

114TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Ms. WARREN (for herself, Mrs. MURRAY, Ms. MIKULSKI, Mr. SANDERS, Mr. CASEY, Mr. FRANKEN, Mr. BENNET, Mr. WHITEHOUSE, Ms. BALDWIN, and Mr. MURPHY) 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) DISCRETIONARY APPROPRIATIONS.—The
9 term “discretionary appropriations” has the mean-
10 ing given such term in section 250 of the Balanced

1 Budget and Emergency Deficit Control Act of 1985
2 (2 U.S.C. 900)).

3 (2) FUND.—The term “Fund” means the Bio-
4 medical Innovation Fund established under section
5 3(a).

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

9 (A) means the amount equal to the great-
10 est amount of discretionary appropriations ap-
11 propriated to such entity for a fiscal year dur-
12 ing the period beginning with fiscal year 2016
13 and ending with the fiscal year before the appli-
14 cable fiscal year; and

15 (B) does not include—

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

21 (ii) amounts collected by the Secretary
22 of Health and Human Services under sub-
23 chapter C of chapter VII of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.
25 379f et seq.);

6 SEC. 3. BIOMEDICAL INNOVATION FUND.

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

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

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

15 (b) COMMITMENT TO BIOMEDICAL INNOVATION.—
16 Not later than September 1, 2016, and every year there-
17 after through 2025, the Secretary of the Treasury shall
18 transfer \$5,000,000,000 from the general fund of the
19 Treasury into the Fund.

20 (c) DISTRIBUTION OF AMOUNTS.—

1 to the entity described in paragraph (2)(A) and the
2 date of enactment of an appropriation Act making
3 full fiscal year appropriations for such fiscal year to
4 the entity described in paragraph (2)(B), the Sec-
5 retary of the Treasury shall calculate the total
6 amount in the Fund that is available to be distrib-
7 uted for such fiscal year in accordance with para-
8 graph (2).

9 (2) DISTRIBUTION OF AMOUNTS IN THE
10 FUND.—Subject to the other provisions of this sec-
11 tion, not later than 30 days after a calculation is
12 made under paragraph (1) for a fiscal year, the Sec-
13 retary of the Treasury shall distribute the amount
14 available to be distributed for such fiscal year to
15 each of the following entities:

- 16 (A) The National Institutes of Health.
17 (B) The Food and Drug Administration.

18 (3) RATIO.—The amount that the Secretary of
19 the Treasury distributes to an entity described in
20 subparagraph (A) or (B) of paragraph (2) during a
21 fiscal year shall bear the same relation to the total
22 amount calculated under paragraph (1) for such fis-
23 cal year as the amount of discretionary appropria-
24 tions appropriated to such entity for such fiscal year
25 bears to the total amount of discretionary appropria-

1 tions appropriated to the entities described in sub-
2 paragraphs (A) and (B) of paragraph (2) for such
3 fiscal year.

4 (4) REQUIREMENTS FOR DISTRIBUTION.—

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

9 (i) the discretionary appropriations
10 for the entity described in paragraph
11 (2)(A) is greater than the applicable min-
12 imum amount for such entity for such fis-
13 cal year; and

14 (ii) the discretionary appropriations
15 for the entity described in paragraph
16 (2)(B) is greater than the applicable min-
17 imum amount for such entity for such fis-
18 cal year.

19 (B) SUBSEQUENT LAW IMPACTING DIS-
20 TRIBUTION.—

21 (i) BELOW MINIMUM AMOUNT.—If a
22 law is enacted or becomes effective after
23 amounts are appropriated to each entity
24 described in subparagraph (A) or (B) of
25 paragraph (2) for a fiscal year and such

1 law decreases the amount appropriated to
2 either such entity for such fiscal year from
3 an amount that is greater than the appli-
4 cable minimum amount to an amount that
5 is less than or equal to such minimum
6 amount, any amounts that were distributed
7 by the Secretary of the Treasury under
8 paragraph (2) shall remain so distributed
9 for such fiscal year.

10 (ii) ABOVE MINIMUM AMOUNT.—If a
11 law is enacted or becomes effective after
12 amounts are appropriated for a fiscal year
13 to each entity described in subparagraph
14 (A) or (B) of paragraph (2) and such law
15 increases the amount appropriated to ei-
16 ther such entity for such fiscal year from
17 an amount that is less than or equal to the
18 minimum amount to an amount that is
19 greater than such minimum amount, and
20 all other conditions for distribution under
21 this paragraph are met for the fiscal year,
22 the amounts in the Fund shall be distrib-
23 uted by the Secretary of the Treasury
24 under paragraph (2) for such fiscal year.

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

11 (5) ALLOCATIONS.—

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

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

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

15 (A) the execution of the Precision Medicine
16 Initiative, which may include—

20 (ii) a diverse national research cohort
21 with a goal of enrolling 1,000,000 participants
22 in the United States to study topics
23 including how genes, the environment, life-
24 style, and diet contribute to health, dis-
25 ease, and wellness; and

8 (B) the execution of the Brain Research
9 through Advancing Innovative
10 Neurotechnologies Initiative (commonly known
11 as the “BRAIN Initiative”), which may include
12 efforts to—

13 (i) develop and apply technology to
14 help scientists understand the brain;

(iii) facilitate comprehensive analysis, integration across platforms of large-scale research and health data, and broad dis-

1 tribution sharing of experimental and data
2 analysis tools;

3 (C) the execution of the Cancer Moonshot
4 Initiative, which may include—

5 (i) cancer clinical trials with a focus
6 on genetics and immunotherapy;

7 (ii) research on cancer biology;

8 (iii) facilitating information and data
9 exchange and transparency between and
10 within research and treatment communities
11 to accelerate the pace of scientific advance-
12 ment; and

13 (iv) supporting the development of en-
14 tities, such as a virtual center of excel-
15 lence, to leverage the combined skills of
16 regulatory scientists and reviewers;

17 (D) research that fosters disruptive innova-
18 tion, such as—

19 (i) research on diseases or conditions
20 for which treatments exist but are inad-
21 equate, including chronic and acute pain;

22 (ii) research on diseases or conditions
23 for which there are unmet medical needs;

24 (iii) research on diseases or conditions
25 for which treatments exist but the side ef-

1 fect profiles of such treatments limit ther-
2 apeutic potential;

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

16 (E) research related to diseases that
17 disproportionately account for Federal health
18 care spending, including spending under the
19 Medicare program under title XVIII of the So-
20 cial Security Act (42 U.S.C. 1395 et seq.), the
21 Medicaid program under title XIX of the Social
22 Security Act (42 U.S.C. 1396 et seq.), the
23 State Children's Health Insurance Program
24 under title XXI of the Social Security Act (42
25 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 Affairs under chapters 17 and 18 of title 38, United States Code, such as research relating to—

(ii) degenerative diseases, or

10 (iii) chronic conditions;

(F) early career scientists, such as
through—

19 (I) who are within 10 years of
20 completing a terminal research de-
21 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

gree; or

(IV) individuals within 10 years

of completing a medical residency; or

(G) 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 geo-

graphic diversity of funding provided by

the National Institutes of Health;

(H) the development, review, and post

ket surveillance of medical products, as de-

mined by the Secretary of Health and

nan Services; and

(I) research to carry out the goals of the

Strategic and implementation plan for advancing

ence to promote public health and advance

ovation in regulatory decisionmaking devel-

l under section 1124 of the Food and Drug

ministration Safety and Innovation Act (21

C. 393 note), and other such research ac-

ies to improve the predictability, consist-

y, and efficiency of science-based decision-

ing concerning medical products, including

itating the timely introduction of new tech-

gies and methodologies in a safe and effec-

manner as determined by the Secretary of

Health and Human Services.

STATEMENT OF FUND BALANCES.—

IN GENERAL.—Amounts in the Fund shall

be invested in interest-bearing obligations of the

United States in the form of special-issue securities,

1 paying interest to the Fund at rates applicable to
2 such securities, and such amounts shall be redeem-
3 able by the Secretary of the Treasury, for purposes
4 of distribution under subsection (c)(2).

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

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

12 (f) TRANSFER TO REDUCE THE DEFICIT.—

13 (1) IN GENERAL.—Subject to paragraph (2), if
14 amounts in the Fund are not distributed by the Sec-
15 retary of the Treasury under subsection (c)(2) for
16 any 3 consecutive fiscal years, the Secretary of the
17 Treasury shall transfer all amounts in the Fund to
18 the general fund of the Treasury for purposes of re-
19 ducing the Federal deficit.

20 (2) YEAR OF DISTRIBUTION.—For purposes of
21 paragraph (1), 3 fiscal years shall not be deemed to
22 be consecutive if during any of such years the Sec-
23 retary of the Treasury has transferred all amounts
24 in the Fund into the general fund of the Treasury
25 in accordance with such paragraph.

1 (g) REPORTS.—

2 (1) SECRETARY REPORTS.—

3 (A) IN GENERAL.—Not later than November 30, 2017, and every year thereafter through 2026, 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.

11 (B) CONTENTS.—Each report shall include, for the fiscal year covered by the report, each of the following:

14 (i) A statement of the amounts, and the source of such amounts, transferred to, credited to, and deposited into the Fund.

17 (ii) A description of any amounts distributed under subsection (c)(2) during the fiscal year.

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

23 (iv) A statement of the amounts invested in interest-bearing obligations of the

1 United States, and the interest earned on
2 such investments.

3 (2) AGENCY REPORTS.—

4 (A) ANNUAL REPORTING.—For each fiscal
5 year in which amounts are available for obliga-
6 tion under subsection (c)(5), the Director of the
7 National Institutes of Health and the Commis-
8 sioner of Food and Drugs shall report on the
9 use of such amounts in the annual budget sub-
10 mission for such fiscal year of the National In-
11 stitutes of Health and the Food and Drug Ad-
12 ministration, respectively.

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

16 “(7) A summary of the use of funds distributed
17 under section 3(c)(2)(A) of the National Biomedical
18 Research Act to the National Institutes of Health
19 from the Biomedical Innovation Fund, established
20 under section 3(a) of such Act, including the
21 amounts allocated to each national research institute
22 and national center, the projects funded by such
23 amounts, the accomplishments that have resulted
24 from such amounts, and the goals for future use of
25 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.

16 SEC. 4. BUDGETARY PROVISIONS.

17 (a) DISCRETIONARY SPENDING LIMITS.—The Office
18 of Management and Budget shall not include amounts dis-
19 tributed under section 3(c)(2) during a fiscal year in de-
20 termining whether there has been a breach of the discre-
21 tionary spending limits under the Balanced Budget and
22 Emergency Deficit Control Act of 1985 (2 U.S.C. 900 et
23 seq.) during the fiscal year.

(b) BUDGET ENFORCEMENT.—If a bill or joint resolution, or amendment thereto or conference report there-

1 on, if enacted, would cause amounts to be distributed
2 under section 3(c)(2), the Chairperson of the Committee
3 on the Budget of the House of Representatives and Chair-
4 person of the Committee on the Budget of the Senate shall
5 not include the budgetary effects of such distribution for
6 purposes of enforcement of budgetary allocations, aggre-
7 gates, levels, and limits in the House of Representatives
8 and the Senate.

9 **SEC. 5. OFFSETS.**

10 It is the sense of the Senate that the amounts trans-
11 ferred under section 3(b) should be offset completely.