Bernie Sanders

TAM17934 S.L.C.

Amendment #3

AMENDMENT NO._____ Calendar No._____

Purpose: To establish a Medical Innovation Prize Fund.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. SANDERS

Viz:

At the end, add the following:

TITLE IX—PRIZE FUND

SEC. 901. SHORT TITLE.

This title may be cited as the "Medical Innovation Prize Fund Act".

SEC. 902. FINDINGS.

Congress makes the following findings:

(1) The development of new medicines and vaccines is necessary to improve health care outcomes.

(2) Market exclusivity for new products is an expensive, inefficient, and unfair mechanism to reward investments in new products.

(3) By de-linking research and development incentives from product prices, and by eliminating legal monopolies to sell products, it is possible to induce investments that are medically more important, procure products at low prices from competitive suppliers, radically lower pricing barriers for access to new medicines, reduce wasteful marketing and research and development activities, and dramatically lower the overall costs of acquiring innovation, while expanding access to that innovation.

(4) By funding innovation prizes at .55 percent of gross domestic product, the United States would provide more than $100,000,000,000 in rewards for successful innovation in 2016.

(5) The development of new medicines benefits from greater sharing of knowledge, data, materials, and technologies.

SEC. 903. PURPOSE.

It is the purpose of this title to provide incentives to encourage entities to invest in research and development of new medicines and to share knowledge, data, materials, and technology, through the establishment of a

Medical Innovation Prize Fund, while enhancing access to such medicines by eliminating legal monopolies on the manufacture, distribution, and sale of such medicines.

SEC. 904. DEFINITIONS.

In this title:

(1) BIOLOGICAL PRODUCT.—The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) BOARD.—The term "Board" means the Board of Trustees for the Fund for Medical Innovation Prizes established under section 907.

(3) DRUG.—The term "drug" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(4) FUND.—The term "Fund" means the Fund for Medical Innovation Prizes established under section 906.

(5) MARKET CLEARANCE.—The term "market clearance" means the approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 905. ELIMINATION OF EXCLUSIVE RIGHTS TO MARKET DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Notwithstanding title 35, United States Code, relevant provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; commonly referred to as the "Hatch-Waxman Act")), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), and any other provision of law providing any patent right or exclusive marketing period for any drug, biological product, or manufacturing process for a drug or biological product (such as pediatric extensions under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) or orphan drug marketing exclusivity under subchapter B of chapter V of such Act (21 U.S.C. 360aa et seq.)), no person shall have the right to exclusively manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product in interstate commerce, including the exclusive right to rely on health registration data or the 30-month stay-of-effectiveness period for Orange Book patents under section 505(j) of such Act (21 U.S.C. 355(j)).

(b) REMUNERATION.—A person that is eligible for prize payments from the Fund as provided for in section 909, 910, or 911 shall receive such payments—

(1) in lieu of any remuneration the person would have otherwise received for the exclusive marketing, distribution, sale, or use of a drug, biological product, or manufacturing process for a drug or biological product but for the application of subsection (a); and

(2) in addition to any other remuneration that such person receives by reason of the nonexclusive marketing, distribution, sale, or use of the drug, biological product, or manufacturing process for a drug or biological product.

(c) APPLICATION.—This section shall apply only with respect to the marketing, distribution, sale, or use of a drug, a biological product, or a manufacturing process for a drug or biological product that occurs on or after October 1, 2018.

SEC. 906. FUND FOR MEDICAL INNOVATION PRIZES.

(a) ESTABLISHMENT.—There is hereby established in the Treasury of the United States a revolving fund to be known as the "Fund for Medical Innovation Prizes", which shall consist of amounts appropriated to the Fund and amounts credited to the Fund under subsection (c).

(b) AVAILABILITY OF FUNDS.—Amounts in the Fund shall be available to the Board, subject to section 917(c), for the purpose of carrying out this title.

(c) AMOUNTS CREDITED TO THE FUND.—The Secretary of the Treasury shall credit to the Fund the interest on, and the proceeds from sale or redemption of, obligations held in the Fund.

SEC. 907. BOARD OF TRUSTEES FOR THE FUND.

(a) ESTABLISHMENT.—There is hereby established (as a permanent, independent establishment in the executive branch) a Board of Trustees for the Fund for Medical Innovation Prizes.

(b) MEMBERSHIP.—The Board shall be composed of 13 members, including—

(1) the Administrator of the Centers for Medicare & Medicaid Services;

(2) the Commissioner of Food and Drugs;

(3) the Director of the National Institutes of Health;

(4) the Director of the Centers for Disease Control and Prevention; and

(5) 9 individuals to be appointed by the President, with the advice and consent of the Senate, of which—

(A) 2 shall be representatives of businesses that provide health insurance to employees;

(B) 2 shall be representatives of entities that provide health insurance and contribute to the co-funding of the Fund for Medical Innovation Prizes under section 917;

(C) 2 shall be representatives of the medical research and development sector, including at least 1 representative of the nonprofit private medical research and development sector; and

(D) 3 shall be representatives of consumer and patient interests, including at least one representative of patients suffering from orphan diseases.

(c) TERMS.—

(1) IN GENERAL.—Except as provided in paragraph (2), each member appointed to the Board under subsection (b)(5) shall be appointed for a term of 4 years.

(2) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment, of the members first appointed to the Board under subsection (b)(5)—

(A) 5 members shall be appointed for a term of 4 years; and

(B) 4 members shall be appointed for a term of 2 years.

(d) VACANCIES.—Any member of the Board appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member of the Board may serve after the expiration of that member's term until a successor has taken office.

(e) COMPENSATION AND TRAVEL EXPENSES.—

(1) COMPENSATION.—Members of the Board shall each be paid not less than the daily equivalent of level IV of the Executive Schedule for each day (including travel time) during which they are engaged in the actual performance of the duties of the Board.

(2) TRAVEL EXPENSES.—Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

(f) CHAIRPERSON; OFFICERS.—The members of the Board shall elect a Chairperson and any other officers of the Board. The Chairperson and any such officers shall be elected for a term of 2 years.

(g) STAFF.—The Board may appoint and fix the pay of such additional personnel as the Board considers appropriate. The staff of the Board shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(h) EXPERTS AND CONSULTANTS.—The Board may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

SEC. 908. POWERS AND DUTIES OF THE BOARD.

(a) DUTIES.—The Board shall—

(1) award prize payments for medical innovation in accordance with this title; and

(2) submit a report to the Congress under section 916.

(b) POWERS OF BOARD.—

(1) HEARINGS AND SESSIONS.—

(A) IN GENERAL.—The Board may, for the purpose of carrying out this title, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Board considers appropriate.

(B) FIRST MEETING.—Not later than 30 days after the initial members of the Board are appointed under section 917(b)(5) and confirmed, the Board shall conduct its first meeting.

(2) POLICIES AND PROCEDURES.—

(A) IN GENERAL.—Not later than 1 year after the initial members of the Board are appointed under section 917(b)(5) and confirmed, the Board shall establish such policies and procedures as may be appropriate to carry out this title.

(B) MAJORITY VOTE.—The policies and procedures of the Board shall require that any determination of the Board be made by not less than a majority vote of the members of the Board.

(C) ADMINISTRATIVE PROCEDURES.—The policies and procedures of the Board shall comply with subchapter II of chapter 5 of title 5, United States Code.

(D) TRANSPARENCY.—The policies and procedures of the Board shall—

(i) comply with sections 552 and 552b of title 5, United States Code (commonly

referred to as the "Freedom of Information Act" and the "Government in the Sunshine Act", respectively); and

(ii) ensure that the proceedings and deliberations of the Board are transparent and are supported by a description of the methods, data sources, assumptions, outcomes, and related information that will allow the public to understand how the Board reaches its criteria-setting and award decisions.

(3) EXPERT ADVISORY COMMITTEES.—To assist the Board in carrying out this title, the Board shall establish independent expert advisory committees, including committees on the following:

(A) Economic evaluation of therapeutic benefits.

(B) Business models and incentive structures for innovation.

(C) Research and development priorities.

(D) Orphan diseases.

(E) Financial control and auditing.

(F) Open source biomedical science.

(4) POWERS OF MEMBERS AND AGENTS.—Any member or agent of the Board may, if authorized by

the Board, take any action which the Board is authorized to take under this title.

(5) MAILS.—The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

SEC. 909. PRIZE PAYMENTS FOR MEDICAL INNOVATION.

(a) AWARD.—For fiscal year 2019, and each subsequent fiscal year, the Board shall award to persons described in subsection (b) prize payments for medical innovation relating to a drug, a biological product, or a new manufacturing process for a drug or biological product.

(b) ELIGIBILITY.—To be eligible to receive a prize payment under subsection (a) for medical innovation relating to a drug, a biological product, or a manufacturing process, a person shall be—

(1) in the case of a drug or biological product, the first person to receive market clearance with respect to the drug or biological product;

(2) in the case of a manufacturing process, the holder of the patent with respect to such process; or

(3) in the case of open source contributions, the persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and nondiscriminatory basis.

(c) CRITERIA.—The Board shall, by regulation, establish criteria for the selection of recipients, and for determining the amount, of prize payments under this section. Such criteria shall include consideration of the following:

(1) The number of patients who would benefit from the drug, biological product, or manufacturing process involved, including (in cases of global neglected diseases, global infectious diseases, and other global public health priorities) the number of non-United States patients.

(2) The incremental therapeutic benefit of the drug, biological product, or manufacturing process involved as compared to existing drugs, biological products, and manufacturing processes available to treat the same disease or condition, except that the Board shall provide for cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, so that the comparison is to products that were not recently developed.

(3) The degree to which the drug, biological product, or manufacturing process involved addresses priority health care needs, including—

(A) current and emerging global infectious diseases;

(B) severe illnesses with small client populations (such as indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)); and

(C) neglected diseases that primarily afflict the poor in developing countries.

(4) Improved efficiency of manufacturing processes for drugs or biological processes.

(5) The extent to which knowledge, data, materials and technology that are openly shared have contributed to the successful development of new products or improved processes for manufacturing products.

(6) In the case of antibiotics or other products for which drug resistance is a significant public health problem, the expected life cycle benefits of the antibiotic or other product, with appropriate adjustments that reward the conservation of the resources, taking into account drug resistance that is related to use of the product.

(7) In the case of products used in stockpiles for potential threats to the public health, the risk adjusted benefits of stockpiling the products.

(d) REQUIREMENTS.—In awarding prize payments under this section, the Board shall comply with the following:

(1) In cases where a new drug, biological product, or manufacturing process offers an improvement over an existing drug, biological product, or manufacturing process and the new drug, biological product, or manufacturing process competes with or replaces the existing drug, biological product, or manufacturing process, the Board shall continue to make prize payments for the existing drug, biological product, or manufacturing process to the degree that the new drug, biological product, or manufacturing process was based on or benefitted from the development of the existing drug, biological product, or manufacturing process.

(2) The Board may not make prize payments based on the identity of the person who manufactures, distributes, sells, or uses the drug, biological product, or manufacturing process involved.

(3) The Board may award prize payments for a drug, a biological product, or a manufacturing process for not more than 10 fiscal years, regardless of the term of any related patents.

(4) For any fiscal year, the Board may not award a prize payment for any single drug, biological product, or manufacturing process in an amount that exceeds 5 percent of the total amount appropriated to the Fund for that year.

(5) For every drug or biological product that receives market clearance, the Board shall determine whether and in what amount to award a prize payment for the drug or biological product not later than the end of the fourth full calendar-year quarter following the calendar-year quarter in which the drug or biological product receives market clearance.

SEC. 910. PRIZES FOR PRIORITY RESEARCH AND DEVELOPMENT.

(a) MINIMUM LEVELS OF FUNDING.—For fiscal year 2019, and each subsequent fiscal year, the Board shall establish and may periodically modify minimum levels of funding under section 909 for priority research and development.

(b) INITIAL MINIMUM LEVELS.—Of the amount appropriated to the Fund for a fiscal year, the Board shall use (subject to the establishment or modification of an applicable minimum level of funding under subsection (a)) not less than—

(1) 4 percent of such amount for global neglected diseases;

(2) 10 percent of such amount for orphan diseases; and

(3) 4 percent of such amount for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.

(c) PUBLIC INPUT; RECOMMENDATIONS.—The advisory committee on research and development priorities (established pursuant to section 918(b)(3)) shall—

(1) solicit public input on research and development priorities; and

(2) periodically recommend to the Board modifications in the minimum levels of funding for prizes for priority research and development under this section.

(d) PROCEDURES.—The Board shall adopt procedures to establish and periodically modify minimum levels of funding under section 909 for priority research and development.

SEC. 911. OPEN SOURCE DIVIDEND PRIZES.

(a) IN GENERAL.—In order to induce greater access and the open sharing of knowledge, data, materials and technology, at least 5 percent of the prize payments from

the Fund shall be dedicated to Open Source Dividend prizes.

(b) PROCEDURES.—

(1) IN GENERAL.—The Board of Trustees shall adopt procedures for the allocation of Open Source Dividend prizes. Such procedures shall—

(A) be fully transparent regarding the process for evaluating the value of open sharing of knowledge, data, materials, and technology;

(B) reward the open, nondiscriminatory and royalty-free sharing of knowledge, data, materials, and technology that has contributed to the development of the new drugs, biological products, or manufacturing processes that are rewarded under sections 909 and 910;

(C) in the case of rewards for contributing to the development of new drugs, biological products, or manufacturing processes rewarded under sections 909 and 910, provide for a time-limited period of nominations for persons or communities whose contributions were considered useful, including the evidence to support such nominations to describe the significance of the contribution; and

(D) provide for rules and procedures to protect against conflicts of interest.

(2) PUBLIC AVAILABILITY OF NOMINATIONS.—The nominations described in paragraph (1)(C), and the evidence supporting such nominations, shall be public. The public shall be allowed to provide commentary and additional evidence on such nominations before awards are made.

SEC. 912. COMPETITIVE INTERMEDIARIES FOR FUNDING INTERIM TECHNOLOGIES.

(a) IN GENERAL.—The Board of Trustees may authorize multiple nonprofit intermediaries to reward projects for interim research and development of products, or for open source dividend prizes. Such intermediaries shall compete for funding from non-Federal entities that co-fund the Fund.

(b) AVAILABILITY.—Prizes awarded by competitive intermediaries shall be available to persons or communities that provide open, nondiscriminatory and royalty-free licenses to relevant intellectual property rights.

(c) RULES.—The Board of Trustees shall adopt rules to ensure the transparency and accountability of any entities authorized to act as competitive intermediaries under subsection (a).

SEC. 913. SPECIAL TRANSITION RULES.

(a) IN GENERAL.—A drug or biological product that is on the market on October 1, 2018, shall remain eligible for prize payments for not more than 10 fiscal years, consistent with section 909(d)(3).

(b) DETERMINATION OF VALUE.—In determining the amount of a prize payment for a drug or biological product described in subsection (a), the Board shall calculate the incremental value of the drug or biological product as of the date on which the drug or biological product was first introduced in the market.

(c) MAXIMUM AMOUNT.—With respect to drugs and biological products described in subsection (a), the Board may award—

(1) of the amount appropriated to the Fund for fiscal year 2019, not more than 90 percent of such amount; and

(2) of the amount appropriated to the Fund for each of the succeeding 9 fiscal years, not more than a percentage of such amount that is equal to 9 percent less the percentage applicable to the preceding fiscal year under this subsection.

SEC. 914. ARBITRATION.

In the case of a drug that is on the market on October 1, 2018, and subject to patents owned by a party other than the person who first received market clearance for

the drug, the Board shall establish an arbitration procedure to determine an equitable division of any prize payments under this title among the patent owners and the person who first received market clearance for the drug.

SEC. 915. ANNUAL AUDITS BY GAO.

(a) AUDITS.—The Comptroller General of the United States shall conduct an audit of the Board every fifth fiscal year following the date of enactment of this Act to determine the effectiveness of the Board—

(1) in bringing to market drugs, vaccines and other biological products, and new manufacturing processes for medicines in a cost-effective manner; and

(2) in addressing society's medical needs, including global neglected diseases that afflict primarily the poor in developing countries, indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), and global infectious diseases and other global public health priorities.

(b) REPORTS.—The Comptroller General of the United States shall submit a report to the Congress concerning the results of each audit conducted under subsection (a).

SEC. 916. REPORT TO CONGRESS.

Not later than 1 year after the date of the enactment of this Act, the Board shall submit to Congress a report containing the findings, conclusions, and recommendations of the Board concerning the implementation and administration of this title, including recommendations for such legislative and administrative action as the Board determines to be appropriate.

SEC. 917. FUNDING.

(a) APPROPRIATIONS.—

(1) START-UP COSTS.—For fiscal year 2019, there are authorized to be appropriated to the Fund, such sums as may be necessary to carry out this title.

(2) PROGRAM IMPLEMENTATION.—For fiscal year 2019 and each subsequent fiscal year, there is appropriated to the Fund, out of any funds in the Treasury not otherwise appropriated, an amount equal to the amount that is .55 percent of the gross domestic product of the United States for the preceding fiscal year (as such amount is determined by the Secretary of Commerce).

(b) AVAILABILITY.—Funds appropriated to the Fund for a fiscal year shall remain available for expenditure in accordance with this title until the end of the 3-year period beginning on October 1 of such fiscal year. Any such funds

that are unexpended at the end of such period shall revert to the Treasury.

SEC. 918. IMPOSITION OF ANNUAL FEE ON HEALTH INSURANCE PROVIDERS.

(a) IMPOSITION OF FEE.—

(1) IN GENERAL.—Each covered entity engaged in the business of providing health insurance shall pay to the Secretary not later than the annual payment date of each calendar year beginning after 2018 a fee in an amount determined under subsection (b).

(2) ANNUAL PAYMENT DATE.—For purposes of this section, the term "annual payment date" means, with respect to any calendar year, a date determined by the Secretary, which in no event, may be later than September 30 of such calendar year.

(b) DETERMINATION OF FEE AMOUNT.—With respect to each covered entity, the fee under this section for any calendar year shall be equal to the amount determined under section 917(a)(2), multiplied by the ratio of the covered entity's net premiums written with respect to health insurance for any United States health risk taken into account under subsection (c) during the preceding calendar year, to—

(1) the sum of net premiums for all covered entities; and

(2) all Federal outlays on health insurance or reimbursement of health care costs, excluding the costs of long-term care.

(c) AMOUNTS TAKEN INTO ACCOUNT.—For purposes of subsection (b), the net premiums written with respect to health insurance for any United States health risk that are taken into account during any calendar year with respect to any covered entity shall be determined as follows:

(1) With respect to a covered entity's net premiums written during the calendar year that are not more than $25,000,000, the percentage of net premiums written that are taken into account is 0 percent.

(2) With respect to a covered entity's net premiums written during the calendar year that are more than $25,000,000 but less than $50,000,000, the percentage of net premiums written that are taken into account is 50 percent.

(3) With respect to a covered entity's net premiums written during the calendar year that are $50,000,000 or more, the percentage of net premiums written that are taken into account is 100 percent.

(d) COVERED ENTITY.—

(1) IN GENERAL.—For purposes of this section, the term "covered entity" means any entity which provides health insurance for any United States health risk.

(2) EXCLUSION.—Such term does not include any governmental entity.