Department of Health and Human Services (HHS)

The Fiscal Year (FY) 2021 President’s Budget (Budget) requests $2.6 billion for the public Health and Social Services Emergency Fund (PHSSEF) and prioritizes emergency medical response capacity, pandemic influenza preparedness, and cybersecurity, and advances medical countermeasure development and stockpiling.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

The Assistant Secretary for Preparedness and Response (ASPR) fulfills HHS’s responsibilities as the lead federal agency for public health emergency preparedness and response. The FY 2021 Budget provides ASPR $2.6 billion to promote nationwide healthcare system readiness and response; deploy emergency resources and medical personnel; and develop and manufacture vaccines, drugs, diagnostics, and technologies to protect Americans from the impact of natural disasters, bioterrorism, and emerging infectious diseases including pandemic influenza.

Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority (BARDA) works with public and private sector partners to support advanced research, development, regulatory approval, and procurement of medical countermeasures to mitigate health effects of chemical, biological, radiological, and nuclear agents; pandemic influenza; and infectious diseases. The Budget provides $562 million for BARDA to support the advanced development of new vaccines, antivirals, and therapeutics for anthrax, smallpox, and viral hemorrhagic fever viruses, broad-spectrum antimicrobials and diagnostics for biothreat pathogens, and treatments for chemical, radiological, and nuclear agents. The Budget also supports BARDA’s Division of Research, Innovation, and Ventures, which invests in public-private partnerships to develop innovative products and technologies to solve systemic health security challenges, including preventing and treating sepsis and identifying early exposure to infectious disease. The Budget provides $160 million within BARDA to support advanced development of broad-spectrum antimicrobials for drug-resistant biothreat pathogens, including vaccines, diagnostics, and novel antibiotic treatments. In FY 2021, BARDA will continue to collaborate with the National Institutes of Health, academia, and private partners to sustain and expand the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X). CARB-X is a novel consortium approach to accelerate investment in early development of innovative medical countermeasures to fight antibiotic-resistant bacteria.

Project BioShield

The Budget provides $535 million for Project BioShield to support late-stage development and procurement of medical countermeasures for the Strategic National Stockpile (SNS) that are sufficiently mature for use during a public health emergency. The Budget requests $200 million less in FY 2021, the amount planned for FY 2021, for procurement of Ebola vaccines, therapeutics, and diagnostics. A total of $200 million from emergency supplemental funding appropriated in FY 2020 will fund ASPR’s FY 2021 procurement of Ebola medical countermeasures.

In 2019, President Trump signed an Executive Order, “Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health,” directing federal agencies to collaborate to improve the effectiveness, production, and supply of influenza vaccines to combat seasonal epidemics and pandemics. The Budget supports the Executive Order and provides an additional $50 million above
FY 2020, a total of $310 million, for pandemic influenza preparedness activities carried out by ASPR and the Office of Global Affairs (OGA).

**Hospital Preparedness Program**
The Hospital Preparedness Program (HPP) supports hospitals and healthcare coalitions to prepare for emergency response. HPP improves patient outcomes, minimizes the need for supplemental state and federal resources during emergencies, and enables rapid recovery. The Budget provides $258 million to fund 62 awardees, including all 50 states, eight United States territories and freely associated states, and four localities.

**Strategic National Stockpile**
The SNS is a national repository of pharmaceuticals, medical supplies, and deployable healthcare facilities available for use in a public health emergency. When state, local, tribal, and territorial responders request federal assistance during an emergency, HHS deploys potentially life-saving medicines and supplies from the SNS. The Budget provides $705 million for the SNS to manage and sustain inventory, procure FDA approved products transitioned from Project BioShield, and train state and local responders nationwide for effective distribution and dispensing of stockpiled products. The Budget supports procurements of high-priority medical countermeasures, including smallpox vaccine, anthrax antibiotics and therapeutics, and pandemic influenza antivirals.
Food and Drug Administration

Priority Areas of Note

The FY 2021 Budget Request is $6.2 billion, an overall increase of 4.5 percent or $265.4 million compared to the FY 2020 Enacted Level. The request includes $3.3 billion for budget authority – an increase of $25.4 million compared to the FY 2020 Enacted Level – and $2.9 billion for user fees – an increase of $240 million compared to the FY 2020 Enacted Level.

FOOD SAFETY

As part of FDA’s FY 2021 Budget request, the Agency is focusing on key areas where resources have been historically underfunded and for which there are rising public health needs as growing markets outpace increases to Agency resources. These areas include: outbreak response, oversight of innovative food products, and better regulation of cannabis derivatives.

Strengthening Response Capabilities for Foodborne Outbreaks: (+$1.2 million)
Additional funding will expand the Center for Food Safety and Applied Nutrition’s (CFSAN) ability to ensure that contaminated food is detected quickly and removed from the marketplace. Whole Genome Sequencing (WGS) has increased number of outbreaks detected and requires increased staffing.

Advancing Safe and Effective Medical Products

Modernizing Influenza Vaccines (+$5.0 million)
This initiative supports the implementation of Executive Order 13877, “Modernizing Influenza Vaccines in the U.S. to Promote National Security and Public Health,” to help make the U.S. influenza vaccine supply more robust, secure, and nimble to combat seasonal influenza epidemics and potential influenza pandemics. FDA requested a total of $5 million across CDER ($0.5M), CBER ($2.0M), CDRH ($0.5M), and Headquarters ($2.0M). This funding will support the development and availability of other medical countermeasures (MCMs) including antiviral drugs, therapeutics, and diagnostic tests.

21st Century Cures (-$5.0 million)
The 21st Century Cures Act (Cures Act) established an “FDA Innovation Account” for FY 2017 – FY 2025 and authorizes funding to carry out designated provisions of Title III, which focus on medical product development activities regulated by FDA. For FY 2021, the Cures Act authorized $70.0 million for the FDA Innovation Account. This amount is $5 million less than the amount authorized for FY 2020.

Expanding Temporary Access to Diagnostic Testing During Certain Emergencies
FDA requests that section 564A of the FD&C Act be amended to allow FDA to issue (and amend or revoke) an order designating that certain approved, cleared or licensed in vitro diagnostic tests (IVDs) can temporarily be used in additional settings, with conditions as deemed warranted, without issuing an Emergency Use Authorization (EUA).
Centers for Disease Control and Prevention

Priority Areas of Note

End HIV Epidemic
$231 million increase (building on the $140 million from FY 20)

Influenza Planning and Response
$40 million in “new” funds tied to the Executive Order

“…to support implementation of the activities outlined in the September 2019 Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, including: expanding vaccine effectiveness monitoring and evaluation, enhancing virus characterization and expanding vaccine virus development for use by industry, increasing genomic testing of influenza viruses, and increasing influenza vaccine use by removing barriers to vaccination and promoting vaccination coverage. Strategic investments in CDC’s influenza program will achieve significant impact in reducing morbidity and mortality in the near term, while newer technologies are still under development. Furthermore, improvements in the development and delivery of seasonal influenza vaccine are critical to the Nation’s ability to prepare and respond for a potential influenza pandemic.”

Global Health Security
$175 million (a $50 million increase over FY 20 enacted)

“CDC’s Global Health Security activities protect Americans from the next, inevitable emerging disease threat and safeguards against future epidemics. With $50.0 million in new resources, CDC will continue to build a sustainable foundation that protects the American people from health threats around the world, focused on helping high risk countries build their own public health capacity to respond to outbreaks. CDC collaborates and supports country-lead response efforts to confront the most challenging health epidemics, often in complex geopolitical settings. However, it is critical that CDC maintain the capacity to address contagious disease threats where they occur—from Ebola in West Africa to polio in Pakistan and Afghanistan to pneumonia of unknown etiology in China.”

Infectious Disease Rapid Response Reserve Fund
$50 million

“The Infectious Diseases Rapid Response Reserve Fund, created in FY 2019, provides CDC with funding that could be used to prevent, prepare for, or respond to an infectious disease emergency, domestic or international. Rapid response is essential to emerging public health threats, and timely action for detection, investigation, and assistance that saves lives. The FY 2021 request continues the investment into the Infectious Disease Rapid Reserve Fund at $50.0 million to allow CDC to initiate timely and effective response to infectious disease emergencies, as necessary.”

Laboratory Capacity
$10 million

“CDC is a world leader in laboratory science, which is fundamental to CDC’s work. Conducted to the highest standards of safety and quality, this science informs public health action. The FY 2021 request includes $10 million to help maintain state-of-the-art laboratory capacity at CDC. This investment will
allow CDC to support supply and equipment needs; improve laboratory data science proficiency, including incorporation of epidemiologic and genomics data; and provide specialized training to CDC laboratory scientists. The United States depends on CDC’s laboratories to respond to public health needs, including for specialized infectious disease diagnostics. Sustaining the excellence of CDC’s laboratories through increased investment ensures the continuation of the vital public health work they support and will help improve CDC’s ability to respond to outbreaks.”

Noted in Cuts Section:
NCEZID: The FY 2021 request reduces funding for Emerging Infectious Diseases, Food Safety, and Antibiotic Resistance. The request also carries forward proposed program reductions for epidemiology and laboratory capacity and healthcare-associated infections, as well as program eliminations for Prion Diseases and Chronic Fatigue Syndrome from the FY 2020 President’s Budget.
Centers for Medicare and Medicaid Services (CMS)

Survey and Certification (S&C) is a CMS administered program that ensures healthcare providers across the Nation meet applicable quality standards through onsite, objective, and outcome-based verification activities carried out by knowledgeable and trained individuals. Included in the S&C is the CLIA Program.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)
The CLIA program is entirely funded by user fees that are charged to the laboratories regulated by the program. The FY 2021 Budget projection for CLIA is $66.4 million in user fee collections, which is an increase from FY 2020 by $1.5 million.

| CMS: Survey and Certification (incl. CLIA) | $754 million | $810 million | $56 million | 7.0% |
National Institutes of Health

Congressional Justification Language of note:

Office of the Director:

- Highlights the anti-harassment efforts the agency has taken at length.
- Highlights efforts to address foreign influence. Here is some of the language:

“NIH research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition. The U.S. biomedical enterprise sets the standard for discovery and innovation excellence for the world. This is made possible because the overwhelming majority of researchers participating on NIH grants, whether U.S. or foreign-born, are honest contributors to the advancement of knowledge that benefits us all. NIH recognizes the importance of scientific collaborations, including those involving international institutions, to advance its mission. Yet, there are threats to the integrity of the biomedical research enterprise, including the failure by some researchers at NIH-funded institutions to disclose contributions of resources from other organizations, diversion of intellectual property produced by NIH-supported biomedical research to other entities, and sharing of confidential information by peer reviewers with others or otherwise attempting to influence funding decisions.”

- Working Group on Enhancing Reproducibility and Rigor in Animal Research:

“In response to growing concern about the rigor and replicability of animal research for improving health outcomes, this group has been charged with assessing and making recommendations to enhance the reproducibility and rigor of animal research by improving experimental design, optimizing translational validity, enhancing training, and increasing the transparency of research studies involving animal models. Building on the efforts already undertaken by NIH to improve rigor, reproducibility, and transparency, and taking into account work done by outside organizations, including the National Academies of Sciences, Engineering, and Medicine, the National Centre for the Replacement, Refinement, and Reduction of Animals in Research, and scientific societies (e.g., American Physiological Society, Society for Neuroscience), the WG will consider how training in animal research can be improved, assess the current state of science in alternative methods to animal models, how animal models of human disease are currently developed, and their use in translational research. This WG is expected to make its recommendations in late FY 2020.”

National Institute of Allergy and Infectious Diseases (NIAID):


Highlights:
- Notes the Executive Order on the Flu Vaccine and that NIAID is fully aligned with the goals of this.
- Increase of $44 million for Tickborne/Lyme disease (aligns with larger HHS priorities and CDC)
- Expresses commitment to continue the universal flu vaccine work at no less than the FY 2020 levels. ($200 million)

- Notes continued work, in partnership with BARDA and CARB-X, on antimicrobial resistance (AMR)

- Notes the importance of preparedness and has a highlight feature on Ebola clinical research as a model for responding to emerging infectious diseases

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK):

- The importance of microbiome research is mentioned both in the “state of the science” and in discussing important areas of future disease research
Department of Agriculture

Priority Areas of Note

Under the President’s proposed budget, $1.6 billion is included in discretionary funding to support extramural agricultural research, education, and extension activities of the National Institute of Food and Agriculture (NIFA), including $600 million for competitive grants through the Agriculture and Food Research Initiative (AFRI). “AFRI programs are aligned with six Farm Bill Priority Areas: 1) plant health and production and plant products; 2) animal health and production and animal products; 3) food safety, nutrition, and health; 4) bioenergy, natural resources, and environment; 5) agriculture systems and technology; and 6) agriculture economics and rural communities. In FY 2021, artificial intelligence (AI) is a priority element of the Administration's “Industries for the Future” initiative and $100 million of the AFRI increase will emphasize AI, Machine Learning, and Predictive Science by investing $100 million in these emphasis areas across the Sustainable Agricultural Systems, Foundational and Applied Science, and Education and Workforce Development programs.”

Although the increased AFRI budget would boost the overall NIFA budget, some of the additional funding for AFRI would negatively affect NIFA capacity-building grants.

Agricultural Pest and Disease Programs “The Budget includes $1.036 billion in discretionary funding to protect agriculture from pests and diseases, address sanitary (animal) and phytosanitary (plant) trade concerns, and enforce animal care legislation. This includes programs that support the U.S. field crop, cotton, forestry, livestock, poultry, and specialty crop industries.

National Bio and Agro-Defense Facility The Budget supports the continued establishment of the National Bio and Agro-Defense Facility (NBAF) and provides $81 million for operations and maintenance costs in 2021. Once construction is complete, USDA will operate NBAF and ARS will use the facility to study diseases that threaten the animal agricultural industry and public health while the Animal and Plant Health Inspection Service (APHIS) performs diagnostics related to foreign diseases of animals. Funding is also requested within ARS and APHIS to transition highly pathogenic animal disease work from the obsolete facilities at the Plum Island Animal Disease Center to NBAF.

Animal Health “The Budget supports a total of $347 million for Animal Health, which includes funding for the National Bio and Agro-Defense Facility. The Budget proposes to enhance animal disease traceability efforts, increase support for veterinary biologics, and continue support for poultry, swine, and aquatic animal health efforts. At the proposed funding level for cattle fever tick (CFT), APHIS would restore activities back to the FY 2019 levels and continue to focus efforts on mitigation activities that reduce CFT from the permanent quarantine zone.”

Plant Health. “The Budget proposes decreases to the Federal share of funding for specific plant pest and disease programs, accounting for recent successes in addressing plant pests. APHIS will continue working with States and other stakeholders to leverage resources in addressing plant health issues.”

Wildlife Services “The Budget includes a total of $129 million for Wildlife Services. APHIS will use this funding to continue to resolve human/wildlife conflicts and protect agriculture, human health and safety, personal property, and natural resources from wildlife damage and wildlife-borne diseases in the United States, including the management of rabies and other zoonotic diseases caused by various wildlife species.”
Department of Energy Office of Science

The President’s Budget proposes a 17% drop in funding at the Department of Energy’s Office of Science including a 42% drop in funding for national laboratories infrastructure and the elimination of the Advanced Research Projects Initiative – Energy (ARPA-E).

Priority Areas of Note

Basic Energy Sciences (BES)
$277 million decrease or 12.5% below the FY 2020 Enacted level
“The Request focuses resources toward early-stage fundamental research, the operation and maintenance of a complementary suite of scientific user facilities, and the highest priority facility upgrades.” BES supports fundamental research to understand, predict, and ultimately control matter and energy at the electronic, atomic, and molecular levels to provide foundations for new energy technologies.

Biological and Environmental Research (BER)
$233 million, or 31.1 percent, below the FY 2020 Enacted level.

“The Request implements Administration priorities for early-stage fundamental research focused on biological and earth and environmental systems that will contribute to a future of stable, reliable, and secure sources of American energy and advance transformative science for economic prosperity. The Request for Biological Systems Science supports core research areas of Genomic Sciences and fully supports the fourth year of the recompeted four DOE Bioenergy Research Centers (BRCs). The BRCs continue to perform new fundamental research underpinning the production of fuels and products from sustainable biomass resources and the building blocks of new technological advances for translation of basic research results to industry.”

Within Genomic Sciences, “the Request prioritizes research activities to continue early-stage core research to understand the complex mechanisms controlling the interplay of microbes and plants within broader organized biological systems, forming the basis for the next generation of biological discovery. Computational Biosciences supports all Genomic Science systems biology activities through the ongoing development of bioinformatics and computational biology capabilities within the DOE Systems Biology Knowledgebase (KBase) and the National Microbiome Data Collaborative (NMDC). The integrative KBase project seeks to develop the necessary hypothesis generating analysis techniques and simulation capabilities on high performance computing platforms to accelerate collaborative and reproducible systems biology research within the Genomic Sciences. The Joint Genome Initiative will operate with reduced user support.
National Science Foundation
Overall decrease of 6%, or $424 million, to $6.328 billion
Increased funding for the administration’s “Industries of the Future”, artificial intelligence and quantum information sciences.

Priority Areas of Note

Directorate for Biological Sciences (BIO)
$79 million decrease to $740.95 million
~200% increases in both artificial intelligence and quantum information science within BIO
BIO investments in genomics, in cellular, organismal and developmental biology, and in bioinformatics spur further development of capabilities in synthetic biology and enhance biotechnology beyond the current state-of-the-art. The accelerating power of this advanced biotechnology promises to sustain U.S. economic growth and innovation across multiple sectors including agriculture, biomanufacturing, pharmaceuticals, and other bioproducts. In this way, BIO programs directly support the Administration’s priorities in and the bioeconomy industries of the future.

Within BIO, the Integrative Organismal Systems (IOS) budget: “Interagency Strategic Plan for Microbiome Research FY 2018-2022” released in April 2018 continues to guide IOS investment into microbiomes, including microbial interactions with the environment, with animals and plants, and important ecosystem services such as soil stability, fertility, and sustainability.

NSF Big Ideas (Crosscutting): Understanding the Rules of Life (URoL).
Continued support at $30 million
“The URoL NSF Big Idea aims to create a new paradigm at the convergence of science, engineering, and technology that will elucidate theoretical frameworks, or rules, to enable prediction of the diversity of solutions that biological systems use to support life processes. URoL activities in FY 2021 will build upon the investments made in FY 2019 and FY 2020. The FY 2020 solicitation supporting microbiome research will continue in FY 2021, enabling deeper exploration of interaction rules. A new solicitation will be developed to support research that addresses convergence approaches for the discovery of scale-invariant rules that govern living systems. The URoL: Research Networks solicitation that will be released in FY 2020 will also continue in FY 2021, supporting networks of researchers, technology developers, and educators in different URoL domains.”
US Geological Survey
Proposed $300 million cut, or 24% of the agency’s budget.

Priority Areas of Note
Consolidation of the Land Resources and Environmental Health Programs
“The 2021 President’s budget proposes: ● Organizational changes to improve integration of USGS scientific programs and align resources more effectively to achieve mission goals and objectives. ● A budget restructure aligning the programs of two smaller mission areas, Land Resources and Environmental Health, with associated programs in other existing mission areas to strengthen integrated research and collaboration, and rationalize the structure of the Ecosystems, Water Resources and Core Science Systems.”

$7.6 million cut to the Biological Threats Research Program, which includes vector-borne diseases of concern to Interior and other Federal agencies.