



CONSORTIUM of SOCIAL SCIENCE ASSOCIATIONS

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ANALYSIS OF THE
DRAFT *21ST CENTURY CURES ACT*

As Marked up by the
House Energy and Commerce Subcommittee on Health

May 19, 2015

On May 14, the House Energy and Commerce Health Subcommittee approved by voice vote its [discussion draft](#) of the *21st Century Cures Act*. An amendment to an earlier discussion draft was introduced by full committee Chairman Fred Upton (R-MI), Rep. Diana DeGette (D-CO), Health Subcommittee Chairman Joe Pitts (R-PA), full committee Ranking Member Frank Pallone, Jr. (D-NJ), and Health Subcommittee Ranking Member Gene Green (D-TX). The bipartisan amendment incorporated federal agency and scientific community feedback to a draft bill the preceding day.

The legislation is scheduled to be considered by the full Energy and Commerce Committee the week of May 18; the Committee will convene for opening statements only on May 19 and on May 20 to mark up the bill.

At the Subcommittee markup, Committee members praised the efforts surrounding the draft bill, echoing Chairman Pitts who noted in his opening statement that “there is much in this bill to be proud of and enthusiastic about and even optimistic for,” but noted that there is still more work to be done to improve the bill. There remain a number of provisions in the new version that have not been clarified or are still under consideration.

The *21st Century Cures Act* has yet to be introduced. Notably, the latest iteration would authorize a \$1.5 billion increase for fiscal years (FY) 2016-2018 to the National Institutes of Health (NIH) at the following levels:

- FY 2016 — \$31.811 billion
- FY 2017 — \$33.331 billion
- FY 2018 — \$34.851 billion.

If appropriated, this would be \$500 million more than the \$1 billion and 3.3 percent increase proposed by the Administration in FY 2016. The Act is an authorization bill, therefore it can only make funding level recommendations.

Additional information on the draft legislation to be marked up is available [here](#).

NIH Innovation Fund (Sec. 1002)

In addition to top-line funding levels for NIH, the draft bill would authorize a five-year, \$10 billion NIH Innovation Fund and \$2 billion per year in mandatory appropriations for each of the fiscal years 2016-2020 via the NIH Director, “in addition to any amounts otherwise made available” to NIH. This funding would be provided from “any of Funds in the Treasury not otherwise appropriated.” The measure would create a new Accelerating Advancement Program (AAP) and would authorize no less than \$500 million in support of high-risk, high reward research, research by early stage investigators, small businesses, and the NIH intramural program. It would preclude these funds from being transferred by the NIH director. The Innovation Fund would provide support to research areas identified via a strategic plan defining research priorities and categorizing areas “to be known as

strategic focus areas,” including biomarkers, precision medicine, infectious diseases, and antibiotics. Basic research would remain a priority.

NIH Research Strategic Plan (Sec. 1021)

The *21st Century Cures Act* would require that the NIH issue five-year plans for “biomedical research strategy” beginning with FY 2016-2020. It would require the NIH institutes and centers (ICs) to develop individual plans using a common template identifying strategic focus areas. The plans would be required to be overarching and have trans-NIH strategic focus areas, “to be known as *Mission Priority Focus Areas*, which best serve the goals of preventing or eliminating the burden of a disease or condition and scientifically merit enhanced and focused research over the next 5 years.” It would direct the NIH to provide a plan and post it on the agency’s website 270 days after enactment of the subsection. Annual progress reviews would also be required.

Increasing Accountability at NIH (Sec. 1022)

The draft bill maintains the current practice of appointing IC directors, which currently entails a Presidential appointment for the director of the National Cancer Institute (NCI) and appointment of the remaining NIH ICs directors by the NIH director. Further, the IC directors would be required to report directly to the NIH director. The IC directors would be appointed for five-year terms; however, the NIH director would have the authority to remove directors prior to expiration of these five-year terms. There is no limit on the number of terms a director can serve. Terms for current IC directors would commence on the date of enactment of the legislation.

The current version of the draft bill maintains the changes to the current grant process, stating: “Before an award is made by a national research institute or national center for a grant for a research program or project...other than an award constituting a renewal of such a grant, the director of such national institute or center shall personally review and approve the award.” The directors are to take into consideration whether the “mission of the national research institute or national center and the scientific priorities identified in the strategic plan and whether other agencies are funding programs or projects to accomplish the same goals.” This version of the draft bill removes language requiring the “goals of the research program or project are a national priority and have public support” and “whether the monetary investment is worth the potential scientific discovery.”

An Institute of Medicine (IOM) study would be required not later than two years after the date of enactment to complete a study on the extent to which biomedical research conducted or supported by Federal agencies is duplicative, and submit a report to the Congress on the results of such study, including recommendations on how to prevent such duplication. The draft removes the provisions requiring a GAO study (see [Update, February 24, 2015](#)).

NIH Travel (Sec. 1025)

Replacing the placeholder in the prior version of the draft bill, this version notes that it is “the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the National Institutes of Health.”

Supporting Emerging Young Scientists

Section 1041 is designed to improve the loan repayment programs (LRP) for NIH researchers. Specifically, it would require the Secretary of the Department of Health and Human Services (HHS) to establish a program “based on workforce and scientific needs” that the Federal government would agree to pay for each year of engaging in research up to \$50,000 of the principal and interest of the educational loans of such health professionals. It also updates the LRP for minority health disparities research, AIDS research, contraception and infertility research, pediatric research, and research generally by increasing the amount available from \$35,000 to \$50,000.

Section 1042 would require the NIH director to provide a report on the agency’s efforts to attract, retain, and develop emerging scientists no later than 18 months after the bill’s enactment.

Capstone Grant Program

The draft bill would create a capstone grant program to support outstanding scientists who have been funded by NIH. The purpose of the Capstone Award would be to “facilitate the successful transition or conclusion of research programs, or for other purposes, as determined by the Director of NIH, in consultation with the directors of the national research institutes and national centers.” The draft bill directs the NIH director, in consultation with the NIH IC directors, to determine duration and amount of each award. Individuals who receive the award, however, will not be eligible to be “principle investigator” status on subsequent awards from the NIH.

Promoting Pediatric Research through NIH

Section 1081 would require the agency to establish a national pediatric research network, composed of national research institutions and national centers that would operate as a consortium. Section 1082 expresses a sense of Congress that the NIH should encourage a global pediatric clinical trial network.

Section 1083 would direct the NIH director to convene a workshop of experts on pediatrics and experts on geriatrics to provide input on the appropriate age groupings to be included in research studies involving human subjects, and acceptable scientific justifications for excluding participants from a range of age groups from human subjects research studies. Not later than 180 days after the workshop’s conclusion, the NIH director is directed to publish guidelines (1) addressing the consideration of age as an inclusion variable in research involving human subjects; and (2) identifying criteria for justifications for any age-related exclusions in such research. Further, the director is to publish the findings and conclusion resulting from the workshop on the NIH’s website. The agency is also directed to disclose the number of children included in research that is supported or conducted by NIH, disaggregated by developmentally appropriate age group, race, and gender.

Advancement of NIH Research and Data Access (Sec. 1101)

The *21st Century Cures Act* would provide authority to the NIH director to “require” NIH recipients of grants to share the public data generated from such research.