

FY2017 House Public Health Related Report Language

Report language is excerpted from the House Appropriations Committee reports for the Labor-Health and Human Services (HHS)-Education bill ([House Report 114-699](#)), Department of Agriculture/Food and Drug Administration (FDA) bill ([House Report 114-531](#)), and the Homeland Security bill ([House Report 114-668](#)).

LABOR-HHS-EDUCATION APPROPRIATIONS BILL

GENERAL SUMMARY OF THE BILL

Protecting the public health is a second priority area the Committee has focused on in this bill. The Committee includes an increase of \$605,399,000 for the Centers for Disease Control and Prevention (CDC), again building upon increases included in the fiscal year 2016 bill and rejecting the Administration's proposal to cut this agency. Funds are provided to continue the antibiotic resistance initiative as well as to support other public health prevention programs.

Within the total funding for CDC, the Committee includes \$390,000,000 for activities to prevent, prepare for and respond to the Zika virus. Funds will be targeted toward impacted States and localities for use in mosquito abatement and control, education campaigns, increasing surveillance and laboratory capabilities and ensuring that State and local health departments have the tools they need to prevent the spread of this virus while we await development of a vaccine.

In light of the recent crises with both Zika and Ebola, the Committee has included \$300,000,000 within the CDC to form a new Infectious Diseases Rapid Response Reserve Fund. This reserve, in which funds will be available until expended, will provide an immediate source of funding, fully paid for with annually appropriated dollars, that the Administration could tap into to quickly respond to a future, imminent infectious disease crisis that endangers American lives without waiting for Congress to act on a supplemental funding bill. Funds would be subject to all existing authorities and limitations.

The Committee has also placed a high priority on combatting the opioid addiction problem by including \$500,000,000 within the Substance Abuse and Mental Health Services Administration to create a network of grants to states, localities, territories and Indian tribes to develop integrated opioid abuse response initiatives focusing on prevention, education, treatment, and recovery services.

Finally, the Committee recommendation includes increases to the Bioshield (\$90,000,000) and the Biomedical Research and Advanced Development Authority (BARDA) (\$8,300,000) programs to ensure that the American people are prepared for and protected against possible bioterrorism attacks.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Health Centers

Perinatal transmission of Hepatitis B.— The Committee is pleased that progress is now being made to develop and implement a strategic plan to reduce the rate of perinatal transmission of Hepatitis B. The Committee notes however, that HRSA has been urged to expand efforts to eliminate perinatal transmission of Hepatitis B for the past three fiscal years and little progress has been made. It is therefore expected that HRSA engage a pilot to test intervention strategies followed by the adoption of a best practices protocol in HRSA funded health care settings as soon as possible in fiscal year 2016.

Tuberculosis.—The Committee notes that the National Action Plan for Combating Drug Resistant Tuberculosis recommends the creation of health-care liaisons between State and local health departments and institutions, including health centers that serve hard to reach groups who are at risk for tuberculosis (TB). HRSA is directed to provide a report to the Committee on the coordination between community health centers and **State and local TB control programs** to help ensure appropriate identification, treatment, and prevention of TB among vulnerable populations.

Bureau of Health Professions

In response to the opioid epidemic, the Committee encourages medical schools and teaching hospitals to enhance existing curricular content on substance abuse and pain management for future prescribers. The Committee supports efforts by HRSA, through its Title VII health professions programs, to provide educational and training grants to medical schools and teaching hospitals to develop innovative educational materials related to substance use disorders and pain management.

Maternal and Child Health Bureau

Neonatal Abstinence Syndrome.—The Committee is alarmed by the drastic rise in the incidence of Neonatal Abstinence Syndrome (NAS), newborns suffering from withdrawal due to drug exposure during pregnancy. The Committee requests an update in the fiscal year 2018 budget request on HRSA efforts that address NAS.

HIV/AIDS Bureau

AIDS Drug Assistance Program.—The Committee recognizes the importance of HIV health care and support services, and supports granting Federal funds to States to address the growth in the number of clients in need of supportive services—including HIV service delivery, home and community-based care services for individuals with HIV disease, continuation of health insurance coverage for low-income persons with HIV disease, and State AIDS Drug Assistance Programs (ADAP)—that maintain persons in care. The Part B program provides 59 grants to States and territories.

The Committee continues to be encouraged by the progress of anti-retroviral therapy in reducing the mortality rates associated with HIV infection and impacting the transmission of HIV infections. The Committee supports continued funding for AIDS medications in ADAP. These funds ensure that low-income individuals maintain access to HIV/AIDS medications. Their importance increases as more individuals are identified through increased testing efforts by **State and local health departments** and seek treatment earlier in the progression of their HIV disease.

Rural Health

Rural Opioid Overdose Reversal Grant

The Committee is concerned about the increasing number of unintentional overdose deaths attributable to prescription and nonprescription opioids. HRSA is urged to take steps to encourage and support the use of funds for opioid safety education and training, including initiatives that improve access for licensed healthcare professionals, including paramedics, to emergency devices used to rapidly reverse the effects of opioid overdoses. Such initiatives should incorporate robust evidence-based intervention training, and facilitate linkage to treatment and recovery services.

CENTERS FOR DISEASE CONTROL AND PREVENTION

In light of the recent crises with both Zika and Ebola, the Committee has included \$300,000,000 within the CDC to form a new Infectious Diseases Rapid Response Reserve Fund. This reserve, in which funds will be available until expended, will provide an immediate source of funding, fully paid for with annually appropriated dollars that the Administration could tap into to quickly respond to a future, imminent infectious disease crisis that endangers American lives without waiting for Congress to act on a supplemental funding bill. Funds would be subject to all existing authorities and limitations.

The Committee recommendation increases support **to state, local, and tribal public health departments** in disease areas like Diabetes, Heart Disease and Stroke prevention activity and furthers efforts to reduce prescription drug overdose. The recommendation expands funding to build **state, local, and tribal preparedness and response capacity** through increased support for the public health preparedness infrastructure. It also provides support to expand **state laboratory capacity** to combat antibiotic resistance and other infectious diseases and supports **flexible funds for states to address**

local and tribal public health issues through the preventative health and health services block grant. Globally, the recommendation continues support for the global polio eradication program and global public health activities.

On Zika, the Committee includes \$390,000,000 across CDC to support domestic and supplemental vector control activities; international and territorial Zika response efforts, and supports a block grant for States and local communities with high potential for local Zika transmission to ensure **local officials have flexibility to address local needs**.

The Committee expects CDC to **provide public health and preparedness goals with measures for each program** in the fiscal year 2018 budget request. The Committee appreciates the new grant table provided in fiscal year 2017 budget request and requests CDC note any year it changed a formula or plans to change a formula for grants and provide the percent of funding for grants with formula funding. The Committee requests a table in the fiscal year 2018 budget request and future budget requests with the percentage of funds used to support intramural activity for each program.

The Committee reinforces its expectation for **CDC to work with state, local and tribal health officials** to move forward with the plan for a single web-based data collection information technology platform for CDC programs to reduce the voluntary reporting burden on states and reduce CDC's total operational costs of its independent program data collection actions. The Committee requests an update on these activities in the fiscal year 2018 budget request.

The Committee remains concerned with duplication of effort and overlapping of responsibilities between NIH and CDC. The Committee encourages CDC and NIH to more actively coordinate on cross-cutting initiatives, ensuring that each agency focuses on its respective core mission. Further the Committee requests an update in the fiscal year 2018 budget request on how each CDC report level program coordinates with the NIH Institutes and Centers (ICs) to share scientific gaps related to activities supported in NIH research portfolios.

Immunization and Respiratory Diseases

Immunization grants are awarded to **states and local agencies** for planning, developing, and conducting childhood, adolescent, and adult immunization programs including enhancement of the vaccine delivery infrastructure. CDC directly maintains a stockpile of vaccines, supports consolidated purchase of vaccines for State and local health agencies, and conducts surveillance, investigations, and research into the safety and efficacy of new and presently used vaccines. The Committee encourages CDC to consider including vaccines produced through recombinant DNA technology.

HIV, Viral Hepatitis, STD, and TB Prevention

Hepatitis C (HCV).— The Committee understands the rates of new HCV infection among American Indians (AI) and Alaska Natives (AN) continue to rise, far surpassing other communities. The Committee directs CDC to **consider the development of a grant program specifically for AI and AN tribes** to support prevention and screening efforts.

Furthermore, the Committee requests CDC work with the Indian Health Service on a targeted action plan to promote HCV prevention, increased screening, and increased access to treatment.

HIV Prevention Activities.—The Committee requests an update in the fiscal year 2018 budget request on steps CDC is taking and plans to take to improve testing rates and reduce late stage diagnosis. The update should include steps being taken to ensure prevention program funds reach the most at risk individuals to best ensure early detection with targeted interventions.

Viral Hepatitis Screening.—The Committee continues to support hepatitis screening activities and urges CDC to prioritize education programs in medically underserved and minority communities.

Emerging and Zoonotic Infectious Diseases

The Emerging and Zoonotic Infectious Disease programs support the prevention and control of infectious diseases through surveillance, outbreak investigation and response, research, and prevention. The recommendation **adds a new funding line dedicated to domestic Zika response and supplemental vector control for States and local communities to address vectorborne diseases**. The request does not provide the increase requested for refugee support.

Tick-Borne Illnesses.—The Committee is concerned about the rate of tick-borne illnesses across the country. The Committee requests an update in the fiscal year 2018 budget request on the prevalence of tick-borne illnesses, including information on the geographic distribution with a particular focus on Lyme disease and Rocky Mountain Spotted Fever. The Committee encourages CDC to review, in conjunction with primary care physicians, its website to ensure physician education programs on Lyme disease include scientific resources and a process to allow treating physicians to provide feedback on CDC provided information.

Vector Borne Disease Program (VBDP).—The Committee continues to support the critical role CDC and its VBDP play to prepare for and fight emerging tropical diseases, such as Dengue, Chikungunya, and Zika. The groundwork laid in the CDC's efforts on Dengue and Chikungunya will be critical to fighting Zika.

Vector Control Guidelines to Reduce the Spread of Disease-Carrying Insects.—The Committee requests CDC develop and maintain an online guideline for use by **States and local communities** with a full scope of vector control options, tools, and other factors State and local jurisdictions may consider as they develop plans to carry out vector control activities to control Zika and other related diseases carried by insects. The Committee expects the document to be available online within 60 days after enactment and updated at least annually.

Chronic Disease Prevention and Health Promotion

Burden of Disease.—The Committee reiterates the desire **for CDPHP programs to expand the use of burden of disease as a significant consideration in resource decisions**. Specifically, the request for applications should have applicants identify the level of community burden reduction expected with funding and funded applicants should track, monitor, and report reductions over time where possible.

Division of Diabetes Translation (DDT).—The Committee expects the DDT to address the diabetes epidemic through education to provide Americans with knowledge that leads to the prevention of diabetes. The Committee reiterates its support for the DDT to leverage Federal resources with public and private organizations to prevent and reduce diabetes in Americans. The Committee requests a report in the fiscal year 2018 budget request that describes the DDT's plan and on-going actions to further use population-adjusted burden of disease as the key criteria in awarding funds. The Committee urges a significant focus of resources on efforts **to expand State, local, and tribal community diabetes control and prevention activities**. The Committee expects CDC will specifically evaluate how to ensure programs support rural communities with a high burden of disease that may have more limited access to other prevention and outreach programs to control or prevent diabetes. Additionally, the report shall describe how the DDT translates research into better prevention and care with its programs.

Diabetes.—The Committee has provided a significant increase for Diabetes prevention and control activities. The Committee expects the increase to go directly to communities with the highest burden of disease to support scientifically validated risk factor reduction measures through competitive awards. The Committee requests a report in the fiscal year 2018 budget request on the amount of CDC diabetes support provided to **State, local, and tribal communities** and the expected impact on these communities.

Good Health and Wellness in Indian Country.—The Committee appreciates the new five-year cooperative agreement to develop a comprehensive approach to good health and wellness in Indian Country. This population is disproportionately affected by chronic disease compared to other racial and ethnic groups in the United States. The Committee notes the program support is in addition to and should not supplant existing funds provided by other CDC activities. CDC is expected to build on these existing programs within Indian Country to allow for **a more comprehensive public health infrastructure in tribal communities** and the ability to develop mechanisms to improve good health and wellness in Indian Country.

Heart Disease and Stroke.—The Committee provides an increase to support heart disease and stroke prevention at **State, local and tribal public health departments**. The Committee expects the increase to go directly to communities with the highest burden of disease to support scientifically validated risk factor reduction measures through competitive

awards. The Committee requests a report in the fiscal year 2018 budget request on how the heart disease and stroke funds provided to communities are expected to impact those with the highest disease burden.

Preterm Birth.—The Committee commends CDC for funding six State-based perinatal collaboratives that focus on improving birth outcomes and improving maternal health and safety using known prevention strategies including reducing early elective deliveries. The Committee encourages CDC to consider, through support, coordination with other center programs, States, and public-private partnerships, ways to identify, measure, and evaluate the effectiveness of the program to increase the number of States receiving assistance for perinatal collaboratives.

Tobacco Prevention.—The Committee notes CDC supports tobacco use and prevention activities throughout numerous programs like the prevention research centers and chronic disease prevention activities. **The Committee provides funding in the tobacco line to focus primarily on underage smoking.**

Lung Cancer.—The Committee directs the CDC tobacco program to ensure its activity includes a program to expand the knowledge to high-risk populations on the value of early detection of lung cancer through screening. The activity should work in conjunction with **local public health departments**, medical providers, insurers, and other public/private partners to ensure appropriate education and awareness is targeted through measurable means to high-risk communities. The Committee requests an update in the fiscal year 2018 budget request on the education and coordination activities CDC is supporting with other Federal and non-Federal partners to encourage screening in high-risk groups.

National Diabetes Prevention Program (NDPP).—The Committee was disappointed that not all new fiscal year 2016 funds were competitively awarded to new awards as requested in the fiscal year 2017 Consolidated Appropriation Act Explanatory Statement. The Committee continues to strongly support the successful NDPP and directs all new funds provided in fiscal year 2016 and 2017 support an increase in the number of new competitively awarded program providers. Specifically, the focus should be on rural providers where the risk and burden of diabetes is greater, and where the program has the potential for the biggest impact. The Committee understands models exist for pairing the capacity of existing program providers with program delivery areas that lack sufficient resources to operate the program. The Committee requests an update in the fiscal year 2018 budget request on how these resources are being used for the provided purposes, how observable weight measure is being maintained, and how peer-reviewed science compares virtual providers to face-to-face providers. The Committee requests CDC include long-term public health measures and how this program coordinates with other CDC and Department of Health and Human Services (HHS) programs. The Committee also requests the total amount of Federal, public and private sector funds leveraged to support the NDDP annually in the fiscal year 2018 budget request and in future budget requests.

Obesity.—The Committee continues support for the rural extension and outreach services program to support grants for rural counties with an obesity prevalence of over 40 percent. The Committee expects support for childhood obesity interventions based on scientific evidence to support measurable outcomes through evidenced-based obesity research, intervention, and prevention programs. The program should include a special focus on areas with the highest population-adjusted burden of obesity and with comorbidities like hypertension, cardiac disease and diabetes. The Committee understands the need to maximize impact of these funds, for this reason and to assure coordination with other activities, CDC should allocate maximum dollars to State programs.

Special Interest Projects (SIPs).—The Committee requests an update in the fiscal year 2018 budget request showing the steps taken to competitively award SIPs. The Committee continues to support CDC's important work on excessive drinking. However, the Committee notes the work on monitoring of youth exposure to alcohol advertising and the level of risk faced by youth from exposure to alcohol advertising may be duplicative with work ongoing in other Federal agencies, such as the Federal Trade Commission (FTC) and NIH. The Committee requests an update in the fiscal year 2018 budget request on steps CDC is taking to reduce overlap and duplication in this area.

Birth Defects and Developmental Disabilities

Surveillance.—The Committee expects CDC and NIH to jointly expand their coordination and sharing of CDC's birth defects surveillance and NIH's research portfolio to accelerate understanding of birth defects. The Committee

specifically expects CDC and NIH to work closely on **surveillance related to potential Zika virus-related birth defects** and future NIH supported research. The NIH and CDC coordination should include microcephaly surveillance, technical assistance, and research, as appropriate. The Committee requests an update in the fiscal year 2018 budget request on the Birth Defects Study to Evaluate Pregnancy Exposures, which seeks to identify birth defects causes and risk factors.

Environmental Health

Asthma.—The Committee encourages CDC to explore methods to **increase the number of States** carrying out programmatic activities. The Committee encourages CDC to use a population-adjusted burden of disease criteria as a significant factor for new competitive awards. The Committee requests a report in the fiscal year 2018 budget request detailing the competitive process.

Newborn Screening Quality Assurance Program.—The Committee understands HHS recommendations are based on evaluations conducted by the Advisory Committee on Heritable Disorders in Newborns and Children with approved conditions compiled in a “Recommended Uniform Screening Panel” (RUSP). Most States screen for the overwhelming majority of the disorders listed on the RUSP but it can take several years for States to add new conditions. The Committee requests CDC provide an update in the fiscal year 2018 budget request on actions planned and on-going to work with States on ways to ensure screening of infants for diseases for which there is a preventable and/or effective treatment. Further, the update should note what steps can be taken to **encourage States to adopt and implement new RUSP conditions** within one year of their addition.

Climate Change.—The Committee does not provide support for CDC’s Climate Change program. The Committee provides funding for programs that allow CDC to focus on more direct public health activities.

Injury Prevention and Control

Gun Research.—The Committee continues the general provision to prevent any funds from being used to advocate or promote gun control. The Committee does not include funding for the proposed Gun Violence Prevention Research.

Injury Control Research Centers.—The Committee provides support within the Injury Prevention Activities line to support activities such as core operations, evaluation of injury control interventions, and training activities within the injury control research centers.

Prescription Drug Overdose (PDO) Prevention Activity.—The Committee commends CDC for its leadership on combatting prescription and opioid drug overdoses. The Committee provides an increase and expects the Director to implement these activities based on population-adjusted burden of disease criteria, including mortality data (age adjusted rate), as significant criteria when distributing funds for the State PDO Prevention activities. The Committee assumes these funds will be distributed via a competitive mechanism and not merely a mathematical formula or standard allocation to each State. Further, the Committee strongly encourages CDC to **support local prevention activity** to determine the effectiveness of naltrexone in treating heroin and prescription drug abuse and reducing diversion of buprenorphine for illicit purposes.

National Vital Statistics System (NVSS).—The Committee continues support for the NVSS which provides data on births, deaths, and fetal deaths. The Committee is aware most States now or will soon have operational electronic birth and death registration systems, an essential tool in monitoring public health and fighting waste, fraud, and abuse in Federal entitlement programs. The Committee requests CDC ensure the modernization of the CDC system to ensure interoperability with state systems.

Traumatic Brain Injury (TBI).—The Committee continues to support CDC’s TBI efforts and encourages the Director to prioritize efforts on American children and youth education, outreach, and similar public health activities.

Global Health

The Committee adds a new funding line dedicated to international and territorial Zika response to address vector-borne disease control to prevent the spread of Zika in the United States and its territories. The Committee expects these funds to supplement, not supplant, existing vector control activities and to be part of a CDC-wide plan that works with States and territories to prevent Zika from impacting Americans.

Public Health Preparedness and Response

Public Health Preparedness.—State and local public health response capabilities are critical for effective all-hazards response. In local jurisdictions, these capabilities are used routinely for isolated events and local disease outbreaks, as well as outbreaks of national significance, creating a proficiency in local public health systems nationwide. State and local public health departments closely coordinate public health and healthcare system emergency preparedness and response capabilities and routinely test response systems in tandem. Continued erosion of State public health and healthcare system response infrastructure, including redirection of funding into disease specific response efforts at the Federal level, threaten to significantly weaken response capacity at the State and local level. Funding should continue to be provided to develop and maintain State public health and healthcare response infrastructure as an all-hazards, capability driven approach. The Committee expects CDC to continue robust support for the public health preparedness program.

Health Care Resources in an Emergency.—The Committee is aware that CDC and the Assistant Secretary for Preparedness and Response (ASPR) will issue new five-year guidance for the joint Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness (PHEP) grants to States. The Committee expects the guidance will further advance the cross-agency program alignment with grant conditions that make meaningful progress on secure communications, improved real-time resource reporting (e.g. available bed types, types of facilities like dialysis, emergency rooms, etc.) to strengthen the reporting of health care resources and improve patient tracking. Further, CDC and ASPR are expected to expand cross-agency coordination activities to improve health care preparedness and response capacity between the PEHP and HPP programs.

Public Health Emergency Preparedness (PHEP) Cooperative Agreement Program.—The Committee has increased funding to restore PHEP capacity lost based on the Secretary's decision to transfer funds from this preparedness program in 2016. CDC should work to ensure States have the tools to quickly detect, monitor, and respond to health threats. The Committee requests CDC explain in the fiscal year 2018 budget request how State PHEP funding is supporting capacity building at the State, tribal, and local levels. The CDC is expected to track PHEP capacity goals via the PHEP index capabilities tool and work with participants to agree on cooperative agreement objectives for each State. The Committee requests an update in the fiscal year 2018 budget request on how CDC is implementing the PHEP index capacity measures.

SNS Replenishment of Medical Countermeasures.—The Committee is concerned the budget request for the SNS is inadequate for acquisition and replenishment of the vaccines and other medical countermeasures with limited or no commercial markets but necessary for emergency response. The Committee is equally concerned with CDC's management of these public-private partnerships relationships. The CDC should increase efforts to work closely with their business partners on planning, developing requirements, and execution of current contracts to take into consideration business continuity. The Committee recognizes the significant government investment in the development and approval of these countermeasures and notes it is critical for HHS to support appropriate acquisition, replenishment and assure business continuity within the public-private partnerships that develop and support a manufacturing base for these countermeasures. The Committee recommendation therefore includes an increase to the SNS.

CDC-Wide Activities

In light of the recent crises with both Zika and Ebola, the Committee has included \$300,000,000 within the CDC to form a new Infectious Diseases Rapid Response Reserve Fund. This reserve, in which funds will be available until expended, will provide an immediate source of funding, fully paid for with annually appropriated dollars, that the Administration could tap into to quickly respond to a future, imminent infectious disease crisis that endangers American lives without waiting for Congress to act on a supplemental funding bill. Funds would be subject to all existing authorities and limitations

The Committee adds a new funding line of Zika block grants specific for States to support counties with high potential for local Zika transmission with flexible funds to support vector-borne disease control and to respond to, prepare for, or prevent the spread of Zika in the United States. The Committee expects these funds to supplement, not supplant, existing vector control activities. The Committee expects CDC to **coordinate with State, local, and tribal public health officials** to develop the criteria for this program. The Committee expects criteria to include measurable objectives related to the Federal, State, and local plans. The Committee requests a report within 30 days after enactment on the coordinated criteria and process CDC will use in the upcoming year for awarding grants to States with counties that have the highest potential for local transmission. The report should include the projected funding level expected for each State, counties within a State, and tribal areas that meet these criteria. The Committee anticipates the composition of recipients in this program to change over time. The Committee expects the CDC PHHSBG program office to provide the oversight, reporting, and program management of this new program within the Public Health Leadership and Support funding line but not from these new funds.

Preventive Health and Health Services Block Grant (PHHSBG)

The Committee rejects the Administration's proposed elimination of the PHHSBG. The Committee restores it to a level of \$160,000,000. The Committee expects CDC to provide these flexible funds to State public health agencies. **States should work with local and tribal public health agencies** to use these resources to address its most critical public health needs through measurable evidence based activities.

Public Health Leadership and Support

The Committee expects the fiscal year 2018 budget include specific details of each budget activity supported with these funds, including functions, mission, full time employees, bonus, travel costs, and other typical object class data and information for each separate activity supported through the Public Health Leadership and Support funding line. For each office and function, the Committee expects the budget to describe clearly what the prior year funds supported, the current year projections, and proposed budget year policy for each activity.

Advocacy Restrictions.—The Committee requests an update in the fiscal year 2018 budget request describing CDC's current mechanisms and process to prevent advocacy violations. Further, CDC should describe its on-going efforts to educate its staff and grant recipients to prevent violations.

Burden of Disease Review.—The Committee appreciates CDC's efforts to provide information online about the health profiles for all 3,143 counties in the United States and willingness to start engaging in how CDC can expand the use of burden of disease as a more significant factor for funding allocations and awards. The Committee requests a timeline and update in the fiscal year 2018 budget request on actions to more broadly use burden of disease (adjusted for population as appropriate) as a significant program factor for funding allocations and awards in CDC public health programs and activities.

State Public Health Laboratories.—**State public health laboratories play an integral role in public health surveillance activities including outbreak detection**, disease surveillance, case finding, and local identification of select agents. This critical infrastructure serves the needs of the local community while participating in and providing necessary information to scalable laboratory networks and surveillance systems. Advancements in laboratory technology have enhanced the capabilities of State laboratories and broadened their role in local protection of community health threats. While certain rare, exceptionally low volume and cost prohibitive testing capabilities may be developed and maintained through national or regional laboratory networks, investments in State laboratories must continue as a first line of defense for our public health system. The Committee expects CDC to continue and enhance public health funding for State public health laboratory testing technology, training and infrastructure.

Sodium Reduction Activity grants.—The Committee notes CDC has identified sodium, among three other nutrients, for an updated Dietary Reference Intake (DRI). The Committee is concerned CDC has put out a request for proposals for grants targeting sodium reduction activities that may not be consistent with completed DRI. Bill language is included directing completion of a DRI on sodium before funds are spent on population-wide sodium reduction activities.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Substance Abuse Treatment

Targeted Capacity Expansion.—The Committee recommends \$61,303,000 for Targeted Capacity Expansion activities. Of this amount, \$50,080,000 is for services that address prescription drug abuse and heroin use in high-risk communities. This funding level will **provide funding for 45 States**. SAMHSA should target States with the highest rates of admissions and that have demonstrated a dramatic increase in admissions for the treatment of opioid use disorders. The United States has seen a 500 percent increase in admissions for treatment for prescription drug abuse since 2000. Moreover, according to a recent study, in the past two years, 28 States saw an increase in admissions for treatment for heroin dependence. The Center for Substance Abuse Treatment is directed to include as an allowable use medication-assisted treatment and other clinically appropriate services to achieve and maintain abstinence from all opioids and heroin and prioritize treatment regimens that are less susceptible to diversion for illicit purposes

Overdose Fatality Prevention.—The agreement reflects strong concerns about the increasing number of unintentional overdose deaths attributable to prescription and nonprescription opioids. SAMHSA is urged to take steps to encourage and support the use of Substance Abuse and Prevention Block Grant funds for opioid safety education and training, including initiatives that improve access for licensed healthcare professionals, including paramedics, to emergency devices used to rapidly reverse the effects of opioid overdoses. Such initiatives should incorporate robust evidence based intervention training, and facilitate linkage to treatment and recovery services.

Viral Hepatitis Screening.—The Committee applauds SAMHSA for encouraging grantees to screen for viral hepatitis including the use of innovative strategies like rapid testing. The Committee notes the disproportionate impact of viral hepatitis among minority populations and the co-infection rate among individuals with HIV/AIDS. The committee urges SAMHSA to work with Minority AIDS grantees to incorporate hepatitis screening into programmatic activities.

Substance Abuse Prevention

Grants to Prevent Prescription Drug and Opioid Overdose Related Deaths.—The Committee recommends \$12,000,000 for discretionary **grants to States to prevent prescription drug and opioid overdose related deaths**. This program will help States equip and train first responders with the use of devices that rapidly reverse the effects of opioids. SAMHSA is directed to ensure applicants outline how proposed activities in the grant would work with treatment and recovery communities in addition to first responders. Furthermore, the agreement provides \$10,000,000 for the Strategic Prevention Framework Rx program to increase awareness of opioid abuse and misuse in communities. SAMHSA shall collaborate with CDC to implement the most effective outreach strategy and to reduce duplication of activities.

Comprehensive Opioid Response.—The Committee recommends \$500,000,000 for Comprehensive Opioid Response grants. SAMHSA, in coordination with CDC, may award **funds to eligible states, units of local government, territories or Indian Tribes**, which may, in turn, sub-grant to non-governmental organizations as appropriate. Funds may be used to plan for and implement an integrated opioid abuse response initiative that incorporates prevention and education, treatment, and recovery services. Eligible activities are as follows: (1) Prevention and education efforts concerning heroin and opioid use, treatment, and recovery; (2) Education of physicians, residents, medical students, and other medical providers who prescribe controlled substances on the prescription drug monitoring program of the State, on the CDC Guideline for Prescribing Opioids for Chronic Pain, and on the treatment of addiction; (3) Expanding prescription drug and opioid addiction treatment programs of the State. This includes the expansion of abstinence-based and medication assistance treatment programs that incorporate training for treatment and recovery support providers; behavioral health therapy for individuals who are in treatment for prescription drug and opioid addiction; screening for and clinically appropriate treatment of hepatitis C and HIV; and screening, early intervention, and referral to treatment for teenagers and young adults in primary care, middle schools, high schools, universities, school-based health centers, and other community-based health care settings; and (4) Developing, implementing, and expanding programs to prevent overdose death from prescription medications and opioids that incorporate a referral to treatment services. Priority shall be given to States with the highest burden of opioid-related overdoses. SAMHSA is directed to brief the

Committee no less than 30 days before issuing a funding announcement regarding the criteria for grant awards. In addition, SAMHSA is directed to brief the Committee no less than 30 days before awarding a grant.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Adult Immunization Quality Measures.—The Committee recognizes the importance of quality measurement tools to ensuring accountability and improvements in care delivery and patient outcomes, including reducing racial and ethnic health disparities. The Committee requests a report in the fiscal year 2018 budget request on steps the agency has taken to improve outcome quality measures applicable to adult immunization under the Medicare and Medicaid programs.

National Diabetes Prevention Program (NDPP).—The Committee understands the CMS Office of the Actuary certified expansion of the NDPP would reduce net Medicare spending and improve the quality of care without limiting coverage or benefits. The Committee requests CMS provide an update in the fiscal year 2018 budget request on the feasibility of establishing a certification process for NDPP providers within CMS. Further, the update should discuss the feasibility of establishing a new provider class of practitioners for the NDPP to allow for the lowest cost and effective delivery method.

ADMINISTRATION FOR COMMUNITY LIVING

Elder Falls - The Committee recommends \$5,000,000 for the Elder Falls program, which is the same as the fiscal year 2016 enacted level and the fiscal year 2017 budget request. Fall prevention grants support the promotion and dissemination of prevention tools to be delivered in community settings.

Chronic Disease Self-Management Program - The Committee recommends \$8,000,000 for Chronic Disease Self-Management program, which is the same as the fiscal year 2016 enacted level and the fiscal year 2017 budget request. This program supports grants to States for low-cost, evidence-based prevention models that use state-of-the-art techniques to help those with chronic conditions address issues related to the management of their disease.

OFFICE OF THE SECRETARY

Abuse Deterrent Opioids.—A recent study indicates that hospitalizations related to opioid abuse and dependence significantly increased from 2002 to 2012, and associated inpatient charges almost quadrupled over the same time period, reaching almost \$15 billion for hospitalizations related to opioid abuse and dependence and more than \$700 million for those related to associated infection in 2012. Considering that Medicaid was the most common primary payer for both types of hospitalizations, the Committee supports actions that Centers for Medicare and Medicaid Services can take to address this challenge in Medicare and Medicaid. Among the strategies to reduce abuse, misuse and diversion of these medications is the availability of Abuse Deterrent Opioids (ADO) approved by the U.S. Food and Drug Administration. The Committee directs HHS to submit a report to the Committee on Appropriations regarding beneficiary access to ADOs and actions that Congress and the Administration can take to reduce barriers.

Office of the Assistant Secretary for Health

HIV/AIDS in Minority Communities.—The Committee recommendation includes \$53,900,000 for specific program activities to address the high-priority HIV prevention and treatment needs of minority communities, the same as the fiscal year 2016 level and the fiscal year 2017 budget request. These funds are provided to promote an effective, culturally competent and linguistically appropriate public health response to the HIV/AIDS epidemic.

Sexual Risk Avoidance.— In implementing these funds, it is the intent of the Committee that HHS provide substantive and practical technical assistance to grantees so they place meaningful emphasis on Sexual Risk Avoidance (SRA) in all educational messaging to teens. The Committee notes that such technical assistance should be provided in the following venues: during National and regional conferences, webinars and one-on-one conversations with funded projects. The Committee further intends that SRA-credentialed experts consult with grantees and HHS staff with oversight of these programs on methodologies and best practices in SRA for teens. The Committee also encourages all operating divisions at HHS that implement or inform youth programs to consistently implement a public health model that stresses risk avoidance or works to return individuals to a lifestyle without risk, particularly as it relates to sexual risk.

Tick-Borne Diseases.—The Committee directs the Secretary to create a Tick-Borne Diseases Advisory Committee (TBDAC) to enhance interagency coordination and communication and minimize overlap regarding efforts to address tick-borne diseases; identify opportunities to coordinate efforts with other Federal agencies and private organizations addressing such diseases; ensure interagency coordination and communication with constituency groups; ensure that a broad spectrum of scientific viewpoints is represented in public health policy decisions and that information disseminated to the public and physicians is balanced; and advise relevant Federal agencies on priorities related to the Lyme and tick-borne diseases. The Secretary should appoint voting members to the Committee who should represent a diversity of scientific perspectives, and specifically should consist of members of the scientific community, representatives of tick-borne voluntary organizations, health care providers, individuals who have been diagnosed with a tick-borne disease or their family members, and representatives of State and local health departments and/or their organizations. The TBDAC should submit a report to the Committee on Appropriations by September 30, 2017.

Office of Minority Health

The Committee recognizes advancements in the treatment and management of hepatitis and encourages OMH to pursue community collaborations that promote awareness and outreach to improve testing, diagnosis, and treatment.

Office of the National Coordinator for Health Information Technology

Prescription Drug Monitoring.—The Committee understands that the spread of the prescription drug epidemic throughout the Nation has made the creation, implementation, and use of State Prescription Drug Monitoring Programs (PDMPs) and their ability to operate in concert with Electronic Health Records (EHR) and electronic prescribing (e-prescribing) systems more important than ever. In furthering this goal, the Committee encourages ONC to continue its support for pilot programs to find usability challenges among PDMP, EHR, and e-prescribing systems; develop and award challenge awards to private entities for health information technology innovation; and offer targeted technical assistance to help medical professionals use PDMP, EHR, and e-prescribing systems. The Committee further encourages ONC to collaborate and coordinate its efforts toward creation, implementation, and use of PDMPs with partner agencies such as the Substance Abuse and Mental Health Services Administration within HHS and the Bureau of Justice Assistance within the Department of Justice.

Immunization Information Systems.—The threat of the disease outbreaks and the ongoing work to target outreach to under immunized communities underscores the importance of maintaining robust immunization information systems (IIS). However, despite widespread availability of state and jurisdictional IIS' and their frequent use by pediatric providers, only 32 percent of adults 18 and over have immunization records in an IIS. The Committee encourages ONC to continue pilots to explore ways to increase the usage of IIS by adults.

Public Health and Social Services Emergency Fund

Office of the Assistant Secretary for Preparedness and Response

Burn Patient Management in Mass Casualty Event.—The Committee directs ASPR to provide a report in the fiscal year 2018 budget request on the current and on-going efforts to improve the logistics of burn patient triage and transfer in the event of a mass casualty event. The Committee understands the ability to maximize efficiency and effectiveness of triage and that subsequent care would be critical to the management of an overwhelming surge in burn patient volume and intensity. Specifically, the report should note the on-going and planned research from across HHS related to treatment and systems capability like the development of a network platform for reporting immediate and surge burn bed availability to match patient acuity or critical providers into the network.

Biomedical Advanced Research and Development Authority.— The Committee remains committed to ensuring the Nation is adequately prepared against CBRN attacks. Public-private partnerships to develop MCMs is required to successfully prepare and defend the Nation against these threats. The Committee supports the goal of market development where there is little or no commercial market. The funds allow for sustained management and funding of critical priorities, facilitate flexible and rapid response to emerging threats, and prevent the loss of resources from year to year, especially when the country is facing such tight budget constraints while threats persist.

The Committee recommends \$72,000,000 for the ASPR's pandemic influenza program. This funding can support research and development of next generation influenza MCMs, preparedness testing and evaluation, and stockpiling.

Biomedical Advanced Research and Development Authority 90- Day Review.—The Committee recognizes BARDA as a critical link in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to enhance the capability of the United States government to develop MCMs for natural and intentional threats to public health. The process relies on inherent Federal capabilities and critical capabilities with private sector partners that are the linchpin to develop needed MCMs, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin. The Committee requests ASPR conduct a comprehensive 90-day review to assess whether: 1) The current structure meets the appropriate capabilities to ensure preparedness; 2) The structure of the capability response platform, such as the Centers for Innovation in Advanced Development and Manufacturing, are appropriate for future advanced technological platforms needs; 3) The current mix of technological capabilities are in place to address potential gaps in the medical countermeasure enterprise and to ensure rapid deployment of medical countermeasures; and 4) BARDA has the correct measures and indicators in place to assure it leverages the resources of PHEMCE, private sector, and other Federal agencies and can report these indicators on a regular basis to the Secretary and other Federal leaders to provide them with an accurate risk assessment of the ability to respond and known limitations. The report shall include recommendations for policy changes, capability adjustments, and other appropriate actions. The report should be provided to the Committees on Appropriations and appropriate authorizing committees, with a public version to be published on the HHS website within 15 days of being submitted to Congress.

Antibiotic Resistance.—BARDA is directed to work closely with CDC and NIAID on the government-wide antibiotic resistance activity. The Committee requests an update in the fiscal year 2018 budget request on the joint BARDA, NIAID, and CDC goals and measurable objectives to ensure the best leveraging of the funds provided to CDC and NIAID for this effort.

USDA-FDA APPROPRIATIONS BILL

UNITED STATES DEPARTMENT OF AGRICULTURE

Animal and Plan Inspection Service

Antimicrobial Resistance.— There is currently no evidence to support the claim that agriculture is largely to blame for the increase in antibiotic-resistant strains of bacteria, and so the Committee supports funding to collect additional data that will inform policy related to the appropriate antibiotic use in all settings across agriculture and clinical medicine. The Committee provides \$9,916,000 for on-farm surveillance and data collection to enhance the understanding of on-farm levels of antibiotic use and the impact on antimicrobial resistance levels. The information collected should clearly delineate between antibiotics used for food-producing and companion animals. Further, to avoid duplication with existing programs like the National Antimicrobial Resistance Monitoring System, the Committee expects surveys regarding on-farm usage to be limited to collecting information about the antibiotics used and should not be utilized for other regulatory purposes. In designing these surveys, the Committee expects the agency to work primarily with end-users of antibiotics and veterinarians providing care to the animals. APHIS will collect this information through its statistical unit under the Confidential Information Protection and Statistical Efficiency Act, which will guarantee that all information collected is protected from distribution in a manner that could identify an individual respondent for the full time the data is in existence. This information is needed for use in the larger National Strategy for Combatting Antibiotic Resistant Bacteria with other federal partners.

Food and Nutrition Service

Child Nutrition Programs

School Meals.—The Committee remains concerned about the challenges and costs that local schools face in implementing the various regulations from the Healthy, Hunger-Free Kids Act of 2010. Some schools are continuing to

have difficulty complying with the whole grain requirements that went into effect on July 1, 2014, and schools are increasingly concerned with further reductions in the sodium requirements. In order to provide schools with the certainty and flexibility they need for the 2017–2018 school year, the Committee continues to extend the whole grain waiver provision to those school food authorities demonstrating a hardship in implementing the whole grain standards. The Committee also continues a provision stating that sodium standards cannot be reduced below Target 1 until the latest scientific research establishes that the reduction is beneficial for children. According to information provided by USDA, the overwhelming majority of research that has been reviewed on this issue was conducted more than 10 years ago, with most research conducted in the 1980s and 1990s. The Committee notes that the requirement that the latest scientific research prove that further sodium reductions are beneficial for children has not been met. As schools seek to implement the school meal standards, the Committee encourages USDA to consider ways to assist schools with technical assistance and training, including the services of not-for-profit culinary institutions, to provide healthy, cost-effective foods that students will eat.

Improper Payments.—The Committee remains concerned about the staggering error rates for the National School Lunch Program (NSLP) and School Breakfast Program (SBP), which were about 16 percent and 23 percent, respectively, in fiscal year 2015. This amounts to \$1,800,000,000 in improper payments for NSLP and \$875,000,000 for SBP. While the error rate for SBP had a small decrease, there was a slight increase in the error rate for NSLP. OIG completed an audit report in May of 2015 that evaluated how FNS is attempting to lower the error rates, and the Committee acknowledges FNS is working to address this issue. The fiscal year 2016 explanatory statement directed FNS to provide a report addressing OIG’s recommendations. The Committee expects this report by June 1, 2016.

Potable Water.—The Committee is aware of the statutory requirement that schools and child care centers make potable water available to children free of charge during meal times in the place where meals are served. The Committee directs USDA to provide a report on the actions that have been taken to ensure that potable water is being provided in schools and child care centers.

Technology Use in School Meal Programs.—The Committee supports increased use of technology as a strategy to combat waste, fraud and abuse in the school meal programs and urges USDA to continue to allow local control in the selection of technology platforms. The Committee directs USDA to clearly communicate to recipients of any funding that can be used for technology infrastructure in or for the support of school meal programs that the funds are intended to establish state systems that are capable of interoperability or interface with the technology platforms selected by school districts.

WIC Nutrition Programs

Zika Outreach and Education.—The Committee is supportive of ensuring pregnant women are educated on the various methods for preventing exposure to the Zika virus during pregnancy. The Committee directs the Department, in consultation with the Centers for Disease Control and Prevention, to continue its education and outreach efforts through the WIC program to provide pregnant women with the information they need to prevent Zika. During fiscal year 2017, the Department is directed to designate \$10,000,000 to assist with Zika outreach and education, with priority given to States with the greatest need.

Supplemental Nutrition Assistance Program

Electronic Benefit Transfer (EBT) Equipment.—The Committee is aware that some farmers markets and farmers selling directly to consumers are interested in EBT equipment that operates for a variety of federal nutrition programs. FNS is encouraged to assist farmers markets and direct-selling farmers in obtaining EBT equipment that allows participation in other federal nutrition programs.

FOOD AND DRUG ADMINISTRATION

Funding for Food Safety- The Committee includes increases of \$33,152,000 for the implementation of FSMA. These increases include \$19,139,000 for the National Integrated Food Safety System (NIFSS) and \$14,013,000 for Import Safety. The increases provided in this bill and the increases provided since fiscal year 2011 should assist the FDA in

preparation for the implementation of FSMA prior to the effective dates of the seven foundational proposed rules. While the FDA has not implemented the final rules, the Committee understands that most businesses will not need to comply with the two rules for preventive controls for human food and for animal food until August 2016 and that the other five rules will not be effective until fiscal year 2017 and later. Within the amount provided for NIFSS, the Committee includes \$5,000,000 to allow for the development of a data exchange to maximize standardization and access to farm data across FDA and States.

The Committee notes that with these increases, the estimated total funding for food safety since FSMA was signed into law on January 4, 2011, would be nearly \$340,000,000. In addition to the increases for FSMA, the FDA utilizes base resources for its comprehensive food safety efforts. The Committee directs the FDA to provide a detailed accounting of its food safety resources in the fiscal year 2018 budget request, including which pre-2011 base resources are now repurposed for activities in support of FSMA and which resources are the result of appropriated increases from fiscal years 2011 to 2017, a detailed explanation of what the FDA has accomplished with increased food safety resources since fiscal year 2011, and how the aggregate total of these base resources for food safety will be utilized in fiscal year 2017.

Antibiotics.—The Committee urges the FDA to work to foster the development of new antibiotics by supporting greater collaboration between industry and the FDA around adaptive clinical trials and labeling changes. The President’s Council of Advisors on Science and Technology has recommended this proposal to help support the type of robust drug development that will be needed to ensure patients are protected from bacterial resistance.

Blood Donor Policies.—The Committee commends the FDA on updating their blood donor policy in the December 2015 Guidance to Industry from a lifetime ban to a one year deferral, however it continues to encourage a permanent policy change based on scientifically supported risk factors and not time passed. The Committee remains concerned that certain questions on the FDA blood donor questionnaire are outdated and discriminatory. This questionnaire should not ask about sexual orientation, rather it should assess risk factors that might expose a potential blood donor to blood-borne illness. The Committee encourages FDA to find an adequate replacement question for the blood donor questionnaire that is cognitively appropriate and will maintain a safe donor pool without discrimination.

Emerging Public Health Threat Funding.—In order for the FDA to mount as rapid a response as possible to the spread of the Zika virus, the Committee reinforces its position that the agency obligate unobligated Ebola funds for the higher threat of Zika. The legislative text of the fiscal year 2015 emergency supplemental provided the FDA with such flexibility to deal with future public health emergencies such as those threats associated with the Zika viruses. Due to ongoing threats, the bill includes an appropriation of \$10,000,000 to support needs related to work on Ebola and Zika, such as support for FDA staff conducting ongoing response activities; support for regulatory science research to develop the tools, standards, and approaches to characterize investigational medical product safety, efficacy, quality, and performance; and support to expedite the development and availability of medical products for Ebola and Zika.

FDA Partnerships under FSMA.—The purpose of FSMA is to reform the nation’s food safety laws to ensure a safe public food supply. As the FDA continues implementation of FSMA, the Committee encourages the FDA to work in partnership with existing government food safety programs, including the use of MOUs, to verify compliance with FSMA rules once they are finalized as a way to eliminate duplication of activities under the law. In addition, the Committee continues to provide \$5,000,000 for the Food Safety Outreach Program under NIFA and expects that NIFA will serve as the sole agency providing food safety training, education, outreach, and technical assistance at the farm level.

Harm Reduction.—It is the Committee recommendation that the FDA consider the benefits of harm reduction as part of evaluations under the Deeming regulations for tobacco products.

Indoor Tanning Devices.—Last December, the FDA proposed two rules intended to prevent the use of sunlamp products, including tanning beds, by certain age groups, reduce the risks for adults using these devices, and require manufacturers to take additional safety precautions. While the Committee remains deeply concerned with the deadly threat of melanoma, it questions some elements of the proposed rules. In particular, the Committee requests that the FDA hold a

meeting with industry officials as it begins to consider the final regulations to discuss such issues as the number of allowable visits by adults and other similar measures that could create an undue economic burden on the industry.

Medical Countermeasures.—The Committee directs that not less than \$24,552,000 shall be available for the FDA’s Medical Countermeasures Initiative. This total is in addition to the unobligated funds remaining to support the FDA’s emergency response to Ebola and related disease outbreaks.

Menu Labeling.—The Committee is concerned about the recent FDA final determination that increased the size and scope of those affected under restaurant menu labeling regulations. Specifically, the final rule attempts to regulate local grocery chains that typically do not qualify as restaurants. The Committee includes bill language which directs the FDA to implement the final rule no earlier than December 1, 2016, at least one-year following agency publication of related guidance to newly regulated stakeholders.

Nutrient Content Claims.—The Committee expects the FDA to amend its “healthy” nutrient content claim regulation to be based upon significant scientific agreement. In addition, to ensure that food producers can make truthful and non-misleading statements about the healthfulness of products, the Committee directs the FDA to make such regulatory changes during the rulemaking process and issue guidance to industry no more than six months after the enactment of this Act providing for the use of the word “healthy” in food labeling statements.

Nutrition Facts Label.—The Committee is concerned that proposed rules that have been issued to revise the Nutrition and Supplemental Facts labels may create confusion and misinformation among consumers. The FDA is encouraged to determine how the proposed new label disclosure statements regarding added sugars would be understood and interpreted by consumers before proceeding with a final rule. Additionally, the FDA should evaluate the consumer perception and impact on healthful nutrient dense foods that use added sugar to make the food more palatable.

Opioid Abuse.—The abuse, misuse and diversion of opioid painkillers has precipitated an epidemic in the United States. The CDC indicates that one American loses his or her battle with addiction every twenty minutes. For years, the Committee has encouraged the FDA to utilize the full breadth of its regulatory authority to address this challenge. The Committee is pleased that, with the Opioids Action Plan, the FDA has acknowledged that the agency shoulders some responsibility for turning the tide of abuse. The FDA’s recent regulatory changes related to scheduling and labeling of opioids are positive developments, as are efforts to encourage the development of abuse-deterrent formulations (ADF) and new evidence-based medication-assisted therapies (MAT).

The use of opioids as first-line therapies for any form of pain has led to over-prescribing, and the CDC has made clear that clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh the risks to the patient. With respect to prescribing patterns, the Committee supports efforts to incentivize ADF use by clinicians and to increase the number of prescribers who receive training on pain management and safe prescribing of opioid drugs in order to decrease inappropriate opioid prescribing. The Committee notes that 38,370 Extended Release/Long-Acting (ER/LA) opioid analgesic prescribers have been trained through the FDA’s Risk Evaluation and Mitigation Strategy (REMS), but is disappointed that this constitutes less than half of the 80,000 prescriber training goal that was established in 2012. Even if the FDA was on track to meet its lofty goal of having 60 percent of ER/LA prescribed take a REMS class by 2017, there will still be some 128,000 prescribers without additional, opioid-specific training. The Committee understands that FDA intends to share these lackluster results with an advisory committee to assess its impact on preventing the misuse and abuse of opioids, and to determine what changes, if any, need to be made to the program.

The Committee notes that treatment is not a “one size, fits all” enterprise and that every patient’s treatment regimen should be tailored by his or her doctor to his or her unique needs. The federal government, therefore, ought to be promoting the full suite of available treatment options—including abstinence-based models and non-opioid medications—rather than picking winners and losers. The Committee supports efforts at the FDA and elsewhere to develop MATs that improve efficacy of daily administration, are resistant to diversion and misuse, and/or help patients

on a path to abstinence. Finally, the Committee has been supportive of naloxone distribution and training licensed healthcare professionals and emergency responders on its use. When considering the appropriateness of providing naloxone over the counter, the Committee asks the FDA to ensure that the administration of naloxone serves as a point of intervention to spur an honest conversation between the patient and his doctor about addiction and treatment.

Premium Cigars.—The Committee includes statutory language exempting premium and traditional large cigars, in keeping with FDA’s intent under Option 2 of its proposed rule “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act (TCA); Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products” (Docket No. FDA–2014–N–0189). The Committee notes that premium cigars are shown to be distinct from other tobacco products in their effects on youth initiation, the frequency of their use by youth and young adults, and other such behavioral and economic factors. Lastly, a large number of participants in this unique business are small and very small operations that might not be able to maintain jobs and a physical presence in the United States due to the financial impact of this pending regulatory burden. Given that there is very little mention of cigars throughout the TCA, it is clear Congress did not intend to focus on the unique subset of premium cigars.

Sodium Guidance.—The Committee is aware that the FDA is considering issuing guidance to food manufacturers in order to reduce sodium in various food categories. It is imperative that any guidance be issued using the latest sound science. The Centers for Disease Control and Prevention and the IOM are working together to update the Dietary Reference Intake (DRI) report on sodium. The FDA is encouraged to issue any voluntary or mandatory guidance based upon an updated DRI report.

Sunscreen Ingredients.—The Committee is significantly concerned that despite the increase in incidence of skin cancer in the United States, the Surgeon General’s 2014 Call to Action to Prevent Skin Cancer, unanimous passage of the Sunscreen Innovation Act (SIA) in Congress and President Obama’s January 2016 Presidential Memorandum creating the White House Cancer Moonshot Task Force to prevent and cure cancer, the FDA has still not approved a new OTC sunscreen ingredient through the process created by the SIA. For several years, the House and Senate Appropriations Committees have directed the FDA to clear the sunscreen backlog and ensure that Americans have access to the latest skin cancer prevention technology (H. Rept. 113–116, H. Rept. 113–468, H. Rept. 114–205, S. Rept. 114–82). The agency has failed to do so. The Committee directs the FDA to work with stakeholders to develop a benefit-risk testing regimen that appropriately balances the benefit of additional skin cancer prevention tools versus the risk of skin cancer to the 5 million Americans that will be diagnosed with the condition this year. The agency is directed to reach agreement with stakeholders on this testing regimen by June 20, 2016 and publish the summary of the meetings and results of the specific testing requirements on its website. The Committee reminds the FDA that section 4(c) of the SIA requires the FDA to report to the Senate Health, Education, Labor and Pensions Committee and House Energy & Commerce Committee on the implementation of the Act on or before May 26, 2016. The FDA shall include in this report a detailed analysis of how the FDA is balancing the Surgeon General’s Call to Action, the President’s Moonshot effort to remove administrative hurdles to cancer prevention, the known public health benefits that regular sunscreen use provides to prevent skin cancer and melanoma, and the long history of safe and effective use of sunscreens currently backlogged at the FDA in comparable countries versus the hypothetical risk sunscreens theoretically may pose to human health in FDA’s GRAS standard. The funding level for the FDA maintains the \$700,000 increase in fiscal year 2016 to help address the critical public health threat resulting from no new sunscreen ingredients being available to the public.

HOMELAND SECURITY APPROPRIATIONS BILL

Chemical, Biological, Radiological, Nuclear, and Explosives Office

As proposed in the President’s budget and consistent with the Department of Homeland Security CBRNE Defense Act of 2015 (H.R. 3875), which the House passed on December 10, 2015, the recommendation **reflects the proposed consolidation of the Office of Health Affairs (OHA)**; the Domestic Nuclear Detection Office (DNDO); the CBRNE threat awareness and risk assessment activities of the Science and Technology Directorate; the CBRNE functions of the Office of Policy and the Office of Operations Coordination; and the Office of Bombing Prevention from NPPD.

Chemical, Biological, and Emerging Infectious Diseases Capability

The Committee recommends \$120,420,000 for Chemical, Biological, and Emerging Infectious Diseases Capability, \$2,500,000 above the amount requested. These additional funds are intended to support the operationalization of successful pilot programs of the National Biosurveillance Integration Center or other high priority or emerging requirements. The Committee has been encouraged by NBIC's efforts to pilot programs that employ novel data sets and information, advanced analytic approaches and tools, and improved methods of collaboration.

As requested, the recommendation includes \$1,000,000 to continue the replacement and recapitalization of current generation BioWatch equipment. The Committee is concerned with recent GAO reports and the Blue Ribbon Study Panel for Biodefense regarding the effectiveness of BioWatch. Two years after the cancellation of BioWatch Gen-3, it does not appear that DHS has made any progress in determining the next steps for this program. The CBRNE Office and S&T must more clearly articulate future technology requirements for the program to the private sector and innovators who are being called upon to help address those needs.

The Committee continues to support the development of an anthrax vaccination program for first responders using vaccines from the Strategic National Stockpile, and is aware of the Department's efforts to begin implementation of a pilot by the end of fiscal year 2017. The Committee expects the fiscal year 2018 budget submission will identify the necessary resources to conduct the pilot. Not later than 60 days after the date of enactment of this Act, the CBRNE Office is directed to brief the Committee on the timeline and implementation plan for the anthrax vaccine pilot.

Science and Technology

The Committee remains concerned by the absence of progress in the development of a next generation BioWatch system and supports efforts by S&T to develop bioassays for high priority threat agents, as well as to test and evaluate new solutions. The Committee is aware of ongoing work by the Department of Defense (DOD), including significant testing and evaluation conducted by the Joint Program Executive Office for Chemical and Biological Defense on biological identification systems. The Committee expects S&T to leverage existing testing and evaluation by DOD, including but not limited to real-time detection technology that has been tested with live agents.

FEDERAL EMERGENCY MANAGEMENT AGENCY

Urban Area Security Initiative

In accordance with the 9/11 Act, at least 25 percent of funds allocated to the State Homeland Security Grant Program and UASI shall be used for Law Enforcement Terrorism Prevention activities. In addition, consistent with fiscal year 2016, the Department shall limit UASI funding to urban areas representing up to 85 percent of the national urban area risk. FEMA is directed to use the most current data available to determine the relative risk score for UASI grants and encourages the Secretary of Homeland Security, in conducting vulnerability and threat assessments of metropolitan statistical areas, to take into consideration increases in average daily population resulting from high levels of tourism.

The Implementing Recommendations of the 9/11 Commission Act of 2007 requires the Administrator of FEMA to conduct an annual assessment of the relative threat, vulnerabilities, and consequences from acts of terrorism faced by each of the 100 most populous metropolitan statistical areas (MSA) in the U.S. Based on this assessment, the Administrator designates high-risk urban areas that are eligible for UASI grants. While the factors included in this assessment are defined in statute, the specific criteria that inform these factors and the methodology used to carry out the assessment are at the discretion of the Secretary and the Administrator, who review them on an annual basis. The Committee is aware of the Secretary's commitment to conduct a thorough review of the methodology and criteria used to support the assessment and designation of high risk urban areas, and includes language in the bill requiring the Secretary to submit a classified report on the assessment of the relative threat, vulnerability, and consequences from acts of terrorism faced by each MSA. The Committee expects this report will reflect any changes, as appropriate, resulting from the Secretary's review, and that the assessment outlined in the report will be applied to the risk determinations for urban areas eligible for UASI grants.