115th CONGRESS 1st Session



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

Ms. WARREN (for herself, Mr. BROWN, Mrs. GILLIBRAND, Mr. FRANKEN, Ms. BALDWIN, and Mr. SANDERS) 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 2017".

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-

2or mutation, virus, or any other second3entific information discovered, if4whole or in part, through research5funded by the Federal Government; of6"(III) relates to, or is base7upon, through the manufacturing8process or testing process of the cord9ered blockbuster drug, technology de10rived, in whole or in part, through relation11search funded by the Federal Government.13"(B) COVERED MANUFACTURER.—The14term 'covered manufacturer' means a person-15"(i) that holds an application approved under section 505 of the Federal16proved under section 505 of the Federal17Food, Drug, and Cosmetic Act or a licens18under section 351 of this Act for a covered19blockbuster drug; or20"(ii) who is a co-licensed partner of21the person described in clause (i) that of22tains the covered blockbuster drug direct23from a person described in this clause of		
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23 from a person described in this clause of	21	the person described in clause (i) that ob-
ľ	22	tains the covered blockbuster drug directly
24 clause (i).	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

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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.

"(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 sec-
tion $503(b)(1)$ of the Federal Food, Drug, and
Cosmetic Act.
"(2) Supplemental payments to increase
CONGRESSIONAL INVESTMENTS IN MEDICAL RE-
SEARCH.—
"(A) SUPPLEMENTAL PAYMENT ASSESS-
MENT AND COLLECTION.—Beginning with the
first fiscal year that begins at least 60 days
after the date of enactment of the Medical In-
novation Act of 2017, and each subsequent fis-
cal year, the Secretary shall, in accordance with
this paragraph, assess and collect supplemental
payments to increase congressional investments
in medical research from each covered manufac-
turer described in subparagraph (B).
"(B) CRITERIA FOR ASSESSING PAY-
MENTS.—A covered manufacturer that meets
both of the following criteria for a calendar year
(referred to in this subparagraph and subpara-
graph (D) as the 'applicable calendar year')
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	2017, 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

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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 2017, 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—

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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—

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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	2017 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-

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scribed in paragraph (4), an amount equal 1 2 to the total amount of supplemental pay-3 ments assessed for such fiscal year under 4 this paragraph. "(G) REMITTING PAYMENTS.—A covered 5 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.—Pay24 ments collected under this paragraph shall be
25 used to supplement and not supplant other

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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-

priated to both agencies listed in subparagraph (A) for such fiscal year.
(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 fis-
cal year, the Secretary may distribute such
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 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

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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

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 "(V) research to identify new biomarkers;
 "(ii) research that advances funda-

(ii) research that tarvances fundate mental knowledge and technology even if it does not provide immediate or near-term clinical or therapeutic benefits, including research and technology that advances the understanding of biochemistry, biology, protein science, immunology, genetics, virology, 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

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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
6	disproportionally impact older individ-
7	uals;
8	"(II) degenerative diseases, and
9	"(III) chronic conditions; and
10	"(iv) early career scientists by—
11	"(I) awarding research project
12	grants that support discrete, specified,
13	circumscribed projects to be per-
14	formed by the investigator in an area
15	representing the specific interests and
16	competencies of such investigator, to
17	investigators—
18	"(aa) who are within 10
19	years of completing a terminal
20	research degree; or
21	"(bb) who are within 10
22	years of completing a medical
23	residency;
24	"(II) awarding grants that sup-
25	port career development experiences

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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

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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

301(i)(2) of such Act has not been paid in accordance with

22 such section, until such payment is made.".