

117TH CONGRESS
2D SESSION

S. 5322

To authorize the collection of supplemental payments to increase congressional investments in medical research, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 20, 2022

Ms. WARREN (for herself, Mr. BROWN, Ms. BALDWIN, Mr. WHITEHOUSE, Mr. VAN HOLLEN, and Mr. SANDERS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To authorize the collection of supplemental payments to increase congressional investments in medical research, 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 “Medical Innovation Act
5 of 2022”.

1 **SEC. 2. AUTHORITY TO ASSESS AND USE SUPPLEMENTAL**
 2 **PAYMENTS TO INCREASE CONGRESSIONAL**
 3 **INVESTMENTS IN MEDICAL RESEARCH.**

4 (a) IN GENERAL.—Section 301 of the Public Health
 5 Service Act (42 U.S.C. 241) is amended by adding at the
 6 end the following:

7 “(i) AUTHORITY TO ASSESS AND USE SUPPLE-
 8 MENTAL PAYMENTS TO INCREASE CONGRESSIONAL IN-
 9 VESTMENTS IN MEDICAL RESEARCH.—

10 “(1) DEFINITIONS.—For purposes of this sub-
 11 section:

12 “(A) COVERED BLOCKBUSTER DRUG.—

13 “(i) IN GENERAL.—The term ‘covered
 14 blockbuster drug’ means any product—

15 “(I) for which the covered manu-
 16 facturer reported to the Securities and
 17 Exchange Commission on a form, in-
 18 cluding form 10-K or form 20-F, or
 19 is otherwise determined by the Sec-
 20 retary to have received, at least
 21 \$1,000,000,000 in net sales in the
 22 previous calendar year; and

23 “(II) that was developed, in
 24 whole or in part, through Federal
 25 Government investments in medical

1 research, as the Secretary determines
2 in accordance with clause (ii).

3 “(ii) DETERMINATION OF FEDERAL
4 GOVERNMENT INVESTMENT.—In deter-
5 mining under clause (i)(II) whether a
6 product was developed, in whole or in part,
7 through Federal Government investments
8 in medical research, the Secretary shall
9 consider whether information included in
10 any patent that claims the covered block-
11 buster drug or that claims a method of
12 using such covered blockbuster drug and
13 with respect to which a claim of patent in-
14 fringement could reasonably be asserted if
15 a person not licensed by the owner engaged
16 in the manufacture, use, or sale of the cov-
17 ered blockbuster drug, or any element of
18 the covered blockbuster drug—

19 “(I) relates to, or is based upon,
20 prior science conducted, in whole or in
21 part, by a person that is or was fund-
22 ed by the Federal Government;

23 “(II) relates to, acts upon, or is
24 based upon knowledge of a signaling
25 pathway, cellular receptor, ion chan-

1 nel, protein, DNA or RNA sequence
2 or mutation, virus, or any other sci-
3 entific information discovered, in
4 whole or in part, through research
5 funded by the Federal Government; or
6 “(III) relates to, or is based
7 upon, through the manufacturing
8 process or testing process of the cov-
9 ered blockbuster drug, technology de-
10 rived, in whole or in part, through re-
11 search funded by the Federal Govern-
12 ment.

13 “(B) COVERED MANUFACTURER.—The
14 term ‘covered manufacturer’ means a person—

15 “(i) that holds an application ap-
16 proved under section 505 of the Federal
17 Food, Drug, and Cosmetic Act or a license
18 under section 351 of this Act for a covered
19 blockbuster drug; or

20 “(ii) who is a co-licensed partner of
21 the person described in clause (i) that ob-
22 tains the covered blockbuster drug directly
23 from a person described in this clause or
24 clause (i).

1 “(C) COVERED SETTLEMENT AGREE-
2 MENT.—

3 “(i) IN GENERAL.—The term ‘covered
4 settlement agreement’ means a settlement
5 agreement (including a consent decree),
6 and except as provided under clause (ii)—

7 “(I) that is between an agency
8 and a covered manufacturer;

9 “(II) that relates to—

10 “(aa) an alleged violation of,
11 or a penalty under, section
12 1128A of the Social Security Act
13 or section 1128B of the Social
14 Security Act;

15 “(bb) an alleged violation
16 under subchapter III of chapter
17 37 of title 31, United States
18 Code (commonly known as the
19 ‘False Claims Act’);

20 “(cc) an alleged violation
21 under the Federal Food, Drug,
22 and Cosmetic Act; or

23 “(dd) an alleged violation of
24 any other Federal civil or crimi-
25 nal law; and

“(III) under the terms of which a covered manufacturer is obligated in an amount not less than a total of \$1,000,000, including civil or criminal penalties with respect to any parties, including governmental and private entities.

“(ii) EXCEPTION FOR SETTLEMENTS NOT AFFECTING TAXPAYERS OR PUBLIC HEALTH.—The term ‘covered settlement agreement’ does not include any settlement agreement that the Secretary determines—

“(I) does not involve an alleged criminal violation; and

“(II) does not relate to—

“(aa) allegations of fraud resulting, or potentially resulting, in a loss of taxpayer dollars; or

“(bb) allegations of conduct having an adverse impact, or a potentially adverse impact, on the health of the public.

“(D) PERSON.—The term ‘person’ has the meaning given such term in section 201(e) of the Federal Food, Drug, and Cosmetic Act.

1 “(E) PRODUCT.—The term ‘product’
 2 means a drug approved under section 505 of
 3 the Federal Food, Drug, and Cosmetic Act or
 4 licensed under section 351, and subject to sec-
 5 tion 503(b)(1) of the Federal Food, Drug, and
 6 Cosmetic Act.

7 “(2) SUPPLEMENTAL PAYMENTS TO INCREASE
 8 CONGRESSIONAL INVESTMENTS IN MEDICAL RE-
 9 SEARCH.—

10 “(A) SUPPLEMENTAL PAYMENT ASSESS-
 11 MENT AND COLLECTION.—Beginning with the
 12 first fiscal year that begins at least 60 days
 13 after the date of enactment of the Medical In-
 14 novation Act of 2022, and each subsequent fis-
 15 cal year, the Secretary shall, in accordance with
 16 this paragraph, assess and collect supplemental
 17 payments to increase congressional investments
 18 in medical research from each covered manufac-
 19 turer described in subparagraph (B).

20 “(B) CRITERIA FOR ASSESSING PAY-
 21 MENTS.—A covered manufacturer that meets
 22 both of the following criteria for a calendar year
 23 (referred to in this subparagraph and subpara-
 24 graph (D) as the ‘applicable calendar year’)
 25 shall be assessed a supplemental payment under

1 subparagraph (A) for the fiscal year beginning
2 in the proceeding calendar year:

3 “(i) A covered manufacturer that,
4 during the 5-year period immediately pre-
5 ceding the date on which the payment is
6 assessed, but not before the date of enact-
7 ment of the Medical Innovation Act of
8 2022, entered into a covered settlement
9 agreement.

10 “(ii) A covered manufacturer that re-
11 ported net income of at least
12 \$1,000,000,000 to the Securities and Ex-
13 change Commission on a form, including
14 form 10–K or form 20–F, or that the Sec-
15 retary otherwise determines to have had
16 net income of at least \$1,000,000,000—

17 “(I) during the applicable cal-
18 endar year; or

19 “(II) during the calendar year in
20 which the covered manufacturer en-
21 tered into a covered settlement agree-
22 ment, as described in clause (i).

23 “(C) PAYMENT AMOUNT.—

24 “(i) IN GENERAL.—A covered manu-
25 facturer described in subparagraph (B)

1 shall be assessed a supplemental payment
2 to increase congressional investments in
3 medical research for a fiscal year equal to
4 the applicable percentage of the net income
5 of the covered manufacturer, as reported
6 or determined as described in subpara-
7 graph (B)(ii), for the previous calendar
8 year, multiplied by the number of covered
9 blockbuster drugs of the covered manufac-
10 turer for that year.

11 “(ii) APPLICABLE PERCENTAGE.—For
12 purposes of determining the amount of a
13 supplemental payment under clause (i), the
14 applicable percentage of the net income of
15 a covered manufacturer is—

16 “(I) 0.75 percent, in the case of
17 a covered settlement agreement under
18 the terms of which the total obligation
19 of a covered manufacturer is in an
20 amount that is less than
21 \$500,000,000;

22 “(II) 1 percent, in the case of a
23 covered settlement agreement under
24 the terms of which the total obligation
25 of a covered manufacturer is in an

1 amount that is at least \$500,000,000
2 but less than \$1,000,000,000; or

3 “(III) 1.5 percent, in the case of
4 a covered settlement agreement under
5 the terms of which the total obligation
6 of a covered manufacturer is in an
7 amount that is at least
8 \$1,000,000,000.

9 “(D) ANNUAL LIMITATION.—In the case of
10 a covered manufacturer that entered into more
11 than 1 covered settlement agreement during an
12 applicable calendar year, such covered manufac-
13 turer shall be assessed a supplemental payment
14 under subparagraph (C) only with respect to
15 the covered settlement agreement under which
16 the total amount obligated of the covered manu-
17 facturer, as described in paragraph
18 (1)(C)(i)(III), is the highest.

19 “(E) PUBLICATION OF PAYMENTS.—Be-
20 ginning with the first fiscal year that begins at
21 least 60 days after the date of enactment of the
22 Medical Innovation Act of 2022, and not later
23 than 60 days before the start of each fiscal
24 year, the Secretary shall publish in the Federal
25 Register, with respect to the next fiscal year—

1 “(i) a list of covered manufacturers
2 subject to the payment under this para-
3 graph;

4 “(ii) a list of the covered blockbuster
5 drugs of each such covered manufacturer;

6 “(iii) the total payment amount as-
7 sessed to each such covered manufacturer;
8 and

9 “(iv) the manner in which payments
10 assessed under this paragraph will be col-
11 lected.

12 “(F) CREDITING AND AVAILABILITY OF
13 SUPPLEMENTAL PAYMENTS.—

14 “(i) IN GENERAL.—Subject to clause
15 (ii), payments authorized under this para-
16 graph shall be collected and available for
17 obligation only to the extent and in the
18 amount provided in advance in appropria-
19 tions Acts. Such payments are authorized
20 to remain available until expended.

21 “(ii) COLLECTIONS AND APPROPRIA-
22 TIONS ACTS.—

23 “(I) IN GENERAL.—The pay-
24 ments authorized by this paragraph—

1 “(aa) subject to subclause
2 (II), shall be collected and avail-
3 able in each fiscal year in an
4 amount not to exceed the amount
5 specified in appropriation Acts,
6 or otherwise made available for
7 obligation, for such fiscal year;
8 and

9 “(bb) shall be available to
10 the Secretary to distribute, as de-
11 scribed in paragraph (3).

12 “(II) PROVISION FOR EARLY
13 PAYMENTS.—Payments authorized
14 under clause (iii) for a fiscal year,
15 prior to the due date for such pay-
16 ments, may be accepted by the Sec-
17 retary.

18 “(iii) AUTHORIZATION OF APPROPRIA-
19 TIONS.—For the first fiscal year that be-
20 gins at least 60 days after the date of en-
21 actment of the Medical Innovation Act of
22 2022 and for each subsequent fiscal year,
23 there is authorized to be appropriated for
24 the purpose of making distributions under
25 paragraph (3) to meet the priorities de-

1 scribed in paragraph (4), an amount equal
2 to the total amount of supplemental pay-
3 ments assessed for such fiscal year under
4 this paragraph.

5 “(G) REMITTING PAYMENTS.—A covered
6 manufacturer assessed a supplemental payment
7 under subparagraph (A) shall remit the pay-
8 ment no later than the first business day on or
9 after October 1 of each fiscal year, or the first
10 business day after the date of enactment of an
11 appropriations Act providing for the collection
12 and obligation of supplemental payments for
13 such fiscal year.

14 “(H) COLLECTION OF ASSESSED PAY-
15 MENTS THAT ARE NOT REMITTED.—In any case
16 where the Secretary does not receive a supple-
17 mental payment assessed under subparagraph
18 (A) within 30 days after it is due, such supple-
19 mental payment shall be treated as a claim of
20 the United States Government subject to sub-
21 chapter II of chapter 37 of title 31, United
22 States Code.

23 “(I) SUPPLEMENT NOT SUPPLANT.—Pay-
24 ments collected under this paragraph shall be
25 used to supplement and not supplant other

1 Federal funds made available to carry out the
2 priorities described in paragraph (4).

3 “(3) DISTRIBUTION OF PAYMENTS TO AGEN-
4 CIES TO INCREASE CONGRESSIONAL INVESTMENTS
5 IN MEDICAL RESEARCH.—

6 “(A) DISTRIBUTION TO AGENCIES.—Sub-
7 ject to subparagraph (C), for the purposes de-
8 scribed in paragraph (4), the Secretary shall
9 distribute the amounts appropriated under
10 paragraph (2)(F)(iii) during a fiscal year to—

11 “(i) the Food and Drug Administra-
12 tion, to be used in accordance with para-
13 graph (4)(A); and

14 “(ii) the National Institutes of Health
15 organized under title IV, to be used in ac-
16 cordance with paragraph (4)(B).

17 “(B) DISTRIBUTION RATIO BETWEEN
18 AGENCIES.—The amount that the Secretary
19 distributes to an agency under subparagraph
20 (A) during a fiscal year shall bear the same re-
21 lation to the total amount appropriated under
22 paragraph (2)(F)(iii) for such fiscal year as the
23 amount of discretionary funds appropriated to
24 such agency for such fiscal year bears to the
25 total amount of discretionary funding appro-

1 priated to both agencies listed in subparagraph
2 (A) for such fiscal year.

3 “(C) ENSURING STABLE CONGRESSIONAL
4 INVESTMENTS IN MEDICAL RESEARCH.—

5 “(i) IN GENERAL.—Supplemental pay-
6 ments collected in accordance with para-
7 graph (2) shall not be distributed under
8 subparagraph (A) for a fiscal year unless
9 appropriations to both of the agencies list-
10 ed in such subparagraph for the fiscal year
11 are equal to or greater than appropriations
12 to such agencies for the prior fiscal year.

13 “(ii) DELAYED DISTRIBUTION.—If, in
14 accordance with clause (i), the Secretary
15 does not distribute payments collected in
16 accordance with paragraph (2) during any
17 portion of a fiscal year, and, at a later
18 date in such fiscal year, the appropriations
19 to the agencies listed in subparagraph (A)
20 become equal to or greater than the
21 amount of appropriations for the prior fis-
22 cal year, the Secretary may distribute such
23 payment at any time in such fiscal year.

1 “(D) CONSIDERATIONS.—In determining
2 amounts appropriated for purposes of subpara-
3 graphs (B) and (C)—

4 “(i) the Secretary shall not consider
5 any amounts appropriated in accordance
6 with paragraph (2)(F)(iii); and

7 “(ii) with respect to the Food and
8 Drug Administration, the Secretary shall
9 not consider amounts appropriated in ac-
10 cordance with subchapter C of chapter VII
11 of the Federal Food, Drug, and Cosmetic
12 Act (relating to user fees collected by the
13 Secretary).

14 “(4) PRIORITIZING URGENT NEEDS IN MEDICAL
15 RESEARCH.—The Secretary shall ensure that the
16 payments distributed under paragraph (3) are used
17 to meet urgent needs in medical research, including
18 priorities as follows:

19 “(A) FDA.—With respect to the Food and
20 Drug Administration, the priority use of the
21 distributions shall include carrying out the
22 goals of the strategy and implementation plan
23 for advancing regulatory science for medical
24 products under section 1124 of the Food and
25 Drug Administration Safety and Innovation Act

1 (21 U.S.C. 393 note), and other such research
2 activities in order to promote the public health
3 and advance innovation in regulatory decision-
4 making, as determined by the Secretary.

5 “(B) NIH.—With respect to the National
6 Institutes of Health, the priority use of the dis-
7 tributions shall include supporting—

8 “(i) research that fosters radical inno-
9 vation, including—

10 “(I) research on diseases or con-
11 ditions for which treatments exist but
12 are inadequate;

13 “(II) research on diseases or con-
14 ditions for which there are unmet
15 medical needs;

16 “(III) research on diseases for
17 which treatments exist but the side ef-
18 fect profiles of such treatments limit
19 the therapeutic potential of such
20 treatments;

21 “(IV) research on new ap-
22 proaches to treatment or diagnosis of
23 a disease using a drug, device, or
24 therapy that, at the time of distribu-
25 tion, is not used or is underused; or

1 “(V) research to identify new bio-
2 markers;

3 “(ii) research that advances funda-
4 mental knowledge and technology even if it
5 does not provide immediate or near-term
6 clinical or therapeutic benefits, including
7 research and technology that advances the
8 understanding of biochemistry, biology,
9 protein science, immunology, genetics, vi-
10 rology, microbiology, or neurology;

11 “(iii) research related to diseases that
12 disproportionately account for Federal
13 health care spending, including spending
14 under the Medicare program under title
15 XVIII of the Social Security Act, the Med-
16 icaid program under title XIX of the Social
17 Security Act, the State Children’s Health
18 Insurance Program under title XXI of the
19 Social Security Act, the TRICARE pro-
20 gram under chapter 55 of title 10, United
21 States Code, and the hospital services and
22 medical care provided through the Vet-
23 erans’ Administration under chapters 17
24 and 18 of title 38, United States Code,
25 and tax credits made available through the

1 amendments to the Internal Revenue Code
2 of 1986 made by the Patient Protection
3 and Affordable Care Act (Public Law 111–
4 148), such as research relating to—

5 “(I) diseases that disproportion-
6 ally impact older individuals;

7 “(II) degenerative diseases; and

8 “(III) chronic conditions; and

9 “(iv) early career scientists by—

10 “(I) awarding research project
11 grants that support discrete, specified,
12 circumscribed projects to be per-
13 formed by the investigator in an area
14 representing the specific interests and
15 competencies of such investigator, to
16 investigators—

17 “(aa) who are within 10
18 years of completing a terminal
19 research degree; or

20 “(bb) who are within 10
21 years of completing a medical
22 residency;

23 “(II) awarding grants that sup-
24 port career development experiences

1 that lead to earlier research independ-
 2 ence; and

3 “(III) awarding grants that sup-
 4 port innovative training programs
 5 that, in addition to scientific training,
 6 provide additional training to enhance
 7 employment opportunities, including
 8 training in management and business,
 9 to—

10 “(aa) graduate students;

11 “(bb) post-doctoral fellows;

12 “(cc) individuals within 10
 13 years of completing a terminal
 14 research degree; or

15 “(dd) individuals within 10
 16 years of completing a medical
 17 residency.

18 “(5) ANNUAL REPORTS.—

19 “(A) SECRETARY OF HEALTH AND HUMAN
 20 SERVICES.—Not later than 180 calendar days
 21 before the end of a fiscal year in which the Sec-
 22 retary has assessed supplemental payments
 23 under paragraph (2), the Secretary shall submit
 24 a report to the Committee on Health, Edu-
 25 cation, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the
2 House of Representatives, which shall include a
3 description of supplemental payments assessed,
4 collected, and distributed under this subsection
5 for such fiscal year, and a list of the covered
6 manufacturers that were assessed supplemental
7 payments and the amount of such assessments.

8 “(B) FDA AND NIH.—For each fiscal year
9 in which amounts are distributed under para-
10 graph (3), the Food and Drug Administration
11 and the National Institutes of Health shall re-
12 port on the use and impact of such amounts in
13 the annual budget submission of such entity.”.

14 (b) EFFECT OF FAILURE TO REMIT PAYMENT.—

15 Section 502 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 352) is amended by adding at the end the fol-
17 lowing:

18 “(ee) If it is a drug that is a covered blockbuster drug
19 (as defined in section 301(i)(1) of the Public Health Serv-
20 ice Act) for which any payment assessed under section
21 301(i)(2) of such Act has not been paid in accordance with
22 such section, until such payment is made.”.

23 (c) SEVERABILITY.—If any provision of this section,
24 any amendment made by this section, or the application
25 of such provision or amendment to any person or cir-

1 cumstance is held to be unconstitutional, the remainder
2 of the provisions of this section, the amendments made
3 by this section, and the application of such provisions or
4 amendments to any person or circumstance shall not be
5 affected.

