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To establish the “Biomedical Innovation Fund”, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. Warren (for herself, Mr. Sanders, Mr. Casey, Mr. Franken, Mr. Bennet, Mr. Whitehouse, Ms. Baldwin, Mr. Murphy, Mr. Kaine, Ms. Hassan, Mr. Cardin, Mr. Van Hollen, Mr. Markey, Ms. Hirono, Mr. Booker, and Ms. Harris) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To establish the “Biomedical Innovation Fund”, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Biomedical Research Act”.

SEC. 2. DEFINITIONS.

In this Act:

(1) DISCRETIONARY APPROPRIATIONS.—The term “discretionary appropriations” has the mean-
ing given such term in section 250 of the Balanced
Budget and Emergency Deficit Control Act of 1985

(2) FUND.—The term “Fund” means the Bio-
medical Innovation Fund established under section
3(a).

(3) MINIMUM AMOUNT.—The term “minimum
amount”, with respect to the applicable entity and
for an applicable fiscal year—

(A) means the amount equal to the great-
est amount of discretionary appropriations ap-
propriated to such entity for a fiscal year dur-
ing the period beginning with fiscal year 2017
and ending with the fiscal year before the appli-
cable fiscal year; and

(B) does not include—

(i) any reduction in an appropriation
under a sequestration order issued under
the Balanced Budget and Emergency Def-
cit Control Act of 1985 (2 U.S.C. 900 et
seq.);

(ii) amounts collected by the Secretary
of Health and Human Services under sub-
chapter C of chapter VII of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

(iii) amounts distributed under section 3(c)(2); or

(iv) amounts appropriated under a supplemental or emergency appropriation Act.

SEC. 3. BIOMEDICAL INNOVATION FUND.

(a) Establishment.—There is established in the Treasury of the United States a fund to be known as the “Biomedical Innovation Fund”, to be administered by the Secretary of the Treasury, consisting of—

(1) the amounts transferred to the Fund under subsection (b); and

(2) any interest earned on the investment of such amounts under subsection (d).

(b) Commitment to Biomedical Innovation.—Not later than September 1, 2017, and every year thereafter through 2026, the Secretary of the Treasury shall transfer $5,000,000,000 from the general fund of the Treasury into the Fund.

(c) Distribution of Amounts.—

(1) Calculation of Annual Fund Amount.—For fiscal year 2018 and each fiscal year thereafter, not later than 15 days after the latter of
the date of enactment of an appropriation Act making full fiscal year appropriations for such fiscal year to the entity described in paragraph (2)(A) and the date of enactment of an appropriation Act making full fiscal year appropriations for such fiscal year to the entity described in paragraph (2)(B), the Secretary of the Treasury shall calculate the total amount in the Fund that is available to be distributed for such fiscal year in accordance with paragraph (2).

(2) Distribution of amounts in the Fund.—Subject to the other provisions of this section, not later than 30 days after a calculation is made under paragraph (1) for a fiscal year, the Secretary of the Treasury shall distribute the amount available to be distributed for such fiscal year to each of the following entities:

(A) The National Institutes of Health.

(B) The Food and Drug Administration.

(3) Ratio.—The amount that the Secretary of the Treasury distributes to an entity described in subparagraph (A) or (B) of paragraph (2) during a fiscal year shall bear the same relation to the total amount calculated under paragraph (1) for such fiscal year as the amount of discretionary appropria-
tions appropriated to such entity for such fiscal year bears to the total amount of discretionary appropri-
ations appropriated to the entities described in sub-
paragraphs (A) and (B) of paragraph (2) for such fiscal year.

(4) REQUIREMENTS FOR DISTRIBUTION.—

(A) IN GENERAL.—The Secretary of the Treasury shall distribute amounts in the Fund during a fiscal year in accordance with para-
graph (2) only if—

(i) the discretionary appropriations for the entity described in paragraph (2)(A) is greater than the applicable min-
imum amount for such entity for such fiscal year; and

(ii) the discretionary appropriations for the entity described in paragraph (2)(B) is greater than the applicable min-
imum amount for such entity for such fiscal year.

(B) SUBSEQUENT LAW IMPACTING DIS-
TRIBUTION.—

(i) BELOW MINIMUM AMOUNT.—If a law is enacted or becomes effective after amounts are appropriated to each entity
described in subparagraph (A) or (B) of paragraph (2) for a fiscal year and such law decreases the amount appropriated to either such entity for such fiscal year from an amount that is greater than the applicable minimum amount to an amount that is less than or equal to such minimum amount, any amounts that were distributed by the Secretary of the Treasury under paragraph (2) shall remain so distributed for such fiscal year.

(ii) ABOVE MINIMUM AMOUNT.—If a law is enacted or becomes effective after amounts are appropriated for a fiscal year to each entity described in subparagraph (A) or (B) of paragraph (2) and such law increases the amount appropriated to either such entity for such fiscal year from an amount that is less than or equal to the minimum amount to an amount that is greater than such minimum amount, and all other conditions for distribution under this paragraph are met for the fiscal year, the amounts in the Fund shall be distrib-
uted by the Secretary of the Treasury under paragraph (2) for such fiscal year.

(C) FAILURE TO MEET REQUIREMENTS.—If the requirements under subparagraph (A) are not met during a fiscal year, amounts in the Fund shall—

(i) not be distributed under paragraph (2); and

(ii) remain in the Fund, earning interest in accordance with subsection (d), until such requirements, or the conditions under subsection (f), are met during a fiscal year.

(5) ALLOCATIONS.—

(A) IN GENERAL.—If amounts are distributed under paragraph (2) during a fiscal year, of the amounts so distributed—

(i) 20 percent shall become available for obligation during the fiscal year during which the distribution is made;

(ii) 20 percent shall become available for obligation during the first fiscal year after the fiscal year during which the distribution is made;

(iii) 20 percent shall become available for obligation during the second fiscal year
after the fiscal year during which the dis-
tribution is made;

(iv) 20 percent shall become available
for obligation during the third fiscal year
after the fiscal year during which the dis-
tribution is made; and

(v) 20 percent shall become available
for obligation during the fourth fiscal year
after the fiscal year during which the dis-
tribution is made.

(B) AVAILABILITY OF AMOUNTS.—Any
amounts distributed under paragraph (2) shall
remain available until expended.

(6) AUTHORIZED USES.—Amounts distributed
under paragraph (2) from the Fund shall be used to
support—

(A) basic research on the underlying basis
for disease to better address disease prevention,
 diagnosis, and treatment;

(B) research that fosters disruptive innova-
tion, such as—

(i) research on diseases or conditions
for which treatments exist but are inad-
equate, including chronic and acute pain;
(ii) research on diseases or conditions for which there are unmet medical needs;

(iii) research on diseases or conditions for which treatments exist but the side effect profiles of such treatments limit therapeutic potential;

(iv) research on new approaches to treatment of diseases using drugs, devices, or therapies that, at the time of distribution under paragraph (2), are not used or are underused; or

(v) research conducted by experienced investigators with a history of productive and innovative research, such that funding provides long-term stability for such research and allows such investigators to take greater risks, be more adventurous in their lines of inquiry, or take the time to develop groundbreaking techniques;

(C) research related to diseases that disproportionally account for Federal health care spending, including spending under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Medicaid program under title XIX of the Social
10
Security Act (42 U.S.C. 1396 et seq.), the
State Children’s Health Insurance Program
under title XXI of the Social Security Act (42
U.S.C. 1397aa et seq.), the TRICARE program
under chapter 55 of title 10, United States
Code, and hospital care and medical services
furnished by the Department of Veterans Af-
fairs under chapters 17 and 18 of title 38,
United States Code, such as research relating
to—

(i) diseases that disproportionally im-

(i) degenerative diseases, or

(iii) chronic conditions;

(D) early career scientists, such as

through—

(i) awarding research project grants

that support discrete, specified, and cir-

cumscribed projects to be performed by the

investigator in an area representing the

specific interests and competencies of such

investigator, to investigators—

(I) who are within 10 years of

completing a terminal research de-
gree; or
(II) who are within 10 years of completing a medical residency;

(ii) awarding grants that support career development experiences that lead to earlier research independence; and

(iii) awarding grants that support innovative training programs that, in addition to scientific training, provide additional training to enhance employment opportunities, including training in management and business, to—

(I) graduate students;

(II) post-doctoral fellows;

(III) individuals within 10 years of completing a terminal research degree; or

(IV) individuals within 10 years of completing a medical residency;

(E) research efforts that increase the potential for breakthrough discoveries across a diverse set of investigators, research groups, and institutions, which may include supporting—

(i) investigators that are members of traditionally underrepresented racial and ethnic groups;
(ii) research groups that are diverse in size; or

(iii) institutions that increase the geographic diversity of funding provided by the National Institutes of Health;

(F) the development, review, and post-market surveillance of medical products, as determined by the Secretary of Health and Human Services; and

(G) research to carry out the goals of the strategy and implementation plan for advancing science to promote public health and advance innovation in regulatory decisionmaking developed under section 1124 of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 393 note), and other such research activities to improve the predictability, consistency, and efficiency of science-based decision-making concerning medical products, including facilitating the timely introduction of new technologies and methodologies in a safe and effective manner as determined by the Secretary of Health and Human Services.

(7) INTERAGENCY TRANSFERS.—Amounts distributed from the Fund under paragraph (2) shall
be available through interagency transfer to support research conducted jointly by the National Institutes of Health or the Food and Drug Administration and other Federal agencies.

(d) INVESTMENT OF FUND BALANCES.—

(1) IN GENERAL.—Amounts in the Fund shall be invested in interest-bearing obligations of the United States in the form of special-issue securities, paying interest to the Fund at rates applicable to such securities, and such amounts shall be redeemable by the Secretary of the Treasury, for purposes of distribution under subsection (c)(2).

(2) DISTRIBUTED AMOUNTS.—Any amounts that have been distributed during a fiscal year under subsection (c)(2) shall not be considered amounts in the Fund for the purpose of this subsection.

(e) PROHIBITION.—Amounts in the Fund may not be made available for any use other than a use described in subsection (c)(6).

(f) TRANSFER TO REDUCE THE DEFICIT.—

(1) IN GENERAL.—Subject to paragraph (2), if amounts in the Fund are not distributed by the Secretary of the Treasury under subsection (c)(2) for any 3 consecutive fiscal years, the Secretary of the Treasury shall transfer all amounts in the Fund to
the general fund of the Treasury for purposes of redu-
cing the Federal deficit.

(2) **Year of Distribution.**—For purposes of paragraph (1), 3 fiscal years shall not be deemed to be consecutive if during any of such years the Sec-
retary of the Treasury has transferred all amounts in the Fund into the general fund of the Treasury in accordance with such paragraph.

(g) **Reports.**—

(1) **Secretary reports.**—

(A) **In general.**—Not later than November 30, 2018, and every year thereafter through 2027, the Secretary of the Treasury shall submit to the Committee on Appropriations of the Senate, the Committee on Appropriations of the House of Representatives, and the authorizing committees a report on the operation of the Fund during the fiscal year.

(B) **Contents.**—Each report shall in-
clude, for the fiscal year covered by the report, each of the following:

(i) A statement of the amounts, and the source of such amounts, transferred to,

credited to, and deposited into the Fund.
(ii) A description of any amounts distributed under subsection (e)(2) during the fiscal year.

(iii) A statement of the balance remaining in the Fund at the end of the fiscal year.

(iv) A statement of the amounts invested in interest-bearing obligations of the United States, and the interest earned on such investments.

(2) AGENCY REPORTS.—

(A) ANNUAL REPORTING.—For each fiscal year in which amounts are available for obligation under subsection (e)(5), the Director of the National Institutes of Health and the Commissioner of Food and Drugs shall report on the use of such amounts in the annual budget submission for such fiscal year of the National Institutes of Health and the Food and Drug Administration, respectively.

(B) NIH REPORTS.—Section 403(a) of the Public Health Service Act (42 U.S.C. 283(a)) is amended by adding at the end the following:

“(7) A summary of the use of funds distributed under section 3(e)(2)(A) of the National Biomedical
Research Act to the National Institutes of Health from the Biomedical Innovation Fund, established under section 3(a) of such Act, including the amounts allocated to each national research institute and national center, the projects funded by such amounts, the accomplishments that have resulted from such amounts, and the goals for future use of such amounts.”.

(C) FDA REPORTS.—For each 3-year period beginning on the date of enactment of this Act, if amounts are distributed under subsection (c)(2)(B) to the Food and Drug Administration for any fiscal year during such 3-year period, the Commissioner of Food and Drugs shall submit, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that describes the allocation of such amounts within the Food and Drug Administration, the projects funded by such amounts, the accomplishments that have resulted from such amounts, and the goals for future use of such amounts.
SEC. 4. BUDGETARY PROVISIONS.

(a) DISCRETIONARY SPENDING LIMITS.—The Office of Management and Budget shall not include amounts distributed under section 3(c)(2) during a fiscal year in determining whether there has been a breach of the discretionary spending limits under the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 900 et seq.) during the fiscal year.

(b) BUDGET ENFORCEMENT.—If a bill or joint resolution, or amendment thereto or conference report thereon, if enacted, would cause amounts to be distributed under section 3(c)(2), the Chairperson of the Committee on the Budget of the House of Representatives and Chairperson of the Committee on the Budget of the Senate shall not include the budgetary effects of such distribution for purposes of enforcement of budgetary allocations, aggregates, levels, and limits in the House of Representatives and the Senate.

SEC. 5. OFFSETS.

It is the sense of the Senate that the amounts transferred under section 3(b) should be offset completely.