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MEMORANDUM

May 30, 2018

BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Matz PC

RE: Senate Appropriations Committee Approves FY 2019 Agriculture, Rural Development, and FDA Bill

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The full Senate Appropriations Committee approved and reported S. 2976,[1] the FY 2019 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill (the Bill) on May 24 by a vote of 31-0.

This memorandum is intended to provide you with an overview of the Committee's recommendations, including items referenced in the Committee's Report, Senate Report 115-259[2] (the Report). The Bill has not yet been scheduled for Senate consideration.

Overview:

The legislation provides $145.4 billion in both mandatory and discretionary funding. This is a decrease of $5.7 billion below FY 2018, and nearly $6.1 billion above the President's request.

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1 https://www.appropriations.senate.gov/imo/media/doc/FY2019%20Agriculture%20Appropriations%20Act,%20S.2976.pdf

2 https://www.appropriations.senate.gov/imo/media/doc/FY2019%20Agriculture%20Appropriations%20Act,%20Report%20115-259.pdf

The mandatory funding in the Bill is $124.9 billion, of which more than $93.3 billion goes for food assistance programs including the Supplemental Nutrition Assistance Program (SNAP) and the Child Nutrition Programs. Discretionary spending will be $23.235 billion in FY 2019, $225 million above FY 2018.

During this markup session, Senate Majority Leader Mitch McConnell (R-KY), a member of the Committee, said he believes that to complete action on appropriation bills it is likely that the Senate could in June begin the consideration of "minibus" bills, *i.e.* the combination of multiple bills into one. Agriculture may be combined with the Energy and Water Appropriations bill.

The following table provides funding by Title, and compares the Committee's 2019 Recommendation with the 2018 Enacted Amounts.

(In thousands of dollars)

Title	Description	2018 Enacted	2019 Committee Recommendation	2019 Compared with 2018
I	Agricultural Programs	$6,966,837	$6,967,783	$946
II	Farm Production and* Conservation program	$25,933,930	$26,825,522	$891,592
III	Rural Economic and Community Development Programs	$3,000,881	$3,000,883	$2
IV	Domestic Food Programs	$104,919,418	$103,040,913	-$1,878,505
V	Foreign Assistance and Related Programs	$2,020,957	$2,152,323	$131,366
VI	Related Agencies and Food and Drug Administration	$2,811,866	$2,970,866	$159,000
VII	General Provisions	$577,096	$488,496	-$88,600
	Supplemental Appropriation for Disaster	$3,645,000	---	-$3,645,000
	Total, New Budget Authority	$151,145,985	$145,446,786	-$5,699,199

Full Committee Consideration:

An audio of the Committee's meeting can be found here[3], beginning at 1:48:00. The markup was brief with opening statements submitted for the record rather than presented. Only one amendment was offered.

Amendments Approved –

Manager's Amendment[4] **–** Subcommittee Chairman John Hoeven (R-ND) offered a package of bill and report amendments which included bill language for Senators Collins, Coons, Feinstein, Graham, Reed, Shaheen, and Udall regarding horse slaughter; report language for Senator Durbin regarding urban agriculture; report language for Senator Murkowski regarding floriculture crops; report language for Senator Collins regarding aquaculture research; report language for Senator Udall regarding the extension service; report language for Senator Udall regarding the Rural Housing Service; report language for Senators Merkley and Shaheen regarding the Multi-Family Housing Revitalization Program; report language for Senator Murkowski regarding the Summer Food Service Program; report language for Senator Collins regarding added sugar labeling; report language for Senators Durbin and Graham regarding dietary supplements; report language for Senator Alexander regarding opioids; and report language for Senator Durbin regarding youth tobacco use prevention. The amendment was agreed to by voice vote.

Bill and Report Highlights:

The following items are offered as a description of some of the more significant items included in the Bill and/or Report. It is not an exhaustive list of all items in the Bill and/or Report. The language is often excerpted from the report.

Agricultural Quarantine Inspection -

Under the Animal and Plant Health Inspection Service (APHIS) –

- The Committee recognizes that prevention of infestations of pests and diseases is much more cost effective than subsequent control or eradication. This is an important Federal responsibility and the Committee provides $32,330,000 for the agricultural quarantine inspections [AQI] function, including pre-departure and interline inspections.
- The Committee is concerned that new fee regulations under the AQI program may not be equitable to small commercial aircraft. The Committee looks forward to seeing the report on AQI user fees as required by Public Law 115–141.

[3] https://www.appropriations.senate.gov/hearings/watch?hearingid=95D0C1AE-5056-A066-607A-3D81F51450CC
[4] https://www.appropriations.senate.gov/download/052418_-fy2019-agriculture-appropriations-act-managers-package

- The Committee notes that assessing AQI treatment monitoring fees on a per-enclosure basis imposes disproportionate impacts on industry and user groups at certain key ports of entry, including ports along the southeast United States. USDA is encouraged to continue conducting a study that specifically outlines the actual costs of treatments, examines the disproportionate impact the fee has on airports and seaports in different regions of the U.S., and evaluates alternative and equitable funding mechanisms. Such report should also incorporate due consideration of the recommendations of the Treatment Fee Working Group's September 27, 2016 ''Report to APHIS''. USDA shall brief the Committee on the status of such study and other efforts to ensure equitable collection of revenues for vital AQI treatment monitoring efforts.

Animal Care –

Under APHIS, the Committee is concerned about dog breeders selling dogs, including dogs sold over the Internet and through other outlets, who refuse to obtain a license and comply with the Animal Welfare Act's humane care and treatment requirements and urges the Department to focus outreach, compliance assistance, and enforcement resources to these actors.

Avian Influenza –

Under APHIS, the Committee recognizes the extreme economic hardship posed to gamebird and egg farmers when flocks are determined to be infected by high and low pathogenic avian influenza, and acknowledges the severe limitations on controlled marketing available to producers of live game birds, as well as the income loss from egg production. The Committee encourages APHIS to provide full indemnity coverage for gamebird and egg operations and cease attempts to limit coverage.

Bee Pests –

Under APHIS, the Committee remains concerned with declining bee populations and the tragic implications for pollination of U.S. agriculture. The Committee directs the agency to continue priority work with other Federal and State agencies and the public to manage, suppress, and eradicate varroa mites, small hive beetles, and other pests and diseases contributing to colony collapse disorder.

Bioenergy Program for Advanced Biofuels –

Under Rural Development, the Committee is concerned with the interim rule proposed by the Department under the Bioenergy Program for Advanced Biofuels program (section 9005 of the Energy title of the farm bill, Public Law 113–79), which is intended to promote the development

of different qualifying advanced fuel categories. The Committee is concerned that the allocation formula for distribution of section 9005 funds among the qualified fuel categories is inequitable, disproportionate, and inconsistent with the purpose and intent of the section 9005 program. The Committee urges the Department to administer the section 9005 program in a way that is fuel and technology-neutral. Consistent with these objectives, the Committee directs USDA to propose amendments to the interim rule to ensure that any final rule to implement section 9005 provides for a more equitable and proportional allocation of funding among the qualified advanced biofuels and the energy pathways they represent.

Cattle Fever Ticks –

Under APHIS, the Committee appreciates the commitment by APHIS, including recent additional funding, to respond to the most recent outbreak of cattle fever ticks. The Committee encourages the agency to maintain this focus and provide adequate funding for all activities under the Cattle Fever Tick Eradication Program [CFTEP]; heighten efforts to coordinate the response with the Department of Interior on national wildlife refuges; and provide sufficient funding for research and scientific tools to be developed that concentrate on the following: new systematic cattle fever tick treatment products with longer treatment intervals for cattle; new cattle fever tick treatment products for wildlife, especially nilgai antelope; and new or improved cattle fever tick preventative therapies, such as vaccines, for both cattle and wildlife hosts.

Citrus Imports —

Under APHIS, Citrus Health Response Program [CHRP] is a national effort to maintain a viable citrus industry within the United States, maintain producer's continued access to export markets, and safeguard citrus producing states against a variety of invasive pests and diseases. These funds are designed to partner with state departments of agriculture and industry groups to address the challenges of citrus pests and diseases. In addition to the funds provided in this account, the Committee encourages APHIS to utilize the funds available in the Plant Pest and Disease Management and Disaster Prevention Programs account to the greatest extent possible in an attempt to sustain the economic viability of the citrus industry.

County Level Agricultural Risk Protection -

Section 747 of the Bill provides funding for a pilot program through the Farm Service Agency to provide State Farm Service Agency offices in each State 8 the opportunity to provide agricultural producers in the State a supplemental payment based on the alternate calculation method for 1 or more counties in a State if the office for that State determines that the alternate calculation method is necessary to ensure that, to the maximum extent practicable, there are not significant yield calculation disparities between comparable counties in the State.

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Food and Drug Administration (FDA) -

FDA receives an appropriation of $2,959,078,000, an increase of $159,000,000 over the amount provided in FY 2018, and $212,842,000 below the budget request. When current user fees are included, FDA's FY 2019 available funding will be $5,419,299,000, an increase of $281,258,000 over FY 2018, and $212,842,000 below the budget request.

The Committee recommendation does not include proposed user fees for food facility registration and inspection, food import, food contact substance notification, cosmetics, and international courier imports. None of these user fee proposals have been authorized by Congress. The Committee will continue to monitor any action by the appropriate authorizing Committees regarding these proposed user fees.

The Committee expects FDA to continue all projects, activities, laboratories, and programs as included in fiscal year 2018 unless otherwise specified. The Committee does not support $29,400,000 of the proposed reductions; however it does accept the $2,500,000 reduction for compounding (which was intended for one-time use) and the $1,500,000 reduction for consumer education and outreach regarding agricultural biotechnology.

The Committee recommendation includes an increase of $163,000,000 for medical product and food safety activities requested in the budget. Included in this funding is $5,000,000 to fully fund the Oncology Center of Excellence; $37,600,000 to modernize the generic drug review process; $20,000,000 for investment and innovation for rare diseases; $11,700,000 to promote domestic manufacturing; $8,200,000 for a new platform for drug development; $6,000,000 for MedTech manufacturing, $7,200,000 for FSMA cooperative agreements; $2,800,000 for food import safety; $5,000,000 to address food safety outbreaks; $500,000 to test antibiotic resistance in imported seafood; and $59,000,000 for opioid prevention activities.

The following matters, among others, are identified in the Report:

- *Added Sugar Labeling* - The Committee remains concerned about potential consumer confusion over the new FDA nutritional labeling requirements for added sugar for single ingredient products like maple syrup and honey, where sugar is naturally occurring in the product rather than added to the product. The Committee is aware that the FDA has had discussions with maple and honey producers regarding their concerns that the labeling requirement as currently drafted could mislead consumers to think that sugar has been added to a pure single-ingredient maple or honey product. The Committee directs the FDA to continue working with the pure maple syrup and honey industries to ensure appropriate labeling for those single-ingredient products where sugar is naturally

occurring in the product rather than added to the product. The Committee is aware of a proposed alternative Nutrition Facts labeling approach that would clearly delineate between ''Added Sugars'' and ''Naturally Occurring Sugars'' in a product, as well as another proposed alternative that would permit labeling denoting ''No Added Sugars'' on applicable products, and directs the FDA to evaluate such proposals. The Committee further directs the FDA to submit a report within 60 days of enactment of this Act describing the research that was conducted prior to issuance of a final rule updating the Nutrition Facts label for packaged foods on May 27, 2016, to determine consumer perception regarding mandatory ''added sugar'' labeling on single ingredient products in which no sugar is added during processing, including pure maple syrup and honey.

- *ADUFA Reporting* -The Committee supports the collection and reporting of accurate and validated data of antimicrobial drug use for food-producing animals, but is concerned that antimicrobial sales and distribution data currently reported under ADUFA 105 have been equated with actual antimicrobial use data. In order for ADUFA reporting to promote public understanding in a meaningful and accurate way, FDA should ensure that such reporting clearly describe the limitations of sales data, including that they do not represent actual use. Therefore, the Committee encourages the Agency to seek alternative methods to better identify and reduce inappropriate antimicrobial drug uses.
- *Alzheimer's Drug Development* - The Committee applauds FDA for revising guidance on Alzheimer's drug development that supports the use of an endpoint on cognition as a biomarker for Alzheimer's disease clinical trials. We are optimistic that this approach will help advance Alzheimer's drug development, particularly evaluation of candidate therapies in patients who are asymptomatic. The Committee encourages FDA to continue supporting innovative approaches to Alzheimer's drug development, including biomarkers development platforms involving industry, academic researchers and patient preference tools.
- *Animal Feed Ingredients* -The Committee is concerned with the slow pace of review and approval of ingredients for feed for animals. The Committee urges FDA to dedicate additional personnel to speed the review and approval process.
- *Anti-counterfeiting Techniques* - The Committee directs the FDA to report back on the benefits and costs of incorporating multilayering and covert technologies with barcoding technology in meeting the provisions of the DQSA for pharmaceutical products within days of the enactment of this Act.
- *Autoantibody Qualification* - The appearance of certain islet autoantibodies in the serum of individuals increases the chance of developing type 1 diabetes at some point in the future. Therefore the Committee encourages the FDA to work with the Type 1 diabetes community on the assessment of potential diabetes biomarkers related to islet autoimmunity, which might help inform the design of clinical studies.

- *Biomanufacturing Innovation* - The Committee supports FDA participation in public-private partnerships to accelerate biomanufacturing innovation and encourages FDA to provide funding for this purpose from within available resources.
- *Breast Density* - The Committee recognizes the importance of patients receiving their own personal medical information and directs the Food and Drug Administration to ensure that mammography reports and summaries received by patients and their providers include appropriate information about breast density specified by the Secretary, including, at a minimum, the effect of breast density in masking the presence of breast cancer on a mammogram, the qualitative assessment of the provider who interpreted the mammogram, and a reminder to patients that individuals with dense breast tissue should talk with their providers if they have any questions or concerns about their summary.
- *Cancer Immunotherapy Clinical Trials* - The Committee is aware of the remarkable promise of cancer immunotherapy and encouraged by the FDA's recent approval of new treatments that harness this approach to fighting cancer. More than 1,500 immuno-oncology clinical trials are in some stage of development. As more patients turn to immune-based treatments, and more clinical trials are conducted to evaluate them, understanding how to recognize and manage the side effects of cancer immunotherapies will become increasingly important. Currently, however, standard parameters for reporting cancer immunotherapy-related adverse events in clinical trials are lacking, and this makes comparisons and management across studies challenging. The Committee, therefore, urges the FDA to work with the research community and the pharmaceutical industry to develop standardized templates for reporting toxicities in cancer immunotherapy clinical trials.
- *Center for Safety and Nutrition Centers of Excellence* - The Committee is aware of the important contribution of the FDA Center for Food Safety and Applied Nutrition's Centers of Excellence [COEs] program in supporting critical basic research as well as facilitating the implementation of the FDA Food Safety Modernization Act. The Committee encourages the Agency to continue to fully utilize the COEs to accomplish these goals, and instructs that it enhance its level of support for FDA Food Safety Modernization Act activities.
- *Clinical Trials* - The Committee acknowledges the responsibilities of FDA to protect public health and advance medical innovation and encourages FDA to continue its efforts to improve the effectiveness of the clinical trial process. The Committee is encouraged by the development of novel digital technologies to facilitate the use of virtual clinical trials that would make it easier for patients to participate in trials regardless of where they live. Through telemedicine, connected sensors, patient engagement applications, and direct data capture tools, virtual trials are conducted geographically near the patient. Direct contact with the patient is still maintained remotely, but reducing or eliminating on-site visits has the potential to increase patient convenience and lower study costs. The Committee recommends that the FDA develop the necessary framework to advance the

use of virtual trials while still maintaining quality data necessary for FDA approval. The FDA shall report to the Committee on their activities to advance digital technologies and the impact on patient access to clinical trials.

- *Computational Medicine* -The Committee appreciates FDA's continued support for and use of modeling and simulation in clinical trials, as well as its work toward the establishment of an affiliation agreement with an academic institution with expertise in this field. This partnership will allow for the development of personalized medical interventions, optimizes the regulatory process with in silico clinical trials and bridges gaps in the current regulatory infrastructure. The Committee directs FDA to formalize this important function in improving outcomes and reducing costs inherent to drug and device discovery.
- *Contact Lens Safety* - The Committee is aware that counterfeit versions of FDA-regulated medical devices exist and is concerned that certain foreign manufactured entrants in the marketplace are providing patients with mishandled or mislabeled versions of FDA-approved contact lenses. The Committee is also concerned about reports of online sales of counterfeit contact lenses. Therefore, the Committee directs the FDA to provide a report that includes a summary of foreign contact lens manufacturing facilities findings, domestic counterfeit contact lens retailer investigations, inspection activities, and any agency oversight and enforcement activities related to imported or re-imported counterfeit contact lens meant for domestic sales.
- *Cotton Ginning* -The Committee is concerned about the impact of the ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' final rule (80 FR 56170; September 17, 2015) on the cotton industry. The Committee notes post-harvest activity of ginning cotton does not transform the resulting cottonseed into a ''processed food,'' and thus, cottonseed should fall within the definition of a ''raw agricultural commodity'' for purposes of rules promulgated pursuant to the FSMA. In addition, the Committee is concerned about the rationale for the definitions of ''primary production farm'' and ''secondary activities farm'' and how these definitions factor into the determination of operations either being exempt from or covered by certain requirements of the final rule. Therefore, the Committee directs the FDA to provide outreach and technical assistance to cotton ginning operations to assist them in complying with the final rule or subsequent guidance documents.
- *Dietary Fiber* - The Committee is concerned that the FDA has not issued final guidance regarding the definition of dietary fiber, and encourages the FDA to issue these final guidance documents and provide sufficient time for food manufacturers to comply.
- *Dietary Supplements* - More than half of Americans take at least one dietary supplement each day, with use particularly prevalent among older persons and in children. While dietary supplements enter the market under the assumption that they are safe, the FDA has documented that some products are contaminated, either intentionally or unintentionally, with inherently unsafe ingredients, including active pharmaceutical

ingredients. These products violate the Dietary Supplement Health and Education Act [DSHEA] and pose potential risks to consumers. The Committee applauds FDA's inspection of and enforcement actions against manufacturers with dietary supplement products that contain ingredients that are potentially harmful or otherwise noncompliant with the law. FDA has indicated it conducts roughly 500 inspections a year and issues approximately 70–80 warning letters on Current Good Manufacturing Practice [CGMP] violations. In order to better detect dangerous products in the market, FDA is encouraged to continue to invest resources into oversight and inspection of manufacturing plants that produce dietary supplements. The Committee has been pleased with the interagency collaboration and urges FDA to continue working with the Department of Justice to remove illegal dietary supplements from the market and directs increased resources toward enforcement of DSHEA, including inspection and enforcement activities. The Committee urges the FDA to issue guidance on new dietary ingredients [NDIs) for dietary supplements that is consistent with the DSHEA while continuing to use current statutory authorities to remove unsafe ingredients and products. The Committee further encourages the FDA to take industry standards and marketplace disruption into consideration when issuing any guidance on NDIs. In addition, the Committee directs FDA to submit, not later than 180 days after enactment of this Act, a report that includes the number of enforcement actions FDA brought against dietary supplement manufacturers and marketers; the manufacturers and marketers of products claiming to be dietary supplements; the number of dietary supplement good manufacturing practice inspections FDA conducted in 2017; the number of FTEs dedicated to dietary supplement inspections; and the number of serious adverse events that were reported to FDA from 2016 to 2017.

- *Digital Health Products* - The Committee is encouraged by the FDA's efforts to implement section 3030 of the 21st Century Cures Act regarding low-risk medical software and launch of the Digital Health Software Precertification [Pre-Cert] Program to learn from software developers about their products and quality processes. The Committee believes that digital health technologies are extremely promising and that consumers should have assurances that the products work as claimed. The Committee is supportive of FDA efforts to increase oversight and enforcement over digital health products to assure that they are compliant with the appropriate regulatory frameworks.
- *Dried Spent Grain* – Sec. 734 of the Bill continues the prohibition on the use of funds made available by this or any other Act to carry out the final rule promulgated by the Food and Drug Administration and put into effect November 16, 2015, in regards to the hazard analysis and risk-based preventive control requirements of the current good manufacturing practice, hazard analysis, and risk-based preventive controls for food for animals rule with respect to the regulation of the production, distribution, sale, or receipt of dried spent grain byproducts of the alcoholic beverage production process.

- *Drug Shortages* - The Committee acknowledges the strides that the FDA has made in reducing the amount of time for review of Generic Drug [ANDAs] applications, but remains concerned about the number of drugs in shortage that providers and patients rely on for care. The Committee encourages FDA to expand upon its current work to offer priority review to ANDAs to reduce the number and severity of drug shortages. The Committee directs the FDA to report to the Committee on how the agency is prioritizing ANDAs in order to mitigate the recent drug shortages, as well as what additional authorities the agency may need to alleviate drug shortages in the future.
- *Electronic Prescription Information* – Sec. 732 of the Bill continues the prohibition on the use of funds made available by this Act to propose, promulgate, or implement any rule, or take any other action with respect to, allowing or requiring information intended for a prescribing health care professional, in the case of a drug or biological product subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)), to be distributed to such professional electronically (in lieu of in paper form) unless and until a Federal law is enacted to allow or require such distribution.
- *Food Contact Notification User Fees* - The Committee recommendation does not include proposed user fees.
- *Food Safety Mission* - The Committee directs the FDA Foods Program to report to the Committee all activities and resources spent on nutrition-related activities for the Center for Food Safety and Applied Nutrition [CFSAN], associated field offices [ORA], and support components.
- *Foreign High Risk Inspections* - The Committee has provided robust funding for this initiative over the last several years and directs the FDA to provide an update on these efforts, including estimated efficiencies and concerns, and plans to continue or expand this effort in the future.
- *FSMA Clarification for Small Farms* - The Committee directs the FDA to provide further clarification to small farms on the requirements for compliance with the Food Safety Modernization Act, including information on the qualified exemptions available to small and very small farms and the actions required to achieve compliance under these exemptions. The Committee also urges the Food and Drug Administration to communicate with (including through appropriate guidance) and offer technical assistance to assist small farms with compliance.
- *FSMA Cooperative Agreements* - The Committee is aware that some states that have entered into cooperative agreements under the State Produce Implementation Cooperative Agreement Program to provide education, outreach, and technical assistance have or are considering changing the state agency responsible for implementing these agreements. The Food and Drug Administration is directed to work with any state that designates a new implementing agency to ensure it can continue to receive funding under existing cooperative agreements without delay or loss of funding.

- *Genetically Engineered Salmon* - Sec. 740 of the Bill provides that during fiscal year 2019, the Food and Drug Administration shall not allow the introduction or delivery for introduction into interstate commerce of any food that contains genetically engineered salmon until the FDA publishes final labeling guidelines for informing consumers of such content.
- *Glass Packaging Technologies* - The Committee encourages the FDA to develop and issue draft guidance to industry to streamline chemistry, manufacturing, and control reporting requirements in order to expedite adoption and remove barriers for the use of innovative glass packaging technologies or processes with the capacity to improve product quality, reduce product recalls, reduce drug shortages, and improve public health.
- *Guidance for Stakeholder Input* - The FDA Center for Veterinary Medicine [CVM] recently updated its list of guidance topics to include possible new topics for consideration as well as revisions to existing FDA CVM guidance documents. In addition to providing the traditional opportunities for public review and comment, the Committee encourages FDA to seek input from relevant industry stakeholders and appropriate scientific experts who can assist FDA in the development of and any revisions to guidance documents prior to a public comment period.
- *Human Drug Review Committee* - The Committee strongly encourages the FDA to fully utilize its authorities under 18 U.S.C. 208(b)(3) to include no less than two members with an expertise in the indication for which the drug is meant to treat on each Advisory Committee when that Committee is reviewing a drug that has been designated as an Orphan Drug.
- *Improving Import Review* - FDA shall report to the Committee how FDA is monitoring the impact of the reorganization under Program Alignment Group, and if such reorganization has improved the consistency of facility inspections and timeliness reviewing imports.
- *Intentional Adulteration* - The Committee supports the important role of food defense plans to protect the food supply from acts intended to cause wide-scale harm to public health. The Committee encourages the FDA to work with businesses to provide clarity on food defense practices that will most effectively protect public health and to take into account appropriate food defense practices businesses have in place, including data supporting such practices.
- *Medical Gas Rulemaking* - The Committee is pleased that the FDA has begun the process to develop separate regulations for medical gases. However, the Committee is concerned that the FDA has missed the statutory deadlines for rulemaking in section 1112 of Food and Drug Administration Safety and Innovation Act [FDASIA] and section 756 of the fiscal year 2017 Consolidated Appropriations Act. The FDA committed to complete separate regulations for medical gases in 1978 in its final rule on current good manufacturing practices, and the Committee believes that now is the appropriate time to complete that commitment for a separate section of regulations for medical gases.

Therefore, the FDA shall issue final regulations required by the fiscal year 2017 Consolidated Appropriations Act no later than December 31, 2018.

- *Medically Necessary Foods* - The Committee is aware that patients with significant medical need for physician-directed medical foods continue to face access challenges resulting from misperceptions on the part of some pharmacy benefit managers and insurance providers who are classifying these products as over the counter in direct contravention of established law, FDA guidance, and FAQs. These challenges continue to underscore the timeliness of clarifying the important pathway for review and oversight of quality medical foods. The Committee looks forward to working with FDA in this regard and requests feedback on how FDA can address the current access challenges as well as work to enhance this important category as it becomes an increasingly essential part of the healthcare system.
- *Misleading Maple Marketing* - The Committee is concerned about the explosion of products marketed using the word maple and related iconography, which intentionally misleads consumers who perceive the use of the word maple and related iconography to mean that a food product contains some measurable quantity of maple syrup to flavor or sweeten the product, which consumers identify as a characterizing ingredient. The Committee directs the FDA to perform a detailed analysis of consumer perception of foods marketed with the word maple or related iconography.
- *Nanotechnology* -The Committee recognizes the increased capabilities that FDA has developed to study environment, health, and safety of nanomaterials within FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research, and its consolidated headquarters at White Oak, Maryland. The Committee expects FDA to continue to support collaborative research with universities and industry on the toxicology of nanotechnology products and processes in accordance with the National Nanotechnology Initiative Environment, Health, and Safety Research Strategy as updated in October 2011.
- *National Antimicrobial Resistance Monitoring System* – The Committee recommendation includes $11,300,000 for the National Antimicrobial Resistance Monitoring System. The Committee directs that no less than $500,000 shall be used to conduct one or more pilot studies to assess types and levels of antibiotic resistance in zoonotic bacteria on food products of species not currently tested by NARMS, such as imported seafood.
- *New Animal Drug Process* - The Committee is concerned about the agency's approval process for genetically engineered animals for human consumption, particularly finfish. Thus, the Committee directs the agency to undertake a review of the process and report to Congress within 90 days of enactment of this Act on how the ''New Animal Drug'' process, created to approve drugs intended for use in animals, can be used as the approval process for genetically engineered animals for human consumption.
- *Olive Oil* - Because of the substantial interest in and consumption of olive oil throughout the United States, driven in part by the significant scientifically-confirmed health benefits

of these oils and the fact that the United States has become a globally-important producer of olive oils, especially extra virgin olive oil, the Committee directs the FDA to establish a separate U.S. Standard of Identity for different grades of olive oil (e.g. refined, virgin and extra virgin) and olive-pomace oils. The Committee is particularly concerned with the number of different state standards for olive oils in the U.S. Because the health benefits of olive oil vary by grade, it is important to establish a uniform set of the standards to better inform and protect consumers. Extra virgin olive oil is the highest quality of olive oil and provides the greatest health benefits for consumers. The FDA is directed to consult and meet with domestic producers and importers of olive oil to develop a science-based Standard of Identity for extra virgin olive oil and olive oil best suited to ensure the integrity of these products for U.S. consumers.

- *Opioids* - The Committee remains deeply concerned about the opioid abuse epidemic that has taken the lives of more than 350,000 Americans from 1999–2016, including more than 42,000 in 2016. As such, the Committee recommendation includes $59,000,000 for FDA to continue its increased activities related to the crisis. This funding is for the FDA to better identify and target firms and organizations importing illicit drugs into the U.S.; maintain increased staffing to inspect packages and the number of packages being inspected; maintain enhanced criminal investigation resources; and maintain increased staff and equipment to efficiently screen imported products.

  As the agency that oversees the approval of these drugs, the FDA has a responsibility to consider the public health impact of opioid misuse, abuse, diversion, and overdose death, while considering the needs of patients with chronic conditions who require regular use of opioid therapies to properly manage their debilitating condition. The Committee supports FDA's commitment to addressing this crisis through all available authorities, and continues to encourages them to continue implementation of the Opioid Action Plan to determine how innovative changes in opioid packaging, distribution, and medication disposal procedures can help mitigate the national opioid crisis, including working to support ongoing efforts at the state and regional level.

  The Committee continues its directive for FDA to refer any drug application for an opioid to an advisory committee for their recommendations prior to approval, unless the FDA finds that holding such advisory committee is not in the interest of protecting and promoting public health.

  The Committee is concerned about marketed opioid products that pose disproportionate overdose risk due to their formulation in which the daily recommended dosage far exceeds the CDC's threshold for dangerous daily opioid intake. The Committee directs the FDA to examine existing data and filings from leading medical and health societies, and remove from the market any ultra-high-dose opioids that the FDA finds are unsafe and pose a public health hazard.

  The Committee notes that, even with recent decreases, opioid prescribing rates dramatically exceed current standards for accepted and effective medical use, with nearly

14 billion opioid doses put on the United States market each year. Therefore, the Committee believes that it is imperative that FDA, consistent with its own Advisory Committee recommendations, take any and all steps necessary to require continuing medical education, aligned with the most recent Centers for Disease Control and Prevention's Guidelines for Prescribing Opioids for Chronic Pain, for providers who write opioid prescriptions, including through the Risk Evaluations and Mitigation Strategy.

The Committee is aware that 80 percent of individuals with opioid use disorder were introduced to opioids via prescription and notes that a growing body of evidence indicates the co-prescription of naloxone along with certain prescriptions has the potential to reduce overdose deaths and opioid overdose related healthcare costs. The Committee directs the Commissioner to seek recommendations from the Drug Safety and Risk Management Advisory Committee regarding a framework for the inclusion of information in the labeling and/or REMS of drugs that are opioids or used in Medically-Assisted Treatment relating to the co-prescription of opioid overdose reversal drugs along with opioids prescribed to patients that meet CDC guidelines as at risk for overdose.

- *Oversight Activities* - The Committee recommendation includes $1,500,000 for the HHS Office of Inspector General specifically for oversight of FDA activities.
- *Partially Hydrogenated Oils* – Sec. 736 of the Bill continues to provide that no partially hydrogenated oils as defined in the order published by the Food and Drug Administration in the Federal Register on June 17, 2015 (80 Fed. Reg. 34650 et seq.) shall be deemed unsafe within the meaning of section 409(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(a)) and no food that is introduced or delivered for introduction into interstate commerce that bears or contains a partially hydrogenated oil shall be deemed adulterated under sections 402(a)(1) or 402(a)(2)(C)(i) of this Act by virtue of bearing or containing a partially hydrogenated oil until the compliance date as specified in such order (June 18, 2018).
- *Patient Experience* - The Committee is aware of FDA's implementation of policies to promote public access to information about how patient experience information factored into the review of approved products. The Committee supports this step forward and encourages FDA to continue refining the instrument and ways to improve its visibility. The Committee also requests that FDA consider ways to include patient-experience information in relevant labeling and accompanying documentation to inform patient/provider decision-making and payer determinations.
- *Patient-Focused Drug Development* - The Committee is appreciative of the steps the FDA has taken to implement subtitle A of title III within the 21st Century Cures Act to better incorporate patient experience in the drug development and approval processes and requests a status report from FDA on implementation of these provisions including any challenges or impediments being faced.

- *Pediatric Device Consortia Grants* - The Committee is pleased that the seven FDA-funded Pediatric Device Consortia have assisted in the development of more than 1,000 potential pediatric medical devices since its inception in 2009, as well as promoting job-growth in the healthcare sector, and as such, continues to support this critical effort. The program funds consortia to assist innovators in developing medical and surgical devices designed for the unique needs of children that often go unmet by devices currently available on the market. The Committee recommendation includes no less than the fiscal year 2018 funding level for Pediatric Device Consortia Grants.
- *Polypharmacy* - The routine usage of five or more prescription medications within the same period is becoming increasingly prevalent among older adults, elevating risk factors for drug-drug interactions and adverse events. The Committee directs the FDA to assess potential impacts of polypharmacy, which might help inform the design of clinical studies.
- *Ready To Eat Foods* - The Committee is aware that FDA is in the process of finalizing guidance regarding Listeria monocytogenes [Lm] in RTE foods. Reducing incidents of listeriosis is an important health goal and the Committee supports efforts to accomplish this objective. The Committee urges FDA to complete a comprehensive risk assessment to ensure any final guidance document is realistic and fully based in science prior to making any changes to the action level of Lm in RTE foods.
- *Seafood Advisory* - The Committee remains concerned that the FDA published final seafood advice for pregnant and nursing women on January 18, 2017, without going through the necessary interagency review, consumer focus group testing, or the opportunity for the public to comment on the scientific peer review. Therefore, the Committee directs the FDA to reissue the final ''Advice About Eating Fish'' (published in 82 Fed. Reg. 6571 (January 19, 2017)) in a manner that is consistent with the FDA's nutrition science on the net effects of seafood consumption.
- *Shellfish Safety* - The Committee urges FDA to complete the single laboratory validation of the liquid chromatography mass spectrometry [LC–MS]-based method for detecting brevetoxins associated with neurotoxic shellfish poisoning in molluscan shellfish. The Committee encourages adoption by the Interstate Shellfish Sanitation Conference of FDA's proposal for the LC–MS method for brevetoxin testing of shellfish as an Approved Method under the National Shellfish Sanitation Program.
- *Sodium* - Sec. 750 of the Bill provides that none of the funds made available by this Act may be used by the Food and Drug Administration to develop, issue, promote, or advance any regulations applicable to food manufacturers for population-wide sodium reduction actions or to develop, issue, promote or advance final guidance applicable to food manufacturers for long term population-wide sodium reduction actions until the date on which a dietary reference intake report with respect to sodium is completed.
- *Sunscreen Labeling Regulations* - The Committee remains significantly concerned that the FDA has not approved a new over-the-counter [OTC] sunscreen ingredient since

implementation of the Sunscreen Innovation Act, which improved the process by which the FDA reviews sunscreen ingredients and required the FDA to finalize an effective sunscreen monograph within 5 years. The Committee directs the FDA to meet with sponsors regarding the development of a testing regimen for sunscreen ingredients, consistent with current scientific standards, that appropriately balances the benefit of additional skin cancer prevention tools versus the risk of skin cancer. The Committee also directs FDA to maintain funding for agency efforts to clear this backlog of sunscreen applications.

In addition, the Committee is disappointed that FDA has not yet finalized a rule limiting the maximum Sun Protection Factor [SPF] to ''50'' or ''50+'' as directed by the fiscal year 2018 Consolidated Appropriations Act, and as such the Committee directs FDA to finalize the rule immediately. The Committee is also disappointed that FDA failed to issue a proposed rule to establish testing and labeling standards for sunscreen sprays and directs FDA to do so immediately.

- *User Fee Negotiations* - The Committee affirms the important role of user fees to support programs across the FDA, and supports the negotiations between the agency and regulated industry partners to compose goals letter establishing clear expectations for both parties regarding timelines and processes associated with implementation of the law. Historically these goals letters are added to the Congressional Record, unedited by Congress, and referenced in the law authorizing the collection of such fees. The Committee is concerned that recent user fee negotiations between FDA and regulated industries have resulted in goals letters submitted to Congress containing policy changes that require statutory changes, and presume that Congress will adopt suggested statutory changes. While the Committee encourages the agency to continue to provide suggested statutory changes in a timely manner to Congress that can help the agency meet its mission, the Committee finds that it is inappropriate for the agency and its regulated industry partners to negotiate statutory or other legal changes as part of user fee goals letters.
- *Vibrio* - The Committee is aware of the public health challenge related to the naturally occurring bacteria called Vibrio parahaemolyticus that can accumulate in shellfish and believes that more scientific research is necessary to develop proper controls that will reduce the risk to consumers and sustain a healthy domestic shellfish industry. The Committee encourages the Food and Drug Administration [FDA] to increase funding for research into Vibrio illnesses associated with the consumption of raw molluscan shellfish, improve risk assessment models, and develop improved rapid detection methods for virulent Vibrio strains.
- *Youth Tobacco Use Prevention* - While FDA has recently announced a new Youth Tobacco Prevention Plan to attempt to curb the use of e-cigarettes among youth, the Committee is concerned with the irresponsible marketing by some manufacturers, as well as the role characterizing flavors play in youth initiation of tobacco products. In March

2018, FDA issued an Advanced Notice of Proposed Rulemaking to examine regulatory options for tobacco product flavorings. The Committee strongly encourages the agency to complete the regulatory process in an expeditious manner, ideally within 1 year, and in a way that supports prevention of youth tobacco initiation. The agency is instructed to provide the Committee with a timeframe for when the regulatory process will be completed. Additionally, the Committee is concerned that FDA is not fully enforcing their prohibition of new or changed e-cigarettes and other nicotine products after August 8, 2016, without prior FDA review and authorization. Therefore, the Committee directs FDA to order the removal of any ''deemed tobacco products'' introduced after the August 8, 2016 deadline without first seeking the required FDA authorization. Finally, the Committee is concerned about the lack of adequate age verification rules to prevent Internet sales of e-cigarette tobacco products to children, and directs FDA to establish these rules within 1 year, both at the time of sale and delivery of the product.

Food Safety –

The Bill funds the Food Safety and Inspection Service at $ 1,039,344,000, which is $7,500,000 below the FY 2018 level, and $17,701,000 below the budget request.

- *Humane Slaughter*.—The Committee directs FSIS to continue to provide annual reports to the Committee on the implementation of objective scoring methods undertaken by FSIS to enforce the Humane Methods of Slaughter Act.

  The Committee also directs FSIS to ensure that personnel hired with funding previously provided specifically for Humane Methods of Slaughter Act 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 training.
- Under the National Institute of Food and Agriculture –
  - *Countering Seafood Fraud* - The Committee remains concerned about countering economic fraud and improving food safety of the U.S. food supply. The Committee is concerned that adequate technology is not yet available to provide for appropriate sampling of the food supply. The Committee believes NIFA should conduct research to develop technologies that will provide rapid, portable and facile screening of fish species at port sites, wholesale, and retail centers.
  - *Food Safety* -The Committee recommends that NIFA prioritize research on funding for new food safety technologies relating to the Nation's meat supply that helps researchers, producers, and manufacturers.
  - *Food Safety and Defense Technology* - The Committee is concerned that insufficient progress is being made in the development of detection technology in the food safety sector. The ability to rapidly, accurately, and cost effectively detect pathogens or contaminants throughout the food supply chain is critical to

protecting the United States from food-borne illnesses and malicious acts. As such, the Committee encourages NIFA to increase research of novel biodetection technologies and the implementation of mobile biodetection platforms in real-world conditions. The Department should consider technologies currently in use or under development in other fields, such as medicine or homeland security, to determine whether the technology can meet the needs in either high volume food production or mobile food defense monitoring.

- *Foodborne Illness Prevention* - The Committee understands the significant threats to public health and to the economic viability of communities impacted by foodborne illness, and believes that coordinated and targeted resources are needed to understand the risks and to develop effective strategies for control. The Committee encourages NIFA, in coordination with the FDA, to establish a Center of Excellence for Foodborne Illness to coordinate a research program to reduce the risk of Listeria monocytogenes.

- *Codex Alimentarius* - The Committee recommends an appropriation of $3,976,000 for the Office of Codex Alimentarius. Funding was previously provided through the Food Safety and Inspection Service.

Forest Products and Forestry –

- Under the Agricultural Research Service, agroforestry can provide on-farm financial and environmental benefits while also addressing the regional and national-scale issues of clean water, wildlife habitat, and hypoxia. Agroforesters manage trees with crops, livestock, and pasture to combine the best of both agriculture and forestry. Recognizing the importance of agroforestry to farm practices and the environment, the Committee recommendation includes no less than the fiscal year 2018 level to develop integrated strategies to manage multifunctional agricultural landscapes that combine trees with agricultural and horticultural crops, forages and grazing livestock for optimal economic, environmental, and natural resources benefits.
- Under the Agricultural Research Service, for forest products, The Committee recognizes the important role of the forests products sector to the U.S. economy. The need to create new and improved value-added products and renewable energy from our Nation's wood supply is critical to the sustainability of the national economy. The Committee recommendation includes no less than the fiscal year 2018 level to support research on wood product quality improvement and improvement in forest products evaluation standards and valuation techniques. ARS shall conduct this research in consultation with the Forest Products Laboratory.
- Under Rural Community Facilities Program, the Secretary is encouraged to prioritize Community Facilities program awards to applications that develop facilities to provide

prevention, treatment, or recovery services for substance abuse disorder and for rural communities facing severe wildfire risk.

- Sec. 739 of the Bill provides $1,000,000 for the Secretary to carry out a pilot program that provides forestry inventory analysis, forest management and economic outcomes modelling for certain currently enrolled Conservation Reserve Program participants. The Secretary shall allow the Commodity Credit Corporation to enter into agreements with and provide grants to qualified non-profit organizations dedicated to conservation, forestry and wildlife habitats, that also have experience in conducting accurate forest inventory analysis through the use of advanced, cost-effective technology. The Secretary shall focus the analysis on lands enrolled for at least eight years and located in areas with a substantial concentration of acres enrolled under conservation practices devoted to multiple bottomland hardwood tree species including CP03, CP03A, CP11, CP22, CP31 and CP40.

Healthy Food Financing Initiative –

Section 751 of the Bill provides $1,000,000 for the Healthy Food Financing Initiative. This is the same as provided in FY 2018 and $1,000,000 over the budget request.

Huanglongbing –

Under APHIS –

- *Emergency Response* - The Committee maintains the increased funding levels for Huanglongbing Emergency Response within the Specialty Crop Pests line item included in fiscal year 2018. The Committee encourages APHIS to allocate sufficient resources in order to continue vital management, control, and associated activities to address citrus greening. The disease, for which there is no cure, has caused a reduction in citrus production by over 60 percent since 2007 in Florida alone. All citrus producing counties in Texas are under quarantine, and California has detected the disease in some backyard trees in the Los Angeles basin. The spread of this disease has called the domestic citrus industry's future into question, costing thousands of jobs and millions in lost revenue and increased production costs per acre. In addition, the agency is encouraged to support priorities and strategies identified by the Huanglongbing Multi-Agency Coordination [HLB–MAC] Group which will benefit the citrus industry. The agency should appropriately allocate resources based on critical need and maximum effect to the citrus industry. The Committee maintains the fiscal year 2018 funding level for citrus health to support priorities and strategies identified by the HLB–MAC group. The MAC is focused on short-term solutions to help the citrus industry, and the cooperative nature of Federal, state, and industry representatives in this group is expected to result in the development

of tools and techniques to address this devastating disease. Helping growers explore new possible solutions, the MAC has been an effective resource. The agency should appropriately allocate resources based on critical need and maximum impact to the citrus industry. These citrus health activities directly protect citrus production on approximately 765,000 acres in the United States worth more than $11,000,000,000 in total.

- *Huanglongbing Multi-Agency Coordination [HLB–MAC] Group* - The Committee recognizes the significant economic impact of this disease on the citrus industry, which is especially acute in Florida and a growing concern in both Texas and California. The Committee also understands that growers are requesting the right to try treatments that have begun to show success in early stages of testing. The Committee encourages the HLB–MAC group to explore and identify new methods to expedite the delivery of promising treatments directly to growers. Finally, the Committee expects any funds which are redirected from existing HLB–MAC projects be repurposed to other priority HLB–MAC projects that are showing promising results to ensure these critical funds remain committed to help facilitate the design and implementation of the rapid delivery pathway to growers.

Invasive Tree Pests –

Under APHIS, the Committee recognizes that the forests products industry and family forest owners are under increasing threat from a growing number of invasive forest pests. It is essential that APHIS carry out a comprehensive program to counter the spread of invasive species and work towards complete eradication of the Asian long-horned beetle. The Secretary is directed to report to the Committee regarding the steps being taken to eradicate the Asian long-horned beetle and spotted lanternfly and to minimize the spread of other pests such as the polyphagous and Kuroshio shot hole borers. As the emerald ash borer continues to spread, APHIS shall continue to assist states that have recent detections of emerald ash borer where assistance will enable states to fully monitor the insect and to inform and manage public and private land owner issues.

Livestock from Mexico –

Under the Office of the Secretary, the Committee is concerned with the ongoing problem of the crossing of livestock from Mexico into the U.S. without proper inspection, which creates risk of disease and loss of forage for U.S. ranchers in the Southwest border region. The Committee directs the agency, in consultation with other Federal and State agencies, to develop a plan of action to better prevent and reduce unauthorized international crossing of livestock on the Southwest border.

National Agriculture Imagery Program –

Within the Salaries and Expenses Account of the Farm Service Agency, the Committee recommends that funding shall be allocated to purchase imagery products to meet programmatic requirements.

National Bio and Agro-Defense Human Capital Development –

Under APHIS, the Committee notes that significant resources have been invested in the new National Bio and Agro-Defense Facility [NBAF] and is concerned about projected staffing shortages of qualified veterinary diagnosticians and scientists for the NBAF, which is slated for full operation in 2022. The Committee provides $3,000,000 to APHIS to ensure necessary steps are taken to develop a qualified workforce that are subject matter experts in foreign, emerging and zoonotic diseases capable of developing, validating and conducting needed diagnostics, performing epidemiologic studies, and completing bioinformatics analyses.

National Environmental Policy Act –

Under the Office of the Secretary, the Committee expresses support for increasing transparency within all agencies of the Department of Agriculture. The agencies are encouraged to disclose costs associated with analyses required by the National Environmental Policy Act.

Nutrition Assistance Programs –

Under the Office of the Under Secretary for Food, Nutrition, and Consumer Services:

- *Food Security in Frontier Communities* -The Committee appreciates the intent of the Food and Nutrition Service to focus on implementing locally-designed initiatives to increase food security in frontier communities within its area of responsibility. Helping these communities to adapt to changing growing conditions and subsistence food availability and to develop the capacity to grow more food locally will improve their tenuous food security and provide opportunities for economic development in extremely low-income regions. The Committee therefore strongly encourages the Food and Nutrition Service to finalize plans to work with relevant stakeholders to develop and implement the plans that were initiated in the past year.
- *Nutrition Program Efficiency* -The Committee encourages the Secretary to focus process and technology improvement grants within the Food and Nutrition Service [FNS] to expand public-private partnerships to increase food security in a cost-efficient and accountable manner.

The following amounts are provided for the various domestic programs:

- Child Nutrition - $23,184,012,000, an decrease of $1,070,127,000 below FY 2018, and $37,072,000 above the budget request:

- $30,000,000 is provided for School Meals Equipment Grants.
- $3,997,000 is provided for Farm to School Tactical Teams to support local and regional food systems.
- $2,929,000 is provided for Food Safety Education.
- $11,203,000 is provided to continue work directly with State and local administrators for technical assistance to promote accuracy in payments.
- $21,639,000 is provided for various studies.
- *Administrative Reviews* - The Committee understands the importance of the formal administrative reviews state agencies conduct as required by the Healthy, Hunger-Free Kids Act. However, the Committee encourages the Secretary to return to the 5-year inspection cycle for schools that consistently comply with Federal standards to allow state agencies more flexibility in performing their oversight and on-sight technical assistance roles. High-risk schools that do not consistently comply with Federal regulations should continue to be reviewed on a more frequent basis. The Committee also encourages FNS to assist state agencies in collaborating with one another when identifying risk factors to ensure that the administrative review process is effective and consistent nationwide.
- *Breakfast Commodities* – Sec. 715 provides a $20,000,000 increase over FY 2018 for Child Nutrition Programs Entitlement Commodities, which are intended for breakfast commodities. How these funds are to be dispersed is not specified.
- *Buy American* -The Committee remains supportive of existing laws requiring school food authorities to purchase domestic commodities or products to serve in school meal programs. The Committee recognizes that despite this statutory requirement, there has been an alarming increase of foreign products served in our schools. The Committee encourages the Secretary to fully define and enforce all applicable Buy American provisions within the Secretary's jurisdiction. Further, the Secretary shall report on all actions taken to comply with this directive within 180 days of enactment of this Act.
- *Farm to School Program* - Successful implementation of Farm to School programs requires broad-based knowledge of best practices regarding coordination among farmers, processors, distributers, students, teachers, dietary and food preparation staff, and USDA professionals. Of the grant funds provided (Sec. 749), the Committee directs the Secretary to use at least $150,000 to coordinate with established entities, such as regional Farm to School institutes, for the creation and dissemination of information on farm to school program development, and to provide practitioner education and training, and ongoing school year coaching and technical assistance.
- *Innovation in School Meals* -The Committee is aware that there are many new, innovative, and healthy products available that meet the National School Lunch Program and School Breakfast Program nutrition standards. The Committee is

concerned about FNS' interpretation of current policies that does not allow schools to get credit for serving any such product unless it visibly represents the food component in its natural or recognizable form. The Committee encourages the Secretary to allow innovative food products made from fruits, vegetables, or legumes that meet nutrition standards for school feeding programs. The Committee understands that many of these foods are already in the retail market and encourages FNS to educate children about the many ways these nutritious foods can be served and enjoyed.

- *Pulse Crops* -The Committee recognizes the nutritional value of pulse crops for children and encourages FNS to support school food authorities in sourcing and serving pulse crops.
- *Summer Food Service Program* -The Committee recognizes that in many rural and frontier areas of the country where homes are widely scattered, children and youth are unable to access congregate feeding sites that participate in the Summer Food Service Program and that existing mobile food delivery efforts are not able to meet the need. The Committee supports the Food and Nutrition Service allowing State Agencies to enable Summer Food Service Program service institutions that serve such areas where eligible children and youth have barriers to access or limited access to a congregate feeding site to use their customary reimbursement payments to develop and implement innovative methods to deliver or otherwise make available foods to eligible children and youth by non-congregate means or in non-congregate settings. In addition, the Committee requests USDA submit a report within 1 year of enactment describing how many Summer Food Service Program grantees, in which states, put in place innovative methods of food delivery by non-congregate means and in non-congregate settings, what innovative methods were used, and how many additional youth were served as a result.
- *Vegetables in the School Breakfast Program* - Current regulations regarding the substitution of starchy and non-starchy vegetables for fruit in the School Breakfast Program are creating undue burdens for school food authorities. To encourage vegetable consumption at breakfast, the Committee encourages FNS to allow any variety of vegetable to be substituted for fruit in the School Breakfast Program.
- *Whole Grain Waivers*.—The Committee encourages FNS to simplify the process for School Food Authorities applying for a whole grain waiver to make the process faster and more user-friendly.

- Special Supplemental Nutrition Program for Women, Infants and Children (WIC) - $6,150,000,000, a reduction of $25,000,000 below the FY 2018 appropriation and $400,000,000 above the budget request. The Committee recommendation fully funds estimated WIC participation in FY 2018.

- Breastfeeding Programs –
  - The Committee provides $60,000,000 for breastfeeding support initiatives.
  - The Committee recognizes new technologies, including telemedicine, that support breastfeeding mothers through access to professional breastfeeding and nutrition consultants. The Committee provides $5,000,000 for competitive grants to allow breastfeeding mothers the ability to interact with International Board Certified Lactation Consultants and all participants access to Registered Dietitians or WIC nutritionists, consistent with the goal of WIC to promote breastfeeding and nutritional health.
- Infrastructure - $19,000,000.
- *WIC Food Package* - The Committee appreciates the work of the National Academies of Science to review and make recommendations for updating the WIC food packages to reflect current science and cultural factors. The Committee notes, however, that while all revised packages now allow some fish, the amounts remain low compared to the recommendations of authoritative agencies such as the World Health Organization and in some cases, sporadic. The Committee strongly encourages the Department to prioritize the health and cultural benefits of fish consumption as regulations are revised to implement the NAS recommendations and to increase the amount of healthful fish above the amounts recommended by the NAS. The Committee also strongly encourages the Department to allow States to prioritize fish over legumes and peanut butter to respond to the cultural preferences of WIC participants in States like Alaska.
- Sec. 724 of the bill rescinds $400,000,000 in unobligated balances.

- Supplemental Nutrition Assistance Program (SNAP) - $73,219,274,000. This is a decrease of $794,225,000 below FY 2018 and $1,002,000 above the budget request.
  - *Food Distribution Program on Indian Reservations [FDPIR] Food Package* -The Committee commends the Department for convening the FDPIR Food Package Review Work Group, which includes tribal representatives and staff from FNS, to increase the amount and variety of traditional foods included in FDPIR food packages and to increase the amount of foods purchased from American Indian and Alaska Native producers and businesses. The Committee directs the Department to provide a report detailing its plans to include a greater variety of traditional foods as regular components of FDPIR food baskets; its plans to identify additional Native American and Alaska Native producers of traditional foods, including wild salmon, caribou, reindeer, elk, and other foods; and its plans to purchase additional traditional foods from a greater number of indigenous producers and businesses.
  - *SNAP Farmers Markets* -The Committee is concerned that there are unnecessary barriers and added costs for organizations that manage farmers markets in

multiple locations. The Secretary shall permit such organizations to become a SNAP-authorized retailer at the level of the organization, provided that the organization notifies FNS of all market locations at which it will accept SNAP benefits. The SNAP-authorized organization will continue to bear legal responsibility for SNAP compliance at all locations it oversees, including exercising proper oversight of SNAP implementation at each participating market location.

- *SNAP Fraud* - A January 2017 OIG report entitled ‘‘Detecting Potential SNAP Trafficking Using Data Analysis’’ found that FNS lacked methods to reconcile data discrepancies across their administration systems, and that retailers were providing benefits to individuals using fraudulent credentials. The Committee directs FNS to provide an update on the implementation of controls to address these problems, as well as data demonstrating whether the controls have reduced error rates.
- *State SNAP Implementation* - The Committee is concerned about implementation of the SNAP program in certain states where states are failing to meet the required deadlines for processing applications. USDA is encouraged to work closely with States to remedy program deficiency and be aggressive in combating any falsification of SNAP implementation data.
- Section 728 of the Bill provides that none of the funds made available by this Act may be used to available by this Act may be used to implement, administer, or enforce the ‘‘variety’’ requirements of the final rule entitled ‘‘Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP)’’ published by the Department of Agriculture in the Federal Register on December 15, 2016 (81 Fed. Reg. 90675) until the Secretary of Agriculture amends the definition of the term ‘‘variety’’ as defined in section 278.1(b)(1)(ii)(C) of title 7, Code of Federal Regulations, and ‘‘variety’’ as applied in the definition of the term ‘‘staple food’’ as defined in section 271.2 of title 7, Code of Federal Regulations, to increase the number of items that qualify as acceptable varieties in each staple food category so that the total number of such items in each staple food category exceeds the number of such items in each staple food category included in the final rule as published on December 15, 2016: *Provided*, That until the Secretary promulgates such regulatory amendments, the Secretary shall apply the requirements regarding acceptable varieties and breadth of stock to Supplemental Nutrition Assistance Program retailers that were in effect on the day before the date of the enactment of the Agricultural Act of 2014 (Public Law 113–79).

- Commodity Supplemental Food Program - $238,120,000, which is the same as FY 2018 and $238,120,000 over the budget request.
- The Emergency Food Assistance Program – The Bill provides $294,000,000 for TEFAP commodities to be purchased with Supplemental Nutrition Assistance Program. The

Committee recommendation provides $64,401,000 for TEFAP administrative funding, the same as in FY 2018 and $10,000,000 over the budget request. In addition, the Committee recommendation grants the Secretary authority to transfer up to an additional 10 percent from TEFAP commodities for this purpose and urges the Secretary to use this authority. The Committee encourages the Secretary to identify opportunities for increasing the supply of TEFAP commodities in the coming fiscal year through bonus and specialty crop purchases. The Department shall make available to the States domestically produced catfish fillets for distribution to local agencies.

- WIC Farmers' Market Nutrition Program - $18,548,000, and directs the Secretary to obligate these funds within 45 days.
- Dietary Guidelines for Americans - The Committee recommendation includes $12,297,000 for the development and dissemination of the 2020 version of the Dietary Guidelines for Americans.

The following amounts are provided for international food assistance programs:

- $1,716,000,000 for Food for Peace Title II grants, $116,000,000 above FY 2018 and an increase of $1,716,000,000 over the budget request.
- $210,255,000 for the McGovern-Dole International Food for Education and Child Nutrition Program, $2,629,000 over FY 2018 and an increase of $210,255,000 over the budget request. The Committee provides an appropriation of $15,000,000 for efforts to build long-term agriculture sustainability and establish a local investment in school feeding programs. With direct U.S. commodity contributions, projects supported by the McGovern-Dole Food for Education Program have significantly improved the attendance, nourishment, and learning capacity of school-aged children in low-income countries throughout the impoverished world. New funding authorities would enable school feeding programs to proactively transition from direct commodity assistance to locally source agriculture products. The Committee directs the Secretary to conduct the Local and Regional Food Aid Procurement Project Program in accordance with the priorities of the McGovern-Dole International Food for Education and Child Nutrition Program.

Organic Production -

- Under the Economic Research Service, organic industry has grown at a tremendous rate over the past several years, and accurate data for the production, pricing and marketing of organic products is essential. Therefore, the Committee encourages ERS to continue and expand the efforts relating to organic data analysis.
- Under the National Agricultural Statistics Service, The Committee encourages NASS and AMS to coordinate activities related to expanding organic price reporting and organic data collection, and provides NASS an additional $250,000 for these activities.

- National Institute of Food and Agriculture will receive $6,000,000 for the organic transition program under the Integrated Activities Account.
- Under the National Institute of Food and Agriculture, USDA's National Organic Standards Board [NOSB] has identified key organic research priorities, many of which would help to address challenges that have limited the growth in organic production in this country. The Committee encourages NIFA to give strong consideration to the NOSB organic research priorities when crafting the fiscal year 2019 RFAs for AFRI and the Organic Transition Program. Given the growing demand for organic products, the Committee also encourages USDA to increase the number of organic research projects funded under AFRI and Specialty Crop Research Initiative [SCRI].
- Under the Agricultural Marketing Service –
    - *National Organic Program* - The Committee provides $15,094,000 for the National Organic Program [NOP], an increase of $3,000,000. A healthy market for organic products requires a clear product distinction backed by a trusted, verified, and enforced label. The Committee recognizes that the NOP, which enforces the organic regulations and ensures they evolve to keep pace with consumer expectations, is essential. In light of recent reports of inadequate enforcement of organic standards, the Committee directs USDA to provide all resources needed for the NOP to deliver the strongest possible oversight before allowing the USDA organic seal to be granted to domestic and international operations and products.
    - *Organic Dairy* - The Committee is disappointed by continued reports of inconsistencies in the enforcement and interpretation of regulations that apply to organic dairy farms. The Committee directs the NOP to resolve these issues, and eliminate any inconsistencies in applying and enforcing regulations relating to the transition of livestock to organic dairy production, and also dry matter intake during the grazing season for organic dairy cattle. The Secretary must ensure that organic inspectors, certification file review staff, and NOP Organic Certification staff have documented training and experience in livestock nutrition and grazing on organic dairies with more than 1,000 milking cows if they are certifying operations of that size, and also that separate dry matter intake calculations are made for each category of dairy cow and not averaged among milking and dry cows, and that inspections are conducted during the grazing season.
    - *Organic Data Initiative* - The Committee includes $250,000 for AMS to coordinate with NASS for activities related to expanding organic price reporting and organic data collection.

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Regional Food Hubs

Under the Rural Business, the Committee encourages USDA to partner with States and other interested partners to build and refurbish food hub and food distribution centers that serve rural farmers but are located in urban areas through programs like the Business and Industry guaranteed loan program.

Research Programs –

- Agricultural Research Service (ARS) - $1,300,966,000 in FY 2019, which is $98,200,000 above FY 2018, and $281,975,000 above the FY 2019 budget request. The Committee does not concur with the President's budget request regarding the termination of research programs and laboratory closures. The Committee expects extramural research to be funded at no less than the fiscal year 2018 levels. The Committee report highlights research activities regarding aerial application research, agricultural genomics, agroforestry, alfalfa research, antimicrobial research and development, aquaculture seedstock, Atlantic salmon breeding program, big data, center for pollinator health, ceratocystis disease, chronic wasting disease, citrus greening disease research, coffee germplasm, cotton ginning, cover crops research and outreach, cranberry research, emerging cereal rust diseases, feed enhancement, floriculture and nursery research, food systems, foodborne pathogens, forage production systems, forest products, fruit fly and exotic pest control, genetic oat research, genomes to fields, high performance computing support, hops research, human nutrition research, industrial hemp germplasm, National Agricultural Library, national apple rootstock breeding program, National Bio and Agro-Defense Facility transition, nutrient density profile, nutrition research and aging, pear genetics and genomics, postharvest dairy research, poultry research, public health research, pulse health initiative, rangeland research, research assistance, resilient dryland farming, Roseau cane, sclerotinia, shellfish research, small grains genomic initiative, soft white wheat falling numbers test, sorghum genetic database, sudden oak death, sugar beet research, sugar cane variety development, sustainable aquaculture, sustainable water use research, tropical and subtropical research, unmanned aerial systems (UAS) precision agriculture applications, U.S. wheat and barley scab initiative, warmwater aquaculture, and wheat and sorghum research.
- National Institute of Food and Agriculture (NIFA) – Research and education activities are funded at $898,535,000 in FY 2019, which is $11,364,000 above FY 2018, and $104,056,000 over the budget request. The Committee recommendation includes $405,000,000 for the Agriculture and Food Research Initiative (AFRI). The Committee notes the importance of this requirement to provide farmers nationwide with greater access to cultivars that are locally and regionally adapted to their soils, climates and farming systems. Because of the agency's lack of progress in prioritizing this effort, the

Committee directs the agency to make regionally adapted, publicly held cultivar development a distinct funding priority within AFRI for fiscal year 2019, and directs the agency to take steps to improve its tracking of public cultivar projects within AFRI and report its progress in meeting this goal. The Committee report highlights research activities regarding agricultural research enhancement awards, agriculture technology, alfalfa and forage research, algae applications in agriculture research, aquaculture disease research, aquaculture research, brucellosis research, cereal crop research, childhood obesity, citrus disease research programs, Community College Centers of Excellence in Agribusiness Workforce Training, countering seafood fraud, diversification in agriculture, dual use/dual benefit, food safety, food safety and defense technology, foodborne illness protection, genomes to phenomes, lowbush blueberries, multi-trophic aquaculture research, oat mites, organic research, protein functionality, public plant and animal breeding, regional research priorities, seafood, small fruits research, specialty crops research initiative, supplemental and alternative crops, sustainable agriculture research and education, Unmanned Aerial Systems in Agriculture, and veterinary corps.

- Extension Activities - $486,692,000 for FY 2019, which is $3,070,000 above FY 2018 and $36,507,000 over the budget request.
- Native American Institutions Endowment Fund - $11,880,000 for FY 2019, the same as in FY 2018, and $23,000 over the budget request.
    - *Farmer Stress Assistance Network* - The Committee is deeply concerned by the high rate of suicides among agriculture workers, which is the highest overall suicide rate among all occupations according to the Department of Health and Human Services. The Committee provides $2,000,000 in a general provision (Sec. 722) for a pilot program to provide competitive grants to State departments of agriculture, State cooperative extension services, and nonprofit organizations to carry out programs to address farmer stress and suicide. The Secretary is directed to submit a report on implementation within 60 days of enactment.
    - *Food and Nutrition Education* - The Committee recognizes the importance of the Expanded Food Nutrition Education Program [EFNEP] and encourages the Secretary to support a special pilot expansion of EFNEP to provide for an evaluation of improved food resource management and diet quality in populations not now served, including the elderly, households living below 185 percent of the poverty level, and low-income households with children of any age.
- *Minority Outreach* -The Committee is concerned that extension service resources do not reach minority, socially disadvantaged, and tribal communities in proportion to their participation in the agricultural sector. All institutions that receive extension activity funding should seek to ensure that an equitable percentage of their overall extension work reaches minority, socially disadvantaged, and tribal communities. The Committee directs NIFA to evaluate distribution of extension resources to these three populations and report to the Committee no later than 90 days after enactment of this Act.

- Integrated Activities (NIFA) - $38,000,000 for FY 2019, which is $1,000,000 above FY 2018, and $24,963,000 over the budget request. The FY 2019 appropriation is specifically allocated as follows: $2,000,000 for the methyl bromide transition program; $6,000,000 for the organic transition program; $2,000,000 for the Regional Rural Development Centers Program; $8,000,000 for the Food and Agriculture Defense Initiative, and $20,000,000 for the Crop Protection/Pest Management Program.
    - *Food and Agriculture Defense Initiative* - The Committee supports the important work being done through the publicly funded diagnostic laboratory network and encourages NIFA to prioritize funding to strengthen animal health diagnostic laboratories, taking into consideration the degree to which the capacity for surveillance, monitoring, response, and capacity is enhanced; the concentration of human and animal populations that are directly at risk; trade, tourism, and cultural considerations; geography, ecology, and climate; evidence of active collaboration with, and support of, the State animal health officials; those States with highest risk for the introduction of foreign and emerging pests and diseases; and evidence of stakeholder support and engagement.
    - *Potato Research* -To minimize the application of pesticides and to maximize the yield and quality of harvested potatoes, the Committee directs the Secretary to support pest management programs in potato growing States.
- Economic Research Service - $86,757,000 for FY 2019, which is the same as FY 2018 and $45,000,000 above the budget request. The Committee report highlights research activities regarding a breastfeeding study, feed costs, low density polyethylene, and organic data analysis.
- National Agricultural Statistics Service - $174,767,000 for FY 2019, which is $16,950,000 below FY 2018, and $9,767,000 above the budget request. The Committee Report highlights activities including alfalfa prices, barley estimates, chemical use data series, floriculture crops report, and organic data collection.

Rural Business Development Grants –

Under Rural Business rural coastal economies have often been economically disadvantaged by the loss of natural resource-related jobs and have been the first rural communities to feel the negative effects of a changing climate. As these rural coastal communities continue to have agriculture-related economic opportunity such as value-added seafood processing as well as new opportunities, the use of Rural Business Development grants may be prioritized in rural coastal communities to support innovation and job growth within all sectors, including for related infrastructure. Particular priority should be given in the case of public-private partnerships and cross-jurisdictional efforts.

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State Rural Development Councils –

Under the Office of the Secretary, the Committee recognizes the successful work of State Rural Development Councils [SRDCs) and their role in advancing rural America and promoting strength and prosperity across the country, and urges the Secretary to provide resources to help improve and expand the impact of SRDCs.

Urban Agriculture –

Under the Office of the Secretary, the Committee is aware of a steady increase in urban garden initiatives taking place in metropolitan areas across the country. The Committee strongly supports such initiatives and recognizes that successful, robust urban gardens can positively impact urban communities and residents in a variety of ways by providing education, entrepreneurial opportunities, and job training; addressing shortages of fresh fruits and vegetables; increasing health and wellness of pregnant women and young children; and reducing obesity rates, recidivism, and urban blight. The Committee commends the Department's efforts to foster such initiatives and encourages the Secretary to increase support and outreach for urban agriculture, including grants, loans, and technical assistance for these innovative urban horticulture projects.

Veterans Programs –

Outreach to Socially Disadvantaged and Veteran Farmers and Ranchers - Under the Office of the Secretary the Committee supports the efforts of the Office of Advocacy and Outreach to increase the accessibility of USDA programs to underserved constituents, and notes that $10,000,000 in mandatory funds is available to assist socially disadvantaged and veteran farmers and ranchers in owning and operating farms and ranches to meet the growing need for financial, production, management, and other assistance to those communities and address workforce shortages. Additionally, the Committee recommendation includes $3,000,000 in discretionary funding for these activities.

Wheat Grading –

Under the Office of the Secretary, Committee is concerned about unfair wheat grading practices that negatively affects American wheat growers that export to Canada. Current Canadian wheat grading law automatically downgrades America wheat to the lowest quality designation regardless of the type or quality of the wheat. In the United States, however, our grading system provides a fair examination for wheat imported from Canada. This discrepancy needs to be addressed to ensure our wheat growers are being treated fairly. Therefore, the Committee urges the Secretary of Agriculture to work with the Department of Commerce and the United States

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Trade Representative to prioritize initiating conversations with the Canadian Government to address trade inequities resulting from Canada's current wheat grading practices.

Zoonotic Disease Collaboration –

Under the Office of the Secretary, the Committee believes that complex problems affecting the health of humans, animals, and the environment are best solved through important communication, cooperation, and collaboration across disciplines, sectors, between agencies, and between other appropriate domestic and international actors. The Committee directs USDA to provide a report within 60 days of enactment of this Act detailing existing collaborative efforts between FDA, USDA, and other agencies to prevent and respond to zoonotic disease outbreaks in animals and humans; a proposed framework to improve these efforts; and specific activities requested to achieve the proposed framework.

We hope this information is helpful to you. Should you have any questions, please contact Roger Szemraj at (202) 789-1212 or rszemraj@ofwlaw.com.