

LEGISLATIVE PROPOSALS

Discretionary Legislative Proposals**Expanding the Hiring Authorities for NIH Undergraduate Scholarship Program.**

In an effort to improve equity in STEM (science, technology, engineering, and math) education, the NIH Undergraduate Scholarship Program (UGSP) offers competitive college scholarships to students from disadvantaged backgrounds. The program offers college scholarships, up to \$20,000 annually, in return for two payback obligations in the form of service to NIH under 42 CFR § 68b.7. The proposal would allow for expanding the hiring authorities that may be used to appoint awardees in the Undergraduate Scholarship Program (UGSP), allowing the use of the more appropriate Intramural Research Training Award hiring authority to appoint all scholarship awardees during the summer payback and some award recipients during the full-year payback obligation. This would allow awardees to receive benefits and support provided to other NIH public health interns and trainees, and would streamline administration of the program compared to appointing awardees using the time-consuming Title 42 employee appointment authority.

Permit the Mailing of Electronic Nicotine Delivery Systems Through the United States Postal Service for Certain Research and Public Health Purposes.

The Prevent All Cigarette Trafficking Act of 2009 (PACT Act), Public Law 111–154, codified in 18 U.S.C. 1716E, imposes certain restrictions on the mailing of cigarettes and smokeless tobacco. Title VI of Division FF of the Consolidated Appropriations Act of 2021 instructed the U.S. Postal Service (USPS) to apply the same restrictions to the mailing of electronic nicotine delivery systems (ENDS). The proposal would allow the mailing of ENDS for the purposes of conducting public health research, investigations, and surveillance. This would remove restrictions that are creating serious obstacles to the ability of NIH-funded researchers to obtain consistent ENDS products and to conduct research on the factors that contribute to ENDS use and addiction, and the potential long-term health consequences of ENDS.

Modify Statutory Requirements for the AIDS Research Advisory Committee (ARAC)

The AIDS Research Advisory Committee (ARAC) was established in 1988 in section 2304 of the Public Health Service Act (42 U.S.C. 300cc-3). The committee's membership was restricted to physicians whose clinical practice includes a significant number of patients with acquired immune deficiency syndrome (AIDS). The ARAC was directed to advise the Director of the National Institute of Allergy and Infectious Diseases (NIAID) or other NIH Institutes on the appropriate research activities to be taken with respect to clinical treatment of AIDS. The proposal would modify statutory requirements for the ARAC that are no longer in line with the current state of science, which recognizes that the advent of effective HIV antiretroviral therapies has enabled nearly all people living with HIV to avoid progressing to AIDS. The requirements of the ARAC limit NIH's ability to receive advice on the current and future directions of HIV/AIDS research. Given NIH's need to receive scientifically appropriate guidance, NIH proposes to modify the statutory requirements of ARAC to reflect the current status of HIV/AIDS science. The modified requirements would allow NIH to address the current and future needs of the research community, and to seek advice from a committee with relevant experience in basic virology, immunology, medicine, community engagement, and public health. The changes would include renaming the committee from the AIDS Research Advisory

Committee to the HIV Research Advisory Committee, revising membership standards to focus on those with basic and clinical research, clinical care, or other expertise as well as lived experience with HIV, and stating the committee's duties to advise NIH on matters relating to the full spectrum of HIV research rather than only AIDS.

Mandatory Legislative Proposals

Reauthorization of the Special Statutory Funding Program for Type 1 Diabetes Research.

Codified in Section 330B of the PHS Act, this Program began in FY 1998 with a funding level of \$30 million per year over 5 years. In December 2000, the Program was renewed to increase the FY 2001 and 2002 levels to \$100 million and to extend the FY 2003 level at \$100 million of mandatory funds. In December 2002, the Program was extended and increased to \$150 million per year for FY 2004-2008. The Program has subsequently been extended multiple times at this annual level of \$150 million. Most recently, the Program was extended at a level of \$150 million per year for FY 2021-2023 and funded in the FY 2024 continuing resolutions at prorated amounts corresponding to the \$150 million annual level. The proposal would reauthorize the NIH Special Diabetes Program for Type 1 Diabetes Research at an annual amount of \$250 million in FY 2024, \$260 million in FY 2025, and \$270 million in FY 2026, as well as exempt this funding from mandatory sequestration. The three-year reauthorization would facilitate planning of long-term research projects, and the reauthorized funding level would restore the lost purchasing power of the program since it was last increased to the level of \$150 million in FY 2004.

Provide Outyear Funding and Enhanced Operating Authorities to the National Cancer Institute to Conduct Initiatives to Deliver Cancer Moonshot Goals.

In February 2022, President Biden announced a reignition of the Cancer Moonshot, highlighting new goals: to reduce the cancer death rate by half within 25 years to improve the lives of people with cancer and cancer survivors, and to reduce cancer health disparities. The legislative proposal would provide \$1.448 billion of mandatory funding in each of FY 2025 and FY 2026 to advance Cancer Moonshot priorities, including doubling cancer clinical trial accruals and establishing a comprehensive cancer data ecosystem to accelerate the pace of cancer discovery and speed the introduction of precision oncology into clinical practice.¹⁹⁸ The proposal would also grant NCI five key operating authorities – Other Transactions Authority, Management and Operating Authority, Strategic Partnership Authority, enhanced pay authority, and facilities improvement authorities -- to support these efforts.

Other Transaction (OT) Authority for Cancer Moonshot activities would enable NCI to scale up clinical trials and other National Cancer program activities to deliver Cancer Moonshot goals. Grants and contracts would remain the norm for many NCI awards, but OT Authority would enable accelerated progress toward cutting cancer deaths in half. OT Authority would permit NCI to take a more active, substantive role in managing the science of trials and would allow NCI to bring non-traditional partners, companies, and individuals into NCI's expanded and re-engineered clinical trial enterprise.

¹⁹⁸ For more information on the reignited Cancer Moonshot, see the NCI FY 2025 Congressional Justification.

Management and Operating (M&O) Authority would grant the NCI Frederick National Laboratory for Cancer (FNLCR) access to a valuable authority that other U.S. national laboratories enjoy, but FNLCR currently lacks. Unlike many of the other existing Federally Funded Research and Development Centers (FFRDCs) at national labs, the NCI FFRDC only has access to basic, limited FFRDC authorities under current law. M&O contracting, as defined by Federal Acquisition Regulations (FAR) subpart 17.6, would be especially beneficial to deliver rapid, creative solutions required for Cancer Moonshot success.

Strategic Partnership Authority would give FNLCR the flexibility to conduct research, development, commercialization, and training activities with or on behalf of other public or private research labs, allowing the labs to access the unique FNLCR facilities, services, and technical expertise to advance cancer science and Moonshot priorities. Another advantage of Strategic Partnerships is the possibility of establishing more flexible terms for intellectual property and licensing rights. This authority would include allowing NCI to accept, retain, and use funds and tangible and intangible property provided by others to support such activities. The authority also allows any funds received to support such activities to remain available until expended.

Enhanced hiring authority would allow NCI to use funds to make or rescind appointments of scientific, medical, and professional personnel without regard to any provision in Title 5 governing appointments and removals under the civil service laws, and may use funds to fix the compensation of such personnel at a rate to be determined by the Director of the NCI, up to the amount of annual compensation (excluding expenses) specified in Section 102 of Title 3, United States Code. The ability of NCI to deliver on the promise of the Cancer Moonshot will significantly depend on NCI's ability to compete with the private sector for top talent to lead Moonshot programs. Using this hiring authority, NCI can attract and hire top talent capable of driving progress in cancer discovery, reducing cancer deaths, and ensuring broad, equitable access to optimum standards of cancer care.

Enhanced facilities and improvement authority would allow NCI to use up to \$50 million for alterations, repairs, improvements, and construction of laboratories and other facilities of the Institute (previous Appropriations acts set this authority at \$30 million). This enhanced authority is particularly important to maintain and enhance research operations at NCI's facilities at Fort Detrick. Fifty years ago, when NCI received Fort Detrick laboratories and facilities from the Army, many were aging, substandard, and needed to be repaired or modernized. Over the years, despite NCI investment, these research facilities continued to age, wear, and degrade. To meet the needs of cancer patients and deliver on Cancer Moonshot goals, NCI must refurbish existing labs at Fort Detrick. This proviso would also support needed repair and improvements to certain NCI facilities at the Bethesda NIH campus.