Implementation of 21st Century Cures Act

Advisory Committee to the NIH Director

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Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH
Implementation of 21st Century Cures Act for NIH Innovation Projects

Cures Language Summary:

- NIH Director to submit a work plan to Congress not later than 180 days after enactment of Cures (June 11, 2017)

- Work plan to include:
  - Recommendations from the Advisory Committee
  - Amount of money to be obligated or expended in each fiscal year (FY2017 – FY2026) for each NIH Innovation Project

http://docs.house.gov/billsthisweek/20161128/CPRT-114-HPRT-RU00-SAHR34.pdf
Implementation of 21st Century Cures Act for NIH Innovation Projects (cont.)

Cures Language Summary

- NIH Director shall seek “recommendations from the Advisory Committee” to the Director of NIH on:
  - The amount of money to be obligated or expended in each fiscal year for each NIH Innovation Project
  - The contents of the proposed work plan – project description and justification
  - Whether such projects are advancing the strategic research priorities identified in the NIH Strategic Plan
NIH Innovation Projects

- Establishes the NIH Innovation Account
  - Support provided to 4 programs
    - Precision Medicine Initiative® (PMI)
    - The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative
    - The Beau Biden Cancer Moonshot℠
    - Regenerative Medicine

<table>
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<th>Fiscal Year</th>
<th>BRAIN</th>
<th>PMI</th>
<th>Cancer Moonshot</th>
<th>Regenerative Medicine</th>
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<td>1,511</td>
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*Not including Presidential initiatives (e.g., Precision Medicine Initiative, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, The Beau Biden Cancer Moonshot℠, Regenerative Medicine).*
NIH Innovation Projects (cont.)

- Establishes the NIH Innovation Account
  - Funding: $4.8B for 10 years that must be appropriated each year
  - Does not count against the budget caps
  - Reauthorizes NIH:
    - FY18: $34,851,000,000
    - FY19: $35,585,871,000
    - FY20: $36,472,442,775

![Graph showing budget allocations](image_url)
NIH-Wide Strategic Plan Framework

Overview
- Mission of NIH
- Unique moment of opportunity in biomedical research
- Current NIH-supported research landscape
- Constraints confronting the community in the face of lost purchasing power

Objective 1: Advance Opportunities in Biomedical Research

Fundamental Science
- Foundation for progress
- Consequences often unpredictable
- Technology leaps catalyze advances
- Data science increases impact/efficiency

Health Promotion/Disease Prevention
- Importance of studying healthy individuals
- Advances in early diagnosis/detection
- Evidence-based reduction of health disparities

Treatments/Cures
- Opportunities based on molecular knowledge
- Breakdown of traditional disease boundaries
- Breakthroughs need partnerships, often come from unexpected directions
- Advances in clinical methods stimulate progress

Objective 2: Set Priorities
- Incorporate disease burden as important, but not sole factor
- Foster scientific opportunity, need for nimbleness
- Advance research opportunities presented by rare diseases
- Consider value of permanently eradicating a pandemic risk

Objective 3: Enhance Stewardship
- Recruit/retain outstanding research workforce
- Enhance workforce diversity
- Encourage innovation
- Optimize approaches to inform funding decisions
- Enhance impact through partnerships
- Ensure rigor and reproducibility
- Reduce administrative burden

Objective 4: Excel as a Federal Science Agency by Managing for Results

NIH...
Turning Discovery Into Health

Lawrence.Tabak@nih.gov