II

116TH CONGRESS
2D SESSION

S. 3163

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 8, 2020

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 Health, Education, Labor, and Pensions

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Innovation Act of 2020''.

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:

''(i) 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, 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 scientific 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 covered blockbuster drug, technology derived, in whole or in part, through research funded by the Federal Government.

"(B) COVERED MANUFACTURER.—The term 'covered manufacturer' means a person—

"(i) that holds an application approved 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 obtains 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)—

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

"(II) that relates to—

"(aa) an alleged violation of, or a penalty under, section 1128A of the Social Security Act or section 1128B of the Social Security Act;

"(bb) an alleged violation under subchapter III of chapter 37 of title 31, United States Code (commonly known as the 'False Claims Act');

"(cc) an alleged violation under the Federal Food, Drug, and Cosmetic Act; or

"(dd) an alleged violation of any other Federal civil or criminal 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.

''(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 2020, 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 and subparagraph (D) as the 'applicable calendar year') shall be assessed a supplemental payment under

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

"(i) A covered manufacturer that, during the 5-year period immediately preceding the date on which the payment is assessed, but not before the date of enactment of the Medical Innovation Act of 2020, entered into a covered settlement agreement.

"(ii) A covered manufacturer that reported net income of at least $1,000,000,000 to the Securities and Exchange Commission on a form, including form 10–K or form 20–F, or that the Secretary otherwise determines to have had net income of at least $1,000,000,000—

"(I) during the applicable calendar year; or

"(II) during the calendar year in which the covered manufacturer entered into a covered settlement agreement, as described in clause (i).

"(C) PAYMENT AMOUNT.—

"(i) IN GENERAL.—A covered manufacturer described in subparagraph (B)

shall be assessed a supplemental payment to increase congressional investments in medical research for a fiscal year equal to the applicable percentage 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.

''(ii) APPLICABLE PERCENTAGE.—For purposes of determining the amount of a supplemental payment under clause (i), the applicable percentage of the net income of a covered manufacturer is—

''(I) 0.75 percent, in the case of a covered settlement agreement under the terms of which the total obligation of a covered manufacturer is in an amount that is less than $500,000,000;

''(II) 1 percent, in the case of a covered settlement agreement under the terms of which the total obligation of a covered manufacturer is in an

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

"(III) 1.5 percent, in the case of a covered settlement agreement under the terms of which the total obligation of a covered manufacturer is in an amount that is at least $1,000,000,000.

"(D) ANNUAL LIMITATION.—In the case of a covered manufacturer that entered into more than 1 covered settlement agreement during an applicable calendar year, such covered manufacturer shall be assessed a supplemental payment under subparagraph (C) only with respect to the covered settlement agreement under which the total amount obligated of the covered manufacturer, as described in paragraph (1)(C)(i)(III), is the highest.

"(E) 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 2020, 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.

"(F) 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 appropriations 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 described in paragraph (3).

"(II) PROVISION FOR EARLY PAYMENTS.—Payments authorized under clause (iii) for a fiscal year, prior to the due date for such payments, may be accepted by the Secretary.

"(iii) AUTHORIZATION OF APPROPRIATIONS.—For the first fiscal year that begins at least 60 days after the date of enactment of the Medical Innovation Act of 2020 and for each subsequent fiscal year, there is authorized to be appropriated for the purpose of making distributions under paragraph (3) to meet the priorities de-

scribed in paragraph (4), an amount equal to the total amount of supplemental payments assessed for such fiscal year under this paragraph.

''(G) REMITTING PAYMENTS.—A covered manufacturer assessed a supplemental payment under subparagraph (A) shall remit the payment 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.

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

''(I) SUPPLEMENT NOT SUPPLANT.—Payments 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 AGENCIES TO INCREASE CONGRESSIONAL INVESTMENTS IN MEDICAL RESEARCH.—

''(A) DISTRIBUTION TO AGENCIES.—Subject to subparagraph (C), for the purposes described in paragraph (4), the Secretary shall distribute the amounts appropriated under paragraph (2)(F)(iii) during a fiscal year to—

''(i) the Food and Drug Administration, to be used in accordance with paragraph (4)(A); and

''(ii) the National Institutes of Health organized under title IV, to be used in accordance 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 relation to the total amount appropriated under paragraph (2)(F)(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 payments collected in accordance with paragraph (2) shall not be distributed under subparagraph (A) for a fiscal year unless appropriations to both of the agencies listed 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)(F)(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 to 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 or diagnosis 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 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;

''(iii) research related to diseases that disproportionally 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 disproportionally 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:

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

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

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

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