

114TH CONGRESS
1ST SESSION

S. 320

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

JANUARY 29, 2015

Ms. WARREN (for herself, Mr. CARDIN, Mr. BROWN, and Ms. BALDWIN) 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 2015”.

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 “(f) 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 that—

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

10 “(II) relates to—

11 “(aa) an alleged violation of,
12 or a penalty under, section
13 1128A of the Social Security Act
14 (42 U.S.C. 1320a–7a) or section
15 1128B of the Social Security Act
16 (42 U.S.C. 1320a–7b);

17 “(bb) an alleged violation
18 under subchapter III of chapter
19 37 of title 31, United States
20 Code (commonly known as the
21 ‘False Claims Act’), or the Fed-
22 eral Food, Drug, and Cosmetic
23 Act (21 U.S.C. 301 et seq.); or

1 “(cc) an alleged violation of
2 any other Federal civil or crimi-
3 nal law; and

4 “(III) requires the payment of
5 not less than \$1,000,000 by a covered
6 manufacturer.

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

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

14 “(II) does not to relate to—

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

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

22 “(D) PERSON.—The term ‘person’ has the
23 meaning given such term in section 201(e) of
24 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 2015, 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 as the ‘appli-
24 cable calendar year’) shall be assessed a supple-
25 mental payment under subparagraph (A) for

1 the fiscal year beginning in the proceeding cal-
2 endar 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 2015, 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.—A covered man-
24 ufacturer described in subparagraph (B) shall
25 be assessed a supplemental payment to increase

1 congressional investments in medical research
2 for a fiscal year equal to 1 percent of the net
3 income of the covered manufacturer, as re-
4 ported or determined as described in subpara-
5 graph (B)(ii), for the previous calendar year,
6 multiplied by the number of covered blockbuster
7 drugs of the covered manufacturer for that
8 year.

9 “(D) PUBLICATION OF PAYMENTS.—Be-
10 ginning with the first fiscal year that begins at
11 least 60 days after the date of enactment of the
12 Medical Innovation Act of 2015, and not later
13 than 60 days before the start of each fiscal
14 year, the Secretary shall publish in the Federal
15 Register, with respect to the next fiscal year—

16 “(i) a list of covered manufacturers
17 subject to the payment under this para-
18 graph;

19 “(ii) a list of the covered blockbuster
20 drugs of each such covered manufacturer;

21 “(iii) the total payment amount as-
22 sessed to each such covered manufacturer;
23 and

1 “(iv) the manner in which payments
2 assessed under this paragraph will be col-
3 lected.

4 “(E) CREDITING AND AVAILABILITY OF
5 SUPPLEMENTAL PAYMENTS.—

6 “(i) IN GENERAL.—Subject to clause
7 (ii), payments authorized under this para-
8 graph shall be collected and available for
9 obligation only to the extent and in the
10 amount provided in advance in appropria-
11 tions Acts. Such payments are authorized
12 to remain available until expended.

13 “(ii) COLLECTIONS AND APPROPRIA-
14 TIONS ACTS.—

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

17 “(aa) subject to subclause
18 (II), shall be collected and avail-
19 able in each fiscal year in an
20 amount not to exceed the amount
21 specified in appropriation Acts,
22 or otherwise made available for
23 obligation, for such fiscal year;
24 and

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

4 “(II) PROVISION FOR EARLY
5 PAYMENTS.—Payments authorized
6 under clause (iii) for a fiscal year,
7 prior to the due date for such pay-
8 ments, may be accepted by the Sec-
9 retary.

10 “(iii) AUTHORIZATION OF APPROPRIA-
11 TIONS.—For the first fiscal year that be-
12 gins at least 60 days after the date of en-
13 actment of the Medical Innovation Act of
14 2015 and for each subsequent fiscal year,
15 there is authorized to be appropriated for
16 supplemental payments under this para-
17 graph an amount equal to the total
18 amount of supplemental payments assessed
19 for such fiscal year under this paragraph.

20 “(F) REMITTING PAYMENTS.—A covered
21 manufacturer assessed a supplemental payment
22 under subparagraph (A) shall remit the pay-
23 ment no later than the first business day on or
24 after October 1 of each fiscal year, or the first
25 business day after the date of enactment of an

1 appropriations Act providing for the collection
2 and obligation of supplemental payments for
3 such fiscal year.

4 “(G) COLLECTION OF ASSESSED PAY-
5 MENTS THAT ARE NOT REMITTED.—In any case
6 where the Secretary does not receive a supple-
7 mental payment assessed under subparagraph
8 (A) within 30 days after it is due, such supple-
9 mental payment shall be treated as a claim of
10 the United States Government subject to sub-
11 chapter II of chapter 37 of title 31, United
12 States Code.

13 “(H) SUPPLEMENT NOT SUPPLANT.—Pay-
14 ments collected under this paragraph shall be
15 used to supplement and not supplant other
16 Federal funds made available to carry out the
17 priorities described in paragraph (4).

18 “(3) DISTRIBUTION OF PAYMENTS TO AGEN-
19 CIES TO INCREASE CONGRESSIONAL INVESTMENTS
20 IN MEDICAL RESEARCH.—

21 “(A) DISTRIBUTION TO AGENCIES.—Sub-
22 ject to subparagraph (C), for the purposes de-
23 scribed in paragraph (4), the Secretary shall
24 distribute the amounts appropriated under
25 paragraph (2)(E)(iii) during a fiscal year to—

1 “(i) the Food and Drug Administra-
2 tion, to be used in accordance with para-
3 graph (4)(A); and

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

7 “(B) DISTRIBUTION RATIO BETWEEN
8 AGENCIES.—The amount that the Secretary
9 distributes to an agency under subparagraph
10 (A) during a fiscal year shall bear the same re-
11 lation to the total amount appropriated under
12 paragraph (2)(E)(iii) for such fiscal year as the
13 amount of discretionary funds appropriated to
14 such agency for such fiscal year bears to the
15 total amount of discretionary funding appro-
16 priated to both agencies listed in subparagraph
17 (A) for such fiscal year.

18 “(C) ENSURING STABLE CONGRESSIONAL
19 INVESTMENTS IN MEDICAL RESEARCH.—

20 “(i) IN GENERAL.—Supplemental pay-
21 ments collected in accordance with para-
22 graph (2) shall not be distributed under
23 subparagraph (A) for a fiscal year unless
24 appropriations to both of the agencies list-
25 ed in such subparagraph for the fiscal year

1 are equal to or greater than appropriations
2 to such agencies for the prior fiscal year.

3 “(ii) DELAYED DISTRIBUTION.—If, in
4 accordance with clause (i), the Secretary
5 does not distribute payments collected in
6 accordance with paragraph (2) during any
7 portion of a fiscal year, and, at a later
8 date in such fiscal year, the appropriations
9 to the agencies listed in subparagraph (A)
10 become equal to or greater than the
11 amount of appropriations for the prior fis-
12 cal year, the Secretary may distribute such
13 payment at any time in such fiscal year.

14 “(D) CONSIDERATIONS.—In determining
15 amounts appropriated for purposes of subpara-
16 graphs (B) and (C)—

17 “(i) the Secretary shall not consider
18 any amounts appropriated in accordance
19 with paragraph (2)(E)(iii); and

20 “(ii) with respect to the Food and
21 Drug Administration, the Secretary shall
22 not consider amounts appropriated in ac-
23 cordance with subchapter C of chapter VII
24 of the Federal Food, Drug, and Cosmetic

1 Act (relating to user fees collected by the
2 Secretary).

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

8 “(A) FDA.—With respect the Food and
9 Drug Administration, the priority use of the
10 distributions shall include carrying out the
11 goals of the strategy and implementation plan
12 for advancing regulatory science for medical
13 products under section 1124 of the Food and
14 Drug Administration Safety and Innovation Act
15 (21 U.S.C. 393 note), and other such research
16 activities in order to promote the public health
17 and advance innovation in regulatory decision-
18 making, as determined by the Secretary.

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

22 “(i) research that fosters radical inno-
23 vation, including—

1 “(I) research on diseases or con-
2 ditions for which treatments exist but
3 are inadequate;

4 “(II) research on diseases or con-
5 ditions for which there are unmet
6 medical needs;

7 “(III) research on diseases for
8 which treatments exist but the side ef-
9 fect profiles of such treatments limit
10 the therapeutic potential of such
11 treatments;

12 “(IV) research on new ap-
13 proaches to treatment of a disease
14 using a drug, device, or therapy that,
15 at the time of distribution, is not used
16 or is underused; or

17 “(V) research to identify new bio-
18 markers;

19 “(ii) research that advances funda-
20 mental knowledge even if it does not pro-
21 vide immediate or near-term clinical or
22 therapeutic benefits, including research
23 that advances the understanding of bio-
24 chemistry, biology, protein science, immu-

1 nology, genetics, virology, microbiology, or
2 neurology;

3 “(iii) research related to diseases that
4 disproportionately account for Federal
5 health care spending, including spending
6 under the Medicare program under title
7 XVIII of the Social Security Act, the Med-
8 icaid program under title XIX of the Social
9 Security Act, the State Children’s Health
10 Insurance Program under title XXI of the
11 Social Security Act, the TRICARE pro-
12 gram under chapter 55 of title 10, United
13 States Code, and the hospital services and
14 medical care provided through the Vet-
15 erans Administration under chapters 17
16 and 18 of title 38, United States Code,
17 and tax credits made available through the
18 amendments to the Internal Revenue Code
19 of 1986 made by the Patient Protection
20 and Affordable Care Act (Public Law 111–
21 148), such as research relating to—

22 “(I) diseases that
23 disproportionately impact older individ-
24 uals;

25 “(II) degenerative diseases, and

1 “(III) chronic conditions; and

2 “(iv) early career scientists by—

3 “(I) awarding research project
4 grants that support discrete, specified,
5 circumscribed projects to be per-
6 formed by the investigator in an area
7 representing the specific interests and
8 competencies of such investigator, to
9 investigators—

10 “(aa) who are within 10
11 years of completing a terminal
12 research degree; or

13 “(bb) who are within 10
14 years of completing a medical
15 residency;

16 “(II) awarding grants that sup-
17 port career development experiences
18 that lead to earlier research independ-
19 ence; and

20 “(III) awarding grants that sup-
21 port innovative training programs
22 that, in addition to scientific training,
23 provide additional training to enhance
24 employment opportunities, including

1 training in management and business,
2 to—

3 “(aa) graduate students;

4 “(bb) post-doctoral fellows;

5 “(cc) individuals within 10
6 years of completing a terminal
7 research degree; or

8 “(dd) individuals within 10
9 years of completing a medical
10 residency.

11 “(5) ANNUAL REPORTS.—

12 “(A) SECRETARY OF HEALTH AND HUMAN
13 SERVICES.—Not later than 180 calendar days
14 before the end of a fiscal year in which the Sec-
15 retary has assessed supplemental payments
16 under paragraph (2), the Secretary shall submit
17 a report to the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate and
19 the Committee on Energy and Commerce of the
20 House of Representatives, which shall include a
21 description of supplemental payments assessed,
22 collected, and distributed under this subsection
23 for such fiscal year, and a list of the covered
24 manufacturers that were assessed supplemental
25 payments and the amount of such assessments.

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

7 (b) EFFECT OF FAILURE TO REMIT PAYMENT.—
8 Section 502 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 352) is amended by adding at the end the fol-
10 lowing:

11 “(dd) If it is a drug that is a covered blockbuster
12 drug (as defined in section 301(f)(1) of the Public Health
13 Service Act) for which any payment assessed under section
14 301(f)(2) of such Act has not been paid in accordance with
15 such section, until such payment is made.”.

○