developing guidance documents that are being informed by the questions received through TAN. FDA will be better able to provide comprehensive, organized information through guidance documents to a broad audience while using a process that includes public input.

The Department of Agriculture Food Safety Inspection Service (FSIS) has a similar system called "AskFSIS" which functions very well as a way to share information with industry and provide answers in a timely fashion. It's a helpful, searchable tool, and the content is public so everyone has access to the same answers. This also provides efficiencies so that the same questions aren't asked again and again.

Question. Have you engaged in any discussions with FSIS to learn from their experience?

Answer. Yes, FDA engaged in lengthy and productive discussions with FSIS from May through September 2015 before launching the FDA FSMA Technical Assistance Network in September 2015. Representatives from FDA visited the FSIS Technical Service Center in Omaha, Nebraska in May 2015 to learn about their system and processes. The following features of the AskFSIS system and processes were adopted by FDA: the staffing structure including administrators and Subject Matter Experts to answer questions; the use of an IT platform (Knowledge Management System) that provides an internal searchable database of questions and answers to promote consistency in responses and tracking of responses; and trending responses to identify those that are frequently occurring so as to inform FDA's guidance documents. The FDA TAN has been well-received by our stakeholders, and we believe that our early engagement with FSIS helped us build a solid foundation for our success.

FSMA—INSPECTION PROCESS

Question. Under FSMA FDA is tasked to develop and implement a comprehensive program to train investigators on a wide range of issues including what the regulations require and how inspections should be conducted. It is essential that regulations are enforced consistently from one region to another, and by both Federal and state officials.

Given the breadth of the new FSMA rules, what specific resources will inspectors have at their disposal during facility inspections when technical questions arise?

Answer. For Preventive Controls inspection and compliance work, FDA is developing an electronic resource library that will include the following resource tools to aid FDA's food safety staff (including state employees performing inspections on FDA's behalf) before, during, and after inspections: special instructions and assignments; FDA guidance documents; links to commodity specific processing videos; fact sheets describing commodity specific processes and potential hazards and controls; and a contact list identifying subject matter experts by area of expertise.

For issues relating to sprouts, FDA also plans to have a resource library that would include resources such as the Produce Safety Rule, FDA guidance, Sprout Safety Alliance training materials and resources, and subject matter expert contacts lists to provide technical and policy support to regulators inspecting sprout operations for compliance with the Produce Safety Rule and the Federal Food, Drug and Cosmetic Act.

For Produce Safety, FDA is establishing a network of regionally-based FDA personnel who will coordinate with state and other partners to fully implement and foster industry compliance with the Produce Safety Rule. This network will provide scientific and technical support to regulators performing inspections.

Question. Has the FDA considered creating a hotline or phone number for inspectors to contact FDA experts?

Answer. In September 2015, FDA launched a FSMA Technical Assistance Network (TAN) to provide technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. FDA is using information specialists and subject matter experts to respond to questions related to FSMA rules and programs. FDA is tracking and trending these questions to assist FDA in prioritizing FSMA guidance and training. FDA is also establishing a technical assistance network to support FDA food safety staff (FDA and State) performing inspections and compliance activities. FDA is identifying a cadre of experts that will be readily available to assist inspectors and compliance staff with technical and policy questions including queries about regulation requirements and applicability.

Question. It is foreseeable that a facility may disagree with an inspector's conclusions and/or interpretation of the rules.

How will these differences be resolved?

Answer. If a facility disagrees with the interpretations of the rules and conclusions reported during an inspection, the first step in the process should be contacting the District Office or state if applicable. Technical experts in the relevant Center (i.e., Center for Food Safety and Applied Nutrition or Center for Veterinary Medicine) would be engaged in questions regarding rule interpretation and application.

If the facility does not believe the District Office or state has been responsive, or they do not understand the process for how to proceed next, then the facility should contact the ORA Ombudsman's office. The facility also may contact the ORA Ombudsman's office (or the FDA Ombudsman's office) for matters it believes are appropriate to raise in a different venue.

Question. When a facility disagrees with an observation reported on a FDA Form 483 (Notice of Inspectional Observations), how should it appeal that decision?

Answer. If a facility disagrees with an observation reported on a FDA Form 483, it would be able to appeal that decision using the same mechanisms utilized for all other inspections. As stated in the previous response, the first step in the process should be contacting the District Office or state if applicable. If that does not resolve the matter, for an FDA decision, a firm can file a formal request for review. FDA regulations (21 CFR 10.75) provide a mechanism for any interested person to obtain formal review of any FDA decision by raising the matter with the supervisor of the employee who made the decision.

Question. Will the FDA provide a centralized, timely mechanism for companies/facilities to appeal an FDA enforcement action?

Answer. If a facility disagrees with an observation reported on a FDA Form 483, it would be able to appeal that decision using the same mechanisms utilized for all other inspections. First, the firm can contact the issuing district office, as stated in the previous response. If that does not resolve the matter, the firm can file a formal request for review. FDA regulations (21 CFR 10.75) provide a mechanism for any interested person to obtain formal review of any FDA decision by raising the matter with the supervisor of the employee who made the decision.

Question. Do you agree that a formal appeals process would also help identify areas where additional inspector training would be helpful?

Answer. See our responses to previous questions describing the review process. FDA agrees that if a state, District Office, or ORA Ombudsman Office have been routinely contacted by regulated entities challenging inspectors' conclusions and/or interpretation of the rules for similar reasons it would potentially help identify areas for improvement. FDA could then consider this information when designing and administering subsequent inspector trainings to help prevent similar future disputes.

FSMA—DEFICIENCY LETTERS

Question. On May 2, 2014, FDA released its Operational Strategy for Implementing the FDA Food Safety Modernization Act, and that document contained a list of administrative compliance tools including "voluntary correction achieved at the district level through deficiency letters . . . . to document significant safety-related deficiencies and request corrective action within a specified period of time."

What is a "deficiency letter"? Please explain why this new enforcement tool is necessary and provide specific examples of situations that would lead to a deficiency letter?

Answer. A deficiency letter is a potential new tool that FDA is considering using to inform a firm of observed violations that appear to pose a significant public health concern and FDA's expectations regarding a timely and effective response to

address the identified concern. The deficiency letter would be issued within a relatively short time period after FDA made observations of non-compliance which, if not corrected quickly, could affect public health. Further, a deficiency letter would describe the enforcement tools available to FDA if, after Agency review, the firm has not adequately corrected the violation(s) and FDA continues to have the same level of concern.

As contemplated, the intent of the deficiency letter would be to immediately, and in a formal way, advise the firm of the situation and to seek expedited compliance for those violations that present a significant public health concern. If the firm does not resolve the deficiency promptly, and further review within FDA supports the seriousness of the violation, FDA would determine what additional Agency action is necessary.

The deficiency letter would have the potential to expedite FDA actions to protect public health. We believe the deficiency letters could enhance FDA's existing tools which include the Form FDA–483, Advisory Letters, and other enforcement tools, potentially decreasing the need for their use, but not replacing them.

Our current thinking is that FDA would issue a deficiency letter only when the likely outcome of the observed violation would have significant public health implications. The specific criteria that would trigger a deficiency letter are still under development.

Question. Please explain in detail the process FDA will be using for issuing deficiency letters including the following: who will issue them, who will review them, under what circumstances will they be issued, how much time will a facility be given to respond, will they be publicly available?"

Answer. FDA is still considering whether to use deficiency letters as a possible compliance tool. If we decide to use deficiency letters, we will establish written standards for determining when to use deficiency letters, including the level of substantiation needed to support issuance. We also would establish written procedures for issuing and responding to deficiency letters.

Question. How will deficiency letters fit into FDA's current administrative process?

Answer. As contemplated, the intent of the deficiency letter would be to achieve expedited compliance for those violations that present the most significant public health concern. Thus, deficiency letters, if employed, would be a more targeted tool than warning letters. If a firm does not expeditiously correct the violation, FDA would be prepared to take further administrative or enforcement action to protect public health.

Question. What is the implication/consequence of getting a deficiency letter?

Answer. As deficiency letters are currently contemplated, a firm receiving a deficiency letter would be informed of any violations that pose the most significant public health concern. The deficiency letter would inform the firm that it should address such a violation in an expeditious manner. If the firm does not correct the violation in an appropriate timeframe, the firm would likely be subject to further administrative or enforcement action.

FSMA—SPENT GRAIN

Question. The Committee understands that FDA is working on clarifying guidance on its dried Distiller's Grains rules. The Committee took action last year on delaying the implementation of the new rule while distillers awaited this guidance.

Please inform the Committee when this guidance will be completed, provide response to what it would contain, and if the intent of the limitation contained in Sec. 750 will be complied with.

Answer. Animal food, including distillers grains used for animal food, must be safe for its intended use and not adulterated. In September 2015, FDA finalized the Preventive Controls for Animal Food (PCAF) rule that established new regulations for current good manufacturing practices (CGMPs) and hazard analysis and risk-based preventive controls for animal food. This rule addressed a range of animal food, including byproducts of human food production used as animal food. Distillers grains from the alcoholic beverage industry are considered human food byproducts.

FDA is currently developing guidance for industry to assist implementation of the rule. In the coming months, we are planning to issue draft guidance on compliance with the CGMPs and draft guidance for human food producers with byproducts going to animal food. Other guidance documents, including a draft guidance document on the hazard analysis and risk-based preventive controls requirements, will follow. We intend to issue these draft guidances before the applicable compliance dates for the PCAF rule. The guidance documents are part of a broader effort to foster and support compliance that also includes education, training, and FDA's

Technical Assistance Network (through which firms can get answers to how the rule applies to their particular operation).

FDA also assures the Committee that as we move forward with implementation of the PCAF rule, we will comply with the requirements of Sec. 750.

LISTERIA

Question. Did FDA's 2013 quantitative risk assessment study include data regarding the risk of Listeriosis associated with consumption of frozen vegetables and frozen food entrees?

Answer. No. The 2013 quantitative risk assessment, issued jointly with the USDA Food Safety and Inspection Service, focused on deli foods and did not include data on frozen vegetables or frozen food entrees. The "Interagency Risk Assessment: Listeria monocytogenes in Retail Delicatessens" may be viewed at http://www.fda.gov/downloads/food/foodscienceresearch/risksafetyassessment/ucm370243.pdf.

Question. What relative risk of Listeria monocytogenes related illnesses does FDA believe frozen foods such as frozen vegetables and frozen food entrees pose compared to other foods historically known to be associated with Listeria monocytogenes?

Answer. The quantitative risk assessments on Listeria monocytogenes that FDA has conducted to date have addressed frozen foods such as ice cream and other frozen dairy products, but have not addressed other frozen foods such as frozen vegetables and frozen food entrees.

Question. Will FDA continue to distinguish between frozen ready-to-eat foods (RTE) and frozen not ready-to-eat (NRTE) foods when frozen NRTE foods bear validated cooking instructions?

Answer. FDA evaluates each situation in which a hazard, such as Listeria monocytogenes or Salmonella, is detected in a frozen food on a case-by-case basis. Where cooking instructions are present on the label of a frozen food, FDA will consider such factors as whether it is reasonable that a consumer or food service facility would thaw the frozen food for consumption without following package cooking instructions, or whether a consumer would follow recipes in which a frozen food would be thawed and included as an ingredient in a fresh, uncooked food such as salsa or a dip.

Question. Will FDA align with global regulatory policy and treat the presence of Listeria monocytogenes in RTE foods on the basis of whether the RTE food does or does not support the growth of Listeria monocytogenes?

Answer. FDA currently is discussing international standards on Listeria monocytogenes in RTE foods that vary based on whether the RTE food does or does not support the growth of Listeria monocytogenes. To further internal dialogue, in December 2015, FDA convened a meeting of the CFSAN Food Advisory Committee (FAC) to consider, among other things, whether FDA should treat the presence of Listeria monocytogenes differently in RTE foods, depending on whether the food supports the growth of Listeria monocytogenes. A majority of the FAC voting members (7 of 11 voting members) recommended that FDA should not treat the presence of Listeria monocytogenes differently in RTE foods, depending on whether the food supports the growth of Listeria monocytogenes. FDA intends to take the recommendations of the FAC into account in its internal deliberations.

More information about the December 2015 FAC meeting, including the agenda, presentations, background information, transcripts and final FAC recommendations, can be found at: http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/foodadvisorycommittee/ucm471769.htm.

Question. Will FDA align its testing guidance to reflect current USDA practice? Specifically, will FDA change its recommendation on when a firm should speciate Listeria and encourage food manufacturers to follow up on a single finding of Listeria spp. on a food contact surface with corrective actions followed by additional testing?

Answer. FDA currently is internally discussing better alignment of FDA's 2008 draft testing guidance to current USDA practices. To inform those discussions, in December 2015, FDA convened a meeting of the CFSAN Food Advisory Committee (FAC) to consider, among other things, whether FDA should change its recommendations on speciation of Listeria and appropriate follow up to a positive finding of Listeria species (spp.) on a food contact surface. The FAC recommended that "FDA should follow the Food Safety and Inspection Service (FSIS) approach for Listeria spp. detected on a food-contact surface, if it tests positive then corrective action should be taken." FDA intends to take the recommendations of the FAC into account in its internal deliberations.

ZIKA

Question. It is my understanding that several vaccine platform technologies have been developed over the last several years and could now be called upon to try to quickly develop vaccines for medical countermeasures, as well as emerging infectious diseases, like Zika.

Can you explain FDA's role working with other agencies and companies to advance vaccine candidates for emerging infectious diseases?

Answer. FDA works closely with other components of the Department of Health and Human Services—including the Office of the Assistant Secretary for Preparedness and Response (ASPR) and its Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC)—as well as with medical product developers, counterpart national regulatory authorities, and other international organizations (e.g., World Health Organization (WHO)) to advance the development and availability of medical products (including drugs, vaccines, and diagnostic tests) to respond to emerging infectious disease outbreaks as quickly and effectively as possible.

FDA's efforts include providing scientific and regulatory advice to product developers and U.S. government agencies that support medical product development to help speed development programs. Specific activities include clarifying regulatory requirements through agency guidance and meetings, reviewing and providing input on pre-clinical and clinical trial designs, and expediting the regulatory review of data as they are received from product developers. As needed, FDA expedites the review of Investigational New Drug (IND) applications and related amendments, which are required for FDA-regulated clinical trials of drugs and vaccines to proceed. In addition, FDA collaborates with WHO and international regulatory counterparts—including the European Medicines Agency, Health Canada, and many others—under confidentiality agreements to provide technical support and scientific advice and to exchange information about investigational products in support of international product development efforts.

Question. What resources are needed to respond quickly and nimbly to emerging infectious diseases and other potential threats to our public health security?

Answer. Emerging infectious diseases and other threats to our public health security—such as the deliberate use of chemical, biological, radiological/nuclear agents—may occur without warning. Responding quickly and effectively to such no-notice events has required resources beyond what base resources can support. For example, to support the response to the Ebola epidemic in West Africa, Congress authorized $5.4 billion in supplemental funding in fiscal year 2015, which included $25 million for FDA. FDA is using this supplemental funding to support ongoing Ebola response activities, including:

—Working closely with interagency partners, product developers, the World Health Organization (WHO) and international regulatory counterparts to encourage and facilitate the development and assessment of vaccines, drugs and diagnostic tests;

—Collaborating with West African health authorities to facilitate access to investigational products as necessary (e.g., for flare-ups) through appropriate mechanisms until approved products are available;

—Maintaining the availability of diagnostic tests under FDA's Emergency Use Authorization authority; and

—Supporting regulatory science to help facilitate Ebola medical product development and review.

To support response to the Zika virus outbeak, the Administration has requested approximately $1.9 billion in supplemental funding including $10 million for FDA. If appropriated, FDA will use the $10 million supplemental Zika funding to support highly targeted regulatory science research required to enhance the efficient development and regulatory review of medical products and blood screening assays for Zika virus; collaboration with and technical support to international partners' response efforts; and FDA staff to support the development, review, regulation, and surveillance of vaccines, diagnostics and therapies.[1]

TOBACCO

Question. Public Health England, the English version of the U.S. Center for Disease Control and Prevention, stated that e-cigarettes are 95 percent less harmful than a combustible cigarette. Moreover, England's government health plan, the Na-

[1] https://www.whitehouse.gov/sites/default/files/omb/assets/budget__amendments/emergency__supplemental__2–22–16__zika.pdf

tional Health Service states that, "There is evidence that e-cigarettes can help people stop smoking." And it is reported that the National Health Service will likely begin prescribing e-cigarettes as a cessation tool in 2016.

Do you share the view of Public Health England and the National Health Service related to reducing the harm associated with combustible tobacco through e-cigarettes?

Answer. Specific to individual health risk, the Public Health England Report's estimate of 95 percent lower risk of e-cigarettes compared to tobacco cigarettes relied upon evidence from a prior paper (Nutt, D. J., L. D. Phillips, D. Balfour, et al., "Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach," European Addiction Research, 20(5):218–225, 2014) to assess the relative harm of electronic nicotine delivery systems (ENDS) products. The Nutt et al (2014) paper employed an analysis model that quantified the relative health harms of 12 tobacco products using a series of 14 harm criteria. The expert panel determined that while cigarettes scored 100 percent in their assessment of maximum relative harm, ENDS products were rated to have only 4 percent maximum relative harm, which contributed to Public Health England's assessment that ENDS are around 95 percent safer than smoking combusted cigarettes. The Report's use of the Nutt et al (2014) paper has several limitations, and the Nutt et al (2014) paper itself observed that it was reporting outcomes based on the decision-conferencing process from a group of experts who were selected without any "formal criterion," though "care was taken to have raters from many different disciplines" and primarily based on geographic location "to ensure a diversity of expertise and perspective". In addition, the authors of the Nutt et al (2014) paper acknowledge that there is a "lack of hard evidence for the harms of most products on most of the criteria". The authors of the Nutt et al (2014) paper did not explain what scientific information was available to the experts upon which they should base their ratings and they did not explain the derivation of the quantitative assessment of each harm criterion. It is unclear if the authors of Nutt et al (2014) paper carried out or referenced a quantitative risk analysis, a standard practice when assessing relative risk, nor did the authors indicate that they used mean levels of exposure to harmful or potentially harmful constituents HPHCs in users or other quantitative evidence as an approximation of risk. FDA does not find the results reported in the Nutt et al (2014) paper to be sufficiently conclusive on the relative risks of using different tobacco products.

FDA is also aware of the National Health Service's position on prescribing e-cigarettes as a cessation tool. No e-cigarettes have been approved by FDA as a cessation product. Moreover, consumers often don't know how much nicotine these devices deliver, making them unreliable for cessation efforts. There are a number of FDA-approved cessation tools on the market that have proven safety and effectiveness and FDA will continue to support and encourage research into cessation tools, including the potential role of e-cigarettes.

The final deeming rule gives FDA the tools it needs to answer important questions about e-cigarettes and how they are made, marketed and used to help establish whether, how, and to what extent they are beneficial or harmful and to whom. Furthermore, subjecting e-cigarettes to FDA's tobacco product authorities will give manufacturers an incentive to conduct research and submit data to establish any potential public health benefit of e-cigarettes.

There are distinctions in the hazards presented by various nicotine-delivering products. Cigarette smoking is the major contributor to the death and disease attributable to tobacco use. Given this, some have advanced the view that certain new non-combustible tobacco products (including ENDS products such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products, given the known carcinogens in smoke and the dangers of secondhand smoke.

Scientific evidence may demonstrate that certain products are less harmful than others at an individual level, but the Tobacco Control Act directs FDA to also take into account the impact on the health of the population as a whole, including both users and non-users of tobacco products, in making regulatory decisions about these products.

Much remains to be learned about the risks of e-cigarettes to health, as well as their possible benefits. E-cigarettes could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use. On the other hand, e-cigarettes could be a detriment to public health. E-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning events, and physical harm from defective prod-

ucts (such as exploding batteries). Anecdotes illustrating both benefits and harms abound, but it is empirical scientific evidence that should drive the actions taken with respect to e-cigarettes.

Question. FDA is committed to using an evidence-based approach to the application of the principles of harm reduction to tobacco regulatory policy.

Does the FDA believe in the concept of tobacco harm reduction? Do you believe that adult smokers have the right to know about the risks and relative risks of different tobacco products and products with nicotine derived from tobacco?

Answer. Section 911 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act, provides a pathway for companies to seek FDA authorization to market a modified risk tobacco product. In deciding whether to issue an order authorizing the marketing of a modified risk tobacco product, FDA takes into account a variety of factors such as the relative health risks to individuals of the product, the likelihood that existing users of tobacco products who would otherwise stop using tobacco products will switch to the product, and the likelihood that persons who do not use tobacco products will start using the product.

FDA is committed to using an evidence-based approach to the application of the principles of harm reduction to tobacco regulatory policy. The Agency is also committed to providing the public with the most accurate health information and evaluating the products under our jurisdiction based on sound scientific evidence.

FDA has communicated the existence of a continuum of risk of nicotine-delivering products to the public. For example, in the proposed deeming rule, FDA asked for comments, data, and research regarding how various new tobacco products should be regulated based on the continuum of nicotine-delivering products and the potential benefits associated with these products, especially e-cigarettes.

There are distinctions in the hazards presented by various nicotine-delivering products. Cigarette smoking is the major contributor to the death and disease attributable to tobacco use. Given this, some have advanced the view that certain new non-combustible tobacco products (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products, given the known carcinogens in smoke and the dangers of secondhand smoke.

Scientific evidence may demonstrate that certain products are indeed less harmful than others at an individual level, but FDA must also take into account the impact on the health of the population as a whole, including both users and non-users of tobacco products, in making regulatory decisions about these products.

Much remains to be learned about the risks of e-cigarettes to health, as well as their possible benefits. E-cigarettes could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use. On the other hand, e-cigarettes could be a detriment to public health. E-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning events, and physical harm from defective products (such as exploding batteries). Anecdotes illustrating both benefits and harms abound, but it is empirical scientific evidence that should drive the actions taken with respect to e-cigarettes.

CTP has identified e-cigarettes as an immediate research priority area, and has funded over 75 research projects since 2012 to better understand e-cigarette initiation, use, perceptions, dependence, and toxicity. This ongoing and funded research will provide important information about these products including a better understanding of e-cigarette users, reasons for use, abuse liability, user perceptions, and health effects.

Question. How will FDA share with adult tobacco consumers the different risks associated with different tobacco products?

Answer. FDA is committed to providing the public with the most accurate health information and evaluating the products under our jurisdiction based on sound scientific evidence.

FDA has communicated the existence of a continuum of risk of nicotine-delivering products to the public. For example, in the proposed deeming rule, FDA asked for comments, data, and research regarding how various new tobacco products should be regulated based on the continuum of nicotine-delivering products and the potential benefits associated with these products, especially e-cigarettes.

Under the Tobacco Control Act, FDA has authority to issue an order authorizing a product to be marketed as a modified risk tobacco product after taking into account a variety of factors such as the relative health risks to individuals of the product, the likelihood that existing users of tobacco products who would otherwise stop

using tobacco products will switch to the product, and the likelihood that persons who do not use tobacco products will start using the product. To date, FDA has not authorized the marketing of any modified risk tobacco product. FDA is currently conducting scientific review of eight modified risk tobacco product applications to determine whether the applicant has provided sufficient scientific evidence for FDA to issue an order allowing the products to be marketed as modified risk tobacco products.

Although industry has introduced newer forms of tobacco products that are not currently regulated under FDA's tobacco product authorities, it is important to note that, if such products are deemed subject to FDA's tobacco product authorities, manufacturers may not market these products as modified risk tobacco products unless they request and receive authorization from the Agency.

BIOSIMILARS

Question. The joint explanatory statement of the House and Senate Appropriations Committee on the Consolidated Appropriations Act, 2016 (Public Law 114–113), expresses the need for FDA to provide the public with a greater opportunity to review and comment on all regulatory standards for the approval and oversight of biosimilar drugs. "Therefore, FDA is directed to provide the Committees with an estimated timeline by which the agency will finalize all pending draft biosimilars guidance documents and regulations. The Committee expect[s] to receive this report no later than 60 days after enactment." This law was enacted on December 18, 2015.

Please provide your response to this request. If you do not have that information, please explain why you have not responded to this request and when you intend to do so.

Answer. The requested report is currently in clearance. The Draft Guidance on Labeling for Biosimilar Products was released on FDA's website on March 31, 2016.

Question. Please provide us with an estimated timeline for publishing draft and final biosimilars guidances for the topics that are listed on FDA's 2016 guidance agenda.

Answer. The Food and Drug Administration (FDA) has worked diligently to issue multiple guidances on biosimilar products since enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). While FDA will continue to work on drafting guidances, reviewing submitted comments, and finalizing guidances in fiscal year 2016, FDA anticipates issuing the biosimilar guidances listed in our guidance agenda within the next 12 months. Please keep in mind that while these are our best estimates, they are subject to change and factors such as workload and a shift in priorities could influence the timeframe.

INTERNET/SOCIAL MEDIA ADVERTISING AND PROMOTIONAL LABELING OF PRESCRIPTION DRUGS

Question. In 2014 the FDA issued draft guidance for industry usage of Internet/social media platforms. Earlier this year, the FDA put out its guidance agenda for 2016 listing new and revised guidance's that are to be published this year. This list included a bullet on "Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices—Use of Links to Third-Party Sites".

Can you tell us what the timeline is for producing this guidance, and will this be the final guidance for the draft put out in 2014?

Answer. The draft guidance issued in 2014 referenced above is the "Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" draft guidance. This draft guidance is not the document listed on the guidance agenda for 2016. The guidance agenda lists the "Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices—Use of Links to Third-Party Sites" draft guidance. FDA continues to work toward publishing this and other draft and revised draft guidances listed on the 2016 guidance agenda.

Question. Are you working with stakeholders in crafting this guidance, and if so do you intend to do so further before putting out the updated guidance?

Answer. FDA has worked with stakeholders since November 2009, when we held a Part 15 public hearing to gather input from our stakeholders (e.g., industry, healthcare professionals, consumers, patient groups, Internet vendors, advertising agencies, and other interested parties) on how FDA can best provide guidance on the promotion of FDA-regulated medical products (including prescription drugs for humans and animals, prescription biologics, and medical devices) using the Internet and social media tools.

When this draft guidance is published, FDA will invite comments from our stakeholders on the draft. After providing this opportunity for public comment, we will review all comments received and carefully consider suggested changes, if any, as we prepare a final version of the guidance document.

INSPECTIONS—RISK BASED INSPECTIONS

Question. As FDA moves toward a more, targeted, risk-based, and efficient inspection model for importing drugs, food, and medical devices this will require better data about these facilities and the companies we are importing from. In the Omnibus, $5 million was included for foreign high-risk inspections to continue efforts to develop and "utilize a targeted, risk-based, and efficient inspection model that incorporates commercially available information on high-risk establishments for onsite verifications."

Can you elaborate on the risk-based decisionmaking and how you are utilizing commercial data to prioritize inspections?

Answer. FDA continues to improve our risk-based decisionmaking inspection models for multiple product areas. In our drug inventory, FDA is employing a site selection surveillance inspection model that runs annually on all facilities in the FDA's inventory allowing for risk-adjusted parity between the foreign and domestic inventory. Several ongoing efforts target improvements to the quality and scope of data feeding into the risk models. Improved accuracy and completeness of data related to the inventory of foreign manufacturing sites under FDA oversight leads to improved risk model outcomes and enhanced inspection planning efficiencies. To that end, FDA uses commercially available data (e.g., the data on businesses available through FDA's enterprise contract with Dun and Bradstreet) and commercial in-country services to verify the accuracy of firm information that feeds into the risk models.

In the food arena, FDA continues to work with our foreign counterparts to develop and implement Systems Recognition agreements. Systems Recognition agreements allow FDA to leverage the findings of the country with whom we have an agreement to help target Agency resources and increase efficiencies in our inspection model. We continue to work towards identifying a Unique Facility Identifier (UFI) that will allow for more comprehensive commercial data to be attached to an entity. In addition, the Agency continues to work to incorporate Geographic Information System (GIS) data with our inventory to extend the capabilities of our risk model. GIS data allows for the analysis of additional layers of data that can be pivotal in making risk-based determinations.

INSPECTIONS—DATA BOUNCE PROCESS

Question. It is my understanding that in 2013 the FDA's Southwest Import District Dallas Office created a program called the Data Bounce Process. Please provide a summary of this program, and input on whether it is something that could be replicated or expanded upon.

Answer. Several years ago, FDA's Southwest Import District (SWID) initiated a project in which some SWID offices accepted entry data from importers of medical devices prior to entry. Via a stand-alone automated process, the SWID staff checked this entry data against existing FDA databases in an effort to verify accuracy of the importer-supplied data. This process helped provide short-term feedback on whether importer-supplied data matched what FDA has in its own systems. Some firms have requested that FDA make this available to all firms importing products FDA regulates. While the agency appreciates this feedback, we have concluded that this limited operation cannot be effectively replicated on a large scale. FDA currently processes more than 34 million import admission decisions each year, and we do not have the IT capability to process a large number of additional test cases. If the program was expanded, additional test cases could easily number several million each year. Therefore, FDA is honing its targeting system to allow for the automated processing of entries where data are complete, accurate, and could fall into lower risk categories. In doing so, we may provide automated releases which increase efficiencies in terms of minimizing delays and enhancing targeting of high risk goods.

We also believe it is helpful where possible to provide instant feedback regarding the acceptability of data necessary for import processing. We are pursuing a similar process through the Automated Commercial Environment (ACE) system. ACE has the capability to screen electronic import submissions and indicate where data is lacking or fails to match syntax such that the entry is not acceptable for processing. This functionality is currently available in ACE. We also are examining opportunities to enhance our IT systems and develop outreach programs to provide immediate

feedback to the import filer when the data they provide does not match the information in our systems.

MEDICAL DEVICE INSPECTION

Question. Concerns exist with the lack of consistency, transparency, and predictability in the FDA medical device inspection process, including discrepancies in how facilities inside the US are inspected versus facilities outside the US, as well as FDA barriers to markets outside the US for products that are available to patients in the US. For example, typically five days is sufficient for the FDA to complete an overseas inspection and determine the suitability of the location to provide product into the US market while inspections inside the US can run several weeks, and even months. These discrepancies lead to variations in inspection standards and potentially competitive advantages for those who choose to manufacture outside the US.

How does the FDA plan to address the discrepancies between inspections performed by FDA within and outside the US?

Answer. A variety of factors are considered when planning and conducting inspections inside and outside the US. The majority of both domestic and foreign FDA inspections last 1 week or less but some inspections both inside and outside the US can last several weeks or longer. Medical Device inspections are conducted using FDA's Quality System Inspection Technique (QSIT), where some (Level I) or all (Level II) subsystems of the firm's quality system are evaluated. The average time to complete a domestic QSIT Level I inspection is 37 hours; 52 percent of domestic inspections are QSIT Level I. The average time to complete a domestic QSIT Level II inspection is 58.5 hours; the remaining 48 percent of domestic inspections are QSIT Level II. Foreign inspections are always QSIT Level II and take an average of 61.4 hours. In situations where a firm has had a previous inspection with a significant number of violations or a firm has received a warning letter, the inspection may last longer because the agency needs to confirm the completion of promised corrective actions and ensure no additional problems create a public health risk. In addition, when FDA identifies a large number of violations in the first few days of an inspection, FDA may extend the length of the inspection to ensure we can fully assess all quality systems and rule out additional concerns.

FDA is also engaged in an extensive Program Alignment initiative, which will create commodity-specific programs for the inspection of medical devices and radiological health products. Program Alignment allows FDA to address the increasing breadth and complexity of our mandate to protect the public health, address the impact of globalization on the food and medical product supply chains, and the ongoing trend of rapid scientific innovation and increased biomedical discovery. Program Alignment allows investigators with specialized knowledge of medical devices and radiological health products and related policies and procedures to focus on inspections of those products rather than expecting investigators to specialize in multiple product areas. Additionally, FDA is working to streamline existing processes, which are intended to improve effectiveness and consistency of inspections performed inside and outside the US.

Further, FDA allows sponsors to submit the results of a third party audit in lieu of a routine surveillance inspection conducted by FDA personnel. Specifically, certain types of audits conducted under the Medical Device Single Audit Plan (e.g., those that are accepted as substitutes for routine inspections) may be deemed to satisfy regulatory requirements of multiple international jurisdictions, and provide flexibility to device sponsors and establishments.

Question. There are reports of FDA withholding/rescinding a company's Certificate for Foreign Governments (CFG), essentially prohibiting the ability to serve markets outside the US, in instances when their products are able remain on the market in the US.

What is the FDA's process for rescinding and reinstating CFG?

Answer. A Certificate to Foreign Government (CFG) is an indication to a foreign government that FDA requirements are met at the time of its issuance. Firms request certificates to facilitate shipments to foreign countries.

FDA/CDRH will not issue a CFG to a firm that has been issued a Warning Letter for Quality Systems violations. Before FDA/CDRH will issue that firm a CFG, FDA/CDRH must have assurance that the firm addressed the violations. Once FDA/CDRH confirms the issues are addressed through an inspection or a submission to FDA from the firm, FDA will issue a letter stating that the violations appear to have been adequately addressed. Only then will FDA issue a CFG to the firm.

FDA/CDRH does not currently rescind CFGs once issued and we have not rescinded any certificates since 2009. CDRH previously rescinded certificates if we be-

came aware that a firm was in violation of the Quality System regulation. It was difficult to physically retrieve rescinded certificates, however, because in most cases CDRH found the certificate had already been sent to the foreign country.

GENERICS

Question. Recently the FDA has proposed a series of initiatives, which, together with the slowdown in generic drug approvals, are contributing to cost increases (labeling rule, same size guidance, Quality Metrics Guidance, delay in guidance for interchangeable generics).

Has FDA examined the collective effects of public health and cost to patients from the implementation of all these proposals? If not, can FDA undertake that examination and report back to the committee?

Answer. One of the initiatives identified in your question is a rule and the other three initiatives are guidance documents. The processes governing consideration of the economic impact of proposed rules and guidance documents are different, as outlined below.

With respect to the proposed rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, any final rule that is adopted will reflect FDA's consideration of public comments and would be accompanied by an analysis of the economic impact of the regulatory change described in the final rule. This regulatory impact analysis would be based on the framework described in Executive Orders 12866 and 13563, and use the best available techniques to quantify anticipated present and future benefits and costs. The regulatory impact analysis would help ensure that any regulation is adopted only upon a reasoned determination that its benefits justify its costs, and is tailored to impose the least burden on society, consistent with obtaining regulatory objectives. As part of the final regulatory analysis, FDA will estimate all of the benefits and all of the costs of the final rule. These benefits and costs will include any potential effects on public health and cost to patients from the implementation of the final rule but will not include the cumulative effects of other proposals or guidance documents. The effects of regulations and guidance documents currently in place are included in the baseline used as the starting point for estimating the effects of the rule.

The process for consideration of guidance documents, including those mentioned in your question, is governed by FDA's Good Guidance Practices (GGP) regulations (see 21 CFR 10.115). FDA's GGP regulations do not require an examination of the costs or impact to the public health associated with following the recommendations described in guidance. Should the recommendations described in guidance cause a particular hardship to its relevant stakeholders, those stakeholders may propose an alternative approach as long as that alternative approach satisfies the relevant statutes and regulations. If a guidance requests or requires that members of the public obtain, maintain, submit, retain, report, or publicly disclose information, the Office of Management and Budget (OMB) must first grant approval of these requests or requirements as an information collection request (ICR) in accordance with the Paperwork Reduction Act. Before the ICR is reviewed and approved by OMB, FDA estimates the total time, effort, or financial resources involved in providing the information and publishes a notice in the Federal Register requesting comments from the public on specific elements outlined in the Paperwork Reduction Act.

Industry, consumers and other stakeholders play a significant role in the agency's guidance development processes. FDA welcomes suggestions of topics for guidances, and in certain instances solicits draft proposals. For example, FDA may issue a "Request for Information" in the Federal Register to gain input on certain topics or participate in public workshops to engage with industry and other stakeholders on topics for which the Agency is considering developing guidance. After a draft guidance is published, comments are reviewed and considered by FDA in preparing the final guidance documents. The public can provide comments on any guidance document at any time.

DIETARY SUPPLEMENTS

Question. Within FDA's Center for Food Safety and Nutrition (CFSAN), how many FTE's are dedicated to enforcement activities? Of that number, how many are focused specifically on enforcing dietary supplement regulations?

Answer. The Office of Compliance is the focal point for enforcement activities within CFSAN, with eight (8) FTEs dedicated to dietary supplement enforcement. The Office of Dietary Supplement Programs (ODSP) is the CFSAN lead for policy development and strategic management of the dietary supplement program, which includes compliance strategy and safety assessments as well as guidelines and regulations. ODSP has authorization for 26 FTEs. Most of ODSP's FTE's devote at least

some of their efforts towards enforcement, but none are focused specifically on enforcement. CFSAN leverages its dietary supplement enforcement activities by partnering with other organizations within FDA, including the Office of Regulatory Affairs, that work on compliance and enforcement matters.

Question. In 2015, how many enforcement actions did FDA bring against dietary supplement manufacturers and marketers? How many dietary supplement good manufacturing practice inspections did FDA conduct in 2015? How many serious adverse events were reported to FDA last year? How many unique dietary supplement formulations were involved in these reports? How many new dietary ingredient notifications were filed with the Agency in 2015? And lastly, how many FTEs are devoted to dietary supplement enforcement and regulatory programs (including inspections of dietary supplement facilities)?

Answer. In fiscal year 2015 FDA issued the following warnings and brought the following enforcement actions against dietary supplement (DS) manufacturers and marketers:

—49 Import Detentions (detentions without physical examination)
—6 Untitled Letters
—83 Warning Letters
—6 Injunctions [Entered by District Courts]

(Data retrieved from FDA's Compliance Management Services database)

In fiscal year 15, FDA:

—Conducted 482 Dietary Supplement GMP inspections. Of those, 445 were of domestic facilities and 37 were of foreign facilities.
—Received 5,336 serious adverse event (AE) reports for products regulated by FDA's Center for Food Safety and Applied Nutrition. Of those serious adverse events reported, 3,098 were for dietary supplements with 3,529 unique product names reported (some AEs report multiple products).
—Received 35 new dietary ingredient notifications.

FDA devotes just over 100 FTEs to dietary supplement enforcement and regulatory programs, including inspections of dietary supplement facilities. Approximately 26 of those FTEs are located in CFSAN's Office of Dietary Supplement Programs (ODSP), which serves as the CFSAN lead for policy development and strategic management of dietary supplement program, including enforcement and regulatory programs. CFSAN's Office of Compliance has approximately 8 FTEs focused on dietary supplement enforcement activities.

Additionally, ORA devotes several FTEs to dietary supplement enforcement and regulatory programs, allocated in fiscal year 15 as follows: approximately 8.45 FTE for sample collections and analyses; 54 FTEs expended for inspections for domestic and foreign dietary supplement firms; and 5 FTEs in the Office of Enforcement and Import Operations, Division of Enforcement, providing support for dietary supplement enforcement and regulatory program activities.

Question. Given that the Office of Dietary Supplement Programs (ODSP) within the Center for Food Safety and Applied Nutrition (CFSAN) at FDA was only created in December 2015, what is the budget and FTE count for ODSP for the remainder of 2016? What is the proposed budget and FTE count for fiscal year 2017?

Answer. In fiscal year 2016, the Center for Food Safety and Applied Nutrition provided the Office of Dietary Supplement Programs (ODSP) a budget of $4.6 million to include funding for payroll and non-payroll requirements. The fiscal year 2016 budget includes 26 approved positions (FTE). The proposed fiscal year 2017 budget for ODSP is $5.9 million and includes additional funds for hiring to reach the approved level of 26 FTE.

Question. What does the Office of Dietary Supplement Programs (ODSP) within the Center for Food Safety and Applied Nutrition (CFSAN) at FDA consider to be the top enforcement priorities in the dietary supplement industry for fiscal year 2017? How were these priorities selected?

Answer. Using risk based prioritization, the Office of Dietary Supplement Programs (ODSP) has determined that in fiscal year 2017 it will use its current authorities and available resources to monitor the safety of dietary supplement products and take compliance and enforcement actions, such as:

—Taking action to remove from the market supplement products that are dangerous to consumers;
—Taking action, in conjunction with FDA's Center for Drug Evaluation and Research, to remove from the market products that contain undeclared pharmaceutical agents and are labeled as dietary supplements;
—Enforcing the dietary supplement good manufacturing practices (GMP) regulations, giving priority to cases with GMP violations that meet the following criteria:

—Potentially compromise product safety;
—Fail to ensure product quality due to lack of testing, procedures, and records; and
—Result in consumer deception, when, for example, manufacturers do not verify the identity of their raw materials
—Taking action against supplement products that bear claims to treat diseases which can result in serious risk of harm to the consumer (such as egregious claims of benefit in treating serious diseases) or widespread economic fraud.

These priorities reflect a risk-based determination of how ODSP's limited resources can best be deployed to protect the public health.

Question. What is the status of FDA's effort to finalize the draft New Dietary Ingredient notification guidance?

Answer. FDA published its draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" (the NDI Draft Guidance) for public comment in July of 2011. FDA reviewed public comments and met on several occasions with industry, consumers, and members of Congress to better understand the concerns raised. We considered the views expressed at those meetings and the many public comments received on the draft guidance as we worked on revisions to provide additional explanation and clarification. The comments received on the original draft guidance caused FDA to conclude that the best course of action would be to reissue the guidance as a revised draft that contains clarifications on several key issues that were the subject of confusion or misinterpretation. We are currently in the later stages of preparing a revised draft guidance, and we hope to publish the revised draft guidance in the near future. All interested individuals and groups will have an opportunity to review and comment on the revised draft guidance before FDA issues any final guidance.

Question. How many facilities are registered as dietary supplement manufacturers with FDA through biannual registration as required by the Food Safety Modernization Act?

Answer. As of March 2, 2016, there are a total of 12 744 (6,522domestic and 6,222 foreign) facilities that have selected food product categories that indicate that they manufacture/process, pack, or hold dietary supplements. Of this total, 7,164 (3,876 domestic and 3,288 foreign) registrations were renewed during the 2014 Biennial Registration Renewal period (October 1, 2014 through December 31, 2014). Under current food facility registration regulations at 21 CFR 1.233(g), the type of activity conducted at a facility is optional information and is not required to be submitted with a registration submission; therefore not all registrations include this information. Currently, there are a total of 4,953 (1,482 domestic and 3,471 foreign) facilities that manufacture/process, pack, or hold dietary supplements that have provided activity type information identifying themselves as "manufacturers/processors."

OVER-THE-COUNTER ANTISEPTICS

Question. The Food and Drug Administration (FDA) is currently re-writing the 1994 tentative final monograph for over-the-counter (OTC) antiseptics. In the 1994 tentative final monograph, FDA delineated several categories associated with antiseptic hand washes, including one specific to food handlers and recognized that different categories of users need different regulatory treatment due to the possible risk to public health (78 Fed.Reg.76444).

Does the FDA intend to recognize the different categories associated with antiseptic hand washes included in the 1994 tentative Final Monograph?

—If not, does FDA intend to include food handlers as a part of the 2013 Consumer Hand Wash Monograph?
—If so, does FDA intend to specify different regulatory conditions that would be associated with antiseptic washes used in the context of food preparation?
—And, if this is the case, does FDA intend to have a more substantive dialogue with stakeholders to ensure clarity about how the rule will be applied in the consumer and food preparation sectors?

Answer. In 1994, FDA identified a category of nonprescription (over-the-counter) antiseptics marketed for use in food handling and processing, and requested relevant data and information regarding these antiseptic products (59 FR 31402 at 31440). FDA continues to consider antiseptics for use by food handlers to be a separate and distinct monograph category from consumer antiseptic monographs, which are labeled and marketed for different intended uses and which raise different issues. The consumer wash rulemaking is not intended to affect products indicated for use by the food industry. In fact, the 2013 consumer antiseptic wash proposed rule specifically mentions that antiseptics for use by the food industry would not be discussed in that proposed rule (78 FR 76444 at 76446). We intend to consider over-

the-counter antiseptic products for use by the food industry separately from consumer wash antiseptics. FDA intends to communicate with stakeholders at the time of publication of the final rule on consumer antiseptic hand washes.

Question. If FDA does not intend to include food handlers in the final monograph, will it be explicitly stated in the regulation and material associated with its release in order to prevent confusion about what should or should not be used by food establishments?

Answer. In 1994, FDA identified a category of nonprescription (over-the-counter) antiseptics marketed for use in food handling and processing and requested relevant data and information regarding these antiseptic products (59 FR 31402 at 31440). FDA continues to consider antiseptics for use by food handlers to be a separate and distinct monograph category from consumer antiseptic monographs, which are labeled and marketed for different intended uses and which raise different issues. The consumer wash rulemaking is not intended to affect products indicated for use by the food industry. In fact, the 2013 consumer antiseptic wash proposed rule specifically mentions that antiseptics for use by the food industry would not be discussed in that proposed rule (78 FR 76444 at 76446). We intend to consider over-the-counter antiseptic products for use by the food industry separately from consumer wash antiseptics. FDA intends to communicate with stakeholders at the time of publication of the final rule on consumer antiseptic hand washes.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

Question. In the Ag-Omnibus end-of-year funding bill for the FDA, we included language to have the compliance date for the FDA final menu labeling regulations be in-line with FDA completing and publishing final guidance that has been in the works for over a year. We thought it is only fair for those who are regulated to have the answers to their numerous questions/concerns, to allow them to forward and allow adequate time to properly comply with these regulations.

Can you tell us the status of the guidance?

Answer. On September 11, 2015, FDA issued the draft guidance for industry, "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)." FDA received a wide range of substantial comments from a variety of stakeholders. FDA is carefully considering all comments received as we work to finalize the guidance. We expect to publish the final guidance in the spring of 2016.

Question. Are you planning to incorporate some of the comments and provide some flexibility that many of the regulated establishments are seeking, into the final document?

Answer. FDA appreciates the extensive input received from stakeholders throughout the process of establishing requirements for menu labeling and in developing guidance to assist industry in complying with the regulations. The menu labeling regulations provide flexibility for covered establishments, such as the ability to choose among several options for determining calorie and other nutrition information for standard menu items. The draft guidance reflects the flexibility of the regulations. We are carefully considering the comments and will incorporate changes as appropriate. We will also work flexibly and cooperatively with establishments covered by the menu labeling final rule to facilitate compliance. We will provide educational and technical assistance for covered establishments and for our state, local, and tribal regulatory partners. We believe this cooperative approach will facilitate successful implementation in a practical way.

Question. I am concerned that many believe the industry has been the only reason for the delay in the menu labeling implementation. Do you agree that the FDA had a predominant role in the delay? The FDA took 3½ years to finalize the regs (April 1, 2011 Proposed Rule followed by Dec. 1, 2014 Final Rule) and then another 10 plus months to issue draft guidance when the FDA itself could not answer the questions from the regulated businesses such as grocery stores and others?

Answer. The successful development and implementation of a complex rulemaking such as menu labeling requires sustained dialogue and close collaboration with the affected industry and other key stakeholders. We recognize that implementing menu labeling requirements nationwide in a collaborative manner has taken a significant amount of time and resources.

As we developed the menu labeling rule, we became increasingly aware of the complexity of the American retail food industry, particularly with respect to foods prepared away from home. FDA received a wide range of substantial comments on the proposed rule from consumers, various food industries, trade associations, and other key stakeholders.

As we move toward implementation, to assist stakeholders with further understanding the menu labeling requirements we have been meeting and will continue to meet with industry groups to discuss the requirements. We will also continue to provide webinars and presentations and respond to industry questions submitted to the Agency's menu labeling inbox. We will work flexibly and cooperatively with establishments covered by the menu labeling final rule to facilitate compliance. We will also provide educational and technical assistance for covered establishments and for our state, local, and tribal regulatory partners. We believe this collaborative approach will facilitate compliance with the requirements in a flexible and practical way.

As you know, the House passed legislation to make some changes to the FDA menu labeling regs so certain entities would have a better opportunity to implement and comply with these regulations. I was joined by Senator King in introducing the Senate companion bill. The bill does not exempt supermarkets, convenience stores, or delivery operations from the menu labeling regulations, but allows some practicality for providing nutritional information to customers based on the different ways that foods are prepared and sold across various venues and formats.

For instance, the House passed bill has provisions such as:

—Preserving local foods or fresh items that may only be sold at one or two store or restaurant locations.

—Allowing for use of a menu or menu board in a prepared foods area or next to a salad bar instead of individually labeling every item

—Allowing an establishment 90-days to take corrective actions to fix an error and clearly stating that oversight authority rests with FDA (and states/municipalities that work with FDA) ;

—Allowing items that are normally ordered off-premises (pizza delivery) to have nutritional information posted as the ordering decision is made online as a means for compliance.

None of these provisions impact FDA's oversight or enforcement authority and no entity that is currently regulated under the menu labeling regulations would be exempt.

Question. FDA did not provide flexibility in these areas in the draft guidance that the agency released last September. Are there any provisions in this bill that FDA is planning on adopting as part of this final guidance you are working on?

Answer. FDA's menu labeling draft guidance reflects the Agency's current thinking on the menu labeling regulation (21 CFR 101.11) and does not impose new requirements. Rather, the draft guidance explains the Agency's interpretation of the regulation and contains recommendations for ways that industry can meet the menu labeling requirements. Industry may use other approaches that satisfy the regulations.

We understand that H.R. 2017, referred to as the "Common Sense Nutrition Disclosure Act of 2015," is still under consideration in Congress. If this bill, as currently written, should become law, FDA would have to engage in rulemaking to amend the current requirements and revise any associated guidance.

QUESTIONS SUBMITTED BY SENATOR STEVE DAINES

FDA FINAL RULE DEADLINES AND MARKET STABILITY LEAD-IN:

Question. On May 1, 2015, the FDA published a Proposed Rule to be added to their 1994 Tentative Final Monograph (TFM) for Healthcare Antiseptics. Yet, the FDA as indicated that this proposed rule will not be finalized until January 2018, despite having received significant public input and concerns with the proposed rule. This delay has left companies in limbo, not knowing whether their new products will need to meet a coming finalized rule to enter the market or for existing products to remain on the market and whether that finalized rule will address their concerns. As an example, this turbulence in the market has caused a 25 percent revenue reduction in 2015 for BioScience Laboratories, a Montana company, and they are currently facing additional staff reductions.

Mr. Commissioner, will the FDA continue to delay addressing concerns with this proposed rule regarding the 1994 Temporary Final Monograph (TFM) for Healthcare Antiseptics and continue to delay publishing a final rule?

Answer. In 1994, FDA published a proposed rule with the agency's tentative determinations as to which ingredients were generally recognized as safe and effective for use in nonprescription antiseptics. Since 1994, FDA's safety standards, our ability to detect and measure antiseptics in the body, and the scientific knowledge about the impact of widespread antiseptic use have evolved. For the past several years,

FDA has been actively engaged in this issue. In 2005 and again in 2014, FDA sought the advice of an FDA advisory committee made up of outside scientific and medical experts. As you know, on May 1, 2015, we published a healthcare antiseptics proposed rule (HCA PR(80 FR25166), which is part of a larger, ongoing review of antiseptic active ingredients by FDA. The HCA PR proposed that all active ingredients used in healthcare antiseptic products marketed under the OTC drug monograph system need additional safety and effectiveness data. In doing so, it proposed to revise certain testing criteria, identified important scientific data gaps for active ingredients used in certain over-the-counter healthcare antiseptic products, and requested additional data to support the ingredients' safety and effectiveness.

Because of the complexity of the HCA PR, FDA provided a public comment period of 180 days after publication, which closed on October 28, 2015. Moreover, the public and regulated industry had 12 months after publication of the proposed rule, or until April 30, 2016, to submit data or new information. Responsive comments on any new data or information may now be submitted for an additional 60 days, until June 30, 2016. Upon the close of the final comment period, FDA will review all data and information submitted to the record in order to complete a final rule. FDA intends to issue the final rule on healthcare antiseptics by January 15, 2018, which is approximately 18 months after the final comment period closes.

FOLLOW-UP

Question. Additionally, will you commit to reducing market turbulence to the full extent possible by preventing such delays in addressing public concerns with proposed rules and publishing final rules in a timely manner, as well as clearly indicating when those final rules will go into effect?

Answer. Senator, we understand your concerns. However, because of the complexity of the healthcare antiseptics proposed rule, FDA provided a public comment period of 180 days after publication, which closed on October 28, 2015. Moreover, the public and regulated industry had 12 months after publication of the proposed rule, or until April 30, 2016, to submit data or new information, and comments on any new data or information may now be submitted for an additional 60 days, until June 30, 2016. Upon the close of the final comment period, FDA will review all data and information submitted to the record in order to complete a final rule. FDA intends to issue the final rule on healthcare antiseptics by January 15, 2018, which is approximately 18 months after the final comment period closes. In the proposed rule, FDA proposed that any final rule would become effective 1 year after the date of the final rule's publication in the Federal Register.

Notice and comment rulemaking is a lengthy and multistep process. Major steps for FDA rulemaking generally include determination that a rule is needed and what the rule should say; review of relevant data; drafting, reviewing, and finalizing the proposed rule; publishing the proposed rule; a public comment period and review of the comments; revising the proposed rule as appropriate; possibly convening an advisory committee meeting, meeting with interested parties, or both; reviewing the draft final rule and finalizing it, and publishing the final rule in the Federal Register.

Even while FDA is moving forward to finalize the healthcare antiseptic rule, FDA has a very broad mandate and multiple public health priorities, with limited resources to address these priorities. FDA's Center for Drug Evaluation and Research (CDER) is responsible for regulating the safety and efficacy of both prescription and nonprescription human drugs. Like FDA as a whole, CDER must continually balance multiple important public health priorities, of which the OTC Drug Review, which includes healthcare antiseptics, is one. CDER does, and will continue to, consider the OTC Drug Review, and the antiseptic rulemakings in particular, among its priorities as it endeavors to appropriately allocate staff and resources within the context of all CDER responsibilities.

QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

TOBACCO

Question. The longer the tobacco deeming regulation takes, the more attempts there will be to include things like the House's language last year, which would have changed FDA's deeming date, and kept e-cigarettes essentially unregulated.

What effect the House's provision last year would have had on access to tobacco products, and the deeming regulation?

Answer. This language contained in last year's House bill aimed to treat newly deemed products in a way roughly modeled on how the TCA treated newly regulated

products when the law was enacted. Specifically, the grandfather date of February 15, 2007, would be changed to the effective date of the deeming final rule, and new tobacco products introduced between the new grandfather date and 21 months afterwards would be permitted to stay on the market as long as an SE report was submitted by the end of the 21 month period. This proposed language would have eroded FDA's ability to regulate certain tobacco products to protect public health. Specifically, the House bill would exempt from FDA review those tobacco products that were marketed before the effective date of the deeming final rule. As a result, these products, including currently marketed flavored e-cigarettes, and novel tobacco products like certain dissolvables, would have been allowed to stay on the market indefinitely without oversight or a scientific evaluation of their risks, potentially threatening public health. Those tobacco products that come on the market after the 21 month transition period would be subject to FDA's premarket authority and would need a marketing order before being sold.

OPIOIDS

Question. FDA has been under fire recently for approving opioids without convening, or against the recommendations of, your advisory panels, especially when the pills are flooding the market. In response, the Agency recently announced a series of steps including re-examining the "risk-benefit" paradigm for opioids to consider public health effects; convening an advisory panel for any new opioids that don't have abuse deterrent properties; and adding additional warnings on labels, among other things.

Could you walk us through each of these decisions and the outcomes you expect they will provide? Specifically, on the risk-benefit paradigm, what will FDA consider that it wasn't already—addiction potential, number of opioids already on the market, anti-deterrence methods?

Answer. These actions are part of a number of actions the Agency outlined in a plan to reassess the approach to opioid medications announced in February. The plan is focused on policies aimed at reversing the epidemic, while still providing patients in pain access to effective medication. This comprehensive action plan will help to mitigate the problem of opioid abuse and confront the epidemic. There are four main pillars to the plan described below.

—Transparency: FDA will be more transparent and open in the approval process for this category of drugs. FDA plans to convene an expert advisory committee before approving any new drug application for an opioid that is not in an abuse-deterrent formulation (ADF). Additionally, we're going to engage the Pediatric Advisory Committee to make recommendations on pediatric opioid labeling before any new labeling is approved. The advisory committee process is going to provide opportunity for public input, which is going to help us better understand and answer the concerns people have about these drugs.

—Improving Communication: Requiring labeling changes and updates to Risk Evaluation and Mitigation Strategies (REMS), FDA hopes to improve communication with the medical community about opioids. Through labeling, our goal is to provide better information to doctors about the risks of these drugs and how to safely prescribe them. In March 2016, FDA released new labeling changes to immediate release opioid labeling that incorporate elements similar to the labeling of the extended-release/long-acting opioid analgesic products. In addition, FDA will evaluate updates to our Risk Evaluation and Mitigation Strategy (REMS) program requirements for opioids with the goal of increasing the number of prescribers who receive training on pain management and improve the safe prescribing of opioids to decrease inappropriate prescribing. That effort will complement work being done at the Department level and at the CDC to help ensure that opioids are prescribed appropriately. We believe that improving prescribing practices is a key component of ending this public health crisis. The nearly 250 million prescriptions for these types of pain killers written each year—enough for every adult in the U.S. to have a bottle of pills—is clear evidence of the work ahead of us.

—Post Marketing: FDA recently strengthened the requirements for drugmakers to conduct post-market analysis of opioid analgesics. This information, especially about long-term use, is currently lacking and we need more and better evidence on the risks of misuse and abuse associated with long-term opioid use and to better understand predictors of addiction, among other issues.

—Product Development: In March, the FDA issued draft guidance with its recommendations for studies that should be conducted to show that a generic copy of a brand-name abuse-deterrent opioid formulation is as abuse-deterrent as the brand-name drug. We believe the availability of less costly generic products

with abuse-deterrent properties may help accelerate prescribers' uptake of abuse deterrent formulations. In addition, FDA is working to improve access to naloxone, which is effective at treating overdoses. The FDA is reviewing options, including the possibility of over-the-counter availability, to make naloxone more accessible.

Question. Is there anything FDA could do to try to curb the number of pills that doctors prescribe, such as shortening the standard course of treatment for acute injuries, so there aren't as many pills left over?

Answer. There is no standard course of treatment for acute injuries described in labeling for opioid analgesics. That is because the duration of treatment will vary depending on the type of injury. It is generally left to the discretion of the treating healthcare provider to decide how many pills to prescribe once the decision has been made to prescribe an opioid analgesic.

Question. FDA has contributed significantly to improving the safety and safe use of opioid analgesics. We are continuing our work to ensure prescribers have the information they need to understand the risks associated with opioid analgesics, as evidenced by the recently announced sweeping changes FDA is requiring to the immediate-release (IR) opioid analgesic labeling, which include safety-related information similar to that added to the extended-release and long-acting (ER/LA) opioid analgesic labeling in 2014. FDA is also requiring changes to the indications for these products to better emphasize that opioid analgesics should be prescribed in situations where non-opioid analgesics are not adequate. Further, the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) requires that drug sponsors make available prescriber education to better inform healthcare professionals about the risks and appropriate use of these drugs. It is the Agency's hope that the significant actions it has taken, along with broader Departmental efforts, will lead to more careful and thoughtful prescribing, and more appropriate use of these drugs.

What role does FDA play in educating doctors and pharmacists about the risks of these drugs?

Answer. The primary tool FDA uses to educate doctors and pharmacists about the risks of prescription drugs, including opioids, is the FDA-approved product labeling. The purpose of the drug labeling is to give healthcare professionals the information they need to prescribe drugs appropriately; to understand the patients for whom the drugs are considered safe and effective; the way the drugs are intended to be used; and the risks and benefits associated with their use. In April 2014, FDA finalized sweeping changes to the labeling for extended-release and long-acting (ER/LA) opioid analgesics to help prescribers better understand the risks of misuse, abuse, neonatal opioid withdrawal syndrome, addiction, overdose, and death associated with these drugs and to more clearly describe the patient population in whom these drugs should be used. On March 22, 2016, FDA sent letters to sponsors of immediate-release (IR) opioid analgesics requiring changes similar to those finalized for the ER/LA opioid analgesics in 2014. These changes to the labeling, once finalized, are expected to emphasize that opioid analgesics should be prescribed only when other treatment options are inadequate or ineffective. For both ER/LA and IR opioid analgesics, the new labeling better enables prescribers to make decisions based on a patient's individual needs, given the serious risks associated with opioids. FDA intends these changes to enable not only a more careful and thorough approach to determining whether opioid analgesics should be prescribed for a particular patient, but also to allow prescribers to better assess whether the serious risks associated with opioids, are offset by the benefits opioids may provide in managing pain for an individual patient.

FDA also uses other tools to educate prescribers about opioid risks. For example, the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy, approved in 2012, requires manufacturers of the ER/LA opioid analgesics to make available, for free or at nominal cost, education courses from for healthcare professionals who prescribe ER/LA opioid analgesics. These continuing education courses educate prescribers about the risks of these opioid analgesics, as well as safer prescribing and use practices for these drugs. Manufacturers of ER/LA opioid analgesics are also required to conduct an assessment of the REMS and submit a REMS assessment report to the Agency for review. On May 3–4, 2016, FDA convened a joint session of the Anesthetic and Analgesic Drug Products and the Drug Safety and Risk Management Advisory Committees to discuss the results of the 36th month ER/LA Opioid Analgesics REMS Assessment submitted by the manufacturers of the ER/LA opioid analgesics in July 2015. The Agency sought the committees' comments as to whether the REMS for this class of drugs assures safe use; is not unduly burdensome to patient access to the drug; and, to the extent practicable, minimizes the burden to the healthcare delivery system. In addition, the Agency sought the committees' com-

ments on any modifications to the ER/LA Opioid Analgesics REMS, including possible expansion of the scope and content of prescriber education, and whether to expand the REMS program to include immediate-release opioids. FDA is evaluating potential modifications to the REMS program requirements for opioids after considering advisory committee recommendations and reviewing existing requirements.

In addition, the Agency utilizes publications such as drug safety communications (DSCs) to inform prescribers and patients of safety issues that should be considered when prescribing and using these drugs. For example, on March 22, 2016, FDA issued a DSC regarding risks of serotonin syndrome for some opioids, and for adrenal insufficiency and androgen deficiency for all opioids, regardless of indication. Further, FDA officials recently published a note in the Journal of the American Medical Association expressing the Agency's dedication to improving the safety of these drugs, and setting forth the Agency's plan to achieve this goal in the coming months.

Question. Why not require an advisory panel for all new opioids, whether or not they have an abuse deterrent formula?

Answer. Seeking advice from external experts on matters related to opioids, including related to this emerging area of science, is a cornerstone of the FDA's 2016 Opioids Action Plan. While we're continuing to learn more about the impact that approved abuse-deterrent (AD) products are having in the community, and supporting research and development of additional technology, the agency plans to seek advisory committee recommendations on new, non-AD brand-name products, and on new AD brand-name products when they raise novel issues. We hope that this public discussion will allow for greater transparency around the FDA's decisionmaking regarding opioid products during this period of reassessment of our policies and regulatory approach to opioids.Judicious use of Advisory Committees is grounded in the recognition that advisory committee meetings demand significant resource commitments by advisory committee members, sponsors and other public participants, as well as for the FDA itself. FDA works to ensure that the finite resources of its advisory committee program are devoted to consideration of the matters in which the agency would most benefit from the advice of outside experts.

Question. Are there new abuse deterrence methods on the horizon?

Answer. Ultimately, the FDA looks forward to a future in which substantially all opioid medications are less susceptible to abuse than the conventional formulations that dominate the market today. However, we are still in the early stages of abuse-deterrent product development—the market has a small number of products using abuse-deterrent technologies, and the agency is assessing each opioid drug product's safety and efficacy on a case-by-case basis. Since the draft guidance on the evaluation and labeling of abuse-deterrent opioids was issued on January 9, 2013, the FDA has approved six extended-release long-acting opioids with labeling describing the product's abuse-deterrent properties consistent with the draft guidance: OxyContin (April 16, 2013); Targiniq ER (July 23, 2014); Embeda ER (October 17, 2014); Hysingla ER (November 20, 2014); MorphaBond (October 2, 2015); and Xtampza (April 26, 2016).

The abuse-deterrent properties of those six products are based on data and described in terms consistent with those set forth in the FDA's 2015 guidance on the topic, Abuse-Deterrent Opioids—Evaluation and Labeling. FDA is prohibited by law from disclosing confidential information about a unapproved applications (e.g., 21 CFR 314.430) and is therefore unable to comment on drugs in development or in the FDA review process. Further, consistent with longstanding Agency practice, we do not discuss the substance of any matters pending before the Agency. However, FDA expects these technologies to improve and expects products containing abuse deterrent properties (both innovator and generic) to become more widely available.

Abuse-deterrent does not mean abuse-proof. Abuse-deterrent opioids are intended to deter abuse by making the products less vulnerable to attempts to manipulate the product for abuse by the oral, nasal, or intravenous routes. However, the products must be able to deliver the opioid in order to provide analgesia and so will remain susceptible to abuse to some extent.

While FDA is gathering data on the impact that approved ADFs are having in practice, and supporting research and development of additional ADF technology, the agency is also asking for advisory committee recommendations on all new non-ADF products to determine whether the benefit of non-AD products continues to offset the risks. FDA hopes that this public discussion will allow for greater transparency around the agency's decisionmaking regarding opioid products during this period of reassessment of our policies and regulatory approach to opioids.

Question. The budget request for FSMA implementation is modest, to say the least. Last year, when FDA's budget was submitted, I was very appreciative that it finally included a realistic request to implement FSMA, and not one that relied on user fees that didn't stand a chance of happening. Congress took that request very seriously and provided full funding—so you know what our commitment is.

Even then, according to FDA's own documents—there was still going to be a funding gap of approximately $166 million needed to successfully implement FSMA. So in a lot of ways, this budget request feels like a step backwards, even though I know we are all in agreement that FSMA has to be done right.

What happens, or does not happen, if you get exactly what you ask for in budget authority, and no new user fees? How much additional funding, no matter the source, would be a responsible level this year to continue to fully support FSMA implementation?

Answer. The fiscal year 2017 President's Budget includes a total of $1.5 billion in proposed resources for food safety. The budget would increase food safety funding by $211.6 million over fiscal year 2016. Specifically to support FSMA implementation, the budget proposed an increase of $25 million in budget authority. The budget also includes two key proposed user fees to support implementation, an import user fee ($105.3 million) and food facility registration and inspection fee ($61.3 million). The sum of these increases represents the total resources needed for FDA to effectively implement FSMA. For example, if FDA does not receive the additional integrated food safety funds requested, we will have to reduce our planned support of State produce safety regulatory programs aligned with FDA's Produce Safety rule. It would in turn hamper education and outreach efforts to farmers.

Question. The biggest part of your proposed increase is $11.3 million for cooperative agreements and grants to implement the produce safety rule. While state and local efforts are no doubt critical, it's concerning that there is no money to train FDA staff. Was the money provided last year for this effort enough? Are FDA staff fully trained and prepared for this entirely new way of doing business?

Answer. Training on the Produce Safety rule will be very important for both FDA and State regulators, as FDA will be working collaboratively with the National Association of State Departments of Agriculture and our State, local, and tribal partners to implement a produce safety regulatory program. fiscal year 16 investments support ongoing work on training plans and materials for the Produce Safety Alliance pre-requisite training; the Produce Safety Regulator Training will be developed and delivered to FDA and State personnel beyond fiscal year 16. As compliance requirements phase in, additional FDA and State personnel will be identified for training.

Quesiton. Enforcement of the both Preventative Control for Human and Animal Foods rules begins in September of this year, but guidance documents, which are important for industry to understand what's expected of them, haven't been published yet. When do you expect to publish them, and how long will that process take? Does FDA, and in turn the states and localities, have everything needed to begin enforcement of this rule, in a consistent way?

Answer. FDA is currently developing guidance documents related to the key FSMA rules, including the preventive controls rules for both human and animal food. These documents are part of a broader effort to foster and support compliance that also includes outreach; education and training programs, particularly for small and midsized firms; and FDA's Technical Assistance Network, through which regulated industry and other members of the public can get answers to specific questions about how the rules apply. The outreach and guidance development process will continue for years to come, but our goal is for key draft guidance documents to be available before the applicable compliance dates.

We are currently on track to issue draft implementation guidances on preventive controls for human food and on Current Good Manufacturing Practices for animal food in the coming months. Additional draft guidance documents on specific hazards and controls are on target for issuance later this year.

We are working with our state, local, and tribal partners to ensure that the new FSMA rules are implemented consistently and in a manner that encourages voluntary compliance. Adequate funding will help ensure the success of these efforts.

Question. Funding was provided to train approximately 1,000 state and local inspectors in fiscal year 16 or about 20 in each state. More than 3,000 state, local and tribal entities will be involved in FSMA implementation. How many additional people will be trained this year?

Answer. FDA's regulator training is being phased in over 3 years based on the staggered compliance dates in the Preventive Controls for human food rule, with a

focus on large firm inspections in year 1 (fiscal year 2017). FDA is on target to train 2,000 FDA and State food safety staff in 2016 in the Food Safety Preventive Controls Alliance Human and Animal Food courses, as a pre-requisite to the Preventive Controls regulator courses. In addition, the 2,000 FDA and State food safety staff will also receive modernized Good Manufacturing Practice (GMP) training for human food facilities and new GMP training for animal food facilities. In fiscal year 2016, FDA's Preventive Controls regulator courses will be offered to the subset of the 2,000 FDA and State food safety staff that will cover the large firm inventory. Food Safety staff is defined as investigators/inspectors, managers, compliance officers and Subject Matter experts, in both FDA and State.

Question. The budget also proposes $14 million to implement the Foreign Supplier Verification Rule, which is vital considering that food imports continue to grow. The first enforcement of this rule is slated to begin in early 2017, although that timeline varies. Will this request be enough?

Answer. In fiscal year 2017, FDA is proposing an additional $14 million in budget authority to support the Foreign Supplier Verification Program (FSVP). FDA would use these additional resources to hire staff to perform FSVP inspections, provide training and technical assistance to FDA staff and importers, and continue outreach on the new FSVP requirements.

Since FSVP is an entirely new program, FDA will need to assess the need for additional resources when we have more experience with the inventory of importers subject to FSVP and compliance rates.

GENETICALLY MODIFIED SALMON

Question. Obviously, I was concerned for multiple reasons when the FDA approved GMO salmon last year to go into our food supply. First, I have grave concerns about what will happen when one of these fish is inadvertently released, and second, I am concerned that it won't be labeled as GMO. So I worked to include language in the Omnibus to keep the salmon out unless it was labeled or FDA published final labeling guidance. In response, FDA issued an import alert to hold any GMO salmon at the border, or return it.

To my first concern, how is FDA planning to work with the fish producers to make sure that none of these fish actually make it into the wild stock and do irreparable harm to the environment for native salmon?

Answer. The approved application pertaining to AquAdvantage Salmon provides for specific conditions including that the GE salmon will be raised only in the two land-based, contained facilities in Canada and Panama that are described in the application. Under this approval, no other facilities or locations, in the United States or elsewhere, are authorized for breeding or raising AquAdvantage Salmon. There are no additional "fish producers" who may raise these salmon. As the sponsor and new animal drug application (NADA) holder, AquaBounty is the sole "fish producer" under the approved application.

In terms of assuring that the GE salmon do not escape the two facilities allowed under the application, the facilities in Canada and Panama have a series of multiple and redundant levels of physical barriers to prevent eggs and fish from escaping. The facilities use land-based tanks—rather than ocean net pens, which are not allowed under the approved application. The first level of barriers (Primary Containment) includes items such as metal screens on tank bottoms, stand pipes, and incubator trays to prevent the escape of eggs and fish during hatching or rearing. Tanks also have covers, nets, jump fences, and screened overflow tanks to prevent escape over the sides of the tanks or incubators. Tank netting also keeps predators such as birds from entering the fish tanks at the outdoor facilities in Panama. All tank drains and stand pipes have covers or sleeves permanently attached to them. In order to prevent eggs or small fish from passing through the pipes or plumbing there is a closed septic system and additional screens and chlorine pucks are used to kill any escaped fish in the main drain area.

Several additional sets of barriers, also in series (Secondary, Tertiary, and sometimes Quaternary Containment), add increased physical security to these primary containment measures described above. These barriers are designed to prevent fish from entering the drainage system or sedimentation pools and the local river (in the case of the Panama facility) and include floor drain covers, barrier screens inside the drains, drum and sock filters, and a series of sedimentation ponds with outlet filters.

To augment physical containment, strict security measures and equipment are in place at both facilities. This includes locked gates for entry and exit to the properties, the presence of guard dogs, perimeter fences with barbed wire, and monitoring systems.

In addition to these physical containment measures, the approval also includes biological containment measures: producing only one sex of fish and making the female fish sterile via triploidy induction (a method used in finfish and shellfish to prevent their sexual maturation and make them sterile).

To ensure that AquaBounty maintains these physical and biological containment measures, they must follow record-keeping and reporting requirements, including ensuring that the triploidy process is within specifications and monitoring physical containment, including reporting of any likely or actual breaches of physical containment.

Furthermore, even if AquAdvantage Salmon could somehow escape and migrate to the Pacific Ocean, there is no reasonable potential for hybridization between escaped AquAdvantage Salmon and native Pacific salmon, which are of a different genus, Oncorhynchus. Farm-raised Atlantic salmon on the west coast of the United States and Canada that have escaped in the Pacific Ocean have not interbred with wild Pacific salmon and, to date, there has been no compelling evidence of any colonization and establishment (i.e., self-sustaining populations) of Atlantic salmon in these areas

As a result of these and other conditions included in the approval, there is a very low likelihood that AquAdvantage Salmon could escape their conditions of confinement and, in the unlikely event they did escape, it is extremely unlikely that they would establish and reproduce conditions at the facility sites.

Question. Can you make a guarantee that these fish, grown in other countries, will be contained?

Answer. The approved AquAdvantage Salmon application allows the GE salmon to be raised only in the two land-based, contained facilities in Canada and Panama that are described in the application. Additionally, these facilities are separately regulated by the relevant regulatory bodies in each respective country. Under this approval, no other facilities or locations, in the United States or elsewhere, are authorized for breeding or raising AquAdvantage Salmon.

If other countries choose to produce GE salmon that will not enter U.S. commerce, those countries will regulate those facilities. FDA does not have jurisdiction to regulate products that are produced outside the United States and never enter the United States.

Question. As you know, FDA approved AquaBounty's production plan to produce GM salmon eggs in Canada and ship them to Panama for fish production. If the company wanted to grow the fish in the U.S., what steps would it have to take to gain FDA approval?

Answer. FDA's approval of the application pertaining to AquAdvantage Salmon does not allow production and grow out of the salmon in any facilities other than those in Canada and Panama. If the sponsor proposes to begin producing GE salmon in the United States (or at additional locations outside of the United States with the intent to import food from them into the United States), it first must submit a supplemental new animal drug application to FDA for the new production facilities, and this supplemental application will require its own National Environmental Policy Act analysis of potential environmental impacts of those facilities.

Question. What repercussions will there be if there is an escape?

Answer. Under the FD&C Act, a new animal drug that does not comply with its approved application is considered "unsafe" and an unsafe new animal drug is "adulterated." 21 U.S.C. §§360b(a); 351(a).

The FD&C Act also deems adulterated any food that contains an unsafe new animal drug. 21 U.S.C. 342(a)(2)(C)(ii). FDA may take enforcement action against adulterated drugs and foods, including refusing admission to imported foods and drugs that appear to be adulterated.

Among the conditions included in the approval, AquaBounty must maintain physical and biological containment measures and report any likely or actual breaches of physical containment. If any such breach occurred in violation of a condition established in the approved application, AquAdvantage Salmon would be deemed "unsafe" and adulterated under these provisions and, therefore subject to FDA enforcement action, including seizure of adulterated product.

QUESTIONS SUBMITTED BY SENATOR JOHN TESTER

PREMIUM CIGARS

Question. Given that premium cigars are enjoyed by adults in moderation, and are inherently less attractive to underage smokers than other tobacco products, how are

you taking into account the unique nature of cigars when promulgating tobacco regulations?

Answer. Although all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars (e.g., small cigars, cigarillos, large cigars, premium cigars) may have the potential for varying effects on public health if there are differences in their effects on youth initiation, the frequency of their use by youth and young adults, and other factors.

In the proposed deeming rule, FDA sought comment on two options for regulating categories of cigars: option one would deem all cigars subject to FDA's tobacco control authorities, and option two would exclude premium cigars. FDA also asked what additional restriction(s) may or may not be appropriate for different kinds of cigars.

FDA reviewed all comments, data, and information submitted to the docket regarding this matter, and will address the issue in the final deeming rule.

QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

OPIOIDS

Question. I have for years pushed the FDA to promote safer alternatives to powerful prescription painkillers, and to remove from the market older, less safe drugs. The FDA's announcement last month to expand access to abuse-deterrent formulations of these powerful drugs is a step in the right direction in response to my concerns. However, the FDA can and must do more.

What plans do you have to ensure the FDA is doing everything in its power to help address the significant opioid crisis we are facing in this country?

Answer. Prescription opioids with abuse-deterrent properties will not fix the problem, but they can be part of a comprehensive approach to combat the opioid epidemic. While the FDA has a responsibility to regulate drugs and help educate prescribers, addressing this epidemic requires the collaboration of multiple Federal agencies, state governments, professional organizations, and other stakeholders.

FDA is changing the Agency's approach to opioid medications. The Agency's opioids action plan, announced on February 4, will focus on policies aimed at reversing the prescription opioid epidemic while still providing patients in pain access to effective relief. This plan includes concrete steps toward reducing the impact of opioid abuse on American families and communities. The plan includes a call for a re-examination of the risk-benefit paradigm for opioids, changes to immediate-release opioid analgesic labeling, improved access to naloxone, and new advisory committee meetings to provide recommendations on pediatric approval issues and any new opioid that does not have abuse-deterrent properties. The Agency will provide updates on progress with the goal of sharing timely, transparent information on a regular basis.

The Agency's action plan is part of the Health and Human Services (HHS) initiative to address the opioid epidemic which is working towards three broad goals: 1) opioid prescribing practices to reduce opioid use disorders and overdose 2) the expanded use of naloxone, used to treat opioid overdoses and 3) expanded use of Medication-assisted Treatment (MAT) to reduce opioid use disorders and overdose . Evaluation is a critical component of the initiative to identify what works and how the most effective interventions can be taken to scale.

FDA STANDARD FOR RAW MILK CHEESE

Question. I continue to be very worried about the potential impact that the FDA's non-toxigenic E. coli standard for raw milk cheeses could have on cheese producers in Vermont and across the United States.

The FDA's move to a standard for non-toxigenic E. coli that requires a thousandfold decrease in the presence of non-toxigenic E. coli in raw milk cheeses could severely limit the production of raw milk cheeses across the country. In December, I helped to lead a bicameral and bipartisan letter to your Deputy Commissioner for Foods and Veterinary Medicine, Mike Taylor, asking several specific questions about the new standard and how it was developed, but the agency's response did not specifically answer all of our questions.

In our letter, we asked whether the science upon which this standard is based has been subject to peer review. In response, the agency cited four different articles. While the articles do support the use of non-toxigenic E. coli as an indicator organism for food safety, they do not recommend the same level that the FDA has called for in raw milk cheeses. The first citation offered does not even seem to be in line with the agency's new standard, with the abstract specifically stating that with re-

gards to raw cow milk samples, "No relationship was detected between E. coli or the total bacterial count and the presence of pathogenic bacteria." In general, the scientific papers referenced do not seem to be particularly relevant to the issues laid out in our letter, with one article discussing the results from samples of raw milk in Malaysia. Therefore, I ask again:

Does the body of scientific evidence specifically support a thousand-fold decrease in the presence of non-toxigenic E. coli in raw milk cheeses?

Answer. First, we would like to clarify that the decrease in the level of non-toxigenic E. coli in cheeses in the Compliance Policy Guide (CPG) is not one thousand-fold, but instead is one hundred-fold, if one compares the maximum permissible levels. Prior to the 2010 revision of the CPG, if one sample had a test result of 10,000 cfu/g or greater, the product was considered violative. Under the current CPG also, if one sample has a test result of 100 cfu/g or greater, the product would be considered violative. Of course, there is a second criterion in the 2010 CPG, namely, 10cfu/g. However, under this criterion, multiple samples from the same lot of product would have to exceed it before the product would be deemed violative.

Regarding the references provided in the letter of Deputy Commissioner Michael Taylor, the references, including the abstract you quoted, were intended to show that there is support in the scientific literature for the use of non-toxigenic E. coli as an indicator of fecal contamination and insanitary conditions of production. For the 2010 CPG, we relied on the available peer reviewed literature (over 70 scientific papers), which showed that non-toxigenic E. coli is generally not present in raw milk, and that when it is present, it is usually at very low numbers, i.e. <100 cfu/g. The literature also shows that the cheese making process, coupled with aging, substantially reduces any non-toxigenic E. coli present. With this information, we concluded that there should not be E. coli in cheese unless the milk used was of poor quality, or the cheese was produced under unhygienic conditions. This conclusion has been supported by the results of our 2014–15 cheese sampling program in which the vast majority of 1606 raw milk cheese samples met the 2010 criteria.

That said, as you may be aware, we have paused our testing for non-toxigenic E.coli in cheese as we take another look and engage stakeholders regarding what role this indicator organism should have in identifying insanitary conditions and process failures for both domestic and foreign cheese and how the results of such testing may be used in support of preventive measures. We intend to further engage our stakeholders in the artisanal sector and scientific experts in dialogue on this issue. We will seek public comment on such issues as the use of a single bacterial criterion for both pasteurized and raw milk cheese, and the appropriate use(s) of non-toxigenic E. coli as an indicator organism in pasteurized and raw milk cheese. Based on this dialogue and input, we will consider and make changes in the 2010 CPG as appropriate.

FDA STANDARD FOR RAW MILK CHEESE

Question. There is a strong desire for transparency in rulemaking and in the process that leads to policy change. I feel strongly, as do our cheesemakers and food safety advocates, that science and data must guide these decisions. The American Cheese Society has requested data to be released on the FDA's raw milk sampling program. I have been told that your staff had initially agreed to share that data. Transparency in this case, and access to this data, could help American raw milk cheesemakers determine if and where changes need to be considered to ensure the production of safe cheese. Access to this data would also help to educate producers and inspectors to ensure that they are working together to continually enhance public health and welfare.

Has the FDA been working to respond to the American Cheese Society's request for data? And if so when can they expect the FDA to finally release the data they had been promised?

Answer. The FDA received a request from the American Cheese Society, dated February 22, 2016, for data from the Listeria Environmental Sampling Program and the Raw Milk Cheese Program. We are diligently working to compile the requested information. The request is currently being processed under the Agency's Freedom of Information Act program. In addition, an external report is being prepared for stakeholders that will discuss the results of the FDA's fiscal year 2014/15 surveillance sampling assignment on raw milk cheese.

GENERIC COMPETITION/PHARMACEUTICAL PRODUCTS SUBJECT TO A REMS

Question. An essential step for generic drug manufacturers seeking to create a low-cost generic drug is to obtain samples of the brand-name drug they wish to replicate so they can conduct bioequivalence and other testing for FDA approval. Unfor-

tunately, some brand-name companies appear to be impeding generic competition by refusing to provide such samples, either by imposing their own restrictions, or by claiming that distribution of their product is prohibited because of an FDA-approved safety protocol known as a "REMS".

Additionally, some brand-name companies appear to be impeding generic competition by refusing to work with potential generic competitors to develop a single, shared safety REMS which in certain cases the FDA requires prior to approving the generic product.

Federal law expressly bars pharmaceutical companies from using REMS restrictions to block generic competition. Furthermore, in December 2014, the FDA issued guidance describing a process the Agency has developed to reassure brand-name drug companies that providing sample product to a generic competitor would not violate a REMS. Nevertheless, numerous generic companies continue to report difficulties in obtaining samples or negotiating a single, shared REMS, thus foreclosing competition.

In your experience, are some brand-name companies engaging in the practices described above, even after the adoption of FDA's December 2014 protocol?

Answer. Yes. FDA has received more than a hundred inquiries from generic companies that want to develop generic drugs but tell us they are unable to because they cannot get access to supplies of the reference listed drug (RLD) to do testing. This is a problem that affects both REMS drugs and non-REMS drugs: in fact, the number of non-REMS products about which we have received these inquiries is actually larger than the number of products subject to REMS about which we have received inquiries.

The problem often arises when generic companies are not able to get access to the RLD through normal distribution channels (i.e., via wholesalers) because limitations on the distribution of the drug are in place. The brand company might limit the distribution of the product on its own initiative for a variety of different business reasons (for example, by selling through a central or small group of pharmacies, some of which may identify themselves as specialty pharmacies). For drugs with a REMS, an element to assure safe use (such as a pharmacy certification requirement) might impact the way the product is distributed.

We understand that some brand companies have refused to sell the RLD to generic companies for testing or have included provisions in their contracts with pharmacies/third parties that prohibit the sale of the RLD to generic companies for testing purposes. We have referred such matters that have been brought to our attention to the Federal Trade Commission (FTC) and encouraged generic companies to also raise these matters with the FTC. We have taken a number of additional steps as well.

Some brand companies have argued that selling the RLD to the generic firm for testing/development would be a violation of their REMS. To address this, we have developed a process, where appropriate, for informing the brand company in writing that FDA will not consider provision of the RLD for these purposes to be a violation of the REMS. We do this by reviewing the bioequivalence study protocols of companies that want to develop generic versions of these REMS drugs to assess whether their protocols have safety protections comparable to those in the applicable REMS. If we determine that they do, we send the brand company a letter stating so and informing them that selling the RLD to the generic company for testing and development will not be considered a violation of the REMS. (This process is described in the December 2014 draft guidance referenced in this question).

However, while these letters make clear that such sales will not subject the brand company to REMS-related enforcement action, some brand companies have argued that they have independent business reasons for not selling the RLD to the generic firm that are unrelated to their REMS and/or that they have no obligation to do so.

Finally, we note that we also continue to have concerns about brand companies blocking or delaying approval of generic drugs using the single, shared system REMS requirement. This is a separate problem from the RLD access issue described above. The development of a single, shared system (which is mandated by the Federal Food, Drug, and Cosmetic Act for REMS that include certain elements, unless FDA waives the requirement for one of the reasons set forth in the Act[2]) necessitates discussion and negotiation between the competitor brand and generic company and agreement on the terms of the single shared system REMS and how it will operate before the generic product can be approved. Brand companies therefore have an incentive to delay generic competition for their products by refusing to agree to single, shared system REMS terms and otherwise prolonging the negotia-

[2] Section 505–1(i)(1)(B)

tions over a single, shared system REMS. We see prolonged negotiations and inability to agree on the terms of a single, shared system REMS regularly.

Question. If yes, would additional tools or legislative changes assist the Agency or other entities in addressing such behavior?

Answer. The Administration has not taken a position on pending legislation in this area.

Question. Could such practices be further addressed by creating a specific cause of action for generic manufacturers to sue in court to obtain the samples they need and/or to secure good faith and timely negotiation on developing a single, shared system of distribution for products that are subject to a REMS?

Answer. The Administration has not taken a position on pending legislation in this area.

Question. How long does the FDA's process normally take to review and approve a generic company's REMS protocol, and are there steps FDA could take to expedite this review?

Answer. The timing of the review of bioequivalence study protocols for drug products subject to a REMS with elements to assure safe use varies based on several factors. These protocols require review by the two separate divisions within the Office of Generic Drugs' (OGD's) Office of Bioequivalence: the Division of Bioequivalence and the Division of Clinical Review. Because review staff in these divisions must prioritize workload to accommodate projects with GDUFA goal dates, the timing of protocol review therefore depends on the complexity of the protocols, the size of the queue, and competing workloads.

OGD has taken a number of steps to streamline and shorten the process for submission and review of bioequivalence protocols. The December 2014 draft guidance described above provides step-by-step guidance to prospective generic applicants on how to submit these protocols and what to include in them. This draft guidance was issued in order to streamline the process, improve the quality of submissions received by the Agency, and thereby reduce review time. OGD has also assigned dedicated staff to coordinate the review of these protocols across the different OGD offices and divisions. OGD continues to evaluate the protocol review process and engage in process refinements and improvements where possible to assure timely and efficient protocol reviews.

LABELING OF GENERIC DRUGS

Question. In 2013, the FDA issued a proposed rule that would ensure that generic drug companies can update their safety labels when they learn new information. This proposed rule is tremendously important because more than 80 percent of consumers take the generic version of a drug when it is available. We need generics to be able to improve their labeling, and be held accountable when they fail to do so.

Unfortunately, the FDA's proposed rule remains caught up in regulatory limbo. Last year, the FDA reopened its rulemaking to consider an industry-backed alternative that would turn existing labeling rules on their head. The industry proposal would ensure that after a generic drug enters the market, no drug company could update its label immediately upon learning of adverse side-effects. Labeling updates would be delayed, and drug companies could not be held accountable if they failed to update their safety information.

One of my constituents, Diana Levine, was able to seek justice after she was injured by a mislabeled drug precisely because of the rules the drug companies are now trying to overturn.

I am gravely concerned by the drug companies' proposal. I am also concerned by the FDA's delay in completing the rulemaking on its initial proposal, which is widely supported by patient groups and safety advocates.

The Unified Agenda for Regulatory and Deregulatory Actions currently states a release date for the final rule of July 2016, following several previous postponements. Is the rule on track to be released at that time?

Answer. The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment periods on the proposed rule regarding the best way to accomplish this important public health objective.

These comments include a summary of FDA's meeting with the Generic Pharmaceutical Association (GPhA) on September 8, 2014, to listen to their comments and views regarding the proposed rule. In addition, on March 27, 2015, FDA held a public meeting at which any stakeholder had the opportunity to present or comment on the proposed rule, or on any alternative proposals intended to improve commu-

nication of important, newly acquired drug safety information to healthcare professionals and the public. In the February 18, 2015, notice announcing the public meeting, FDA reopened the docket for the proposed rule until April 27, 2015, to allow for the submission of written comments concerning proposals advanced during the March public meeting.

FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), healthcare associations, drug and pharmacy associations, brand and generic drug companies, law firms, state governments, and Congress, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment (see Docket No. FDA–2013–N–0500).

Question. The Unified Agenda, available at http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201604&RIN=0910–AG94, currently lists an anticipated publication date of April 2017 for the final rule on "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products." The dates for rules in the Unified Agenda are projected dates that may be adjusted to reflect ongoing work on specific rules.Will the FDA commit to work expeditiously to complete the rulemaking process, with a focus on consumers and patient safety?

Answer. The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment periods on the proposed rule regarding the best way to accomplish this important public health objective.

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QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

Question. I am encouraged by the FDA's increased attention to the growing epidemic of prescription opioid misuse and abuse and the need to improve treatment options for chronic pain. As you mentioned in your recent article in the New England Journal of Medicine[3], there is little high-quality evidence on the safety and efficacy of opioids as a long-term treatment for chronic pain. It is critical that we fill the gap in research and promote the development of safer treatments that pose less risk of addiction for patients experiencing chronic pain.

How is the FDA collaborating with other government agencies, including the National Institutes of Health, to prioritize the development of non-addictive therapies for chronic pain and to generate high-quality evidence to support their use?

Answer. To help combat the opioid epidemic, the FDA is encouraging drug development efforts that make it harder to abuse opioids, and the agency looks forward to the day, hopefully soon, when the majority of opioids in the United States are marketed in effective abuse-deterrent forms. However, development of and transition to use of opioids with meaningful abuse-deterrent properties is only one component of a multi-pronged approach to addressing abuse of opioid medications. For example, the FDA is also working to support the efficient development of non-opioid alternatives for treating pain that have lower (or no) abuse potential. Encouraging the development of these products requires both scientific and translational develop-

[3] Califf, Robert M., M.D., Janet Woodcock, M.D., and Stephen Ostroff, M.D. "A Proactive Response to Prescription Opioid Abuse." New England Journal of Medicine, 4 Feb. 2016. <http://www.nejm.org/doi/full/10.1056/NEJMsr1601307#t=article>.

ment work. FDA has past and ongoing work in this area, supported through our participation in the ACTTION Public Private Partnership[4] (PPP) in a wide variety of areas.

ACTTION is working to improve study methods for developing novel, safe, and effective analgesic drug products. Through scientific assessment of FDA's clinical trial databases and publically available data, the PPP plans to develop novel and evidence-based approaches to improve the design of analgesic clinical trials. The PPP also coordinates scientific workshops that bring together key experts, including stakeholders from industry, professional organizations, academia, and government agencies.

Additionally, as part of the FDA's recently announced plan aimed at reversing the opioid epidemic, the agency has contracted with the National Academy of Medicine to provide us with advice on how we should incorporate current evidence about the public health impact of opioid use, both for people who are prescribed opioids and for non-patients, into regulatory activities concerning opioids. We look forward to the recommendations from NAM and other experts about reassessing our risk-benefit paradigm for opioids based on the current state of the science.

FDA also continuously strives for enhanced collaboration between NIH and FDA. FDA leadership recently participated in a meeting of the FDA–NIH Joint Leadership Council, an organization through which senior leaders from both agencies address ways to facilitate new processes, such as FDA review of combination therapies and its consideration of rare disease trials with fewer patients enrolled. The participants on the FDA–NIH Joint Leadership Council work together to help ensure that regulatory considerations form an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process. Such collaboration and integration advances the development of new products for the treatment, diagnosis, and prevention of common and rare diseases, as well as enhances the safety, quality, and efficiency of the clinical research and medical product approval process.

Question. How will the FDA in fiscal year 2017 improve post-market surveillance of medical devices? And, in addition to recalling such devices when they are found to be unsafe for patients, how will the agency better protect patients from adverse effects and complications while said devices are under investigation?

Answer. FDA takes device post market safety very seriously. There will always be limitations to how much CDRH can learn about a device before it goes to market, diligent postmarket surveillance can identify safety signals, prevent patient harm, and lead to device improvements. The Center for Devices and Radiological Health's (CDRH) current postmarket surveillance tools, such as passive reporting, limit our ability to rapidly address safety concerns.

For this reason, FDA has proposed the development of a national evaluation system for medical devices (system).

In 2011, the Institute of Medicine (IOM) published a report recommending that FDA develop and implement a comprehensive medical device postmarket surveillance strategy to collect, analyze, and act on medical device postmarket performance information. In 2012 and 2013, CDRH set out a vision and strategy[5] for creating such a system. In 2015, two multi-stakeholder groups issued reports[6] supporting the vision and made recommendations providing further direction for establishing this system. Further, CDRH's 2016–2017 Strategic Priorities[7] include increasing access to and use of real-world evidence to support regulatory decisionmaking. The development of the post market evaluation system is integral to meeting those goals.

The principal challenge for implementing the system is lack of funding. The system needs investment from various stakeholders to operate and build on existing infrastructure and to establish and operate a governing body. The fiscal year 17 President's Budget contains a request for $1.8 million for the system. While the long-term vision for the system involves multi-stakeholder participation and investment, in order to garner meaningful financial support from the private sector, the NES needs a core investment. We would like others in the medical device ecosystem, such as payers and professional societies, to also have an important role in the development of this system. Finally, this investment will support precision med-

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[4] ACTTION: Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks

[5] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm.

[6] http://www.brookings.edu/events/2015/02/23-future-of-medical-device-safety-and-innovation;www.brookings.edu/about/centers/health/projects/development-and-use-of-medical-devices/mds/2016-planning-board.

[7] http://www.fda.gov /downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf.

icine. One of the biggest problems facing the success of Precision Medicine is the challenge of determining which devices are best suited for which patients because of the high cost of developing evidence. Data that can answer these questions is generated every day as a part of routine clinical practice (evidence from clinical experience or "real world" data).

To better protect patients from potential adverse events or outcomes while a postmarket device safety issue is under evaluation, the FDA communicates clear and easily understood information about the risks and benefits of a device to patients and healthcare providers. FDA uses a range of tools to disseminate information widely, including our website and through letters and meetings with healthcare providers and patient groups.

To support increased communication on potential safety issues, in December 2015, CDRH released a draft guidance called "Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')." An emerging signal is new information about a medical device used in clinical practice that the FDA is monitoring or analyzing; that has the potential to impact patient management decisions and/or alter the known benefit risk profile of the device; that has not yet been fully validated or confirmed; and for which the FDA does not yet have specific recommendations.

Historically, FDA has communicated important information we learned about in the postmarket context after completing an analysis of available data and, in most cases, after having reached a decision about relevant recommendations for the device user community. This guidance is designed to inform the public of our evolving efforts to share information in a more timely way that allows patients to make the most informed medical decisions with their healthcare provider as close to real-time and based on the most current data as possible.

FDA has taken additional important steps to facilitate the identification and evaluation of postmarket safety concerns. FDA issued a final rule establishing a unique device identification system to provide a standardized way to identify devices across different information sources including electronic health records and device registries using unique device identifiers (UDIs).

Question. The 2015–2020 Dietary Guidelines recognized that sugar that is added to increase the palatability of naturally tart fruits, like cranberries, can aid a healthy dietary pattern by supporting the consumption of fruits and vegetables. In considering the proposed added sugar DV for labeling, what is the FDA doing to ensure that consumers will be not be misled on the healthfulness of nutrient dense products that contain added sugar, when comparing similar fruit products with equal or more intrinsic sugars and calories?

Answer. An added sugars declaration on the Nutrition and Supplement Facts labels, if finalized, would be just one piece of information that consumers can use to help them construct a healthful dietary pattern. We recognize that the added sugars declaration would be new information that consumers would not have seen before; therefore, in collaboration with Federal and other partners, we plan to engage in educational and outreach activities for consumers and health professionals about the use of information on the Nutrition and Supplement Facts labels, including any information about added sugars, if finalized. In the education and outreach activities, FDA plans to indicate that consumers should consider all of the information on the label, including total sugars and calories, when constructing a healthful dietary pattern, and not focus on just one specific nutrient.

Question. Artisan cheesemakers in Wisconsin have expressed concerns over the uncertain regulatory climate for raw milk cheese production. In particular, FDA's approach in conducting sampling at cheese facilities as it reviews raw milk cheese and non-toxigenic E. coli levels created a great deal of uncertainty and concern within the industry, despite the industry's attempts to work with FDA. Though cheese producers cooperated extensively in providing samples, FDA did not share the results from those tests in a timely way with individual businesses or the industry. When can cheesemakers and their industry groups expect to receive comprehensive results from the Listeria Environmental Sampling Program and the Raw Milk Cheese Sampling Program?

Answer. An external report is being prepared for stakeholders that will discuss the results of the FDA's fiscal year 2014/15 surveillance sampling assignment on raw milk cheese. We expect that report to issue in the coming months. FDA will release results of Listeria sampling conducted at cheese firms, as resources allow.

Question. As the FDA works to complete its guidance document on environmental Listeria, is there any quantitative data on incidence and levels of Listeria monocytogenes in frozen foods such as frozen vegetables and frozen food entrees? In frozen foods where Listeria monocytogenes has been implicated in the reportable

food registry, does FDA have any quantitative data? If so, please share that data with the subcommittee.

Question. FDA recently queried the database for Reportable Food Registry submissions and found thirty-eight (38) primary submissions for Listeria monocytogenes in frozen foods between 2009 and the present. Of these submissions, nine (9) met the criteria for reportable food and were classified as Class I recalls because there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death to humans or animals. Twenty-seven (27) submissions were considered non-reportable because the food failed to meet the Class I recall standard or because it did not meet the criteria of a reportable food (e.g., the food is not regulated by FDA or the report is not submitted by a manufacturer, processor, packer or holder of food required to be registered with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act). Two (2) submissions are awaiting decisions on recall classification.

FDA occasionally collects quantitative data from frozen food products on an as needed basis to assist in an investigation but has not conducted a comprehensive survey of the frozen food industry. In two investigations in the past 2 years, FDA collected quantitative data. In one investigation involving an ice cream outbreak, the data revealed that 99.4 percent of samples of the ice cream involved in the outbreak contained detectable L. monocytogenes at levels ranging from less than 0.03 cells of L. monocytogenes per gram to greater than 208 cells per gram. In the second investigation involving frozen vegetables subject to recall, FDA collected samples from thirty-three (33) product lots stored in the firm's warehouse freezer. Eight (8) lots (24 percent) tested positive for the presence of L. monocytogenes.

Question. The fiscal year 16 omnibus included report language that asked the Administration for a timeline for updating the dietary reference intake (DRI) for sodium as part of the fiscal year 17 budget request. An update was not included in the fiscal year 17 budget request. Can you share the specific 2016 timeline and plan for the update of the sodium DRI as requested in the Omnibus report?

Answer. FDA has prioritized updating the DRI for sodium and is collaborating with the Centers for Disease Control and Prevention and other Federal agencies to update the DRI for sodium as expeditiously as possible. A detailed timeline is not yet available.

SUBCOMMITTEE RECESS

Senator MORAN. Again, Commissioner, thank you, and, Acting Commissioner Ostroff, thank you very much for your leadership of the agency.

And we stand adjourned.

[Whereupon, at 2:42 p.m., Wednesday, March 2, the subcommittee was recessed, to reconvene subject to the call of the chair.]

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2017

WEDNESDAY, MARCH 9, 2016

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

The subcommittee met at 2:05 p.m., in room SD–124, Dirksen Senate Office Building, Hon. Jerry Moran (chairman) presiding.

Present: Senators Moran, Blunt, Cochran, Hoeven, Daines, Merkley, Tester, Udall, and Baldwin.

DEPARTMENT OF AGRICULTURE

STATEMENT OF HON. THOMAS VILSACK, SECRETARY

ACCOMPANIED BY:
DR. ROBERT JOHANSSON, CHIEF ECONOMIST
MICHAEL YOUNG, BUDGET OFFICER

OPENING STATEMENT OF SENATOR JERRY MORAN

Senator MORAN. I call this Committee hearing together, and we appreciate the Secretary joining us once again.

As you would expect, the purpose of our hearing is to examine the Administration's fiscal year 2017 budget request.

In addition to Secretary Vilsack, we welcome Dr. Johansson. Thank you very much for joining us last week in a discussion about agricultural economics.

Mr. Young, thank you very much for your presence today.

Agriculture supports 16 million jobs nationwide. It is certainly the backbone of my State, my community and States and communities across the country. We also know, unfortunately, as Dr. Johansson indicated to us last week, farmers are facing a dramatic reduction in commodity prices and falling revenues. We know the facts indicate that from 2013 through 2015, net farm income fell 54 percent.

In these times, it is critical that our Nation's safety net for farmers and ranchers perform well and allow them to continue to grow and raise the safest, most affordable and abundant food supply in the world.

As I indicated in our conversation with the agriculture (ag) economists, in the absence of doing that, they will not be around

in good times. Therefore, I would express my disappointment that, once again, the President's budget proposes significant cuts to crop insurance, even though we had a grassroots effort that successfully reversed a reduction. That reduction pales in comparison to what this year's proposal in the budget requests.

As this Subcommittee works to craft this year's appropriations bill, my priorities will be to focus on supporting agricultural producers and the rural communities in which they live, and keeping a strong safety net will be at the forefront of that effort.

I look forward to discussing these issues and others at today's hearing. When Senator Merkley arrives, we will give him the opportunity to make any statements that he would like to make, then we will turn to Secretary Vilsack.

[The statement follows:]

PREPARED STATEMENT OF SENATOR JERRY MORAN

This hearing will come to order. Good afternoon. The purpose of today's hearing is to discuss the Department of Agriculture's fiscal year 2017 budget request.

Secretary Vilsack, Dr. Johansson, and Mr. Young—thank you for being here today.

Agriculture supports more than 16 million jobs nationwide and forms the backbone of our rural communities. However, as you well know, our nation's farmers and ranchers have faced a drastic downturn in commodity prices and falling revenues. From 2013 to 2015, net farm income fell by a staggering 54 percent.

In times like these, it is critical that our nation's safety net for farmers and ranchers performs well and allows them to continue to grow and raise the safest, most affordable, and abundant food supply in the world.

I'm disappointed that once again the president's budget proposes massive cuts to the crop insurance program—even after the grassroots effort by so many last fall successfully reversed a reduction that pales in comparison to the proposals in this year's budget request.

As the subcommittee works to craft this year's appropriations bill, my priorities will focus toward supporting agriculture producers and rural communities. Keeping a strong safety net intact will be one of those priorities.

I look forward to discussing these issues and others at today's hearing. I would now like to turn to our Ranking Member, Senator Merkley, for his opening statement.

Senator MORAN. Secretary Vilsack, we are going to begin with your testimony. Thank you very much. Welcome.

SUMMARY STATEMENT OF HON. THOMAS VILSACK

Secretary VILSACK. Mr. Chairman, thank you very much. To Senator Merkley and other members of the committee, thank you for the opportunity to be here today.

I thought I would take this opportunity to point out that budgets are oftentimes a lot about numbers. But behind each of these numbers, there are individuals and people that we care deeply about. So I thought I would take a little bit of my time today to discuss the people who will be benefited from the agricultural budget.

The budget we submitted to the Senate and to the House will support 43,000 farm loans. We already, over the last 7 years, provided 239,000 farmers with the credit that they need to be able to operate and own their farm operation, 80 percent of those resources going to those beginning in the farming business and socially disadvantaged producers.

This budget will continue to support our export assistance efforts. Every dollar we invest in export assistance generates $35 of activity. We are excited about the possibility during the last 7

years of reaching nearly $1 trillion of ag exports, which is a record, a 45-percent increase over the previous 7-year period. This budget does provide adequate coverage for the $92 billion crop that will be grown and raised this year through crop insurance and provides what we estimate to be an 18-percent return on investment for the company's crop insurance.

It will provide enough resources to add 44 million acres to an already record number of enrolled acres in our conservation program. We are particularly pleased with the reaction and response to the Regional Conservation Partnership Program (RCPP), which is now leveraging nearly $2 for every $1 that we are investing in conservation.

In addition to providing opportunities for credit, we also will, as the Chairman indicated, continue to administer the farm bill safety net programs. Last year, we provided 900,000 farms agriculture risk coverage (ARC) or price loss coverage (PLC) payments, totaling $5.2 billion. Our expectation is that that amount will increase this year to provide the necessary bridge to better times.

At the same time, we are also going to make sure that we create more innovation and opportunity in rural America. The budget we propose will support 55,000 new jobs added to the 450,000 jobs that we have saved or created as a result of investments in over 100,000 businesses in the last 7 years through rural development.

This budget will finance 167,000 home loans, which will allow us to exceed 1 million home loans in the last 7 years.

We finance nearly 1,000 community facilities, provide safer and better water for 1.7 million rural Americans, which will reach nearly 20 million rural Americans who have benefited from over 5,000 water and wastewater projects that have been financed by the U.S. Department of Agriculture (USDA) since I have been Secretary.

Our budget proposes a threefold increase in broadband grants. There are a multitude of reasons for business, for farmers as well as potential expansion of distance-learning and telemedicine, which will become critically important in rural America if we are to make sure that our youngsters are well-prepared for a very competitive future, and if we are able to deal with the opioid issue, which I know is an issue that many of you are very, very concerned about, as I am.

This budget will also fully fund our research initiative, our competitive research initiative, meeting the goal that was set when the National Institute of Food and Agriculture (NIFA) was first established of $700 million of assistance for research. There has never been a more important time in agriculture for additional research, whether it is pollinators, antimicrobial resistance, pests and diseases that we are dealing with as a result of a changing climate.

We have already netted 429 patents, 953 inventions, and 714 new plant varieties just in the time that I have been Secretary, through our research initiative.

We will also continue to support and provide additional resources for the important role of the Agricultural Research Service (ARS) within USDA.

On the nutrition side, this budget will support 8.1 million WIC (Women, Infants and Children Program) participants with continued expanded access to our school lunch and school breakfast pro-

gram. I am particularly interested and hopeful that we are able to see an expansion of our summer program. The President has proposed an approach that will allow 1 million youngsters the opportunity to access food during the summer months.

This also will provide an opportunity for us to focus on senior citizens and their access to the Supplemental Nutrition Assistance Program (SNAP). Only 41 percent of eligible senior citizens are currently receiving the benefits of SNAP. We would like to see the percentage increase.

This is a budget, Mr. Chairman, that also will allow for an expansion of local and regional food systems in the bio-based economy.

I would say that even though this is not the purview of this particular Subcommittee, I would hope that this is the year that we finally fix the fire budget, because that has implications and impacts on every other aspect of USDA's budget.

Candidly, I am at the point now where folks have raised concerns about trails and a variety of other facets of the Forest Service that we are not going to do what we have done in the past, which is transfer money for fire suppression. Hopefully, this is the year that Congress get serious about fire suppression.

This is also a budget, I might add, that is $1.8 billion less than the budget that was submitted in the first full year of this Administration. So we have been dealing with constrained budgets, but we have done this through the administrative services process, which has saved $1.4 billion, and through a process improvement program, which has saved over 300,000 hours of time and which also saved $65 million to constituents and customers that we serve, all in an effort to try to continue to do better and more with less.

I look forward to questions from the Subcommittee, and I appreciate the opportunity to be here.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS J. VILSACK

Mr. Chairman and distinguished members of this Subcommittee, I appreciate the opportunity to appear before you to discuss the Administration's priorities for the Department of Agriculture (USDA) and provide you an overview of the President's 2017 budget proposals for the Department. Joining me today are Robert Johansson, USDA's Chief Economist, and Michael Young, USDA's Budget Officer.

For more than 7 years, I have had the honor and privilege of serving as Secretary of Agriculture. I have traveled to all 50 states and heard from farmers, ranchers and Americans far and wide, from all walks of life about the impact that USDA's staff, programs and services have on their lives. I could not be more proud of the work the men and women of USDA do each and every day.

Seven years ago I first appeared before this Subcommittee to present this Administration's first budget request for USDA. I made a commitment to make sure that USDA's programs provide a high level of service to advance rural economic opportunity, improve family farm profitability, ensure the safety of our food, expand export opportunities, strengthen local food systems, protect our natural resources, address civil rights and combat hunger and malnutrition.

Seven years later, I can say that the men and women of USDA have made significant advancement in achieving our goals and they have done it with essentially the same discretionary funding level in fiscal year (FY) 2015 as in fiscal year 2009, and with 9,354 fewer total staff years in 2015 than in 2009. Critical to our success was the Blueprint for Stronger Service that allowed us to reduce spending, streamline operations and cut costs. Through the Blueprint for Stronger Services we completed a thorough review of the Department's administrative functions so that we could build a more efficient and effective workplace. Our savings and cost avoidance results for the American taxpayer have totaled over $1.4 billion since 2010. Through

these results and the institutional changes resulting from the Department's focus on process improvement, shared services, and strategic sourcing, the impacts of the Blueprint will continue to grow into the future.

Before getting to our fiscal year 2017 budget request, I want to highlight some of the great work that we have done to expand opportunities in rural America since fiscal year 2009. In fiscal year 2015, American agricultural producers achieved $139.7 billion in exports, the third highest year on record. Agricultural exports climbed more than 45 percent in value, totaling over $911 billion, between 2009 and 2015, the best seven year stretch in history. In addition, agricultural exports have increased in volume, demonstrating an increasing global appetite for American-grown products. Between 2009 and 2015, U.S. companies participating in USDA-endorsed trade shows reported total on-site sales of more than $1.7 billion and more than $8.7 billion in 12-month projected sales. An independent study found that U.S. agricultural exports increase $35 for every market development dollar expended by government and industry.

USDA has worked to open new markets worldwide for farm and ranch products. Trade agreements, like those with Panama, Colombia and South Korea, create opportunities for trade growth. U.S. agricultural exports to these three countries grew by nearly 28 percent, from $7.6 billion in fiscal year 2012, when the trade agreements were first going into effect, to $9.7 billion in fiscal year 2015, supporting approximately 73,000 American jobs in 2015. USDA assisted with the recently concluded negotiations on the Trans-Pacific Partnership (TPP). When implemented, the TPP agreement, with 11 Pacific Rim countries representing nearly 40 percent of global GDP, will provide new market access for America's farmers and ranchers by lowering tariffs and eliminating other barriers. Rural America needs the good deal laid out in the TPP agreement. We are committed to working closely with Congress to obtain support for this historic deal so that our businesses can sell more rural-grown and rural-made goods around the world, and we can help more American workers compete and win. Rural exports support farm income, which translates into more economic activity in rural areas. It is estimated that for each dollar of agricultural exports another $1.27 in business activity is stimulated.

Access to credit is critical to the sustainability of small and beginning farmers. To make agriculture a reality for new and beginning farmers and ranchers, we have provided about 237,000 direct and guaranteed farm ownership and operating loans totaling $33.3 billion, 80 percent of which have been made to beginning farmers and ranchers and socially disadvantaged producers.

New and beginning farmers and ranchers are a fundamental part of the agricultural marketplace and are needed to carry-on America's strong legacy of agriculture productivity. However, according to the 2012 Census of Agriculture, their numbers are continuing a 30 year downward trend. To reverse this trend, we need to equip the next generation of farmers and ranchers with the tools they need to succeed. Under the leadership of Deputy Secretary Krysta Harden, USDA has increased access to our programs by collaborating with partners and improving customer service to increase opportunities for all sizes, segments, and types of farmers and ranchers to break down the barriers they face during the first 10 years of business. For example, USDA initiated a microloan program that has provided more than 16,800 low-interest operating loans, totaling over $373 million to producers across the country, and has recently expanded this to include farm ownership loans. We have also developed an innovative web tool and conducted other outreach activities, to help support key groups like veterans, women, and the socially disadvantaged, as well as facilitate intergenerational transfer of farms and ranches. To ensure the success and sustainability of beginning farmers and ranchers, USDA has created an agency priority goal that will publically share USDA performance goals and progress in support of new and beginning farmers.

We recognized that a spark was needed to transform rural America from a primarily agri-based economy to one that makes, creates and innovates. That is why we focused our efforts on taking advantage of the emerging bioeconomy, including biomanufacturing and advanced biofuels, local and regional food systems, broadband, and telemedicine. Our efforts not only supported the most productive agricultural sector in the world, but also assisted rural communities to be places where all businesses, farm and non-farm alike, have prospered and created jobs. We also saw the need to provide increased opportunities to allow everyone to share in the prosperity of the growing economy. So we targeted our efforts to the poorest communities, invested in new and beginning farmers, and supported our veterans, which have increased opportunities for hard working Americans. Our efforts are bearing fruit. Over the last 5 years unemployment rates in rural areas have fallen considerably and fairly consistently in rural areas, with unemployment rates falling by a full percentage point or more in each of the last 2 calendar years. These efforts

have contributed to the employment gains in rural America that have happened since 2009 and have led to increased economic activities in high poverty communities.

We have also recognized rural opportunities beyond agriculture by making historic investments in rural communities, making them more attractive to non-farm businesses and talented hard-working individuals looking to get ahead. USDA has sought to revitalize rural areas and diversify our nation's agriculture by making significant investments in rural infrastructure. Since 2009, we invested a total of $13.3 billion in new or improved infrastructure in rural areas through 10,623 water projects. These improvements helped nearly 18 million rural residents gain access to clean drinking water and better waste water disposal. Modernized electric service was delivered to more than 5.5 million subscribers and over 180,000 miles of electric lines were funded. We helped nearly 103,000 rural small businesses grow, creating or saving nearly 450,000 jobs between fiscal year's 2009 and 2015. Since 2009, USDA assisted more than 1.1 million rural families to buy or refinance a home, helping 141,000 rural Americans become homeowners in fiscal year 2015 alone.

USDA continues to lead the way for renewable energy by supporting the infrastructure needed to grow the new energy economy. Since 2009, RD has supported over 15,000 renewable energy projects to help producers and rural businesses save energy and increase their profitability and increase the production of renewable fuels. The Department has helped thousands of rural small businesses, farmers and ranchers improve their bottom lines by installing renewable energy systems and energy efficiency solutions, which will generate and save more than 9.4 billion kWh, enough energy to power 820,000 American homes annually. Under expanded authority provided by the 2014 Farm Bill, we are working to expand the number of commercial biorefineries in operation that produce advanced biofuels from non-food sources through the Biorefinery Assistance Program. This focus on renewable energy has resulted in support for the construction of 6 advanced biofuels production facilities, over 2,200 wind and solar renewable electricity generation facilities, and 93 anaerobic digesters to help farm operations capture methane to produce electricity.

In addition, we made available $100 million in grants under Biofuel Infrastructure Partnership (BIP) to nearly double the number of fueling pumps nationwide that supply renewable fuels to American motorists, such as E15 and E85. Twenty one states are participating in the BIP, with matching funds from state and private partners, providing $210 million to strengthen the rural economy by increasing the demand for advanced biofuels and expanding marketing opportunities for farmers. We also took new steps to support biobased product manufacturing that promises to create new jobs across rural America, including adding new categories of qualified biobased products for Federal procurement and establishing reporting by Federal contractors of biobased product purchases. We released a study of the bioeconomy last year and found the biobased products industry generates $369 billion and 4 million jobs each year for our economy. The expanding bioeconomy means more choices for customers and new jobs for rural America. Shifting just 20 percent of the current plastics produced into bioplastics could create an increase of 104,000 jobs.

USDA's place-based efforts are making sure that the programs that help alleviate the impact of poverty are available and accessible even in the poorest and persistently poor areas. In 2016, we expanded the StrikeForce Initiative to four additional states to include a total of 970 counties, parishes, boroughs, and census areas in 25 states and Puerto Rico. We know that place-based efforts work and we have seen StrikeForce bring economic opportunity directly to rural Americans where they live and help rural communities leverage their assets. In 2015, in StrikeForce target areas, USDA partnered with more than 1,000 organizations to support 56,600 investments that directed more than $7.5 billion to create jobs, build homes, feed kids, assist farmers and conserve natural resources in some of the nation's most economically challenged areas. Since the initiative was launched in 2010, USDA has invested more than $23 billion in high-poverty areas, providing a pathway to success and expanding the middle class.

Between 2009 and 2014, USDA invested more than $800 million in more than 29,100 local and regional food businesses and infrastructure projects. In fiscal year 2015, USDA directly supported nearly 10,000 farms and ranches, food entrepreneurs and communities through local food-related projects, which reflects the implementation of FSA microloans. As a result, the market for local food has grown to at least $12 billion in 2014 from $5 billion in 2008. Given the current growth of local foods, some industry sources estimate that the market's value could hit $20 billion by 2019. In addition, USDA has made expanding SNAP recipients' access to fresh fruits and vegetables through farmers markets a priority in recent years. In 2008, about

750 farmers markets and direct marketing farmers accepted SNAP. In 2015, almost 6,500 of these markets and farmers accepted SNAP.

Research provides the foundation for developing innovative practices needed to feed the growing global population, while protecting and conserving our natural resources. USDA's in-house research and our work with land-grant universities have delivered science-based knowledge and practical information to farmers, ranchers and forest landowners to support decisionmaking, innovation and economic opportunity. Between fiscal year 2009 through fiscal year 2015, USDA filed 883 patent applications with the U.S. Patent and Trademark Office and was issued 429 patents. In fiscal year 2015, USDA held 421 income-bearing licenses. It also had 301 cooperative research and development agreements, of which 106 involved small businesses.

USDA has facilitated the adoption of new technologies by streamlining the process for making determinations on petitions involving biotechnology. These improvements provided more rapid and predictable availability of biotechnology products to farmers, ultimately providing technologies to growers sooner and more choices to consumers. In fiscal year 2015 alone, USDA reviews found safe genetically enhanced varieties of potato, corn, soybean, cotton, and alfalfa. USDA estimates that the cumulative number of actions taken to deregulate biotechnology products based on a scientific determination that they do not pose a plant pest risk will increase from a cumulative total of 82 actions in fiscal year 2009 to an estimated cumulative total of 126 actions in 2017.

Since 2009, USDA has worked to safeguard America's food supply, prevent foodborne illnesses and improve consumers' knowledge about the food they eat. For example, USDA adopted a zero tolerance policy for raw beef products containing six strains of shiga-toxin producing E. coli, giving products that test positive for any of these strains the same illegal and unsafe status USDA has long given products testing positive for E. coli O157:H7. Additionally, USDA set tougher standards for Salmonella and new standards for Campylobacter on poultry carcasses, and developed the first ever Salmonella and Campylobacter standards for chicken parts, which are more commonly purchased than whole carcasses. Together, USDA estimates these new standards will reduce illnesses by about 75,000 annually, and help the agency meet Healthy People 2020 goals. The total number of illnesses attributed to USDA-regulated products fell nearly 11 percent from 2009 to 2015, which equates to more than 46,000 avoided illnesses on an annual basis.

The Administration continues its strong support for the Supplemental Nutrition Assistance Program (SNAP), the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and other critical programs that reduce hunger and help families meet their nutritional needs. SNAP kept at least 4.7 million people, including nearly 2.1 million children, out of poverty in 2014. Because hunger does not take a vacation during the summer months when school meals are unavailable, we have expanded the Summer EBT for Children demonstration pilots over the last 2 years, in tandem with the Summer Food Service Program. Summer meal participation has increased by almost 16 percent since 2009. In total, summer meals sites have served over 1.2 billion meals to low-income children since 2009. During the school year, over 97 percent of schools are successfully meeting nutrition standards by serving meals with more whole grains, fruits, vegetables, lean protein and low-fat dairy, and less sodium and fat. I am pleased the Senate Agriculture Committee passed a bill that ensures progress will continue improving our children's diets and urge Congress to reauthorize these programs for our young people without delay.

America's farmers, ranchers and landowners have led the way in recent years to conserve and protect our soil, water and wildlife habitat. With the help of Farm Bill programs, USDA partnered with a record number of producers since 2009 to create not only a cleaner, safer environment, but to create new economic opportunities. We have enrolled a record number of private working lands in conservation programs and implemented strategies—such as landscape-scale efforts—to restore our forests and clean our water supply. In fiscal year 2015, one such landscape-scale effort provided a noteworthy achievement in that 90 percent of the greater sage-grouse's breeding habitat in the western United States is protected as a result of our Working Land for Wildlife efforts and the work of our many partners. Due to this achievement, the U.S. Fish and Wildlife Service has determined this species does not warrant protection under the Endangered Species Act (ESA). In addition to wildlife benefits, conservation practices have reduced the amount of nitrogen leaving fields by about 26 percent, phosphorus by 46 percent, and the estimated amount of eroded soil by 60 percent over the past 7 years. Through the Regional Conservation Partnership Program (RCPP), we leveraged $800 million to support 115 high-impact conservation projects across the nation that will improve the nation's water quality,

support wildlife habitat and enhance the environment. We have also offered producers multiple new opportunities to utilize the Conservation Reserve Program to retire marginal agricultural lands, restore grasslands and forests, and protect valuable wildlife habitat. But just as important as protecting our natural resources, we have increased economic opportunities for rural America by boosting outdoor recreation, which adds more than $640 billion in consumer spending each year.

To build on these accomplishments, we need to do more to transform rural America and increase opportunities for families. To do this, the 2017 Budget will continue to expand opportunity for America's agricultural producers, rural communities, and the most vulnerable populations. Critical investments are made to strengthen rural communities, expand agricultural trade, provide more opportunities for hard working American families, modernize key infrastructure, and build resilience in the face of a changing climate.

USDA's total budget for 2017 we are proposing before this Subcommittee is $146.8 billion, of which approximately $127 billion is mandatory funding. The majority of these funds support crop insurance, nutrition assistance programs, farm commodity and trade programs and a number of conservation programs. The budget includes mandatory funds to fully support estimated participation levels for SNAP and Child Nutrition Programs. For discretionary programs of interest to this Subcommittee, our budget proposes $19.7 billion, approximately $309 million below the 2016 enacted level. That level fully funds expected participation in WIC. It includes the funding needed to meet our responsibility for providing inspection services to the Nation's meat and poultry establishments.

The budget also includes $1.4 billion to renew approximately 271,000 rental assistance agreements. This funding is critical to ensure housing stability for elderly and disabled tenants without the means to otherwise obtain safe, affordable housing. I appreciate the Subcommittee's assistance in ensuring we have the resources and flexibility in fiscal year 2016 needed to address challenges facing the Rental Assistance Program. The budget also funds single family housing at the 2016 enacted level, providing over 166,000 homeownership opportunities.

The 2017 budget provides a strong farm safety net and makes investments to meet challenges of a competitive global market, changing climate, and making agriculture a reality for new and beginning farmers. The budget proposes a loan level of approximately $6.4 billion for direct and guaranteed farm ownership and operating loans, about 80 percent of the loans will be made to beginning farmers and ranchers and socially disadvantaged producers. The Farm Service Agency will offer mentorship opportunities, support landowners who wish to sell or rent their land to beginning farmers and ranchers, increase local outreach and educational efforts, support agricultural youth organizations, provide loan fee waivers for veterans, and target additional farm loan funding to veteran farmers and ranchers. The budget doubles the funding for the Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Grant Program for a total of $20 million. Funding will be used to assist these groups in owning and operating farms and ranches, while increasing their participation in agricultural programs and services provided by USDA. The 2017 budget also includes a $5 million increase for the Sustainable Agriculture Research and Education Program to help beginning farmers and ranchers adopt sustainable agricultural practices.

The rural economy will be even stronger because of the investments in rural infrastructure made by USDA. We will make over $1 billion in investments in rural businesses estimated to provide over 55,000 jobs in rural areas. We will facilitate the growth of the bioeconomy with a $25 million increase in competitive research funding to support development of biobased energy sources. In addition, the budget includes $91 million in discretionary funding and $359 million in mandatory funding for a total of $450 million for REAP to assist agricultural producers and rural small businesses to take advantage of renewable energy. We also propose $6.5 billion in loans to rural electric cooperatives and utilities that will support the transition to clean-energy generation and increased energy efficiency. Funding for broadband grants is more than tripled to assist in bringing critically needed broadband service to more rural communities. In addition, the budget includes a total of $35 million for Distance Learning and Telemedicine grants to support improved education and medical services in rural areas which may help partially address the particular challenges tied to rural America's opioid abuse epidemic. Over $2.2 billion is targeted to community facilities, which will expand educational opportunities for students, facilitate delivery of affordable healthcare, and ensure the availability of reliable emergency services. Through a pilot called Rural Corps, USDA will work in partnership with local organizations to deploy highly trained staff and increase the likelihood that investments in infrastructure and economic development are strategic, creating jobs and long-term economic benefits.

Additional resources are proposed to address the acute and long-term needs of socially disadvantaged populations, including $20 million for a new competitive grant Home Visits for Remote Areas Program that will provide support for high-need maternal, child, and family health in remote rural areas and Indian country. It should be noted that such populations are more likely to experience poverty in rural areas where over 18 percent of the total population and over 25 percent of children live in poverty. We are also proposing $25 million to support a Rural Child Poverty demonstration project to implement multi-generational strategies to addressing rural child poverty, which includes $5 million to support alignment of data and eligibility determination systems across programs. The budget also includes increased support to build the capacity of 1890 Institutions to meet the growing need for agriculture assistance in high poverty areas. Further, we propose an increase of about $7 million to enhance research, education, and extension efforts in tribal areas through long-term capacity building at 1994 Institutions and expansion of the federally Recognized Tribes Extension Program (FRTEP). This will lead to increased professional training opportunities, a 25 percent increase in the number of Indian students working on summer internships, and a doubling of the number of FRTEP staff engaged in 4–H activities to 72.

Access to nutritious food is essential to the well-being and productivity of all Americans. The budget makes substantial investments in address child hunger in the summer. It provides an increase of $3 million in discretionary funding to continue the successful Summer Electronic Benefit Transfer for Children (SEBTC) demonstration pilots. Beyond the expansion of the pilots, the 2017 budget proposes to invest $12.2 billion over 10 years to make the program permanent and begin phased-in nationwide implementation. Rigorous evaluations of SEBTC pilots have proven effective in reducing very low food security in children for about one-third of the children who would have otherwise experienced it and in improving children's nutrition. The proposal would reach almost one million low-income children beginning in the summer of 2017, increasing to nearly 20 million children after 10 years. Given the harm that hunger imposes on children, this is a smart, evidence-based investment.

The budget includes an increase of $30 million to strengthen animal disease preparedness and response capabilities funding needed to stem the impacts of significant pests and diseases. Minimizing such impacts allows for an abundant food supply as well as provides trade opportunities for our producers. Over the last few years, USDA has addressed some of the worst animal disease outbreaks in recent history with the emergence of novel swine enteric coronavirus disease in the swine industry and the highly pathogenic avian influenza outbreak last year that infected 232 flocks and resulted in the depopulation of approximately 50 million birds.

Food for Progress and the McGovern-Dole International Food for Education and Child Nutrition Program will continue to provide benefits to millions of people overseas. These programs have helped to engage recipient countries not only by delivering food assistance, but also by fostering stronger internal production capacity and infrastructure, generating employment, boosting revenue, and developing new markets and productive economic partnerships. The budget provides $20 million, $5 million through the McGovern-Dole program, to support the local and regional procurement of food aid commodities for distribution overseas to complement existing food aid programs and to fill in nutritional gaps for targeted populations or food availability gaps caused by unexpected emergencies. Also, the budget proposes the authority to use up to 25 percent of Title II resources for these types of flexible emergency interventions that have proven to be so critical to effective responses in complex and logistically difficult emergencies.

The budget recognizes that there is a direct correlation between the capacity of this country to continue to sustainably meet a growing demand for food, feed and fiber and the amount of resources that we put into agricultural research. Long-term agricultural productivity growth relies on innovation through research funded by both public and private sectors. Analysis by the Economic Research Service shows that long-term agricultural productivity is fueled by innovations in animal/crop genetics, chemicals, equipment, and farm organization that result from public and private research and development. The 2017 budget includes $700 million for competitive grants through the Agriculture and Food Research Initiative, including $325 million in mandatory funding that would bring the program up to its authorized level. This significant investment is needed to ensure tools are in place to adapt to challenges faced by agricultural producers, while still feeding a growing population. A portion of this funding will support the President's clean energy efforts through the development of commercial-scale advanced biofuels and biobased products that are compatible with existing infrastructure. Also, the budget more than doubles the funding available to address antimicrobial resistance in pathogens of humans and

livestock, and to seek answers to key questions about the relationships among microbes and livestock, the environment, and human health. Further, the budget includes $36 million for research to address the decline of pollinator health by understanding, preventing, and recovering from pollinator losses.

We appreciate the Subcommittee's action to fund critical research infrastructure in 2016. To continue the process of laboratory improvement, the budget proposes additional investments in research infrastructure to further reduce the backlog of USDA's laboratory construction and renovation needs. These investments include $30.2 million for the Agricultural Research Technology Center in Salinas, CA, where research is done on alternatives to methyl bromide and development of scientifically based organic crop production practices for weed, insect, and disease control, as well as $64.3 million for the Foreign Disease-Weed Science Research Laboratory in Ft. Detrick, MD.

The 2017 budget fully funds the EQIP and CSP programs at the Farm Bill authorized levels. The unprecedented level of funding provided for EQIP will support conservation practices on an additional 11.5 million acres, which will help farmers and ranchers make their operations more resilient to climate change, increase access to greenhouse gas markets, and protect wildlife habitat, among other benefits. The funding for CSP will allow 10 million more acres to be enrolled. The budget also provides an increase of $11 million to support conservation planning, which will result in over 8,000 additional conservation plans. This translates into 2.9 million additional acres of planned conservation. The strong support for conservation planning as well as robust funding for the mandatory conservation programs follows through with the principles laid out in USDA's Building Blocks for Climate Smart Agriculture and Forestry.

Science and data are the primary tools that the Food Safety and Inspection Service (FSIS) uses to prevent foodborne illness and protect public health. As part of this effort, the budget includes $8.5 million to further modernize FSIS' science-based decisionmaking process by developing and deploying new tools to reduce the prevalence of foodborne illnesses.

To enhance nutrition education and the provision of healthy meals, the budget includes a $4 million increase to promote healthful behaviors that can reduce incidence of chronic disease and obesity, and lower healthcare costs. Included in this is an initiative to research and implement cutting-edge initiatives to help Americans put healthy eating behaviors, based on the Dietary Guidelines for Americans and MyPlate, into practice. We will also develop the first-ever dietary guidelines for the birth to age two group and pregnant women. In 2013, The Pew Charitable Trusts and the Robert Wood Johnson Foundation released a report that found 88 percent of schools need at least one additional piece of kitchen equipment to serve healthier meals that meet science-based nutrition standards. The budget also requests an increase of $5 million, for a total of $35 million, for grants to help schools purchase needed equipment to prepare and serve healthier meals.

The budget requests funding to establish an in-country presence in Cuba to cultivate key relationships, gain firsthand knowledge of the country's agricultural challenges and opportunities, and develop programs for the mutual benefit of both countries. U.S. agricultural exports have grown significantly since trade with Cuba was authorized in 2000. In fiscal year 2014, Cuba imported over $2 billion in agricultural products including $300 million from the U.S., and an in-country presence will capitalize on opportunities this nearby market provides for U.S. agricultural exporters.

We have identified additional opportunities to modernize and strengthen the Department. The budget includes resources to pursue these efforts, including $20 million to continue the modernization of the Headquarters complex that when finalized could yield annual savings of over $45 million through a reduction in rent and security costs. The budget also provides an increase of $18 million to fund a relocation or renovation of FNS headquarters in 2017. In addition, the Department is proactively addressing the cyber security threats posed against the network and systems of USDA. Through an investment of an additional $10 million in 2017, the Department will enhance its ability to monitor and prevent breaches of the systems used to house data of importance to our employees and customers.

The 2014 Farm Bill included several reforms to the Federal crop insurance program; however, there remain further opportunities for improvements and efficiencies. The President's 2017 budget includes two proposals to reform crop insurance, which are expected to save $18 billion over 10 years. This includes reducing subsidies for revenue insurance that insure the price at the time of harvest by 10 percentage points and reforming prevented planting coverage. These reforms will make the program less costly to the taxpayer while still maintaining a quality safety net for farmers.

We have accomplished much over the last 7 years. The budget presented to you will continue our progress. I would be happy to answer any questions you may have about our budget proposals.

SNAP CONVENIENCE STORE RULE

Senator MORAN. Mr. Secretary, we appreciate your presence here, and I appreciate the number of times you have reached out to me and provided me with information and meeting in the office and the phone calls, and I am grateful for the working relationship that we have.

Let me just ask a couple questions and then we will move to my colleagues quickly, and I will have an opportunity to ask more again later.

But let me start with the SNAP issue. February 17, the Food and Nutrition Service (FNS) published proposed rules in regard to SNAP. As you will recall, this was a significant, contentious issue in the farm bill.

My question to you is, my understanding is that those proposed rules have a significant consequence on potentially the convenience store setting, perhaps small grocery store setting. And I have a particular interest in that because in many rural communities, there is no grocery store. A convenience store is one of the sole providers of food in many communities across rural America.

I would be interested in hearing your thoughts, but my specific question is, would you entertain positively the idea of a longer comment period than the 60 days that you are currently proposing?

Secretary VILSACK. Mr. Chairman, obviously, we will respect your request and certainly take a look at what extension would make sense. We obviously want to take a look at the comments and find out what people think and feel about this. But we obviously want to give people appropriate time to comment on this.

This is an important issue. It is an important issue from the standpoint of the convenience store. It is also an important issue in terms of access to good, wholesome food, as we deal with this obesity crisis and the health care costs that are associated with obesity and the diseases that result from obesity.

Part of the challenge is that folks who do live in rural, remote areas do not have access to the wide array and diversity of food that others are fortunate to have, and we believe it is not asking too much for convenience store owners and operators to be able to provide a broader array of resources and choices for people who are SNAP beneficiaries.

So that is the purpose of the rule. I think there is also the belief that we can partner with these convenience stores in an effort to increase and enhance the nutritional value of what is being sold at the convenience stores.

GIPSA PROPOSED RULES

Senator MORAN. I appreciate what I took as a positive comment, that you will take a look at potentially extending the comment period. I appreciate that, Mr. Secretary.

Let me ask about another rule. On Monday, you indicated in conversations in front of an organization here, I think in Washington, DC, that you anticipated that there would be revised Grain Inspec-

tion, Packers and Stockyards Administration (GIPSA) rules, and you expected them to be finalized before you leave office.

Given the overwhelming congressional opposition to the previously proposed rules, what changes to GIPSA rules do you plan to make? And what discussions and outreach have you had with stakeholders in this regard?

Secretary VILSACK. Mr. Chairman, that process is still ongoing, and no commitments, specifically, have been made in terms of what those rules will look like.

We realize that Congress lifted the restriction on our ability to work on these issues. I have asked the team to take a look at what modifications or changes would be appropriate, given the concerns that have been expressed in the past, and also to determine whether or not what we were considering a couple years ago, whether or not that still makes sense in today's market.

They are putting together that work plan, and I will be more than happy when that process is completed to obviously provide you additional information on precisely what we are thinking.

But the key here is to make sure that the playing field is level between those who are owners and those who are producers, to make sure that there is not an unfair advantage in that relationship and to make sure, especially in difficult times, that those who invested a lot of hard-earned resources and time are treated fairly if a contract is terminated or for some reason a contract is modified.

We have had examples where folks have been dealt a very serious and difficult blow in tight circumstances. The avian influenza situation was sort of a reminder to us about the importance of that relationship, particularly as we did indemnification payments for those who lost birds. We found that not all those indemnification payments were going to the producers who were economically suffering as well.

So we want to make sure it is a fair and equitable relationship, and that is the purpose of our review of those rules.

Senator MORAN. Mr. Secretary, what do you expect the timeframe to be? What schedule are you on?

Secretary VILSACK. I would say that I suspect that some of these rules may very well be finalized and some of these rules may be proposed, given the nature of the concerns that were expressed in the past.

I would hope that we would be able to get work plans completed and we would get something over to the Office of Management and Budget (OMB) relatively soon. I would hope that we would be able to get that done sometime in early spring. And then there is the review by OMB, which can take sometimes up to 90 days or longer.

Then hopefully that process is expedited so that sometime in late summer, early fall, we are in a position to provide information specifically to the public for their comment and review. At that point, any adjustments that need to be made can be made. And hopefully by the time of year end, we will know what the rules will be or what they are at least proposed to be.

AVIAN INFLUENZA

Senator MORAN. Mr. Secretary, you mentioned avian flu. This is a topic of conversation that you and I have had one-on-one, but certainly in the hearing that we had a year ago on your budget, this was a significant issue and concern.

Is there something that USDA has learned that we would now be in a better position, should this kind of occurrence reappear? And then if you would bring us up-to-date on what has transpired in other countries in regard to our exports in regard to avian flu?

Secretary VILSACK. We have learned a great deal, Mr. Chairman.

First of all, we have learned the necessity of making earlier determinations and quicker determinations, so we have beefed up our laboratory capacity. We would like to be able to make determinations within a 24-to-48-hour time period when something arises on a farm. We then would like to be able to work with that producer to be able to depopulate within 24 hours. And we have learned that there are a multitude of ways in which that can potentially be done under each particular circumstance.

We have learned the need to pre-position assets, or at least have an awareness and understanding of how disposal will be handled in advance as opposed to after the fact, which can delay disposal, which can in turn create potential greater risk.

We have learned our indemnification systems needed to be altered a bit to reflect a more appropriate balance between the producer, the taxpayer, and USDA. We were cleaning up situations in some of these poultry facilities that had not been cleaned up for a decade, as opposed to cleaning up the specific cause or problem with avian influenza. So there was a better balanced approach there.

The difference between providing the owner of the birds all of the indemnification and now some kind of equitable ratio, if you will, between owner and producer in terms of indemnification so we can keep producers in business.

We have learned the necessity of constantly researching this, because it is constantly mutating and evolving.

And we have also learned the necessity of at least having prepositioned vaccine, not that we would necessarily use it, but there may be a circumstance or situation where it is appropriate. And we have basically wargamed what that would look like and what we would have to do in order to utilize vaccine.

In terms of the trade issue, we are seeing many of those who initially banned all poultry sales beginning to understand, from an international rules standpoint, the need to look at this regionally. We have actually seen some that have become even State-specific and some bans that have even become very specific to the county or counties.

So we have seen an expansion of opportunity. About 77 percent of the poultry exports are currently in the right place. We are still working with some of our friends in China, for example.

But for the most part, I think people have taken the right approach to regionalization or Statewide bans as opposed to countrywide bans.

Senator MORAN. Mr. Secretary, it seems as if you have learned a lot, which I assume means the USDA, the Federal Government, are better prepared for another occurrence, should it arise.

Are there any legislative changes that are required to help you accomplish a better response?

Secretary VILSACK. I would only say, Mr. Chairman, I think the research aspect of USDA needs to continue to be beefed up, because we are constantly dealing with things like this. But I do not know that we necessarily need a legislative change. But if there are, we will be happy to get some information to you. I do not know of anything, off the top my head.

[The information follows:]

We do not foresee needing any legislative changes to enhance our response to HPAI.

Senator MORAN. Thank you very much.

Senator Merkley.

OPENING STATEMENT OF SENATOR JEFF MERKLEY

Senator MERKLEY. Thank you very much, Mr. Chairman.

Thank you, Mr. Secretary. We are well along in the journey now, an 8-year journey serving President Obama, and I believe you are the only member of the Cabinet who has been there from the starting line and is still with us, and I assume is planning to go across the finish line. I want to thank you for these 8 years of service.

Secretary VILSACK. Thank you.

RENTAL ASSISTANCE PROGRAM

Senator MERKLEY. As you indicated to the Chairman, I know you have learned a lot in the post over these many years on so many different issues. Certainly, in your introduction you mentioned food, water, and shelter, that is everything from SNAP to water purification programs to housing programs. It really reflects on the essential functions that your Department has for millions, millions of Americans.

I just wanted to note your March 7 speech where you called upon Congress to pass mandatory genetically modified organism (GMO) labeling. I know you and I have very different definitions of what that would look like, but I stand with you shoulder-to-shoulder in the cause of mandatory labeling.

I wanted to turn to the housing component. One of the issues we had last year is that, under rental assistance, the project-based rent subsidy program, we had a situation where, essentially, we ran out of money to pay the share of the rent that we were responsible for as the Federal Government.

That appears to be fully addressed in the budget for fiscal year 2017, but I just wanted to raise it and ask if people across the country who were involved in providing project-based housing can rest assured that we have it covered this time?

Secretary VILSACK. Senator, I think we do. That is what I have been told. We certainly appreciate the work of yourself and Members of this Subcommittee to resolve that aspect of our Rental Assistance Program.

We have, as you know, the other issue of maturing mortgages and loan payoffs, which will result potentially, unless we deal with those, in a lot of these units coming out of the program, in which case you are going to have a lot of families that are going to be looking for housing and not be able to afford it.

Senator MERKLEY. You turned immediately to my second topic. We have recently been able to get some data from the Department on maturing mortgages in Oregon, but it is important that across the Nation we know when mortgages are maturing so nonprofits can attempt to buy them in places where they would go to much higher market rates.

I know your team has been working on this issue, but I just wanted to emphasize how hard it is to recover this housing if we lose it out of the affordable portfolio.

Years ago, I worked on a program called LIHPRHA, Low-Income Housing Preservation. It was a very similar situation, only in urban settings. Now we have this in rural settings. So anything I can do, and I am sure many members would say the same, to assist the Department in trying to make sure we identify the expiring projects and do everything possible to preserve them certainly would like to see happen.

Secretary VILSACK. Senator, 75 percent of these loans potentially will become due and paid off in the next 10 years, so that is 75 percent of the units.

One thing that you may want to think about is the ability of vouchering for those folks who are in a position where their unit ultimately gets out of the program. Another way that we are looking at it is being able to extend these mortgages and refinancing, so that improvements can be made to the property with the savings that results from extension and refinancing.

So there are some creative solutions here, but we need to get focused on this in the very near future.

RURAL ENERGY SAVING PROGRAM

Senator MERKLEY. I look forward to exploring with the Subcommittee the possibilities, because this will be very important to the housing stock in America.

I wanted to turn to the Rural Energy Savings Program. The Rural Energy Savings Program, the concept was that we could create a lot of jobs in rural America if people could take loans on their electric bill and be able to replace their windows or add installation. It put a lot of people to work, and often the energy savings would pay for the improvements themselves, plus virtually all these products are made in America, so we get more bang for the buck because we get the local construction contractor employed but it also creates jobs in American manufacturing.

We had the initial program funded last year. I was wondering if you have any information whether we have been able to get it stood up on its feet and have it running?

Secretary VILSACK. Senator, as you know, we worked with a program that was similar to what you proposed with an interest rate that was higher. We were in the process of implementing that and learning from that, recognizing that there were some serious learn-

ing curves for the research and extension centers (RECs) that we were dealing with.

We recently announced a statewide initiative in Vermont, where we learned quite a bit and created sort of a template.

The proposal that you were the leader on last year, we expect and anticipate to stand up sometime this spring. We would anticipate and expect that there will be quite an interest in a interest-free or zero-interest loan program. But now that we know how to set it up, I think we will see more of these projects, because I think it is popular, and I think there is a great deal of potential there.

Senator MERKLEY. I can tell you, in Oregon, the employment rate has not rebounded at all in rural areas the way it has in urban areas. I know you know this to be the case across the country, so it is a win-win program on several levels.

Secretary VILSACK. Help us fix the fire budget, and that situation in rural Oregon will change.

Senator MORAN. Senator Blunt.

Senator BLUNT. Thank you, Chairman.

STREAMING FARM PROGRAM

Secretary Vilsack, I want to join Senator Merkley and Senator Moran in appreciating your service, appreciating really how much you bring to this job, I think every year more than the year before. It is amazing how much there is still to learn, and I am impressed by how you dedicated yourself to learning how important this is.

The future challenges and opportunities for agriculture are great, if not greater than they have ever been. Hopefully, we can figure out how to make the most of that.

Just two or three pretty quick questions here. One is, I continue to hear from our friends in agriculture the desire for more streamlining in the reporting process.

My good friend Blake Hurst, who is the president of the Missouri Farm Bureau, was telling me the other day he has to go into the Farm Service Agency (FSA) office and file his report on crop insurance, and then he has to go to his crop insurance agent, and then the crop insurance agent has to refile the same information with Risk Management.

Are we making any progress in trying to streamline that time cost, both to Federal employees and to the people that they work for?

Secretary VILSACK. We are, Senator. Last year we launched and this year we implemented FSA Plus, which is allowing folks to access their records at home. This year we started with a pilot project in Iowa and Illinois, to try to test market how we would be able to have better coordination between the Risk Management Agency (RMA) and FSA and the reporting. We then extended that to a number of other States. Now we are prepared this year to go Nationwide.

So the concerns that he has expressed, I think by the end of this year, he will be much happier than he has been, and he will also be able to access all of his records, all of his maps, all of his information from his home computer with FSA Plus.

Senator BLUNT. I know that is a project that has been out there all the time you have been running the Department.

Secretary VILSACK. It has.

NATIONAL SCHOOL LUNCH PROGRAM

Senator BLUNT. It is frustrating and challenging for all of us. I look forward to seeing it come to a conclusion.

Now, you will remember my mom and dad were dairy farmers, so I come to this next topic with my own personal point of view, which is pretty strongly held.

But I believe that there are significant parts of the country now where packaged bottled water is being offered as a substitute for milk in school cafeterias. Historically, USDA has recommended school children consume 2.5 to 3 servings of milk or other dairy products every day because of the potassium, vitamin D, and calcium.

I guess my two questions are, because I believe the facts are that is an accurate statement about water as an alternative to milk, is packaged bottled water a reimbursable item in the National School Lunch Program?

Secretary VILSACK. I believe it is, but I do not for a fact know that. We can check.

I do know that we are encouraging more dairy products. It does not necessarily have to be milk. Greek yogurt is now a protein substitute, so there is a lot of interest—and, frankly, we are trying to be responsive to what school districts are asking us to provide them with and for.

But I will check on the reimbursement issue.

Senator BLUNT. I am not a big advocate for us buying water as one of the alternatives at lunch. There are other ways to get water, I would think.

USDA funds being used, do you think that is through the National School Lunch Program then? Or it might be and you are going to check and get back to us on that?

Secretary VILSACK. I will check on that.

[The information follows:]

Water is not a food component or food item that is required for the reimbursable meal under the National School Lunch Program. As required by the Healthy, Hunger-Free Kids Act of 2010, potable water must be made available to students during meal service at no cost to students. However, school districts may not promote or offer water or other beverages as an alternative selection to the required fluid milk component on the meal service line. Most schools meet the potable water requirement by providing a water fountain or a cooler filled with tap water in the cafeteria. For the majority of operators, USDA expects compliance with the potable water requirement to incur minimal or no costs. However, USDA does not prohibit use of the nonprofit school foodservice account to purchase non-program food such as water. USDA is working with State agencies and local school districts during the Administrative Review process to provide technical assistance and corrective action when necessary to eliminate the occurrence of choices between milk and water or other beverages during meal service.

BROADBAND PROGRAM

Senator BLUNT. So Senator McCaskill and I wrote a letter recently to Federal Communications Commission (FCC) Chairman Tom Wheeler. Our concern is that the remaining funds available under phase II of the Connect America Fund, it is critically important that rural constituents all over—our letter was specifically focused on Missouri—have the same access to fiber optics and other

advanced broadband networks as their urban counterparts at a comparable price.

Secretary VILSACK. I certainly agree. We have conveyed those same sentiments to the Chairman. Our hope is that as they look at the Connect America and some of the other programs that we will continue to see an expansion of broadband.

Also, we believe it is going to be important for us to continue to stay in that game from a grant and loan perspective. That is why our budget reflects a significant increase in the broadband projects.

DRUG USE IN RURAL AMERICA

Senator BLUNT. I think social access, economic opportunity, all those things matter. It may be that social access may lead to my last question, which is one—you and I talked right after the President asked you to play a leadership role in this effort to curb heroin and opioid use.

On the floor of the Senate this morning, as we were trying to move through this bill, I made the point that actually more people die of drug overdoses now in rural America than urban America. More people die outside a metropolitan statistical area, even if that area may be quite far from the hub of that.

Do you want to talk a little bit about the challenge to rural America of this epidemic of opioid and heroin use and overdose?

Secretary VILSACK. Well, it is a complicated problem. It is one that requires a series of steps. We have to have more prescribers trained in the appropriate prescription of pain medication. I think we have to have, frankly, reasonable expectations on the part of patients as well, in terms of precisely what doctors can and cannot do in terms of pain relief.

I think it is going to be important for us, particularly in rural areas, for our first responders to have access to the overdose reversal drugs that are available, that are now in a nasal spray, now more readily available. In fact, we might want to consider a general prescription that would allow family members to have access to that reversal drug, just in case, knowing that if a loved one is in trouble, being able to respond quickly.

It is going to be necessary for us to look at ways in which we can encourage States, and specifically the State of Missouri, to have a better monitoring program, so we can prevent doctor shopping, and that we have interoperability between States. We have many States with these programs, but they do not necessarily communicate, so if you are on a border community, you can potentially game the system.

I think it is going to be important for us to look at ways in which we can increase support for medication-assisted treatment, and perhaps not just limit it to physicians but perhaps physician assistants or some other medical professional, particularly in rural areas, to be able to be involved in the basic prescribing of those things in terms of trying to meet the needs.

You mentioned broadband, telemedicine, and access to services. That may be a way of providing services without necessarily brick-and-mortar investment.

We need to make sure people understand that mental health services and substance abuse services are now covered by insur-

ance. There is, I think, a lack of understanding about that. We frankly need to engage the entire community, particularly the faith-based community, in making recovery support efforts more readily available.

I know in my own personal situation, my mother struggled. She would have never been able to recover but for Alcoholics Anonymous (AA) and some of the support that she had from people similarly situated. There are not places today in many rural communities where those meetings can take the place. Faith-based organizations I think have a particularly interesting role and opportunity there.

So it takes a broad approach. I think the Administration looks forward to working with you and others to try to make sure we put the resources behind all of these solutions, because it is a horrendous problem and tens of thousands of people are dying, and hundreds of thousands of families are being impacted and affected by this.

Senator BLUNT. Thank you for your leadership there and in other areas, Mr. Secretary.

Mr. Chairman, thank you for the time.

Senator MORAN. Thank you, Senator Blunt.

Senator Tester.

Senator TESTER. Thank you, Mr. Chairman, for allowing me to speak and giving me these glasses so I can read.

NORTHERN PLAINS AGRICULTURAL RESEARCH LABORATORY

It is good to have you here, Secretary Vilsack. I am going to start out a little parochial right now with an ARS station in Sidney.

I do not know all the information about it because it was just pointed out to me today by a producer from eastern Montana, that it is being repurposed or potentially may be taking a step toward closure. So I just want to get some input from you on what is going on. If you do not know, you can certainly get back to me.

But these guys do incredible research. It is an incredible facility, as I am sure they all are. It does research on saw fly and other kinds of pests. You now the issue with barley scab showing up in Montana. So these research facilities are really, really important.

Can you give me an idea what the plans are for that?

Secretary VILSACK. The budget that we proposed requested an increase in the ARS budget. Part of that increase would be targeted actually toward the facility that you mentioned.

It currently supports 41 scientists. I do not know of any plan to reduce that number, or reduce the support for those 41 folks.

Obviously, research projects come in. Some get concluded and new ones begin. So I am not sure that is necessarily repurposing, but perhaps there is a different focus given a particular disease or pest. But I do not know of any desire to close or reduce the importance of that.

RESEARCH BUDGET

Senator TESTER. That is what I wanted to hear. You answered that very, very well.

The research for Smith-Lever dollars and Hatch are flat at about $302 million and $44 million, respectively. These are also very,

very important. Could you shed some light? Has the use of those also flattened out? Or does demand far exceed? Tell me what is going on.

Secretary VILSACK. Yes, it is a combination of having an overall number for our budget, and the challenge in our budget where fire suppression, WIC, rental assistance, and food safety eat up to 50 percent of the budget. Oftentimes, when those items have to be increased, it impacts and affects the other 50 percent.

It is also a fact that we are trying to look at our competitive grant programs as a way of encouraging more collaboration between universities. Many universities are receiving resources from that that ultimately help to support the university and support the capacity university, so it is a balance.

Senator TESTER. I got you. I think that you have done some positive things for research in here. But you know, you know how important research is. For farmers to do trial and error is a good way to go broke.

So moving forward, you are in office for another 10 months.

Secretary VILSACK. I am in office for another day, for sure. I serve at the pleasure of one guy.

Senator TESTER. One never knows what might happen to you. I stand corrected.

But moving forward, are you confident that this budget that you are putting forward, those priorities on research particularly, will be heading in the right direction, moving into the next administration, whoever that might be?

Secretary VILSACK. I am confident, because I think we have addressed both short-term and long-term, traditional and nontraditional, challenges that agriculture is going to face.

This is an incredibly complex and changing world that our farmers are living in. I think we have figured out a way in which we can provide them assistance and help, if our research budget is adequately funded.

WATER AND WASTE DISPOAL PROGRAMS

Senator TESTER. Okay. I want to talk about rural development and water infrastructure, critically important in rural America, as you well know. $244 million for loans and grants to rural businesses, tripling of funding of broadband grants, which is really important.

There is a reduction though in grants and loans for water and waste disposal programs. If you look around this country, and I know I am preaching to the choir here, these systems are for the most part wore out. So why the reduction?

Secretary VILSACK. Well, because in the past several years, we reduced the business and industry loan programs, and we have reduced and not adequately funded some, so it is about balance, number one.

Number two, we are looking for leveraged opportunities. We are trying to get the private sector more engaged in investing in these water projects. We are finding that there is interest in this. Pension plans, some of the private investment that we have been cultivating at USDA to leverage our scarce resources are now seeing 3-percent or 4-percent payment on a 30-year loan quite attractive.

We are actually working to try to look at our own portfolio to see whether or not we can maximize the value of that portfolio and create an incentive for the private sector to invest hundreds of millions if not billions of dollars.

So it does not necessarily mean that less work is going to be done, Senator. It just means that we have to be creative about where the financing is going to come from. We are being very creative at USDA.

RURAL COMMUNITY POPULATIONS

Senator TESTER. We appreciate that creativity. I just want to talk about something. We had a roundtable that the Chairman and Ranking Member put on. Dr. Johansson was at it here a couple weeks ago.

One of the things that is going on in rural America that I also know you know about is depopulation in a big, big way. We are seeking rural communities dry up, I think at a faster rate than I have ever seen in my lifetime.

In the last 40 years since I graduated from high school, the little town I am from, if you go by enrollment in high school, is two-thirds smaller than it was when I went to school there, more than two-thirds.

I know there is big equipment out, and I know it is more efficient, and we do have more technology that makes things move. But I mean, where I live, and it is different in every area, but you know, 1,000 acres was an average farm. I have folks around me that farm 20,000 acres and north of that even.

So is this just something that is going to continue? Are there things that we can do to encourage smaller farms maybe? Or encourage more people to move into rural America?

Because you have schools that are closing down. You have cities that have to build schools. They are just all sorts of social problems that all cost money.

Secretary VILSACK. Senator, in my lifetime, American agriculture has increased its productivity 170 percent, with 22 million fewer farmers——

Senator TESTER. Yes.

Secretary VILSACK [continuing]. On 26 percent less land.

Here is the problem. In the past, we did not create a companion economy to the extraction economy that was part and parcel of rural America.

We now have a companion economy. It involves local and regional food assistance. We supported nearly 1,000 infrastructure investments in local and regional food systems supporting 162,000 producers. We are beginning to see that prosper.

We are seeing conservation. Howard Buffett came to our Outlook Forum and talked about the need for people to understand that conservation can actually be profitable. He is proving it in his operation.

And the bio-based economy, the ability to transfer and produce a multitude of materials and chemicals and fabrics and fibers and fuels from bio-based systems.

So we are headed in the right direction on two data points. One, the unemployment rate is coming down, which is good. And two,

the poverty rate in rural America in the last 2 years has come down faster than in any preceding 25 years.

So we are beginning slowly to turn around. Now, we are not going to get out of the fix that you mentioned overnight because we did not get into it overnight. But I think we are headed in the right direction.

And I am hopeful that this companion economy that you all have helped to support with farm bills and budgets continues.

Senator TESTER. Thank you.

Thank you, Mr. Chairman.

Senator MORAN. The Senator from Montana, Senator Daines.

Senator DAINES. Montana and Montana, Jon. All good.

Senator TESTER. Back to back.

BRUCELLOSIS

Senator DAINES. Secretary Vilsack, thanks for being here today.

Agriculture is Montana's number one industry. It is a $5 billion a year economy for us.

Last year, I was pleased to be able to work with the Montana Grain Growers and other stakeholders to reform and reauthorize the Grain Standards Act to ensure that Montana farmers are protected from disruptions in federally mandated grain inspections, like what happened at the Port of Vancouver.

I remember having literally farmers jumping off of a combine in the middle of the harvest running to Great Falls to meet with you and talk about the crisis we had. I was glad to see we got it resolved, and I look forward to ensuring this new law is implemented effectively moving forward, so we can prevent the crisis from happening again. Thank you for your help on that.

I want to shift gears and talk about brucellosis. I live about an hour north of the Yellowstone National Park. I went from kindergarten through college there in Bozeman.

As you know, there is significant bison herd within Yellowstone National Park and the greater Yellowstone ecosystem.

My question is, how is your Department and the Animal and Plant Health Inspection Service (APHIS), in particular, coordinating and cooperating with State agencies in Montana like the Fish, Wildlife and Parks in Montana and the Department of Livestock on disease management efforts, particularly regarding brucellosis in the greater Yellowstone area?

Secretary VILSACK. A number of years ago, we entered into an arrangement with the folks at Yellowstone, the State officials and others, to address this. I can get you more information, Senator, on the success of that, but I think we were able to isolate and provide a much better environment relative to the bison and other animals.

So I would be happy to get you more detail about that, but I know that we have been working collaboratively with folks on this.

[The information follows:]

The Greater Yellowstone Area (GYA) wild elk and bison populations have persistent levels of brucellosis and the potential for continued exposure to livestock. To address this unique challenge, we assist with the Interagency Bison Management Plan (IBMP) operations in the GYA in cooperation with our fellow IBMP partners. These partners include the National Park Service; the U.S. Forest Service; the Montana Department of Livestock; the Montana Department of Fish, Wildlife, and Parks; the Intertribal Buffalo Council, the Confederated Salish and Kootenai Tribes,

and the Nez Perce Tribe. We also facilitate and participate in studies to develop brucellosis risk mitigation measures.

The ultimate goal of the IBMP activities is to reduce the risk of brucellosis transmission from wild bison and elk in the GYA, while maintaining a viable wild bison population. In addition to the cooperative effort, each IBMP agency is actively conducting activities that are in line with their own agency's mission. Recently, we sponsored a review of brucellosis control in the GYA by a National Academy of Sciences panel, and we are waiting on the report's release later this year. This report will describe the likely effectiveness and trade-offs of options that could be used to address brucellosis in the GYA. It will also describe and prioritize further research needed to reduce uncertainties and advance the knowledge base on brucellosis vaccines, vaccine delivery mechanisms, and diagnostics. APHIS will use the findings from this report to help guide the development of a unified strategy to deal with brucellosis in the GYA.

Specific to Montana, APHIS provides cooperative agreement funds to support brucellosis mitigation activities. APHIS personnel also work with the State on every aspect of the brucellosis program, such as sample collection and testing for surveillance, responding to detections, and conducting epidemiological investigations. In collaboration with the Agricultural Research Service and the States of Montana and Wyoming, APHIS has developed and continues to develop non-lethal techniques to detect and eliminate the disease from bison and elk populations.

Senator DAINES. Speaking of collaboration, I am going to throw something out there, something to consider. In prior years, there was extensive collaborative effort. I think actually we had better communication. There are a lot of moving parts here between State agencies, Federal agencies, and private groups.

It was called the Greater Yellowstone Interagency Brucellosis Committee. It brought together a diverse group of stakeholders, including representatives from Montana, Idaho, Wyoming—obviously, this crosses borders—as well as USDA and the Interior. The working group improved communication and furthered efforts to provide sound science surrounding wildlife disease management throughout the Greater Yellowstone area.

Unfortunately, this effort lapsed in 2006, 10 years ago, and no similar working group has filled that void. I have heard concerns in talking to farmers, ranchers, and stakeholders that the result has been a deterioration in communication between agencies, Federal, State, as well as private groups, regarding disease management in the Greater Yellowstone Ecosystem.

So my question is, would the USDA be supportive of reestablishing that Greater Yellowstone Interagency Brucellosis Committee, or perhaps something similar?

Secretary VILSACK. Senator, I appreciate you bringing this up. My understanding was that we were in the process of a focused, collaborative effort. But if that is not the case, I will certainly go back and ask our team to figure out a way in which we can be more collaborative as a working group or whatever it is.

We have been trying to stress collaboration with the local folks at every level. So if that is not happening, we need to make it happen.

GENETICALLY MODIFIED ORGANISMS

Senator DAINES. I appreciate that, if that would be an outcome from this hearing. We could certainly have that communication and bring that concern and try to bring those groups together again. The word from back home is that it really was valuable.

I want to shift gears now and talk a bit about what is going on in the area of GMOs and biotech. Last weekend, you were quoted

at a commodities conference, referring to GMOs, stating, "I am here to say unequivocally they are safe to consumers."

With that in mind and notwithstanding marketing efforts or the hurdles of getting legislation through Congress, which is a topic of discussion here as we sit here today, are there any safety concerns or any sound scientific research that would warrant the mandatory labeling of GMOs?

Secretary VILSACK. No, but that is not obviously the issue. The issue is that folks in States have made decisions based on referendums and State legislators to create labeling systems that are applicable within State borders.

That creates a circumstance and situation, as you know, where we are going to have a hodgepodge and chaotic circumstance were individual States and/or individual companies are going to make their own decision about what they are going to put on the package. It is going to create confusion. It is going to create additional expense. It may limit access to food, or it may increase the cost of food. It does not have to be.

There is a way, in my view, where you can respect a consumer's right to know, if they have interest in knowing the production process by which their food has been produced, but doing it in a way that does not convey the wrong impression about the safety of the food.

Senator DAINES. So I guess getting to this issue of mandatory versus voluntary, I mean I think to be clear, a decision to implement mandatory labeling would then not be based on safety concerns or sound science, but on other factors?

Secretary VILSACK. It would be based on balancing the desire on the part of a growing amount of consumers who want to know, and companies are in the business of selling to consumers—obviously, the customer is always right kind of thing—with doing it in a way that does not send the wrong message about the safety.

In the past, we have labeled, we have put something on the package, either to talk about caloric content or nutrition or a known risk. That is not what this is about, which is why I have suggested the establishment of the smart label process, which would essentially give consumers who are interested information that they are interested in, but not in a way that conveys a false impression about the safety of the product.

Senator DAINES. I think we agree it is critical we address this issue in a timely manner, given what is going on in Vermont.

Secretary VILSACK. Absolutely.

Senator DAINES. And I have no issue with the voluntary programs that meet market demands or consumer preferences.

That being said, I do believe the USDA's priority should be with making determinations based on sound science regarding the safety of biotech products within its jurisdiction, not on marketing or mandatory labeling efforts that really have no bearing on food safety or plant pest risk.

Secretary VILSACK. Well, I am trying to avoid a chaotic circumstance, Senator. I am certainly hopeful that there are at least 60 of you who feel the same way I do.

Senator DAINES. All right. Thank you.

Senator MORAN. We are pleased to have the Chairman of the Full Committee with this.

Senator Cochran, you are recognized.

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you.

Thank you to the panel for being here and helping us sort through the requests we have for funding of various activities administered by the Department of Agriculture.

One of the bright spots in what appeared to be some questions that all seemed to be having trouble being administered or costing too much or contributing to the deficit and all kinds of bad things, what we found out is that the Department of Agriculture has won a big victory in the labeling of domestically produced farm fish grown and sold in the United States.

They were having to compete with fish from overseas that were mislabeled or suggested that they were superior in some ways to domestically produced fish.

So thank you for the good, strong support and effort in defining the new limits and the new requirements that help to give customers and consumers an opportunity to choose. They are finding out that they are choosing to buy American, and that is encouraging in this day of real tough international competition in so many areas of agriculture and food production and marketing.

The end of my speech.

Senator MORAN. Mr. Chairman, thank you for joining us.

We now recognize the Senator from New Mexico.

Senator UDALL. Thank you very much, Chairman Moran.

And thank you, Senator Vilsack, for your service.

Secretary VILSACK. I am a Secretary. I am not a Senator.

Senator UDALL. Secretary. I understand. I understand, and you were a Governor before that. And you like to get things done, I know.

Senator MORAN. Would you like those words stricken from the record?

[Laughter.]

STRIKE FORCE INITIATIVE

Senator UDALL. Secretary Vilsack, thank you very much for your service and thank you for being here. Just a couple things I wanted to ask your support on.

The New Mexico delegation recently sent you a letter in support of the Navajo Promise Zone applications submitted by the Navajo Technical University and also submitted by the Navajo Nation for what is called a Tribal Promise Zone.

It is an extremely high priority for me. Let me tell you why here.

The Navajo Nation faces significant challenges, high poverty, lack of basic infrastructure, lack of housing, public safety deficiencies, among other things. The unemployment rate there is totally unacceptable. It is near 50 percent. And an equally large percentage of the population is below the poverty level.

They have made steady progress on economic development in recent years, but they really needed a boost. I think this Promise Zone would really make a difference.

As part of the President's efforts, this Promise Zone will help the Navajo Nation help tackle the issues outlined in their application, which I have talked a little bit about here.

I simply urge you to give consideration to their request. I know there are many communities in need, but few face the extremely difficult conditions we see on the Navajo Nation.

Secretary VILSACK. That is one of the reasons why we have already included that area in our StrikeForce Initiative at the USDA. But you are right, the Promise Zone would extend that kind of approach to all Federal agencies.

I appreciate the comment, Senator, and I will take that back to the team.

Senator UDALL. Secretary Vilsack, could you tell me a little bit about the StrikeForce effort there?

Secretary VILSACK. Sure. StrikeForce was designed to focus on the areas of persistent poverty in this country. The reality is 85 percent of persistently poor areas in this country are, in fact, in rural areas.

What we found early in the Administration was that we were not doing enough work in those areas to get folks to understand how to basically apply for programs where they could get help.

So we instructed our team, our FSA team, our nutrition team, our rural development teams, and our NRCS team, to go to communities across the country where there is persistent poverty and basically work with a community-building organization to identify projects and needs that we could address through USDA programs.

It is now operating in 920 counties, 21 States, and several tribal areas. The result is that we have invested $26.3 billion in over 190,000 investments that have been made in the StrikeForce areas.

I would imagine a significant percentage of those would never have been made but for the attention and intense work relationship that we have created.

We are now working with over 1,500 community-building organizations and partners. It has been I think a successful endeavor.

And I think that has led us to take a look at the Promise Zone and some place-based initiatives as well throughout the entire Federal Government.

COLONIAS

Senator UDALL. Thank you very much for that initiative, because I have many communities in my State that I think need that kind of initiative and kind of push that you are making there.

This next issue is an issue that I raised last year, and it is yet to be resolved. Two communities in New Mexico, Chaparral and Sunland Park, our designated colonias. I think you are probably familiar with that term. It is on your USDA rural Web site. But it means neighborhoods or communities within 150 miles of the United States-Mexico border that are economically distressed.

They both have been designated colonias, and they are ineligible for some USDA rural development funds because of the USDA's formula for determining a rural community based on proximity to a municipality.

In this case, because of their proximity to El Paso, Texas, even though they are in New Mexico, even though they do not benefit

from any support or municipal services from a city or county like El Paso, which they are close to, and because they are not in the same State, these communities have high poverty rates, limited public sector funding, separated by over 40 miles from Las Cruces, the nearest city.

These communities need rural development funds for critical housing projects, economic development funding, infrastructure improvements. The area is seeing increasing traffic at the nearby Santa Teresa Port of Entry, which is positive, but really underscores the need for infrastructure.

So waivers have been used for similar situations in the past, but we are experiencing difficulty with waivers in these cases. Would you work with me and within your authority to ensure that these two communities do not fall through the cracks and are made eligible for rural development assistance?

Secretary VILSACK. Senator, as you were outlining your request, I turned to my staff to ask whether or not waivers were available, and we will certainly work with you and your team to figure out, if they are, how to use them, and if they are not, what else we could potentially do to provide—because colonias is part of our StrikeForce Initiative. So we obviously are cognizant of the challenges of that particular area, so we will be happy to try to find a creative solution to the problem they are facing there.

Senator UDALL. Thank you very much. I could not think of a better person to be Secretary of Agriculture because you served as Governor from a rural State. You know rural communities and how they are struggling. I sure appreciate this effort in terms of the StrikeForce and look forward to working with you. Thank you very much.

I yield back, Mr. Chairman.

Senator MORAN. You had no time to yield back, but thank you for the effort.

The Senator from North Dakota.

FARM PROGRAMS SURVEY DATA

Senator HOEVEN. Thank you, Mr. Chairman.

Good to see you, Mr. Secretary. Thank you for your work on behalf of our farmers and ranchers. As you know, we want to make the farm bill as farmer-friendly as possible.

That is particularly important right now with low commodity prices. We are seeing real stress out there in the ag world on the part of our farmers and ranchers with these low commodity prices.

One area that we can help in terms of making sure that the farm bill is farmer-friendly is with the National Agricultural Statistics Service (NASS) data. I think that you are already working on this with your FSA Administrator Val Dolcini.

But in some cases, that NASS data, because there are not enough survey forms sent in for some counties, we are getting a bad result.

It is not unique to North Dakota. It is occurring in other States as well. I believe in Iowa, and I do not know about Kansas, but a number of States. We have counties, and there are not enough of the survey forms that come back and so the NASS information is

not used. Instead, we are using Risk Management Agency (RMA) information. And we are getting a bad result.

What I mean by that is if you take counties, for example, in North Dakota, Logan and Lamoure, and you compare them to similar counties in terms of the average for corn, for example, for the year. If we do not have enough NASS data, we use the RMA data, and we are getting a result that does not correlate with like counties. So other counties that typically have about the same yield, those farmers get an ARC payment. But because the RMA data is so high, it is disqualifying farmers in Logan and Lamoure counties, for example, from getting in an ARC payment on corn.

That is one example. There are other examples around the country.

So we have asked Val Dolcini at FSA to allow us to work with the FSA Director in the respective State and use comparable counties that have adequate NASS data, so we do not get a skewed result. It is very important to farmers, particularly with low commodity prices.

So what can you tell me in terms of your willingness to provide this flexibility? I know you are doing an interagency analysis or study, I think is the term for it. But what can you do to help here, Secretary, so we can get this fixed?

Secretary VILSACK. Well, as you know, Congress made the decision to do a county program as opposed to an individual program. I think they probably did that because of the cost of the individual program and the need to generate savings in the overall program. So we obviously have to deal with the county program, and we have to have some kind of process by which we can try to treat as many of the several thousand counties that we are dealing with as fairly and equitably as we can.

So we have come up with a proposal, the outline that you have addressed, which we have looked at NASS data first. If there are inadequate numbers of surveys, we ought to focus on making sure we get farmers to respond to those surveys, so we have adequate information.

If we do not, we go to RMA information. If we are not satisfied that that is appropriate or correct, we have empowered our State Committees to basically take a look and provide some direction.

So we think we have some degree of predictability and consistency without necessarily creating a circumstance where we cannot address the anomaly or the inaccuracy of information.

I am more than happy to go back to our team and basically make sure that we are in a position to be able to explain why we are making the decisions we are making. If we cannot, then we obviously need to do something different.

Senator HOEVEN. My understanding is it is currently in this interagency review. I do not know what the results of that are.

If, in fact, the State Committee is empowered to make a decision, I think that is where we need to go. Again, it is making sure you are giving discretion out there in the field to your directors to make a good decision.

Secretary VILSACK. That is the key, a good decision. We do not necessarily want to create a circumstance where everybody is not happy with whatever it is they ultimately get, because then you

create a very confusing circumstance and you end up getting an individual program when you really, by statute, are directed to have a county program.

So I think there is a balance here. I am more than happy to try to be flexible, but I think we do have to have some system.

Senator HOEVEN. I hear you. Of course, we want the NASS survey forms to come in, so you have adequate data and you have good data. But where that has not occurred, just so that that State Committee or FSA Director, however you decide you want to do it, is empowered to say, okay, this is a nonsensical result. We will make an adjustment.

My question is, I do not think we have gotten that response back from FSA. They are still doing this interagency review. This has been going on since November. I am asking for your help to get an answer.

Secretary VILSACK. You deserve an answer, Senator. We will try to get you one quickly.

Senator HOEVEN. All right, thank you very much, Secretary.

CROP INSURANCE PROGRAM

The other thing I will just mention, if you have any reaction, that is great. I am very concerned about any reductions to the support for crop insurance. That is the number one risk-management tool for our farmers. You are probably not surprised to hear me say that because you and I have had this discussion before.

But I am very concerned about that and I am going to make sure we do everything we can to support crop insurance. In fact, we included language in the farm bill to make sure that did happen.

On the positive side, though, I appreciate the support that you have provided for Agricultural Research Service, ARS, and for NIFA, National Institute of Food and Agriculture. I think that research area is incredibly important, incredibly impactful for our farmers and ranchers. So if you have some thoughts there, I would welcome them.

Secretary VILSACK. Just briefly on the crop insurance, there are two areas. One is on the prevented planning. Our Inspector General, and I think the Government Accountability Office, have been critical of the way in which that program operates. So I think it is appropriate for us to be responsive to those criticisms. What we have proposed in the budget is our effort at being responsive.

On the price harvest loss option, where we are proposing a slightly different arrangement between the producer, the government, and the insurance company, where we are currently financing 62 percent of the premium, we think it is probably fair to taxpayers that it be more of a 50/50 partnership. Those are the two proposals.

Senator HOEVEN. I would point out that since 2008, $12 billion has been taken out of crop insurance support. And you want a robust number of companies out there providing crop insurance to have a competitive market, and we have to be careful or you are not going to have enough competition out there to have a robust market.

Secretary VILSACK. That is true. Our projections I think for return on investment with this budget is 18 percent.

Senator HOEVEN. For which they have to cover all of their costs.

Secretary VILSACK. Well, not all their costs, because there is also an additional resource for administrative and operating costs.

Senator HOEVEN. Right. But again, at the end of the day, if they cannot make enough money to continue to stay in that business and to cover costs, you are going to have fewer and fewer agencies. You are not going to have a robust insurance group out there providing crop coverage.

Secretary VILSACK. I am not sure either one of these two proposals necessarily impacts the issue that you have raised, but I am certainly sensitive to the fact. That is why we are continuing look at the return on investment. We had a couple of years where it was difficult, but we are beginning to see more profitability in that part of the operation. I think it was 15 percent or 13 percent last year, 18 percent projected for this year.

Senator HOEVEN. Again, I appreciate that. I understand your point of view, though I do not agree with it.

I do want to again emphasize that crop insurance support has been reduced by $12 billion since 2008. I think there are a lot of programs across the Federal Government that have not contributed as much in terms of help with finding savings as crop insurance.

Secretary VILSACK. You do not have to tell me about reductions, Senator. My overall operating budget is less than it was in 2010.

Senator HOEVEN. Secretary, again, thanks for what you do. Thanks for your willingness to take a look at the NASS data. I appreciate it.

Senator MORAN. Senator Merkley.

RURAL BROADBAND PROGRAM

Senator MERKLEY. Thank you, Mr. Chairman.

I thought I would turn to a piece of the picture that I hear about a lot that has not been mentioned yet, and that is rural broadband. Everywhere I go in Oregon, folks note the importance of it to the success of their rural communities.

So I wanted to explore this a little bit, because, as I understand it, USDA recently rewrote the broadband loan program regulations to reflect the changes in the 2014 Farm Bill. It really has just kind of gotten going, but I believe you are now proposing eliminating this.

Meanwhile, the grant program, which has increased, is a distinctly different program. The grant program serves a small number of poor, unconnected communities. The number of communities it focused on in fiscal year 2015 was five communities.

So I think there is concern that there is going to be a sacrifice of a program that serves large expanses for assisting a small number of communities, and whether or not that really reflects the demand for rural broadband. There is probably a lot more thinking behind it. I thought I would just give you a chance to explain it.

Secretary VILSACK. Senator, I appreciate the question. What we have found is that it is not impossible for companies to secure loans. But to the extent that they can get grant funds that either reduce the amount they have to borrow or to reduce the interest rate on the loan, that makes it much more likely that they are in a position to do significant improvements and expansions.

So listening to what we believe the industry is telling us is necessary to get more broadband in more places, combining that with hopefully with what the FCC is attempting to do and hoping it works properly to create more incentive and more resource for expansion of broadband, the combination of those two.

So that is why we are proposing an increase in the grant program, because we think that will generate more activity than simply a loan program.

Senator MERKLEY. Thank you for that explanation. I look forward to tracking that because it is of so much importance.

My colleague from Wisconsin has arrived, and I am going to turn this over to her. Just in closing out my comments, thank you again for your service over 7-plus years and counting. There are many more questions I have that I will be submitting to you for the record, but I do not need to address them at this point. Thank you.

Senator MORAN. The Senator from Wisconsin.

My intention is to have the Senator from Wisconsin ask her questions. I have a few follow-up questions, and then we would anticipate concluding the hearing.

WATER AND WASTE WATER TREATMENT PROGRAM

Senator BALDWIN. I thank the Chair.

Mr. Secretary, in Wisconsin, water issues are on everyone's mind, as our rural communities are facing many challenges to protect their water quality.

In particular, Kewaunee and Door Counties in Wisconsin's northeastern region have nitrate and bacteria contamination in their groundwater. Testing is showing that more and more private wells are contaminated.

Local stakeholder groups are working with the State Department of Natural Resources (DNR) to talk about long-term solutions. But as those deliberations continue, rural families remain without immediate solutions to these very pressing concerns and the obvious need for safe drinking water.

Mr. Secretary, I believe your Department can help, but it is going to take some really, really hard work. So I would ask you how you see the USDA playing a role in these communities in Wisconsin, and would you commit to working with me and the local communities to offer both immediate and long-term solutions that help watersheds in this vital region of our State and our country?

Secretary VILSACK. Senator, do you know offhand what the population is of those two communities? Is it greater than 10,000 or less than 10,000?

Senator BALDWIN. Both counties I believe would be greater, but they might be close. They are sparsely populated.

Secretary VILSACK. Well, the first line of response to your question is, to the extent that the infrastructure that treats water can be modernized, obviously, the USDA has our water and wastewater treatment programs that are available.

We also have a partnership with CoBank and other farm credit agencies that are providing infrastructure loans that USDA cannot do or will not do or does not have enough resources to do. It is leveraging our resources.

We have had a series of partnerships with the farm credit system where we will fund half a project and the CoBank will fund the other half. They made a $10 billion commitment to infrastructure in rural areas across the United States.

The third alternative, on this side of the equation, is to work with us to identify potentially private sector investors who might be willing to provide the financing to improve the systems.

So those are three basic avenues of financing infrastructure. We will be more than happy to work with you and have our rural development people work with those two counties in those two areas.

You asked for a short- and long-term solution. Obviously, long-term is to try to work with conservation programs to try to prevent the problem from getting worse and ultimately reversing it.

Actually, Wisconsin has a number of communities like Green Bay that are working with the Fox River that are trying to create ecosystem markets where essentially regulated industries would be able to pay farmers for conservation that would allow them to satisfy a particular ecosystem regulation, or there may be a corporate entity that is looking from a social responsibility perspective.

We just did an event with Chevrolet on carbon credits, for example, in North Dakota, a working ranch in North Dakota.

So we are trying to create more ecosystem market opportunities in Wisconsin. That requires us to be able to measure and verify and quantify the conservation results. If you can do that, and I would encourage those folks to consider a Conservation Innovation Grant, a CIG grant, which we have used in the past to help create a measurement and certification and qualification system.

Let me just give one other piece of this. There is also the regular Natural Resources Conservation Service (NRCS) programs and the Conservation Reserve Program (CRP). There is a continuous program that potentially could be used to develop bioreactors in those conservation programs that would allow for better filtering of contaminants, nitrates and so forth.

So there is a body of steps that can be taken short term and long term to try to address this.

Senator BALDWIN. I appreciate that, and there has been, as I was mentioning, a good local collaboration not only with our State DNR but I know a real interest in these collaborations on long-term solutions at the Federal level.

I will just restate that many of the residents impacted have private wells. They, therefore, have an immediate need for clean drinking water. So I hope we can follow up this exchange with ways in which the USDA can help meet those very important and immediate needs.

Secretary VILSACK. What we were able to do in a slightly different situation in California where it was drought and they had private wells, but they just did not have any water in the well, we were able to take a look at whether they were adjoining an area of municipal systems that could potentially be extended to those private homes that were serviced by a private well.

So I do not know if that is possible at all in what you are talking about, but that is something.

CLASSICAL BREEDING RESEARCH

Senator BALDWIN. I appreciate your commitment to work with me and local communities, and we will certainly follow up.

I did have one other question that I wanted to address to you, Mr. Secretary. In addition to being America's dairyland, Wisconsin also produces a lot of specialty crops, and we have a very vibrant and rapidly growing organic sector, second only to the State of California in the number of organic farms within our State.

The specialty crops and organic farmers have a great need for new varieties and breeds that are adapted regionally and respond to market demands that can help them grow their markets, so-called seeds and breeds.

In response to this Subcommittee's work last year and direction in the fiscal year 2016 spending bill, I know that the USDA is producing a report on classical breeding investments, but this committee also directed the agency to create a specific competition for classical breeding so that proposals for this specific type of research compete against each other and not against other different research fields.

So we have yet to see progress on that particular front. For Wisconsin farmers, it is not about the academic competition. It is about having the varieties that they need right on the farm to help them make it through tough years.

So I hope that you will commit to resolving this issue this year, and pushing forward with that specific competition for classical breeding research.

Secretary VILSACK. I will certainly take a look at that. I will tell you that there is an intent and interest in this area. We are investing a bit more time and energy in it.

We are also making sure that our own seed banks are available, in the event there is a situation where we do not have seed in the past. So it is a combination of preserving the past and also preparing for new varieties.

I said earlier that our research has already created, over the time I have been Secretary, 714 different plant varieties, so we are involved and engaged in this. I think there is a good balance between where we have genomic information, using that, where we do not, using the classical breeding. So it is a combination and balance.

AGRICULTURAL RESEARCH

Senator BALDWIN. I thank the Chairman and Ranking Member for their leniency in watching the clock.

Senator MORAN. Thank you, Senator Baldwin, for joining us today, and thank you for your questions of the Secretary.

Mr. Secretary, let me editorialize just for a moment.

In regard to agriculture research, our fiscal year 2016 agriculture appropriation bill provided $350 million for the Agriculture and Food Research Initiative (AFRI), a $25 million increase. That is the highest funding level this program has received since its inception. We worked hard under the allocation that we had to provide additional support for agriculture research. You mentioned its importance, as have a number of my colleagues.

My editorial comment is that we cannot compete with the Administration's budget when they use mandatory spending as the solution to funding this and many other programs, not just in your budget but across the Federal Government, Federal Government-wide.

Again, this is a budgetary issue beyond your scope, but it is important that the Administration recognize that when they make a budget request to us as appropriators, we do not have the ability to provide funding with mandatory spending. I think they know that. It sets a bar. Perhaps it is just posturing to suggest that the Administration, your Department is more interested in agricultural funding than we are. But when we come to the amount of money that we have within our jurisdiction to provide support for agriculture research, in my view, we have been there.

CUBA OFFICE

You have been kind enough to attempt to include me in a visit to Cuba. I appreciate that invitation. I have been a longtime advocate for lifting the embargo, particularly as it relates to food, medicine, and agriculture commodities to Cuba. I had some success in that regard when I was a member of the House of Representatives.

Your budget includes some funding for changes that may occur in our relationship or is occurring in our relationship with Cuba. What is the circumstance by which you ask for dollars for agricultural representation in Cuba?

And secondly, knowing that the appropriations process in which you are asking for this money to be included, that may be a controversial request, I am not certain. But even if it is not, this process takes a long time. So what is USDA doing in Cuba today to help assist in the export, sale of agriculture commodities.

Secretary VILSACK. Senator, the embargo statute basically prohibits the Department of Agriculture from using any of its market assistance programming money, so we cannot directly help promote, as we do in other countries. That is one of the reasons why we need to get rid of the embargo.

But even if we get rid of the embargo tomorrow, we would not necessarily be prepared to do everything we are potentially able to do in Cuba, in terms of regaining market share that we have lost over the years because we do not have the relationships and people on the ground to basically know the people that we need to know on the Cuban side to be able to effectuate more trade. That is the reason why we have asked for personnel to be down in Cuba, to be permanently located down there, so they can create the relationships so that when the embargo is in fact lifted and we can use promotion resources, that we are in a position to move expeditiously to take full advantage.

Senator MORAN. I do not know off the top my head the amount of dollars you have requested.

Secretary VILSACK. I think it is $1.5 million for five or six people.

Senator MORAN. I think that is right. So the point you are making is that is not to assist directly in support subsidization of any sale to Cuba or to any marketing program.

Secretary VILSACK. Correct.

Senator MORAN. It is directly related to the ability to have USDA personnel in Cuba, developing relationships with potential customers.

Secretary VILSACK. And also to do an evaluation of the pests and diseases that we may potentially confront when our relationship becomes more bilateral.

The second piece of this is that there are commodity groups that are quite interested in doing business down there, because they realize that we have a competitive advantage that we have not taken full advantage of. They are asking us to explore ways in which they themselves, apart from what we cannot do, can they be more aggressive in their promotion efforts.

We are looking for ways we can find—a way for them to be more aggressive, so that without necessarily direct support from USDA, commodity groups, State ag commissioners, State ag secretaries, individual farm groups will be able to promote product.

Senator MORAN. Mr. Secretary, in that regard, my understanding of the current state of the law in regard to Cuba is that we can sell agriculture commodities, food, and medicine to Cuba for cash.

Secretary VILSACK. It is harder, but we can.

Senator MORAN. So commodity groups could promote those sales today. Is that true?

Secretary VILSACK. Yes. The question is whether or not any of the resources, the check off dollars, for example, could potentially be used by those commodity groups. We are in the process of trying to figure out the answer to that question. We do not want to unnecessarily create a circumstance where we are violating the law. We want to make sure we understand the law.

But this is a tremendous opportunity for us. It is just nuts that we do not have more of a market share than we do down there.

Senator MORAN. Dr. Johansson, in his commentary to us, in his conversation with us last week, indicated significant opportunities and compared it to the Dominican Republic, as I recall.

Secretary VILSACK. Eighty percent of Cuban food is imported, 80 percent. And I think we do 10 percent, 15 percent of their needs today. We should be doing 50 percent.

BROADBAND OPPORTUNITIES

Senator MORAN. We have seen significant improvements in the opportunity to sell. I think it was 2010, maybe 2011, the law was changed to allow the sales. And regulations were altered about that point in time, money had to be received upfront, whether it was when the ship left the United States or when it arrived in Havana. Then the third-party financing issues.

But those are regulatory issues that perhaps will be addressed. But this issue of Cuba will be one of broad interest in Congress. It has its opponents, which I discovered in my time working on this issue.

Let me return to a topic that we visited about last year in this same setting. I encouraged you, and you indicated that you do and would, continue your conversations with the Federal Communications Commission. I have expressed an ongoing concern about the ability for particularly rural telephone companies to be able to

repay loans they owe the Rural Utilities Services (RUS) based upon decisions that the FCC has and is continuing to make.

I would again highlight this issue for you in the sense that it is important I assume to you that we allow those companies to expand broadband opportunities in rural America, but also you may have a default rate of significant magnitude if the FCC makes decisions, particularly as it relates to the Universal Service Fund that would have consequences to a telephone company, a broadband provider, let me be broader than that, a broadband provider's ability to repay RUS.

Secretary VILSACK. We are cognizant of that. I can assure you that we indicate to FCC concern in that space. So we are keeping an eye on it. We have advised them of your concerns and of our concern.

Senator MORAN. On the same topic of broadband, I am an advocate, obviously, for expansion of those opportunities in places that are unserved. I have worried from time to time that various programs, perhaps more related to the Stimulus package than the programs under your Department, have provided loans and subsidization for companies to compete in already existing territory in which broadband services exist.

Could you tell me the current state of at least your programs, those that you are responsible for, and their ability to obtain support from your Department to compete with existing broadband providers?

Secretary VILSACK. Yes. We do not have unlimited resources, so we have to make sure that they do the job. We are mostly focused on unserved and underserved areas. I do not believe we are creating circumstances where we are encouraging competition here. We are trying to meet an unmet need.

Senator MORAN. You used a few words there that cause me to ask you to confirm that to me.

Secretary VILSACK. Sure. I am not trying to be evasive here. I am reasonably certain that our focus is on unserved and underserved areas. It is not based on places where there is already service.

Now, I would say that we may be in a situation where we are trying to upgrade the service that is being provided, so that download speeds and upload speeds are increased. I do not think that falls within the scope of your question, because it is not competition. It is about working with an existing operation to improve their service.

Senator MORAN. I know of circumstances in which loans or grants were made to provide service to areas that had no service. But in order to make that financially possible, the territory in which the loan could be used included areas that already had service. So areas that already had service got competition. They were larger communities, and I assume the theory was that revenue generated in that larger area makes it economically more viable for service to be provided in places that are much smaller that have no service.

But my view is that the government program is the subsidy, not creating additional service in places that are already served, and taking the revenue that is generated there to support areas that do not have service.

Secretary VILSACK. You deserve a more detailed answer. We will make sure you get it.

[The information follows:]

The Farm Bill Broadband Loan Program funds broadband facilities in rural service territories with at least 15 percent unserved households,as per statute in Title VI of the Agricultural Act of 2014 (Public Law 113–79, Section 6104 2(B)i). A household is considered unserved if it is not receiving broadband service as defined in the latest Notice of Funding Available (NOFA). The program offers incentives for loan applicants to go into areas with at least 50 percent unserved households. Areas with three existing broadband service providers are not eligible for funding. Applications that are proposing to provide service at the Broadband Lending Speed as defined in the NOFA will receive priority consideration for funding.

MCGOVERN DOLE PROGRAM

Senator MORAN. I appreciate that. I am almost done, Mr. Secretary.

Food aid, and particularly the McGovern-Dole—in Kansas, we would say the Dole-McGovern program. You are proposing reductions in the spending in that area.

If we agree with your position, your budget request, how would USDA absorb those cuts? Are there ongoing programs that would be affected? Do you have countries that you would specifically exclude from the program? So if there is less money, how would you spend the money that you would have remaining?

Secretary VILSACK. As you well know, the Dole-McGovern, McGovern-Dole program is designed not to be a permanent level of support for countries, but it is designed to show the wisdom of basically linking education and food with the hope that the host country would eventually take over that responsibility. So there very well may be countries where we have been active and involved in providing assistance for an extended period of time, but which we think it is time for them to basically pick up the mantle, if you will. That may be a consequence.

So it may be that there is not a circumstance where we are necessarily going to cut off or cut out people who are currently receiving service or assistance without some substitute from the host country.

The other possibility is that we are proposing to use a small portion of McGovern-Dole for local purchases, which may potentially leverage those dollars more effectively as well.

So I would be more than happy to give you a more detailed response to that question, but it does point out the challenge. Whenever we have conversations about budgets, we always focus on individual programs. But the reality is your circumstance and our circumstance in putting a budget together, it is all about choices.

If we did not have a finite number that we had to deal with, if we could fix the fire budget, it creates more flexibility in our budget.

FOREST FIRE BORROWING

Senator MORAN. Is there another opportunity you would like to say that, Mr. Secretary?

Secretary VILSACK. Yes. To be very, very candid, Mr. Chairman, this is one area that has frustrated me more than any since I have

been Secretary, because everybody—everybody—knows this is a problem.

The reason I feel so strongly about this is last year during our award ceremony, I had to give out seven American flags to family members who lost loved ones in forest fires. The reason why some of them were lost was because we have not been able to do the job that we need to do in restoring and making our forests more resilient because every year we borrow money from those very accounts to put fires out.

To me, a fire is no doggone different than a flood or tornado or hurricane, where we fund not out of an operating budget, but out of an emergency budget.

If we could just create a circumstance where those large, uncontrolled, very expensive fires could be dealt with, it would create more flexibility within this budget, and many of the concerns that you all have addressed here, which we share, could potentially be more adequately addressed.

NATIONAL BIO AND AGRO-DEFENSE FACILITY

Senator MORAN. Thank you for your passion and for your compassion.

Mr. Secretary, I appreciate you being in Manhattan, Kansas, when we cut a ribbon on the National Bio and Agro science facility. Thank you very much, soon to be a Department of Agriculture operation.

I just would highlight, as transition occurs from Plum Island to the National Bio and Agro-Defense Facility (NBAF), my impression is that there may be USDA employees who do not relocate. We want to work with you to make certain that the training and recruitment, retention opportunities exist at USDA to make certain that when the day comes that you are fully staffed with the highly capable and significant expertise in this important issue of protecting our homeland.

Secretary VILSACK. Well, that is certainly an appropriate request, Mr. Chairman. Thank you.

NEW, BEGINNING, AND VETERAN FARMERS AND RANCHERS

Senator MORAN. Finally, your budget proposes a $5 million increase in the Office of the Secretary. This sounds like a difficult question, but it is for something that I find very appealing, for new, beginning, women, and Veteran farmers. I am not certain how you intend to utilize those dollars, but I would highlight for you that our Subcommittee intends to have a hearing in the next several weeks on this topic of how to bring veterans into agriculture.

Secretary VILSACK. We have finally, after a good deal of effort, secured commitments from the Department of Defense to begin the process of going on base. As service men and women are leaving the service, they receive a series of briefings on opportunities. In the past, agriculture has not been part of that process. Now we are getting permission to be part of that process.

We want to be able to provide those veterans with the opportunity to know how they might be able to access a chance to be a farmer.

If you go on our Web site, probably the most popular aspect of our Web site in the last 6 months has been are Beginning Farmer Web site that we revamped. You can actually go in now and you can plug in your wish list of what kind of farmer you would like to be, what you would like to grow, how big you would like to be. It will give you essentially a personalized plan for the programs within USDA that can provide help and assistance, whether it is a microloan, conservation, help with crop insurance, whatever it might be.

We think the combination of more education of those returning veterans about opportunities that do, in fact, exist within agriculture, the greater the interest will be.

So to the extent that we can sort of spread our tentacles in a much wider base than we have in the past, I think that will be helpful.

We also know that 70 percent of the world's farmers are women, and there is an increasingly greater interest among women in this country to participate. Again, it requires outreach. It requires a little time. It requires access to information and providing an easy way for people to get information.

So that is the purpose of this. The Deputy, Secretary Krysta Harden, who is no longer with the agency, was a great proponent of this. I think her work has been very successful.

If you look at the recent census, you are going to see an increase in women farmers. You are going to see an increase in farmers of color. And you are also going to see an increased interest in working with other veterans' groups to see bring veterans into the farming business.

Senator MORAN. Mr. Secretary, I applaud those efforts. We have seen a number of just individuals—Gary LaGrange, who is retired military in my hometown, has created opportunities for veterans returning with traumatic injuries to enter farming, in this case, beekeeping, in a very successful way.

Incidentally, legislation that I have introduced has passed the Small Business Committee to create an opportunity for veterans to use their G.I. Bill. I welcome my colleagues who are still here to join us in this effort, to use their G.I. Bill to get education, training vocationally to become farmers, or other business men and women to become entrepreneurs, which farming is.

So we look forward to working with the Department to accomplish that.

I would be less than polite if I did not give my colleagues a chance—I hope they say no—but does anybody have anything to follow up before I conclude the hearing?

Senator Merkley.

FOREST FIRE BORROWING

Senator MERKLEY. Thank you, Mr. Chair.

Since you offered, I just wanted to address the fire borrowing. Senator Wyden and I have been working with Senator Murkowski and have been chief advocates of ending fire borrowing. We worked very hard to persuade the Administration to back this plan. The Administration backed it. Thank you.

It is not in this Subcommittee's jurisdiction, but it is absolutely important. I hope every meeting you go into, you will be talking about it.

We did make a significant change last year. That is that the firefighting was funded at 100 percent of the previous 10-year average, plus a $600 million buffer. Given the impact of the Pacific blob and its change in precipitation in the forests of the Northwest, there is a chance that there will be no fire borrowing this year. We will wait and see. We will see what the summer looks like.

But you are absolutely right. I will just put a huge exclamation point. The mega-fires, the large fires, should be treated as the natural disasters they are. We have constantly robbed fire health and hazardous fuel buildup on the floor of the forests, we have constantly robbed that to pay for fighting fires. People say, why do you always go to the backend when it is at the point of disaster, rather than treat the forest right on the front end?

So thank you for your advocacy on it. Please continue in every possible setting. All of us from the Northwest who suffer these terrible fires are grateful.

Secretary VILSACK. Senator, I appreciate those comments. I just want to underscore, I am not going to authorize transfers.

Senator MERKLEY. Oh, yes, not from this committee to another. But that is not the point. Yes, I understand. You are saying you are going to block——

Secretary VILSACK. I am not going to authorize it because basically that takes everybody off the hook.

Senator MERKLEY. Well, I think that should focus a lot of minds here on Capitol Hill.

Secretary VILSACK. I hope so.

Senator MERKLEY. Thank you.

Senator MORAN. Senator Baldwin.

Senator BALDWIN. Thank you. At the risk of not saying no to your offer, I want to also add my words of agreement with tackling the fire borrowing issue.

Certainly, Wisconsin is not a State where we have many forest fires, but we have a significant part of our Northwoods with a very active timber industry and small businesses dependent upon sustainable management of our forests. I feel like we absolutely must tackle this.

I just want to say, not only to the Secretary, but to the Chair and Ranking Member, how pleased I am to be on the Subcommittee, and how much I look forward to working on a number of issues with you over this appropriations season. I wanted to just call attention to two that I did not have a chance to refer to during my question period, which is promoting agricultural innovation through the Value-Added Producer Grant program, and everything we can do to help new producers get their start with the Beginning Farmer programs, in addition to the ones the chairman and the Secretary just discussed. I am a big fan and look forward to working with all of you on that.

CLOSING STATEMENT OF SENATOR JERRY MORAN

Senator MORAN. Senator Baldwin, we appreciate your participation and presence on the Subcommittee. We look forward to working with you on that and other issues.

Senator Merkley, thank you very much for your kindness and the working relationship that we have.

Mr. Secretary, you have been complimented by members of this Subcommittee on both sides of the aisle. I would add my compliments to you. This is the only the second year that I have chaired this Subcommittee, so while I have been on it, this is the time I have had the most opportunity to get acquainted with you, mostly in this setting.

What I would say is that I am impressed, pleased, about the level of your knowledge, the amount of detail that you know. There is something perhaps to what Senator Blunt said about experience, 7 years. I guess I should not assume this is your last opportunity to appear in a budget hearing before this Subcommittee. Perhaps it is. But I would like to thank you for being a Secretary who apparently, seemingly, knows what is going on to a large extent at the Department that you head. That is pleasing to me.

We are going to try to do everything that I can do to become comparable in level of knowledge as a member of this Appropriations Committee, so that I can have a full and complete understanding as best as possible on the details of what goes on at USDA, and, in our case, the Food and Drug Administration (FDA). I want to be knowledgeable as well and look forward to developing greater expertise as you have developed over the last 7 years. I thank you for your public service.

Secretary VILSACK. Mr. Chairman, thank you very much. It has been an honor to appear before this Subcommittee.

I really feel blessed that I get to work with incredibly dedicated people at USDA. We all work for just an amazing group of people who live, work, and raise their families in rural areas who do so much for this country and oftentimes what they do is underappreciated or not appreciated at all. So I appreciate this privilege that I have, and I consider it a deep honor. Thank you.

Senator MORAN. Mr. Secretary, thank you very much.

I will not diminish what you just said by sounding very formal now, but I have magic words I must say.

For Members of the Subcommittee, any question that you would like to submit for the hearing record should be turned into Subcommittee staff within 1 week, which is Wednesday, March 16. We would appreciate it if you would have responses back from USDA within 4 weeks of that time.

SUBCOMMITTEE RECESS

Senator MORAN. I thank the gentlemen who accompanied you today, and I believe that concludes our hearing.

Thank you.

[Whereupon, at 3:45 p.m., Wednesday, March 9, the subcommittee was recessed, to reconvene subject to the call of the chair.]

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2017

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 2017 budget request for programs within the subcommittee's jurisdiction.]

PREPARED STATEMENT OF ACADEMY OF NUTRITION AND DIETETICS

The Academy of Nutrition and Dietetics appreciates the opportunity to submit testimony for the fiscal year 2017 appropriations. The Academy is the world's largest organization of food and nutrition professionals, and is committed to improving the nation's health with nutrition services and interventions provided by registered dietitian nutritionists. Nationwide, The Academy has over 75,000 members. As Congress begins work on fiscal year 2017 appropriations, we strongly urge you to fully fund Federal nutrition programs that will provide a return on investment to improve health and build strong economies. Investment in these programs through the appropriations process will help prevent costly healthcare expenses due to chronic diseases.

SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC)

WIC serves low-income women and young children until the age of five, providing them with a nutritious monthly food package, nutrition education, healthcare and social service referrals to ensure that this at-risk population receives the quality nutrition and healthcare essential for healthy growth and development. We are asking you to please:

—Fund WIC at $6.350 billion to support a projected caseload of 8.02 million participants. Monitor food cost inflation and caseload to ensure that appropriated levels meet anticipated needs.
—Provide $150 million to replenish the WIC Contingency Fund for unforeseen food cost or participation increases.
—Provide $80 million for breastfeeding peer counselors to improve breastfeeding initiation and duration among the target population,
—$75 million for Management Information Systems/Electronic Benefits Transfer (EBT) funding to improve client access, retailer efficiency, and program integrity,
—$14 million for infrastructure improvements
—$26 million for program initiatives and evaluation

AGRICULTURE, FOOD AND NUTRITION RESEARCH

As you consider the fiscal year 2017 budget, we ask for your support of the President's budget for the National Institute of Food and Agriculture (NIFA). The Na-

tional Institute of Food and Agriculture (NIFA) funds agriculture and nutrition research that is vital for communities and the nation to have new technologies and intervention to improve the health and food security of Americans. In doing so, we ask that you:

—Support the President's budget to the Agriculture and Food Research Initiative (AFRI). These research efforts work with local communities and states to conduct high-quality research to help assure that our food supply is adequate for the future; and

—Consider restoring the funding for Agricultural Research Services (ARS) to 2014 levels. ARS is an essential in-house, scientific research agency. This agency often provides the solutions to food and nutrition problems that affect Americans every day, from field to table.

SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM (SNAP) AND NUTRITION EDUCATION AND OBESITY PREVENTION GRANT PROGRAM (SNAP-ED)

We recognize that Supplemental Nutrition Assistance Program (SNAP) is a mandatory program, but we want convey the importance of the program, and urge you to protect this vital lifeline for families. SNAP helps to put food on the table for about 47 million people each month. SNAP participation closely follows changes in unemployment and underemployment and so is responsive to changes in need. SNAP-Ed empowers participants to make healthy food choices using this knowledge received from the innovative and engaging nutrition education to purchase, prepare and store nutritious foods. SNAP-Ed is targeted to fit the local communities it serves in all 50 states and territories, and outcomes include sustained changed behavior change towards healthier habits.

During this appropriations cycle, we ask that you:

—Support SNAP as it continues to respond to the need for food assistance with timely benefits; and

—Support SNAP-Ed and protect mandatory investments in this program.

CHILD NUTRITION PROGRAMS

Child nutrition programs operate in school, daycare, after school, and summer settings, providing nutritious meals and snacks to fuel children with the energy they need to thrive in the classroom and beyond. We ask that you:

—Support the National School Lunch Program, School Breakfast Program, Summer Food Service Program, Child and Adult Care Food Program, and the Fresh Fruit and Vegetable Program to provide children with nutritious meals and snacks; and

—Continue to provide funding, at $35 million, for grants that would allow schools to purchase kitchen equipment. This will allow schools to serve healthier meals at a more reasonable price, and is a long overdue need for schools.

—Provide adequate funding for training and technical assistance to states for successful implementation of the Healthy Hunger-Free Kids Act. This can be done by:

—Increasing funding to the National Food Service Management Institute, which successfully ran the USDA's Team Up for Success mentorship program for food service operators;

—Fully fund Team Nutrition program, up to $25 million, in order to provide nutrition education competitive grants to states and localities.

—Summer Food Service Program EBT Demonstrations are innovative ways to tackle the hunger gap that occurs for children when school is out of session. Please meet the request to expand, over a ten-year window, this program to provide monthly food assistance to low-income children in the summer via an electronic benefits transfer (EBT) card. This is an easy way for families to have access to healthy foods in the summer months.

COMMODITY ASSISTANCE PROGRAMS

The Emergency Food Assistance Program (TEFAP) is a win/win for farmers, producers, processors and low-income consumers to assure access to healthy foods through our nation's charitable food system, delivering nutrient-rich food through pantries, shelters, and kitchens and providing support for storage and distribution. The TEFAP program staff works in tandem with SNAP-Ed staff to help assure the consumption of these foods through nutrition education including preparation and safe storage. In order to help mitigate declining resources for the purchase of TEFAP foods, the President's Budget includes a legislative proposal to add an addi-

tional $30 million for the purchase of TEFAP foods in fiscal year 2017 and returns future funding to fiscal year 2015 levels.

We ask that you:

—Fund TEFAP commodities at $329 million, as provided by the 2014 farm bill. TEFAP commodities are distributed to low-income people through food banks, pantries, kitchens and shelters.

Commodity Supplemental Food Program (CSFP) CSFP provides a nutritious monthly food package to low-income seniors living at or below the poverty line. The CSFP food package is designed to meet the specific nutritional needs of this target population, combating the poor health conditions often found in food insecure seniors. As the senior population continues to grow, we ask that you:

—Fund CSFP at $236 million. This funding level is enough to support caseload in the existing 46 States, the District of Columbia, and two Indian reservations

SUPPORTING LOCAL FARMERS AND IMPROVING HEALTH

To support local farmers while improving the health of Americans, we ask that you:

—Provide $17 million for WIC Farmers' Market Nutrition Program (FMNP), which provides vouchers to low-income women, infants, and children;

—Provide $21 million for the Seniors Farmers' Market Nutrition Program, which provides vouchers for low-income seniors; and

—Provide $9 million for Community Food Projects to meet food needs of low-income people, increase community self-reliance, and promote comprehensive responses to food, farm and nutrition issues.

—Provide funding for Healthy Food Financing Initiative

FOOD AND DRUG ADMINISTRATION FUNDING

—The Academy supports the President's request to the Food and Drug Administration's (FDA) regarding implementation of the Food Safety Modernization Act (FSMA).

DEVELOPING LEADERS

To ensure a pipeline of leaders dedicated to improving health and reducing hunger in our country, we ask that you:

—Provide $2 million for the Congressional Hunger Center for the operation of the Bill Emerson National Hunger Fellowships and Mickey Leland International Hunger Fellowships, which focus on developing solutions to hunger based on experience at local field placements and national policy organizations.

We appreciate your support on these recommendations. We know that these expenditures will make for smart, long-term investments into the health of Americans.

[This statement was submitted by Mary Pat Raimondi MS, RD Vice President, Strategic Policy and Partnerships Academy of Nutrition and Dietetics.]

PREPARED STATEMENT OF AMERICAN COMMODITY DISTRIBUTION ASSOCIATION

On behalf of the American Commodity Distribution Association (ACDA), I respectfully submit this statement regarding the 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.

We urge the subcommittee to provide $329 million for the purchase of commodities to be distributed by the Emergency Food Assistance Program (TEFAP), to fully fund administrative expense funding for TEFAP at $100 million; to approve the President's request for $236,120,000 for the Commodity Supplemental Food Program (CSFP) including an additional 20,000 caseload slots to allow modest expansion of the program; and to continue to actively monitor two matters: flexibility in the operation of school meal programs; and recommendations of the Multiagency Task Force on commodity procurement required by Section 4205 of the Agricultural Act of 2014 (Public Law 113–79).

ACDA is a non-profit professional trade association, dedicated to the growth and improvement of USDA's Commodity Food Distribution Program. ACDA members include: state agencies that distribute USDA-purchased commodity foods; agricultural organizations; industry; associate members; recipient agencies, such as schools and soup kitchens; and allied organizations, such as anti-hunger groups. ACDA members are responsible for distributing over 2.2 billion pounds of USDA-purchased commodity foods annually through programs such as National School Lunch Program (NSLP), the Emergency Food Assistance Program (TEFAP), Summer Food

Service Program (SFSP), Commodity Supplemental Food Program (CSFP), Charitable Institution Program, and Food Distribution Program on Indian Reservations (FDPIR).

FUNDING FOR TEFAP COMMODITIES

ACDA strongly supports the proposal in the President's budget to provide $30 million to offset declines in 2014 Farm Bill-authorized funding for commodities under The Emergency Food Assistance Program (TEFAP). When coupled with the $299 million provided by the Farm Bill, TEFAP commodity funding would total $329 million. TEFAP operators continue to find a significant need for TEFAP foods, and without the additional $30 million these needs are likely to go unmet. We agree with USDA's claim that the need for TEFAP is increasing as certain adult SNAP recipients lose eligibility due to the reestablishment of time limits on their participation.

FULLY FUND TEFAP ADMINISTRATIVE FUNDS AT $100 MILLION

We continue to urge the subcommittee to fully fund TEFAP Administrative Funds at $100 million. TEFAP providers face significant needs for food handling and storage, and have experienced increased costs in recent years.

ACDA appreciates the increase to $54,401,000 provided in the fiscal year 2016 Consolidated Appropriations Act and the President's request for $59,401,000 for fiscal year 2017, but 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 in order to maintain their operations. Using food dollars for operating expenses is too often necessary, and reduces the ability of these operators to provide food assistance to more individuals and families who continue to face difficult times. We urge the Committee to not force this choice upon operators that are experiencing reduced private donations in addition to increased demands.

FUNDING FOR THE COMMODITY SUPPLEMENTAL FOOD PROGRAM

ACDA supports the President's request for $236,120,000 which would provide for a modest caseload increase for the Commodity Supplemental Food Program (CSFP). We thank the Congress for having provided an additional $900,000 in fiscal year 2016. That increase has allowed Virginia to begin CSFP operations. We know that many states have requested caseload increases given the need for this program now focused on seniors. Virginia, along with the seven states that started programs following your action in fiscal year 2015—Connecticut, Florida, Hawaii, Idaho, Maryland, Massachusetts and Rhode Island—would be candidates for this expansion, along with other long-operating programs.

PROVIDING REASONABLE FLEXIBILITY IN SCHOOL MEAL PROGRAMS

ACDA appreciates the action taken in the fiscal year 2015 and fiscal year 2016 Acts to provide reasonable and responsible flexibility in school meal standards, and remains hopeful that these matters will be addressed as part of the reauthorization of child nutrition programs. ACDA appreciates and supports the inclusion of Section 309 of the "Improving Child Nutrition Integrity and Access Act of 2016", as approved unanimously by the Senate Agriculture Committee, providing flexibility in school meal programs. ACDA supports the delay in the Target 2 sodium standard contingent upon the latest scientific research indicating that further reduction in sodium is necessary to safeguard the health of children. However, ACDA members remain concerned about the practicality of meeting a more stringent standard. We also appreciate the whole grain flexibility because various regions continue to experience problems with specific grain items such as bagels, grits, biscuits, and tortillas that are difficult to obtain as whole grain rich products or are not readily accepted by students. ACDA continues to support emphasizing the importance of fruits and vegetables in all forms—fresh, frozen, canned and dried—as noted in the 2015–2020 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.

INTERAGENCY PANEL FOR EVALUATION AND IMPROVEMENT OF THE USDA FOODS PROGRAM

As a result of Section 4205 of the Agricultural Act of 2014, a multiagency task force has been established at USDA for continuous evaluation and improvement of the USDA Foods program. The first annual report was submitted to Congress last year, and work has been undertaken on several important matters. FNS, AMS, and FSA are now engaging in Business Process Reengineering to determine improvements in the ordering, procurement, and receiving of USDA Foods. ACDA expects to actively participate in this project. We encourage the Committee to monitor this and other actions taken by this task force.

We look forward to continuing to partner with you and USDA in the delivery of these important food assistance programs.

[This statement was submitted by Ed Herrera, President, American Commodity Distribution Association.]

PREPARED STATEMENT OF AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation (AFBF) would like to acknowledge and thank the subcommittee for its historical work directed to the support of agriculture, our nation's food supply and the well-being of rural America.

2014 FARM BILL PROGRAMS

AFBF strongly opposes reopening the 2014 Farm Bill. That law is a careful balance of priorities and should not be reopened before its expiration in 2018 to achieve additional budget savings. Overall Farm Bill spending—including the nutrition programs—comprises just 2 percent of the total Federal budget. The entirety of the farm safety net constitutes less than one-third of 1 percent of the overall budget. The law was crafted to make a significant contribution to deficit reduction from the farm titles above and beyond the continuing contributions made through sequestration. No other sector of the economy has made similar efforts toward deficit reduction, yet many who benefit from the food, fuel, feed and fiber produced in rural America continue to look to agriculture for additional cuts.

PROGRAM THAT PROMOTES BIOTECHNOLOGY

AFBF supports funding for the Animal and Plant Health Inspection Service's (APHIS) Biotechnology Regulatory Services if there are appropriate levels of congressional oversight to ensure APHIS' new regulatory considerations are science- and risk-based, transparent and predictable, while promoting innovation in plant breeding and facilitating trade.

AGRICULTURAL RESEARCH PRIORITIES

Agricultural research has enabled America's farmers to become the most efficient in the world. However, without a commitment to further agricultural research and technological advancement, even America's farmers could be hard-pressed to meet the challenges of feeding the world's growing population.

AFBF supports funding USDA's Agriculture and Food Research Initiative at the level authorized when the program was established in the 2008 Farm Bill.

AFBF supports funding for the National Agricultural Statistics Service and the Economic Research Service, which provide essential information to farmers.

PROGRAMS THAT PROMOTE ANIMAL HEALTH

AFBF supports adequate funding for APHIS' work on the USDA Antimicrobial Resistance Action Plan.

AFBF supports funding at the authorized level for 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.

AFBF supports funding for the National Animal Health Laboratory Network, which provides an early warning system for emerging animal diseases, at the authorized level.

AFBF supports funding for 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.

AFBF supports funding for the FDA's Center for Veterinary Medicine, which oversees the safety of animal drugs, feeds and biotechnology-derived products.

PROGRAMS THAT EXPAND INTERNATIONAL MARKETS AND SAFEGUARD U.S. AGRICULTURE

AFBF supports funding at authorized levels for the following programs and activities:

—The Foreign Agricultural Service, Market Access Program, Foreign Market Development Program, Emerging Markets Program and Technical Assistance for Specialty Crops Program, all of which increase demand for U.S. agriculture and food products abroad.

—USDA to open and staff an office in Cuba. This office will help U.S agriculture to expand access, understand opportunities and increase sales into the Cuban marketplace.

—Public Law 480 programs, which provide foreign food aid by purchasing U.S. commodities.

—APHIS Plant Protection and Quarantine personnel and facilities, which protect U.S. agriculture from costly pest problems that enter from foreign lands.

—APHIS trade issues resolution and management activities that are essential for an effective response when other countries raise pest and disease concerns (i.e., sanitary and phytosanitary measures) to prohibit the entry of 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.

PROGRAMS THAT ENHANCE AND IMPROVE FOOD SAFETY AND PROTECTION

AFBF supports funding for food protection at the Food and Drug Administration and Food Safety and Inspection Service (FSIS) directed to the following priorities:

—Implementation of the Food Safety Modernization Act

—Increased education and training of inspectors

—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

—Indemnification for producers who suffer marketing losses due to inaccurate government-advised recalls or warnings.

AFBF supports funding for a National Antimicrobial Residue Monitoring System to detect trends in antibiotic resistance among foodborne bacteria.

AFBF supports adequate funding for the Food Animal Residue Avoidance Databank, which aids veterinarians establish science-based recommendations for drug withdrawal intervals.

AFBF opposes the administration's request for new user fees for inspection activities. Food safety is for the public good, and as such, it is a justified use of public funds.

AFBF opposes any provision that would prohibit FSIS from inspecting equine processing facilities under the Federal Meat Inspection Act. Prohibiting the harvest of livestock for reasons unrelated to food safety or animal welfare sets an extremely dangerous precedent.

PROGRAMS THAT ENSURE CROP PROTECTION TOOLS

AFBF supports funding the Minor Crop Pest Management Program (IR-4) because developing pest control tools has high regulatory costs, and this funding ensures safe and effective agrichemicals and biopesticides are available for small, specialty crop markets.

AFBF supports funding the Office of Pesticide Management Policy, which promotes the development of new pest management approaches and is critical for crop protection.

AFBF supports funding the APHIS Plant Pest and Disease programs, which eradicate, suppress and contain plant pests.

PROGRAMS THAT STRENGTHEN RURAL COMMUNITIES AND RURAL HOUSING

AFBF supports funding for the following rural development programs:

—Value-Added Agricultural Producer Grants, the Rural Innovation Initiative, the Rural Microentrepreneur Assistance Program, Business and Industry Direct

and Guaranteed Loans, the Resource Conservation and Development Program, the Beginning Farmer and Rancher Development Program and Cooperative Services, which foster business development in rural communities.
—The Rural Utilities Service for rural broadband and telecommunications services, and the Distance Learning and Telemedicine Program.
—Community Facility Direct and Guaranteed Loans, which fund the construction, enlargement or improvement of essential community facilities.
—Agriculture in the Classroom, which helps students gain greater awareness of the role of agriculture in the economy and society.

AFBF supports modifying USDA Section 514 financing to allow farmers who are entering the H–2A program to use the housing built with these funds to house H–2A workers. AFBF also supports allowing famers to obtain this financing to build new housing for H–2A workers. These modifications will eliminate some of the main impediments from entering the H–2A program.

PROGRAMS THAT SUPPORT WILDLIFE SERVICES

AFBF supports funding the Wildlife Services programs that prevent and minimize an estimated $1 billion worth of wildlife damage, while protecting human health and safety from conflicts with wildlife.

PROGRAM THAT ENCOURAGES RENEWABLE ENERGY

AFBF supports funding the Renewable Energy for America Program, which offers a combination of grants and guaranteed loans for farmers to purchase renewable energy systems.

[This statement was submitted by Zippy Duvall, President, American Farm Bureau Federation.]

PREPARED STATEMENT OF AMERICAN FARM BUREAU FEDERATION

Chairman Moran, Ranking Member Merkley, and members of the Subcommittee, thank you for your continued leadership and support for U.S. agriculture. The above signed steering committee members of the Agriculture Workforce Coalition appreciate this opportunity to submit our views regarding the fiscal year 2017 Agriculture, Rural Development, Food and Drug Administration and Related Agencies appropriations bill, and respectfully requests this statement be made part of the official hearing record.

The labor situation in agriculture has been a concern for many years, but is moving towards a breaking point. Today, large segments of American agriculture face a critical lack of workers, a shortage that makes our farms and ranches less competitive with food from abroad and that threatens the abundant, safe and affordable domestic food supply American consumers enjoy today.

Repeated evidence over the past decades has shown that there are some jobs in agriculture that Americans simply do not want to do. Although many of these jobs offer wages competitive with similar, non-agricultural occupations, they are physically demanding, conducted outdoors in all seasons and weather, and are often seasonal or transitory. It is for this reason that farmers have grown to rely on foreign workers to perform this work.

The overarching challenge to workforce stability in agriculture is the widely acknowledged lack of authorized work status by a large number of agricultural workers despite the prevalence of documentation presented by workers to the contrary. The only option for farmers and ranchers to legally find the workers they need is the H–2A temporary work visa program, a program that has not worked for many agricultural employers.

The H–2A program's basic framework is overly restrictive and difficult to maneuver. In recent years the program has become even more bureaucratic, burdensome and costly to use. But, each year, more and more farms have to turn to the H–2A program for legal foreign labor to meet their workforce needs.

The demand on the program is increasing as producers have nowhere else to turn; yet the administrative weight of the program cannot keep up. H–2A employment has doubled in the past 4 years and will double again in the next 2 years or less. This means bureaucratic red tape and delays in the program result in workers showing up at the farm well after the date they were needed to be there, and millions of dollars in agricultural production is lost in the interim.

To improve access to the H–2A program, specifically the housing requirements, we seek the following:

FARM LABOR HOUSING PROGRAM

The U.S. Department of Agriculture's (USDA) Farm Labor Housing (FLH) program provides loans and grants for the development of on-farm and off-farm housing. The program is operated by USDA's Rural Development Housing and Community Facilities Program office.

Specifically, Section 514 loans are provided to buy, build, improve, or repair housing for farm laborers. The range of eligible tenants was expanded in the 2008 farm bill but legally admitted temporary laborers, such as H–2A workers, remain ineligible.

Amending the list of eligible tenants who can use Section 514 housing to include H–2A workers will incentivize use of the program as a means of accessing a legal workforce. We recommend the following language be included in the fiscal year 2017 appropriations bill:

> 42 U.S.C 1484(f)(3)(A) is amended to read: (A) such person shall be a citizen of the United States, a person legally admitted for permanent residence or a person legally admitted and authorized to work in agriculture;

HOUSING ALLOWANCE

Currently, the H–2A Program does not allow for the use of housing allowances. Working through USDA's Rural Development Housing and Community Facilities Program office, we recommend the use of housing allowances be allowed under the H–2A program unless the Secretary of Agriculture determines insufficient community based housing exists. The housing allowance could be based on HUD fair market rental rates for a two bedroom dwelling occupied by four individuals.

This change would provide greater flexibility to workers within the H–2A program and removes one of the more significant program barriers. Specifically, we seek the following language as part of the fiscal year 2017 appropriations bill:

> 8 USC 1188(c)(4) is amended as follows: Provided further that an employer may provide a housing allowance unless the Secretary of USDA determines insufficient community based housing exists.

CONCLUSION

We remain steadfast in our pursuit of broader immigration reform that meets both the short- and long-term workforce requirements of all of agriculture—both those producers with seasonal labor needs, and those with year-round needs. Yet we recognize such reforms may not come to fruition in the near term.

Left with no other alternative, we seek your support for the inclusion of these modest adjustments as you prepare fiscal year 2017 appropriations legislation.

Thank you again, and members of the Subcommittee, for the opportunity to share our views. We look forward to working with the committee to ensure continued benefits for rural communities, consumers, American agriculture and our nation as a whole.

[This statement was submitted by Lisa Van Doren, Vice President & Chief of Staff, Government Affairs, National Council of Farmer Cooperatives.]

PREPARED STATEMENT OF AMERICAN FARMLAND TRUST

NATURAL RESOURCES CONSERVATION SERVICE

I am John Larson, Executive Director of Programs of American Farmland Trust. I am writing in support of full mandatory funding for agricultural conservation programs administered by the Natural Resources Conservation Service (NRCS) as enacted in the Agriculture Act of 2014. We also urge the subcommittee to support the discretionary appropriation of $860 million for NRCS's Conservation Operations (CO) account.

American Farmland Trust is the only national conservation organization dedicated to protecting farmland, promoting sound farming practices, and keeping farmers on the land. Since its founding in 1980 by a group of farmers and citizens concerned about the rapid loss of farmland to development, AFT has helped save millions of acres of farmland from development and led the way for the adoption of conservation practices on millions more.

Mandatory conservation program funding provided by the Agricultural Act of 2014 is invaluable to producers and landowners in helping implement conservation practices on private agricultural land. Agricultural producers and other private landowners share in the cost, and thus help leverage the Federal investment in con-

servation. Conservation systems provide protection and restoration of soil health, water quality, water conservation, air quality, wildlife habitat and other natural resource concerns. These are real public benefits. Further, the voluntary adoption of conservation practices can help avoid the need for governmental intervention and regulation on private lands while protecting the landscape.

The American Farmland Trust is keenly aware of the budget deficits plaguing this country and that is why American Farmland Trust supported the Agricultural Act of 2014, which saved taxpayers $23 billion and consolidated or eliminated over 100 programs. As part of these reductions, mandatory conservation programs were cut by over $6 billion and close to a dozen conservation programs were eliminated or consolidated. Sequestration has also reduced conservation funding significantly. Additional cuts or Changes in Mandatory Programs (CHIMPS) imposed on conservation programs will seriously reduce the Federal share of investment in conservation on working lands.

As the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies deliberates on fiscal year 2017 agricultural program funding, I urge you to refrain from imposing caps or other limits on the mandatory funding already established and enacted by Congress in the Farm Bill. These programs include the Agricultural Conservation Easement Program (ACEP), the Environmental Quality Incentives Program (EQIP), and the Conservation Stewardship Program (CSP). Imposing caps not only cuts fiscal year 2017 funding for needed conservation work, it also has the effect of reducing baseline in future years that further undermines these essential programs.

For example, through the Agricultural Land Easement component of ACEP (and the earlier Farmland Protection Program), millions of acres of productive farmland has been protected from being converted to non-agricultural use. This has occurred primarily though state and local farmland protection programs and land trusts that have partnered with USDA and shared the cost of easements as well as covered most of the transaction costs like appraisals, recording fees, and the like. The proceeds from easements have also allowed producers to install conservation measures on protected lands as well as cover other important business and family expenses while keeping the land in agricultural use.

American Farmland Trust also asks for your support of the full $860 million in the President's budget proposal for the Conservation Operations account of the Natural Resources Conservation Service (NRCS). Conservation Technical Assistance supports the critical, voluntary conservation practices that ensure soil health, water quality, water conservation, air quality, wildlife habitat and other natural resource concerns. Funding for Conservation Operations allows for the delivery of critical conservation programs and helps ensure the best technical and scientific knowledge is available to producers and landowners. This account funds the "boots on the ground" work of NRCS and it is critical to delivery of conservation benefits.

American Farmland Trust believes conservation of our natural resources requires a strong public-private partnership and mandatory farm bill conservation funding along with the technical assistance provided by the Conservation Operations account is key to providing on-the-ground conservation benefits.

[This statement was submitted by John Larson, Executive Director for Programs, American Farmland Trust.]

PREPARED STATEMENT OF AMERICAN FOREST FOUNDATION

The American Forest Foundation (AFF) urges the Subcommittee to support strong funding for fiscal year 2017 for programs that are essential to helping America's 22 million family forest owners, some 282 million acres, conserve and manage their forests to provide the clean water and air, wildlife habitat, sustainable wood supplies, and other benefits, that all Americans benefit from.. Maintenance of these programs will help family forest owners adequately prepare for increasing threats and save landowners, communities, and industries from expensive restoration in the future. We urge the Subcommittee to support:

—Animal and Plant Health Inspection Service Tree and Wood Pests program at the fiscal year 2016 level of $54 million and Specialty Crops program at the fiscal year 2016 level of $156 million;

—Farm Bill authorized levels for the Environmental Quality and Incentives Program (EQIP), Conservation Stewardship Program (CSP), and the Agricultural Conservation Easement Program (ACEP);

—NRCS, Conservation Operations at $761 million to grow conservation technical assistance;

—National Institute for Food and Agriculture (NIFA), Renewable Resources and Extension Program at $4 million;
—NIFA, McIntire-Stennis, Cooperative Forestry Research at $34 million; and
—Continuation of the Joint Chief's Landscape Restoration Partnership.

The American Forest Foundation is a nonprofit conservation organization that works on the ground with family woodland owners through a variety of programs, including the American Tree Farm System®, to protect the values and benefits of America's family forests, including the clean water, wildlife habitat, and sustainable wood supplies these lands provide all Americans. Families and individuals own over one-third of our nation's forests, stewarding more acres than the Federal government or forest industry[1]. Recent analysis by AFF and other partners shows these lands are at risk. In the West, for example, over 4 million acres of family woodlands that are essential for protecting the west's already scarce water supply, are at high fire risk. The US Forest Service predicts by 2020, more than 18 million acres of family forests are threatened by housing development. These are just a few of the growing threats to family woodlands. To combat these ever increasing pressures, we must ensure these families have the financial tools, technical information, and policy support to keep their forests as forests, for both current and future generations.

APHIS INVASIVE PEST AND PATHOGEN FUNDING

According to the National Woodland Owner Survey, the threat of forest pests is a top concern for family forest owners. When an invasive species infests a family's forest, it can destroy their investment, making recovery difficult, as most families don't generate regular income.

To provide family forest owners with the tools needed to fight this growing threat, Congress should at least provide level funding for the APHIS Tree and Wood Pests program. This program funds eradication efforts for invasive species and works to prevent the further spread of invasive species like the Asian Long-Horned Beetle and the Emerald Ash Borer. Close to 500 species of foreign insects and diseases have become established in the U.S., and a new damaging pest is introduced, every 2 to 3 years. It is APHIS' responsibility to prevent such introductions and to respond effectively when pests are introduced.

We ask the Subcommittee to continue providing $156 million to the "Specialty Crops" budget account, which funds APHIS' program to stop spread of the sudden oak death pathogen via trade in nursery plants. Since 1975, U.S. imports (excluding petroleum products) have risen almost six times faster than APHIS staff capability to conduct inspections of those imports. In just 3 years, from 2009 to 2012, more than 90 new plant pests have been detected in the United States.

FARM BILL CONSERVATION PROGRAMS

Farm Bill Conservation Programs provide tools to family forest owners, leveraging the family's own resources to implement conservation activities on their lands—treatments that can protect the numerous public benefits we all enjoy. Forest owners participate in programs like the EQIP and CSP, to help them manage invasive insect infestations, reduce wildfire risks, implement water quality improvements, and improve species habitat. The 2014 Farm Bill strengthened these programs for forest owners and increased opportunities to use resources for collaborative conservation efforts on a landscape scale. To realize the full impact, we urge Congress to support full-funding of these programs at the levels authorized in the Farm Bill. Congress should also provide strong support for NRCS Conservation Operations, which fund technical assistance for landowners and support the implementation of Farm Bill conservation programs.

NIFA RENEWABLE RESOURCES EXTENSION PROGRAM

The Renewable Resources Extension Program supports outreach and education to forest owners, so they have the education and tools they need to be good stewards. This is especially important for family forest owners who are currently unengaged in the management of their forests. The extension foresters supported by this program are essential to landowners, providing them with valuable information—everything from dealing with forest management issues to tax advice for new forest owners. This why it is key to support the program with $4 million in funding.

[1] USDA, USPRS National Woodland Owner Survey. 2013 Updated Data.

NIFA MCINTIRE-STENNIS COOPERATIVE FORESTRY RESEARCH

The forestry research carried out by the nation's land grant universities is funded through the McIntire-Stennis Program. This program provides essential tools and information for family forest owners, and also supports critical family forest research, so that we may identify barriers to stewardship. Finally, it helps train the next generation of forestry professionals to provide forest owners the tools and technical assistance they need. Maintaining the funding level at $34 million will ensure that the research conducted will help family forest owners improve their stewardship.

JOINT CHIEF'S LANDSCAPE RESTORATION PARTNERSHIP

While we don't offer a specific funding level, we also want to recognize the important work happening through the Joint Chief's Partnership. This Partnership between NRCS and the U.S. Forest Service is making significant strides in landscape-scale conservation—allowing these agencies to work together to cross boundary lines and implement conservation and management at a significant scale. For example, in the Blue Mountains of Oregon, with support from the U.S. Forest Service to conduct outreach and engagement with family forest owners, and with cost-share resources from NRCS, a collaborative of Federal and state agencies, university extension programs, and national, state, and local non-profits are partnering to help landowners restore their forests and reduce their fire risk across nearly 200,000 acres, complementing the work of their neighbors- both public or private- all in an effort to increase by four-fold the pace and scale of cross-jurisdictional forest restoration. This is just one of many examples of the incredible success this initiative is having and will have, not just on individual owners, but on a significant scale to protect water, wildlife, wood supplies, and many other benefits.

Thank you for considering these requests. We recognize that the Subcommittee must find areas to reduce spending, but we hope that the Subcommittee will consider the impact these reductions have on millions of family forest owners, along with all other Americans who benefit from well-managed, working forests. We, at AFF, thank the Subcommittee for the opportunity to provide some insight on these programs, and appreciate consideration of our testimony.

[This statement was submitted by Tom Martin, President & CEO, American Forest Foundation.]

PREPARED STATEMENT OF AMERICAN FOREST & PAPER ASSOCIATION

INTRODUCTION

AF&PA supports $6.9 million to provide for implementation of the declaration requirement of the Lacey Act, as amended by the 2008 Farm Bill; recommends maintaining funding for the "Tree and Wood Pests" category to aid in combating these, and other pests and diseases; requests $33.9 million for the McIntire-Stennis Cooperative Forestry Research Program; support the Public-Private Partnership for an Innovation Institute focused on nanocellulosics proposed in the U.S. Department of Agriculture budget, and we would like your support and assistance in ensuring that robust funding is included for the Center for Food Safety and Applied Nutrition and that Congress expresses its intention to continue funding the operation of the Food Contact Notification (FCN) program.

The American Forest & Paper Association (AF&PA) is the national trade association of the forest products industry, representing pulp, paper, packaging and wood products manufacturers, and forest landowners. Our companies make products essential for everyday life from renewable and recyclable resources that sustain the environment.

The forest products industry accounts for nearly 4 percent of the total U.S. manufacturing GDP, manufactures approximately $210 billion in products annually, and employs nearly 900,000 men and women. The industry meets a payroll of approximately $50 billion annually and is among the top 10 manufacturing sector employers in 47 states. Within the jurisdiction of this subcommittee, continued resources for protecting forest health and providing adequate resources to enforce existing trade laws are essential. Specific recommendations follow.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)—LACEY ACT ENFORCEMENT

AF&PA supports $5.5 million to provide for implementation of the declaration requirement of the Lacey Act, as amended by the 2008 Farm Bill. Full and effective

implementation and enforcement of the Lacey Act will enable American forest product companies to compete fairly in the global marketplace, help keep jobs in the United States, and deter the destructive impacts of illegal logging on forests and forest-dependent communities in developing countries. When fully implemented, the law requires U.S. importers of wood and wood products to file a declaration identifying the genus/species name and country of harvest—a critical measure intended by the law's sponsors to increase supply chain transparency and assist Federal agencies in fair and strong enforcement. The prohibition and the declaration requirement affect a wide array of American industries, so it is critical that the declaration process generates data in a streamlined, cost-effective manner without unduly burdening legitimate trade. To that end, APHIS—which is responsible for implementing the declaration provision—needs $6.9 million in funding to fully implement congressional mandates, including to establish an electronic declarations database and to add internal capacity to perform data analysis needed for monitoring and enforcement purposes.

APHIS —PLANT PESTS

AF&PA recommends maintaining funding for the "Tree and Wood Pests" category to aid in combating these, and other pests and diseases. As world trade continues to expand, global weather patterns shift, and an increasingly affluent world population has the ability to travel to—and demand products from—the far corners of the globe, the inadvertent, yet inevitable introduction of nonnative pests and diseases into the United States continues. Additional funding is vitally needed to aid in combating pests such as the Asian longhorn beetle, the Emerald Ash borer, and the Sirex woodwasp, as well as diseases such as Phytopthora ramorum. These are but a sampling of the diseases that harm commercial timber stands, community parks, and private forest landowners. American citizens most certainly will bear the cost of combating these and other emergent threats. We believe a comprehensive, coordinated response to each is more effective and more economical.

We also support the Public-Private Partnership for an Innovation Institute focused on nanocellulosics proposed in the U.S. Department of Agriculture budget. A collaborative national institute will carry out transformative research, supporting fundamental science and providing opportunities to apply science, technology and advanced practices to create opportunities for new business ventures funded by industry. This institute will ensure that the United States is the leading source of commercial cellulosic nanomaterials research, innovation and production. A National Institute focused on nanocellulosics will promote economic growth, increase the productivity of the agricultural and forestry sector, create new jobs and support existing employment in rural communities and contribute to conservation of the forest resource.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE—MCINTIRE-STENNIS COOPERATIVE FORESTRY RESEARCH

AF&PA requests $33.9 million for the McIntire-Stennis Cooperative Forestry Research Program. Approximately one-third of the United States is forested and these forests enhance our quality of life and economic vitality and are an invaluable source of renewable bioproducts, outdoor recreation, clean water, fish and wildlife habitat, and carbon sequestration. Sustaining these forests in a healthy and productive condition requires a strong, continuing commitment to scientific research and graduate education. Foundational financial support for university-based forestry research and graduate education comes from the McIntire-Stennis Cooperative Forestry program, funded through the USDA's National Institute of Food and Agriculture. Funds are distributed each of the 50 states with a dollar-for-dollar match required from the states. Additional funding is needed to provide the additional scientific research needed to address critical forest issues such as fires, storms, insects, diseases, urbanization, fragmentation, and lost economic opportunities; and develop new knowledge and innovations to sustain healthy, productive forests and address the challenges facing forest owners, forest products manufacturers and all Americans who benefit from our forest resources.

FOOD AND DRUG ADMINISTRATION—FOOD CONTACT NOTIFICATION PROGRAM

AF&PA supports continued funding of the Food Contact Notification Program. The Food Contact Notification (FCN) program protects consumer health, food safety and quality while providing packaging manufacturers with an efficient process that is less burdensome than the food additive approval process. It has allowed packaging manufacturers to bring new, more environmentally-friendly products to market that have extended product shelf life, thereby increasing consumer value.

As Congress begins work on appropriations legislation for FDA in the coming weeks, we would like your support and assistance in ensuring that robust funding is included in the Appropriations bills for the Center for Food Safety and Applied Nutrition, and that Congress expresses its intention to continue the operation of the FCN program. Congress should reject a proposal, included in the Administration's fiscal year 2016 budget request, calling for industry user fees to cover certain costs of administering the FCN program. AF&PA appreciates that the subcommittee has previously rejected proposals to eliminate the FCN program.

[This statement was submitted by Elizabeth Bartheld, Vice President, Government Affairs, American Forest & Paper Association- Government Affairs Department.]

PREPARED STATEMENT OF AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

This statement includes a summary of our fiscal year 2017 funding requests for increasing the capacity of the 1994 Institutions so that they might truly begin to fulfill their land-grant vision and mission of self-sufficient, place-based peoples employing an Indigenous model that incorporates holistic planning, traditional knowledge, and the integration of education, research, and extension activities.

SUMMARY OF REQUESTS

The Equity in Educational Land-Grant Status Act, the legislation that created the 1994 (tribal college) land-grant institutions, was signed into law over two decades ago. In those 20 years, the number of 1994s has grown to 34, but funding for the five 1994-specific programs has grown very little and remains wholly inadequate. We recognize the current economic constraints and believe that the increases recommended in the President's fiscal year 2017 Budget are a solid first step to ultimately achieving a level of equity within the nation's land-grant system. The 1994s' programs are administered by USDA's National Institute of Food and Agriculture (NIFA) and Rural Development. In NIFA, the TCUs request: 1994s' competitive Extension, $6.7 million in fiscal year 2017; 1994s' competitive Research program, $3.9 million in fiscal year 2017; 1994s Education Equity Grants, $3.7 million in fiscal year 2017; a doubling of the corpus in the Native American Endowment fund; and in Rural Development, Rural Community Advancement Program (RCAP), $8 million for the TCU Essential Community Facilities Grants program to help address the critical facilities and infrastructure needs that advance their capacity to participate as full land-grant partners.

Additionally, funding levels are not the only inequities that exist within the nation's land-grant system. The 1994 institutions are the only Federal land-grant institutions that are prohibited from participating in the McIntire-Stennis (forestry) grants program and from competing for Children, Youth and Families at Risk (CYFAR) and federally Recognized Tribes Extension Program (FRTEP) grants.

—McIntire-Stennis: In 2008, McIntire-Stennis was amended to include Tribal lands in the formula calculation for funding of state forestry programs. However, the 1994 institutions, which are the Tribal Land-Grant colleges, were not included in the funding formula; nor were states required to include them in funding distributions. This oversight is significant, because 75 percent of Tribal land in the U.S. is either forest or agriculture holding. In response to the dearth of American Indian professionals in the forestry workforce in Montana and across the United States, Salish Kootenai College (SKC) launched a Forestry baccalaureate degree program in 2005. In 2013, SKC became the first tribal college land-grant to join the National Association of University Forest Resource Programs, a consortium of 85 forestry schools, the vast majority of which receive McIntire-Stennis funding. However, when SKC recently sought specialty accreditation for its program, the college was told that it was "one forestry researcher short" of the optimum number needed. Participation in the McIntire-Stennis program, even with the required 1–1 match, would help SKC secure the researcher it needs to gain this accreditation. Although currently, only SKC has a baccalaureate degree in forestry, considering the wealth of forested land on American Indian reservations, other such programs could arise at the nation's other 1994 (Tribal College) Land-Grant institutions, to further advance the growth of the Native workforce in this vital area.

—Children, Youth, and Families at Risk (CYFAR) and federally Recognized Tribes Extension Program (FRTEP): The 1994 Institutions are the only land-grant institutions that are statutorily barred from participating in programs administered under Smith-Lever 3(d). However, certain programs therein are intended

to address serious situations that are prevalent in Tribal communities. Access to two programs in particular would be especially valuable to the 1994s.

CYFAR: In some of the 1994 tribal communities, suicide among Native youth is nine to 19 times as frequent as among other youth. Native youth have more serious problems with mental disorders, including substance abuse and depression, than other youth, and perhaps surprisingly, are more affected by gang involvement than any other racial group. American Indians also have the highest high school drop-out rates in the nation and some of the highest unemployment and poverty rates, as well. Yet, our Native children and youth are the only group in the country essentially excluded from the benefits of the CYFAR program, because the 1994 institutions cannot apply for competitively awarded CYFAR grants. CYFAR supports comprehensive, intensive, community-based programs and promotes building resiliency and protective factors in youth, families, and communities. There is no argument that the 34 Tribal College and University land-grant institutions (1994s) are truly community-based institutions.

FRTEP: The USDA's federally-Recognized Tribes Extension Program is only open to 1862 and 1890 Land-Grants. The program's stated purpose is: "supports extension agents on American Indian reservations and tribal jurisdictions to address the unique needs and problems of American Indian tribal nations. Emphasis is placed on assisting American Indians in the development of profitable farming and ranching techniques, providing 4–H and Youth development experiences for tribal youth, and providing education and outreach on tribally-identified priorities (e.g., family resource management and nutrition) using a culturally sensitive approach." Ironically, the 1994 Land-Grants, which are chartered by and directly serve federally recognized American Indian tribes and are located on or near Indian reservations are barred from participating in this program. This apparent oversight in eligibility rights needs to be rectified. A clear step toward recognizing the 1994 Institutions as true partners in the Land-Grant system would be to afford them eligibility to compete for grant funding under the Smith-Lever 3(d) programs, particularly the Children, Youth, and Families at Risk (CYFAR) program; and (2) federally Recognized Tribes Extension Program (FRTEP). We strongly urge the committee to include language in the fiscal year 2017 Agriculture Appropriations bill or accompanying report, to recognize the 1994 Land-Grant Institutions as full partners in the land-grant system by making them eligible to finally participate in these programs open to all other land-grants.

Illustration of Inequities in Land-Grant System Funding: The first Americans were not granted Federal Land-Grant status until 1994. As earlier stated, initial funding of programs established under this Act was very modest and today, over 20 years since the enactment of the Equity in Educational Land-Grant Status Act of 1994, funding remains untenably inadequate. A clear illustration of the inequity in land-grant programs funding can be found in the latest appropriations for land-grant programs. In fiscal year 2016, Congress appropriated $476 million for extension activities. The 1862s (state) received $300 million in formula-driven extension funds; 1890s (18 HBCUs) received $46 million; and 1994s (34 TCUs) received $4.5M for competitively awarded grants. Further, the 1994s cannot access over $85.5M in Smith-Lever 3(d) grant funds. These inequities cannot be justified or allowed to continue. The first Americans, last to join the nation's land-grant family, deserve parity.

PROGRAMS—SOLID INVESTMENT IN ECONOMIC CAPACITY

In the past, due to lack of expertise and training, millions of acres on Indian reservations lay fallow, underused, or had been developed using methods that caused irreparable damage. The Equity in Educational Land-Grant Status Act of 1994 is helping to address this situation and is our hope for the continued improvement of our reservation lands. Our current land-grant programs remain very small, yet critically important to us. It is essential that American Indians explore and adopt new and evolving technologies for managing our lands and natural resources. With increased capacity and program funding, we will become even more fundamental contributors to the agricultural base of the nation and the world.

CONCLUSION

The 1994s have proven to be efficient and effective vehicles for bringing educational and career opportunities to American Indians/Alaska Natives and the promise of self-sufficiency to some of this nation's poorest and most underserved regions. The small Federal investment in the 1994s has already paid great dividends in

terms of increased employment, access to quality higher education, and economic development. American Indian reservation communities are second to none in their potential for benefiting from effective land-grant programs; and no institutions better exemplify the original intent of Senator Morrill's land-grant concept than the 1994s. We truly appreciate your support and recognition of the 1994s' important role in the nation's land-grant system. We ask you to renew your commitment to help move our students and communities toward self-sufficiency and request your full consideration of our fiscal year 2017 appropriations requests.

[This statement was submitted by Meg Goetz, AIHEC Vice President for Advocacy, American Indian Higher Education Consortium.]

PREPARED STATEMENT OF AMERICAN SEED TRADE ASSOCIATION

The American Seed Trade Association respectfully submits the following requests for the U.S. Department of Agriculture fiscal year 2017 appropriations. Founded in 1883, ASTA's mission is to enhance the development and movement of quality seed worldwide. ASTA's diverse membership consists of over 700 companies involved in seed production, distribution, plant breeding and related industries in North America. ASTA represents all varieties of seeds, including grasses, forages, flowers, vegetables, row crops and cereals. For more information about this request, please contact Jane DeMarchi, Vice President for Government and Regulatory Affairs at the American Seed Trade Association.

USDA intramural research programs conduct research that requires a long-term investment leading to high-impact payoff. Management and utilization of vast collections of genetic resources are the type of research that can't be done by an individual university or company. It is important that Congress recognize how vital these collections are to the ability of the U.S to provide the essential materials for food, feed, and fiber for the world.

Agricultural Research Service
National Plant Germplasm System (NPGS)
Request: At least $44 million

The Agricultural Research Service (ARS) National Plant Germplasm System (NPGS), a network of 26 labs that preserve the genetic diversity of crop plants, is a critical resource for scientists to access genetic diversity. This access helps bring forth new varieties that can resist pests, diseases, and environmental stresses for all types of cropping systems, including organic, conventional and biotech. In addition, it is a vital resource for horticulture and conservation research.

The NPGS is currently funded at approximately $44 million. This amount is insufficient to maintain and distribute the collections to U.S. researchers who are developing varieties for conventional and organic farmers and other landscape uses. ASTA recommends increasing funding for the NPGS so it can better fulfill its mission.

Agricultural Research Service
National Plant Germplasm System (NPGS)
Germplasm Enhancement of Maize (GEM)
Request: $2.7 million

The Germplasm Enhancement of Maize (GEM) program within the funding for the ARS NPGS focuses on adapting exotic corn germplasm for use in the U.S. and on identifying useful genetics in exotic landraces to develop new hybrids. These resources are then made available to any breeders who request them. Over 500 inbred lines have been released to date. Because these materials are adapted to temperate U.S. conditions, U.S. seed companies are saved 6–8 years in the breeding cycle.

The continued success of American agriculture is intimately linked to corn production. USDA estimates that 13.6 billion bushels were harvested in 2015. However, U.S. corn production is based predominantly on two races of maize from more than 250 New World races. This limited genetic diversity renders the U.S. corn crop, and therefore, the global food supply, more vulnerable to attack by new diseases. The GEM materials can play an important role in fighting new diseases in the U.S. and globally. Examples include the catastrophic Maize Lethal Necrosis which is causing significant crop losses in Africa, and Late Wilt, a very devastating disease in Egypt which has now been reported in Spain.

GEM is a model public-private partnership between the Federal government, universities, and companies of all sizes. In addition to its significant research contributions, GEM also facilitates development of future researchers. So far, the GEM project has trained 18 Ph.D. and 14 M.S. students. The current funding for GEM is approximately $1.6 million. Private industry provides over $625,000 of in-kind support annually for this effort, and industry germplasm contributions to GEM are currently valued at over $3 billion.

Demand for maize germplasm continues to increase, and GEM has already distributed more than 21,000 seed samples. ASTA supports an increase in GEM funding for both research and operations costs, and the need to establish consistent winter nurseries for seed increases and regeneration. We recommend increasing funding of the Germplasm Enhancement of Maize to $2.7 million.

GEM Private Cooperators:

3rd Millennium Genetics	Santa Isabel, Puerto Rico
AgiWise, L.L.C.	Ames, IA
AgReliant Genetics, LLC	Lebanon, IN
1BASF Plant Science Breeding, L.L.C.	Research Triangle Park, NC
Beck's Superior Hybrids, Inc.	Atlanta, IN
Brownseed Genetics	Bay City, WI
CRD Advisors, LLC	Kelley, IA
DKD Genetics, Inc.	Vincennes, IN
Dow AgroSciences	Indianapolis, IN
DuPont Pioneer	Johnston, IA
FFR Cooperative	Lafayette, IN
Forage Genetics	Nampa, ID
Genetic Enterprises Int'l	Luther, IA
Global Investors, LP	Des Moines, IA
Hoegemeyer Enterprises	Hooper, NE
Ingredion Inc.	Indianapolis, IN
Illinois Foundation Seeds, Inc.	Tolono, IL
JFS and Associates, LTD	Harlan, IA
MBS Genetics, LLC.	Story City, IA
Monsanto Company	St. Louis, MO
PANNAR Seed	Johnston, IA
Professional Seed Research, Inc.	Sugar Grove, IL
SEEDirect	Woodstock, IL
Summit Genetics	Carroll, IA
Syngenta Seeds, Inc.	Minnetonka, MN
Terrell Seed Research	Wabash, IN
Trimble Genetics International, LLC	Johnstown, IA
Wyffels Hybrids	Geneseo, IL

National GEM Public Cooperators:
Cornell University
Iowa State University
Louisiana State University
North Carolina State University
North Dakota State University
Ohio State University
Purdue University
Texas A&M University
The University of Delaware
The University of Illinois
The University of Missouri
The University of Nebraska
The University of Tennessee
The University of Wisconsin
Truman State University
USDA–ARS multiple locations

USDA-Natural Resources Conservation Service
Plant Material Centers
Request: $14.5 million

ASTA recommends that the USDA–NRCS Plant Material Centers be fully-funded at $14.5 million. The network of 25 PMCs across the country seek out and test plants and plant technologies that restore and sustain healthy natural regional ecosystems. A key function of the centers is to evaluate plants for conservation traits

and to make these materials available to commercial growers, who in turn provide plant materials to the public.

The materials developed by the Plant Material Centers are critical to many USDA goals, including improving soil health, increasing pollinator and wildlife habitat and expanding the availability of new cover crop solutions.

Nationwide, 500 of the 700 releases from the PMCs are currently under commercial production. This work can't be duplicated by the private sector seed industry, which lacks the resources to develop and test materials to address such an extensive range of concerns for the entire United States.

[This statement was submitted by Andrew W. LaVigne, President & CEO American Seed Trade Association.]

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY (AG)

The American Society for Microbiology (ASM) urges Congress to approve the President's proposed fiscal year 2017 budget for research and food safety programs at the Department of Agriculture (USDA). The proposed budget would ensure that the USDA is able to adequately fund programs that support research and development critical to sustaining a safe and competitive food and agriculture system in the United States. The ASM strongly supports funding the National Institute of Food and Agriculture (NIFA) with $1.379 billion, including $700 million for the Agriculture and Food Research Initiative (AFRI), the level authorized by Congress when it was established in the 2008 Farm Bill. The ASM recommends $1.256 billion for the Agricultural Research Service (ARS), USDA's in house research. Agriculture remains a strong and consistent contributor to the US economy, with the USDA estimating a total of $775.8 billion in economic activity annually and the source of one in twelve US jobs. However, agriculture research only accounts for 2 percent of Federal R&D spending, regardless of clear links among innovative research, productivity, public health and market value.

USDA RESEARCH ADVANCES US AGRICULTURE AND PRODUCTIVITY

AFRI funding has been well below the $700 million level authorized by Congress when it established AFRI in the 2008 Farm Bill, re-authorized in 2014. In fiscal year 2014, AFRI received 3,875 proposals, of which 1,640 were recommended for funding, but only 390 won support due to budget constraints. Currently, AFRI is able to fund only one out of 10 grant proposals.

Economic analyses cited by USDA show that investment in agriculture research and extension yields $20 in returns for every dollar spent. The economic potential is evident in the agency's 883 patent applications and 429 issued patents during 2009–2015. Last year, the USDA technology transfer portfolio included 421 licenses generating income and 301 cooperative R&D agreements, many with small businesses. The value of US exports has risen more than 45 percent since 2009; in 2009–2015, exports totaled over $911 billion.

Increased funding is needed for NIFA's mission to assure food safety and nutritional security, advance food and agricultural systems through science and technology, support rural economies and create jobs and train the next generation of food and agriculture scientists by supporting research, education and extension activities at US universities and colleges. In its farm bills, Congress outlined the priority areas for AFRI grants: plant health and production and plant products; animal health and production and animal products; food safety, nutrition and health; bioenergy, natural resources and environment; agriculture systems and technology; and agriculture economics and rural communities. AFRI has awarded grants to universities, businesses, foundations, non-profits, community groups, associations and Federal and international partners.

AFRI studies include food processing technologies like irradiation and microwave pasteurization and how pathogens survive on fresh produce. A major effort currently focuses on Huanglongbing (HLB), a bacterial infection commonly known as citrus greening, which last year infected more than 75 percent of the Florida citrus crop. Researchers are developing bactericides, therapeutic delivery systems and new genetic approaches to stop this economically devastating disease.

Each year, AFRI provides funding for the education and training of nearly 2,500 undergraduate, graduate and postdoctoral students for careers in the agricultural, food, natural resource and human sciences. Federal projections through 2020 indicate that, at present funding levels, US education institutions will not graduate sufficient numbers of new workers in agricultural fields, in fact falling short by 22,500. The fiscal year 2017 budget will continue USDA's education of the general public

and agricultural producers. NIFA just announced creation of five centers across the United States to conduct training, education and technical assistance tailored toward small farm owners, food processors and other specific audiences.

The Agriculture Research Service employs more than 6,500 staff to conduct approximately 700 research projects at 90-plus USDA laboratories in the United States and abroad. USDA scientists either access existing or innovate new leading edge science and technology to advance the agency's basic and applied research. This year, as example, ARS will continue development and use of genomics technologies to improve livestock and crop production. Genetically engineered (GE) crops that can resist pests became commercially available for major crops in 1996. By 2013, farmers had planted 170 million acres with GE crops, about half of US farmland in crop use.

The ARS fiscal year 2017 request outlines priority areas that include antimicrobial resistance, climate change, water supplies, avian influenza and foreign animal diseases. Drug resistance is growing and ASM applauds the additional $22 million requested to address this problem in humans and livestock. Two million Americans have drug resistant illnesses every year and more than 23,000 die. The increase will support vaccines to help reduce nontherapeutic antibiotics in food animals, studies on the gut microbiome and its effects on immune development and identification of specific nutrients with immune benefits. A recent report from the Food and Drug Administration reiterated that US sales of medically important antibiotics approved for livestock use rose by 23 percent between 2009 and 2014, reinforcing concerns about risks to humans. The fiscal year 2017 funding will facilitate much needed research on possible connections and solutions.

USDA RESEARCH PROTECTS FOOD SECURITY AND FOOD SAFETY

USDA regulates the nation's supply of domestic and imported meat, poultry, catfish and processed eggs, to ensure products are wholesome, safe and properly labeled. Each year, there are new reminders of the potentially serious consequences of contaminated food supply systems. One in six Americans gets sick with foodborne illnesses each year, with about 128,000 hospitalized. USDA partners with numerous public health stakeholders to reduce the societal and economic costs of these illnesses.

USDA research that provides science based strategies to stop foodborne threats, preserve productivity and safeguard food security. USDA food guidelines and rules depend upon science; examples are the new Federal standards to further reduce Salmonella and Campylobacter bacteria in certain poultry products. Based on risk assessments, the agency estimates that implementation could prevent an average of 50,000 illnesses annually.

FSIS coordinates its far flung activities, including inspections of food production establishments, with other USDA and non-USDA programs to ensure an integrated farm to table approach. Annual FSIS budgets support approximately 8,000 Federal in plant and field personnel, many of them stationed at about 6,400 slaughtering and processing establishments, import houses and other facilities. FSIS also supports state inspection programs and helps strengthen data infrastructure for nationwide food safety. FSIS relies upon the latest scientific knowledge and capabilities, especially screening technologies that detect contaminants faster and more accurately, are field ready and real time and provide more quantitative data. Currently, USDA is seeking techniques that identify all contaminants in a sample, whether microbiological or chemical. Sample analyses are increasingly reliant upon cutting edge genetics. The fiscal year 2017 request includes USDA implementation of a whole genome sequencing initiative to identify pathogens with great precision and improve the speed and accuracy of outbreak investigations. This also is relevant to USDA's role in the national antimicrobial resistance initiative.

Protecting animal and plant health from threats inside the United States and beyond consistently improves both food safety and food security. The fiscal year 2017 budget proposes additional support against the threat of avian influenza and other animal diseases found in other nations that could enter US agriculture, decimating production and export markets. The 2015 outbreak of highly pathogenic avian influenza was the worst animal disease outbreak in US history, costing the Federal government over $1 billion in eradication efforts and the industry huge losses in poultry flocks and export income. More than 400 USDA staff and nearly 3,000 USDA contracted personnel worked with states and industry to eliminate infected flocks at more than 200 locations, killing 50 million birds.

Facing the specter of foot and mouth disease (FMD) is one AFRI supported effort that showcases the need for robust research funding. This highly contagious viral disease is considered the most important animal disease in the world. The US eradi-

cated FMD in 1929, but its persistence around the world makes it very difficult to control. A 2001 outbreak in the United Kingdom cost an estimated $6 billion. FMD in the United States would shut down our exports of fresh beef, pork and dairy products. When US beef exports dropped in 2003 due to a single case of mad cow disease, the cumulative loss to the economy was an estimated $16 billion. Some estimates of possible US economic impacts from an uncontrolled FMD outbreak approach $200 billion. The fiscal year 2017 budget includes additional funds for the Animal and Plant Health Inspection Service (APHIS) to acquire FMD vaccines for the FMD Vaccine Bank. FMD vaccines must be matched to the specific type and subtype of virus causing the outbreak and available vaccines are not adequate to respond effectively to an outbreak of FMD in the US.

Long term investments in agriculture R&D programs benefit the producers on US farms and ranches, our expansive food industry and individual consumers. USDA food safety programs directly protect the public daily. The ASM asks Congress to fully support the fiscal year 2017 budget requested to guarantee the health and productivity of US agriculture.

[This statement was submitted by Public and Scientific Affairs Board, American Society for Microbiology.]

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY (FDA)

The American Society for Microbiology (ASM) recommends that Congress appropriate at least an additional $100 million for the Food and Drug Administration (FDA) in the fiscal year 2017 budget. This increase would fund the FDA at $2.8 billion, instead of the $2.7 billion, or 1 percent increase, proposed by the Administration. Although the total FDA budget, which relies heavily upon user fees, is $4.8 billion, $80 million over fiscal year 2016, the Administration's proposed budget would result in flat or lower funding for numerous FDA programs that continue to grow in order to protect the public health and safety and because of legislated responsibilities. FDA regulated products account for about 20 cents of each consumer dollar. FDA oversees all drugs, vaccines, medical devices and cosmetics as well as 80 percent of the nation's food supply. Every year, these product sectors are increasing in volume, diversity and global sourcing and intensifying FDA's regulatory role. The ASM believes it is critical to appropriate additional Federal appropriations for the FDA.

The ASM appreciates that the FDA request does include funding earmarked for important efforts like food safety, the Cancer Moonshot and precision medicine. However, we are disappointed by the lack of substantial increased support for public health related problems under FDA purview, such as the threat of growing drug resistance among infectious diseases and a more forceful implementation of the 2011 Food Safety Modernization Act (FSMA) passed by Congress.

The ASM asks that Congress provide FDA with the resources needed to fulfill its mission to safeguard the public health, contribute to the discovery of new healthcare and consumer products, and boost US global competitiveness in science and technology.

FDA ACTIONS PROTECT AND SERVE PUBLIC HEALTH

In the past year, FDA efforts have targeted Zika and Ebola viruses, infections acquired in healthcare settings and nontherapeutic antibiotic use in food animals. Contaminated cucumbers, cilantro, ice cream and salad greens were among the newsworthy causes of foodborne outbreaks reminding us that foodborne illnesses require rapid FDA responses. FDA has unique input into the healthcare continuum, by evaluating the safety and efficacy of new and marketed drugs, vaccines, medical devices and other products for human and animal use. As of February, the agency's evaluation of Ebola related products had included at least ten diagnostics and three vaccine candidates, clinical trials of the ZMapp therapeutic and review of unsuccessful drug candidates and blood donor Ebola guidance issued in December. The agency had fast tracked evaluation of ZMapp, granting it an "orphan drug" designation to accelerate testing of the experimental drug. Its collaborative efforts with other stakeholders stimulated R&D on possible countermeasures and broadened patient access to better healthcare. FDA has begun work on improved Zika diagnostics, including assays built upon reverse transcription polymerase chain reaction (RT–PCR). FDA is also evaluating proposed vector control through genetically engineered mosquitoes. When new candidate vaccines and drugs have been developed, the FDA will be ready to expedite their review as well.

In 2015, FDA issued approvals for 56 new drugs and biologics, compared to 50 in 2014. Among the approved products are treatments for hepatitis C, multiple myeloma, HIV infection and plague as well as a vaccine for use after anthrax exposure. Two other drugs were the fifth and sixth approved under the Qualified Infectious Disease Product protocol for rare but serious infections, aimed at stimulating drug R&D through priority review. Also approved were a diagnostic test to differentiate among types of HIV infection and an improved duodenoscope design to reduce infection risk during medical procedures.

In the United States, nearly 40 percent of our finished drugs and 80 percent of active ingredients used in drug manufacture are imported. The heightened global sourcing of US consumer products is clear to any shopper, but the chore of FDA oversight is far more complex. FDA regulated products originate from more than 200 countries, entering through more than 300 US ports. FDA estimates that shipments have more than tripled in the past decade, from 8 million import entry lines per year to more than 29 million today. At present, fewer than 2 percent of incoming shipments are inspected by the available FDA staff, often cited as proof of FDA budget shortfalls.

The ASM recognizes the monumental task of guaranteeing our food supply's safety and security. Chronically understaffed, FDA foods inspection, regulatory and investigation programs are challenged daily. FDA registered food producing and manufacturing sites comprise 133,000 foreign and 97,000 domestic facilities. FDA currently has resources to inspect about 1,000 foreign facilities per year. The Department of Agriculture (USDA) estimates that foods grown or processed outside the country account for about 20 percent of the US food supply, including about half of fresh fruits, 20 percent of fresh vegetables and 80 percent of seafood.

Last fall, FDA finalized five of the seven major rules that implement the core mandates of the FSMA legislation. Following huge effort by the agency, interagency partners and public comment, the rules address both domestic and foreign sources. Two of the preventive controls rules focus on modern food manufacturing processes for both human and animal foods, holding food companies more accountable for monitoring facilities. The third rule establishes science based standards to reduce contamination in produce, a frequent source of foodborne illnesses. The others specifically target imports through the Foreign Supplier Verification Program and accreditation of third party certification bodies to audit foreign foods and facilities. The ASM acknowledges the effort leading to these crucial food safety measures. However, the most effective implementation of FSMA goals depends upon both cutting edge FDA science and adequate fiscal support.

FDA SCIENCE ADVANCES PRODUCT SAFETY

In September, the advisory FDA Science Board released its in depth report on the current state of FDA science, Mission Possible: How FDA Can Move at the Speed of Science. Report authors were tasked to evaluate how FDA can best review products from emerging and future trends in science and technology, elevate its own scientific culture, and leverage collaborations with other stakeholders. Also included was assessment of intra-agency progress made since the Board's 2007 report, FDA Science and Mission at Risk. The report commended proactive moves like the new Office of the Chief Scientist and FDA offices in other countries, plus the effort to better regulate cutting edge technologies like genome sequencing, computing and stem cells.

The ASM agrees with the report's warning that some serious problems persist, indictments of ongoing funding shortfalls. Noted examples are failures to allocate the substantial amounts of FDA funding needed for the FSMA mandate's complete implementation and FDA's own scientific methods and technologies too often lagging behind industry and others. As the agency responsible for the safety and efficacy of huge consumer sectors, FDA clearly must have routine access to the latest science and technologies to best serve the public. The US responses to the 2014–2015 Ebola epidemic, and now the Zika virus, rely upon FDA science to help guide policy development, facilitate clinical trials and undertake fast track reviews of candidate drugs, diagnostics and vaccines. More broadly, next-generation diagnostics now being developed by industry often are based upon metagenomic sequencing that FDA must be prepared to evaluate. Another instance of FDA activities that must be based on sound science is reviewing foods from genetically engineered (GE) plants and animals. In November, FDA announced its approval of GE salmon, the agency's first for a GE animal for human consumption, as well as related guidance documents on labeling. It also released a final guidance for labeling foods derived from GE plants. Beyond the needed laboratory expertise, FDA regulatory actions increasingly require newer types of highly sought technical personnel like bioinformaticians.

Since 2008, the FDA foods program has utilized whole genome sequencing (WGS) to identify the microbial causes of foodborne illnesses faster and more accurately. Continued WGS improvements are dramatically reducing times required for identification from 14 days to just a few days, as well as pinpointing the source of outbreaks down to the farm or facility level. Last year, WGS was used extensively in outbreak investigations, linking contaminated imported cucumbers to a few specific firms and Listeria infections to certain ice cream manufacturers. FDA established the first national lab network of whole genome sequencers, called GenomeTrakr, which has accumulated more than 43,000 sequenced microbial isolates since 2013. FDA scientists are also using other next generation technologies like flow cytometry and fluorescence. FDA recently reduced the average number of days to serotype food pathogens to three days.

FDA PARTNERSHIPS SUPPORT NATIONAL INITIATIVES, LEGISLATION

Under its regulatory role, FDA reinforces multiple national efforts against threats to our collective health and quality of life. Some, like FSMA implementation, require extensive FDA actions that seriously stretch agency resources. Another example is FDA's participation in the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB) and other efforts to address rising drug resistance among pathogens. Related FDA efforts encompass the areas of drugs, biologics, medical devices, and veterinary medicine. In 2015, the agency published its final Veterinary Feed Directive rule and an industry guidance to further promote judicious use of antimicrobials in food producing animals, placing their use under veterinary supervision.

To support the newly launched National Cancer Moonshot Initiative, FDA will develop a virtual Oncology Center of Excellence, to leverage collective expertise in drugs, biologics and medical devices to expedite R&D of novel products. The Center additionally will contribute to FDA's current support of the 2015 Precision Medicine Initiative, under which FDA has already approved a targeted therapy and companion diagnostic test for certain lung cancers.

The ASM appreciates that some FDA responsibilities would receive earmarked funding in the fiscal year 2017 budget, but we urge Congress to increase Federal appropriations for the FDA, which includes so many programs that have needs and are critical to public health and safety.

[This statement was submitted by Public and Scientific Affairs Board, American Society for Microbiology.]

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 $700 million and that the Agricultural Research Service receive $1.161 billion in fiscal year 2017, the Administration's proposed funding levels. ASN has more than 5,000 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 influencing U.S. 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 research, education, and extension and integrated, competitive grants that address key problems of national, regional, and multi-state importance in sustaining all components of agriculture. These components include human nutrition, farm efficiency and profitability, ranching, renewable energy, forestry (both urban and agro forestry), aquaculture, food safety, biotechnology, and conventional breeding. AFRI has funded cutting-edge, agricultural research on key issues of timely importance on a competitive, peer-reviewed basis since its establishment in the 2008 Farm Bill. Adequate funding for agricultural research is critical to provide a safe and nutritious food supply for the world 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.

In order to achieve those benefits, AFRI must be able to advance fundamental sciences in support of agriculture and coordinate opportunities to build off of these discoveries. Therefore, ASN requests that the AFRI competitive grants program receive $700 million, the Administration's proposed funding of AFRI, in fiscal year 2017, which would double AFRI funding. Current flat and decreased funding for AFRI hinders scientific advances that support agricultural funding and research.

AGRICULTURAL RESEARCH SERVICE

The Agricultural Research Service (ARS) is the Department of Agriculture's lead scientific research agency. The ARS 7conducts research to develop and transfer solutions to agricultural problems of high national priority. USDA's program of human nutrition research is housed in 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. 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.

Nutrition monitoring conducted in partnership by the USDA/ARS 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 is responsible for tracking nutritional status and health parameters.) Nutrition monitoring is an inherently governmental function and findings are essential for multiple government agencies, as well as the public and private sector. Nutrition monitoring is essential 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 needed funds to update USDA's food and nutrient databases and the "What We Eat in America" dietary survey, both maintained by the USDA/ARS, are appropriated to ensure the continuation of this critical surveillance of the nation's nutritional status and the many benefits it provides.

It is the job of ARS to ensure high-quality, safe food, and other agricultural products; assess the nutritional needs of Americans; sustain a competitive agricultural economy; enhance the natural resource base and the environment; and provide economic opportunities for rural citizens, communities, and society as a whole. Therefore, ASN requests that ARS receive at least $1.161 billion in fiscal year 2017, with Congress directing the use of some of these funds for both intra-and extramural human nutrition research. Resources above current funding levels are necessary to ensure the critical surveillance of the nation's nutritional status and to continue the many other benefits that ARS provides. With such funding, the ARS will be able to support its vision of leading America towards a better future through agricultural research and information.

[This statement was submitted by Patrick J. Stover, Ph.D., President, American Society for Nutrition.]

PREPARED STATEMENT OF AMERICAN SOCIETY OF PLANT BIOLOGISTS

On behalf of the American Society of Plant Biologists (ASPB), we submit this statement for the official record in support of funding for agricultural research by the U.S. Department of Agriculture (USDA). ASPB supports the fiscal year 2017 requested level of $700 million for the Agriculture and Food Research Initiative (AFRI), which administers competitive funding for innovative research on issues such as food security, global health, and renewable energy. ASPB also supports the fiscal year 2017 requested level of $1.286 billion for the Agricultural Research Service (ARS).

This testimony highlights the critical importance of plant biology research and development to addressing vital issues including: achieving a sustainable food supply and food security; energy security, attaining reduced reliance on all petrochemical

products through game-changing sustainable renewable biomass utilization approaches; and protecting our environment.

FOOD, FUEL, ENVIRONMENT, AND HEALTH: PLANT BIOLOGY RESEARCH AND AMERICA'S COMPETITIVENESS AND SELF-SUFFICIENCY

We often take plants for granted, but they are vital to our very existence, competitiveness, and self-sufficiency. New plant biology research is now addressing the most compelling issues facing our society, including: identifying creative and imaginative approaches to reaching Congress's goals of achieving domestic fuel security/self-sufficiency; environmental stewardship; sustainable and secure development of even better foods, feeds, building materials, and a host of other plant products used in daily life; and improvements in the health and nutrition of all Americans.

Our bioeconomy and Federal partnership is based upon foundational plant biology research—the strategic research USDA funds—to make needed key discoveries. Yet limited funding committed to basic discovery now threatens our national security and leadership. Indeed, Bill Gates wrote, "Given the central role that food plays in human welfare and national stability, it is shocking—not to mention short-sighted and potentially dangerous—how little money is spent on agricultural research." [1] This is especially true considering the significant positive impact crop and forest plants have on the nation's economy (the agricultural sector is responsible for one in 12 American jobs [2]).

Given these concerns and our nation's fiscal situation, the plant science community has been working toward addressing our nation's looming challenges. With funding from USDA, the National Science Foundation, the Department of Energy, and the Howard Hughes Medical Institute, ASPB brought together representatives from across the full spectrum of plant science research to develop a community agenda document, Unleashing a Decade of Innovation in Plant Science: A Vision for 2015–2025 (plantsummit.files.wordpress.com/2013/07/plantsciencedecadalvision10–18–13.pdf). The report, part of an ongoing and iterative process, puts forth a ten-year consensus plan to fill critical gaps in our understanding of plant biology toward addressing the grand challenge of sustainably feeding the world and providing other useful plant products in the face of burgeoning population growth, diminishing natural resources, and climate change.

IMMEDIATE RECOMMENDATIONS

The ASPB membership has extensive expertise and participation in the academic, industry, and government sectors. Consequently, ASPB is in an excellent position to articulate the nation's plant science priorities and standards needed as they relate to agriculture. Our recommendations are as follows:

—Since the establishment of the National Institute of Food and Agriculture (NIFA) and AFRI, interest in USDA research has increased dramatically—a trend ASPB hopes to see continue in the future. However, an increased, strategic and focused investment in competitive funding and its oversight is needed if the nation is to continue to make ground-breaking discoveries and accelerate progress toward resolving urgent national priorities and societal needs. ASPB encourages the Committee to fund AFRI at the requested $700 million level in fiscal year 2017.

—The Agricultural Research Service (ARS) provides vital strategic research to serve USDA's mission and objectives and as well as the nation's agricultural sector. The need to bolster and enhance ARS efforts to leverage and complement AFRI is great given the challenges in food and energy security. ASPB is supportive of a strong ARS and recommends a congressional appropriation of the requested $1.286 billion in fiscal year 2017.

—USDA has focused attention in several key priority areas, including water for food production, food safety, childhood obesity, climate variability and change, and sustainable energy. Although ASPB appreciates the value of such strategic focus, we give our most robust support for AFRI's Foundational Program. This program provides a basis for outcomes across a wide spectrum, often leading to groundbreaking developments that cannot be anticipated in advance. Indeed, it is these discoveries that are the true engine of success for our bioeconomy.

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[1] Gates, Bill. (Jan 2012). 2012 Annual Letter from Bill Gates. Retrieved from http://www.gatesfoundation.org/annual-letter/2012/Pages/home-en.aspx.

[2] Vilsack, Tom. (Mar. 9, 2012). Public Comments Before PCAST. Retrieved from http://www.tvworldwide.com/events/pcast/120309/globe__show/default__go__archive.cfm?gsid=1977&type=flv&test.

—Current estimates predict a significant shortfall in the needed agricultural scientific workforce as the demographics of the U.S. workforce change.[3] For example, there is a clear need for additional training of scientists in the areas of interdisciplinary energy research and plant breeding. ASPB applauds the ongoing support of the NIFA Fellows program and calls for additional funding for specific programs (e.g., training grants and fellowships) to provide this needed workforce over the next 10 years and to adequately prepare these individuals for careers in the agricultural research of the future.
—Considerable research interest is now focused on the use of plant biomass for energy production. However, if we are to use crops and forest resources to their full potential, we must expend extensive effort to improve our understanding of their underlying biology and development, their agronomic performance, and their subsequent processing to meet our goals. Therefore, ASPB calls for additional funding targeted at efforts to increase the utility and agronomic performance of bioenergy crops using the best and most imaginative science and technologies possible.
—ASPB encourages some flexibility within NIFA's budget to update and improve its data management capabilities.

[This statement was submitted by Tyrone C. Spady, PhD, Director of Legislative and Public Affairs.]

PREPARED STATEMENT OF AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS

On behalf of the American Society for the Prevention of Cruelty to Animals (ASPCA) and our 2.5 million supporters nationwide, thank you for the opportunity to submit this written testimony. Founded in 1866, the ASPCA was the first humane organization in North America. Our mission, as stated by founder Henry Bergh, is "to provide effective means for the prevention of cruelty to animals throughout the United States." As you craft the fiscal year 2017 Agriculture Appropriations bill, the ASPCA asks that you please consider the following provisions.

CONTINUE THE CURRENT BAN ON FEDERAL FUNDING FOR HORSE SLAUGHTERHOUSE INSPECTIONS

Congress included in the fiscal year 2016 Consolidated Appropriations Act a provision continuing the long-standing ban on Federal funding for USDA inspections at domestic horse slaughterhouses.

Americans do not eat horse meat, and national polling indicates that 80 percent of American voters oppose the slaughter of horses for human consumption. Cruelties associated with horse slaughter are well-documented. Whether in the U.S. or over the border, horses are forced into cramped trailers and trucked long distances to slaughter with insufficient food, water, or rest. Many horses are injured, trampled, and even killed during the journey. Horses that survive endure an inherently cruel slaughter process. As extreme flight animals, horses are ill-suited for stunning. In USDA-regulated plants, many endured repeated blows, sometimes remaining conscious during dismemberment. USDA documented rampant violations and cruelty in domestic horse slaughter facilities, including photos of protruding broken bones, eyeballs hanging by a thread of skin, and open wounds.

As American horses are not raised for food, throughout their lives they are routinely given numerous drugs prohibited by the FDA for use in animals intended for human consumption. A 2010 Food and Chemical Toxicology Journal article detailed the ubiquitous use of phenylbutazone in race horses subsequently sent to auction and then to slaughter only days after medication.[1] A New York Times investigation revealed a virtual arms race of illegal drug use in horses to mask pain and evade drug tests including "cobra venom, Viagra, blood doping agents, stimulants, and cancer drugs," and the resulting food safety threats.[2] The Food Safety and Inspection Service (FSIS) cannot test for these harmful substances without a system to

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[3] President's Council of Advisors on Science and Technology. (Dec. 2012). Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise, p. 41. Retrieved from http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast__agriculture__20121207.pdf.

[1] 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.

[2] "Death and Disarray at America's Racetracks." The New York Times: March 24, 2012.

track horses' health histories, and trainers are constantly experimenting with new stimulants to gain a competitive edge.

The European Union (EU) announced a ban on imports of horse meat from Mexico to the EU as of January 1, 2015, following a scathing audit of EU-certified Mexican horse slaughter plants, which kill tens of thousands of American horses each year. The report stressed that because horses are not raised as food-producing animals in Mexico or the United States, they are routinely given many medications that are illegal for use in food animals. U.S. tax dollars should not be used to prop up an industry that has no regard for animal welfare or human health.

The ASPCA requests that the Subcommittee continue the prohibition on Federal funding for horse slaughterhouse inspections by the USDA by including the following language:

None of the funds made available in this 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).

ENSURE THAT ARS RESEARCH COMPLIES WITH THE ANIMAL WELFARE ACT

A 2015 New York Times exposé revealed appalling abuse of animals at USDA's U.S. Meat Animal Research Center (USMARC).[3] The article revealed a shocking array of animal experiments occurring at the USMARC with little regard for welfare, e.g., a live, unanaesthetized pig dissected and then improperly euthanized, and lambs left to die of exposure to extreme weather and predation in order to develop "easy-care" sheep. The research at the USMARC inflicts terrible suffering on animals at taxpayer expense. Since 2006, USDA's Agricultural Research Service (ARS) has spent nearly $200 million at USMARC.

The cows, sheep, and pigs used in these experiments are exempt, by statute, from the basic standards of the Animal Welfare Act (AWA), which exempts animals used in agriculture production research. Though exempted by statute, USDA's internal policies mirror some of these basic protections. However, investigative reports from USDA last year noted that USMARC filed to follow its own animal welfare standards.[4][5][6] In particular, these reports showed a need for further review of internal animal welfare policies and that USMARC's Institutional Animal Care and Use Committee (IACUC) was not properly constituted.

The ASPCA appreciates the Subcommittee's continued attention to this important issue. We supported the inclusion of language in the fiscal year 2016 Consolidated Appropriations Act which compels USDA to provide written certification to Congress that its animal welfare policies have been updated to comply with the AWA—including properly constituting IACUCs—and provides funding to facilitate inspection of ARS facilities by the Animal and Plant Health Inspection Service (APHIS).

The ASPCA requests that the Subcommittee continue to include language to ensure that all ARS facilities comply with the Animal Welfare Act, including regular APHIS inspections, and we encourage the continuation of funding to support these inspections.

INCREASE AWA ENFORCEMENT FUNDING FOR THE INSPECTION OF LICENSED BREEDERS

One of the functions of USDA's Animal and Plant Health Inspection Service (APHIS) is to ensure the humane care and treatment of animals by enforcing the requirements of the Animal Welfare Act (AWA). Included in this mandate is the inspection of large-scale commercial dog breeding operations. Dogs raised in these facilities typically spend their entire lives in small, crowded cages, continually producing litters of puppies for the pet trade. Although the AWA provides very minimal

[3] "U.S. Research Lab Lets Livestock Suffer in Quest for Profit." The New York Times: January 19, 2015.

[4] "Findings and Recommendations on the Animal Care and Well-Being at the U.S. Meat Animal Research Center to the Secretary of Agriculture and the REE Under Secretary." Agricultural Research Service—Animal Handling and Welfare Review Panel. Pre-Public Hearing Report. March 9, 2015.

[5] "Findings and Recommendations on the Phase II Review of the Animal Care and Well-Being at the Agricultural Research Service to the REE Under Secretary." Agricultural Research Service—Animal Handling and Welfare Review Panel. Pre-Public Hearing Report. July 6, 2015.

[6] "ARS: U.S. Meat Animal Research Center Review—Interim Report" USDA Office of Inspector General. Audit Number: 02007–0001–31 (1). September 28, 2015.

standards which should be improved, those operations not in compliance with even the very limited Federal requirements must be held accountable. When facilities fall out of compliance, dogs can suffer for extended periods in deplorable conditions, without veterinary care, exercise, food, water, and socialization.

In September 2013, USDA issued a final rule that, for the first time, required commercial breeders who sell puppies directly to the public—sight unseen over the Internet or mail—to be licensed and inspected. At the time, the Department estimated that 2,600–4,640 additional dog breeders, as well as 325 cat breeders, would require licensure. With already limited resources, the addition of thousands of new licensees will make it nearly impossible for USDA to provide the necessary enforcement without an increase in funding.

The ASPCA requests that the Subcommittee increase the current funding for APHIS's AWA enforcement.

PROHIBIT INCREASED LINE SPEEDS FOR POULTRY SLAUGHTER PLANTS

USDA's Food Safety and Inspection Service (FSIS) Modernization of Poultry Slaughter Inspection Rule, finalized in 2014, stopped short of increasing already-too-fast line speeds for certain poultry slaughter plants from 140 to 175 birds per minute. Faster slaughter speeds will lead to more live birds entering the scalding tank. As noted in a recent Washington Post article, nearly 1 million chickens are unintentionally boiled alive each year because already-fast-moving slaughter lines fail to kill the birds before they are dropped into scalding water to facilitate defeathering.[7]

The ASPCA requests that the Subcommittee prohibit FSIS from increasing line speeds at poultry slaughter plants.

EXCEED THE STATUTORY FUNDING CAP FOR HORSE SORING ENFORCEMENT

APHIS is also charged with protecting horses through its enforcement of the Horse Protection Act (HPA) of 1970. Since passage of the HPA in 1970, a $500,000 statutory funding cap on activities under the Act has hampered USDA's effective enforcement of horse soring activities. Congress can choose to ignore the cap and fund the program at higher levels, which it did in the fiscal year 2016 Consolidated Appropriations Act by funding HPA enforcement at $697,000.

The ASPCA requests that the Subcommittee continue to exceed the statutory funding cap to allow the USDA to better enforce the Horse Protection Act and prevent the cruel practice of horse soring.

[This statement was submitted by Nancy Perry, Senior Vice President, Government Relations.]

PREPARED STATEMENT OF ANIMAL WELFARE INFORMATION CENTER

Thank you for the opportunity to submit testimony on fiscal year 2017 funding priorities for the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS), Animal and Plant Health Inspection Service (APHIS), and Food Safety Inspection Service (FSIS).

USDA–ARS-NATIONAL AGRICULTURAL LIBRARY—ANIMAL WELFARE INFORMATION CENTER

The Animal Welfare Information Center (AWIC) serves as a training and education resource for those who use animals for research, testing, and teaching, and the need for its services continues to outstrip its resources. AWIC's activities are vitally important, as they facilitate science-based decisionmaking and compliance with Federal animal welfare regulations. We request that AWIC funding remain consistent with the fiscal year 2017 budget proposal.

USDA–APHIS-ANIMAL WELFARE

APHIS's Animal Welfare activities are critical to the proper regulation and care of animals protected under the Animal Welfare Act (AWA), 7 U.S.C. §§2131–2159, and the Horse Protection Act (HPA), 15 U.S.C. §§1821–1831. We request that, consistent with the Department's request, $29 million be allocated to Animal Welfare activities.

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[7] "USDA Plan to Speed Up Poultry-Processing Lines Could Increase Risk of Bird Abuse." The Washington Post: October 29, 2013.

USDA–APHIS-ANIMAL WELFARE—ANIMAL WELFARE ACT ENFORCEMENT—CLASS B DEALERS

We are grateful that Congress maintained in the fiscal year 2016 omnibus a provision prohibiting the renewal of existing licenses or the issuance of new licenses to Class B dealers who sell random source dogs and cats for use in research, experimentation, teaching, and testing. One existing license doesn't expire until December, so it will be necessary to continue this prohibition into fiscal year 2017. Moreover, it will also be needed to ensure that there is no lapse during which these dealers try to get back into business or others are tempted to apply for new licenses. It is true that very few of these dealers remain—all the more reason to head off challenges to the progress that has been made in shutting down this abuse-ridden industry that has trafficked in stolen pets, consigned animals to misery, and was found to be "not necessary" to NIH-related research. Therefore, we ask you to include the following language in the agriculture appropriations bill for fiscal year 2017: None of the funds made available by this Act may be used to carry out any activities or incur any expense related to the issuance of licenses under section 3 of the Animal Welfare Act (7 U.S.C. 2133), or the renewal of such licenses, to class B dealers who sell random source dogs and cats for use in research, experiments, teaching, or testing. Nothing in this provision, however, should be construed as preventing the Department from carrying out all necessary oversight, inspection, compliance, and enforcement activities with respect to any entity holding a valid class B license who sells random source dogs and cats for use in research, experiments, teaching, or testing, or with respect to any entity doing so without a license as required under 7 U.S.C. 2133.

USDA–APHIS-ANIMAL WELFARE—HORSE PROTECTION ACT ENFORCEMENT

We support and incorporate by reference the testimony submitted by The Humane Society of the U.S. on behalf of AWI and our partner organizations concerning fiscal year 2017 funding for HPA enforcement. The HPA was enacted to end soring, the cruel practice of applying chemical and mechanical irritants to the legs and hooves of horses to produce an exaggerated gait. Yet soring, condemned as "one of the most significant welfare issues affecting any equine breed or discipline,"[1] has continued as limited funding has hampered enforcement. Because USDA inspectors are able to attend a mere fraction of Tennessee Walking Horse shows, monitoring responsibility often falls to "Designated Qualified Persons" (DQPs), usually industry insiders willing to ignore violations. Reliance on DQPs has been an abysmal failure. Statistics show that USDA inspectors' presence at shows results in a far higher rate of violations than occurs when DQPs are present. For example, at the 2013 Tennessee Walking Horse National Celebration, 86 of 128 horses tested positive for soring agents.[2] We ask that Congress appropriate $705,000 for HPA enforcement.

USDA–APHIS-WILDLIFE SERVICES—WILDLIFE DAMAGE MANAGEMENT

APHIS's Wildlife Services (WS) program allocates millions of dollars each year to lethal wildlife management, relying on methods that are cruel, ineffective, costly, and outdated. WS uses poisons, traps, snares, and firearms to indiscriminately kill animals—including endangered species, family pets, and countless non-target animals—while ignoring humane and cost-efficient alternatives. WS' irresponsible practices even threaten public safety and national security (e.g., the use of Compound 1080). Last year, two individuals died during an aerial gunning operation that WS was conducting to exterminate coyotes in New Mexico; unfortunately, this most recent fatal accident is not the first such case. In view of the most recent fatal plane crash, as well as the overall lack of transparency surrounding WS's activities, we urge the Subcommittee to include report language requiring the agency to provide detailed information about its aerial gunning operations. Specifically, WS should identify any additional safety measures the agency has instituted since the most recent fatal accident; the dollar amount spent per operation (e.g., for aircraft rental or lease, fuel costs, personnel costs including fees paid for pilots if not agency personnel, and other payments made to private aerial companies or individuals contracted by WS); funding received from outside sources to carry out aerial gunning activities (whether through cooperator agreements or from state agencies, local governments, or private landowners); specific locations where operations were conducted; the number and species of animals killed per operation; and information re-

[1] American Association of Equine Practitioners, Putting the Horse First: Veterinary Recommendations for Ending the Soring of Tennessee Walking Horses (2008).
[2] Id.

garding whether targeted animals were identified in a specific conflict or were part of a preemptive shooting mission.

USDA–APHIS-INVESTIGATIVE AND ENFORCEMENT SERVICES

APHIS' Investigative and Enforcement Services (IES) handles investigations related to APHIS programs, which involves: evidence collection; civil and criminal investigations; and investigations in collaboration with Federal, state and local enforcement agencies. IES also works with USDA's Office of General Counsel to handle stipulations and administrative proceedings. Consistent with the fiscal year 2017 budget proposal, we request $16,410,000 so that the Service may fulfill its responsibilities, particularly its increasing HPA and AWA investigatory demands.

USDA–ARS—ANIMAL WELFARE FOR FARM ANIMALS USED IN AGRICULTURAL RESEARCH

Last year the New York Times released an investigation that revealed shocking instances of animal abuse at the U.S. Meat Animal Research Center (MARC). Experiments at this Federal facility over the last several decades were the subject of a year-long investigation by the Times, involving the review of thousands of pages of internal records obtained through the Freedom of Information Act. MARC has received almost $200 million in Federal funding since 2006, and it is one of approximately 40 Agricultural Research Service facilities that conduct agricultural research involving animals. The Committee took seriously the allegations raised by the Times piece and responded by making 5 percent of the ARS budget for fiscal year 2016 contingent on ARS updating its animal care policies and requiring that all ARS facilities at which animal research is conducted have a fully functioning Institutional Animal Care and Use Committee (IACUC) to ensure compliance with animal welfare standards. The Committee also provided $400,000 to APHIS to conduct inspections consistent with the AWA at each ARS facility that uses animals in research. We request a continuation in fiscal year 2017 of that $400,000 to APHIS, as well as a renewed requirement for a fully functioning IACUC at each ARS facility where animal research is conducted, along with the following bill language: "Provided further, That the Animal and Plant Health Inspection Service and Agricultural Research Service shall work together to ensure an effective animal welfare inspection program for ARS facilities and ensure that these facilities are in full compliance with the Animal Welfare Act."

USDA–FSIS—HUMANE METHODS OF SLAUGHTER ACT ENFORCEMENT

USDA allots an extremely small portion of its resources to Humane Methods of Slaughter Act (HMSA) enforcement. In fiscal year 2015, for instance, only 2.6 percent of all FSIS verification procedures were performed for activities related to humane handling and slaughter. Uneven enforcement among districts, repeat violators, and inadequate training and humane slaughter expertise among inspectors remain serious problems. The problems of inadequate and inconsistent enforcement can be resolved by increasing the number and qualifications of personnel assigned to humane handling and slaughter duties. We request that no fewer than 160 full-time equivalent positions be dedicated to inspections and HMSA enforcement. In addition, a minimum of two District Veterinary Medical Specialists should be assigned per district to provide for increased auditing and training to help uncover problems before they result in egregious humane handling incidents.

USDA–FSIS—HORSE SLAUGHTER FACILITY INSPECTIONS

For years, Congress has approved language to prevent the use of tax dollars to fund horse slaughter facility inspections. This language is critical to protect horses, taxpayers, communities and public health. We strongly support the continued inclusion of this prohibition in fiscal year 2017.

[This statement was submitted by Christopher J. Heyde, Deputy Director, Government and Legal Affairs.]

PREPARED STATEMENT OF CATHOLIC RELIEF SERVICES

Catholic Relief Services (CRS) requests a minimum of $1.716 billion in fiscal year 2017 appropriations for the Food for Peace program, and of this urges $375 million be designated for non-emergency development programs. CRS also requests $201 million for the McGovern-Dole Food for Education program, and $80 million for the USDA Local and Regional Procurement program.

CRS AND THE U.S. CATHOLIC CHURCH

CRS is the international relief and development agency of the U.S. Catholic Church. We are one of the largest implementers of U.S. funded foreign assistance. Our work reaches millions of poor and vulnerable people in over 100 countries. CRS works with people and communities based on need, without regard to race, creed, or nationality. CRS often partners with the local Catholic Church within the countries we operate in. This engenders substantial trust in us by local populations and gives us an expansive reach no other aid organization can duplicate.

FOOD FOR PEACE—AGILE, RESPONSIVE, AND IMPACTFUL

The Food for Peace (FFP) program is the flagship international food aid program of the US government. It provides funding for emergency food aid programs that assist communities in acute need and funds long-term development programs to address underlying causes of hunger, both of which CRS currently implements. FFP programs are subject to comprehensive reporting requirements and are targeted to meet specific and measurable goals. More importantly though, FFP directs resources to the most vulnerable people and communities. As such, few other US foreign assistance resources are as important for poverty alleviation and saving lives. The following provides a brief snapshot of the critical work that CRS accomplishes in its FFP-funded projects.

ETHIOPIA—JOINT EMERGENCY OPERATION

Ethiopia, a country with over 90 million people, has been particularly hard hit by the El Nino weather phenomena, leading to the most severe drought the country has faced in decades. About 80 percent of Ethiopia's population are subsistence farmers and 95 percent of farms are rain-fed. Due to El Nino, some regions have not seen rain in over a year, leading to steep declines in crop yields and hundreds of thousands of livestock deaths. Presently, over 10 million Ethiopians are in need of emergency food assistance. Further, while there are expectations that rains will return to dry areas during this year's rainy season (July-September), it is also projected that emergency conditions will persist in drought effected areas through at least September 2016 (see Chart 1).

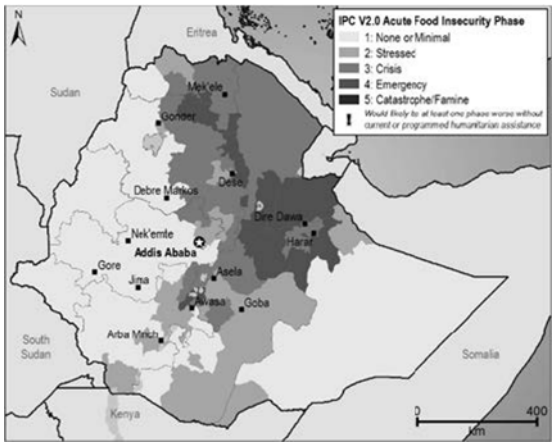

Chart 1—Projected Food Insecurity Levels, Ethiopia, June-Sept 2016. Source: FEWS Net.

Catholic Relief Services manages the Joint Emergency Operation (JEOP), an emergency food aid program funded by FFP. JEOP is implemented through a consortium of international and national NGOs. Its current operational service area includes 76 woredas (counties). Activities are coordinated with the Government of Ethiopia (GoE) and the World Food Program (WFP). In addition to the emergency food distributions targeting the most vulnerable, the JEOP has implemented a Behavior Change Communication strategy to improve nutrition for children, supported the formation of savings and internal lending communities (i.e., microfinance), and has trained community members to regularly provide information on food security indicators that feed into national food security warning systems.

With the onset of the El Nino-driven drought, JEOP has ramped up food distribution operations (see Chart 2). By December 2015, JEOP served almost 2.6 million beneficiaries throughout Ethiopia. Beneficiaries generally receive a ration of wheat or sorghum, yellow split peas and vegetable oil, sourced largely from the United States. JEOP also provides Corn Soy Blend+ and vegetable oil to organizations implementing emergency supplementary feeding. Between September 2015 and January 2016, Food for Peace has supplied the JEOP with three separate commitments for commodities totaling over 360,000 metric tons.

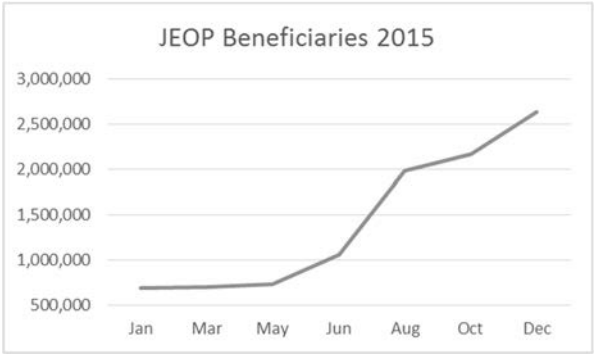

Chart 2—JEOP Beneficiary level 2015.

The JEOP has provided much needed stability for millions of Ethiopians at a critical time. During this same period the GoE and WFP have devoted significant resources to address the country's acute food emergency needs. While the world community has come up short in answering GoE and WFP's calls for additional funding, the U.S., primarily through the JEOP, has remained steadfast in its support to Ethiopia. Despite overall resource constraints, the worst case scenario has thus far been avoided in Ethiopia, thanks in no small measure to the JEOP. Many Ethiopians are alive today thanks to this program. The JEOP presently has enough resources to continue operations through July 2016, and we expect FFP to continue to help Ethiopia get over this hurdle.

SOUTH SUDAN—JONGLEI FOOD SECURITY PROGRAM

South Sudan, bordering Ethiopia to the southwest, is the newest country in the world, having secured independence from Sudan in 2011. To support the new country, USAID awarded Catholic Relief Services funding for a multi-year FFP development program, the Jonglei Food Security Program (JFSP). Operating in Jonglei State, the largest and most populous state in South Sudan, the program was to address root causes of food insecurity through food for work programs to build community assets and support for small farmers, among other things. However, in 2013 the country was plunged into a civil war.

Jonglei was one of the epicenters of the conflict. The ensuing insecurity prevented CRS from continuing JFSP development activities and ultimately damaged or destroyed much of the community assets and farming improvements made through the program. Fleeing for their safety, many residents of Jonglei state left their homes for the safety of camps both inside South Sudan and in neighboring countries. Given the radically different nature of the needs in Jonglei, CRS worked with the Office of Food for Peace to convert JFSP into an emergency response program. From 2014–2015, JFSP funding was used to provide emergency food assistance to nearly 140,000 people. Some areas in need were impossible to reach by land because of the fighting. Partnering with WFP, food supplies were airlifted into remote areas of Jonglei to CRS staff, who then continued emergency food distributions to those hardest hit.

In August 2015, government and opposition forces signed a peace agreement. While fighting continues in some places in the country, the peace has largely held in Jonglei State and staff and officials on the ground credit JFSP in part. The calm has allowed resumption of development activities in some areas, and relief convoys to enter other regions for the first time in over 2 years. Most people and officials in these areas did not believe aid convoys would be allowed in. When convoys began arriving earlier this year, they were met by people cheering and dancing. One local official commented that "this is not food for work but food for hope." Our staff noted

that "at least in Jonglei, the food convoys have brought a feeling that real peace might be feasible." We have already seen a number of internally displaced people coming back to Jonglei, and it is our expectation that continued engagement through JFSP will direct most people's energy and focus back to preparing for the planting season instead of fighting.

Building a dike through Food for Work in South Sudan

MALAWI—WELLNESS AND AGRICULTURE FOR LIFE ADVANCEMENT

In 2014, CRS completed Wellness and Agriculture for Life Advancement (WALA), a five-year development Food for Peace project in Malawi. As with most Food for Peace development projects, WALA took a multi-sectoral approach to food security. The project included helping farmers adopt new and better techniques and technology, connecting them to markets, addressing the nutritional needs of young children and expecting mothers, providing better access to water for agriculture and hygiene, helping communities build productive assets, and among other interventions. While most program success indicators showed strong results, one standout area was in watershed rehabilitation and management.

Heavy rains characterize the wet season in Malawi. Communities targeted by WALA are prone to soil erosion from rushing water running off their land during these rains. In the lean season, many water sources for these communities would dry up and most small farmers could not produce enough food over the year to get them through this period. Given these circumstance, through food for work, WALA introduced a number of communities to techniques, like water absorption trenches, that slow and reduce run off and help water percolate into the soil. Check damns were constructed in areas where run-off had formed gullies. Native cover crops, grasses, and trees were introduced in key areas of farm land to help with soil retention and to improve nutrient content.

The results of these efforts have been dramatic. The water table has risen, resulting in more water availability in wells. Wells and streams that would dry up during the lean season now flow year round. Water clarity in streams has increased also. Over just one or 2 years, check damns have filled gullies, helping farmers reclaim farmland. With more moisture and nutrients in the soil, and more land to cultivate, agricultural yields have increased. Neighboring communities not in the WALA program noted these successes and on their own adopted the knowledge and techniques used in WALA.

These programs demonstrate huge successes—addressing the acute needs of people griped by severe drought in Ethiopia, being able to shift between emergency and development work as needs change and to capitalize on opportunities for peace in South Sudan, and in making a foundation for a better life more resilient life for people in Malawi. Unfortunately, needs are expanding. The world is seeing more people being impacted by shocks like conflict and weather patterns like El Nino, and potentially La Nina later in the year. The funding requested for FFP, $1.716 billion, will be critical for the US to respond to the growing emergency needs around the world. Further, directing more than the minimum level of funding to FFP development programs will help more communities get ahead, so that when shocks to strike, they are better prepared to meet their own needs.

MCGOVERN-DOLE AND USDA LRP

McGovern-Dole Food for Education programs provide food for school lunch programs. In many cases, the lunch provided through McGovern-Dole is the only meal children receive all day. Parents who would not otherwise send their children to school are motivated to do so because they know their children will be fed. This has been especially true for girls, whose education is not traditionally encouraged in many parts of the world. Catholic Relief Services currently implements five McGovern-Dole programs. In addition to school feeding, we also use McGovern-Dole resources to strengthen teacher training and to make improvements to schools.

The USDA Local and Regional Procurement (LRP) program, made permanent by the 2014 Farm Bill, is intended to be used in conjunction with McGovern-Dole programming and we view it as critical to the sustainability of school lunch programs. Specifically, we believe these funds can be used to establish the systems needed to source food used in school lunches from local farmers. This will entail helping these farmer grow the quality and quantity needed for school lunches and organizing parent groups to manage school canteens. Ultimately, once these systems are in place, local governments can assume responsibility for these programs.

IMPROVING FOOD AID

Catholic Relief Services supports several improvements to the current food aid system, including the phasing out of requirements to monetize food aid commodities, reducing the burden of agricultural cargo preferences on food aid, and giving implementers greater flexibility to determine how food aid resources are used. We refer you to testimony Catholic Relief Services submitted to the Senate Foreign Relations Committee in April 2015 and the House Agriculture Committee in September 2015 for more details concerning these improvements.

[This statement was submitted by Dr. Carolyn Woo, President and Chief Executive Officer.]

PREPARED STATEMENT OF UNITED STATES CONFERENCE OF CATHOLIC BISHOPS

On behalf of the United States Conference of Catholic Bishops' Committees on Domestic Justice and Human Development and International Justice and Peace, Catholic Charities USA, Catholic Relief Services and Catholic Rural Life, we wish to address the moral and human dimensions of fiscal year 2017 Agriculture Appropriations. We urge you to support robust funding for both domestic and international food aid, and for conservation and rural development programs, and to resist cuts to them. Many of these program areas have already been subject to reductions. Further cuts would be harmful to vulnerable people and communities.

In For I Was Hungry and You Gave Me Food, the U.S. bishops wrote, "The primary goals of agricultural policies should be providing food for all people and reducing poverty among farmers and farm workers in this country and abroad." Adequate nutrition is essential to protect human life and dignity. We must also promote good stewardship of the land and natural resources. In our soup kitchens and parish food pantries, we see the faces of poor and hungry people every day. As a faith community, we feed those without work, pregnant women and children, and seniors on limited incomes.

We acknowledge the difficult challenges Congress and the Administration face to match scarce resources with real needs. But a just spending bill cannot rely on disproportionate cuts in essential services to poor and vulnerable people.

The nation continues to see historic levels of food insecurity that have persisted well beyond the end of the Great Recession, and this reality is confirmed by the experience of our food banks, pantries, and congregate meal sites. Catholic Charities agencies continue to provide food services well above pre-recession levels, with agencies reporting 10.4 million food services delivered to clients, a 64 percent increase from 2007. Despite our increased efforts, more than 48 million Americans (nearly 1 in 6) live in food insecure households. With this reality, our nation must prioritize programs that assist poor and hungry people and promote good stewardship. In addition to refraining from making cuts that impact programs like SNAP, which provide greater levels of food security to millions of people, it is vital to provide robust funding for the following programs:

WIC.—Fund the Women, Infants, and Children nutrition program at $6.37 billion to ensure that all qualified families receive vital nutritional support, investments are made in technology to improve program operations, and sufficient reserves are built to prepare for economic volatility. In particular, we urge investment of $75 mil-

lion in management information systems and technology to assist with the transition to electronic benefit transfer (EBT) systems to help streamline operations.

TEFAP.—Provide full funding levels as required by the 2014 Farm Bill for the Emergency Food Assistance Program and food distribution grants in local communities. Cuts to the program could force some of our parishes and other charities and food pantries to turn away hungry people when they continue to need our help.

CSFP.—Fund the Commodity Supplemental Food Program at $236 million to ensure adequate food assistance is provided to the growing population of low-income seniors. Faith communities and other charities are essential in providing food packages to hungry seniors in their local communities and, as the population continues to age, our ministries are experiencing increasing demand for food services from seniors that must be addressed.

CSP.—Provide adequate funding for the Conservation Stewardship Program to help farmers better conserve and care for farm land for future generations. Strong conservation programs are necessary to promote good stewardship of creation and provide needed support to family farms.

VAPG.—Maintain current funding for the Value Added Producer Grants program to help farmers and ranchers develop new farm and food-related businesses to increase rural economic opportunity and help farm and ranch families thrive.

We also ask you to prioritize international food security programs. With an estimated 805 million people chronically undernourished globally (UN–FAO), our nation must support:

International Food Assistance.—The Administration has proposed funding Food for Peace at $1.35 billion in fiscal year 2017, $350 million less than what Congress appropriated in fiscal year 2016. Food for Peace provides emergency assistance to people in crises, and is essential to the U.S. response to civil strife around the world as well as to the severe drought in many countries brought on by El Niño. Now is not the time to make drastic cuts to this program. We ask Congress to maintain Food for Peace funding at $1.716 billion for fiscal year 2017. Similarly, we encourage Congress to reverse the Administration's proposed cut to school feeding and maintain funding for the McGovern-Dole program at $201.6 million in fiscal year 2017.

Developmental Food Aid.—Congress must protect and direct an adequate amount of Food for Peace funding to development food assistance programs. These programs build resilience, strengthen agricultural capacity, and improve livelihoods for the most vulnerable, reducing the need to provide future emergency assistance. Pursuant to the 2014 Farm Bill, a minimum of $350 million of Food for Peace resources must be used in development programs, but more may be directed for this purpose. We request that Congress direct a total of $375 million of Food for Peace resources to development purposes, and that USAID have the flexibility to use Development Assistance resources to reach part of this total.

Reforms to Food Aid System.—A key reform in the 2014 Farm Bill is the USDA Local and Regional Procurement program, to be implemented in conjunction with McGovern-Dole, which will help responsibly transition school feeding programs to local governments. We request that the full authorized level of $80 million be provided to the USDA LRP program. Further, we support making food aid programs like Food for Peace more efficient by allowing them to use local and regional procurement when appropriate to local circumstances and efficiency gains should also be reinvested in programs to expand their reach and not used to justify funding cuts. We also encourage Congress to explore changes to agricultural cargo preferences to reduce costs to food aid programs, as a means to achieve greater efficiencies.

At a time of continuing budgetary constraints and competition for agricultural resources, the needs of those who are hungry, poor and vulnerable should come before assistance to those who are relatively well off. With other Christian leaders, we urge the committee to draw a "circle of protection" around programs that serve those in greatest need and to prioritize their needs first. We urge you to protect and fund programs that feed hungry people, help the most vulnerable farmers, strengthen rural communities and promote good stewardship of God's creation.

Most Reverend Thomas G. Wenski
Archbishop of Miami
Chairman, Committee on Domestic Justice and Human Development

Most Reverend Oscar Cantú
Bishop of Las Cruces
Chairman, Committee on International Justice and Peace

Sr. Donna Markham, OP, Ph.D.
President & CEO
Catholic Charities USA

Dr. Carolyn Y. Woo
President
Catholic Relief Services

Mr. James Ennis
Executive Director
National Catholic Rural Life

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 at least $15.2 million from the U.S. Department of Agriculture's Environmental Quality Incentive Program Financial Assistance (EQIP FA) for the Colorado River Basin Salinity Control Program in the fiscal year 2017 Appropriation bill. Funding for the salinity control program 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.

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 an average of more than 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 CAP 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 million 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 damages at about $382 million per year. Modeling by Reclamation indicates that damages will rise to approximately $614 million per year by the year 2035 without continuation of the Program. These damages include:

—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.

Funding for salinity control will prevent the water quality of the Colorado River from further degradation and significant increases in economic damages to municipal, industrial and irrigation users.

HISTORY OF THE USDA'S COLORADO RIVER BASIN SALINITY CONTROL PROGRAM

Recognizing the rapidly increasing salinity concentration in the Lower Colorado River and its impact on water users, Arizona joined with the other Colorado River Basin States in 1973 and organized the Colorado River Basin Salinity Control Forum (Forum). In 1974, the Forum worked with Congress in the passage of the Colorado River Basin Salinity Control Act (Act) to offset increased damages caused by continued development and use of the waters of the Colorado River.

In implementing the Act, Congress directed that the Colorado River Basin Salinity Control Program should be implemented in the most cost-effective way. The Program at the United States Department of Agriculture is currently funded under the Environmental Quality Incentives Program (EQIP) of the Natural Resources Conservation Service (NRCS) and under Reclamation's Basinwide Program.

Congress authorized a salinity control program (Program) for the United States Department of Agriculture (USDA) through an amendment of the Act in 1984. With the enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA), Congress directed that the Program should continue to be implemented as part of the newly created EQIP. Since the enactment of the Farm Security and Rural Investment Act (FSRIA) in 2002, 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). The FCEA addressed the cost sharing required from the Basin Funds. In so doing, the FCEA named the cost sharing requirement as the Basin States Program (BSP). The BSP will provide 30 percent of the total amount that will be spent each year by the combined EQIP and BSP effort. With the passage of the Agricultural Act of 2014 the authorities for USDA to implement salinity control activities in the Colorado River Basin were 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. The mix of funding under EQIP, cost sharing from the Basin States and efforts, and cost sharing brought forward by local producers have created a most remarkable and successful partnership.

The threat of salinity continues to be a concern in both the United States and Mexico. In 2012, a five-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 salinity standards. The CAWCD and other key water providers are committed to meeting these goals.

CONCLUSION

Implementation of salinity control practices through EQIP has proven to be a very cost-effective method of controlling the salinity of the Colorado River. CAWCD urges the subcommittee to include at least $15.2 million from the USDA's Environmental Quality Incentive Program Financial Assistance for the Colorado River Basin Salinity Control Program in the fiscal year 2017 Appropriation bill. Additionally, there is needed sufficient Technical Assistance dollars to adequately implement the program. Continuation of EQIP at the requested 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 Theodore C. Cooke, General Manager, Central Arizona Project.]

PREPARED STATEMENT OF CENTER FOR PROGRESSIVE REFORM

A national network of advocates including Oxfam America, the National Employment Law Project, and Nebraska Appleseed have called your attention to the dangerous conditions that workers face in poultry slaughter facilities, owing to the speed with which young chickens and turkeys are processed. The stories presented in their testimonies and comments, along with the data they have provided, should be enough to warrant rejection of any proposal to allow line speeds to increase at those facilities through the appropriations process as it relates to the Food Safety Inspection Service's New Poultry Inspection System.

These comments approach the issue from a slightly different perspective, but arrive at the same conclusion: using the appropriations process to increase line speeds at poultry slaughter facilities violates principles of good government and will cause lasting damage to workers, their families, and their communities.

On both sides of the aisle, Members of Congress for years have derided the use of "earmarks" to direct government spending toward favored projects and policies. As explained below, such derision should apply with greater force to the abuse of the appropriations process to direct spending away from projects and policies that are opposed by a determined minority of members of Congress. Such actions upend the normal legislative process and entrench a system of policymaking that undermines core principles of representative democracy. Last summer, the Center for Progressive Reform published a report on the misuse of appropriations riders to direct agency policymaking.[1] The report's length precludes inclusion in these comments, per the committee's rules, but its key findings are worth noting here:

—Prohibiting agencies from taking actions disfavored by the rider's sponsors is legislating by extortion

Appropriations bills offer ideal vehicles for the use of extortionate riders, because they must be enacted on an ongoing and periodic basis or else the government will cease functioning. As the deadline for completing appropriations bills approaches, the leverage that proponents of particular riders wield to coerce acquiescence in their demands grows greater. With the threat of government shutdown looming, other legislators will feel increasingly compelled to vote in favor of the bill even though they are opposed to a particular rider and would not support it as a stand-alone measure. Similarly, the president may find it difficult to veto an appropriations bill simply because of the antiregulatory riders it contains.

—Negative riders enable secret sabotage of popular safeguards

In contrast to the procedures that govern traditional authorizing legislation, a distinct lack of transparency and accountability marks the appropriations process. In particular, the process of adding riders to appropriations bills is clouded in secrecy, which can make it nearly impossible for the public to hold legislators accountable for sponsoring especially controversial proposals. Because antiregulatory riders are often buried in appropriations bills that run hundreds of pages in length, it is easy for them to slip past the scrutiny of concerned citizens and lawmakers. These bills thus offer the proponents of antiregulatory riders an ideal opportunity to conceal their attacks on popular protections.

The caps on poultry slaughter line speeds, for instance, were a major point of contention when the Department of Agriculture's Food Safety Inspection Service (FSIS) developed the New Poultry Inspection System. The rulemaking process that FSIS followed, rooted in the Administrative Procedure Act, ensured that the final safeguards reflected the views of stakeholders ranging from workers to experts from the Department of Labor's Occupational Safety and Health Administration. No such process for engaging experts, much less the workers who would be affected by a line-speed increase, is in place here.

—Riders lobotomize the deliberative process that should govern lawmaking

The use of antiregulatory riders also enables lawmakers to engage in a powerful form of substantive policymaking but without the due deliberation that normally accompanies the enactment of authorizing legislation. Broadly speaking, Congress divides the labor of preparing bills for full consideration between the authorization committees—which are responsible for considering substantive legislation creating, modifying, or eliminating Federal

[1] "Earmarking Away the Public Interest: How Congressional Republicans Use Antiregulatory Appropriations Riders to Benefit Powerful Polluting Industries" by CPR Member Scholars Thomas McGarity and Richard Murphy, and CPR Senior Policy Analyst James Goodwin (July 2015), available at http://progressivereform.org/articles/Anti-Reg__Riders__1503.pdf.

programs—and the budget and appropriations committees—which are responsible for funding authorized programs. The institutional design and processes of authorization committees renders them far more suitable to engage in substantive policymaking. Antiregulatory riders generally do not receive anywhere near the same level of deliberative consideration from appropriations committees that usually takes place in authorization committees for the provisions of substantive legislation.

—Antiregulatory riders encourage pandering to corporate interests
Because they are adopted with little transparency or deliberation, antiregulatory riders are uniquely well designed to provide individual lawmakers with the ability to confer benefits on favored special interests. Much like traditional earmarks, which Congress has effectively banned, antiregulatory riders are thus highly susceptible to abuse by Members of Congress looking for an easy way to curry favor with politically powerful businesses or industries.

Thank you for the opportunity to provide these comments.

[This statement was submitted by Matthew Shudtz, Executive Director, Center for Progressive Reform.]

PREPARED STATEMENT OF CHOOSE CLEAN WATER COALITION

The undersigned members of the Choose Clean Water Coalition request continued support for clean water in the Chesapeake Bay watershed through the Agricultural Act of 2014 (2014 Farm Bill) conservation programs. There are 87,000 farms in the six-State Chesapeake region; those that are well run protect their water resources and add much to our landscape, environment and economy. We want to ensure that these responsible farms and farmers remain economically viable. Stopping cuts to these conservation programs is critical to maintain and restore clean water to the rivers and streams throughout the Chesapeake Bay region, and for the Bay itself. These programs are essential for regulated agricultural operations to meet Federal regulations under the Clean Water Act and help farmers meet state regulations that address both farm health and water quality.

We urge you to maintain full funding for mandatory agricultural conservation programs in fiscal year 2017. The 2014 Farm Bill set us on a new path toward clean water in our region, but only if key conservation programs are funded as Congress intended. With the support of much of the conservation community and clean water advocates, the 2014 Farm Bill eliminated nearly a dozen conservation programs (including the Chesapeake Bay Watershed Initiative) and reduced mandatory funding overall to save American taxpayers approximately $6 billion.

Two-thirds of the 18 million people in the Chesapeake region get their drinking water directly from the rivers and streams that flow through the cities, towns and farms throughout our six State, 64,000 square mile watershed. The quality of this water is critical to both human health and to the regional economy. Much of the work and funding necessary to achieve and maintain clean and healthy water in this region would be accomplished through the Farm Bill's new Regional Conservation Partnership Program (RCPP). The President's fiscal year 2017 budget proposes full funding for mandatory conservation programs that are critical to maintaining a fully funded RCPP. In particular, we urge you to fund the Environmental Quality Incentives Program at $1.65 billion to help willing producers implement conservation practices on their farms.

In May 2014, the Chesapeake Bay Watershed was designated as one of eight Critical Conservation Areas under the new RCPP. For the first 3 years of RCPP funding, the Chesapeake received $27.6 million, with a few million more going to other projects partially in the Chesapeake Bay watershed. This is a precipitous drop from the Chesapeake Bay Watershed Initiative where our region's producers received $47.6 million annually for conservation practices. This is a huge shortfall for conservation in our region and any further cuts to the RCPP will exacerbate this funding drop off. We urge you to maintain the 2014 Farm Bill's negotiated mandatory funding levels for all conservation programs, including the RCPP.

In order to follow a common sense path to maintain economically viable well run farms and to have healthy local water and a restored Chesapeake Bay, which is critical for our regional economy, we request full funding for all conservation programs in the Farm Bill for fiscal year 2017.

Thank you for your consideration on this very important request to maintain funding for these programs which are critical to both our agricultural community and for clean water throughout the mid-Atlantic region.

American Rivers
Anacostia Watershed Society
Audubon Naturalist Society
Blue Heron Environmental Network Inc.
Blue Ridge Watershed Coalition
Blue Water Baltimore
Cecil Land Use Association
Chapman Forest Foundation
Chesapeake Bay Foundation
Chesapeake Wildlife Heritage
Citizens for Pennsylvania's Future
Clean Water Action
Coalition for Smarter Growth
Conservation Pennsylvania
Conservation Voters of Pennsylvania
Delaware Nature Society
Earth Forum of Howard County
Eastern Pennsylvania Coalition for Abandoned Mine Reclamation
Environment America
Environment Maryland
Environment Virginia
Friends of Accotink Creek
Friends of Dyke Marsh
Friends of the North Fork of the Shenandoah River
Green Muslims
Interfaith Partners for the Chesapeake
Izaak Walton League of America
James River Association
Lackawanna River Conservation Association
Lynnhaven River NOW
Maryland Conservation Council
Maryland League of Conservation Voters
Mattawoman Watershed Society
Mehoopany Creek Watershed Association
National Aquarium
National Parks Conservation Association
National Wildlife Federation
Natural Resources Defense Council
Nature Abounds
Otsego County Conservation Association
Otsego Land Trust
PennEnvironment
Pennsylvania Council of Churches
Piedmont Environmental Council
Potomac Conservancy
Potomac Riverkeeper
Potomac Riverkeeper Network
Rivanna Conservation Society
Rock Creek Conservancy
Sassafras River Association
Savage River Watershed Association
Shenandoah Riverkeeper
Shenandoah Valley Network
Sidney Center Improvement Group
Sierra Club—Maryland
Sierra Club—Pennsylvania
Sierra Club—Virginia
Sleepy Creek Watershed Association
South River Federation
St. Mary's River Watershed
Stewards of the Lower Susquehanna
Trout Unlimited
Upper Potomac Riverkeeper
Upper Susquehanna Coalition
Virginia Conservation Network
Virginia League of Conservation Voters
Water Defense
West & Rhode Riverkeeper
West Virginia Rivers Coalition

[This statement was submitted by Peter J. Marx, Federal Affairs, Choose Clean Water Coalition.]

PREPARED STATEMENT OF 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 man-induced salt loading to the Colorado River creates environmental and economic damages. The U.S. Bureau of Reclamation (Reclamation) has estimated the currently quantifiable damages at about $382 million per year. Modeling by Reclamation indicates that the quantifiable damages will rise to approximately $614 million per year by the year 2035 without continuation of the Program. 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 $15.2 million in EQIP FA in 2017 is in keeping with the Program's Plan of Implementation and is required to prevent further degradation of the quality of the Colorado River and increases in downstream economic damages.

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 the most cost-effective way. The Program is currently fundedunder EQIP through NRCS and under Reclamation's Basinwide Program. The Act requires that the Basin States cost share 30 percent of the overall effort. Historically, recognizing that agricultural on-farm improvements were some of the most cost-effective strategies, Congress authorized a program for the United States Department of Agriculture (USDA) through amendment of the Act in 1984. With the enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA), Congress di-

rected that the Program should continue to be implemented as part of the newly created Environmental Quality Incentives Program. Since the enactment of the Farm Security and Rural Investment Act (FSRIA) in 2002, 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). The FCEA addressed the cost sharing required from the Basin Funds. In so doing, the FCEA named the cost sharing requirement as the Basin States Program (BSP). The BSP will provide 30 percent of the total amount that will be spent each year by the combined EQIP and BSP effort. With the passage of the Agricultural Act of 2014 the authorities for USDA to implement salinity control activities in the Colorado River Basin were 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. 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.

After longstanding urgings from the States and directives from Congress, NRCS has recognized that this Program is different than 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 Forum supports this funding plan which recognizes the need for $15.2 million in EQIP FA allocations in fiscal year 2017. Additionally, there is needed sufficient 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.

The 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 every 3 years. 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 the higher salinity concentrations in the water will be more widespread in the United States and Mexico.

Concentration of salt in the Colorado River causes approximately $382 million annually in quantified damages and significantly more in unquantified damages in the United States and results in poor water quality for United States users. Damages occur from:

—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;
—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 an increase in sewer fees in the industrial 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.

Over the years, NRCS personnel have developed a great 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 and design 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 will prevent the water quality of the Colorado River from further degradation and significantly increased economic damages to municipal, industrial and irrigation users.

[Testimony Submitted by Don A. Barnett, Executive Director, Colorado River Basin Salinity Control Forum.]

PREPARED STATEMENT OF COLORADO RIVER BOARD OF CALIFORNIA

This testimony is in support of fiscal year (FY) 2017 funding for the Department of Agriculture (USDA) associated with the activity that assists Title II of the Colorado River Basin Salinity Control Act of 1974 (Public Law 93–320). 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 $15.2 million in EQIP Financial Assistance (FA) annually is required to prevent further degradation of the quality of the Colorado River and increased downstream economic damages.

The Colorado River Board of California (Colorado River 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 2014 Plan of Implementation. The Forum's 2014 Plan of Implementation can be found on this website: http://coloradoriversalinity.org/docs/2014%20Final%20REVIEW%20-%20complete.pdf. If adequate funds are not appropriated, significant damages associated with increasing salinity concentrations of Colorado River water will become more widespread in the United States and Mexico.

The Program benefits both the Upper Basin water users through more efficient water management and the 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, lower fertilizer 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.

After longstanding urgings from the states and directives from Congress, NRCS recognized that this Program is different than 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 headwater 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 three-year funding plan for the salinity efforts under EQIP. The Colorado River Board supports this funding plan which recognizes the need for $15.2 million in EQIP FA allocations in fiscal year 2017. Additionally, there is needed sufficient Technical Assistance dollars to adequately implement the program.

Over the thirty-two years since the passage of the Colorado River Basin Salinity Control Act, much has been learned about the impact of salts in the Colorado River system. Currently, the salinity concentration of Colorado River water causes about $382 million in quantifiable damages in the United States annually. Economic and hydrologic modeling by Reclamation indicates that the quantifiable damages could rise to more than $614 million by the year 2035 without the continuation of the Salinity Control Program. For example, damages can be incurred related to the following activities:

—a reduction in the yield of salt sensitive crops and increased water use to meet the leaching requirements in the agricultural sector,
—increased in the amount of imported water,
—an increased 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 an increase in sewer fees in the industrial sector,
—a decrease in the life of treatment facilities and pipelines in the utility sector,
—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 of 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 an effective salinity control program will avoid the additional economic damages to users in California and the other states that rely on Colorado River water resources.

[This statement was submitted by Tanya Trujillo, Executive Director, Colorado River Board of California.]

PREPARED STATEMENT OF CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation and the approximately 30,000 people with cystic fibrosis (CF) in the United States, we are pleased to submit the following testimony to the Senate Appropriations Committee's Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for fiscal year 2017. In order to encourage efficient review of drugs for cystic fibrosis and other rare diseases, we urge the Committee to prioritize the Food and Drug Administration (FDA) by providing at least $2.85 billion in fiscal year 2017. We encourage special consideration and support for the Center for Drug Evaluation and Research (CDER), its Office of New Drugs (OND), and the Office of Orphan Products Development (OOPD).

Drug approvals by the FDA reached an 18 year high in 2014, and more than 400 rare disease drugs and biologics have been approved in the last 30 years. As the agency's responsibilities continue to grow and we enter an unprecedented era of innovation in drug development for rare diseases, even more needs to be done.

Cystic fibrosis is a rare genetic disease that causes the body to produce thick mucus that clogs the lungs and other bodily systems, resulting in life-threatening infections and other complications. There are nearly 2,000 mutations of the CF gene that can impact those with CF, and with the advent of precision medicine, therapies are being customized to treat a patient's specific genetic makeup.

As this new concept in drug development quickly becomes a reality, it opens the door for the advancement of new targeted therapies in many important areas of medicine, including cancer and rare diseases like CF.

There are currently two therapies that have been approved to treat the underlying cause of CF in more than 30 percent of those with the disease. One such therapy, Kalydeco, was approved in 2012 to treat 4 percent of patients with CF based on their underlying CF-causing mutation. The approval was subsequently expanded to treat 8 percent of those with the disease soon after. Kalydeco's initial review time was 3 months, one of the fastest in the FDA's history. A second targeted therapy, Orkambi, was approved in 2015 to treat the most common mutation that causes cystic fibrosis. Orkambi was the first drug to receive the FDA's breakthrough therapy designation, and it underwent a six-month expedited review.

This success is a testament to what can be achieved when stakeholders collaborate across sectors to ensure a swift review of critical drugs for patients. Throughout the review processes for Kalydeco and Orkambi, the Cystic Fibrosis Foundation and renowned CF experts worked closely with the drugs' sponsor Vertex Pharmaceuticals and the FDA to provide valuable insight on specific issues related to CF, clinical research on CF treatments, and other issues related to the product and its review. We believe that the collaboration and efficiency displayed throughout these trials can serve as a model for best practices in clinical trials for rare diseases.

Since its creation, the Breakthrough Therapy Designation at the FDA has been widely successful at accelerating the approval of new treatments that demonstrate substantial improvement over existing medications. Cystic fibrosis treatments were the first designated as breakthrough therapies, and the process has effectively increased efficiency and communication between the FDA and drug sponsors. Unsurprisingly, sponsor requests for the Breakthrough Therapy Designation have increased dramatically since the program's inception in 2012. In the program's first 2 years alone, CDER received more than 200 requests for breakthrough designation, and more than half of the therapies that were granted an expedited review through this program were for rare or orphan diseases, like cystic fibrosis. Sponsor requests for breakthrough therapy designation are expected to increase further in the coming years, and expanded funding and support for this program is critical to ensure that new breakthrough therapies receive an efficient yet rigorous review.

As new, more advanced personalized treatments like Kalydeco and Orkambi move through the pipeline, it is critical that the FDA has the resources necessary to further develop innovative methods for reviewing and evaluating the safety and efficacy of targeted therapies. The CF Foundation has significantly expanded its research investments with leading companies to accelerate the discovery and development of new genetically-targeted treatments. The Foundation is supporting 45 studies in 2016, including examination of several new targeted therapies. One series of studies planned for 2016 has the potential to treat the underlying cause of the disease in more than 85 percent of those with CF. It is crucial that the FDA have sufficient funding to provide a swift and efficient review of new treatments for rare, life threatening conditions, where there is an urgent need for new, targeted therapies.

A number of clinical trial design issues have been identified that may arise in review of rare and precision medicine therapies. As precision medicine continues to develop, robust funding is particularly crucial as the FDA will need to find new, innovative ways to handle unprecedented challenges in drug development and review.

For example, recruiting sufficient numbers of participants to support a classic clinical trial design for a rare disease population is often not possible, simply because there is a smaller pool of patients. This issue becomes even more significant with the advent of precision medicine as therapies become targeted to smaller populations based on unique genetic mutations within the CF population. As potential new therapies come under review, it may be necessary to test combinations of drugs in populations that include patients with several different CF mutations and develop and test single and combination therapies in n of 1 trials (those that consist of a single patient). The FDA needs adequate funding to develop new regulatory pathways and approaches to handling variations in trial design that both maintain safety and efficacy standards while facilitating the development of treatments for patients with rare diseases.

Researchers and clinicians are also concerned about the challenges inherent in executing placebo-controlled trials for genetically-targeted treatments when successful, genetically-targeted drugs are already approved and on the market. In addition to the ethical question of asking trial participants to suspend their use of the best available therapies, there is also a concern that such a request would dissuade participation in clinical trials for the next generation of targeted therapies.

As evaluating the safety and efficacy of targeted therapies becomes more challenging, there is also greater need for the use of biomarkers and the development of additional outcome measures. Biomarkers with the potential to reasonably predict clinical outcomes could play a tremendous role in accelerating drug development and review. However, the FDA needs adequate funding to accelerate classification

of biomarkers and ensure that they are being examined throughout the clinical trials process. Similarly, Patient Reported Outcomes (PROs) are a largely untapped source of valuable data and information that can help advance understanding of efficacy throughout a clinical trial. As the FDA is looking at new and innovative ways of evaluating treatments, the agency needs the resources to consider new sources of valuable data to further inform and accelerate the review process.

Overall, as drug development advances, the FDA must be supplied with the proper resources to balance the need for an efficient and rigorous review process with the flexibility required to accommodate deviations from the standard clinical trial process.

To this end, we commend the regulatory science initiative formed by the NIH and the FDA, which aims to accelerate the development and use of new approaches to evaluate drug safety, efficacy, and quality. With additional funding, the FDA will have greater ability to partner with key stakeholders to promote discussions and workshops of study designs that will maximize the progression of multiple effective and safe therapies through the development pipeline. Continued collaboration of the FDA with the NIH as well as external stakeholders offers immense promise for helping to expedite the drug development process and put safe and effective drugs in the hands of patients. However, this type of collaboration cannot move forward without adequate funding.

In addition, the CF Foundation is enthusiastic about the potential for clinical trial, clinical care, claims, and other healthcare-related data to be utilized to improve drug discovery, development, and delivery. The Foundation has been a pioneer in the development and utilization of a robust data repository through the CF patient registry, and our therapeutics development network (TDN) has successfully encouraged clinical trial partners to share data. We ask that Congress support efforts by the FDA to explore strategies and guidelines for clinical trial data sharing. As drug development research advances, data sharing is vital to the acceleration and efficiency of new discovery.

This is a time of great hope and optimism for the cystic fibrosis community and those with other rare diseases as more therapies that treat the underlying cause of CF move through the pipeline. However, the FDA faces critical challenges as targeted therapies are being brought up for review, including small patient populations and the need for greater flexibility in trial design. Additional funding to foster stakeholder collaboration to find solutions to these challenges and encourage clinical trial data sharing will help move much-needed treatments more efficiently to those who need them most.

Once again, we urge the Committee to make funding for the Food and Drug Administration a priority in fiscal year 2017 by providing at least $2.85 billion in funding for the agency through the appropriations process. The CF Foundation stands ready to work with the Committee, FDA, and Congressional leaders on the challenges ahead. Thank you for your consideration.

[This statement was submitted by Preston W. Campbell, III, MD., President and CEO, Cystic Fibrosis Foundation.]

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 requests discretionary appropriations of at least $1.884 billion in fiscal year (FY) 2017 for USDA's National Institute of Food and Agriculture (NIFA), including at least $700 million for the Agriculture and Food Research Initiative (AFRI). The Society also supports a discretionary funding level of at least $1.286 billion for the Agricultural Research Service (ARS), including funding for the ARS Crop Protection budget at a minimum of the fiscal year 2016 enacted level of $195 million to preserve valuable pest management research programs in fiscal year 2017.

The international stature of the United States as a producer and exporter of food, fiber, and other agricultural commodities has long been associated with innovation-fueled increases in productivity. Steady growth in agricultural output over the past half-century has been accompanied by substantially smaller increases in inputs1, so that today fewer farmers are producing more food, without expanding land in cultivation, at lower costs to consumers. Increased productivity has been achievable through improved technology, spurred by Federal investment in research and development. There are signs, though, that longstanding growth in productivity may be slowing, at a time when demands on the agricultural sector are steadily increasing.

Ensuring food safety, security, quality, and environmental sustainability are among today's greatest challenges to U.S. agriculture—yet the U.S. global share of public investment in agriculture and food research and development has declined significantly in the past three decades.

Cutting-edge agriculture science, including entomology, is critical to meeting these challenges. Globalized trade has led to major redistribution of pest species, from indigenous areas where they are kept in check by natural enemies to new areas where they can rapidly expand their ranges. Beyond competing directly with humans by consuming crop plants, invasive insect pests also threaten food security by acting as vectors of plant diseases. The Asian citrus psyllid, the principal vector of the invariably fatal bacterial citrus greening disease, for example, has already caused over $9 billion in losses to citrus growers in Florida alone.[1] Moreover, by outcompeting and displacing native species, invasive arthropods compromise ecosystem services provided by biotic communities, including pollination, nutrient cycling, and water regulation and purification.

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. In addition, AFRI's Education and Literacy Initiative supports more than 2,000 trainees annually that will become the next generation workforce of agricultural and food scientists. ESA appreciates the Subcommittee's efforts to increase the AFRI budget since the program's establishment and enthusiastically supports the requests for $700 million for AFRI in fiscal year 2017, the full amount authorized in the 2008 Farm Bill. ESA also supports the proposed inclusion of pollinator health as a special area of emphasis within the AFRI Foundational Program, including plans to allocate $10 million for new grants in the area of pollinator health to continue to support the government-wide initiative. America's insect pollinators contribute to the production of over 90 fruit, vegetable, nut, and fiber crops; collectively, pollination services of managed and wild pollinators in the US have been valued at more than $17 billion annually. Populations of many of these pollinators, however, have been declining even as demand for pollination services for expanding acreages of fruit, nut, and vegetable crops has increased.

To maximize its limited resources, AFRI supports projects that address key societal challenges and build foundational knowledge in high-priority areas of the food and agricultural sciences, such as food safety and food security. For example, annual honey bee colony losses due, in part, to infestation by the varroa mite have created enormous problems for U.S. beekeepers and for the growers dependent on honey bees for pollination services. Scientists funded by AFRI have used genomic resources to identify receptor targets in the nervous system unique to the mite and are designing and testing synthetic analogues of the neuropeptides that interact with those receptors for mite control, thereby sparing honey bees and other non-target species.[2] In addition to AFRI, other NIFA grants support programs to study and implement scientifically based approaches to reduced-risk integrated pest management (IPM), which has implications for human health, the environment, and the economy.

As USDA's intramural research agency, ARS funds research of broad consequence to our nation's agriculture enterprise, including in the areas of crop and livestock production and protection, human nutrition, food safety, and environmental stewardship. The ARS Crop Protection research program builds knowledge and develops approaches that are made available to crop producers, enabling better control of pest and disease outbreaks as they occur. In addition, the ARS Crop Production research program develops and approves safe and effective strategies for reducing crop loss and providing a dependable food supply. ESA supports maintaining level funding with President's fiscal year 2016 budget request, with $195 million for the Crop Protection account and $218 million for the Crop Production account. In addition to the additional funding proposed within AFRI and ARS, ESA supports USDA's participation in multi-agency activities to investigate pollinator health and develop implementation plans to prevent, slow, or reverse pollinator population decline.

ESA, headquartered in Annapolis, Maryland, is the largest organization in the world serving the professional and scientific needs of entomologists and individuals in related disciplines. Founded in 1889, ESA has over 7,000 members affiliated with educational institutions, public health agencies, private industry, government laboratories, the U.S. military, and many nonprofit organizations. Members include

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[1] National Academy of Sciences, 2014. Spurring Innovation in Food and Agriculture: A Review of the USDA Agriculture and Food Research Initiative Program. Washington: National Academies Press.

[2] AFRI Competitive Grant, 2016, "Development of honey bee-safe acaricidal peptidomimetics," http://portal.nifa.usda.gov/web/crisprojectpages/1009168-development-of-honey-bee-safe-acaricidal-peptidomimetics.html.

academic scientists, teachers, extension service personnel, administrators, marketing representatives, research technicians, consultants, students, pest management professionals, and hobbyists, among others.

Thank you for the opportunity to voice support from the Entomological Society of America for USDA research programs.

[This statement was submitted by May Berenbaum, PhD, President, Entomological Society of America.]

PREPARED STATEMENT OF FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY (FASEB)

DEPARTMENT/OFFICE ADDRESSED IN TESTIMONY: USDA AFRI AND ARS

The Federation of American Societies for Experimental Biology (FASEB) is composed of 30 societies with 125,000 members, making it the largest coalition of biomedical research associations in the United States. FASEB enhances the ability of scientists and engineers to improve health, well-being, and productivity through research and is recognized as the policy voice of biological and biomedical researchers.

The United States Department of Agriculture (USDA) funds research through a competitive grants system, the Agriculture and Food Research Initiative (AFRI), and an "in-house" effort administered by the Agricultural Research Service (ARS). These programs support research that addresses some of the grand challenges of our time: food production, global food security, human nutrition, agriculture economics, and sustainable bioenergy. Grants are awarded to state agricultural experiment stations, colleges, university research foundations, and other research institutions, as well as private organizations. AFRI funded over 1,200 research projects in all 50 states between 2009 and 2011. ARS currently supports more than 2,000 scientists at 90 laboratories throughout the country.[1]

Since AFRI was established in 2008, the program has supported research to develop new varieties of wheat and barley that will better tolerate changes in climate and lettuce that requires less water, which will allow farmers to conserve resources and save money. Other projects established methods to improve communication, analysis, and data sharing about corn farming practices in order to ensure production can be sustained despite the threat of extreme weather events. In addition, a USDA-funded team of engineers and scientists created a mobile application to help farmers comply with Environmental Protection Agency regulations that mandate the collection and submission of data on soil, crops, and nutrient management plans. ARS scientists have discovered genes and molecular markers in honey bees that have led to the breeding of new bees that are resistant to the adverse effects of mites and chalkbrood disease, as well as the application of technologies to help reduce exposure of the bees to pesticides.

Examples of promising USDA-funded research include:

—Laser Tool Detection of Salmonella: Scientists funded by USDA at Purdue University have developed a new method for the detection of Salmonella bacterial contamination in food. By using a laser to scan bacteria isolated from food samples, the new technology can identify potential contamination about three times faster than traditional methods. This rapid screening could ultimately lead to more thorough and rapid food inspections, thus reducing morbidity from Salmonella food poisoning.[2]

—Molecular Mechanisms of Herbicide Resistance: Compounds called safeners are routinely applied to cereal crops to protect them from weed-killing herbicides. However, the precise mechanism by which these safeners work remained largely unknown. Recently, USDA-supported researchers at the University of Illinois have discovered that specific molecules for detoxifying herbicides in cereal plants are upregulated when safeners are applied. This insight will aid in the management of herbicide use, and similar detoxification processes in plants may prove to be useful traits for resistance to other stressors, including drought, pests, or disease.[3]

—Computer Modeling of Food-borne Pathogen Growth: One of the greatest challenges in food safety is to ensure that different foods are handled properly to prevent the growth of harmful, contaminating microbes. In order to enhance the

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[1] http://www.ars.usda.gov/is/np/ARSImpacts/ARSImpacts.pdf.

[2] http://www.purdue.edu/newsroom/releases/2014/Q1/laser-tool-speeds-up-detection-of-salmonella-in-food-products.html.

[3] http://www.grainnet.com/articles/University-of-Illinois-Researchers-Learn-More-About-Herbicide-Defense-Switch-in-Cereal-Crops-146822.html.

ability of food companies to ensure the safety of their products, ARS scientists at the USDA Eastern Regional Research Center have developed a software package that models the growth and proliferation bacteria in different environments. These models can then be used to develop effective management practices that reduce the instance of foodborne illness.[4]

—Uncovering the Links between Maternal Traits and Fetal Development: An important area of ongoing research seeks to understand how mothers' health during pregnancy might affect children's growth and development. Using advanced imaging techniques, USDA ARS-funded researchers at the Arkansas Children's Nutrition Center have discovered a relationship between maternal obesity during pregnancy and brain structure in newborns. This study is part of a growing literature suggesting previously unknown ways in which maternal health has profound neurological effects on fetal development. Such studies therefore not only shed light on fundamental mechanisms of human brain development, but also could help with design of dietary and exercise interventions for expecting mothers that improves infant health.[5]

—Development of Drought and Disease Resistant Corn: Drought represents a major threat to crop production. To begin to address this problem, USDA-funded researchers at Texas A&M University have been exploring the genetics of corn varieties grown in different regions of the United States. Through this work, the team has begun to breed more productive varieties of corn that show greater resistance to drought and opportunistic infections. These efforts will be especially important for growers in the most drought prone regions.[6]

—Improving the Safety of Leafy Green Vegetables: Bleach, hydrogen peroxide, or other toxic chemicals are often used to remove bacteria from leafy vegetables. Researchers at the University of Arizona supported by the USDA have discovered that non-toxic plant antimicrobial and other organic compounds can be just as effective in cleaning produce. Pursuing these alternative strategies has the potential to both increase food safety and reduce the adverse health and environmental impacts of using harsh cleaning agents on food plants.[7]

—Combating the Spread of Antimicrobial Resistance: The proliferation of antibiotic-resistant microbes poses a significant threat to both human and animal health. However, scientists are only beginning to understand the details of how antibiotic resistance emerges and spreads, both within agricultural and non-agricultural settings. To address this, AFRI-funded scientists are playing an integral role as part of broader national efforts to deal with this critical challenge. For example, researchers at the University of Minnesota have begun to study the evolution of antibiotic resistant E. coli and Salmonella on poultry farms in the hopes of developing better management strategies that will improve both food safety and public health.[8]

NEW INVESTMENTS WILL ACCELERATE THE PACE OF AGRICULTURAL RESEARCH

New technologies and improved techniques are needed to address serious agricultural-related crises facing our country including the ongoing drought in California, childhood obesity, pollinator collapse, and citrus greening. Other challenges include changing weather patterns that shift growing seasons and threats posed by increasing varieties of invasive weeds, pests, and pathogens. Investment in USDA will help us to better understand the relationship between food consumption and behaviors, dietary patterns, and various health outcomes, including those related to obesity and the development of chronic diseases. USDA-funded research leads to nutrition education and obesity prevention strategies and interventions that advance public health.

Federal funding for competitive agriculture research can provide the answers that will build the foundation of knowledge to help solve current and future societal problems. Harnessing this potential would generate new knowledge in the food, nutrition, and agricultural sciences, and translate those fundamental discoveries into practical solutions that benefit all sectors of society and every geographic region in the country. Sustaining a competitive agriculture economy is also critical in order to respond to new and emerging problems, such as identifying ways to better manage the avian flu epidemic.

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[4] http://portal.errc.ars.usda.gov/PMP.aspx.
[5] http://www.ncbi.nlm.nih.gov/pubmed/25919924.
[6] http://nifa.usda.gov/blog/breeding-program-brings-better-safer-corn-south.
[7] http://nifa.usda.gov/blog/improving-safety-leafy-greens.
[8] http://portal.nifa.usda.gov/web/crisprojectpages/1005062-systems-approach-to-identifying-targeted-interventions-for-minimizing-antibiotic-resistance-in-the-poultry-production-system.html.

Accelerating the pace and productivity of agricultural research will require sustained increases for AFRI and ARS. A National Research Council (NRC) review of the AFRI program concluded that, "ARFI plays a critical and unique role in the nation's overall research and development (R&D) portfolio because its mandated scope, mission, and responsibilities are focused on the most important national and international challenges facing food and agriculture. But it has not been given the adequate resources needed to meet contemporary and likely future challenges."[9] The NRC report further recommended that the U.S should strengthen its public investment in agricultural R&D to ensure that it continues its ability to remain a global leader in innovation, food production, and health promotion.

Opportunities for agricultural research are growing, as Congress recognized by expanding USDA's research mandate in the 2014 Farm Bill to include diseases that can be transmitted from animals to humans and the effectiveness of conservation practices in addressing nutrient losses. Despite receiving increased funding over the last few years, AFRI's budget is still only half of the level authorized in the 2014 Farm Bill, limiting the program's capacity to satisfy the expanded research focus areas mandated by Congress. In addition, inadequate funding combined with AFRI's multi-year commitments to existing projects have reduced the availability of funds for individual, investigator-initiated grants.

AFRI's continued success will depend on securing additional funding to meet the recommended authorization level. With a budget of $700 million (an increase of $350 million over fiscal year 2016), AFRI could support more than 500 new research grants. An ARS budget of $1.2 billion ($60 million above fiscal year 2016) will allow for the continued growth of agricultural research efforts.

FASEB recommends a minimum of $700 million for AFRI and $1.2 billion for ARS in fiscal year 2017. These funding levels represent a first step toward a longer-range commitment to sustain the vital field of agricultural research.

Thank you for the opportunity to offer our support and recommendations for USDA research programs.

PREPARED STATEMENT OF FOOD FOR PEACE TITLE II (FFP)

As you prepare appropriations legislation for fiscal year 2017, we thank you for your past leadership in protecting poverty-focused international development and humanitarian assistance accounts specifically related to food security and nutrition. As a group of organizations that are supportive of these programs, we would like to thank Congress for the increase to Food for Peace Title II (FFP) funding we saw in fiscal year 2016, and call upon Congress to continue to provide similarly robust funding for Food for Peace in fiscal year 2017. Further, we request that Congress direct at least $375 million of Food for Peace funding to long-term development oriented non-emergency programs.

For over 60 years, Food for Peace has enabled the United States to reach more than 3 billion people with food assistance, addressing not only food security needs, but helping to build stability in regions that might otherwise pose greater national security concerns. As we consider the protracted conflicts in Syria, South Sudan, Yemen, and Iraq, as well as ongoing cyclical weather patterns like El Niño and a potential La Niña, projected global needs in fiscal year 2017 will be significant. Providing robust funding of FFP as was done in fiscal year 2016 will allow the U.S. to reach over 47 million people with lifesaving food aid and maintain its global leadership.

As the largest U.S. government food aid program, Food for Peace Title II also provided funding for non-emergency development programs that focus on the underlying sources of chronic hunger through multiyear investments in nutrition, agricultural productivity, and diversification of household incomes. These programs help poor communities build resilience to droughts and floods, improve farming practices and integrate into local markets, allowing them to better withstand shocks and reduce the need for emergency assistance. These programs move poor farmers away from poverty and help them realize the dignity of providing for their families. In parallel with robust funding to the overall Food for Peace budget, we request at least $375 million of FFP funding—a small increase over the minimum level of $350 million required by the Farm Bill—be directed to development, non-emergency programming. Additionally, we remain supportive of the Community Development Fund including its use within non-emergency food assistance programming.

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[9] The National Academies Press. Spurring Innovation in Food and Agriculture: A Review of the USDA Agriculture and Food Research Initiative (2014).

We look forward to continuing to work with you in advancing efforts that address food insecurity, and we once again thank you for your leadership in protecting international humanitarian and development assistance accounts including Food for Peace Title II.

1.) Mercy Corps
2.) Food for the Hungry
3.) ADRA International
4.) Catholic Relief Services
5.) CNFA
6.) World Vision US
7.) PCI
8.) ACDI/VOCA

PREPARED STATEMENT OF FOOD FOR PEACE (PUBLIC LAW 480)

The undersigned organizations support sustained funding for the Food for Peace (Public Law 480) and Food for Progress international food aid programs and oppose proposals to reduce funding or to shift these resources to overseas commodity procurement and cash assistance. These bedrock food aid programs have enjoyed strong bipartisan support for over 60 years because they share America's agricultural bounty with those who need it most.

Our food aid programs have constantly evolved and improved over the years. They provide well-honed and dependable systems for identifying the appropriate commodities for targeted populations, and for procuring and shipping these commodities through an aid pipeline that is second to none. The transparency, accountability, and reliability of this system are the result of decades of cooperation through a uniquely sustainable public-private partnership among tens of thousands of committed Americans at faith-based and other non-governmental organizations, and in agriculture, labor, industry, and government.

Growing, manufacturing, bagging, and shipping nutritious U.S.-grown food creates jobs and economic activity here at home, provides crucial cargo for our U.S. Merchant Marine, which is essential to our national defense sealift capability, and sustains a robust domestic constituency for these programs not easily replicated in alternative foreign aid programs. Overseas, Food for Peace has an established track record of preventing childhood starvation and providing life-saving tools that families need to work their way out of the most dire poverty. Food for Progress fights hunger by promoting free enterprise in emerging democracies through development of the agricultural sector. Both of those programs are proven methods for tackling food insecurity head-on with concrete results.

In addition to feeding the hungry and facilitating developmental programs to end the cycle of hunger, U.S. food aid programs are also some of our most effective, lowest-cost national security and diplomatic tools. Bags of U.S.-grown food bearing the U.S. flag and stamped as "From the American People" serve as ambassadors of our Nation's goodwill, which can help to address the root causes of instability. In a time of growing global food insecurity and extremism, these programs need to be expanded, not eliminated or slashed to fund dubious proposals.

We therefore oppose shifting food aid resources to overseas commodity procurement and cash assistance, and strongly encourage sustained funding for Food for Peace and Food for Progress, preserving the unique qualities that have made them the world's most successful, most dependable humanitarian assistance programs.

American Association of Port Authorities
National Council of Farmer Cooperatives
American Great Lakes Ports Association
National Potato Council
American Maritime Congress
National Sorghum Producers
American Maritime Officers
Navy League of the United States
American Maritime Officers' Service
North American Millers' Association
American Soybean Association
Potomac Maritime, LLC
APL Limited
Potomac Shipping International, LLC
Central Gulf Lines, Inc.
Sailors' Union of the Pacific
Euro-America Shipping & Trade, Inc.
Schuyler Line Navigation Company, LLC
Hapag-Lloyd USA, LLC
Seafarers International Union
Intermarine, LLC
Teras Cargo Transport (America), LLC
International Organization of Masters,
Transfer Logistics LLC
Mates & Pilots
Transportation Institute
Liberty Maritime Corporation
US Dry Bean Council
Maersk Line, Ltd.
US Rice Producers Association

Marine Engineers' Beneficial Association
USA Dry Pea and Lentil Council
Maritime Institute for Research and Industrial Development
USA Maritime
USA Rice
National Association of Wheat Growers
Virginia Port Authority
National Barley Growers Association
Waterman Steamship Corporation
National Corn Growers Association

[This statement was submitted by Bryant E. Gardner, Partner, Winston & Strawn LLP.]

PREPARED STATEMENT OF FOOD & WATER WATCH

On behalf of the non-profit consumer advocacy organization Food & Water Watch, I welcome this opportunity to express our views on the fiscal year 2017 appropriations bill under your jurisdiction.

FOOD SAFETY AND INSPECTION SERVICE

We remain opposed to the New Poultry Inspection System (NPIS) that is being implemented for several reasons: 1) there is still no proof that this privatized inspection model will make poultry safer. In fact, when we asked agency officials at a recent meeting for testing statistics from plants that have actually shifted to NPIS to demonstrate that poultry that is slaughtered under this new system is safer, they could not do so; 2) the agency still has not addressed the issue of designating certain strains of Salmonella and Campylobacter as adulterants. It is baffling to us that the Obama Administration has failed to request this authority from the Congress; 3) we remain concerned that the company sorters who are taking over inspection responsibilities on the slaughter lines have not received proper training; 4) the reticence of the poultry industry to shift to this new system illustrates to us that it is not confident that NPIS will work. The excuses that the agency lists in its fiscal year 2017 Explanatory Notes for not achieving its salary savings goals for fiscal year 2016 are not accurate; 5) the agency still seems to be interested in increasing line speeds in poultry facilities. There are rumors that there might be a rider attached to the fiscal year 2017 Agriculture Appropriations bill to revoke the 140 birds per minute cap for young chicken plants shifting to NPIS. We strongly oppose any such efforts. The one remaining USDA inspector left on the slaughter line in NPIS plants is responsible for inspecting 2.33 birds every second. This is an impossible task. To increase the line speed to 175 is totally irresponsible. We urge the subcommittee to provide vigorous oversight over the implementation of NPIS because it is not achieving the food safety goals that the agency touted when the rule was finalized.

We support the agency's $4.5 million funding request so that it can perform genomic sequencing in its pathogen identification work, and its $3 million request to expand laboratory analysis. We do not support its $1 million request for advanced analytics for its Public Health Information System (PHIS). As we have alerted the subcommittee on several occasions in the past, the implementation of PHIS has been problematic. Our concerns were corroborated by the USDA Office of Inspector General in its August 2015 audit report of the IT system. When we recently asked agency officials what this additional money would be used for, they were equivocal. Instead of giving the agency additional money to prop up a failed IT system, we strongly urge that the subcommittee get concrete answers from the agency regarding this funding request. We should not be throwing good money after bad for a system that has already cost substantially more than originally estimated.

We also urge the subcommittee to request from the agency a detailed plan on how it intends to deal with the chronic staffing shortages in the inspection workforce across the country. There are some FSIS regions that continually have double-digit vacancy rates. This is impacting the ability of the remaining inspectors to complete their inspection tasks. Food & Water Watch published an analysis of the impact of the staffing shortages in September 2015.[1]

Food & Water Watch supported the rule to transfer the inspection of siluriformes from the U.S. Food and Drug Administration to FSIS. We were disappointed with the length of time for the final rule to be published and with the interference of the Office of U.S. Trade Representative in the development of that rule. We are concerned with the length of the transition period contained in the rule, especially for exporting countries. We did not see in the agency's budget request additional funding for more import inspection personnel to deal with imported siluriformes. We

[1] See http://www.foodandwaterwatch.org/news/usda-records-reveal-staffing-shortages-undermining-food-safety.

urge the subcommittee to ask the agency how intends to deal with the inspection of imported siluriformes at our ports-of-entry.

We are concerned with the agency's recent publication of audit reports for the poultry inspection system in the People's Republic of China (PRC), in which it has concluded that it intends to move forward with rulemaking to permit the PRC to export its own poultry to the U.S. The food safety system in the PRC is weak at best and corrupt at worst. On March 7, a story appeared in a food trade publication in which the head of the PRC's Food and Drug Administration admitted that his agency could not keep up with investigating all of the cases of adulterated food that had entered into that country's food supply.[2] We have always been suspicious that the PRC poultry equivalency determination has had a nexus with the re-opening of the Chinese market to U.S. beef. Trade cannot trump food safety and we urge the subcommittee to insert statutory language in the fiscal year 2017 bill to require the agency to provide regular reports to Congress on this issue.

Furthermore, we urge the subcommittee to continue to prohibit USDA from purchasing poultry products from the PRC for the various nutrition programs it administers, including the National School Lunch Program.

GRAIN INSPECTION PACKERS AND STOCKYARDS ADMINISTRATION

We urge the subcommittee to exclude any legislative riders that limit the authority of the Secretary of Agriculture under the Packers & Stockyards Act (P&SA) of 1921. The P&SA is a vital Federal statute that protects livestock farmers and ranchers from unfair, deceptive, fraudulent and anticompetitive business practices by the meatpacking and poultry companies. The 2008 Farm Bill directed USDA to write rules to address the market power and predatory business practices of the highly consolidated and vertically integrated meatpacking and poultry industries that were finalized in a considerably diminished form in 2011, but previous agricultural appropriations provisions have hindered USDA from providing basic protections and safeguards for U.S. farmers and ranchers. The 2014 Farm Bill did not revisit these provisions and the Consolidated Appropriations Act of fiscal year 2016 did not include any version of the prior policy riders. The subcommittee should continue to exclude any policy riders that undermine the work of the Secretary and the Agriculture Committees.

FOOD AND DRUG ADMINISTRATION

We are concerned that the funding request made by the administration for the implementation of the Food Safety Modernization Act (FSMA) is not adequate. The administration, again, is relying on user fees to fund most of the implementation work for fiscal year 2017 even though it knows that Congress will not enact such fees. We urge the subcommittee to work with the agency to determine a realistic appropriations request so that the implementation of FSMA can continue.

We are requesting $10 million to help small and mid-size farms and small processing facilities comply with new proposed food safety regulations. This training program, authorized in FSMA, is one of the best and least costly ways to improve food safety outcomes without resorting to excessive farm regulation. The program received $5 million in fiscal year 2016. The President's fiscal year 2017 budget requests $5 million. We are requesting $10 million for fiscal year 2017, because food safety training for family-scale operations is critical at this stage of FSMA implementation.

[This statement was submitted by Wenonah Hauter, Executive Director, Food & Water Watch.]

PREPARED STATEMENT OF FRIENDS OF AGRICULTURAL RESEARCH—BELTSVILLE

Mister Chairman and Members of the Subcommittee, thank you for this opportunity to present our statement supporting funding for the Department of Agriculture's Agricultural Research Service (ARS), and especially for its flagship research facility, The Henry A. Wallace Beltsville Agricultural Research Center in Beltsville, Maryland. We strongly recommend full fiscal-year 2017 funding for the Beltsville center.

The world-famous agricultural research center has led national agricultural progress for well over a century. A national and world treasure—home to the world-

[2] See http://www.foodnavigator-asia.com/Policy/Food-safety-chief-FDA-struggling-to-cope-with-scale-of-adulteration.

famous Beltsville Small White Turkey—the center generates enormous benefits for our country.

NOTABLE RECENT ACCOMPLISHMENTS

The American Chemical Society recently named Beltsville a National Historic Chemical Landmark for the discovery and isolation of the light-sensitive plant pigment phytochrome. Hailed as a leading plant science discovery of the 20th century, the research required 41 years of intensive research effort.

A natural nitrogen-fixing strain of Rhizobium bacteria identified and patented at Beltsville is used to inoculate some 55 million acres of soybeans in the United States. A reduced reliance on petroleum-based nitrogen fertilizer remains an essential goal for our country.

The Food Components and Health Laboratory of the Beltsville Human Nutrition Research Center recently found that tree nuts have lower calorie content than currently listed on food labels. These findings improve food labeling and help consumers make better food choices.

Dr. Hyun Soon Lillehoj, a Beltsville senior research molecular biologist, received a 2015 Samuel J. Heyman Service to America Medal in Career Achievement ("the Sammies"), for her research to reduce the use of antibiotics in commercial poultry.

Yet, Beltsville faces devastating decline and obsolescence from long-deferred essential maintenance and repairs to buildings, roadways, and its electrical grid infrastructure. Roadways are in great need of repairs and an independent assessment of some of the bridges revealed such disrepair as to become "life safety issues."

These issues cry out for attention. We estimate and recommend that a dedicated annual appropriation of $3 million is needed to address long-delayed repairs and maintenance. The Beltsville campus consists of approximately 6,000 acres and 308 buildings containing laboratories, offices, greenhouses, animal facilities, repair shops, farm buildings, and other specialized facilities. There are 37.6 miles of paved roadways, many of which are in an urgent need of repair. Most buildings were constructed in the 1920s and 1930s, the oldest in 1805.

WE TURN NOW TO SELECTED ITEMS WITHIN THE PRESIDENT'S FISCAL YEAR 2017 BUDGET PROPOSAL

First, we would confirm our sincere appreciation and gratitude that the Consolidated Appropriations Act of 2016 includes $37.1 million in Federal funding to modernize research laboratories at the Beltsville Agricultural Research Center. As mentioned before many Beltsville laboratories were built in the 1920s, 1930s 1950s and 1960s and are now more than 60 years old. This funding will be used to modernize Building 307, which has been largely vacated because its space is no longer functional for research activities.

We also are very pleased that the President's fiscal year 2017 budget includes increases in critically important research initiatives, which would lead to creating new jobs, enhancing American agriculture competitiveness in the global economy, assuring future food security, protecting crops and animals from diseases and reducing their vulnerability to climate change, while improving the economic and environmental sustainability of American agriculture. The scientists of the Henry A. Wallace Beltsville Agricultural Research Center are recognized world leaders in the scientific disciplines that are necessary to successfully execute the President's proposed research initiatives. Specifically, we would like to highlight the following initiatives that will enhance the Center's research programs.

CLIMATE CHANGE-RESILIENCE CROPS THAT RESPOND AND ADAPT TO CLIMATE CHANGE

The proposed budget provides $292,500 for the Henry A. Wallace Beltsville Agricultural Research Center to identify and evaluate management practices that maximize plant genetic potential to achieve optimal yield. This will be achieved by determining how rising temperatures and carbon dioxide alter physiological processes, growth, and crop quality and how genetic make-up makes plants adaptable or resistant to environmental changes. Also, these additional funds will be used to advance our understanding of the effects of climate change on pests and beneficial insects, so crops can be better protected against insect pests.

CLIMATE CHANGE-REDUCE VULNERABILITY OF AGRO-ECOSYSTEMS TO CLIMATE CHANGE

The budget proposes $90,000 in new funding to the Henry A. Wallace Beltsville Agricultural Research Center to model the impact of long-term weather, using Long-Term Agro-Ecosystem Research (LTAR) data, on crop and livestock productivity. In 2012, ARS organized ten of its existing research watersheds, ranges, and farms into

a LTAR network to conduct research to support sustainable agricultural production. In fiscal year 2014, ARS added eight additional LTAR sites, thereby increasing coverage in key agricultural production regions, while strengthening ties between USDA science and the Nation's land grant university system. Thus ARS began to transform existing long-term research infrastructure, both within and outside of USDA, to address all components of agricultural sustainability (i.e., productivity, economics, environmental quality, ecosystem services, and human and social well-being). The fiscal year 2017 $90,000 increase will fund the newly designated unfunded site in the Chesapeake Bay.

COMBATING ANTIMICROBIAL RESISTANCE

The budget proposes $2,890,800 of new funding for the Henry A. Wallace Beltsville Agricultural Research Center to create new tools to combat antimicrobial resistance in animals and the environment. Among expected benefits are novel approaches to boosting animal natural immune systems for resistance to parasitic infections, gut stabilization against pathogens, or novel strategies using antimicrobial growth promoters to limit the consequences of host reactivity to pathogens and protection of public health.

SAFE AND ABUNDANT WATER SUPPLIES

A $225,000 increase is provided for the Henry A. Wallace Beltsville Agricultural Research Center to develop safe and abundant water supplies to support U.S. agricultural production by using non-traditional water sources.

Mr. Chairman, this concludes our statement. Thank you for consideration and support for the educational, research, and outreach missions of The Henry A. Wallace Beltsville Agricultural Research Center.

[This statement was submitted by Allan Stoner, Ph.D., President, Friends of Agricultural Research—Beltsville, Inc.]

PREPARED STATEMENT OF FRIENDS OF AGRICULTURAL STATISTICS AND ANALYSIS

The undersigned groups, which include various members of the Friends of Agricultural Statistics and Analysis, strongly support Federal investment to advance agricultural statistics and research in the United States Department of Agriculture's (USDA) Economic Research Service (ERS) and the USDA National Agricultural Statistics Service (NASS). We support funding for these agencies in fiscal year 2017 (fiscal year 17) at levels that are at least $91.3 M for ERS and $176.6 M for NASS.

USDA produces valuable data that directly informs decisions by food and agricultural market participants; agricultural input and food businesses; banks and other credit institutions; and those who make food, farm, economic development, and trade policy. American agriculture, rural America, food, and resource-based industries depend on the reliable production of timely, accurate, and objective food, agricultural, rural economic, and resource statistics and market information. Additionally, the statistics and analysis made possible by these agencies provides a greater understanding of farm household dynamics, advances evidence-based policy approaches, and gives insight into the health of the farm economy.

The National Agricultural Statistics Service (NASS) is committed to providing timely, accurate, and useful statistics in service to U.S. agriculture. The agency conducts hundreds of surveys every year and prepares reports and information to communicate the survey results. Production and supplies of food and fiber, prices paid and received by farmers, farm labor and wages, farm finances, chemical use, and changes in the demographics of U.S. producers are only a few examples of the information gathered. NASS reports the facts on American agriculture, facts needed by people working in and depending upon U.S. agriculture. A primary concern of NASS is to "safeguard the privacy of farmers, ranchers, and other data providers, with a guarantee that confidentiality and data security continue to be our top priorities."

The mission of the Economic Research Service (ERS) is to inform and enhance public and private decisionmaking on economic and policy issues related to agriculture, food, the environment, and rural development. To accomplish this mission, ERS manages a comprehensive program of economic research and analysis (including development of economic and statistical indicators), which is coordinated with NASS efforts. ERS also works with NASS to develop the content of and covers the cost of more than half of the Agricultural Resource Management Survey (ARMS), NASS's largest farm operator survey. Also, ERS independently conducts its own National Household Food Acquisition and Purchase Survey. Connecting with and work-

ing closely with researchers across the U.S., ERS issues cooperative agreements and grant awards and works with land-grant partners on many projects. These essential collaborations could be threatened if support waivers. Finally, the ERS is a primary source of economic information and research in USDA; the work it does improves the Department's program effectiveness.

USDA's data products and analytical programs provide the U.S. with an important edge against increasingly fierce global agricultural competition. These programs benefit the entire supply chain, starting at the farm gate and enhancing decisions throughout national and international food, feed, fiber, and fuel economies. Public data products and projections serve to improve the accuracy of the expectations of market participants, reducing market pricing errors. The U.S. agricultural data information and analysis system is second to none, worldwide. Today, NASS is experiencing increased demand for its statistical products and reports. Similarly, ERS is experiencing significant requests for its research, data products, and services. To continue to build future trade and finance capacity in an increasingly competitive marketplace, the U.S. must invest in and leverage all of its strengths, including the food and agricultural data and information system.

We encourage you to support these agencies so that they can continue to provide essential information to farm and agribusiness, government agricultural program, and food policy decision makers.

Thank you in advance for your thoughtful consideration of this information.

Agricultural & Applied Economics Association
American Association of Mycobacterial Diseases
American Dairy Science Association
American Society of Agronomy
American Society of Animal Science
American Society of Farm Managers and Rural Appraisers
American Statistical Association
American Sugar Alliance
Consortium of Social Science Associations
Council of Professional Associations on Federal Statistics
Crop Science Society of America
Deere & Company
FASS
Global Cold Chain Alliance
International Association of Refrigerated Warehouses
Mycobacterial Disease of Animals Multistate Initiative
National Association for the Advancement of Animal Science
National Association of State Departments of Agriculture
National Coalition for Food and Agriculture Research
National Farmers Union
National Sustainable Agriculture Coalition
North American Regional Science Council
Poultry Science Association
Restaurant Services, Inc.
Soil Science Society of America
The Fertilizer Institute

[This statement was submitted by Steve Pierson on behalf of the undersigned members of the Friends of Agricultural Statistics and Analysis.]

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of the undersigned horse industry, veterinary, and animal welfare organizations, and former Senator Joseph Tydings, we submit the following testimony seeking funding for the USDA/APHIS Horse Protection Program of $705,000 for fiscal year 2017. We recognize that Congress is focused on the imperative of cutting Federal spending. But we believe that it should be possible to achieve meaningful reductions in the overall budget while still addressing shortfalls in very specific accounts that are vital and have been seriously underfunded. This $705,000 is urgently needed to begin to fulfill the intent of the Horse Protection Act—to eliminate the cruel practice of soring—by allowing the USDA to strengthen its enforcement capabilities for this law.

In 1970, Congress passed the Horse Protection Act to end soring, the intentional infliction of pain to the hooves and legs of a horse to produce an exaggerated gait, practiced primarily 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 lower front legs of the horse, then the legs are wrapped for days in plastic wrap and bandages to "cook" the chemicals deep into the horse's flesh. This makes the horse's legs extremely painful and sensitive, and when ridden, the horse is fitted with chains that slide up and down the horse's sore legs, forcing him 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, in an attempt to remove 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 Horses, Racking Horses, 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 of the Act 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. However, limited funds allow USDA attendance at less than 20 percent of the approximately 400 Tennessee Walking Horse shows held annually. So the Agency set up an industry-run system of certified Horse Industry Organization (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. To perform this function, some 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 appears to have attempted to step up its enforcement efforts in recent years, and has 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 are significant actions that should have 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 enhanced resources to carry out its responsibilities under this Act as Congress, and the public, expects.

In years past, inspections were limited to physical observation and palpation by the inspector. Protocols for the use of new technologies, such as thermography and "sniffer" devices (gas chromatography/mass spectrometry—or GC/MS—machines), have been implemented, which can help inspectors identify soring more effectively and objectively. The results of USDA's recent GC/MS testing for 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) are staggering: 175 of the 200 random samples (87.5 percent) taken by the USDA at the industry's pinnacle event—the 2015 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 purchase and put enough of this testing into use in the field, allowing for industry players to continually evade detection. In 2015 and 2014, USDA was able to afford to collect and test samples at only 11 of the Big Lick industry's largest shows; in 2013, only 17; and in 2012, only 24. With increased funding, the USDA could purchase more equipment and dispatch more inspectors to use it properly, greatly increasing its ability to enforce the HPA.

Currently, when USDA inspectors arrive at shows affiliated with some industry organizations, many of the exhibitors load up and leave to avoid being caught with sored horses. While USDA could stop these trailers on the way out, 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. The fact 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 Horses, Racking Horses, 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) issued a white paper condemning 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 an audit of the Horse Protection Program, and issued its final report in September of 2010. The report recommends the abolition of the DQP program, and an increase in funding for APHIS enforcement of the Horse Protection Act. The Agency concurred with the findings and recommendations in the report, specifically 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.

It is unacceptable that more than 40 years 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 want and need to fulfill their duty to protect these horses as effectively and safely as possible.

We appreciate the opportunity to share our views about this serious problem, and thank you for your consideration of our request.

Keith Dane, Senior Advisor, Equine Protection
The Humane Society of the United States

Former U.S. Senator Joseph Tydings
Original sponsor of the Horse Protection Act

Teresa Bippen, President
Friends of Sound Horses, Inc.

W. Ron DeHaven, DVM MBA
Executive Vice President
American Veterinary Medical Association

Kathleen Anderson, DVM, President
American Association of Equine Practitioners

Chris Heyde, Deputy Director, Government and Legal Affairs
Animal Welfare Institute

Nancy Perry, Senior Vice President, Government Relations
American Society for the Prevention of Cruelty to Animals (ASPCA)

Robin Lohnes, Executive Director
American Horse Protection Association

Donna Benefield, Vice President
International Walking Horse Association

Angie Biddison, President
Plantation Walking Horses of Maryland

Jayme Clark, President
National Plantation Walking Horse Association

Susan Crotty, President
Plantation Walking Horse Association of California

Ian Walker, President
United Pleasure Walking Horse Association

Lucy Rangel, President
Gaitway Walking Horse Association, Inc.

Bonnie Yeager, President
International Pleasure Walking Horse Registry

Penny Austin, President
One Horse At a Time, Inc. Horse Rescue

Kristin Herman, M.D., Vice President
Northern California Walking Horse Association

Raydene Walker
Tennessee Walking Horse Association of Oklahoma

Wayne Eastman, President
New York State Plantation Walking Horse Club

Libby Wright
San Francisco Bay Area Tennessee Walking Horse Club

Burl Latshaw, President
Pennsylvania Pleasure Walking Horse Association

David Green, Director
Tennessee Walking Horse Exhibitors' Association of Oregon

[This statement was submitted by Keith Dane, Vice President of Equine Protection, The Humane Society of the United States.]

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

Thank you for the opportunity to provide testimony on fiscal year 2017 funding for the following USDA accounts of great importance to The Humane Society of the United States:

—FSIS/Horse Slaughter—language mirroring fiscal year 2016 omnibus provision
—APHIS/Animal Welfare Act Enforcement—$28,696,000
—APHIS/Horse Protection Act Enforcement—$705,000
—ARS/Animal Welfare for Farm Animals Used in Agricultural Research—language maintaining APHIS inspections of ARS facilities to ensure AWA compliance, including fully functioning IACUCs for each facility at which animal research is conducted
—APHIS/Investigative and Enforcement Services—$16,410,000
—FSIS/Humane Methods of Slaughter Act Enforcement—language to ensure compliance with humane handling rules for live animals as they arrive and are offloaded and handled in pens, chutes, and stunning areas; robust national training in humane handling and inspection techniques; and annual program evaluation for humane handling inspections

—OIG/including Animal Fighting Enforcement—$100,998,000
—NIFA/Veterinary Medical Services Act—$6,500,000
—APHIS/Emergency Management Systems/Disaster Planning for Animals—$969,000
—APHIS/Animal Welfare Act Enforcement—language to maintain bar on licensing Class B dealers of "random source" dogs and cats

At this time of intense budget pressure, we appreciate your outstanding past support for enforcement of key animal welfare laws by USDA and urge you to sustain this effort in fiscal year 2017. While we understand the focus on reducing Federal spending, we believe there should be room for careful decisionmaking within the budget to achieve macro-level cuts and at the same time ensure adequate funding for specific accounts that are vital and have previously been underfunded. We therefore request the following for fiscal year 2017:

FSIS/HORSE SLAUGHTER

We request inclusion of the same language barring USDA from the expenditure of funds for horse slaughter inspections as was included in the fiscal year 16 omnibus. This provision is vital to prevent renewed horse slaughter activity in this country, particularly given discoveries of horsemeat in other food products in the EU and U.S. Horse slaughter is cruel and poses serious public health risks. American horses are raised to be companions, athletes and work horses, and they are often treated with drugs, both legal and illegal, that can endanger the food supply. There is currently no system in the U.S. to track drugs and veterinary treatments given to horses to ensure that their meat is safe for human consumption. Horse slaughter is also inherently inhumane and cannot be made humane for horses. The methods used to kill horses rarely result in quick, painless deaths, as horses are skittish animals and often endure repeated blows to make them unconscious, sometimes remaining conscious during the slaughtering process. USDA reports show that over 92 percent of horses going to slaughter are healthy and could have gone on to lead productive lives. However, "kill buyers" profit by selling horsemeat from healthy horses that bring the best price per pound for their meat, and they frequently outbid rescue groups at auctions. Inclusion of language to bar the expenditure of funds on horse slaughter inspections would protect consumers and horses, and would prevent the needless waste of American taxpayer dollars (particularly at a time when budget pressures are so great) on a practice that 80 percent of the American public opposes.

APHIS/ANIMAL WELFARE ACT (AWA) ENFORCEMENT

We request $28,696,000 for AWA enforcement under APHIS. We commend the Committee for responding in recent years to the urgent need to properly fund the Animal Care division to improve its inspections of approximately 10,399 sites, including commercial breeding facilities, laboratories, zoos, circuses, and airlines, to ensure compliance with AWA standards. In May 2010, USDA's Office of Inspector General released a report criticizing the agency's history of lax oversight of dog breeders—finding that inhumane treatment and horrible conditions often failed to be properly documented and yielded little to no enforcement actions. Secretary Vilsack called for more inspections and a tougher stance on repeat offenders and the agency must have the resources to follow through on that commitment. USDA is also implementing new regulations to cover large-scale commercial dog breeders selling puppies directly to the public via the Internet and other means, and to end imports from foreign puppy mills where puppies are mass produced under inhumane conditions and forced to endure harsh long-distance transport. Animal Care is actively licensing new facilities that now require USDA regulatory oversight under the retail pet store rule. Animal Care currently maintains 112 inspectors (with 12 vacancies) who perform and oversee animal welfare compliance inspections, compared to 64 inspectors at the end of the 1990s. Animal Care also maintains cadres of species specialists (6) who support inspectors with complex regulatory compliance issues and compliance specialists (9) who support the pre-licensing process and other aspects of compliance assurance. An appropriation at the requested level would allow the agency to continue to address the concerns identified by the OIG, enforce the new rule on direct sales and the puppy import ban, and provide adequate oversight of the many licensed/registered facilities.

APHIS/HORSE PROTECTION ACT (HPA) ENFORCEMENT

We request $705,000 for strengthened enforcement of the Horse Protection Act. Congress enacted the HPA in 1970 to make illegal the abusive practice of "soring," in which unscrupulous trainers deliberately inflict pain on Tennessee Walking Horses' hooves and legs to create an exaggerated, high-stepping gait and gain unfair

competitive advantage at horse shows (e.g., applying caustic chemicals, using plastic wrap and tight bandages to "cook" those chemicals deep into the horse's flesh for days, attaching heavy chains to strike against the sore legs and heavy, stacked horseshoes that force the horse's legs into unnatural angles, jamming hard objects into the sensitive areas of the feet, cutting the hooves down to expose the live tissue, and using salicylic acid or other painful substances to slough off scarred tissue or numbing agents in an attempt to disguise the sored areas). A report released in October 2010 by USDA's OIG documents significant problems with the industry self-monitoring system on which the APHIS inspection program currently relies, and calls for funding to enable the agency to more adequately oversee the law. Several horse show industry groups, animal protection groups, and the key organization of equine veterinarians have also called for funding to enable USDA to do a better job enforcing this law. With the current level of funding, Animal Care has been able to attend less than 20 percent of the approximately 400 Tennessee Walking Horse shows held annually. Sustained support is essential to ensure that this program doesn't lose ground now that it is finally beginning to address the need for additional inspectors, training, security (for threats of violence against inspectors), and advanced detection equipment (thermography and gas chromatography/mass spectrometry machines).

ARS/ANIMAL WELFARE FOR FARM ANIMALS USED IN AGRICULTURAL RESEARCH

We request language to ensure that Federal dollars are not used for agricultural research without conforming to AWA standards. An investigation last year by the New York Times revealed shocking instances of animal mistreatment and neglect associated with experiments conducted on farm animals at the USDA/ARS U.S. Meat Animal Research Center, and repeated disregard for objections raised by the Center's own veterinary staff. We appreciate that the Committee took these concerns seriously and commend the Committee for its ongoing oversight. In the omnibus, 5 percent of the ARS budget for fiscal year 2016 was made contingent on ARS updating its animal care policies and requiring that all ARS facilities at which animal research is conducted have a fully functioning Institutional Animal Care and Use Committee to ensure compliance with standards and principles of scientific integrity equivalent to the AWA. In addition, $400,000 was allocated to APHIS to conduct inspections at each ARS facility using animals in research. We request a continuation in fiscal year 2017 of that $400,000 to APHIS (included in the request above for $28,696,000), as well as a renewed requirement for a fully functioning IACUC at each ARS facility where animal research is conducted, along with the following bill language: "Provided further, That the Animal and Plant Health Inspection Service and Agricultural Research Service shall work together to ensure an effective animal welfare inspection program for ARS facilities and ensure that these facilities are in full compliance with the Animal Welfare Act."

APHIS/INVESTIGATIVE AND ENFORCEMENT SERVICES (IES)

We request $16,410,000 for APHIS Investigative and Enforcement Services. We appreciate the Committee's consistent support for this division, which handles many important responsibilities, including the investigation of alleged violations of Federal animal welfare laws and the initiation of appropriate enforcement actions. The volume of animal welfare cases is rising significantly, and an appropriation at the requested level would enable the agency to keep pace with the additional enforcement workload.

FSIS/HUMANE METHODS OF SLAUGHTER ACT (HMSA) ENFORCEMENT

We request language to ensure strengthened HMSA enforcement. We appreciate the committee's inclusion of language in the fiscal year 16 committee report regarding humane slaughter. USDA oversight of humane handling rules for animals at slaughter facilities is vitally important not only for animal welfare but also for food safety. Effective day-to-day enforcement can prevent abuses like those previously documented in undercover investigations, and reduce the chance of associated food safety risks and costly recalls of meat and egg products. We therefore urge inclusion of language directing FSIS to ensure that inspectors hired with funding previously specified for HMSA enforcement focus their attention on overseeing compliance with humane handling rules for live animals as they arrive and are offloaded and handled in pens, chutes, and stunning areas, and that all inspectors receive robust national training in humane handling and inspection techniques. In addition, past OIG and GAO audits have revealed inconsistent enforcement and documentation, and recommended that USDA develop more objective criteria and metrics for determining HMSA enforcement actions. We therefore also request that the agency de-

velop an annual program evaluation for its humane handling inspections program that includes document review, field staff surveys, and monitoring to assess the degree of consistency and objectivity of implementation of the HMSA by all levels of inspection staff.

OIG/ANIMAL FIGHTING ENFORCEMENT

We request $100,998,000 for the Office of Inspector General to maintain staff, improve effectiveness, and allow investigations in various areas, including enforcement of animal fighting laws. We appreciate the Committee's inclusion of funding and language in recent years for USDA's OIG to focus on animal fighting cases. Congress first prohibited most interstate and foreign commerce of animals for fighting in 1976, established felony penalties in 2007, and strengthened the law as part of the Farm Bills enacted in 2002, 2008, and 2014. We are pleased that USDA is taking seriously its responsibility to enforce this law, working with state and local agencies to complement their efforts and address these barbaric practices, in which animals are drugged to heighten their aggression and forced to keep fighting even after they've suffered grievous injuries. Dogs bred and trained to fight endanger public safety, and some dogfighters steal pets to use as bait for training their dogs. Cockfighting was linked to an outbreak of Exotic Newcastle Disease in 2002–2003 that cost taxpayers more than $200 million to contain. It's also been linked to the death of a number of people in Asia reportedly exposed through cockfighting activity to bird flu. Given the potential for further costly disease transmission, as well as the animal cruelty involved, we believe it is a sound investment for the Federal government to increase its efforts to combat illegal animal fighting activity. We also support the OIG's auditing and investigative work to improve compliance with the AWA, HPA, HMSA and downed animal rules.

NIFA/VETERINARY MEDICAL SERVICES ACT

We request $6,500,000 to continue implementation of the NVMSA (Public Law 108–161). We appreciate that Congress is working to address the critical maldistribution of veterinarians practicing in rural and inner-city areas, as well as in government positions at FSIS and APHIS. A 2009 GAO report identified that an inadequate number of veterinarians to meet national needs is among the foremost challenges facing veterinary medicine. Having adequate veterinary care is a core animal welfare concern. To ensure adequate oversight of humane handling and food safety rules, as well as our nation's defense against bioterrorism (the Centers for Disease Control estimates that 75 percent of potential bioterrorism agents are zoonotic—transmitted from animals to humans) and public health problems such as those associated with pet overpopulation, parasites, rabies, chronic wasting disease, and bovine spongiform encephalopathy ("mad cow" disease), USDA must be able to fill vacancies in its veterinary positions. Educational debt has more than doubled since 2003 when Congress authorized this program. Veterinary school graduates face a crushing debt burden of $135,000 on average (for 88 percent of them, the burden averages $170,000), with an average starting salary of just $70,000. Nearly 1,000 veterinarians have applied for assistance under this program since 2010; at current funding levels, fewer than 60 awards can be made each year. We also support the Veterinary Services Grant Program authorized in the 2014 Farm Bill to help address gaps in veterinary shortage situations by preparing veterinarians for rural practice.

APHIS/EMERGENCY MANAGEMENT SYSTEMS/DISASTER PLANNING FOR ANIMALS

We request $969,000 for Animal Care under APHIS' Emergency Management Systems line item. Hurricanes Katrina and Rita demonstrated that many people refuse to evacuate if they are forced to leave their pets behind. The Animal Care division develops infrastructure to help prepare for and respond to animal issues in a disaster and incorporate lessons learned from previous disasters. These funds are used to support state and local governments' efforts to plan for protection of people with animals, and to enable the agency to participate, in partnership with FEMA, in the National Response Plan.

APHIS/ANIMAL WELFARE ACT ENFORCEMENT/CLASS B DEALERS

We request language to maintain the bar on expenditures for licensing of Class B dealers who sell "random source" dogs and cats for use in research, teaching, or testing. We commend the Committee for including language to protect pet owners and animals from Class B dealers who sell "random source" dogs and cats for use in research and are notorious for subjecting animals to shocking cruelty and using

fraudulent means (including pet theft) to acquire them. This language also protects taxpayers, since overseeing Class B dealers has been an unjustifiable drain on USDA resources and the National Academy of Sciences determined that there is no scientific need for these dealers. We urge inclusion of the following language: "None of the funds made available by this Act may be used to carry out any activities or incur any expense related to the issuance of licenses under section 3 of the Animal Welfare Act (7 U.S.C. 2133), or the renewal of such licenses, to class B dealers who sell random source dogs and cats for use in research, experiments, teaching, or testing. Nothing in this provision, however, should be construed as preventing the Department from carrying out all necessary oversight, inspection, compliance, and enforcement activities with respect to any entity holding a valid class B license who sells random source dogs and cats for use in research, experiments, teaching, or testing, or with respect to any entity doing so without a license as required under 7 U.S.C. 2133."

We are very grateful for the Committee's past support, and hope you will be able to accommodate these modest requests to address some very pressing problems affecting millions of animals in the United States. Thank you for your consideration.

[This statement was submitted by Mimi Brody, Director of Federal Affairs, The Humane Society of the United States.]

PREPARED STATEMENT OF IZAAK WALTON LEAGUE OF AMERICA

FUNDING FOR FARM BILL CONSERVATION PROGRAMS & NATURAL RESOURCES CONSERVATION SERVICE TECHNICAL ASSISTANCE

The Izaak Walton League of America thanks the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for the opportunity to submit testimony regarding fiscal year (FY) 2017 appropriations. With 43,000 members in nearly 240 chapters nationwide, the League is one of the most established conservation organizations in the United States. Our membership recognizes the important role of conservation initiatives in maintaining and enhancing both the environmental integrity and economic viability of agricultural landscapes.

Securing full mandatory funding for Farm Bill conservation programs in fiscal year 2017 is an appropriations priority for the League. Additionally, a modest increase in discretionary technical assistance funding for the Natural Resources Conservation Service (NRCS) is essential to meet the demand from producers who voluntarily seek to incorporate conservation planning on their farms and ranches. Therefore, we urge the Subcommittee to support full mandatory conservation program funding in the fiscal year 2017 appropriations cycle, and support the President's budget request to fund Conservation Technical Assistance (CTA), part of the Private Lands Conservation Operations account, at $761.7 million.

Mandatory Conservation Program Funding

The 2014 Farm Bill provides mandatory funding for critical existing conservation programs—including the Conservation Stewardship Program (CSP) and Environmental Quality Incentives Program (EQIP)—as well as new conservation initiatives, such as the Regional Conservation Partnership Program (RCPP) and Agricultural Conservation Easement Program (ACEP). These programs offer essential opportunities for farmers and ranchers to voluntarily implement valuable conservation practices on their land with financial and technical assistance. However, the funding levels set in the most recent Farm Bill amount to $6 billion in cuts to conservation programs when accounting for sequestration,[1] making it impossible for these programs to meet the demand from the many farmers.

Shortly after these reduced funding levels were agreed to in the Farm Bill, the fiscal year 2015 appropriations cycle cut nearly $600 million more from programs like CSP and EQIP through direct funding and acreage reductions.[2] Both programs serve as covered programs for RCPP, meaning these cuts effectively reduced funding for this popular, innovative program early in its implementation. While the League was encouraged that cuts were not made to CSP in fiscal year 2016, the substantial

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[1] National Sustainable Agriculture Coalition, 2014 Farm Bill Drill Down: The Bill by the Numbers, published February 4, 2014. http://sustainableagriculture.net/blog/2014-farm-bill-by-numbers/.

[2] National Sustainable Agriculture Coalition, Final Budget Bill Guts Conservation Funding and Farming Protections, published December 11, 2014. http://sustainableagriculture.net/blog/fy15-final-cromnibus/.

$321 million cut to EQIP will further limit access to conservation funding for producers and, in turn, reduce the environmental benefits delivered to the American public.

For the first time in recent memory, the President's fiscal year 2017 budget proposes no cuts to Farm Bill conservation programs.[3] We urge the Subcommittee to follow suit and support full funding for these programs. Changes in mandatory program spending (CHIMPS) have become all too common, with disproportionate impacts on the Farm Bill's Conservation Title.[4] The more than five billion dollars cut from conservation programs since the 2002 Farm Bill[5] have had real consequences for farmers interested in protecting natural resources on their land. This is money that could help producers take voluntary actions to improve wildlife habitat. It is money that could help farmers install buffer strips along rivers and streams, protecting water quality for rural residents and downstream municipalities. And it is money that could promote soil health practices, such as cover crops, that improve the long-term productivity of our nation's agricultural lands—productivity that will be essential to feeding a growing population and supporting rural economies.

Conservation Technical Assistance Funding

Farmers developing conservation plans for their operations rely on assistance from NRCS staff. Funding for this technical assistance comes from the CTA portion of the Conservation Operations account and also supports implementation of the Farm Bill conservation programs. The President's fiscal year 2017 budget proposes a modest increase in CTA funding, setting aside $761.7 million for this critical agency function.

Providing landowners with technical assistance to develop and implement conservation plans promotes efficiency by helping producers tailor best management practices to meet their needs, fit their property, and address specific resource concerns. It is estimated that the proposed increase in CTA funding will put an additional 8,300 conservation plans on as many as 2.9 million additional acres.[6] The League strongly supports this much needed increase in discretionary spending for CTA.

Farm Bill conservation programs are delivering tremendous benefits, but have yet to reach their full potential due to consistent and excessive cuts. In fiscal year 2017, the League urges the Subcommittee to support full mandatory funding levels for conservation programs, honoring the commitment to these programs agreed upon by Congress in the 2014 Farm Bill. Furthermore, CTA provides critical assistance to producers attempting to protect natural resources on their farm through conservation planning and practice implementation. We urge the Subcommittee to provide $761.7 million for CTA, which is consistent with the President's fiscal year 2017 budget request.

[This statement was submitted by John Sisser, Conservation Associate, Izaak Walton League of America.]

PREPARED STATEMENT OF MEADVOCACY.ORG

There is an urgent need for a systemic overhaul at the Department of Health and Human Services (HHS), including the National Institute of Health (NIH) and the Centers for Disease Control (CDC), in regards to its funding and handling of the disease myalgic encephalomyelitis (ME).

Myalgic Encephalomyelitis (ME) is chronic, serious disabling, neuroimmune disease that affects an estimated one million American men women and children in the U.S. Yet, the past three decades, since the major Lake Tahoe outbreak where the disease was defined, there have been very little scientific advances and no FDA approved treatments for this heavily burdened disease. This is due to the fact HHS,

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[3] Izaak Walton League of America, President's Budget Fully Funds Agriculture Conservation Programs, published February 9, 2016. http://www.iwla.org/news-events/news/2016/02/10/budget-fully-funds-agriculture-conservation-programs.

[4] From fiscal year 2003–2010, over 50 percent of all farm bill CHIMPS targeted the Conservation Title. Between fiscal year 2007–2010, that number increased to 83 percent. National Sustainable Agriculture Coalition report using Jim Monke and Megan Stubbs, Reductions in Mandatory Agriculture Program Spending, CRS Report for Congress (Congressional Research Service, May19, 2010).

[5] National Sustainable Agriculture Coalition comparing budget authority to appropriations bills.

[6] Office of Budget and Program Analysis, USDA. 2017 President's Budget, Natural Resources Conservation Service. http://www.obpa.usda.gov/27nrcs2017notes.pdf.

NIH and CDC have marginalized, neglected, underfunded and mistreated this patient community.

Advances in the science of the disease have been mostly squashed by the gross lack of funding by NIH for this severely disabling disease. In addition, misinformation and badly outdated information published by the CDC, along with the lack of education about the disease in medical schools, have caused a dearth of palliative care for patients nationwide. Most importantly, after 30 years, we still are not any closer to finding a possible treatment or cure to help the millions of ME patients.

MEadvocacy.org is a growing grassroots movement of advocates and patients who are rising up and saying it is time for a change. We are lawyers, laborers, teachers, students, fathers, mothers, and children. Our productive lives have been cut short by this debilitating disease and we have no hope of treatment or cure. We have had enough and are saying, "No More!"

ME INCIDENCE AND PREVALENCE

ME, also known in the U.S. as chronic fatigue syndrome (CFS) and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), sickens an estimated 850,000 to 2.5 million people in the U.S. and 17 million worldwide. A majority of patients are disabled, unable to work, attend school or participate in activities of daily life. A quarter are so severely affected as to render them bedbound, unable to care for themselves.

ME HISTORY, CRITERIA AND NAME

ME has a long history, appearing worldwide in epidemic and endemic forms. A 1955 outbreak in London resulted in Dr. A. Melvin Ramsay describing it as an infectious neuromuscular illness and coining the term "myalgic encephalomyelitis." Disregarding this, the CDC broadly redefined the disease and renamed it the marginalizing name, chronic fatigue syndrome (CFS), in response to 1985 cluster outbreaks of the disease in Incline Village, Nevada and Lyndonville, New York. This redefinition resulted in three decades of confused research findings rather than answers to the cause and treatment of this disease. In addition, the undignified name and poor criteria caused stigmatization and marginalization of patients.

DISEASE BURDEN AND FUNDING

Some ME patients have died prematurely from complications of ME. Others have died at their own hands due to the severity and length of their suffering without proper palliative care, as well as dismissal and stigmatization by the medical community. If we do not act on behalf of these severely affected patients, we are complicit in their suffering and untimely deaths. The patients will not carry this burden quietly any longer and we are looking at Congress to require HHS to properly fulfill their duty to ME sufferers.

In 2009, Dr. Nancy Klimas, the director of AIDS research at the Miami Veterans Affairs Medical Center stated:

> "My H.I.V patients for the most part are hale and hearty thanks to three decades of intense and excellent research and billions of dollars invested. Many of my CFS patients, on the other hand, are terribly ill and unable to work or participate in the care of their families. I split my clinical time between the two illnesses, and I can tell you if I had to choose between the two illnesses, (in 2009) I would rather have HIV. But CFS, which impacts a million people in the United States alone, has had a small fraction of the research dollars directed towards it. ""(http://consults.blogs.nytimes.com/2009/10/15).

In the intervening 7 years, nothing has changed. It is very clear that real change at HHS regarding this disease will not come about naturally. We have come to you, the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, for help in addressing this dire need for oversight and investigation.

It is estimated that the burden to the economy for ME is between $17 to 24 billion, yet NIH funding for research has stagnated at a mere $5 million a year, less than funding for hay fever. HHS has placed funding for ME at the rock bottom of their funding budget list. The yearly allocation for ME/CFS is a fraction of what other similarly burdened diseases receive.

> HHS/NIH funding data for 2014 US patient population Funding per patient—HIV/AIDS—$2 billion 978 million 1,200,000 $2,481; M.S.—$102 million 400,000 $255; Parkinson's—$139 million 1,000,000 $139; Alzheimer's $564 million 5,300,000 $106; ME/CFS—$5 million 1,000,000 $5.

The great divide between NIH funding for ME and other diseases cannot be explained away. Simply advising and recommending that NIH increase funding for ME, has not worked. The Secretaries of Health and Human Services have not responded to most of the nearly 100 recommendations made by the Chronic Fatigue Syndrome Advisory Committee (CFSAC) during the past 10 years. It ignored specific requests by CFSAC, medical experts, patient advocates, patients and their families to adopt ME expert-authored, well-defined criteria for the disease.

The department did not heed the call by President Obama as a result of a call out at a townhall meeting by the wife of a patient. It has not listened to the many recommendations by this Appropriation Committee over the past twenty years. In order to fund ME on par with MS, a similarly serious disease, ME would need $250 million a year to bring them on par with other similarly burdened diseases yet, gets a mere $5 million.

We need a different approach and a complete overhaul at all agency levels. We need an investigation by Congress into the mishandling and neglect of ME by HHS, NIH and CDC and active, ongoing Congressional oversight until HHS' negative bias is rectified. We are therefore coming to you for help in this matter.

The following are the recommendations and goals that we at MEadvocacy.org feel the Appropriations Committee needs to require that HHS meet, in order to bring Myalgic Encephalomyelitis back on par with other similarly burdened diseases:

1. Fund biomedical research for ME commensurate with its severity and burden to patients and the economy. We are asking for specific funding in the amount of $250 million, the amount we believe is needed to bring ME on par with other similarly burdened diseases. HHS should clearly allocate funds to study patients from past ME cluster outbreaks as well as the study of the epidemiology of patients with severe ME. The additional funding needed for ME might be accomplished by means of a sliding scale of allocation from other diseases related to immune, cognitive and nervous system dysfunctions.

2. Heed the ME stakeholders' request to adopt the diagnostic and research criteria authored by those experienced in the disease, namely the 2003 Canadian Consensus Criteria (CCC), which has been adopted by the International Association of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (IACFS/ME). In a letter to the Secretary of HHS, 50 experts in the disease declared their consensus agreement to adopt the CCC. This was endorsed by a letter signed by 171 advocates as well as a petition signed by over 6,000 patients. The 2011 revision known as the International Consensus Criteria (ICC) would be an alternatively acceptable criteria for adoption.

3. Retain the historical name for this disease, myalgic encephalomyelitis, which has been coded since 1969 by the World Health Organization under neurological disease with the code G93.3. In addition, ME appears in the 2015 U.S. ICD Codes as U.S. ICD–10–CM with the same coding. Additionally, we request that the Appropriation Committee recommends HHS:

4. Return ME to the National Institute of Allergy and Infectious Disease (NIAID) or place it in the National Institute of Neurological Disorders and Stroke (NINDS), which also manages similar neuroimmune diseases such as MS, fibromyalgia, and Lyme Disease. The Office of Research on Women's Health, where ME is currently housed, is entirely inappropriate for disease, which also strikes men and children.

5. Provide opportunities for dissemination of information through the development of a curriculum for all U.S.-based medical schools, as well as physician continuing education, about ME as defined solely by disease experts, in order to provide the tools needed for physicians and other medical professionals to appropriately recognize and treat this disease. Currently, this would mean using either the 2003 Canadian Consensus Criteria or the 2011 International Consensus Criteria, not the overly broad criteria developed by the non-expert IOM panel. In addition, the CCC or ICCPrimer should be widely distributed and made available to clinicians, particularly primary care physicians, nationwide in order to facilitate the best care for their ME patients.

6. Partner openly and transparently with stakeholders within 1 year to establish a comprehensive, aggressive and fully-funded cross-agency strategy and implementation plan, with well-defined objectives and milestones, and to develop a plan to monitor progress and provide for Congressional oversight.

"We've documented, as have others, that the level of functional impairment in people who suffer from CFS is comparable to multiple sclerosis, AIDS, end-stage renal failure, chronic obstructive pulmonary disease. The disability is equivalent to that of some well known, very severe medical conditions."

[This statement was submitted by Dr. William Reeves, former CDC Chief of Viral Diseases Branch MEadvocacy.org.]

PREPARED STATEMENT OF NATIONAL ASSOCIATION FOR THE ADVANCEMENT OF ANIMAL SCIENCE (NAAAS)

As President of the National Association for the Advancement of Animal Science (NAAAS), I am writing to request the subcommittee's support for critical animal science research within the National Institute for Food and Agriculture (NIFA) and the Agricultural Research Service (ARS). Specific programmatic requests for NIFA include:

Hatch Act	$244,000,000
Agriculture and Food Research Initiative	700,000,000
Smith Lever, Section 3(b) and (c)	300,000,000
Section 1433	10,000,000
Veterinary Medicine Loan Repayment Program	5,000,000
Veterinary Services Grant Program	2,500,000
Food Animal Residue Avoidance Database Program	2,500,000
Food and Agriculture Defense Initiative	10,000,000

The 2014 farm bill includes an important expansion of Section 1433 to establish a new competitive research grants mechanism to address critical priorities in food security, one health and stewardship. The expanded authority came in response to a historic funding disparity for the animal sciences and represents a strong opportunity to address significant challenges facing animal agriculture.

The new competitive grants program in Section 1433 provides a mechanism to focus resources on high priority areas to help animal agriculture meet future challenges. It is important to get the new competitive program started as soon as possible. We respectfully request that $10 million for Section 1433 in fiscal year 2017, as an important step toward the goal of meeting the program's authorized level of $25 million.

For ARS, NAAAS recommends $1,286,000,000 for fiscal year 2017. ARS has the potential to make significant progress towards solving problems facing America's livestock and poultry producers but is consistently receiving funding disproportionate to its contributions to the farm economy. ARS intramural research is uniquely suited for projects that require a long term investment leading to high-impact payoffs, while maintaining the capacity and readiness to respond to emerging and pressing problems. ARS also plays a critical role in partnering with the universities and industry to advance science and address emerging issues. NAAAS requests that the committee to provide funding at least $1.286 billion for ARS in fiscal year 2017. Within this total, NAAAS supports the President's budget request for $95 million for buildings and facilities. This level would enable ARS to continue its work to address high priority facility needs.

BACKGROUND AND JUSTIFICATION

As the world's population grows and natural resources become limited, animal agriculture research is necessary now more than ever to improve efficiency in order to continue providing safe and abundant food supplies for the growing global community. It is imperative that the increased food production be done in a manner that will protect our natural resources while maintaining America's global competitiveness in producing animals and animal products. Global demand for food is expected to increase from 70 to 100 percent by 2050. Meat consumption is estimated to increase by 73 percent, dairy consumption is estimated to increase 57 percent, and per capita egg consumption in developing countries is expected to rise by almost 40 percent.

Innovations in animal science will play an important role in the future success of animal agriculture and the rural economy. Livestock and poultry sales account for 40 percent of all farm income. When feed crops consumed by livestock are included, the contribution to farm income is 60 percent. The United States must step up its investments in agricultural research to maintain its status as a leading producer of safe, affordable and abundant food and meet increasing demands.

Unfortunately, current funding by the United States Department of Agriculture (USDA) to support the animal sciences is not proportionate with the economic contributions of animal agriculture. In fact, investment in the animal sciences has been declining for many years, even for programs such as the Agriculture and Food Research Initiative (AFRI) that have received increased appropriations. This trend was highlighted by National Academy of Sciences in its report "Critical Role of Animal Science Research in Food Security and Sustainability" (see http://www.nap.edu/

openbook.php?record__id=19000) that was released in January 2015. The report recognizes the historic underfunding of animal sciences and calls for increased investments. This imbalance in support for animal science puts U.S. animal agriculture at a major disadvantage at a critical time when livestock and poultry producers are striving for global competitiveness, improving sustainability and working to feed a growing global population.

To address this shortfall in Federal investments supporting the animal sciences, new resources must be dedicated to meet critical priorities in animal science. The National Association for the Advancement of Animal Science (NAAAS) has identified a series of value propositions where additional Federal investments can drive innovation in the high priority areas of Food Security, One Health and Stewardship.

FOOD SECURITY—CHALLENGES AND OPPORTUNITIES

With a projected increase in global population by 2050, food production must double which requires increased efficiency of the use of limited natural resources to meet expected increases in meat and milk consumption by 73 percent and 58 percent, respectively. With land, water and other natural resources being limited relative to this demand, maintaining or reducing the environmental impact of increased production will be challenging. New knowledge and technology offers meat and dairy producers and the allied pre- and post-harvest industries that support them an opportunity to increase income using sustainable production methods while meeting expanding demand.

Accelerated research in systems biology and genomics can provide sustainable increases in overall production efficiency by 50 percent in 2025 through enhanced performance. Such applications will provide abundant, safe, nutritious and affordable food from animal sources to consumers across the world.

ONE HEALTH CHALLENGES AND OPPORTUNITIES

The one health concept recognizes that animal, human and ecological health are inextricably linked and are best addressed using a systems approach as alluded to in the National Institutes of Health Roadmap (see http://nihroadmap.nih.gov). The human and livestock genome projects are providing revolutionary insights for improving human health; however, the application of genomics biology to animal agriculture offers much more for our global society. It is clear that an abundant, affordable and safe food supply continues to be the foundation for human health, economic stability and political stability necessary for improved quality of life in the United States and worldwide. A major opportunity of the One Health concept is to enhance vital agricultural and biomedical capabilities that embrace functional genomics, proteomics and bioinformatics to sequence, map and explore genomes of important species of animals, crops and microbes. This is essential for increasing profitability of livestock enterprises through improved production efficiencies and approaches to enhance animal health and wellbeing.

Modern transportation, global movement of animals and people, and intensive livestock management systems create increased risks for either accidental or intentional introduction of infectious diseases. Zoonoses pose risk of disease transmission from animals to people and vice versa, with both health and economic impacts. Some 58 percent of new human diseases are zoonotic, and environmental conditions influence the transmission of disease. The results of outbreaks of highly infectious diseases in animals cause mortality and morbidity, as well as catastrophic trade and other economic impacts. A major concern with such outbreaks is the need to employ systems of containment and eradication that ensure continuity of business operations during intervention, especially in intensive livestock production systems. Interdisciplinary research can help understand how pathways are integrated in complex organisms, determine how disturbances in these pathways lead to disease and disease resistance, and desired phenotypes that enhance production agriculture and animal health, as well as mitigate transmission of zoonotic diseases.

Through this approach of using systems biology to generate new knowledge and technologies, major opportunities will be forthcoming to improve human and animal health using sustainable management practices, as well as advanced methods for early detection, prevention, and recovery from outbreaks of disease and to produce safer foods of animal origin.

STEWARDSHIP CHALLENGES AND OPPORTUNITIES

Livestock operations must continue to make major advances in the efficiency and sustainable use of natural resources for both extensive and intensive production systems. More effective use of land, water, energy and other natural resources that generate inputs to animal production as well as for animal production itself are

needed. Stewardship of the animals and their relationship to the communities in which they exist are key elements of the total equation. As demand for food increases, animal production will be increasingly forced to use marginal lands where stewardship is even more challenging. New innovations and technologies are urgently needed to meet future demands for foods of animal origin, stewardship of natural resources, and economic survival of food animal production. Science-based information for appropriate policy and regulatory paradigms is required. Modern science, ranging from basic research in plant and animal genomics, transcriptomics and bioinformatics is essential to underpin genetic selection for development of new and more drought-resistant feeds and forages to improve overall food animal production efficiencies and management practices. This approach is essential to realizing advances in animal and plant agriculture required to meet demands and maintain a healthy, natural resource base.

In order to realize the innovations and outcomes identified, increased public funding of agricultural research will be needed. NAAAS appreciates the opportunity share its views on the drivers for innovation in animal science and the need for increased Federal investments. Please let us know if you have any questions or if NAAAS can be of any assistance as the committee continues its work on the Federal investment in science.

[This statement was submitted by Ken Odde, President of the National Association for the Advancement of Animal Science.]

PREPARED STATEMENT OF NATIONAL ASSOCIATION OF NUTRITION AND AGING SERVICES PROGRAMS (NANASP)

On behalf of the National Association of Nutrition and Aging Services Programs (NANASP), an 1,100-member nonpartisan, nonprofit, membership organization for national advocates for senior health and well-being, and on behalf of the Academy of Nutrition and Dietetics, a 76,000 member organization of food and nutrition professionals, committed to improving the nation's health through healthy and safe food choices, we thank you for the opportunity to offer testimony in support of the Department of Agriculture's proposed increases for the following programs within the Food and Nutrition Services:

—$900 million for the Supplemental Nutrition Assistance Program (SNAP), including $10 million to implement state options to streamline application processes for older adults;

—$14 million for the Commodity Supplemental Food Program

We also support the $20.6 million request for the Senior Farmers' Market Nutrition Program.

One in six older Americans struggles with hunger and food insecurity. These numbers continue to grow with the growth of the aging population; more than 10,000 seniors turn 65 every day. However, only 39 percent of eligible seniors are enrolled in SNAP—meaning that millions of seniors are going hungry.

One reason commonly given for lack of older adult enrollment in SNAP is lack of ability to fill out the application. Therefore, the President's request for $10 million to implement state options to streamline application processes for seniors based on successful state demonstrations in increasing senior participation in SNAP is incredibly important. By streamlining the process, seniors will be able to apply more easily, thus making it more likely that they will complete the application and receive the benefits they desperately need.

We also support the proposed increase for the Commodity Supplemental Food Program. It currently serves more than 600,000 low-income people nationwide, and it is the only USDA nutrition program that provides monthly food assistance specifically targeted at low-income seniors. However, the program is funded at a set level annually and therefore cannot serve all eligible seniors. It is also unavailable in Alabama, Virginia, West Virginia and Wyoming. This increase would address current demand and fund new caseloads to a total of 639,000 participants.

Finally, at a minimum, we support the President's request for $20.6 million for the Senior Farmers' Market Nutrition Program. This program puts fresh produce into the hands of low-income seniors and supports local markets, roadside stands, and community-supported agriculture operations (CSAs). However, fewer than 836,000 seniors were able to participate in 2013 and received an average benefit of only $31/year in groceries since the program is funded at a set level. Further, it is unavailable in seven states. Thus, we support its expansion and higher funding for this program if at all possible.

Investments in these nutrition programs are cost-effective because many common chronic conditions such as hypertension, heart disease, diabetes, and osteoporosis can be effectively prevented and treated with proper nutrition. The Academy of Nutrition and Dietetics estimates that 87 percent of older adults have hypertension, high cholesterol, diabetes, or some combination of all of these. These seniors need healthy meals to avoid serious medical care—and this care would place an expensive burden on Medicare and Medicaid.

Older adults who are not receiving proper meals can also become malnourished and undernourished. This makes it harder for them to recover from surgery and disease, makes it more difficult for their wounds to heal, increases their risk for infections and falls, and decreases their strength that they need to take care of themselves. Malnourished older adults are more likely to have poor health outcomes and to be readmitted to the hospital—their health costs can be 300 percent greater than those who are not malnourished on entry to the healthcare system.

As more than 10,000 seniors turn 65 every day, now is the time to provide a greater investment in these proven and cost-effective programs.

Thank you for your past and future support.

[This statement was submitted by Ann Cooper, Chair and Robert Blancato, Executive Director National Association of Nutrition and Aging Services Programs.]

PREPARED STATEMENT OF NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

As Congress prepares legislation for fiscal year 2017 appropriations for Federal agencies, the National Association of State Departments of Agriculture (NASDA) encourages you to support important programs to ensure a safe, affordable, and abundant food supply. NASDA represents the Commissioners, Secretaries, and Directors of agriculture in all fifty states and four territories. As elected and appointed officials, our members are strong advocates for agriculture and partner with a number of Federal agencies in regulating, marketing, and serving the agricultural industry.

FOOD AND DRUG ADMINISTRATION

Integrated Food Safety System: Increase for the Food Safety Modernization Act (FSMA) state implementation programs at $100 million NASDA estimates state programs will need an investment of $100 million annually. The requested amount is necessary for the development and operation of programs which will implement the three major FSMA programs (Preventive Controls: Human Food, Preventive Controls: Animal Food, and Produce Safety). The sooner FDA's expenditures to states reach the $100 million per year mark, the more systematic and timely the implementation of FSMA will be at the state level. While the U.S. arguably has the safest food system in the world we can do better if we focus on prevention.

Center for Veterinary Medicine (CVM): Fund CVM program areas at $196.7 million; National Antimicrobial Resistance Monitoring System (NARMS) funding at $10.8 million; Combating Antibiotic Resistance Initiative at $35 million for USDA CVM oversees the safety of animal drugs, feeds and biotechnology-derived products. Further, we request that the new user fees established by the Animal Drug User Fee Act (ADUFA) of $22.977 million be included in the fiscal year 17 appropriations bill. ADUFA establishes a system of performance standards to improve the new animal drug review process at CVM. NASDA thanks Congress for increasing NARMS funding for meat testing by $3 million last year and supports the Administration's request for an additional $35 million for the USDA and $1 million for the CVM for research, monitoring, and surveillance under the CARB.

U.S. DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service (AMS): Fully fund the Specialty Crop Block Grant Program at the authorized amount of $72.5 million; fully fund the Specialty Crop Multi-State Program at the authorized amount of $4 million. The SCBG Program is critical to the expanding the availability of high quality, safe, and nutritious specialty crops to consumers while adding value to producers through research and extension activities.

Agricultural Research Service (ARS): Fully fund ARS at $1.426 billion; fully fund Office of Pest Management Policy (OPMP) at $3 million; fully fund National Agricultural Law Center (NALC). ARS works towards solving problems facing America's crop, livestock and poultry producers as well as natural resources, human nutrition, food production and food processing. NASDA urges the committee to fully fund the OPMP at $3 million as they provide crucial leadership in the coordination of inter-

agency activities between USDA, EPA, FDA, and state agencies. NASDA encourages continued extramural funding for the NALC and its partners in the Agricultural & Food Law Consortium through the USDA–ARS National Agricultural Library. Requested report language: The Committee expects USDA–ARS National Agricultural Library extramural research consortium projects to be funded at no less than the fiscal year 2014 levels.

Animal and Plant Health Inspection Service (APHIS): Fund APHIS program areas at $901 million; fully fund Cooperative Agricultural Pest Survey (CAPS) Program; fully fund Wildlife Services at $105 million; fully fund Feral Swine Control at $20 million; new research funding for National Animal Health Monitoring System (NAHMS). Any reductions to APHIS' budget could result in deterioration of essential services and impair the Agency from carrying out its fundamental mission, which is "to protect the health and value of American agriculture and natural resources." The CAPS program, WS programs and the national control program for feral swine programs are crucial to state, industry and Federal coordination in researching, detecting and resolving conflicts with pests and animals. NASDA supports fully funding NAHMS for antibiotic research which conducts studies on the health and management of U.S. livestock populations.

Food Safety Inspection Service (FSIS): Remove Prohibitions on USDA Horse Meat Inspections; fully fund State Food Safety and Inspection at $63 million. We encourage the committee to resist attempts to include language that would prohibit funding for USDA ante-mortem horse inspection. Further, NASDA urges the committee to restore funding for State Food Safety and Inspection programs to $63 million, which is critical for states that provide state meat inspections under a variety of programs regulated by FSIS.

Foreign Agricultural Service (FAS): Market Access Program (MAP) at $200 million; Foreign Market Development (FMD) program at $34.5 million. MAP and FMD encourage the development and expansion of commercial agricultural export markets and assists small businesses in accessing foreign markets.

National Agricultural Statistics Service (NASS): Funding for NASS of at least $176.6 million. NASS statistics provide the information necessary for producers, agribusinesses, farm organizations, economists, and others for critical decisionmaking in agricultural marketing and investing. NASS data is vital to keeping agricultural markets stable, efficient, and fair by making available objective data to commodity market buyers and sellers.

National Animal Health Laboratory Network (NAHLN): Fully fund NAHLN at $15 million. NAHLN is a cooperative effort between USDA–APHIS, NIFA, university, and state veterinary diagnostic labs. NAHLN is an early warning system for emerging and foreign animal diseases and we urge the committee to fund NAHLN at the authorized amount.

National Institute for Food and Agriculture (NIFA): Fund National Agriculture in the Classroom (AIC) at $1 million; Fully fund Agriculture and Food Research Initiative (AFRI) at $700 million; Funding for Veterinary Medical Loan Repayment Program (VMLRP) at $5 million; the Veterinary Services Grant Program (VSGP) at $2.5 million; Fund Food Animal Residue Avoidance Database (FARAD) at $2.5 million and Section 1433 at $10 million. AIC is a critical educational tool in inspiring our next generation of farmers, workforce members and consumers. Further, NASDA is supportive of language directing AFRI to address pollinators, antibiotic resistance and advancing drug approvals to treat minor species. Also, the expanded Section 1433 maintains the program for animal health and disease and adds a competitive grant program focusing on priorities in food security, one health and stewardship.

Natural Resources Conservation Service (NRCS): Fully fund—the Environmental Quality Incentives Program (EQIP) at $1.65 billion; the Conservation Stewardship Program (CSP) at 10.34 million acres; the Regional Conservation Partnership Program (RCPP), the Agriculture Conservation Easement Program (ACEP) at $500 million. Farm Bill Title II conservation programs are invaluable programs in helping farmers, ranchers, and landowners address conservation concerns. Voluntary, incentive-based conservation programs are the bedrock for agriculture's efforts to improve water and air quality, soil health, and address water quantity concerns and resist overly burdensome regulatory efforts.

U.S. Forest Service: Forest Inventory and Analysis (FIA) program at $83 million. The FIA program surveys America's forests and provides information for monitoring trends in habitat, wildfire risk, insect and disease threats and other resource questions.

CONCLUSION

NASDA asks that you give our requests careful consideration as work to fund the nation's agricultural policy priorities in fiscal year 17. NASDA is a partner and co-regulator with Federal agencies in the implementation of a host of food, agricultural and natural resources programs. NASDA Members have a unique wealth of information, experience, and expertise. NASDA stands ready to work with you and your staff to expeditiously pass the agriculture appropriations bill. Thank you for your consideration, and please let us know if you have any questions.

[This statement was submitted by Barbara P. Glenn, Ph.D., Chief Executive Officer—NASDA.]

PREPARED STATEMENT OF NATIONAL ASSOCIATION OF STATE ENERGY OFFICIALS (NASEO)

Chairman Moran and Ranking Member Merkley, I am David Terry, Executive Director of the National Association of State Energy Officials (NASEO), and I am testifying in support of fiscal year'17 funding for the energy title of the Farm Bill. The mandatory levels of the energy title of the Farm Bill should be preserved. Specifically, we support funding of at least $19 million in additional discretionary spending for the Rural Energy for America (REAP) program (Section 9007 of the last multi-year Farm Bill), in addition to $49 million in mandatory funding for REAP. The REAP program was created in the 2002 Farm Bill and it has been a huge success. Over 10,000 energy efficiency and renewable energy projects have been implemented in every state since 2003. With a required $3 match of non-Federal funds for every Federal dollar invested in REAP, over $1.6 billion in matching funds have been provided. This program has specifically benefitted farmers, ranchers and rural small businesses. 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 is about rural economic development. The Biomass Crop Assistance Program supports producers who will supply biomass feedstocks for advanced biofuels. We urge the Subcommittee to provide $50 million for this effort in fiscal year'17, $24 million above the mandatory funding. Finally, we support $15 million in mandatory funding and $4 million in discretionary funding, a total of $19 million for the Rural Energy for America Loans program.

NASEO represents the energy offices in the 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, helps create jobs, increases agricultural productivity, saves energy for farmers, ranchers and rural small businesses, generates energy, promotes use of alternative fuels, reduces our dependence on imported petroleum and saves money in rural America. The cost is very low and the payback is very high.

In fiscal year 2017, we urge your support for the REAP program, the Rural Energy for America Loans program, the Biomass Crop Assistance Program.

[This statement was submitted by David Terry, Executive Director, National Association of State Energy Officials.]

PREPARED STATEMENT OF NATIONAL ASSOCIATION OF WHEAT GROWERS

The National Association of Wheat Growers joins the National Wheat and National Barley Improvement Committees in urging the Committee to provide an additional $3.3 million over the budget request for funding the USDA–ARS US Wheat & Barley Scab Initiative (USWBSI). This increase would provide the full $10 million authorized by section 7303 of the Agricultural Act of 2014. We are also requesting an additional $3.44 Million to support a Small Grains Genomic Initiative within the Agricultural Research Service.

Wheat is a very important crop and source of economic activity. As USDA's Economic Research Service has reported, the United States is a major wheat-producing country, with output typically exceeded only by China, the European Union, and India. Almost half of the U.S. wheat crop is exported. Wheat is the principal food grain produced in the United States. In the last decade, wheat ranked third among U.S. field crops in both planted acreage and gross farm receipts, behind corn and soybeans. According to the National Agricultural Statistics Service, more than 2 billion bushels of wheat with a weighted average farm price value of approximately $12 billion was harvested from more than 46 million acres across 42 states.

We appreciate that you have provided important support for scab research over the past several years. Since fiscal year 2003, Congress has annually provided $6.7 million. The mission of the USWBSI is to enhance food safety and supply by reducing the impact of Fusarium Head Blight (scab) on wheat and barley. The USWBSI is an organization of grower, researcher, and industry stakeholders, providing annual recommendations to ARS for a mission directed competitive grant program. The USWBSI is the consortium of land-grant colleges and universities authorized in farm bills over the years, in partnership with USDA–ARS scientists and research locations throughout the US.

However, the increase of $3.3 million is necessary because scab is an emerging threat in new regions of the country, including the Western states of Colorado, Idaho, Montana, Oregon, California and Washington. Wet conditions throughout the US in 2014 resulted in widespread scab outbreaks, negatively impacting yields and resulting in high levels of the mycotoxin deoxynivalenol (DON, aka vomitoxin) in grain that was rejected by elevators, mills, and maltsters, causing disruptions in supply, economic losses to growers, and increased costs for end users.

The additional programmatic funding of $3.3 million requested is proposed to be allocated 50 percent to the USWBSI and 50 percent in permanent base funding increases to ARS units conducting scab and supporting research.

For the $1.65 million increase proposed for the multi-institutional and multi-discipline directed competitive grant program of the USWBSI, we recommend the following allocations to enhance research in states currently receiving funding and to expand to other states where research is needed.

Budget	Allocation
Accelerated Breeding	$500,000
Scab Management	500,000
Genomic Selection	300,000
Research infrastructure in emerging areas	100,000
Additional DON testing	250,000
Total USWBSI Request	1,650,000

We also propose that ARS, in consultation with the USWBSI Executive and Steering Committees (comprised of grower, researcher, and industry stakeholders), determine how to allocate the $1.65 million proposed for permanent base funding increases to ARS locations conducting scab research or supporting research.

We also request an additional $3.44 Million to Support a Small Grains Genomic Initiative under the ARS Salaries and Expenses Account. Those funds would be distributed as follows.

—Next Generation Genotyping—Funding of $1.5 million is needed so that all four USDA–ARS Small Grains Regional Genotyping Laboratories (Fargo, ND; Manhattan, KS; Raleigh, NC; Pullman, WA) can meet their mission to facilitate application of genomic information and DNA marker technologies for improvement and breeding of wheat, barley, and oat varieties. Small grains breeders must be equipped with genotypic data that give them rapid access to traits of value so they can be incorporated into improved varieties to counter threats to the crops from diseases, insects, and climate; maintain grain quality; increase yields, and improve other agronomic characters. Of particular importance is the hiring of a bioinformatics support scientist to analyze and interpret data to meet the needs of scientists doing research on breeding and genetics of small grains, and to integrate the enormous amounts of generated data into the nationwide "Big Data" network being developed by the USDA–ARS. The scientist will also oversee and maintain local genotyping lab computing resources.

—Barley & Wheat Quality Phenotyping and Research—Funding of $1.79 million is needed so that all five USDA–ARS Barley and Wheat Quality Laboratories (Madison, WI; Fargo, ND; Manhattan, KS; Wooster, OH; Pullman, WA) can meet their missions to advance the quality and utilization of barley and wheat grain in the U.S. for the betterment of U.S. consumers, farmers, and the brewing, milling, baking, and processing industries.

In this age of modern genomics, substantial resources have been directed at cutting edge DNA technologies, but adequate resources for the phenotyping (measurable characterization) of barley and wheat quality have not been provided. Wheat and malting barley varieties developed with the aid of genomic technology, but lacking the quality characteristics required for domestic and export market end-users, are of little value.

The remaining $150,000 of our request for the Small Grains Genomic Initiative would be for barley doubled haploid work.

The National Association of Wheat Growers, working with its team of 22 state wheat grower organizations to benefit the wheat industry at state and national levels, appreciates your consideration of our requests.

[This statement was submitted by Gordon Stoner, President National Association of Wheat Growers.]

PREPARED STATEMENT OF NATIONAL COMMODITY SUPPLEMENTAL FOOD PROGRAM ASSOCIATION

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 2017 at $236,120,000 as requested by the U. S. Department of Agriculture. NCSFPA would also like to thank the Subcommittee for providing sufficient funding in fiscal year 2016 to bring on 1 additional new state with a previously approved plan of operation by USDA. Low-income seniors in the state of Virginia will begin receiving the nutritionally balanced CSFP food packages this year.

CSFP is a unique program which brings together Federal and state agencies, along with public and private entities. In fiscal year 16, the CSFP provides services through 150 non-profit community and faith-based organizations at 1,800 sites located in 47 states, the District of Columbia, and two Indian Tribal Organizations (Red Lake, Minnesota and Oglala Sioux, South Dakota). Each month 619,000 participants 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. Even though the budget request would provide assistance to an additional 20,000 seniors, it is important to note that current participating states have requested another 142,149 caseload slots to meet the need in their service areas. We are sure the additional caseload will be well used.

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 purchases foods at wholesale prices, directly supporting American farmers. The average food package cost is estimated at $23, while the retail value is approximately $50.00.

—The CSFP involves the entire community. 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 2013 supplemental report by Ziliak and Gundersen for the National Foundation to End Senior Hunger; The State of Senior Hunger in America 2011: An Annual Report demonstrated that seniors continue to face ever increasing food insecurity challenges despite the end of the Great Recession. The proportion of seniors age 60 or older facing hunger increased by over 15 percent from 2010 to 2011. Additionally, from 2001 to 2011, the number of seniors experiencing the threat of hunger, the risk of hunger, and hunger has increased by 88 percent, 109 percent, and 200 percent, respectively.

The 1997 report by the National Policy and Resource Center on Nutrition and Aging at Florida International University, Miami— Elder Insecurities: Poverty, Hunger, and Malnutrition indicated that malnourished elderly patients experience 2 to 20 times more medical complications, have up to 100 percent longer hospital stays, and incur hospital costs $2,000 to $10,000 higher per stay. Proper nutrition promotes health, treats chronic disease, decreases hospital length of stay and saves healthcare dollars.

In a 2013 NCSFPA survey, more than half of seniors living alone reported an income of less than $750 per month. One-half of respondents from two-person house-

holds reported an income under $1,000 per month. 25 percent were enrolled in the Supplemental Nutrition Assistance Program (SNAP) and 50 percent said they ran out of food during the month. 70 percent of senior respondents said they choose between medicine and food.

In 2012, an informal NCSFPA senior participant survey revealed individual accounts of the value of CSFP benefits. An Arkansas recipient tells us that they would not otherwise be able to eat the balanced meals that CSFP provides each month. Arkansas program operators talk about the importance of interaction between seniors and program staff, saying this interaction is very important for the well-being of recipients, and recipients are able to live more stable, self sufficient lives as a result. Colorado participants say that they would not be able to have juice and cereal without CSFP, and many appreciate the program because they are homebound. Seniors in St. Louis, Missouri, say that CSFP foods help them get through to their next checks. Participants in Nebraska say that they don't know what they would do without this food, calling the program a "lifesaver". New Hampshire participants tell us that they use CSFP as a primary source of nutrition each month and would see a dramatic loss in food availability without the program. One Wisconsin recipient said that they would starve without the program, while others said that CSFP on their limited income meant that they could pay their telephone and electric bills.

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 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 Food and Nutrition Service of the Department of Agriculture for their continued innovations to strengthen the quality of the food package and streamline administration.

The Senate 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 $236,120,000 million for the Commodity Supplemental Food Program in order to allow us to provide needed services.

Again, thank you for your continuing support. We look forward to working with you on behalf of CSFP participants.

PREPARED STATEMENT OF NATIONAL COTTON COUNCIL

The NCC is the central organization of the United States cotton industry. Its members include growers, ginners, cottonseed processors and merchandizers, merchants, cooperatives, warehousers and textile manufacturers. A majority of the industry is concentrated in 17 cotton-producing states. The downstream manufacturers of cotton apparel and home furnishings are located in virtually every state. Farms and businesses directly involved in the production, distribution and processing of cotton employ almost 200,000 workers and produce direct business revenue of more than $27 billion. Annual cotton production is valued at more than $6 billion at the farm gate, the point at which the producer markets the crop. Accounting for the ripple effect of cotton through the broader economy, direct and indirect employment surpasses 420,000 workers with economic activity well in excess of $100 billion. In addition to the cotton fiber, cottonseed products are used for livestock feed, and cottonseed oil is used as an ingredient in food products as well as being a premium cooking oil.

The NCC welcomes the opportunity to provide the following recommendations and requests for fiscal year 2017 appropriations for programs which make important contributions to our industry's ability to compete and prosper in a world market.

FUNDING PRIORITIES

Cotton Pests (APHIS): The National Cotton Council requests $11.52 million (level with the fiscal year 2016 and fiscal year 2015 appropriations) for the APHIS Cotton Pests Account. This will allow APHIS to continue to provide coordination, technical assistance and funds for Boll Weevil Eradication and Pink Bollworm Eradication programs. Grower assessments provide the balance of program funds. As these pro-

grams near completion, the Federal funding becomes even more critical to ensure the complete eradication of these cotton pests for the benefit of those in post eradication maintenance. Additional details for the Boll Weevil Eradication Program and the Pink Bollworm Eradication Program are provided below:

Boll Weevil Eradication (APHIS—Cotton Pests): The NCC requests $8.1 million (level with the fiscal year 2016 and fiscal year 2015 appropriations) for APHIS to provide Federal support to the National Buffer Zone in the Lower Rio Grande Valley (LRGV) in Texas, the last "frontier" for Boll Weevil Eradication efforts since 97 percent of the U.S. cotton acreage is now free of boll weevils. This Zone is also the only remaining active eradication zone in the U.S. APHIS funds are only provided to this active eradication zone in keeping with a commitment that grower assessments provide 100 percent of the cost of maintenance programs once an area or region is declared "weevil free." The program continues to produce documented economic and environmental benefits. Cotton in the United States is now produced with an average of less than three annual applications of pesticides per acre for all insects. This compares to the 15 to 20 applications per acre prior to boll weevil eradication and adoption of cotton varieties containing Bt technology for worm control.

Continuation of Federal funding is critical as the program strives to complete eradication in the LRGV of Texas. The NCC recognizes that the movement of boll weevils from Tamaulipas, Mexico, into the LRGV has prolonged the eradication efforts of the U.S. However, the eradication efforts in the LRGV continue to make progress and the area also serves as the National Buffer, protecting the remainder of the U.S. cotton acreage from re-infestation of the boll weevil. The NCC's Boll Weevil Action Committee has created the International Technical Advisory Committee to share and coordinate technical procedures with the Tamaulipas, Mexico program in an effort to enhance their eradication progress thereby ending this weevil migration. In addition, the NCC is cooperating with APHIS in developing another liaison committee to include Mexico program officials to identify additional resources and technical assistance required by the Tamaulipas program.

We also respectfully request that APHIS be directed to make every effort to minimize overhead and administrative expenses for boll weevil eradication to ensure field operations are funded to the fullest extent possible.

Boll Weevil Eradication (FSA)—The NCC requests sufficient funding to allow FSA to make up to $60 million in loans to eligible producer-controlled organizations carrying out Boll Weevil and Pink Bollworm eradication programs. This authority has existed since fiscal year 2005 and has been critically important to the success of the programs. There has not been a forfeiture on any loan made by FSA for the purpose of carrying out Boll Weevil and Pink Bollworm eradication efforts.

Pink Bollworm Eradication (APHIS—Cotton Pests): The NCC requests $3.42 million (level with the fiscal year 2016 and 2015 appropriations) be provided to APHIS to continue support for the pink bollworm program. The Pink Bollworm Eradication Program is based predominantly on the mass release of sterile insects generated by a Phoenix, AZ rearing facility.

The funds requested for fiscal year 2017 will enable the Pink Bollworm Rearing Facility (PBRF) in Phoenix, AZ, to maintain a colony of pink bollworm moths with the capability to provide sterile moths for release if a wild moth is captured. The PBRF is a partnership between the California growers and APHIS. The cost share for pink bollworm is essential to provide APHIS' expertise and operational coordination in mass rearing and area-wide aerial releases of millions of sterile moths.

> The Pink Bollworm Eradication Program did not document the capture of any native pink bollworm moths in 2013 for the U. S., which allowed the program to begin a confirmation phase in 2014. There was no documented capture of any native pink bollworm moths in 2014 or in 2015. The density of monitoring traps remained high for the 2014 year in order to verify that no native populations are present. The trapping density will gradually decline over the next several years before eradication is confirmed. A response plan has been developed by technical experts to respond to localized areas as needed if a native capture is documented during this confirmation phase. Growers contribute funds through assessments and incur significant expense associated with purchasing and planting biotech seeds during the active eradication period.

Market Access Program (MAP).—The NCC strongly supports the funding level in the Agricultural Act of 2014 of $200 million for MAP. Cotton Council International (CCI), the foreign market development arm of the NCC, has the critical mission of maintaining and expanding exports of US cotton and cotton products in Asia, Europe, Africa, and Central and South America. The value of U.S. cotton fiber exports exceeds $5 billion, and exports of value-added cotton products contribute an addi-

tional $3 billion to the overall value of cotton exports. Activities carried out using MAP and Foreign Market Development (FMD) funds have been documented as contributing to increased export sales of cotton fiber and value-added manufactured cotton products. Independent studies reveal that for every dollar spent by USDA cooperators, including CCI, U.S. exports increase $35, a 35-to-1 return on investment. For the cotton industry, this represents over one billion dollars in export value or an additional 7,000 jobs to the U.S. economy. The cotton industry believes CCI's programs are an effective catalyst for private sector investments, with the industry investing $2.02 for every dollar of MAP funds received.

Foreign Market Development (FMD).—The FMD program is used to encourage and support U.S. commodity groups to undertake long-term market development and trade servicing. These funds are used for programs with detailed market assessments, strategic program development and ongoing evaluations. These funds create unique market development and trade servicing value and, like the MAP funds, are closely monitored by USDA for compliance with U.S. laws. FMD is currently funded at $34.5 million and requires at least a dollar-for-dollar industry match. The industry requests that funding for FMD be continued at the level authorized in the Agricultural Act of 2014. The cotton industry believes CCI's programs are an effective catalyst for private sector investments with industry investments totaling $1.31 for every dollar of FMD funds received.

Foreign Agricultural Service (FAS).—The industry supports sufficient funding to ensure FAS is adequately staffed to carry out important market development and trade enhancing functions in headquarters and abroad. The industry supports the Presidential initiative to streamline and make U.S. export programs more effective. We believe FAS's market research and market development assistance combined with the MAP and FMD programs serve as a model for successful public-private partnerships. We believe it is important that U.S. agriculture continue to have an agency like FAS with close links to domestic USDA programs to promote U.S. exports, collect market data, assist exporters, remedy trade disputes and assist in the development of trade policy.

Farm Service Agency (FSA).—The NCC supports adequate funding so that FSA can continue to deliver essential farm and conservation programs and services.

Risk Management Agency (RMA).—The NCC supports adequate funding so that RMA can continue to administer essential insurance products.

Agricultural Research Service (ARS).—The cotton industry continues to be concerned with the financial support of this important intramural research agency. ARS programs and facilities conduct vital research programs in fiber quality, production agronomic systems and textiles that ultimately support U.S. cotton production and post-harvest processing as well as the U.S. textile industry's efforts to remain competitive in global markets. We urge the Committee to instruct USDA not to close any facilities or discontinue any projects without first consulting with industry stakeholders.

The NCC specifically requests an increase of $1.68 million in funding for the three cotton ginning research units to be distributed as follows: Southwestern Cotton Ginning Research Laboratory, Mesilla Park, NM, $468,000; Cotton Production and Processing Research Unit, Lubbock, TX, $752,000; and the Cotton Ginning Research Unit, Stoneville, MS, $460,000. All three ginning research units need additional funding immediately to address scientific personnel needs, conduct research, and offset the impact of inflation after years of flat or decreasing budgets.

We request that the Committee maintain funding for the research units managing cotton programs conducted at the Southern Regional Research Center in New Orleans, LA, and the various cotton breeding and cotton entomology programs including support for the Cotton Germplasm Collection managed by the Southern Plains Crop Germplasm Unit housed at the Southern Plains Agricultural Research Center in College Station, TX.

We agree with the President's Council of Advisors on Science and Technology (PCAST) December 2012 report, "Agricultural Preparedness and the Agricultural Research Enterprise," that significant additional funding for agricultural research is warranted for maintaining a viable U.S. industry. However, we differ with the report's emphasis on increasing competitive funding of research. We continue to urge a balanced approach among intramural, competitive and formula funding in order to maintain an effective research infrastructure while encouraging innovative research at the highest levels. For ARS to continue its part in this research enterprise, additional funding is needed. We urge the Committee to provide ARS with additional overall funding as soon as economic conditions allow the Committee to respond to the PCAST report's funding level recommendations.

Thank you for your consideration of our recommendations and of our funding requests for fiscal year 2017. Please contact me with any questions or if additional information is needed.

[This statement was submitted by Reece Langley, Vice President—Washington Operations.]

PREPARED STATEMENT OF NATIONAL EMPLOYMENT LAW PROJECT

The National Employment Law Project (NELP) submits the following testimony on the fiscal year 2017 Appropriations for the Food Safety and Inspection Service regarding the New Poultry Inspection System Program. NELP conducts research, education and advocacy to assure that the basic protections afforded by our nation's labor and employment laws extend to all workers, including low wage workers.

NELP opposes any amendment to the Appropriations bill that would allow poultry plants entering the U.S. Department of Agriculture's (USDA) New Poultry Inspection System (NPIS) program to increase their lines speeds in defiance of the recently promulgated USDA standard: Modernization of Poultry Slaughter Inspection. We strongly urge the Committee to oppose this amendment that would rewrite the USDA's rule, subverting the normal rulemaking process without any formal public comment or input from the public, who along with poultry line workers, will be negatively affected by any change to this rule.

In August of 2014, the USDA's Food Safety and Inspection Service (FSIS) promulgated the final rule for the Modernization of the Poultry Slaughter Inspection System. The final rule went through almost 2 years of public comment. When the final rule was published, it did not permit an increase in maximum line speeds in poultry plants.

When this rule was first proposed for public comment in 2012, it contained a proposed increase in maximum line speeds in poultry plants. FSIS asked for comment on this provision, specifically acknowledging the potential for an increase in line speeds to effect employee health and safety. According to USDA, this proposed provision increasing allowable line speeds received the most comments from the public. The comments were focused on the negative effects the increased line speeds would have on the health and safety of workers in the poultry slaughter establishments as well as consumer safety.

In response to all the comments received in the rule making, USDA FSIS decided not to increase the line speed from 140 to 175 birds per minute (bpm) in poultry slaughtering facilities. In the preamble to the final rule, the agency further noted concerns regarding 20 plants that are already in a pilot program (HIMP) that allowed these pilot facilities to increase line speeds to 175 bpm. USDA noted that the data from this existing pilot program found that the average line speed in these plants is 131 bpm—well below the currently allowed 140 bmp and far below the 175 permitted.

The primary concern echoed in the many comments from academia, worker organizations and consumer organization was the detrimental effect of increased line speed on the health and safety of the tens of thousands of workers in the industry. Poultry slaughter and processing workers face many serious job hazards that can lead to serious injury, illness and death. In fact workers in poultry plants are injured at almost twice the rate of workers in private industry. Further the incidence rate of occupational illness cases reported by the industry is more than six times the national average for all U.S. industries. And it is well established, that these rates are under reported. As USDA noted in the preamble to the final rule, and OSHA stated in its new emphasis program in the poultry industry "the literature suggests the likelihood of substantial under-reporting of worker injuries and illnesses by poultry industry employers."

Poultry processing workers make thousands of forceful cuts a day, using knives and scissors, in cold and damp conditions, with acidic chemicals being sprayed over the meat, and incidentally their bodies, as it moves down the line. Work related musculoskeletal disorders (MSD's) are of significant concern among poultry processing workers. These disorders, including carpal tunnel syndrome, tendonitis, and epicondylitis, affect the nerves, tendons and muscles. Poultry workers face incidence rates seven times higher than other manufacturing workers for work related carpal tunnel syndrome. In 2014 and 2015, in cooperation with the USDA, the National Institute of Occupational Safety and Health (NIOSH) conducted studies at two different poultry processing facilities and found high prevalence rates among production workers for carpal tunnel syndrome (CTS): 42 percent and 34 percent, respectively of CTS among workers.

USDA acknowledged the danger to workers of increased line speeds in the preamble of its final rule, and also acknowledged that more study and review was needed before any change in line speed would be made. There has been no such study or review done since this rule was promulgated. Such a review would have to be prospective and take years—to assure that the safety of the tens of thousands of workers is not sacrificed on the altar of decreased government spending.

Just last month, OSHA sent a hazard alert letter to a poultry company in Ohio for exposing workers to hazardous campylobacter bacteria. Workers at the poultry processing plant had contracted the infection—which can lead to serious gastrointestinal infection. This same company has racked up nearly $1.9 million in fines from the U.S. Department of Labor's Occupational Safety and Health Administration from its two plants in Ohio. OSHA had earlier found that this same company fired a 17 year old after his leg was amputated because of a failure by the company to install a safety mechanism.

That is not an isolated instance. The speed of work in poultry plants already causes far too many workplace injuries and may be impacting consumer safety as well. OSHA citations and newly released reports have found that to keep the lines going at full speed, workers are often denied their legal right to use a bathroom, soiling themselves at work. Poultry processing plants also penalize workers for taking any sick days, so workers come to work sick while handling the meat on the line.

As workers get injured because companies don't comply with basic safety precautions, they don't file workers compensation and heal. The companies do everything they can to preclude that. So instead, workers leave the plants. Many plants report turnover between 50–100 percent.

Poultry processing workers are among the most vulnerable people in the country. Most are minorities and immigrants; some are newly resettled refugees. They are pursuing the American dream—working hard, arduous jobs in a harsh environment—all to help put food on our table.

Congress should not allow the industry to speed up its lines after the USDA studied the issue, heard from the American public, and promulgated a rule that would not allow such an increase. This would be a subversion of the entire rule making process, it would demonstrate utter disregard for the rule of law, and would be a direct slap in the face to the workers and communities that sacrifice to feed America.

[This statement was submitted by Deborah Berkowitz, Senior Fellow National Employment Law Project.]

PREPARED STATEMENT OF NATIONAL YOUNG FARMERS COALITION

Thank you for the opportunity to share our appropriations priorities for fiscal year 2017. Congress and the USDA have made significant progress in recent years towards better serving young, beginning farmers. The National Young Farmers Coalition (NYFC) is excited for the role Federal funding can play furthering this growth.

NYFC represents, mobilizes, and engages young farmers to ensure their success. We envision a country where young people who are willing to work, get trained and take a little risk can support themselves and their families in farming. NYFC has 29 local chapters across the country and represents more than 1,400 dues-paying members.

NYFC requests the following funding be included in the fiscal year 2016 Agriculture Appropriations bill:

1. New, Beginning, and Veteran Farmers and Ranchers Regional Coordinators ($3.9 mil)
2. NRCS's Agricultural Conservation Easement Program (ACEP) at the mandatory program level ($500 mil)
3. FSA's Direct Operating Loans (to provide $1.46 billion in loans) and Direct Farm Ownership Loans (to provide $1.5 billion in loans)
4. Beginning Farmer and Rancher Individual Development Accounts ($1.5 mil)
5. Food Safety Outreach Program ($10 mil)

New, Beginning, and Veteran Farmers and Ranchers Regional Coordinators ($3.9 mil)

NYFC has been working with the USDA to better serve young and beginning farmers. In contrast to established farmers or those coming from a farm family, beginning first-generation farmers require different services from the USDA and need more help than others finding these services. For example, young farmers often seek

smaller operating loans when launching a business than an established farmer. With this in mind, NYFC helped create the popular microloan program at the Farm Service Agency (FSA) that provides operating loans at an appropriate scale for young farmers. Innovative program design and outreach has a proven track record of reaching previously underserved young farmers.

To build on this success, NYFC has been urging the USDA, and FSA in particular, to provide specialized resources for young, beginning farmers and dedicated staff to help these farmers navigate the USDA. The proposed regional coordinators do precisely this. The twenty-five staff positions funded by this request will help young farmers access the services that are already available to them, but underutilized, such as conservation programs and farm loans. The $3.9 million in funding for the proposed outreach staff, as requested in the President's budget, is critical to amplify and leverage the resources already provided for farmers at the USDA and build the next generation of our nation's farmers.

NRCS's Agricultural Conservation Easement Program (ACEP) at the Mandatory Program Level ($500 mil)

Between 2007 and 2012, over 7 million acres of agricultural land were developed to nonfarm use in the United States.[1] This contributes to the more than 24 million acres converted from agriculture between 1982 and 2010, a disproportionately high amount of which contained prime soils.[2] Agricultural conservation easements are a proven tool to stem this tide and protect farmland from development. ACEP provides a critical source of matching funds for the land trusts and state and local programs that are purchasing these easements across the country.

The 2014 Farm Bill provided $500 million in mandatory funding for ACEP in fiscal year 2017. It is critical that this program retains its full, mandatory funding. Even with this full mandatory funding level, this program is funded at $81 million less than its component programs prior to the 2014 Farm Bill. An additional reduction in funding would be devastating to this program.

FSA's Direct Operating Loans (to provide $1.46 billion in loans) and Direct Farm Ownership Loans (to provide $1.5 billion in loans)

FSA operating and ownership loans are crucial for young farmers. Without these loans, many of these individuals would not be able to access credit for their farm. In fiscal year 2015, the funding available for Direct Farm Ownership Loans was dramatically increased—from approximately $.5 billion to $1.5 billion. NYFC was excited to see this increase, since we have heard numerous complaints from farmers about insufficient funds in past years.

While this increased loan level met the demand for Direct Farm Ownership Loans in fiscal year 2016, we faced a shortfall for Direct Farm Operating Loans. With the recent fluctuations in crop prices, the lending market has grown more cautious and more farmers have needed to turn to FSA for their credit needs. Without an increase in loan authority, we expect a shortfall in Direct Farm Operating Loans in fiscal year 2017 and a significant backlog of loan applications by beginning farmers and others not served by commercial credit. This would be a serious problem for both these individual farmers and our broader agricultural community, which is facing a shortage of beginning farmers. We strongly support funding for these loan programs sufficient to provide $1.46 billion in Direct Farm Operating Loans and $1.5 billion in Direct Farm Ownership Loans.

Beginning Farmer and Rancher Individual Development Accounts ($1.5 mil)

Individual development accounts (IDAs) help young and beginning farmers become successful entrepreneurs by matching funds that they put into a savings account while taking required business planning courses. IDA programs have been instrumental in helping young people start businesses in states including Michigan, Iowa, and California. The Beginning Farmer and Rancher IDA pilot program was created in the 2008 Farm Bill and reauthorized in 2014. In spite of the successes of privately run programs around the country, the Federal IDA pilot program has never been funded. As the existing farmer population continues to age and the need for young farmers grows, it has never been more important that the Federal IDA pilot program receive $1.5 million in funding.

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[1] USDA National Agriculture Statistics Service. (2014). 2012 Census of Agriculture. http://www.agcensus.usda.gov/Publications/2012/Full__Report/Volume__1,—Chapter__1__US/st99__1—001__001.pdf.

[2] American Farmland Trust. (n.d.). Farmland by the Numbers. http://www.farmland.org/programs/protection/American-Farmland-Trust-Farmland-Protection-Farmland-by-the-numbers.asp.

Food Safety Outreach Program ($10 mil)

Food safety training has become a particularly important concern for young farmers. The new food safety regulations, finalized by the Food and Drug Administration (FDA) last year, set forth expansive new requirements for farms. Farmers are going to need training and outreach in order to understand the maze of new requirements being asked of them. The Food Safety Outreach Program, administered by USDA's National Institute for Food and Agriculture (NIFA), was authorized to meet this need. It funds farmer and food processor training efforts focused on helping small and mid-sized family farms; beginning farmers; diversified, sustainable, and organic agricultural operations; and on-farm processors adapt to new regulatory pressures.

We are very grateful for the $5 million funding that was appropriated to this program last year. However, this only scratches the surface of the on-the-ground need for training and outreach. We request the Food Safety Outreach Program be funded at $10 million. At this funding level, the Food Safety Outreach Program would reach roughly 16,600 farmers across the country. While this number is small relative to the need, without any training, the final FDA regulations will hurt small and mid sized producers and processors and fall far short of the goal of improving food safety.

[This statement was submitted by Eric Hansen Policy Analyst, National Young Farmers Coalition.]

PREPARED STATEMENT OF NATIONAL ORGANIC COALITION

I am submitting this testimony on behalf of the National Organic Coalition (NOC) to detail our fiscal year 2017 funding requests for USDA programs of importance to the organic sector.

USDA/AGRICULTURAL MARKETING SERVICE (AMS)

National Organic Program
Request: $9.094 million

Organic agriculture is one of the fastest growing sectors of agriculture, fueled by strong consumer demand. Over the last decade, sales of organic food and beverages have averaged double-digit annual growth. The organic sector has grown to over $36 billion industry in annual sales with over 21,764 certified organic family farmers and other businesses.

The National Organic Program (NOP) is the agency charged with regulating and enforcing the USDA organic label. NOP was funded at about $9.02 million for fiscal year 2016. We are requesting $9.094 million for NOP, consistent with the Administration's fiscal year 2017 budget request.

USDA (AMS, NASS, ERS)

Organic Data Initiative
Request: Report language for AMS—Continue and Expand Organic Price Reporting
Request: Report language for NASS—Continue and Expand Organic Data Collection
Request: Report language for ERS—Continue and Expand Organic Data Analysis Work

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 providing mandatory funding, Section 10004 of the 2014 Farm Bill authorizes $5 million annually in discretionary funding for this effort.

As the organic industry matures and grows at a rapid rate, the lack of national data for the production, pricing, and marketing of organic products has been an impediment to further development of the industry and to the effective functioning of many organic programs within USDA. Organic data collection and analysis at USDA has made significant strides in recent years, but remains in its infancy.

We are requesting report language urging AMS, NASS, and ERS to continue to expand their organic data collection within its base activities.

Organic Transitions Program
Request: $5 million

The Organic Transition 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 some of the 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.

The Organic Transition Program was funded at $5 million in fiscal year 2010, and about $4 million for fiscal years 2011 through 2016. The Administration's fiscal year 2017 budget requests level funding. We are seeking $5 million to restore the program to its fiscal year 2010 level.

As demand for organic food and beverages continues to grow at a very 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. USDA's National Organic Standards Board has identified a list of organic research priorities, many of which would address challenges that have limited the growth in domestic production.

The funding increase that we are requesting would help to address these needs. In addition, we are requesting the following report language to accompany the increase in funding for the program:

> "As domestic consumption of organic food and beverages continues to grow, domestic supply is not able to keep up with the demand. USDA's National Organic Standards Board (NOSB) has identified key organic research priorities, many of which would help to address issues that have limited growth in organic production in this country. The Committee provides an increase in funding for the Organic Transition Program, and urges the agency to strongly consider the NOSB organic research priorities when crafting the fiscal year 2017 RFA for the program."

Agriculture and Food Research Initiative (AFRI)
Request: Report language on public cultivar development

In recent decades, public resources for cultivar development have dwindled, while resources have shifted toward genomics and biotechnology, with a focus on a limited set of major crops. This problem has been particularly acute for organic and sustainable farmers, who seek access to germplasm well suited to their unique cropping systems and their changing local environments and climates.

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 research grants, consistent with the concerns expressed by the Appropriations Committee in preceding appropriations cycles.

Unfortunately, USDA has made only modest progress toward addressing the classical breeding Farm Bill and appropriations directives. We are requesting the following report language stressing that funding for classical breeding and public cultivar development should be a distinct priority and funding stream within AFRI, consistent with report language included in the fiscal year 2016 Senate report:

> Section 7406 of the Food, Conservation, and Energy Act of 2008 specifies priority areas with 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 notes the importance of having publicly available cultivars and breeds that are specifically bred to be adapted to the soils, climates, and farming systems of farmers of all regions. The Committee reiterates the request made in the fiscal year 2016 Senate report, and strongly urges NIFA to make public cultivar and breed development an increased priority for funding within the AFRI program and to create a separate priority area for this important work. The Committee further requests a report from the agency as to its plans for implementing this important requirement. [NOTE: Most of this is

identical to the language in the fiscal year 2016 Senate Report, except for the bolded text, which is updated.]

Agriculture and Food Research Initiative (AFRI)
Request: Report language on organic research

Organic agriculture is one of the fastest growing, and most promising, sectors of the U.S. agricultural economy. The benefits for organic research benefit not only the organic sector, but conventional farmers as well. Research to help farmers with the latest science on addressing pest problems and nutrient needs on their farms without expensive off-farm inputs is extremely helpful to organic and conventional farmers alike. We are requesting the following report language urging NIFA to increase funding for the organic research through the AFRI program, to help keep pace with the rapidly growing organic sector, and to help address the shortage of domestic supply to meet growing demand for organic products:

As in recent years, the Committee continues to prioritize funding for the Agriculture and Food Research Initiative (AFRI), as the flagship competitive grants research program for agriculture. However, in doing so, it is critical that the agency take actions to ensure that AFRI meets the needs of the full spectrum of the U.S. food and agriculture sector. The Committee notes that only about 0.1 percent of AFRI funding was used for research to address challenges of the U.S. organic sector during the period of fiscal years 2010–2014. As the organic sector struggles to boost domestic production in order to respond to the growing consumer demand for organic products, funding for organic research is critical, and the AFRI program should be part of that solution. The Committee urges the agency to execute a plan to incorporate organic research needs into the AFRI program more fully, and requests a report on the progress toward that goal.

Sustainable Agriculture Research and Education (SARE)
Request: $30 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. The President's fiscal year 2016 budget requests $30 million for SARE, and we are supporting that $30 million request for the combined activities of SARE.

Food Safety Outreach Program
Request: $10 million

We are requesting $10 million to help small and mid-size farms and small processing facilities comply with new proposed food safety regulations. This training program, authorized in the Food Safety Modernization Act of 2010 (FSMA), is one of the best and least costly ways to improve food safety outcomes without resorting to excessive farm regulation. The program received $5 million in fiscal year 2016. The President's fiscal year 2017 budget requests $5 million. We are requesting $10 million for fiscal year 2017, because food safety training for family-scale operations is critical at this stage of FSMA implementation.

Hatch Act Formula Grants
Request: 10 percent increase in funding, targeted to increase the public plant and animal breeding capacity of land grant institutions to address farmers' need for regionally adapted cultivars and breeds.

The capacity of our nation's land grant institutions (LGUs) to address the needs of local farmers for locally and regionally adapted cultivars and breeds has reached crisis levels, and funding for these efforts has been in a steady decline. As a result, farmers must rely on seeds and breeds that are outdated, and have not been improved to address changing climates, pest challenges, farming systems, and consumer demands. For all regions of our nation to optimize their productive capacity in an environmentally sustainable manner, it is critical that the farmers of the region have access to the most up-to-date cultivars that have been breed in that region to meet ever-changing conditions. A recent survey of LGUs shows that since 1994, the U.S. has lost 33 percent of its public plant breeding programs. On a regional basis, the analysis shows a 47 percent loss in public plant breeding programs in the Northeast, a 33 percent loss in the Midwest, a 35 percent loss in the West, and a 21 percent loss in the Southeast.

Therefore, we are requesting a 10 percent increase in funding for Hatch Act formula grants, to be targeted to foster the next generation of public plant and animal breeders at our national LGUs by focusing on the development of publicly available, regionally adapted cultivars and breeds.

USDA/RURAL BUSINESS COOPERATIVE SERVICE

Appropriate Technology Transfer for Rural Areas (ATTRA)
Request: $2.5 million

ATTRA, authorized by Section 6015 on the Agricultural Act of 2014, is a national sustainable agriculture information service providing practical information and technical assistance to farmers, ranchers, Extension agents, and educators interested in sustainable agriculture. ATTRA interacts with the public through its call-in service and website, and provides excellent publications to address some of the frequently asked questions of farmers and educators. We request $2.5 million for fiscal year 2017 for ATTRA.

[This statement was submitted by Steven Etka, Policy Director, National Organic Coalition.]

PREPARED STATEMENT OF NATIONAL SUSTAINABLE AGRICULTURE COALITION

Thank you for the opportunity to present our fiscal year 2017 funding requests. On behalf of our 44 member organizations from around the country, we submit the following USDA requests, in the order they appear in the appropriations bill:

DEPARTMENTAL ADMINISTRATION

Office of the Secretary—Outreach Services Supporting New, Beginning, and Veteran Farmers and Ranchers. We urge you to meet USDA's request for $5 million for Department-wide enhanced outreach to beginning, women, and military veteran farmers.

Office of Advocacy and Outreach. The Office of Advocacy and Outreach coordinates policy and outreach in four vital areas—small farms and beginning, socially disadvantaged, and veteran farmers. We urge that $1.2 million be provided for the OA&O, as requested by USDA.

Outreach and Assistance for Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers. We strongly support USDA's request of $10 million in discretionary funding. Combined with no limitation in mandatory spending, this appropriation would restore the historical program funding level to meet increased demand for technical assistance by military veteran farmers, and other underserved producers.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

Sustainable Agriculture Research and Education Program. We strongly urge you to meet USDA's request of $30 million for this competitive grants research program. SARE has helped turn farmer-driven research, education, and extension into profitable practices for over 25 years. The program consistently yields practical farm innovations on a more accelerated timeframe than other competitive research programs. At $30 million, SARE would be at half its authorized level and half the level recommended by the National Academy of Sciences. Due to high demand and inadequate funding, USDA has been able to fund only 6 percent of SARE pre-proposals for research and education competitive grants in recent years. Increasing funding to $30 million would begin to address this disparity. It would enable SARE to expand its prized work on soil health, cover cropping, and rotational grazing. It will also allow USDA to expand its backing for research to support beginning farmers, including on-farm research in which innovative young farmers can work with others in the SARE team to experiment with new production and management systems on a portion of their farm. The increase would also help SARE expand its unique graduate student research program, helping create the next generation of agricultural scientists who will make the breakthrough sustainability discoveries of the future.

Organic Transitions Integrated Research Program. We request $5 million to invest in innovative organic research with strong farmer delivery mechanisms built in. Restoring this funding level will keep organics from falling further behind in its fair share of the research budget.

Food Safety Outreach Program. We strongly urge you to provide $10 million to help small and mid-size farms and small processing facilities comply with the new FSMA food safety regulations. We are pleased Congress appropriated $5 million for FSOP for fiscal year 16. However, the major FSMA rules are final now and are in the process of being implemented; at $10 million in fiscal year 2017, FSOP would reach roughly 16,600 farmers across the country. While still small relative to the need, this funding level addresses the magnitude of the situation, namely that without adequate training, the FSMA regulations will hurt small and mid sized producers and processors and fall far short of the goal of improving food safety—no matter how much more money gets appropriated for FSMA implementation and enforcement overall.

FARM SERVICE AGENCY

Direct Farm Ownership Loans, Direct Operating Loans, and Individual Development Accounts. Direct farm loans provide crucial capital for beginning farmers and others not adequately served by commercial credit. This is critical in light of the increasing age of farmers and the land access challenges faced by new and aspiring farmers. USDA's fiscal year 2017 budget proposes increased funding for Direct Farm Operating loans in order to meet the high demand by farmers unable to obtain commercial credit due to low commodity prices and a more constrained lending market. Without this increase, FSA will face a substantial funding shortfall and many farmers will be unable obtain the operating capital they need to make it through the growing season. Similarly, the Beginning Farmer and Rancher Individual Development Account (IDA) program, if funded, will enable limited-resource beginning farmers and ranchers to save for asset-building purchases, including equipment and breeding stock, to jump start their operations. The IDA program requires a 50 percent local match as well as financial management training as the core component of the program. We support USDA's request for program levels of $1.5 billion for Direct Farm Ownership loans, $1.46 billion for Direct Operating Loans, and $1.5 million for the IDA program. We also support the USDA request for guaranteed ownership and operating loans.

New, Beginning, and Veteran Farmer and Rancher Initiatives. We support the Administration's request for $3.9 million for a certification program to help veteran farmers prequalify for loans, FSA staff devoted to providing outreach to beginning and veteran farmers, a pilot for a new farmer mentoring network, and funding for cooperative agreements to support assistance to new farmers and to work with landowners to help them transition their farm to the next generation. This combined package will serve as a critical tool for supporting veterans and investing in the next generation of farmers.

NATURAL RESOURCES CONSERVATION SERVICE

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 conserve resources on their farms. NRCS also uses CTA funds to assess conservation practices and systems, and to collect, analyze, and disseminate data on the condition of the nation's natural resources. USDA's fiscal year 2017 budget request proposes to increase CTA funding by 2.5 percent from $741.6 million to $760.7 million. We urge you to approve this increase, which will help more producers develop site-specific plans to conserve water, prepare for extreme weather, and address natural resource concerns on their land.

RURAL BUSINESS—COOPERATIVE SERVICE

Appropriate Technology Transfer for Rural Areas. For nearly 30 years, the ATTRA program has provided practical, cutting edge information to farmers, extension agents, and others. In fiscal year 2015, ATTRA provided assistance to more than 2.2 million agricultural producers and businesses, and organized presentations, workshops, and field days in 25 locations across the U.S. attended by at least 15,000 people. For fiscal year 2017, we urge you to provide $2.75 million, and increase of $250,000 over the President's request and last year's funding level. This increase will support the expansion of ATTRA's Armed to Farm program that trains returning military veterans to farm. The small increase will enable ATTRA to expand its work to meet the needs of aspiring veteran farmers. To date, veterans from 22 states have attended these week-long trainings. A recent survey of Armed to Farm participants found that 80 percent have continued to farm, have started farming, or are in the process of starting a farm.

Value-Added Producer Grants. VAPG offers competitive grants to farmers and ranchers developing farm- and food-related businesses that boost farm income and create jobs in rural America. These grants may be used to fund business and marketing plans and feasibility studies or to acquire working capital to operate a value-added business venture or alliance. Despite its proven success as a driver of rural economic development, the President has not requested a funding increase for VAPG since fiscal year 2014. We request $15 million in discretionary funding and no changes in mandatory program spending, to bring the program up to its 2014 funding levels.

Rural Microentrepreneur Assistance Program. RMAP provides business training and microloans to owner-operated businesses with up to ten employees. It targets very small business development, the leading job creator in rural communities, and is the only Federal program that finances the capitalization of revolving microloan funds for rural areas. We support USDA's fiscal year 2017 budget request for $2.9 million for microlending and $2 million for grants to support microbusiness training and technical assistance, as well as no changes in mandatory program spending.

GENERAL PROVISIONS

A suite of distinct but interrelated farm bill programs, including the Environmental Quality Incentives Program (EQIP) and Conservation Stewardship Program (CSP), work together to give farmers the tools they need to protect and rebuild soil, provide clean water, and enhance wildlife habitat. Congress should not re-open the 2014 Farm Bill through the appropriations process. That bill cut $6 billion from conservation programs, including over $2 billion from the CSP. The fiscal year 2015 CRomnibus cut an additional 23 percent from CSP and 16 percent from EQIP, forcing USDA to turn away 75 percent of the eligible producers who applied. Additional cuts to mandatory spending for conservation will mean that the number of farmers denied access to the programs will grow even larger; and less participation in voluntary conservation programs means more pollution and more regulation, as well as less productive and profitable farmlands. We strongly oppose changes in mandatory program spending to these critical conservation programs.

Finally, we oppose the inclusion of any policy riders that limit implementation and enforcement of the Packers & Stockyards Act. Limiting USDA's ability to protect market transparency has no rightful place in the appropriations bill or any other legislation.

PREPARED STATEMENT OF OREGON WATER RESOURCES CONGRESS

The Oregon Water Resources Congress (OWRC) strongly supports the fiscal year 2017 budget for the U.S. Department of Agriculture's (USDA) Natural Resources Conservation Service (NRCS) programs. It is crucial that the Regional Conservation Partnership Program (RCPP) has adequate resources and we request a minimum of $200 million to leverage partnerships and tackle the complex natural resources conservation issues facing the nation. Furthermore, we are strongly supportive of coordinated Federal agency watershed planning and request funding for the Small Watershed Rehabilitation Program, a minimum of $250 million.

OWRC was established in 1912 as a trade association to support the protection of water rights and promote the wise stewardship of water resources statewide. OWRC members are local governmental entities, which include irrigation districts, water control districts, drainage districts, water improvement districts, and other agricultural water suppliers that deliver water to roughly 1/3 of all irrigated land in Oregon. These water stewards operate complex water management systems, including water supply reservoirs, canals, pipelines, and hydropower production.

RCPP BENEFITS & NEEDS

OWRC strongly supports the RCPP, and while we are encouraged by the request for $100 million in fiscal year 17 in the President's budget, an increase of $7 million from 2016 enacted levels, additional funding is still needed. The RCPP is a critical tool for districts and other agricultural water suppliers in developing and implementing water and energy conservation projects in Oregon. In the past, the Agricultural Water Enhancement Program (AWEP) has been highly successful in developing cooperative approaches on a basin-wide scale, and historically, the Cooperative Conservation Partnership Initiative (CCPI) partnerships allowed Federal, State and Local interests to address Endangered Species Act (ESA) and Clean Water Act (CWA) issues in watershed basins and sub basins.

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. Financial assistance has diminished in recent years and there is a backlog of unmet need. For example, in February 2016, USDA announced that they received 265 applications requesting nearly $900 million dollars, which was four times the amount of available funding. They were able to only fund 84 projects.

OWRC would like to thank the Administration for not cutting funding to Environmental Quality Incentives Program (EQIP), in accordance with the 2014 Farm Bill. As demonstrated by the huge demand for RCPP funding, programs like EQIP need to remain in light of the need for investment in conservation projects. While we applaud the continued existence of EQIP, $1.65 billion is not enough to keep the program effective. It is essential the EQIP have at least $2 billion in appropriations funding if Congress would like to see widespread results. Furthermore, with the numerous new and potential listings under ESA and increased water regulations under the CWA, there is a dire need for additional funding to support conservation efforts nationwide.

While we recognize that the Administration has increased funding for some NRCS programs, the need for additional financial assistance still far outweighs the proposed budget. NRCS programs are essential to irrigation districts in developing and implementing conservation projects that benefit not only the individual farmers they serve but also the entire watershed and community as a whole. Furthermore, conservation projects also benefit the economy through job creation and ensuring the future viability of American agriculture.

RCPP helps fill a funding void for multi-partner conservation projects and allow farmers to pool together and leverage the dollars invested in the off-farm project with the addition of EQIP on-farm projects. The effects of drought and climate change combined with ESA and CWA regulation has created a daunting set of circumstances for irrigated agriculture in the West. RCPP and EQIP have become an essential lifeline for farmers to adapt to climate change. It is critical to increase funding for new eligible RCPP projects that benefit the environment and economy and alleviate some of the negative effects of drought and climate change.

EXAMPLES OF SUCCESSFUL AWEP PROJECTS IN OREGON

Oregon has had several successful AWEP projects over the past several years, including three from our member districts (described below). Additionally, in Oregon, NRCS is helping develop the Save Water, Save Energy Initiative, a multi-agency cooperative effort to develop a clearinghouse of information on financial incentives and technical expertise to assist districts and their water users in implementing conservation measures. Additional innovative projects like these could be developed and implemented in Oregon if more funding is made available.

—The Whychus Creek/Three Sisters Irrigation District Collaborative Restoration Project focuses on irrigation water efficiency with irrigation improvements in the Upper Division of the Three Sisters Irrigation District, which is the project partner. The effort will improve stream flows and water quality for native fish while providing farmers a reliable supply of water. Fiscal year 2013 Funding: $180,000; fiscal year 2012 $251,300

—The Talent Irrigation District Project works with agricultural producers to install conservation practices that will properly utilize limited surface water resources, improve water quality on flood irrigated land by converting to more efficient irrigation systems, and apply irrigation water management to eliminate irrigation runoff. Fiscal year 2013 Funding: $0; Fiscal year 2012 Funding: $4,470

—The Willow Creek Project helps landowners in the Lower Willow Creek Watershed portion of Malheur County convert to water-saving irrigation systems, reduce irrigation runoff, and improve water quality in Willow Creek and Malheur River. The project partner is the Vale Oregon Irrigation District. Fiscal year 2013 Funding: $180,000; Fiscal year 2012 $251,300

SMALL WATERSHED REHABILITATION PROGRAM AND WATERSHED PLANNING NEEDS

OWRC also strongly supports 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 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 Small Watershed Rehabilitation Program to fully update their infrastructure.

SWCD has two dams built under PL–566 and while they were built to seismic standards 50 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, municipal water and recreation. Additionally, it is important to note that even a small earthquake has the potential to severely damage the dams and cause intensive flooding and damage in the surrounding area. To date, SWCD has been authorized to receive funding for planning, design and construction of one of their dams and planning and design on the other. However, SWCD will still need considerable funding dollars to complete construction on the second dam.

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 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. Additionally Laurance Lake, which is formed by Clear Branch Dam, and its tributaries, are the primary spawning and rearing habitat for Hood River Basin Bull Trout, a threatened species under ESA. Rehabilitation of Clear Branch Dam will improve fish passage connectivity for Bull Trout and improve water temperature for spawning, rearing and migration.

Once planning and design studies are complete, both MFID and SWCD will know what the costs will be to make the necessary improvements to their dams, which is currently estimated at over $10 million for both SWCD dams and $9.8 million for MFID. In light of the high costs to fix just 3 of the PL–566 dams, a minimum of $250 million is needed to address and repair high priority dams like the ones here in Oregon.

Our member districts, the farms and other water users they serve, and the communities in which they are located benefit greatly from the NRCS programs described in our testimony. Oregon's agricultural community is actively committed to water conservation programs, but those programs require robust Federal participation if the agricultural community is to be able to continue its efforts to address Oregon's water supply needs through conservation. Increasing the budget for NRCS programs is a strategic investment that will pay both environmental and economic dividends to Oregonians and America as a whole. Thank you for the opportunity to provide testimony on the proposed fiscal year 17 budget for the USDA's NRCS Programs.

[This statement was submitted by April Snell, Executive Director, Oregon Water Resources Congress.]

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 2017 funding requests for USDA programs of importance to the organic farming sector.

USDA/NATIONAL INSTITUTE OF FOOD AND AGRICULTURE (NIFA) ORGANIC TRANSITIONS PROGRAM REQUEST: $5 MILLION

The Organic Transition Program, is a critical research grant program that helps farmers address some of the challenges of organic production and marketing. The demand for research on organic agriculture is outpacing the available funds in this program. According to NIFA, only 38 percent of the applicants to this program receive funding. USDA's National Organic Standards Board (NOSB) has identified a number of organic research priorities that cannot be funded due to a lack of resources. An increase in the Organic Transition Program would allow the NOSB to address some of the research issues that limit the growth of the organic industry. And given the innovative nature of organic agriculture, many of these research projects benefit all farmers, not just those in the organic sector. The Organic Transition Program was funded at $5 million in fiscal year 2010, and about $4 million for fiscal years 2011 through 2015. We are seeking $5 million to restore the program to its fiscal year 2010 level to in order to address the current low funding rate for this program.

USDA/AGRICULTURAL MARKETING SERVICE (AMS) NATIONAL ORGANIC PROGRAM REQUEST: $15 MILLION

The National Organic Program is the regulatory program housed within the USDA Agriculture Marketing Service responsible for developing national standards

for certified agricultural organic products. These standards assure consumers that products within the USDA organic seal meet consistent, uniform standards. The NOP is vital for meeting the growing consumer demand for organic products. Recognizing continued growth of the industry, we ask for $15 million, the full amount authorized in the 2014 Farm Bill. This amount reflects the strong growth of the sector. The industry current returns over $200 for every $1 spent on the NOP so an increased investment would garner a strong return for the Federal government. Moreover, this would give NOP the resources it needs to fully enforce the organic regulations globally, to continue to develop international equivalence arrangements to expand the market for American organic products worldwide; and to develop organic standards for emerging sectors.

USDA/NATIONAL INSTITUTE OF FOOD AND AGRICULTURE (NIFA)—AGRICULTURE AND FOOD RESEARCH INITIATIVE- PUBLIC CULTIVAR AND BREED DEVELOPMENT—REPORT LANGUAGE

Section 7406 of the Food, Conservation, and Energy Act of 2008 specifies priority areas with 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 notes the importance of having publicly available cultivars and breeds that are specifically bred to be adapted to the soils, climates, and farming systems of farmers of all regions. The Committee reiterates the request made in the fiscal year 2016 Senate report, and strongly urges NIFA to make public cultivar and breed development an increased priority for funding within the AFRI program and to create a separate priority area for this important work. The Committee further requests a report from the agency as to its plans for implementing this important requirement.

USDA/NATIONAL INSTITUTE OF FOOD AND AGRICULTURE (NIFA)—AGRICULTURE AND FOOD RESEARCH INITIATIVE- ORGANIC RESEARCH

As in recent years, the Committee continues to prioritize funding for the Agriculture and Food Research Initiative (AFRI), as the flagship competitive grants research program for agriculture. However, in doing so, it is critical that the agency take actions to ensure that AFRI meets the needs of the full spectrum of the U.S. food and agriculture sector. The Committee notes that only about 0.1 percent of AFRI funding was used for research to address challenges of the U.S. organic sector during the period of fiscal years 2010–2014. As the organic sector struggles to boost domestic production in order to respond to the growing consumer demand for organic products, funding for organic research is critical, and the AFRI program should be part of that solution. The Committee urges the agency to execute a plan to incorporate organic research needs into the AFRI program more fully, and requests a report on the progress toward that goal.

USDA/SUSTAINABLE AGRICULTURE RESEARCH AND EDUCATION (SARE) REQUEST: $30 MILLION

The SARE program is another valuable research program with a focus on environmentally sound practices and systems, with organic production research as one of the beneficiaries. Consistent with the increased demand for organic research, as well as the challenges presented by a changing climate, we are requesting $30 million for the SARE Program to assist farmers as they try to improve and adjust their growing practices.

USDA/RURAL BUSINESS COOPERATIVE SERVICE—APPROPRIATE TECHNOLOGY TRANSFER FOR RURAL AREAS (ATTRA)REQUEST: $2.75 MILLION

ATTRA, a national sustainable agriculture information service, is an important source of information and technical assistance for for farmers, ranchers, Extension agents, and educators on sustainable agriculture.

USDA/CONSERVATION TECHNICAL ASSISTANCE REQUEST: $760.7 MILLION

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 conserve resources on their farms. NRCS also uses CTA funds to assess conservation practices and systems, and to collect, analyze, and disseminate data on the condition of the nation's natural resources. The President's fiscal year 2017 budget request proposes to increase CTA funding by 2.5 percent from $741.6 million to $760.7 million. We urge you to approve this increase, which will help more producers develop site-spe-

cific plans to conserve water, prepare for extreme weather, and address natural resource concerns on their land.

[This statement was submitted by Jane E. Shey Policy Associate, Organic Farming Research Foundation.]

PREPARED STATEMENT OF ORGANIC TRADE ASSOCIATION

Chairman Moran, Ranking Member Merkley, and Members of the Subcommittee, I am Laura Batcha, Executive Director and CEO of the Organic Trade Association (OTA).[1] The organic sector continues to be one of the fastest-growing sectors of American agriculture, a vibrant market that has grown to $39 billion in sales, at double digit growth rates in recent years. The industry is comprised of over 19,500 American organic businesses, and creates jobs at four times the rate of the economy as a whole.

Despite the growth in production, demand outpaces supply. Organic food sales make up nearly 5 percent of total food sales, while organic acreage is less than 1 percent of total U.S. cropland, and consumer demand continues to grow. Over 80 percent of U.S. families, spanning racial and economic lines, buy organic. Organic is a mainstream market, and a production system with independent marketplace dynamics. When viewed as a distinct class, organic ranks fourth in food/feed crop production at farm-gate values. This parallel stream of commerce and production is a bright spot in the American marketplace of innovation and entrepreneurship.

The 2014 Farm Bill offered an enhanced array of resources to help the organic sector continue to grow, innovate, create new markets and jobs, provide certified operations new tools to succeed, and ensure consumers access to safe and nutritious food supply. To facilitate this, we respectfully request the following funding levels: USDA (AMS) National Organic Program—$15 million; USDA (NIFA) Organic Transition Research Program—$5 million; USDA (AMS) Organic Data Initiative—$309,000; and USDA (NASS) Organic Data Initiative—$250,000. We also request report language urging USDA to ensure organic operations have full access to a variety of programs at the Department.

NATIONAL ORGANIC PROGRAM (NOP)

OTA requests $15 million for NOP, which enforces the organic regulations and ensures they evolve to keep pace with consumer expectations. Recognizing the strong growth of the industry, we ask for the full amount authorized in the 2014 Farm Bill. These resources would allow NOP to fully enforce the organic regulations globally, develop international equivalence arrangements to expand the market for American organic products, and develop organic standards for emerging sectors. Moreover, increased NOP funding is a strong investment, as there is a return on investment of $200 for every dollar spent on NOP.

NATIONAL ORGANIC CERTIFICATION COST-SHARE PROGRAM (NOCCSP)

The NOCCSP assists producers and handlers in obtaining certification, but is not currently being implemented using all congressionally-granted authority. Report language directing USDA to act to the full extent of its authority would support both the Department-wide desire to utilize all available programs to support transition, and State organic programs, which are critical to enforcement. We request the following language: "Congress directs the USDA to act to the full extent of its authority in administering the NOCCSP to producers and handlers of agricultural products obtaining certification under the national organic production program. This includes reimbursing State organic program fees as well as certification costs associated with transition to organic production and handling. In particular, USDA should revise their NOCCSP Terms and Conditions document in accordance with the letter and intent of the law."

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[1] The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 8,500 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect ORGANIC with a unifying voice that serves and engages its diverse members from farm to marketplace.

ORGANIC TRANSITION RESEARCH PROGRAM (ORG)

OTA requests that ORG, which supports research, extension and higher education programs for organic producers, be funded at $5 million. ORG consistently receives many more funding requests than it can accommodate, and while organic sales have grown to nearly 5 percent of retail agriculture sales, research funding provided to organic agriculture has never exceeded 2 percent.

ORGANIC DATA INITIATIVE (ODI)

ODI has been successful in providing valuable information to Congress, government agencies, and the organic industry. We ask for a modest amount $309,000 in discretionary funding for AMS (to continue and expand collections of organic pricing information) and $250,000 for NASS (to continue to collect and disseminate data regarding organic agriculture).

ADDITIONAL REQUESTS FOR REPORT LANGUAGE

Farm to School: "The Farm to School program seeks to build healthy communities by strengthening schools' supply chain and educational linkages to fresh fruits, vegetables and other commodities; however, increased access to organic foods in schools has not been fully realized. Organic operations are well-positioned to create opportunities for students to directly engage in agricultural STEM opportunities and create lasting healthy eating habits, additional goals of the law. The Committee understands the need for improved access to and interaction with certified organic operations and directs USDA to improve participation by certified organic operations in an effort to reduce hunger and improve access to local healthy food."

Beginning Farmer and Rancher Development Program: "The Committee recognizes that to meet increasing consumer demand for organic products, domestic producers must either shift to organic production or enter organic production. Beginning farmers and ranchers selecting organic production should be given the tools they need. USDA should prioritize the needs of beginning farmers and ranchers opting for organic production and support programs and services that address their specific needs."

Environmental Quality Incentives Program: "The Committee recognizes that the Organic Initiative is not intended to be the only way for organic producers to access EQIP funding. USDA is encouraged to track usage of all EQIP funds by certified organic producers, in order to determine how to best meet their needs."

Regional Conservation Partnership Program: "RCPP allows for conservation projects which leverage public and private funding. Organic farmers implement a wide variety of creative methods to improve the environment. The Committee urges that 5 percent of the RCPP budget be allocated to projects focused on organic production and its conservation benefits. In particular, NRCS funds may be used to provide technical assistance to "explore opportunities to diversify agricultural operations and develop and apply sustainable agricultural systems," which is particularly relevant to certified organic farmers and those seeking to transition to organic. USDA should ensure that no barriers exist to certified organic and transitioning farmers receiving 5 percent of RCPP funds."

CONCLUSION

Organic agriculture creates economic opportunities for farmers and rural communities, while improving and conserving the environment and giving consumers additional choice in the market. Meeting these requests will help to ensure the continued growth of U.S. organic agriculture by promoting and supporting the integrity of the organic label, providing important data, and continuing to support research for organic agriculture. I thank the Committee and look forward to working with you to advance the organic industry.

[This statement was submitted by Laura Batcha, Executive Director & CEO.]

PREPARED STATEMENT OF OXFAM AMERICA

On behalf of Oxfam America, Greater Minnesota Worker Center, Nebraska Appleseed Center for Law in the Public Interest, Northwest Arkansas Workers' Justice Center, Southern Poverty Law Center, and Western North Carolina Worker Center.

The following comments are submitted on behalf of a coalition of organizations working to improve the conditions of workers in poultry processing. We remain con-

cerned by recent comments made by members of Congress, about the need to increase poultry processing plant evisceration line speeds, currently regulated by the USDA Food Safety and Inspection Service.

In August 2014, USDA finalized a new rule on Modernization of Poultry Slaughter Inspection after a full public comment period and significant input from occupational health experts and workers. The new rule explicitly removed the originally proposed line speed increase and kept line speeds for plants choosing to adopt the modernized inspection regime at 140 birds per a minute, the same rate that had preceded the rulemaking. USDA kept in place this line speed despite a draft rule that would have increased line speed to 175 birds per a minute after reviewing evidence on the threat to worker health and safety by increased speeds.

A new report by Oxfam America, "Lives on the Line: The Human Cost of Cheap Chicken, and recent worker survey by the Northwest Arkansas Workers' Justice Center echoed nearly every study about labor in the poultry industry: current line speed presents a constant threat to workers' health and safety. It is fast, relentless, and dangerous.[1] Any additional increase in line speeds will only add to those threats.

The high speed exacerbates dangers to workers from repetitive motions, sharp tools, and chemicals; heightens risks to consumers as workers cut corners while handling food; and increases liability for the companies as risks grow. Poultry workers already suffer occupational illnesses at six times the national average; carpal tunnel syndrome at seven times the average; and amputations at three times the average. Line speed directly impacts these numbers. In a survey of 302 workers in Alabama, the Southern Poverty Law Center (SPLC) found that "78 percent of workers surveyed said that the line speed makes them feel less safe, makes their work more painful and causes more injuries."[2]

We urge the members of this Committee to reject any attempts to use the Appropriations process to legislate an increase in the maximum allowable line speed in poultry processing plants, as such an increase will only further exacerbate the well-documented risk of permanently crippling injuries to poultry workers and undermine USDA's recent rulemaking on this very issue.

Workers commonly say that they are treated like "perpetual motion machines", doing the same motions an estimated 20,000 times per shift, unable to pause or slow down for even a few seconds.[3] Workers report averaging between 35 and 45 birds per minute (BPM), meaning they process a chicken every two seconds. The higher the line speed the faster each worker must operate. More motions mean a greater likelihood of developing musculoskeletal disorders (MSDs). The constant pace means workers rarely can step back, change position, or stretch. These risks are exacerbated by cold and humid plant conditions. Dozens of medical studies have documented the elevated rate of painful and crippling MSDs in the workforce.[4] They are

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[1] Oxfam America, "Lives on the Line: Human Cost of Cheap Chicken", October 26, 2015, http://www.oxfamamerica.org/explore/research-publications/lives-on-the-line/.

[2] Fritzsche, Unsafe at These Speeds.

[3] Hall, Alexander, and Ordonnez, "The Cruelest Cuts," Charlotte Observer, September 30, 2008, http://www.charlotteobserver.com/news/special-reports/cruelest-cuts/article9012839.html.

[4] See, for example, the National Institute for Occupational Safety and Health (NIOSH) report conducted by Kristin Musolin et al., Musculoskeletal Disorders and Traumatic Injuries Among Employees at a Poultry Processing Plant, Health Hazard Evaluation 2012—0125, April 2013; Schulz et al., "Upper Body Musculoskeletal Symptoms of Latino Poultry Processing Workers and a Comparison Group of Latino Manual Workers," American Journal of Industrial Medicine 56, no. 2 (July 2012); van Rijn et al., "Associations Between Work-Related Factors and Specific Disorders of the Shoulder—A Systematic Review of the Literature," Scandinavian Journal of Work, Environment & Health 36, no. 3 (2010); GAO, Workplace Safety and Health: Safety in the Meat and Poultry Industry; Punnett and Wegman, "Work-Related Musculoskeletal Disorders: The Epidemiological Evidence and the Debate," Journal of Electromyography and Kinesiology 14, no. 14 (2004); National Research Council and Institute of Medicine, Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities (2001); Latko et al., "Cross-Sectional Study of the Relationship Between Repetitive Work and the Prevalence of Upper Limb Musculoskeletal Disorders," American Journal of Industrial Medicine 36, no. 2 (1999); Frost et al., "Occurrence of Carpal Tunnel Syndrome Among Slaughterhouse Workers," Scandinavian Journal of Work, Environment & Health 24, no. 4 (1998): 285; Werner et al., "Median Mononeuropathy Among Active Workers: Are There Differences Between Symptomatic and Asymptomatic Workers?" American Journal of Industrial Medicine 33, no. 4 (1998): 374; Chiang et al., "Prevalence of Shoulder and Upper-Limb Disorders Among Workers in the Fish-Processing Industry," Scandinavian Journal of Work, Environment & Health 19, no. 2 (1993).Hagberg, Morgenstern, and Kelsh, "Impact of Occupations and Job Tasks on the Prevalence of Carpal Tunnel Syndrome," Scandinavian Journal of Work, Environment & Health 18, no. 6 (1992); Chiang et al., "The Occurrence of Carpal Tunnel Syndrome in Frozen Food Factory Employees," Kaohsiung Journal

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also at risk of cuts, lacerations, and amputations that increase as speed accelerates. The constant repetitive motions cause pain in hands, fingers, arms, shoulders, backs, as well as swelling, numbness, and loss of grip. These injuries affect the ability to work, do chores, and even lift children.

The Government Accountability Office documented how fast line speeds prevents workers from taking precautions like sharpening knives: "The faster the pace at which the production line moves, the less able workers may be to perform tasks needed for safety."[5]

Two-thirds (66 percent) of the poultry workers interviewed by Southern Poverty Law Center in 2013 described suffering from hand or wrist pain, swelling, numbness or an inability to close their hands. This rate was even higher among workers doing the jobs most affected by line speed reaching as high as 86 percent for workers cutting chicken wings.

OSHA studied musculoskeletal disorder risk factors for years and found that employers could protect workers from musculoskeletal issues "by reducing the speed at which the employer performs the tasks." Still employer-mandated processing quotas and rapid line speeds mean that workers often have to rush and strain themselves to keep up. Workers who reported an injury due to line speed also reported higher mean and median piece/pound processing rates per minute, in some cases almost double the rates reported by workers who did not experience injury due to line speed. Women also reported higher rates of line speed related injury than men.

Over half (54 percent) of workers surveyed answered yes to the question, "Have you ever been forced to do things because of time pressure or line speed that might harm the health and safety of the consumer?"

Poultry workers from across the country have felt the consequences of excessive line speed:

—One worker in reported that the speed inched up as the hours went by: "As soon as the first shift leaves, around six o'clock, that's when it speeds up and starts to get hard. You can't stand the pain on your shoulders, your hands, because of that repetitive movement."

—"There are so many problems happen as the lines go so fast," one worker said. "There might be 20-plus chickens that we cut [in] one minute. The line is going so fast that sometimes we accidentally cut our hands."

—Another worker offered, "Sometimes I get headache because the line is fast. I would almost pass out sometimes [because] the line is fast."

—"These jobs were very repetitive," said a worker, who cut chicken wings and breasts. "My hands swelled up and were extremely painful. When I was in so much pain that I had to stop, I asked for breaks, but the company told me I had to keep working. Because of the pressure to work fast, I can't use my arms, wrists and hands the way I could before I worked in the poultry plant."

—Current worker: "The majority of people who work there harm their fingers and their hands due to the line speed. Everyone knows this1A. . .It's too much chicken . . .Too fast."

We recommend the members of this Committee reject any attempts to use the Appropriations process to legislate an increase the maximum allowable line speed in poultry processing plants, as such an increase will only further exacerbate the well documented risk of permanently crippling injuries to poultry workers and undermine USDA's recent rulemaking.

[This statement was submitted by Jeffrey Buchanan, Senior Domestic Policy Advisor, Oxfam America.]

PREPARED STATEMENT OF PICKLE PACKERS INTERNATIONAL, INC.

SUMMARY

Sustained and increased funding is desperately needed to maintain the research momentum built over recent years and to defray rising fixed costs at laboratory facilities. Companies in the pickled vegetable industry generously participate in funding and performing short-term research, but the expense for long-term research needed to insure future global competitiveness is too great for individual companies to shoulder on their own.

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of Medical Sciences 6, no. 2 (1990). Silverstein et al., "Occupational Factors and Carpal Tunnel Syndrome," American Journal of Industrial Medicine 11, no. 3 (1987).

[5] GAO, Workplace Safety and Health: Safety in the Meat and Poultry Industry.

Additional Budget Requests for fiscal year 2017

Funding needs for USDA/ARS laboratories are as follows:

REQUESTS FOR PROGRAM ENHANCEMENT—PICKLED VEGETABLES

	Amount
Emerging Disease of Crops	$500,000
Quality and Utilization of Agricultural Products & Food Safety	500,000
DApplied Crop Genomics	500,000
DSpecialty Crops	500,000
Total Program Enhancements Requested—Pickled Vegetables	$2,000,000

USDA/ARS Research Provides:

—Consumers with over 150 safe and healthful vegetable varieties providing vitamins A, C, folate, magnesium, potassium, calcium, and phytonutrients such as antioxidant carotenoids and anthocyanins.

—Genetic resistance for many major vegetable diseases, assuring sustainable crop production with reduced pesticide residues—valued at nearly $1 billion per year in increased crop production.

—Classical plant breeding methods combined with bio-technological tools, such as DNA markers, genetic maps, and genome sequencing to expedite traditional breeding and increase efficiency.

—New vegetable products with economic opportunities amidst increasing foreign competition.

—Improved varieties suitable for machine harvesting, assuring post harvest quality and marketability.

—Fermentation and acidification processing techniques to improve the efficiency of energy use, reduce environmental pollution, and reduce clean water intake while continuing to assure safety and quality of our products.

—Methods for delivering beneficial microorganisms in fermented or acidified vegetables and producing reduced sodium, healthier products.

—New technology and systems for rapid inspection, sorting and grading of pickling vegetable products in the field and at the processing facility.

Health and Economical Benefits

—Health agencies continue to encourage increased consumption of fruits and vegetables, useful in preventing heart disease, cancer, stroke, diabetes and obesity.

—Vegetable crops, including cucumbers, peppers, carrots, onions, garlic and cabbage (sauerkraut), are considered "specialty" crops and not part of commodity programs supported by taxpayer subsidies.

—Current farm value for just cucumbers, onions and garlic is estimated at $2.4 billion with a processed value of $5.8 billion. These vegetables are grown and/or manufactured in all 50 states.

The pickled vegetable industry strongly supports and encourages your committee in its work of maintaining and guiding the Agricultural Research Service. To accomplish the goal of improved health and quality of life for the American people, the health action agencies of this country continue to encourage increased consumption of fruits and vegetables in our diets. Accumulating evidence from the epidemiology and biochemistry of heart disease, cancer, diabetes and obesity supports this policy. Vitamins (particularly A, C, and folic acid), minerals, and a variety of antioxidant phytochemicals in plant foods are thought to be the basis for correlation's between high fruit and vegetable consumption and reduced incidence of these debilitating and deadly diseases.

As an association representing processors that produce over 85 percent of the tonnage of pickled vegetables in North America, it is our goal to produce new products that increase the competitiveness of U.S. agriculture as well as meet the demands of an increasingly diverse U.S. population that is encouraged to eat more vegetables. The profit margins of growers continue to be narrowed by foreign competition. This industry can grow by meeting today's lifestyle changes with reasonably priced products of good texture and flavor that are high in nutritional value, low in negative environmental impacts, and produced with assured safety from pathogenic microorganisms and from those who would use food as a vehicle for terror. With strong research to back us up, we believe our industry can make a greater contribution to-

ward reducing product costs and improving human diets and health for all economic strata of U.S. society.

Many small to medium sized growers and processing operations are involved in the pickled vegetable industry. We grow and process a group of vegetable crops, including cucumbers, peppers, carrots, onions, garlic, cauliflower, cabbage (Sauerkraut) and Brussels sprouts, which are referred to as 'minor' crops. None of these crops are in any "commodity program" and do not rely on taxpayer subsidies. However, current farm value for just cucumbers, onions and garlic is $2.4 billion with an estimated processed value of $5.8 billion. These crops represent important sources of income to farmers and rural America. Growers, processing plant employees and employees of suppliers to this industry reside in all 50 states. To realize its potential in the rapidly changing American economy, this industry will rely upon a growing stream of appropriately directed basic and applied research from four important research programs within the Agricultural Research Service.

APPLIED CROP GENOMICS

The USDA/ARS has the only vegetable crops research unit dedicated to the genetic improvement of cucumbers, carrots, onions and garlic. ARS scientists account for over half of the total U.S. public breeding and genetics research on these crops. Their efforts have yielded cucumber, carrot and onion cultivars and breeding stocks that are widely used by the U.S. vegetable industry (i.e., growers, processors, and seed companies). These varieties account for over half of the farm yield produced by these crops today. All U.S. seed companies rely upon this program for developing new varieties, because ARS programs seek to introduce economically important traits (e.g., pest resistances and health-enhancing characteristics) not available in commercial varieties using long-term high risk research efforts. The U.S. vegetable seed industry develops new varieties of cucumbers, carrots, onions, and garlic and over twenty other vegetables used by thousands of vegetable growers. Their innovations meet long-term needs and bring innovations in these crops for the U.S. and export markets, for which the U.S. has successfully completed.

ARS scientists have developed genetic resistance for many major vegetable diseases that is estimated at $670 million per year in increased crop production, not to mention environmental benefits due to reduction in pesticide use. New research has resulted in cucumbers with improved disease resistance, pickling quality and suitability for machine harvesting. New sources of genetic resistance to viral and fungal diseases, tolerance to environmental stresses, and higher yield have recently been identified along with molecular tools to expedite delivery of elite cucumber lines to U.S. growers.

There are still serious vegetable production problems which need attention. For example, losses of cucumbers, onions, and carrots in the field due to attack by pathogens and pests remains high, yield and nutritional quality needs to be significantly improved and U.S. production value and export markets should be enhanced. Genetic improvement of all the attributes of these valuable crops are at hand through the unique USDA lines and populations (i.e., germplasm) that are available and the new biotechnological methodologies that are being developed by the group. The achievement of these goals will involve the utilization of a wide range of biological diversity available in the germplasm collections for these crops. Classical plant breeding methods combined with bio-technological tools such as DNA markers, genetic maps, and genome sequences to expedite traditional cucumber, carrot and onion breeding and increase its efficiency. With this, new high-value vegetable products based upon genetic improvements developed by our USDA laboratories can offer vegetable processors and growers expanded economic opportunities for U.S. and export markets.

QUALITY AND UTILIZATION OF AGRICULTURAL PRODUCTS & FOOD SAFETY

The USDA/ARS maintains a food science research unit that our industry looks to for new scientific information on the safety of our products and development of new processing technologies related to fermented and acidified vegetables. Major accomplishments include: pasteurization treatments currently used for most acidified vegetables; the preservation technology used for manufacturing shelf stable sweet pickles; fermentation technology (purging) used to prevent the formation of air pockets within fermented pickles; and a fermentation technology that eliminates the use of sodium chloride for commercial cucumber brining operations. With the passage of the Food Safety Modernization Act, commercial producers of acidified foods must prove that they meet critical limits established for microbial safety. USDA/ARS has provided technical expertise and the scientific data currently used to support required process filings, and have helped establish a scientific basis for acidified food

regulations. Further research is needed to evaluate safe and efficient processing conditions for environmentally friendly low salt and calcium salt vegetable fermentation technologies. Additional funding is needed for this and other important research initiatives detailed below.

First, nearly all retail pickled vegetables are pasteurized for safety and shelf stability. Current steam and water bath pasteurizers rely on technology from the 1940s and 50s. Promising new technologies include continuous flow microwave technology and "hot-fill-and-hold" pasteurization. Research efforts to further develop these technologies will reduce water use and significantly improve energy efficiency with new, scientifically validated thermal processing technologies.

Second, additional research that offers significant economic and environmental advantages to the U.S. industry includes the reduction or replacement of salt in commercial vegetable fermentations and bulk acidification. Calcium substitution of salt in commercial vegetable processing has the potential to significantly reduce chloride levels in waste waters and sludge currently delivered to landfills; and create opportunities to manufacture reduced sodium, fermented vegetable products. Reducing environmental impact and production costs for the manufacture of healthier vegetable products is essential to the sustainability of the U.S. industry.

Third, the market for fermented vegetable products is rapidly growing in the U.S. These products are attractive to consumers seeking "natural" or "traditional" foods. Novel fermented foods are being imported, manufactured and sold by small business (farmer's markets) and large companies. For many of these fermented foods, little is known about the safe fermentation conditions, appropriate storage times and temperatures and shelf life. While these fermented foods may contain healthful probiotic bacteria and offer new flavors and expanded markets for vegetable grown in the US, the potential microbial hazards are undefined. Little data is available in the scientific literature to define safe fermentation practices. Research is needed to help both producers and regulatory agencies define safe fermentation practices to meet food safety modernization act standards for novel imported and locally manufactured fermented vegetable products.

SPECIALTY CROPS

The USDA/ARS conducts research on the development and application of innovative engineering technologies for rapid, nondestructive measurement and grading of fruits and pickling vegetables to ensure and enhance product quality and marketability, reduce food loss, and achieve labor cost savings. The research program is well recognized for its pioneering research and development and technology transfer effort in imaging and spectroscopic inspection technologies, which have found wide applications in food quality and safety inspection. Currently, ARS researchers are developing a new generation of sensing technologies, which are much more effective and efficient than the current inspection systems, for quality evaluation and grading of pickling vegetables and fruits at the processing facility and in the field.

Sensor and automation is critical to ensuring and enhancing food quality and safety, reducing product loss and production cost, and improving traceability. Modern automated food quality inspection systems have been in use for some time, but they have not been able to fully meet the increasing demands for food quality, safety and traceability from the consumer and by the governmental regulatory agencies. The ARS engineering research program will provide new, cutting-edge food quality inspection technology for pickling vegetable and specialty crop growers and processors, helping them deliver best quality, consistent products to the consumer at affordable prices. Expansion of the ARS research in food quality sensing and automation would enable addressing key technical challenges in the development of new generation food quality inspection technology and allow fast transfer and dissemination of the developed technologies to the U.S. specialty crop industries. This would help the U.S. specialty crop industries maintain competitive advantages in the global marketplace.

EMERGING DISEASE OF CROPS

USDA/ARS vegetable research addresses national problems confronting the vegetable industry of the southeastern U.S. The mission of the laboratory is to develop disease and pest resistant vegetables, and also new, reliable, environmentally-sound disease and pest management practices that do not rely on conventional pesticides. Programs currently address 14 crops, including those in the cabbage, cucumber, and pepper families, all of major importance to the pickling industry. USDA/ARS research is recognized world-wide, and its accomplishments include over 150 new vegetable varieties and many improved management practices.

Increasing current funding levels for this program will directly benefit the southeastern vegetable industry. Vegetable growers depend heavily on synthetic pesticides to control diseases and pests. Without the availability of certain pesticides that have been eliminated for use, producers are likely to experience crop failures unless other effective, non-pesticide control methods are readily identified. In this context, the research on improved, more efficient and environmentally compatible vegetable production practices and resistant varieties continues to be absolutely essential. This research can help provide U.S. growers with a competitive edge they need to sustain and keep their industry vibrant, allowing it to expand in the face of increasing foreign competition. Current cucumber varieties are highly susceptible to a new strain of the downy mildew pathogen which has caused considerable damage to commercial cucumber production in eastern, midwestern, as well as western states in recent years. Increasing funding to allow hiring a new plant pathologist will facilitate the conduct of key research to address this critical situation.

FUNDING NEEDS FOR THE FUTURE

It remains critical that USDA/ARS funding continues the forward momentum in pickled vegetable research that the U.S. now enjoys and to increase funding levels as warranted by planned expansion of research projects to maintain U.S. competitiveness.

It is important to note that fiscal year 2015 Enacted/fiscal year 2016 Estimated funding for USDA/ARS laboratories totaled $11,247,000. However, fiscal year 2015 Enacted/fiscal year 2016 Estimated funding for all cucurbits equaled just $3,916,000 with only $2,112,000 directed toward cucumber and pickled vegetable research. For fiscal year 2017, PPI is requesting an additional $2,000,000 in program enhancements that will provide needed research for cucumber and pickled vegetables.

EMERGING DISEASE OF CROPS

There is a critical need to increase funding to support plant pathology research to address cucumber diseases, especially the disease caused by a new strain of the downy mildew pathogen responsible for recent extensive damage to cucumber and other cucurbit productions in the eastern states. A pathologist is especially needed to characterize pathogen strains and to develop new management approaches, as well as resistant cucumber varieties, to combat the disease. Ultimately, a new plant pathologist position will accomplish research that results in more effective protection of cucumbers from disease without the use of conventional pesticides.

	Amount
Fiscal year.	
2015 Enacted	$598,000
2016 Estimate	598,000
2017 (Proposed budget)	To be determined
2017 Additional Request (Plant Pathologist & support)	500,000

QUALITY AND UTILIZATION OF AGRICULTURAL PRODUCTS AND FOOD SAFETY

The current funding includes research and development for a variety of vegetable products, including fermented and acidified vegetables. For new research initiatives to reduce energy and water use, reduce environmental impact from commercial fermentations, and develop new health-promoting food (probiotic) technology, we request additional support of $500,000 to fully fund the scientists and support staff, including graduate students and post-doctorates, for carrying out the research and acquiring necessary equipment.

	Amount
Fiscal year.	
2015 Enacted	$595,000
2016 Estimate	595,000
2017 (Proposed budget)	To be determined
2017 Additional Request (Post-doctoral and Pre-doctoral Research Associate, new equipment & support).	500,000

APPLIED CROP GENOMICS

Emerging diseases, such as downy mildew, southern root knot nematode, and angular leaf spot of cucumber, threaten production of the crop in all production areas. Yield and quality traits found in diverse cucumber germplasm must be bred into U.S. crop cultivars. We request an additional $500,000 to fully fund the scientists and support staff, including graduate students and post-doctorates for identifying, researching and applying genomic tools to develop new sources of genetic resistance to emerging diseases, improve yield and quality.

	Amount
Fiscal year.	
2015 Enacted	$458,000
2016 Estimate	458,000
2017 (Proposed budget)	To be determined
2017 Additional Request (Post-doctoral and Pre-doctoral Research Associate & support).	500,000

SPECIALTY CROPS

The current funding is far short of the level needed to carry out research on inspection, sorting and grading of pickling cucumbers and other vegetable crops to assure the processing and quality of pickled products. An increase of $500,000 in the current base funding level would be needed to fund the research engineer position.

	Amount
Fiscal year.	
2015 Enacted	$145,000
2016 Estimate	145,000
2017 (Proposed budget)	To be determined
2017 Additional Request (Research Engineer & support)	500,000

[This statement was submitted by Brian Bursiek, Executive Vice President, Pickle Packers International, Inc.]

PREPARED STATEMENT OF SOCIETY FOR WOMEN'S HEALTH RESEARCH (SWHR)

The Society for Women's Health Research (SWHR®) urges the Committee to prioritize and provide an increase to the fiscal year 2017 budget authority (BA) appropriations (non-user fees) for the Food and Drug Administration (FDA) of $2.85 billion, an increase of $120 million over fiscal year 2016. Our request is based on FDA's current workload, planned programs, and emerging public health priorities. Additionally, SWHR supports an allocation of $10 million for the FDA Office of Women's Health (OWH) for fiscal year 2017.

For over 25 years, SWHR has been widely considered a thought-leader in promoting research on biological differences in disease and we are dedicated to transforming women's health through science, advocacy, and education.

Our organization has long advocated that drug and device scientific advancements should demonstrate adequate subpopulation testing prior to approval by FDA. The Agency has made great improvements in improving the completeness and quality of demographic subgroup data collection, reporting and analysis of subgroup data collection, identifying barriers to subgroup enrollment in clinical trials, employing strategies to encourage greater participation, and making demographic subgroup data more available to the public. However, in order for greater improvement, Congress must invest in FDA's core functions. SWHR is committed to the belief that the FDA, as regulator of products representing approximately 20 percent of American consumer spending, should receive priority funding as its responsibilities are critical to the health and well-being of all Americans.

The FDA has broad jurisdiction and is responsible for:

—Protecting public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

—Advancing public health by helping to speed innovations that make medicines more effective, safer, and more affordable and providing accurate, science-based information needed by patients and consumers to safely use medicines and foods to maintain and improve their health.
—Regulating the manufacturing, marketing and distribution of tobacco products to protect public health and to reduce tobacco use by minors.
—Ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Each year, Congress adds ever increasing responsibilities to the Agency (most recently food safety, sunscreen labeling, drug safety, and compounding) but fails to provide appropriate funds to meet those demands reasonably, thereby straining the FDA's abilities and forcing it to choose among competing public health priorities. This is a dangerous precedent which poorly serves the health and safety of the America people. Many of the mandated programs that Congress has tasked the Agency with are not covered by user fees, leaving FDA in need of a larger budget authority appropriation in order to fulfill its duty. SWHR believes that sustained investment in the FDA and its regulatory responsibilities is absolutely essential if the U.S. is to meet the needs of its citizens, especially women, and maintain its gold standard in scientific transformation and medical product advancement.

SWHR is a strong supporter of stakeholder engagement with the Agency, and are active in the user fee agreement process for prescription and generic drugs, as well as medical devices and biologics. Such opportunities allow for FDA to discuss process improvements that will speed the approval of safe and effective medical products for patients and consumers. The increased emphasis on patient-focused drug development, risk/benefit analysis, and innovative clinical trial design will only further efforts to bring lifesaving treatments to market.

However, Congressionally-allocated funds are desperately needed to support FDA post-market surveillance activities, improve technical assistance to industry to reduce review times, and enhance its communications with patients and consumers. Post-market surveillance is critical to ensure that drugs and devices, when available to a wider patient population, are truly safe and effective for all populations. The American public cannot, and should not, rely on industry to conduct the bulk of these activities. The 21st Century Cures Act, recently passed by the House, and its companion Senate Innovation's effort, focus on the need to bring medical products to the market more quickly. A large part of that process is improving clinical trials to be faster and less expensive. The biopharmaceutical and biopharmaceutical services industries, along with the FDA and other key stakeholders, have made great strides in improving the clinical trial process; however, clinical trials will never be able to give us the information that is obtained once the drug or device is approved and used in the population. This makes it more critical that FDA has a strong and robust post marketing surveillance program. While the MedWatch and similar programs do exist, they will need additional resources to ensure FDA staff and others as appropriate can quickly respond to reduce morbidity and mortality related to potential safety issues.

Additional FDA funding will also support improved technical assistance for its industry partners by supporting staff resources to develop, review, and approve guidance. Timely release of guidance documents is critical to ensure industry partners can develop processes and submit applications with the most pertinent information for review. Such releases would also allow for increased opportunities for innovation by promptly responding to a changing drug/device development environment.

Finally, additional funding would allow FDA to enhance its communications with the public. Such funding could support building a consumer-friendly FDA interface; making it much easier for patients and consumers to navigate. Funding could also be used to continue the patient-focused drug development meetings and other workshops and listening sessions, allowing FDA to connect directly with the American public it serves.

ACTION PLAN TO ENHANCE THE COLLECTION AND AVAILABILITY OF DEMOGRAPHIC SUBGROUP DATA

FDA, working with industry, must ensure that clinical trials examine differences in subpopulations ensuring appropriate representation to achieve statistical significance and analysis. In 2014, FDA released its "Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data" (Action Plan), as directed by section 907 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). The Action Plan, largely developed and implemented by the OWH and the Office of Minority Health, provided an outline of long and short term actions

and implementation strategies the FDA is undertaking to examine sex, race, ethnicity and age-based differences through medical research, to allow subgroup-specific data to be more widely available for use in medical practice, and to improve the participation of women, minorities and the elderly in research trials.

SWHR hopes that FDA will continue to work towards the goals outlined in that plan which will be beneficial for patients, consumers, and the healthcare community at large. The Agency has worked with stakeholders to ensure that the subgroup data is appropriately analyzed, reported and presented by FDA and sponsors in a meaningful way to patients and the medical community. However, many components of the Action Plan remain, for example, it is critical that the Agency update its 2005 Guidance for Industry on the Collection of Race/Ethnicity Data in Clinical Trials.

As part of the Action Plan, FDA also has a critical regulatory role in human subject research. Women and minority populations have historically been underrepresented in medical research, and although women and minorities are now being enrolled in clinical trials at greater rates, much work remains to ensure that these groups are included and retained in trials at appropriate levels to provide statistically significant results. Through the Action Plan, FDA recognized the need to increase representation of these population groups in clinical trials and the need for more analyses on how medical drugs and devices in development affect women and men differently as well as racially, ethnically and by age. Women should have confidence that drugs, devices and biologics approved for patient use have been appropriately analyzed for sex differences and the finding publicly reported in a meaningful way for usage by both healthcare providers and patients.

SWHR has long sought the transparency of demographic subgroup data that FDA uses as the basis of its approval decision. This issue was a priority area of the Action Plan and in 2014, the Agency launched the "Drug Trial Snapshot" website to provide information about who participated in clinical studies for new molecular entities and original biologics. The Snapshot website also includes information on study design, results of efficacy and safety studies, and information on any differences in efficacy or safety that were apparent in subgroup populations.

The Snapshot website is a step in the right direction; however, we believe that the website could be improved to revolutionize the way Snapshots benefits patients. SWHR believes that Snapshots could be improved by contextualizing the data presented with all relevant information relating to the intersection of age, race, and sex to provide those using the website a thorough understanding of their benefits and risk as individual users of a certain drug or biologic. Additionally, the website is not easily found on FDA's webpage. FDA has signaled that they view the website as an iterative process, and are open to hearing stakeholder feedback on how to improve the site. However, these efforts require the Agency to receive sustained funding and resources and SWHR believes that Congress must commit to continued and robust investment in FDA to provide for the advancement and increased transparency of drug development.

FDA OFFICE OF WOMEN'S HEALTH

OWH has proven itself to be vital player in advancing women's health issues at the Agency; including the expansion of existing research projects and helping to foster new collaborations related to advancing the science of women's health. OWH's programs ensure that sex and gender differences in the efficacy of drugs (such as metabolism rates), devices (sizes and functionality), and diagnostics are taken into consideration in reviews and approvals.

American women rely on the tools OWH provides to them to help with their healthcare decisions. Each year, OWH consumer pamphlets are the most requested of any documents at the government printing facility in Colorado; with more than 8 million distributed to women across America, including target populations such as Hispanic communities, seniors and low-income citizens. These pamphlets discuss topics such as breast cancer screening, diabetes, menopause hormone therapy, and medication use during pregnancy. In addition, OWH's website is a vital tool for consumers and physicians, providing free, downloadable fact sheets on over one hundred different illnesses, diseases, and health related issues for women. Among the most popular, OWH provides medication charts on select chronic diseases, listing all the treatment options available for each disease. We must maintain these vital functions that healthcare professionals and the public understand and utilize daily to make healthcare decision.

In partnership with the National Institutes of Health Office of Research on Women's Health, OWH created a website for on-line sex and gender courses to provide additional educational tools for medical practice and scientific innovation. All three

courses offer free continuing education credits for physicians, pharmacists and nurses.

Last year, OWH unveiled the Women's Health Research Roadmap (Roadmap) to build on knowledge gained from previously funded research and assist OWH in coordinating future research activities with other FDA research programs and external partners. The Roadmap outlined priority areas where new or enhanced research is needed, creates strategic direction for OWH to help maximize the impact of OWH initiatives, and ultimately promote optimal health for women. It was also designated a key FDA commitment in FDA's August 2014 Action Plan.

To fully implement the Research Roadmap and continues it's important work, SWHR requests an allocation of $10 million for the FDA Office of Women's Health (OWH) for fiscal year 2017. We believe these recommended budget allocations would enable the FDA to address resource shortages across its centers, but also implement critical improvements in infrastructure and support a substantial investment in the OWH, the office responsible for advancing the health of women through policy, science, and outreach and one of the leading voices in increasing the participation and analysis of women and other subpopulations in clinical trials.

In conclusion, we thank the Committee for its past support of the FDA and its centers. It is our hope that the Committee continue to invest in the Agency to help ensure a healthier future for all Americans. We look forward to continuing to work with you.

[This statement was submitted by Leslie S. Ritter, Vice President, Public Policy, Society for Women's Health Research.]

PREPARED STATEMENT OF THE WILDLIFE SOCIETY

The Wildlife Society appreciates the opportunity to submit testimony concerning the fiscal year 2017 budgets for the Animal and Plant Health Inspection Service (APHIS), National Institute of Food and Agriculture (NIFA), Natural Resources Conservation Service (NRCS), and Farm Service Agency (FSA). The Wildlife Society was founded in 1937 and is an international non-profit scientific and educational association representing nearly 10,000 professional wildlife biologists and managers. Our mission is to inspire, empower, and enable wildlife professionals to sustain wildlife populations and habitats through science-based management and conservation. We respectfully request the following programmatic funding in fiscal year 2017 to ensure that the Federal budget supports the important work of managing and conserving our nation's wildlife resources. Thank you in advance for considering the views of wildlife professionals.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Wildlife Services, a unit of APHIS, resolves human/wildlife conflicts and protects agriculture, human health and safety, personal property, and natural resources from wildlife damage and wildlife-borne diseases in the United States. The Wildlife Society recognizes wildlife damage management as an important part of modern wildlife management.

In fiscal year 2017, the President has proposed a decrease in funding for Wildlife Damage Management by approximately $15 million. While we acknowledge this decrease partially reflects the removal of a one-time capital investment of $5.8 million in aircraft equipment from fiscal year 2016, we are highly concerned by the additional extent of this proposed decrease and the effect it might have on the continued success of programs managed by Wildlife Services, like the National Rabies Management Program. Therefore, we encourage Congress to fund Wildlife Damage Management at or beyond the fiscal year 2015 funding levels of $90 million for fiscal year 2017.

Before wildlife damage management programs are undertaken, careful assessment should be made of the problem, including the impact to individuals, the community, and other wildlife species. A key budget line in Wildlife Service's operations is Methods Development, which funds the National Wildlife Research Center (NWRC). Much of the newest research critical to state wildlife agencies is being performed at NWRC. In order for state wildlife management programs to be the most up-to-date, the work of the NWRC must continue. The Wildlife Society recommends the continued funding of Methods Development at $19 million in fiscal year 2017.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

The Renewable Resources Extension Act (RREA) provides an expanded, comprehensive extension program for forest and rangeland renewable resources. RREA funds, which are apportioned to State Extension Services, effectively leverage cooperative partnerships at an average of four to one, with a focus on private landowners. The need for RREA educational programs is greater than ever because of continuing fragmentation of land ownership; urbanization; diversity of landowners needing assistance; increasing societal concerns about land use; and increasing human impacts on natural resources. Authorized at $30 million, RREA has been appropriated at roughly $4 million per year since fiscal year 2008. To meet the growing need for sustainable outreach initiatives, The Wildlife Society recommends that Congress increase the funding for RREA to at least $10 million for fiscal year 2017.

The McIntire-Stennis Cooperative Forestry Program is essential to the production, utilization, and protection of forestry resources, including fish and wildlife, on nonindustrial, private forestlands. As the demand for forest products grows, the nation will increasingly rely on privately held forests to supplement resources obtained from national forest lands. However, commercial trees take many decades to produce. In the absence of long-term research, such as that provided through McIntire-Stennis, the nation may have difficulty meeting future forest-product needs in a sustainable manner. We appreciate the $34 million provided for McIntire-Stennis in fiscal year 2016 and urge Congress to continue this funding in fiscal year 2017.

NATURAL RESOURCES CONSERVATION SERVICE

The Natural Resources Conservation Service (NRCS) is the primary Federal agency that works with private landowners to help them conserve, maintain, and improve their natural resources, thereby making them more resilient and valuable to society. NRCS emphasizes science-based conservation, and through a variety of voluntary, incentive-based programs, offers technical assistance and cooperative problem solving at the community level. Demand for NRCS programs and the backlog of qualified applicants has far outnumbered the agency's present capacity under current funding. With increased pressure on farmlands from biofuel development, urban sprawl, and the concurrent declines in wildlife habitat and water quality, the need for NRCS conservation programs continues to grow.

For fiscal year 2017, the President has requested $1.9 billion for Private Lands Conservation Operations (PLCO), including $1.0 billion of mandatory funding and $860 million of discretionary funding; which includes the Conservation Technical Assistance (CTA) program. CTA provides discretionary funding for NRCS to support implementation of Farm Bill programs. The Wildlife Society is strongly supportive of the fiscal year 2017 budget proposal of $761 million in funding for CTA, a slight increase from fiscal year 2016. An increase in funds will allow for further implementation of the changes that resulted from the 2014 Farm Bill. In the 2014 Farm Bill, Congress demonstrated strong support for the use of mandatory funds for Technical Assistance (TA), but these funds can only be used in association with a specific Farm Bill program. Appropriated funds for CTA are still essential for NRCS to provide efficient customer service and strong conservation results. The Wildlife Society therefore encourages Congress to provide $860 million for discretionary TA, including $761 million for CTA, and $1.0 billion for mandatory TA in fiscal year 2017, per the President's request.

The Wildlife Society also recommends that all Farm Bill conservation programs be funded at levels mandated in the 2014 Farm Bill, including $500 million for the Agriculture Conservation Easement Program (ACEP) and 1.65 billion for the Environmental Quality Initiatives Program (EQIP). Demand for these programs continues to grow, yet during a time when greater assistance is needed to address natural resource challenges and conservation goals, the NRCS can only fund a small portion of the overall demand for these popular programs.

FARM SERVICE AGENCY

The President's request would provide funding for the Conservation Reserve Program (CRP) at $1.9 billion in fiscal year 2017. Lands enrolled in CRP are important for the conservation of soil on some of the Nation's most erodible cropland. These lands also contribute to water quantity and quality; provide habitat for wildlife that reside on agricultural landscapes; sequester carbon; and provide a strategic forage reserve for periodic compatible use in times when other livestock forage is limited due to drought or other natural disasters. We strongly encourage Congress to fund

CRP at $1.9 billion per the President's request, or at a level that fully utilizes the program's general enrollment authority.

FISCAL YEAR 2017 APPROPRIATIONS RECOMMENDATIONS—THE WILDLIFE SOCIETY

USDA Agency/Unit	Program	fiscal year 2015 Enacted	fiscal year 2016 Estimate	fiscal year 2017 POTUS	fiscal year 2017 The Wildlife Society
APHIS/Wildlife Services	Wildlife Damage Management	90M	101M	86M	90M
	Methods Development	19M	19M	19M	19M
NIFA/Formula Grants	RREA	4M	4M	4M	10M
	McIntire-Stennis Coop. Forestry	34M	34M	34M	34M
NRCS/PLCO	PLCO-Discretionary TA	846M	851M	860M	860M
	PLCO-Mandatory TA	900M	903M	1,034M	1,034M
	PLCO-Total	1,746M	1,754M	1,894M	1,894M
NRCS/Farm Bill Conservation Programs	ACEP	394M	419M	500M	500M
	EQIP	1,347M	1,329M	1,650M	1,650M
	TOTAL-Farm Bill Programs	3,184M	3,123M	3,885M	3,885M
FSA/Conservation Programs	Conservation Reserve Program	1,741M	1,841M	1,923M	1,923M

[This statement was submitted by Byron Ken Williams, PhD, Chief Executive Officer, The Wildlife Society.]

Prepared Statement of World Food Program USA

REQUEST

World Food Program USA (WFP USA) is a non-profit organization that works to solve global hunger by raising U.S. support for the mission of the UN World Food Programme. Specifically, we request the following funding levels for three essential programs within the jurisdiction of the subcommittee:

—Title II Food for Peace—$1.75 billion
—McGovern Dole Food for Education and Child Nutrition Program—$209.5 million
—Local and Regional Procurement Program—$80 million
—We also request bill language be included in the General Provisions regarding non-emergency, development activities in the Title II Food for Peace account.

To maintain strong U.S. leadership in solving hunger and to respond to critical emergency needs worldwide, WFP USA urges the subcommittee to provide the strongest possible funding for global food security programs. Our specific funding requests mirror those in the InterAction Choose to Invest fiscal year 2017 recommendations, which have been formally endorsed by a coalition of 168 U.S.-based, non-governmental and faith-based organizations.

BACKGROUND

Strong bipartisan support for a comprehensive approach to ensuring global food security has made the United States a global leader in the effort to solve hunger, catalyzing significant progress worldwide. Today there are over 200 million fewer hungry people compared to 1990 estimates. Undernourishment and child mortality have been nearly halved during this time. These trends demonstrate that the goal of zero hunger is achievable if the positive policies and programs the U.S. has put into place are sustained.

Despite this dramatic progress, there are still 795 million chronically hungry people in the world today. Undernourishment still affects 12.9 percent of developing country populations. And in 2015, 5.9 million children under five died prematurely, with nearly half of these child deaths associated with undernutrition.

In addition, there are now four ongoing crises classified at the most severe level of humanitarian emergency. These crises in Syria, Iraq, South Sudan, and Yemen are the result of internal conflicts that have caused massive population displace-

ments. In fact, there are now over 60 million displaced people worldwide, including both refugees and those internally displaced: the highest number since World War II. In response to these and other crises, the 2016 UN humanitarian consolidated appeal estimated global humanitarian needs at $17.2 billion, which was more than double the estimated need level in 2012.

The United Nations World Food Programme (WFP) is the world's largest humanitarian organization, providing critical food and nutrition support to roughly 80 million of the world's hungriest people each year. WFP estimates that total global food assistance requirements for 2017 will exceed $8 billion.

FOOD FOR PEACE

Food for Peace (FFP) provides emergency food and development assistance to millions suffering from hunger and malnutrition. For the past 60 years, Food for Peace has been the primary vehicle for providing food aid in response to natural disasters, crises, and conflicts around the world. Maintaining robust funding for Food for Peace Title II and finding ways to stretch that funding further is imperative.

While the United States remains the largest donor of global food assistance, the reach of U.S. food assistance has been stretched by record levels of need in 2016. Supporting FFP at $1.75 billion would allow the U.S. to reach 45–50 million people with lifesaving food aid and maintain its global leadership.

The United Nations World Food Programme (WFP) is the largest U.S. food aid partner, implementing programs that account for roughly 90 percent of Food for Peace emergency food aid funding. WFP estimates $6.5 billion will be required to fund its 2017 emergency food assistance programs. About $1.2 billion—almost 20 percent of total WFP emergency needs—will be required just for the humanitarian crisis in Syria and the Syrian refugees in neighboring countries. Needs from both weather-related disasters and conflicts will continue to persist across Sub-Saharan Africa, and Southwest Asia.

Food for Peace provides the bulk of funding for the U.S. to contribute its historical average of about 30 percent of WFP emergency, relief, and recovery programs. Other countries provide over 60 percent of the annual contributions to WFP, which means that U.S. food aid channeled through WFP helps leverage additional international assistance.

We also support the inclusion of administration-requested bill language to address section 412(e) of the Food for Peace Act, 7 U.S.C. 1736f(e). It is our view that other U.S. Agency for International Development resources which support non-emergency, development activities can be used to satisfy the statutory requirements of this section in a manner that maximizes flexibility to support both emergency and non-emergency food activities.

MCGOVERN DOLE INTERNATIONAL FOOD FOR EDUCATION AND CHILD NUTRITION PROGRAM

The McGovern-Dole International Food for Education and Child Nutrition Program provides U.S. agricultural products and technical assistance for school feeding projects in low-income, food-deficit countries that are committed to universal education. The McGovern-Dole program provides school-age children in poverty-stricken countries with what is often their only full meal of the day and protects vulnerable children, especially during times of natural disasters and economic shocks.

Serving food at school helps solve chronic hunger and can be life-changing for the world's poorest children. School meals also help get students into the classroom, giving them an important key to a better future: an education. In areas where enrollment rates for girls are low, McGovern-Dole supported programs work with families and communities to make it possible for more girls to attend school. This sometimes includes giving girls take-home rations that encourage families to send daughters to school and also benefit younger children at home. Girls' education has a powerful ripple effect on families and communities. One study has shown that the more education girls have, the less likely their children will be malnourished.

The UN World Food Programme calculates that $3.2 billion is needed per year to reach all 66 million primary school-age children that go to school hungry every day. While an investment of $209.5 million for school feeding represents a small fraction of overall global investment in school feeding programs by donor and host country governments, U.S. resources remain critical for low-income countries to continue school feeding programs. We urge the committee to fund the McGovern-Dole program at a level of $209.5 million in fiscal year 2017.

LOCAL AND REGIONAL FOOD PROCUREMENT PROGRAM

We recommend fully funding the Local and Regional Procurement (LRP) Program, which was newly authorized at $80 million in the Agricultural Act of 2014. The 2014 Farm Bill conference report's statement of managers affirms that the intent of LRP programming is to complement existing food aid programs, especially the McGovern-Dole Food for Education and Child Nutrition Program.

Linking the new USDA LRP program to the McGovern-Dole program improves the chances of long-term sustainability of school feeding programs supported by McGovern-Dole. A fundamental objective of U.S. support to international school feeding is for countries to eventually take over, manage, and fund their own school feeding programs. This means developing locally sustainable systems for the purchase and management of food used in school feeding programs to move away over time from reliance on U.S.-donated commodities. U.S. support for LRP can help countries make that transition to national ownership. While Congress funded LRP activities in fiscal year 16, more is needed to demonstrate its full potential. Continued funding of the newly authorized LRP program will strengthen the McGovern-Dole supported programs and hasten this transition to recipient country responsibility and ownership.

[This statement was submitted by Richard Leach, President and CEO, World Food Program USA.]

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

SUBJECT INDEX

DEPARTMENT OF AGRICULTURE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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