

117TH CONGRESS  
1ST SESSION

# H. R. 4124

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

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 2021

Ms. CLARKE of New York 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

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## 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 2022  
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, 2022, and every year there-  
19 after through 2031, 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 2022 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 disproportionately 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 disproportionately 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, 2023, and every year thereafter through  
13 2032 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.

○