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S. 626

To de-link research and development incentives from drug prices for new medicines to treat HIV/AIDS and to stimulate greater sharing of scientific knowledge.

IN THE SENATE OF THE UNITED STATES

MARCH 20, 2013

Mr. SANDERS 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 de-link research and development incentives from drug prices for new medicines to treat HIV/AIDS and to stimulate greater sharing of scientific knowledge.

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 ''Prize Fund for HIV/AIDS Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) The Centers for Disease Control and Prevention estimates that more than 1,100,000 people

are living with HIV in the United States, and that 1 in 5 of those people living with HIV is unaware of their infection.

(2) An estimated 49,000 Americans become infected with HIV each year.

(3) More than 15,000 people with AIDS still die each year in the United States.

(4) Through 2010, more than 636,000 people with AIDS in the United States have died since the epidemic began.

(5) Globally, UNAIDS estimates that more than 34,000,000 persons are living with HIV.

(6) Persons with HIV/AIDS require access to antiretroviral drugs.

(7) In the United States, public and private sector expenditures on antiretroviral drugs currently exceed $9,000,000,000 per year.

(8) The United States Federal Government is the largest funder of treatments for HIV/AIDS in the developing world.

(9) The development of new medicines and vaccines for HIV/AIDS is a national priority.

(10) Market exclusivity for new products is an expensive, inefficient, and unfair mechanism to reward investments in new products, and has created

hardships for persons with HIV/AIDS and businesses that employ persons with HIV/AIDS.

(11) By de-linking research and development incentives from product prices, and by eliminating legal monopolies to sell new medicines for the treatment of HIV/AIDS, it is possible to induce investments that are medically more important, procure products at low prices from competitive suppliers, and introduce more efficient incentives for research and development.

SEC. 3. PURPOSE.

It is the purpose of this Act to provide sustainable financing of incentives to encourage investments in research and development of new medicines for HIV/AIDS and to share knowledge, data, materials, and technology, through the establishment of a Prize Fund for HIV/AIDS, while enhancing access to such medicines by eliminating legal monopolies on the manufacture, distribution, and sale of such medicines.

SEC. 4. DEFINITIONS.

In this Act:

(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) 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).

(3) DUAL USE PRODUCT.—The term ''dual use product'' means a product that is a qualifying treatment for HIV/AIDS and that has a significant use for other diseases.

(4) FUND.—The term ''Fund'' means the Prize Fund for HIV/AIDS established under section 7.

(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).

(6) QUALIFYING TREATMENT FOR HIV/AIDS.—The term ''qualifying treatment for HIV/AIDS'' means an antiretrovial drug, biological product, vaccine, or other treatment primarily used for HIV/AIDS that has been certified as a qualifying product by the Secretary of Health and Human Services, for purposes of the Prize Fund for HIV/AIDS.

SEC. 5. 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 qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment for HIV/AIDS (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 qualifying treatment for HIV/AIDS or a manufacturing process for a qualifying treatment for HIV/AIDS 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 Prize Fund for HIV/AIDS 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 qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment for HIV/AIDS 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 qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment for HIV/AIDS.

(c) APPLICATION.—This section shall apply only with respect to the marketing, distribution, sale, or use of a qualifying treatment for HIV/AIDS or a manufacturing process for a qualifying treatment for HIV/AIDS that occurs on or after October 1, 2014.

(d) DUAL USE PRODUCTS.—In the case of a dual use product, the elimination of exclusive rights under subsection (a) shall apply only with respect to the manufacture, distribution, marketing, sale, or use of the product for the treatment of HIV/AIDS.

SEC. 6. QUALIFYING TREATMENTS FOR HIV/AIDS.

Prize payments from the Fund under section 8 shall be limited to qualifying treatments for HIV/AIDS, as defined in section 4.

SEC. 7. PRIZE FUND FOR HIV/AIDS.

(a) ESTABLISHMENT.—There is hereby established in the Treasury of the United States a revolving fund to be known as the ''Prize Fund for HIV/AIDS'', which shall consist of amounts appropriated to the Fund and amounts credited to the Fund under subsection (d).

(b) PRIZE FUND ADMINISTRATION.—The Secretary of Health and Human Services shall designate a Prize Fund Director and other officials as needed to administer the Fund.

(c) ADVISORY BOARD.—The Secretary of Health and Human Services shall appoint an advisory board for the Fund.

(d) 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. 8. PRIZE PAYMENTS FOR MEDICAL INNOVATION.

(a) AWARD.—For fiscal year 2015, and each subsequent fiscal year, the Prize Fund Director shall award to persons described in subsection (b) prize payments for medical innovation relating to a qualifying treatment for

HIV/AIDS, or a new manufacturing process for such a qualifying treatment for HIV/AIDS.

(b) ELIGIBILITY.—To be eligible to receive a prize payment under subsection (a) a person shall be—

(1) in the case of a qualifying treatment for HIV/AIDS that is 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 for a qualifying treatment for HIV/AIDS, the holder of the patent with respect to such process; or

(3) in the case of open source contributions with respect to a qualifying treatment for HIV/AIDS, the persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and nondiscriminatory basis.

(c) CRITERIA.—The Prize Fund Director 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 benefit from the qualifying treatment for HIV/AIDS or manufacturing process involved.

(2) The incremental therapeutic benefit of the qualifying treatment for HIV/AIDS 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 Prize Fund Director 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) Improved efficiency of manufacturing processes for drugs or biological processes.

(4) 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.

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

(1) In cases where a new qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment of HIV/AIDS offers an improvement over an existing qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment

and such new qualifying treatment or manufacturing process competes with or replaces the existing qualifying treatment or manufacturing process, the Prize Fund Director shall continue to make prize payments for the existing qualifying treatment or manufacturing process to the degree that the new qualifying treatment or manufacturing process was based on or benefitted from the development of the existing qualifying treatment or manufacturing process.

(2) The Prize Fund Director may award prize payments for a qualifying treatment for HIV/AIDS or a manufacturing process for a qualifying treatment for HIV/AIDS for not more than 10 fiscal years, regardless of the term of any related patents.

(3) For any fiscal year, the Prize Fund Director may not award a prize payment for any single qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment in an amount that exceeds 50 percent of the total amount appropriated to the Fund for that year.

(4) For every qualifying treatment for HIV/AIDS that receives market clearance, the Prize Fund Director shall determine whether and in what amount to award a prize payment for the qualifying treatment for HIV/AIDS not later than the end of

the fourth full calendar-year quarter following the calendar-year quarter in which the qualifying treatment for HIV/AIDS receives market clearance.

SEC. 9. 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 Prize Fund Director 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 qualifying treatment for HIV/AIDS or manufacturing processes that are rewarded under section 7;

(C) in the case of rewards for contributing to the development of new qualifying treatment for HIV/AIDS or manufacturing processes re-

warded under section 7, 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. 10. COMPETITIVE INTERMEDIARIES FOR FUNDING INTERIM TECHNOLOGIES.

(a) IN GENERAL.—The Prize Fund Director may authorize multiple nonprofit intermediaries to manage Fund payments to reward projects for interim research and development of new qualifying treatments for HIV/AIDS, 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 commu-

nities that provide open, nondiscriminatory, and royalty-free licenses to relevant intellectual property rights.

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

(d) ALLOCATION.—The Secretary of Health and Human Services shall determine how much of the Fund shall be managed by competitive intermediaries to reward projects for interim research and development of new qualifying treatments for HIV/AIDS or for open source dividend prizes.

SEC. 11. SPECIAL TRANSITION RULES.

(a) IN GENERAL.—A qualifying treatment for HIV/AIDS that is on the market on October 1, 2014, shall remain eligible for prize payments for not more than 10 fiscal years, consistent with section 8(d)(3).

(b) DETERMINATION OF VALUE.—In determining the amount of a prize payment for a qualifying treatment for HIV/AIDS described in subsection (a), the Prize Fund Director shall calculate the incremental value of the qualifying treatment for HIV/AIDS as of the date on which the qualifying treatment for HIV/AIDS was first introduced in the market.

(c) MAXIMUM AMOUNT.—With respect to qualifying treatment for HIV/AIDS described in subsection (a), the Prize Fund Director may award—

(1) of the amount appropriated to the Fund for fiscal year 2015, 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. 12. ARBITRATION.

In the case of a qualifying treatment for HIV/AIDS that is on the market on October 1, 2014, and subject to patents owned by a party other than the person who first received market clearance for the qualifying treatment for HIV/AIDS, the Prize Fund Director shall establish an arbitration procedure to determine an equitable division of any prize payments under this Act among the patent owners and the person who first received market clearance for the qualifying treatment for HIV/AIDS.

SEC. 13. FUNDING.

(a) APPROPRIATIONS.—

(1) START-UP COSTS.—For fiscal year 2015, there are authorized to be appropriated to the Fund,

1 such sums as may be necessary to carry out this
2 Act.
3 (2) PROGRAM IMPLEMENTATION.—For fiscal
4 year 2015 and each subsequent fiscal year, there is
5 authorized to be appropriated to the Fund, and
6 there is appropriated, out of any funds in the Treas-
7 ury not otherwise appropriated, an amount equal to
8 0.02 percent of the gross domestic product of the
9 United States for the preceding fiscal year (as such
10 amount is determined by the Secretary of Com-
11 merce).
12 (3) AVAILABILITY.—Funds appropriated to the
13 Fund for a fiscal year shall remain available for ex-
14 penditure in accordance with this Act until the end
15 of the 3-year period beginning on October 1 of such
16 fiscal year. Any such funds that are unexpended at
17 the end of such period shall revert to the Treasury.
18 (b) IMPOSITION OF ANNUAL FEE ON HEALTH IN-
19 SURANCE PROVIDERS.—
20 (1) IN GENERAL.—Each covered entity engaged
21 in the business of providing health insurance shall
22 pay to the Secretary, not later than the annual pay-
23 ment date of each calendar year beginning after
24 2014, a fee in an amount determined under para-
25 graph (3).

(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.

(3) DETERMINATION OF FEE AMOUNT.—

(A) IN GENERAL.—The total of all fees paid by all covered entities for any given year shall be the amount described in subsection (a)(2) multiplied by the ratio of the number of persons receiving treatments for HIV/AIDS that are insured in the private sector to the number of persons receiving treatments for HIV/AIDS who received insurance or reimbursements or care from the public sector.

(B) INDIVIDUAL CONTRIBUTIONS.—With respect to each covered entity, the fee under this section for any calendar year shall be equal to 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 the sum of such net premiums for all covered entities, multiplied by the amount under subparagraph (A).

(c) AMOUNTS TAKEN INTO ACCOUNT.—For purposes of subsection (b)(3), 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.

SEC. 14. DONOR INNOVATION PRIZE FUND.

(a) IN GENERAL.—In order to further separate product prices from research and development incentives and to facilitate the supply of low-cost generic drugs for the treatment of HIV/AIDS in developing countries, there is established in the Treasury of the United States a ''Donor Innovation Prize Fund''.

(b) AMOUNT IN FUND.—The amount in the Donor Innovation Prize Fund shall consist of—

(1) an amount set aside by the Secretary of Health and Human Services that is equal to 10 percent of the amount of money estimated by such Secretary as the cost of qualifying treatments for HIV/AIDS used by programs supported by the President's Emergency Plan for AIDS Relief (commonly referred to as ''PEPFAR'') or other federally supported programs to fund the treatment of HIV/AIDS in developing countries; and

(2) other amounts donated to the Fund as described in subsection (d).

(c) USE OF FUNDS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall use the funds from the Donor Innovation Prize Fund to reward the owners and developers of products that permit open competition for products in developing countries, either by not patenting products, providing nondiscriminatory royalty-free open licenses to all patents and other intellectual property claims on at least a field of use for the treatment of HIV/AIDS in developing countries, or through licenses to the Medicine Patent Pool.

(d) ENCOURAGEMENT BY SECRETARY.—The Secretary shall encourage other donors and developing country governments to contribute a similar fraction of drug purchase budgets to the Donor Innovation Prize Fund, in order to facilitate greater competition for generic drugs, while providing a sustainable source of rewards for innovation.

(e) PRIZES.—The Secretary shall establish and award prize payments from the Donor Innovation Prize Fund by applying similar eligibility rules, selection criteria, and requirements as are applied with respect to prize payments awarded from the Prize Fund for HIV/AIDS under section 8.

(f) TRANSPARENCY.—The Secretary shall adopt procedures to ensure that the operation of the Donor Innova-

tion Prize Fund is transparent and supported by a description of the methods, data sources, assumptions, outcomes, and related information that will allow the public to understand how the Secretary reaches its criteria-setting and award decisions.

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