

FY 2016 BUDGET HIGHLIGHTS

On Monday, February 2, 2015, President Barack Obama released his \$3.99 trillion budget request for fiscal year (FY) 2016, increasing spending 6.4% over FY 2015 enacted levels. The President's budget would also end the automatic across-the-board spending cuts known as sequestration.

While the President's budget serves as an important statement of the Administration's priorities for the fiscal year, this document serves as a mere starting point for the upcoming appropriations process. Congress must still enact legislation to appropriate funds for discretionary funding and to create, eliminate, or modify programs and policies in existing statutes.

Several of the budget's many provisions of importance to the biomedical and life sciences sectors are detailed below.

Department of Health & Human Services

The President's budget requests a total of \$83.8 billion in discretionary funding for the Department of Health and Human Services in FY2016, representing an overall \$4.8 billion increase over the FY 2015 enacted level.

National Institutes of Health

An essential focus-area for CHI, the President's budget requests \$31.3 billion for NIH in 2016, a modest \$1 billion increase from 2015 actual levels. Although the increase in funding would fall far short of reversing the overall damage done by a decade of flat funding and the impact of sequestration on NIH, the Administration's proposal is a step in the right direction, and also provides additional funding to several key initiatives that would support the biomedical innovation ecosystem:

- The President's budget request estimates that NIH will dedicate \$17.2 billion, or 55% of the overall budget, to support a total of 36,447 research project grants, including 10,000 new and competing awards. This is an increase of 1,200 grants from FY 2015 levels.
- \$215 million to support the President's new cross-Department project, the Precision Medicine Initiative, to help accelerate the ability to improve health outcomes and better treat diseases. Of these funds \$200 million would be dedicated to NIH:
 - \$130 million would go to NIH to recruit at least 1 million volunteers and analyze their full genetic makeups, as well as to expand clinical trials for possible cancer medications.
 - \$70 million to NIH's National Cancer Institute (NCI) to further study genetic causes of cancers and use study findings to assist with drug development.
- \$135 million, an increase of \$70 million over FY2015, to expand the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the cross-agency brain-mapping project aimed at revealing the underlying pathology of a vast array of brain disorders.
- The budget includes a total of \$993 million across HHS in support of the Administration's National Strategy to Combat Antibiotic Resistant Bacteria, an increase of \$491 million. This program supports the research, development and clinical trials of new drug candidates and diagnostic products to ensure the continued availability of effective therapeutics for the treatment of bacterial infections. Of these funds, \$461 million would be dedicated to NIH, an increase of \$100 million over FY2015.

- \$638 million included for Alzheimer’s research, an increase of \$51 million, to invest in a variety of basic and translational research activities.
- \$566 million for the Common Fund, a \$20 million increase, to support trans-NIH, cross-cutting initiatives.
- Makes permanent the Research and Experimentation (“R&D”) Tax Credit.

CHI will continue to focus our education and advocacy efforts on securing a truly appropriate, stable and consistent level of funding for NIH (and other biomedical research agencies) in FY2016 and beyond.

Food and Drug Administration (FDA)

The President’s budget requests \$4.9 billion in total funding for the FDA, an increase of \$425 million (or 9%) above FY2015 enacted levels. Much of this increase was achieved by the Administration’s request for \$277 million in additional user fees, a 10% rise from the levels set under the *FDA Safety and Innovation Act* (FDASIA). Without the inclusion of industry supported user fees, the FDA appropriation is requested at \$2.75 billion, an increase of \$148 million over FY2015 (or a nearly 6% increase).

CHI was pleased to see the Administration’s commitment to FDA’s critical mission reflected in this proposal, especially at a time when the agency is implementing four major laws passed by Congress since 2010, including a biosimilars approval pathway, food safety modernization, drug and device safety and promotion of innovation, and the recently enacted *Drug Quality and Security Act*. Sustainable funding is essential as the agency implements these vast public health enterprises among a continually increasing workload.

Additional funds to the FDA that CHI welcomes in the FY2016 budget proposal:

- \$456 million to the Center for Devices and Radiological Health (CDRH), a \$16 million increase from FY2015.
- An additional \$15 million to the FDA for new antimicrobial resistance activities in support the Administration’s National Strategy on Combating Antimicrobial Resistant Bacteria.
- \$10 million to support the President’s Precision Medicine Initiative by establishing databases to help the FDA create the regulatory structure to integrate genetic information into device development.

Biodefense and Public Health Preparedness

The President’s budget requests a total of \$1.9 billion to support federal activities related to public health preparedness and response, and countering potential biological, nuclear, radiological, and chemical threats, an increase of \$677 million above FY2015 levels. Given the recent outbreak of Ebola in West Africa, CHI finds the Administration’s budget request in this space to be very encouraging and representative of the funding needed to properly prepare the nation for any bioterrorism or pandemic threat. Specifically, the budget request includes:

- \$1.5 billion for the Assistant Secretary for Preparedness and Response (ASPR), an increase of \$437 million.
- \$522 million for the Biomedical Advanced Research and Development Authority (BARDA), an increase of \$49 million, advanced development of devices to measure an individual’s exposure to biological

agents, antidotes for chemical agents, and antiviral and vaccine candidates against Ebola and Marburg viruses.

- \$646 million for the Bioshield Special Reserve Fund (SRF), a \$391 million increase in appropriations.
- \$571 million to support the Strategic National Stockpile.
- An additional \$192 million to support the continued effort to combat antibiotic-resistant bacteria within BARDA, an increase of \$108 million over FY 2015.
- \$170 million for ongoing pandemic influenza activities including support for diagnostics advanced development, vaccine stockpiling, international preparedness, and the advanced development of immunotherapeutics.

Centers for Disease Control and Prevention (CDC)

The President's budget request for CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) is \$11.5 billion, a \$250 million increase above FY2015 enacted levels, representing important investments in several public health priorities. This total includes \$914 million from the Prevention and Public Health Fund. Specifically, the President's proposal:

- Builds on the emergency Ebola spending approved by Congress last year with an appropriation of \$699 million for Emerging and Zoonotic Infectious Disease activities (a \$294 million increase in funding) to develop disease detection and response systems. This appropriation proposal includes an increase of \$264 million to implement the surveillance, prevention, and stewardship activities of the National Strategy to Combat Antibiotic Resistant Bacteria to reduce the emergence and spread of antibiotic resistant pathogens.
- Contains \$63 million for CDC's Viral Hepatitis program, an increase of \$32 million over FY 2015, to focus on controlling the emerging epidemic of hepatitis C virus (HCV) infection in young people, working to eliminate mother-to-child transmission of hepatitis B virus (HBV) infection, and decreasing premature death resulting from chronic viral hepatitis infection.

Biosimilars

Unfortunately, the President's budget request once again proposes to generate health system savings by dramatically reducing incentives for the development of innovative new biological therapies. CHI continues to have serious concerns that these proposals would discourage biotech innovation, further reduce venture investment into life sciences and delay innovative lifesaving medicines for patients with unmet medical needs. Notably, the budget proposal would:

- Provide seven years of exclusivity to brand biologic manufacturers, rather than 12 years as awarded under current law and supported by CHI.
- Modifies Medicare Part B payment for innovator biological products allowing them to be classified in the same category as their biosimilars counterpart. Reimbursement would be based on the weighted average sales price (ASP) of the reference biological product and all of its biosimilars, plus 6 percent. The President estimates this proposal would save money in Medicare and Medicaid (\$4.4 billion in Medicare savings over 10 years).

Prescription Drugs

The President's budget request also proposes to generate health system savings by (re)proposing a number of changes to prescription drug spending. Numerous of these provisions are opposed by CHI and the broader biomedical industry. Specifically, the President's proposal:

- Modifies Medicare Part B drug reimbursement by lowering payment from 106 percent of ASP (or, "ASP+6") to 103 ("ASP+3"). In order to preserve access to care, the budget would also require manufacturers to provide a specified rebate determined by the Secretary if the physician's cost for the drug exceeds ASP+3. The Administration projects this provision would produce \$7.4 billion in savings over 10 years.
- Proposes to close the coverage gap for brand drugs in Medicare Part D by 2017, three years earlier than under current law, by increasing discounts offered by drug manufacturers from 50% to 75% (\$9.4 billion in savings over 10 years).
- Gives the Secretary authority to negotiate prices for biologics and high cost prescription drugs in the Medicare Part D program.
- Allows Medicare to impose mandatory rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the Part D Low-Income Subsidy, beginning in January 2017. The Administration proposes to require manufacturers to pay the difference between rebate levels they already provide Part D plans and the Medicaid rebate levels, and projects that this provision would save the government \$116.1 billion over 10 years.

Health IT

The President's budget request includes \$92 million (\$32 million above FY2015) for the Office of the National Coordinator for Health Information Technology (ONC) to continue to make strategic investments in standards development, harmonization, and pilots in order to accelerate industry progress in specific areas that require interoperability.

In addition, \$5 million will go toward ONC to help develop interoperability standards and policies to address privacy issues and help with secure data exchange across various systems in coordination with the President's Precision Medicine Initiative.

For more information about the FY2016 Budget, contact Todd Gillenwater, CHI's Senior Vice President – Public Policy (Gillenwater@chi.org or 202-974-6313) or Jenny Carey, CHI's Director of Federal Government Relations and Alliance Development (Carey@chi.org or 202-974-6323).