

CLSA Analysis of President Trump's Fiscal Year 2021 Proposed Budget Request

Overview:

On Monday, February 10, 2020 President Trump released his \$4.8 trillion proposed budget request for fiscal year 2021 (FY 21). [See the Office of Management and Budget's (OMB) budget materials [here](#) and fact sheets [here](#).] We have prepared the below summary and analysis of the numerous biomedical and life sciences-related provisions included in the President's proposal. **The summary is listed in alphabetical order by federal agency, and then by subagency and/or initiative.**

As a reminder, the President's budget request is typically used by Congress to 1) inform its budget and 2) draft its appropriations bills – the latter of which ultimately fund the government. Therefore, especially when the House, Senate, and Presidency are controlled by different parties, the President's budget request in its entirety is unlikely to become law. However, it is important to view the proposed budget as a window into the Administration's priorities for the coming year.

Questions? Contact Jenny Nieto (jnieto@califesciences.org), CLSA's Vice President of Federal Government Relations & Alliance Development, Molly Fishman (mfishman@califesciences.org), CLSA's Director of Federal Government Relations, and Dani Mitchell (dmitchell@califesciences.org), CLSA's Manager of Federal Government Relations & Program.

U.S. Department of Agriculture (USDA):

Agricultural Technology:

- \$1.4 billion requested for the Agricultural Research Service (ARS), a \$200 million decrease from FY20 enacted levels.
- \$600 million requested for competitive grants through the Agriculture and Food Research Initiative (AFRI), an \$175 million increase from FY20 enacted levels.
 - \$100 million of the increase is to emphasize AI, Machine Learning, and Predictive Science for the Administration's "Industries for the Future" Initiative.

U.S. Department of Education (ED)

Science, Technology, Engineering and Mathematics (STEM)

- \$90 million requested for Career and Technical Education (CTE) National Programs to support high-quality STEM and computer science CTE programs.

U.S. Department of Energy (DOE):

Renewable & Clean Energy Technologies:

- \$720 million requested for the Energy Efficiency and Renewable Energy (EERE) R&D program, a decrease of 74% from FY20 enacted levels.

U.S. Department of Health & Human Services (HHS)

- \$94.5 billion in discretionary funding and \$1.3 trillion in mandatory funding requested overall for HHS in FY2021 (FY21), a 10% decrease in discretionary funding from the FY20 enacted levels.

Centers for Disease Control and Prevention (CDC)

- \$7.06 billion requested for CDC’s discretionary budget authority, a decrease of approximately \$708 million from FY20 enacted levels. Includes:
 - \$894 million requested for the Prevention and Public Health Fund;
 - \$541 million requested for the Public Health Service (PHS) Evaluation Funds;
 - \$427 million cut to CDC’s chronic diseases activities;
 - \$58 million requested for CDC’s infectious diseases and opioid epidemic activities, a \$48 million increase from FY20 enacted levels.

Centers for Medicare and Medicaid Services (CMS):

Analysis of Key CMS-Related Drug Pricing Reform Provisions

- The President’s budget request expresses support for "comprehensive drug pricing reform legislation, including modernization of the Part D benefit", asserting that doing so would reduce the federal deficit by \$135 billion over the next ten years.
- The budget request does not expressly support the bipartisan Senate Finance Committee passed S. 2543, the *Prescription Drug Pricing Reduction Act (PDPRA)*, sponsored by Chairman Chuck Grassley (R-Iowa) and Ranking Member Ron Wyden (D-Ore.).
 - However, the \$135 billion in projected savings closely matches the Congressional Budget Office’s (CBO) score for PDPRA.
 - Many are interpreting this as a tacit endorsement of this legislation by the White House.
 - Supporting budget documents also indicate that the Administration “supports legislative efforts to improve the Medicare Part D benefit by establishing an out-of-pocket maximum, improving incentives to contain costs, and reducing out-of-pocket expenses for seniors” and “changes to bring lower-cost generic and biosimilar drugs to patients” that “would increase competition, reduce drug prices, and lower out-of-pocket costs for patients at the pharmacy counter”.
- Notably, the budget request does not mention the Administration’s ideas to establish an International Pricing Index (IPI) or implement a Most Favored Nation policy, both of which would generally tie what Medicare pays for some drugs to the amount paid by other countries.
- Also noteworthy, the budget request reduces [Medicaid spending](#) over the next ten years by 16%, and calls for “Medicaid reform [that] will restore balance, flexibility, integrity, and accountability to the State-Federal partnership”.
 - Although details are lacking, it appears to allude to the Administration’s recent proposal to transform Medicaid from an “entitlement” program to a “block grant” program.
 - The Medicaid reductions, in combination with the section entitled “health care reform vision” – that combines cuts on Medicaid spending and cuts to Affordable Care Act (ACA) federal subsidies – **add up to a combined trillion dollars in healthcare cuts** according to the [New York Times’ analysis](#).

Analysis of Key CMS-Related Anti-Kickback Statute & Physician Self-Referral Provisions:

- HHS’s FY21 budget request states that it will continue to work on the goals outlined in its 2019-issued proposed rules to “modernize key regulations that advance the movement to value-based

care and paying for outcomes” via reforms to the Anti-Kickback Statute and the Physician Self-Referral regulations (Stark Law).

- Effective CY2022, HHS will:
 - create new, regulatory exceptions to the Stark Law for value-based arrangements allowing “physicians and other healthcare providers to design and enter into value-based arrangements that improve quality outcomes, produce health system efficiencies, and lower costs”;
 - establish a “new process for physicians to self-report inadvertent, technical non-compliance violations of the law and excludes physician-owned distributors from the indirect compensation exception, if physician owners generate more than 40 percent of the physician-owned distributor’s business” [A budget impact is not available.]; and
 - reinforce the law’s “goal of protecting patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician’s financial self-interest”.

Analysis of Key CMS-Related Prior Authorization Provisions:

- The budget request states that effective CY2022, HHS will establish a prior authorization program for “high utilization practitioners of radiation therapy, physical therapy services, advanced imaging, and anatomic pathology services”.
 - The budget request notes that both the Medicare Payment Advisory Commission (MedPAC) & the U.S. Government Accountability Office (GAO) have found that certain in-office ancillary services are “prone to inappropriate physician self-referral and overutilization”.
 - The budget impact of this proposal is not available.

Analysis of Key CMS-Related Medical Device Provisions:

- The budget request notes that CMS finalized a proposal last year to allow for an alternative pathway for new technology add-on payments (NTAP) under the Inpatient Prospective Payment System (IPPS) and pass-through payment status under the Outpatient Prospective Payment System (OPPS) for medical devices that receive the FDA breakthrough device designation for accelerated approval or clearance beginning in FY20.
- It also notes that CMS increased the NTAP amount from 50 percent to 65 percent, or 75 percent for some antimicrobials, to more adequately cover the costs and incentivize the use of these new technologies.
- The budget request flags that CMS clarified what it means for a device to meet the substantial clinical improvement criteria necessary to obtain these increased new technology add-on payments.
- Finally, the budget request mentions that CMS established a transitional add-on payment adjustment to support the use of new and innovative renal dialysis equipment or supplies furnished by dialysis facilities.

Food and Drug Administration (FDA)

- \$6.2 billion requested for Food and Drug Administration (FDA), an increase of \$265.4 million (4.5%) over FY20 enacted levels. Includes:
 - \$3.3 billion for budget authority, an increase of \$25.4 million over FY20 enacted levels; and
 - \$2.9 billion for user fees, an increase of \$240 million over FY20 enacted levels.

- Note: Increases to prescription and generic drug user fees appear to be the source supporting the growth of the FDA budget.
- Funding for key FDA programs include:
 - Human Drugs: \$2.02 billion requested for the Center for Drug Evaluation and Research (CDER), an increase of \$49.2 million over FY20 enacted levels.
 - Biologics: \$425 million requested for the Center for Biologics Evaluation and Research (CBER), an increase of \$6 million over FY20 enacted levels.
 - Devices: \$638.5 million requested for the Center for Devices and Radiological Health (CDRH), an increase of \$38.6 million over FY20 enacted levels.
- Other funding increases of interest include:
 - \$18 million requested to build an integrated knowledge management system and portal for medical devices to implement FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence, and cybersecurity.
 - \$119.6 million requested for Bioterrorism-Medical Countermeasure activities, an increase of \$5 million above FY 20 requested levels.
 - \$5 million requested to support Executive Order 13877 "Modernizing Influenza Vaccines in the U.S. to Promote National Security and Public Health" at CDER (\$0.5M), CBER (\$2.0M), CDRH (\$0.5M), Headquarters (\$2.0M).
 - \$10 million requested for artificial intelligence (AI) and other emerging technologies at CDRH (\$5 mil), Office of Regulatory Affairs (ORA - \$2.1 mil), Center for Food Safety & Applied Nutrition (CFSAN - \$1.6 mil), and Headquarters (\$1.5 mil).
 - The budget request also proposes the establishment of a new user fee program: the over-the-counter monograph user fee. *[Congress would first have to pass legislation to authorize FDA to collect user fees under any such programs.]*

21st Century Cures Act (Cures Act)

- In the budget request, FDA notes that the *Cures Act* authorized \$70 million for the FDA Innovation Account for FY21, \$5 million less than the Act authorized for FY20.
 - FDA says that it will use the authorized funding to "accelerate medical product innovation, reduce regulatory burden, increase efforts for critical scientific and methodological research, and increase the involvement of patients and their perspectives in research and the medical product development process".
 - The budget request does not include any additional funds for the FDA Innovation Account outside what was authorized by the *Cures Act*.

Cannabis/CBD

- The budget request includes \$5 million from FDA directed towards the regulation of cannabis and CBD derived prescription drugs and consumer products.
 - It prioritizes the development of new policy, review of product applications, inspections, enforcement, and targeted research into this category of products.
 - It also flags that FDA has seen a large increase in unlawful and unregulated CBD products since the passage of the Farm Bill that could harm patients.
- The \$5 million within FDA includes:
 - \$2 million to the Office of Regulatory Affairs (ORA);

- \$2 million to the Center for Food Safety and Applied Nutrition (CFSAN);
- \$500,000 to FDA Headquarters; and
- \$500,000 to the Center for Veterinary Medicine.

Drug Pricing

- The budget request for FDA contains language dedicating itself to promoting efforts and supporting bipartisan drug pricing proposals to make the development of generics and biosimilars more “transparent, efficient, and predictable” and to “address regulatory barriers...and [close] loopholes that hinder development of generics, will promote more competition, and advance patient access to more affordable medicines”.

Outside Statement on FDA’s FY21 Budget Proposal

The Alliance for a Stronger FDA – a multi-stakeholder alliance representing consumers, patient groups and industry united in advocating for FDA funding – offered tempered praise of the Administration’s continued commitment to FDA, but said “further increases are going to be needed for FDA because the mission and responsibilities of FDA are still growing and the science is becoming more complex”. *The Alliance for a Stronger FDA’s statement is available [here](#) and analysis [here](#).*

National Institutes of Health (NIH)

- The President’s budget requests \$38.7 billion for NIH, \$3.0 billion less than the FY20 enacted levels.
 - Includes \$404 million in resources made available through the *21st Century Cures Act (Cures Act)* and \$248 million in mandatory resources.
- Funding for several key initiatives that would support the biomedical innovation ecosystem include:
 - \$190 million for the NIH Innovation Account (*Cures Act*)
 - \$355 million to support the highest priority research activities of the Agency for Healthcare Research and Quality (AHRQ), that will be relocated into a proposed new National Institute for Research on Safety and Quality (NIRSQ) at NIH. *[The budget request proposes closing AHRQ again this year, however Congress would first have to pass legislation to authorize the closure, and the creation of a new Institute.]*
 - \$1.4 billion for opioids and pain research across NIH, including \$532.6 million for the Helping to End Addiction Long-term (HEAL) initiative.
 - \$50 million for the second year of the 10-year National Cancer Institute (NCI) initiative to accelerate and expand drug discovery and clinical trials via the creation of a national shared data resource for childhood cancer research.
 - \$15 million for the Institutional Development Award (IDeA) program States Pediatric Clinical Trials Network (ISPCTN) to broaden access to cutting-edge, multi-site pediatric clinical trials.
 - \$16 million to support the President’s *Ending the HIV Epidemic: A Plan for America*, which aims to reduce new infections in the U.S. by 75% by 2025 and 90% by 2030.
 - Includes \$6 million previously provided in FY20 to expand the NIH-sponsored Centers for AIDS Research (CFAR) within the National Institute for Allergy and Infectious Diseases (NIAID).
- The budget request also lists the following overall national priorities for NIH to be addressed by investment in research:
 - combatting the opioid epidemic, eradicating HIV, supporting neonatal research, developing novel approaches to treating sickle cell disease, supporting the Childhood Cancer Data

Initiative, increasing investments to develop a universal influenza vaccine, improving prevention and treatment of tick-borne diseases, continuing the precision medicine initiative, developing new approaches to address chronic disease with artificial intelligence, and establishing a consortium charged with innovating large-scale gene vector production.

Outside Statements on NIH's FY21 Budget Proposal

Research!America – an advocacy-oriented alliance comprising members from a vast array of medical, health and scientific fields – issued a statement expressing appreciation that the Administration's proposed increases to NIH “advance much-needed progress in pediatric cancer and pain research.” However, it said that overall, the proposed budget would “deal a devastating blow to patients and their families”. Specifically, Research!America cited “steep cuts to NIH which would undermine crucial, lifesaving research” and cuts to other “critical investments,” such as the “cuts[s to] CDC by 10%, NSF by 7%, and zero[ing] out the budget for AHRQ” as some of the reasons for its concern. *Research!America's full statement on the FY21 budget request is available [here](#).*

The Association of American Universities (AAU) in a statement expressed concern that despite the fact that the entire FY21 budget request “prioritizes some areas of research – such as artificial intelligence”, overall the “deep funding cuts and policy proposal” in the budget request could “harm America's position as the world's leader in research, science, and higher education”. AAU also called for reinvesting in the “government-support research and government-university partnership that have made our nation and its universities, laboratories, technology, and economy the envy of the world”. *AAU's statement on the FY21 budget request is available [here](#).*

Office of the National Coordinator for Health Information Technology (ONC)

Health IT:

- \$51 million requested for the ONC to continue “to advance the interoperability and usability of health IT while reducing provider burden, combatting information blocking, and advancing standards development” - a decrease of \$9 million from FY20 enacted levels.

HHS Cross-Agency Initiatives

Biodefense and Public Health Preparedness

- \$2.6 billion requested for the Public Health and Social Services Emergency Fund (PHSSEF), a \$1 million decrease from FY20 enacted levels.
 - The PHSSEF provides emergency medical response capacity, pandemic influenza preparedness, and cybersecurity, and advances medical countermeasure development and stockpiling.
- \$562 million requested for Biomedical Advanced Research Development Authority (BARDA, which has supported the development of more than 100 chemical, biological, radiological, and nuclear (CBRN) medical countermeasure product candidates.
 - BARDA has been level funded since the FY19 Continuing Resolution (CR).
- \$535 million request for Project BioShield, a \$200 million reduction from FY20 enacted levels.
 - However, this cut is offset by \$200 million the entity received last year in an emergency supplemental Ebola funding package, to “be available to procure medical countermeasures in FY 2021.”

- Project BioShield supports HHS efforts to protect the public against CBRN threats through rapid support of research, late-stage development, and acquisition of high priority and novel medical countermeasures.
- \$705 million requested (level funding) for the Strategic National Stockpile, a program that provides ongoing support for management, delivery, storage, and replenishment costs to the medical countermeasures included in the stockpile.
- \$310 million requested for HHS Pandemic Influenza activities, an increase of \$50 million above FY20 enacted levels.
- \$88 million requested to support the National Disaster Medical System (NDMS), an \$11 million increase above FY20 enacted levels.
 - NDMS is a federally coordinated system of intermittent federal employees who deploy in the event of a natural or manmade disaster to provide critical medical services, protect public health, and help communities recover faster.
- \$413 million requested for the CDC’s “Emerging and Zoonotic Infectious Disease” program, a decrease of \$157 million from FY20 enacted levels.
- \$532 million requested (a reduction of \$39 million) for CDC’s global health activities that “help protect Americans from major health threats such as Ebola, Zika virus, and pandemic influenza.”
 - Explanatory documents indicates that of this, an additional \$50 million has been invested, for a total of \$175 million, to “continue efforts to help protect 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... 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 2019 Novel Coronavirus (2019-nCoV) in China”.

Combating Antibiotic Resistant Bacteria:

- \$160 million requested within BARDA to support advanced development of broad-spectrum antimicrobials for drug-resistant biothreat pathogens, including vaccines, diagnostics, and novel antibiotic treatments.
 - Includes support for collaboration with the NIH, academia, and private partners to sustain and expand the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X).
 - CARB-X – a novel consortium approach to accelerate investment in early development of innovative medical countermeasures to fight antibiotic-resistant bacteria – has accelerated the efforts of 47 companies, with six projects advancing to clinical evaluation.
- \$138 million requested (a \$1 million increased over FY20 enacted levels) to support CDC efforts to prevent, detect, and respond to antibiotic-resistant infections.

Combating the Opioid Epidemic

- \$5 billion is requested across HHS agencies to combat the opioid overdose epidemic, including \$169 million in new funding. This includes:
 - \$1.6 billion for SAMHSA State Opioid Response Grant program – an increase of \$85 million over FY 2020 enacted levels;
 - \$1.9 billion for SAMHSA’s Substance Abuse Prevention and Treatment Block Grant;

- \$655 million for Health Resources and Services Administration (HRSA) to support the opioid and substance abuse response in community health centers and to support the response to the drug problem in rural America;
- \$75 million for FDA’s opioids activities;
- \$575.6 million for CDC’s opioid abuse and overdose prevention activities; and
- \$1.4 billion for opioids and pain research across NIH, including:
 - \$266.3 million within National Institute of Drug Abuse (NIDA) to respond to the opioid crisis.

Ending the HIV Epidemic: A Plan for America

- \$716 million requested for the second year of the *Ending the HIV Epidemic* initiative, which aims to reduce new infections in the U.S. by 75% by 2025 and 90% by 2030. This includes:
 - \$371 million for CDC to reduce new HIV infections;
 - \$302 million for Health Resources and Services Administration (HRSA) to deliver HIV care through the Ryan White HIV/AIDS Program and to supply testing, evaluation, prescription of PrEP, and associated medical costs through the Health Centers program;
 - \$27 million to the Indian Health Service (IHS) to tackle the epidemic in American Indian and Alaska Native communities; and
 - \$16 million for NIH for evaluation activities to identify effective interventions to treat and prevent HIV.

National Science Foundation (NSF)

- \$7.74 billion requested for NSF in FY21, a \$675 million increase above the FY20 requested levels, but ultimately a 6.5% decrease from the FY20 enacted levels.