

116TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

Ms. WARREN (for herself, Ms. BALDWIN, Mr. BROWN, Mr. SANDERS, and Ms. HARRIS) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**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 2019”.

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

1                   “(III) under the terms of which a  
2                   covered manufacturer is obligated in  
3                   an amount not less than a total of  
4                   \$1,000,000, including civil or criminal  
5                   penalties with respect to any parties,  
6                   including governmental and private  
7                   entities.

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

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

15                         “(II) does not to relate to—

16                                 “(aa) allegations of fraud re-  
17                                 sulting, or potentially resulting,  
18                                 in a loss of taxpayer dollars; or

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

23                   “(D) PERSON.—The term ‘person’ has the  
24                   meaning given such term in section 201(e) of  
25                   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 2019, 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 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 2019, 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           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           “(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 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                  disproportionally 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.