

116TH CONGRESS
1ST SESSION

H. R. 5400

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2019

Ms. CLARKE of New York (for herself and Mr. LOEBSACK) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Rules, and the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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-

1 ing given such term in section 250 of the Balanced
2 Budget and Emergency Deficit Control Act of 1985
3 (2 U.S.C. 900).

4 (2) FUND.—The term “Fund” means the Bio-
5 medical Innovation Fund established under section
6 3(a).

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

10 (A) means the amount equal to the great-
11 est amount of discretionary appropriations ap-
12 propriated to such entity for a fiscal year dur-
13 ing the period beginning with fiscal year 2020
14 and ending with the fiscal year before the appli-
15 cable fiscal year; and

16 (B) does not include—

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

22 (ii) amounts collected by the Secretary
23 of Health and Human Services under sub-
24 chapter C of chapter VII of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 379f et seq.);
3 (iii) amounts distributed under section
4 3(c)(2); or
5 (iv) amounts appropriated under a
6 supplemental or emergency appropriation
7 Act.

8 **SEC. 3. BIOMEDICAL INNOVATION FUND.**

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

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

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

17 (b) COMMITMENT TO BIOMEDICAL INNOVATION.—
18 Not later than September 1, 2020, and every year there-
19 after through 2029, the Secretary of the Treasury shall
20 transfer \$10,000,000,000 from the general fund of the
21 Treasury into the Fund.

22 (c) DISTRIBUTION OF AMOUNTS.—

23 (1) CALCULATION OF ANNUAL FUND
24 AMOUNT.—For fiscal year 2020 and each fiscal year
25 thereafter, not later than 15 days after the latter of

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

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

18 (A) The National Institutes of Health.

19 (B) The Food and Drug Administration.

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

1 tions appropriated to such entity for such fiscal year
2 bears to the total amount of discretionary appropria-
3 tions appropriated to the entities described in sub-
4 paragraphs (A) and (B) of paragraph (2) for such
5 fiscal year.

6 (4) REQUIREMENTS FOR DISTRIBUTION.—

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

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

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

21 (B) SUBSEQUENT LAW IMPACTING DIS-
22 TRIBUTION.—

23 (i) BELOW MINIMUM AMOUNT.—If a
24 law is enacted or becomes effective after
25 amounts are appropriated to each entity

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

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

1 uted by the Secretary of the Treasury
2 under paragraph (2) for such fiscal year.

3 (C) FAILURE TO MEET REQUIREMENTS.—

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

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

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

13 (5) ALLOCATIONS.—

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

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

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

24 (iii) 20 percent shall become available
25 for obligation during the second fiscal year

1 after the fiscal year during which the dis-
2 tribution is made;

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

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

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

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

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

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

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

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

3 (iii) research on diseases or conditions
4 for which treatments exist but the side ef-
5 fect profiles of such treatments limit thera-
6 peutic potential;

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

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

20 (C) research related to diseases that
21 disproportionally account for Federal health
22 care spending, including spending under the
23 Medicare program under title XVIII of the So-
24 cial Security Act (42 U.S.C. 1395 et seq.), the
25 Medicaid program under title XIX of the Social

1 Security Act (42 U.S.C. 1396 et seq.), the
2 State Children's Health Insurance Program
3 under title XXI of the Social Security Act (42
4 U.S.C. 1397aa et seq.), the TRICARE program
5 under chapter 55 of title 10, United States
6 Code, and hospital care and medical services
7 furnished by the Department of Veterans Af-
8 fairs under chapters 17 and 18 of title 38,
9 United States Code, such as research relating
10 to—

11 (i) diseases that disproportionally im-
12 pact older individuals;

13 (ii) degenerative diseases; or

14 (iii) chronic conditions;

15 (D) early career scientists, such as
16 through—

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

23 (I) who are within 10 years of
24 completing a terminal research de-
25 gree; or

1 (II) who are within 10 years of
2 completing a medical residency;

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

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

12 (I) graduate students;

13 (II) post-doctoral fellows;

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

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

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

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

1 (ii) research groups that are diverse
2 in size; or

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

6 (F) the development, review, and post-mar-
7 ket surveillance of medical products, as deter-
8 mined by the Secretary of Health and Human
9 Services; and

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

24 (7) INTERAGENCY TRANSFERS.—Amounts dis-
25 tributed from the Fund under paragraph (2) shall

1 be available through interagency transfer to support
2 research conducted jointly by the National Institutes
3 of Health or the Food and Drug Administration and
4 other Federal agencies.

5 (d) INVESTMENT OF FUND BALANCES.—

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

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

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

20 (f) TRANSFER TO REDUCE THE DEFICIT.—

21 (1) IN GENERAL.—Subject to paragraph (2), if
22 amounts in the Fund are not distributed by the Sec-
23 retary of the Treasury under subsection (c)(2) for
24 any 3 consecutive fiscal years, the Secretary of the
25 Treasury shall transfer all amounts in the Fund to

1 the general fund of the Treasury for purposes of re-
2 ducing the Federal deficit.

3 (2) YEAR OF DISTRIBUTION.—For purposes of
4 paragraph (1), 3 fiscal years shall not be deemed to
5 be consecutive if during any of such years the Sec-
6 retary of the Treasury has transferred all amounts
7 in the Fund into the general fund of the Treasury
8 in accordance with such paragraph.

9 (g) REPORTS.—

10 (1) SECRETARY REPORTS.—

11 (A) IN GENERAL.—Not later than Novem-
12 ber 30, 2021, and every year thereafter through
13 2030 the Secretary of the Treasury shall sub-
14 mit to the Committee on Appropriations of the
15 Senate, the Committee on Appropriations of the
16 House of Representatives, and the authorizing
17 committees a report on the operation of the
18 Fund during the fiscal year.

19 (B) CONTENTS.—Each report shall in-
20 clude, for the fiscal year covered by the report,
21 each of the following:

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

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

4 (iii) A statement of the balance re-
5 maining in the Fund at the end of the fis-
6 cal year.

7 (iv) A statement of the amounts in-
8 vested in interest-bearing obligations of the
9 United States, and the interest earned on
10 such investments.

11 (2) AGENCY REPORTS.—

12 (A) ANNUAL REPORTING.—For each fiscal
13 year in which amounts are available for obliga-
14 tion under subsection (c)(5), the Director of the
15 National Institutes of Health and the Commis-
16 sioner of Food and Drugs shall report on the
17 use of such amounts in the annual budget sub-
18 mission for such fiscal year of the National In-
19 stitutes of Health and the Food and Drug Ad-
20 ministration, respectively.

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

24 “(7) A summary of the use of funds distributed
25 under section 3(c)(2)(A) of the National Biomedical

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

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

1 **SEC. 4. BUDGETARY PROVISIONS.**

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

9 (b) BUDGET ENFORCEMENT.—If a bill or joint reso-
10 lution, or amendment thereto or conference report there-
11 on, if enacted, would cause amounts to be distributed
12 under section 3(c)(2), the Chairperson of the Committee
13 on the Budget of the House of Representatives and Chair-
14 person of the Committee on the Budget of the Senate shall
15 not include the budgetary effects of such distribution for
16 purposes of enforcement of budgetary allocations, aggre-
17 gates, levels, and limits in the House of Representatives
18 and the Senate.

19 **SEC. 5. OFFSETS.**

20 It is the sense of the House of Representatives that
21 the amounts transferred under section 3(b) should be off-
22 set completely.

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