

S.L.C.
Elizabeth Warren

AMENDMENT NO. 1 Calendar No. _____

Purpose: To establish the "Biomedical Innovation Fund".

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

(no.) _____

(title) Promoting Biomedical Research and Public Health for Patients Act

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. WARREN (for herself, Mrs. MURRAY, Ms. MIKULSKI, Mr. SANDERS, Mr. CASEY, Mr. FRANKEN, Mr. BENNET, Mr. WHITEHOUSE, Ms. BALDWIN, and Mr. MURPHY)

Viz:

1 At the appropriate place, insert the following:

2 **TITLE _____ —BIOMEDICAL**
3 **INNOVATION FUND**

4 **SEC. _01. SHORT TITLE.**

5 This title may be cited as the "National Biomedical
6 Research Act".

7 **SEC. _02. DEFINITIONS.**

8 In this title:

9 (1) **DISCRETIONARY APPROPRIATIONS.**—The
10 term "discretionary appropriations" has the mean-
11 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 __03(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.);

1 (iii) amounts distributed under section
2 __03(c)(2); or

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

6 **SEC. __03. 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

13 (2) any interest earned on the investment of
14 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.—

21 (1) CALCULATION OF ANNUAL FUND
22 AMOUNT.—For fiscal year 2017 and each fiscal year
23 thereafter, not later than 15 days after the latter of
24 the date of enactment of an appropriation Act mak-
25 ing full fiscal year appropriations for such fiscal year

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.

1 (C) FAILURE TO MEET REQUIREMENTS.—

2 If the requirements under subparagraph (A)
3 are not met during a fiscal year, amounts in the
4 Fund shall—

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

7 (ii) remain in the Fund, earning inter-
8 est in accordance with subsection (d), until
9 such requirements, or the conditions under
10 subsection (f), are met during a fiscal year.

11 (5) ALLOCATIONS.—

12 (A) IN GENERAL.—If amounts are distrib-
13 uted under paragraph (2) during a fiscal year,
14 of the amounts so distributed—

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

18 (ii) 20 percent shall become available
19 for obligation during the first fiscal year
20 after the fiscal year during which the dis-
21 tribution is made;

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

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

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.

9 (B) AVAILABILITY OF AMOUNTS.—Any
10 amounts distributed under paragraph (2) shall
11 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—

17 (i) basic research on the underlying
18 basis for diseases to better address disease
19 prevention, diagnosis, and treatment;

20 (ii) a diverse national research cohort
21 with a goal of enrolling 1,000,000 partici-
22 pants 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

1 (iii) the development and use of the
2 information technology to leverage existing
3 or future research cohorts and clinical net-
4 works, support secure data exchange with
5 the consent of participants, and allow re-
6 searchers to access data generated from
7 the cohorts;

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;

15 (ii) support interdisciplinary and
16 multi-institute research collaborations, in-
17 cluding coordination with privately funded
18 efforts to advance the understanding of the
19 human brain and improve the diagnosis
20 and treatment of nervous system disorders
21 and injuries; and

22 (iii) facilitate comprehensive analysis,
23 integration across platforms of large-scale
24 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 thera-
2 peutic potential;

3 (iv) research on new approaches to
4 treatment of diseases using drugs, devices,
5 or therapies that, at the time of distribu-
6 tion under paragraph (2), are not used or
7 are underused; or

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 disproportionally 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

1 under chapter 55 of title 10, United States
2 Code, and hospital care and medical services
3 furnished by the Department of Veterans Af-
4 fairs under chapters 17 and 18 of title 38,
5 United States Code, such as research relating
6 to—

7 (i) diseases that disproportionately im-
8 pact older individuals;

9 (ii) degenerative diseases, or

10 (iii) chronic conditions;

11 (F) early career scientists, such as
12 through—

13 (i) awarding research project grants
14 that support discrete, specified, and cir-
15 cumscribed projects to be performed by the
16 investigator in an area representing the
17 specific interests and competencies of such
18 investigator, to investigators—

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

22 (II) who are within 10 years of
23 completing a medical residency;

1 (ii) awarding grants that support ca-
2 reer development experiences that lead to
3 earlier research independence; and

4 (iii) awarding grants that support in-
5 novative training programs that, in addi-
6 tion to scientific training, provide addi-
7 tional training to enhance employment op-
8 portunities, including training in manage-
9 ment and business, to—

10 (I) graduate students;

11 (II) post-doctoral fellows;

12 (III) individuals within 10 years
13 of completing a terminal research de-
14 gree; or

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

17 (G) research efforts that increase the po-
18 tential for breakthrough discoveries across a di-
19 verse set of investigators, research groups, and
20 institutions, which may include supporting—

21 (i) investigators that are members of
22 traditionally underrepresented racial and
23 ethnic groups;

24 (ii) research groups that are diverse
25 in size; or

1 (iii) institutions that increase the geo-
2 graphic diversity of funding provided by
3 the National Institutes of Health;

4 (H) the development, review, and post-
5 market surveillance of medical products, as de-
6 termined by the Secretary of Health and
7 Human Services; and

8 (I) research to carry out the goals of the
9 strategy and implementation plan for advancing
10 science to promote public health and advance
11 innovation in regulatory decisionmaking devel-
12 oped under section 1124 of the Food and Drug
13 Administration Safety and Innovation Act (21
14 U.S.C. 393 note), and other such research ac-
15 tivities to improve the predictability, consist-
16 ency, and efficiency of science-based decision-
17 making concerning medical products, including
18 facilitating the timely introduction of new tech-
19 nologies and methodologies in a safe and effec-
20 tive manner as determined by the Secretary of
21 Health and Human Services.

22 (d) INVESTMENT OF FUND BALANCES.—

23 (1) IN GENERAL.—Amounts in the Fund shall
24 be invested in interest-bearing obligations of the
25 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 Novem-
4 ber 30, 2017, and every year thereafter through
5 2026, the Secretary of the Treasury shall sub-
6 mit to the Committee on Appropriations of the
7 Senate, the Committee on Appropriations of the
8 House of Representatives, and the authorizing
9 committees a report on the operation of the
10 Fund during the fiscal year.

11 (B) CONTENTS.—Each report shall in-
12 clude, for the fiscal year covered by the report,
13 each of the following:

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

17 (ii) A description of any amounts dis-
18 tributed under subsection (c)(2) during the
19 fiscal year.

20 (iii) A statement of the balance re-
21 maining in the Fund at the end of the fis-
22 cal year.

23 (iv) A statement of the amounts in-
24 vested 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 __03(c)(2)(A) of the National Bio-
18 medical Research Act to the National Institutes of
19 Health from the Biomedical Innovation Fund, estab-
20 lished under section __03(a) of such Act, including
21 the amounts allocated to each national research in-
22 stitute and national center, the projects funded by
23 such amounts, the accomplishments that have re-
24 sulted from such amounts, and the goals for future
25 use of such amounts.”.

1 (C) FDA REPORTS.—For each 3-year pe-
2 riod beginning on the date of enactment of this
3 Act, if amounts are distributed under sub-
4 section (c)(2)(B) to the Food and Drug Admin-
5 istration for any fiscal year during such 3-year
6 period, the Commissioner of Food and Drugs
7 shall submit, to the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate and
9 the Committee on Energy and Commerce of the
10 House of Representatives, a report that de-
11 scribes the allocation of such amounts within
12 the Food and Drug Administration, the projects
13 funded by such amounts, the accomplishments
14 that have resulted from such amounts, and the
15 goals for future use of such amounts.

16 **SEC. __04. BUDGETARY PROVISIONS.**

17 (a) DISCRETIONARY SPENDING LIMITS.—The Office
18 of Management and Budget shall not include amounts dis-
19 tributed under section __03(c)(2) during a fiscal year in
20 determining 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.

24 (b) BUDGET ENFORCEMENT.—If a bill or joint reso-
25 lution, or amendment thereto or conference report there-

1 on, if enacted, would cause amounts to be distributed
2 under section __03(c)(2), the Chairperson of the Com-
3 mittee on the Budget of the House of Representatives and
4 Chairperson of the Committee on the Budget of the Sen-
5 ate shall not include the budgetary effects of such distribu-
6 tion for purposes of enforcement of budgetary allocations,
7 aggregates, levels, and limits in the House of Representa-
8 tives and the Senate.

9 **SEC. __0**

10 5. OFFSETS.—

11 It is the sense of the Senate that the amounts
12 transferred under section __03(b) should be offset
13 completely.