

Section by Section: The National Biomedical Research Act

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are critical to the next generation of biomedical innovation. These agencies need predictable, robust funding in order to conduct the research, development, and review of tomorrow's new discoveries and medical breakthroughs.

The National Biomedical Research Act would create a new funding stream, the Biomedical Innovation Fund, which would provide \$10 billion per year in new funding for select initiatives at our nation's top research institutions, NIH, and FDA, in years when congressional appropriations to the agencies increase. It will provide stability to our nation's scientists while protecting the integrity of other programs under the jurisdiction of the Labor-Health and Human Services (HHS) and Agriculture Appropriations Subcommittees.

Section 1. Short Title

Section 2. Definitions

Minimum amount – the amount of appropriations that an entity received in the previous fiscal year. The minimum amount is calculated without regard to sequester, user fees, distributions of the Biomedical Innovation Fund, or supplemental appropriations.

Section 3. Biomedical Innovation Fund

(a) and (b) *Establish the “Biomedical Innovation Fund”* – The “Fund” will receive \$10 billion from the Treasury each year from 2020-2029 and will keep any interest earned from investments in the Fund.

(c)
(2) and (3) *Distribution and Ratio* – The NIH and the FDA will receive a proportion of the Fund equal to that of the agency's proportion of discretionary funding compared to all agencies receiving monies from the fund.

(4) *Requirements for Distribution* –
The NIH and the FDA will only receive distributions from the Fund in years with the agencies appropriations are greater than the amount appropriated in prior year (the Minimum amount).

Laws passed after an appropriations bill that decrease funding for an agency below the “trigger” will not impact the distribution of the Fund. Laws passed after an appropriations bill that increase funding for an agency above the “trigger” will allow the Fund to be distributed if the “trigger” was not met in the appropriations bill.

If conditions for distribution are not met in a fiscal year, the fund will not be distributed and collect interest until conditions are met.

(5) *Allocation* – If the conditions for distribution are met, 20% of the amount available in the fund will be paid out that year, and each of the subsequent 4 years. This brings certainty and predictability to the funding. Monies will be available until expended.

(6) *Authorized Uses* – The Fund must be used to support—

- (A) basic research on the underlying basis of disease
- (B) research that fosters disruptive innovation
- (C) research related to diseases that disproportionately account for Federal health care spending
- (D) early career scientists
- (E) improving diversity in science
- (F) the development, review, and post-market surveillance of medical products

(G) regulatory science

(7) Interagency Transfers – Specifies that Fund dollars may be made available through interagency transfer to support research conducted jointly by the FDA or NIH and other federal agencies.

(d) *Investment of the Fund* – Amounts in the Fund not used for distribution will be invested in interest-bearing obligations of the United States in the form of special-issue securities. Any amounts that have already been distributed will not be invested. All earned interest will be used for purposes of the Fund.

(e) *Prohibition on Use* – The Fund may not be used for any purpose besides the activities listed in (c).

(f) *Deficit Reduction* – If the minimum amount for distribution of the Fund is not met for 3 consecutive years, all money in the Fund will be deposited into Treasury to reduce the deficit.

(g) *Reporting* – Each year, the Secretary of the Treasury will issue a report on the amounts and sources of the money transferred to the Fund, the expenditures from the Fund, and with recommendations about additional authorities to fulfill the purpose of the fund. Each agency will report about the use of the fund, the projects funded, the accomplishments that have resulted from the Fund, and the goals for future use of the Fund.

Section 4. Budgetary Provisions

Instructs the Office of Management and Budget to determine a breach of discretionary spending limits without the monies paid out by the Fund to assure that other programs in the Labor-HHS and Agriculture appropriations bills are not impacted.

Section 5. Offsetting Amendments

Sense of the Senate that the bill should be fully offset.