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, Mr. CARDIN, Mr. BROWN, and Ms. BALDWIN) introduced the following bill; which was read twice and referred to the Committee on __________________

__________________________________________________________

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”.


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

(a) In General.—Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

“(f) Authority to Assess and Use Supplemental Payments to Increase Congressional Investments in Medical Research.—

“(1) Definitions.—For purposes of this subsection:

“(A) Covered blockbuster drug.—

“(i) In general.—The term ‘covered blockbuster drug’ means any product—

“(I) for which the covered manufacturer reported to the Securities and Exchange Commission on a form, including form 10–K or form 20–F, or is otherwise determined by the Secretary to have received, at least $1,000,000,000 in net sales in the previous calendar year; and

“(II) that was developed, in whole or in part, through Federal Government investments in medical research.
research, as the Secretary determines in accordance with clause (ii).

“(ii) DETERMINATION OF FEDERAL GOVERNMENT INVESTMENT.—In determining under clause (i)(II) whether a product was developed, in whole or in part, through Federal Government investments in medical research, the Secretary shall consider whether information included in any patent that claims the covered blockbuster drug or that claims a method of using such covered blockbuster drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the covered blockbuster drug, or any element of the covered blockbuster drug—

“(I) relates to, or is based upon, prior science conducted, in whole or in part, by a person that is or was funded by the Federal Government;

“(II) relates to, acts upon, or is based upon knowledge of a signaling pathway, cellular receptor, ion chan-
nel, protein, DNA or RNA sequence
or mutation, virus, or any other sci-
entific information discovered, in
whole or in part, through research
funded by the Federal Government; or

“(III) relates to, or is based
upon, through the manufacturing
process or testing process of the cov-
ered blockbuster drug, technology de-
derived, in whole or in part, through re-
search funded by the Federal Govern-
ment.

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

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

“(ii) who is a co-licensed partner of
the person described in clause (i) that ob-
tains the covered blockbuster drug directly
from a person described in this clause or
clause (i).
“(C) COVERED SETTLEMENT AGREEMENT.—

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

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

“(II) relates to—

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

“(bb) an alleged violation under subchapter III of chapter 37 of title 31, United States Code, (commonly known as the ‘False Claims Act’) or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or
“(cc) an alleged violation of any other Federal civil or criminal law; and

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

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

“(2) SUPPLEMENTAL PAYMENTS TO INCREASE CONGRESSIONAL INVESTMENTS IN MEDICAL RESEARCH.—

“(A) SUPPLEMENTAL PAYMENT ASSESSMENT AND COLLECTION.—Beginning with the first fiscal year that begins at least 60 days after the date of enactment of the Medical Innovation Act of 2015, and each subsequent fiscal year, the Secretary shall, in accordance with this paragraph, assess and collect supplemental payments to increase congressional investments in medical research from each covered manufacturer described in subparagraph (B).

“(B) CRITERIA FOR ASSESSING PAYMENTS.—A covered manufacturer that meets both of the following criteria for a calendar year (referred to in this subparagraph as the ‘applicable calendar year’) shall be assessed a supplemental payment under subparagraph (A) for
the fiscal year beginning in the proceeding cal-
endar year:

“(i) A covered manufacturer that,
during the 5-year period immediately pre-
ceding the date on which the payment is
assessed, but not before the date of enact-
ment of the Medical Innovation Act of
2015, entered into a covered settlement
agreement.

“(ii) A covered manufacturer that re-
ported net income of at least
$1,000,000,000 to the Securities and Ex-
change Commission on a form, including
form 10–K or form 20–F, or that the Sec-
retary otherwise determines to have had
net income of at least $1,000,000,000—
“(I) during the applicable cal-
endar year; or

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

“(C) PAYMENT AMOUNT.—A covered man-
ufacturer described in subparagraph (B) shall
be assessed a supplemental payment to increase
congressional investments in medical research for a fiscal year equal to 1 percent of the net income of the covered manufacturer, as reported or determined as described in subparagraph (B)(ii), for the previous calendar year, multiplied by the number of covered blockbuster drugs of the covered manufacturer for that year.

“(D) Publication of Payments.—Beginning with the first fiscal year that begins at least 60 days after the date of enactment of the Medical Innovation Act of 2015, and not later than 60 days before the start of each fiscal year, the Secretary shall publish in the Federal Register, with respect to the next fiscal year—

“(i) a list of covered manufacturers subject to the payment under this paragraph;

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

“(iii) the total payment amount assessed to each such covered manufacturer; and
“(iv) the manner in which payments assessed under this paragraph will be collected.

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

“(i) IN GENERAL.—Subject to clause (ii), payments authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such payments are authorized to remain available until expended.

“(ii) COLLECTIONS AND APPROPRIATIONS ACTS.—

“(I) IN GENERAL.—The payments authorized by this paragraph—

“(aa) subject to subclause (II), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and
“(bb) shall be available to
the Secretary to distribute, as de-
scribed in paragraph (3).

“(II) Provision for early
payments.—Payments authorized
under clause (iii) for a fiscal year,
prior to the due date for such pay-
ments, may be accepted by the Sec-
retary.

“(iii) Authorization of appropriation.—For the first fiscal year that be-
gins at least 60 days after the date of en-
actment of the Medical Innovation Act of
2015 and for each subsequent fiscal year,
there is authorized to be appropriated for
supplemental payments under this para-
graph an amount equal to the total
amount of supplemental payments assessed
for such fiscal year under this paragraph.

“(F) Remitting payments.—A covered
manufacturer assessed a supplemental payment
under subparagraph (A) shall remit the pay-
ment no later than the first business day on or
after October 1 of each fiscal year, or the first
business day after the date of enactment of an
appropriations Act providing for the collection
and obligation of supplemental payments for
such fiscal year.

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

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

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

“(A) DISTRIBUTION TO AGENCIES.—Sub-
ject to subparagraph (C), for the purposes de-
scribed in paragraph (4), the Secretary shall
distribute the amounts appropriated under
paragraph (2)(E)(iii) during a fiscal year to—
“(i) the Food and Drug Administra-
tion, to be used in accordance with para-
graph (4)(A); and

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

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

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

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

“(ii) Delayed Distribution.—If, in accordance with clause (i), the Secretary does not distribute payments collected in accordance with paragraph (2) during any portion of a fiscal year, and, at a later date in such fiscal year, the appropriations to the agencies listed in subparagraph (A) become equal to or greater than the amount of appropriations for the prior fiscal year, the Secretary may distribute such payment at any time in such fiscal year.

“(D) Considerations.—In determining amounts appropriated for purposes of subparagraphs (B) and (C)—

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

“(ii) with respect to the Food and Drug Administration, the Secretary shall not consider amounts appropriated in accordance with subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic
Act (relating to user fees collected by the Secretary).

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

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

“(B) NIH.—With respect to the National Institutes of Health, the priority use of the distributions shall include supporting—

“(i) research that fosters radical innovation, including—
“(I) research on diseases or conditions for which treatments exist but are inadequate;

“(II) research on diseases or conditions for which there are unmet medical needs;

“(III) research on diseases for which treatments exist but the side effect profiles of such treatments limit the therapeutic potential of such treatments;

“(IV) research on new approaches to treatment of a disease using a drug, device, or therapy that, at the time of distribution, is not used or is underused; or

“(V) research to identify new biomarkers;

“(ii) research that advances fundamental knowledge even if it does not provide immediate or near-term clinical or therapeutic benefits, including research that advances the understanding of biochemistry, biology, protein science, immu-
technology, genetics, virology, microbiology, or neurology;

“(iii) research related to diseases that disproportionately account for Federal health care spending, including spending under the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act, the State Children’s Health Insurance Program under title XXI of the Social Security Act, the TRICARE program under chapter 55 of title 10, United States Code, and the hospital services and medical care provided through the Veterans Administration under chapters 17 and 18 of title 38, United States Code, and tax credits made available through the amendments to the Internal Revenue Code of 1986 made by the Patient Protection and Affordable Care Act (Public Law 111–148), such as research relating to—

“(I) diseases that disproportionately impact older individuals;

“(II) degenerative diseases, and
“(III) chronic conditions; and
“(iv) early career scientists by—
“(I) awarding research project grants that support discrete, specified, circumscribed projects to be performed by the investigator in an area representing the specific interests and competencies of such investigator, to investigators—
“(aa) who are within 10 years of completing a terminal research degree; or
“(bb) who are within 10 years of completing a medical residency;
“(II) awarding grants that support career development experiences that lead to earlier research independence; and
“(III) awarding grants that support innovative training programs that, in addition to scientific training, provide additional training to enhance employment opportunities, including
training in management and business,
to—

“(aa) graduate students;
“(bb) post-doctoral fellows;
“(cc) individuals within 10 years of completing a terminal research degree; or
“(dd) individuals within 10 years of completing a medical residency.

“(5) Annual reports.—
“(A) Secretary of Health and Human Services.—Not later than 180 calendar days before the end of a fiscal year in which the Secretary has assessed supplemental payments under paragraph (2), the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, which shall include a description of supplemental payments assessed, collected, and distributed under this subsection for such fiscal year, and a list of the covered manufacturers that were assessed supplemental payments and the amount of such assessments.
“(B) FDA AND NIH.—For each fiscal year in which amounts are distributed under paragraph (3), the Food and Drug Administration and the National Institutes of Health shall report on the use and impact of such amounts in the annual budget submission of such entity.”.

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

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