

# 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

- the date of enactment of an appropriation Act mak-ing 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 Sec-retary of the Treasury shall calculate the total amount in the Fund that is available to be distrib-uted for such fiscal year in accordance with para-graph (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-

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

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-

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

Medicaid program under title XIX of the Social  $\,$ 

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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

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

## (d) Investment of Fund Balances.—

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- (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).
- 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.—

(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 reducing 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 Secretary 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, 2021, and every year thereafter through 2030 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 include, 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.

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

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.

#### 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.
- 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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