

113TH CONGRESS
1ST SESSION

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

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.

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 “Prize Fund for HIV/
5 AIDS Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) The Centers for Disease Control and Pre-
9 vention estimates that more than 1,100,000 people

1 are living with HIV in the United States, and that
2 1 in 5 of those people living with HIV is unaware
3 of their infection.

4 (2) An estimated 49,000 Americans become in-
5 fected with HIV each year.

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

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

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

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

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

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

21 (9) The development of new medicines and vac-
22 cines for HIV/AIDS is a national priority.

23 (10) Market exclusivity for new products is an
24 expensive, inefficient, and unfair mechanism to re-
25 ward investments in new products, and has created

1 hardships for persons with HIV/AIDS and busi-
2 nesses that employ persons with HIV/AIDS.

3 (11) By de-linking research and development
4 incentives from product prices, and by eliminating
5 legal monopolies to sell new medicines for the treat-
6 ment of HIV/AIDS, it is possible to induce invest-
7 ments that are medically more important, procure
8 products at low prices from competitive suppliers,
9 and introduce more efficient incentives for research
10 and development.

11 **SEC. 3. PURPOSE.**

12 It is the purpose of this Act to provide sustainable
13 financing of incentives to encourage investments in re-
14 search and development of new medicines for HIV/AIDS
15 and to share knowledge, data, materials, and technology,
16 through the establishment of a Prize Fund for HIV/AIDS,
17 while enhancing access to such medicines by eliminating
18 legal monopolies on the manufacture, distribution, and
19 sale of such medicines.

20 **SEC. 4. DEFINITIONS.**

21 In this Act:

22 (1) BIOLOGICAL PRODUCT.—The term “biologi-
23 cal product” has the meaning given such term in
24 section 351 of the Public Health Service Act (42
25 U.S.C. 262).

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

4 (3) DUAL USE PRODUCT.—The term “dual use
5 product” means a product that is a qualifying treat-
6 ment for HIV/AIDS and that has a significant use
7 for other diseases.

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

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

17 (6) QUALIFYING TREATMENT FOR HIV/AIDS.—
18 The term “qualifying treatment for HIV/AIDS”
19 means an antiretroviral drug, biological product, vac-
20 cine, or other treatment primarily used for HIV/
21 AIDS that has been certified as a qualifying product
22 by the Secretary of Health and Human Services, for
23 purposes of the Prize Fund for HIV/AIDS.

1 **SEC. 5. ELIMINATION OF EXCLUSIVE RIGHTS TO MARKET**
2 **DRUGS AND BIOLOGICAL PRODUCTS.**

3 (a) IN GENERAL.—Notwithstanding title 35, United
4 States Code, relevant provisions of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including
6 amendments made by the Drug Price Competition and
7 Patent Term Restoration Act of 1984 (Public Law 98–
8 417; commonly referred to as the “Hatch-Waxman Act”)),
9 the Medicare Prescription Drug, Improvement, and Mod-
10 ernization Act of 2003 (Public Law 108–173), and any
11 other provision of law providing any patent right or exclu-
12 sive marketing period for any qualifying treatment for
13 HIV/AIDS or manufacturing process for a qualifying
14 treatment for HIV/AIDS (such as pediatric extensions
15 under section 505A of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 355a) or orphan drug marketing ex-
17 clusivity under subchapter B of chapter V of such Act (21
18 U.S.C. 360aa et seq.)), no person shall have the right to
19 exclusively manufacture, distribute, sell, or use a quali-
20 fying treatment for HIV/AIDS or a manufacturing proc-
21 ess for a qualifying treatment for HIV/AIDS in interstate
22 commerce, including the exclusive right to rely on health
23 registration data or the 30-month stay-of-effectiveness pe-
24 riod for Orange Book patents under section 505(j) of such
25 Act (21 U.S.C. 355(j)).

1 (b) REMUNERATION.—A person that is eligible for
2 prize payments from the Prize Fund for HIV/AIDS shall
3 receive such payments—

4 (1) in lieu of any remuneration the person
5 would have otherwise received for the exclusive mar-
6 keting, distribution, sale, or use of a qualifying
7 treatment for HIV/AIDS or manufacturing process
8 for a qualifying treatment for HIV/AIDS but for the
9 application of subsection (a); and

10 (2) in addition to any other remuneration that
11 such person receives by reason of the nonexclusive
12 marketing, distribution, sale, or use of the qualifying
13 treatment for HIV/AIDS or manufacturing process
14 for a qualifying treatment for HIV/AIDS.

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

20 (d) DUAL USE PRODUCTS.—In the case of a dual use
21 product, the elimination of exclusive rights under sub-
22 section (a) shall apply only with respect to the manufac-
23 ture, distribution, marketing, sale, or use of the product
24 for the treatment of HIV/AIDS.

1 **SEC. 6. QUALIFYING TREATMENTS FOR HIV/AIDS.**

2 Prize payments from the Fund under section 8 shall
3 be limited to qualifying treatments for HIV/AIDS, as de-
4 fined in section 4.

5 **SEC. 7. PRIZE FUND FOR HIV/AIDS.**

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

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

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

18 (d) AMOUNTS CREDITED TO THE FUND.—The Sec-
19 retary of the Treasury shall credit to the Fund the interest
20 on, and the proceeds from sale or redemption of, obliga-
21 tions held in the Fund.

22 **SEC. 8. PRIZE PAYMENTS FOR MEDICAL INNOVATION.**

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

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

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

5 (1) in the case of a qualifying treatment for
6 HIV/AIDS that is a drug or biological product, the
7 first person to receive market clearance with respect
8 to the drug or biological product;

9 (2) in the case of a manufacturing process for
10 a qualifying treatment for HIV/AIDS, the holder of
11 the patent with respect to such process; or

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

17 (c) CRITERIA.—The Prize Fund Director shall, by
18 regulation, establish criteria for the selection of recipients,
19 and for determining the amount, of prize payments under
20 this section. Such criteria shall include consideration of
21 the following:

22 (1) The number of patients who benefit from
23 the qualifying treatment for HIV/AIDS or manufac-
24 turing process involved.

1 (2) The incremental therapeutic benefit of the
2 qualifying treatment for HIV/AIDS or manufac-
3 turing process involved as compared to existing
4 drugs, biological products, and manufacturing proc-
5 esses available to treat the same disease or condi-
6 tion, except that the Prize Fund Director shall pro-
7 vide for cases where drugs, biological products, or
8 manufacturing processes are developed at roughly
9 the same time, so that the comparison is to products
10 that were not recently developed.

11 (3) Improved efficiency of manufacturing proc-
12 esses for drugs or biological processes.

13 (4) The extent to which knowledge, data, mate-
14 rials, and technology that are openly shared have
15 contributed to the successful development of new
16 products or improved processes for manufacturing
17 products.

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

21 (1) In cases where a new qualifying treatment
22 for HIV/AIDS or manufacturing process for a quali-
23 fying treatment of HIV/AIDS offers an improvement
24 over an existing qualifying treatment for HIV/AIDS
25 or manufacturing process for a qualifying treatment

1 and such new qualifying treatment or manufacturing
2 process competes with or replaces the existing quali-
3 fying treatment or manufacturing process, the Prize
4 Fund Director shall continue to make prize pay-
5 ments for the existing qualifying treatment or manu-
6 facturing process to the degree that the new quali-
7 fying treatment or manufacturing process was based
8 on or benefitted from the development of the exist-
9 ing qualifying treatment or manufacturing process.

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

15 (3) For any fiscal year, the Prize Fund Direc-
16 tor may not award a prize payment for any single
17 qualifying treatment for HIV/AIDS or manufac-
18 turing process for a qualifying treatment in an
19 amount that exceeds 50 percent of the total amount
20 appropriated to the Fund for that year.

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

1 the fourth full calendar-year quarter following the
2 calendar-year quarter in which the qualifying treat-
3 ment for HIV/AIDS receives market clearance.

4 **SEC. 9. OPEN SOURCE DIVIDEND PRIZES.**

5 (a) IN GENERAL.—In order to induce greater access
6 and the open sharing of knowledge, data, materials, and
7 technology, at least 5 percent of the prize payments from
8 the Fund shall be dedicated to Open Source Dividend
9 Prizes.

10 (b) PROCEDURES.—

11 (1) IN GENERAL.—The Prize Fund Director
12 shall adopt procedures for the allocation of Open
13 Source Dividend Prizes. Such procedures shall—

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

17 (B) reward the open, nondiscriminatory,
18 and royalty-free sharing of knowledge, data,
19 materials, and technology that has contributed
20 to the development of the new qualifying treat-
21 ment for HIV/AIDS or manufacturing proc-
22 esses that are rewarded under section 7;

23 (C) in the case of rewards for contributing
24 to the development of new qualifying treatment
25 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-

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

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

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

13 **SEC. 11. SPECIAL TRANSITION RULES.**

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

18 (b) DETERMINATION OF VALUE.—In determining the
 19 amount of a prize payment for a qualifying treatment for
 20 HIV/AIDS described in subsection (a), the Prize Fund Di-
 21 rector shall calculate the incremental value of the quali-
 22 fying treatment for HIV/AIDS as of the date on which
 23 the qualifying treatment for HIV/AIDS was first intro-
 24 duced in the market.

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

4 (1) of the amount appropriated to the Fund for
5 fiscal year 2015, not more than 90 percent of such
6 amount; and

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

12 **SEC. 12. ARBITRATION.**

13 In the case of a qualifying treatment for HIV/AIDS
14 that is on the market on October 1, 2014, and subject
15 to patents owned by a party other than the person who
16 first received market clearance for the qualifying treat-
17 ment for HIV/AIDS, the Prize Fund Director shall estab-
18 lish an arbitration procedure to determine an equitable di-
19 vision of any prize payments under this Act among the
20 patent owners and the person who first received market
21 clearance for the qualifying treatment for HIV/AIDS.

22 **SEC. 13. FUNDING.**

23 (a) APPROPRIATIONS.—

24 (1) START-UP COSTS.—For fiscal year 2015,
25 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).

1 (2) ANNUAL PAYMENT DATE.—For purposes of
2 this section, the term “annual payment date”
3 means, with respect to any calendar year, a date de-
4 termined by the Secretary, which in no event, may
5 be later than September 30 of such calendar year.

6 (3) DETERMINATION OF FEE AMOUNT.—

7 (A) IN GENERAL.—The total of all fees
8 paid by all covered entities for any given year
9 shall be the amount described in subsection
10 (a)(2) multiplied by the ratio of the number of
11 persons receiving treatments for HIV/AIDS
12 that are insured in the private sector to the
13 number of persons receiving treatments for
14 HIV/AIDS who received insurance or reim-
15 bursements or care from the public sector.

16 (B) INDIVIDUAL CONTRIBUTIONS.—With
17 respect to each covered entity, the fee under
18 this section for any calendar year shall be equal
19 to the ratio of the covered entity’s net pre-
20 miums written with respect to health insurance
21 for any United States health risk taken into ac-
22 count under subsection (c) during the preceding
23 calendar year, to the sum of such net premiums
24 for all covered entities, multiplied by the
25 amount under subparagraph (A).

1 (c) AMOUNTS TAKEN INTO ACCOUNT.—For purposes
 2 of subsection (b)(3), the net premiums written with re-
 3 spect to health insurance for any United States health risk
 4 that are taken into account during any calendar year with
 5 respect to any covered entity shall be determined as fol-
 6 lows:

7 (1) With respect to a covered entity’s net pre-
 8 miums written during the calendar year that are not
 9 more than \$25,000,000, the percentage of net pre-
 10 miums written that are taken into account is 0 per-
 11 cent.

12 (2) With respect to a covered entity’s net pre-
 13 miums written during the calendar year that are
 14 more than \$25,000,000 but less than \$50,000,000,
 15 the percentage of net premiums written that are
 16 taken into account is 50 percent.

17 (3) With respect to a covered entity’s net pre-
 18 miums written during the calendar year that are
 19 \$50,000,000 or more, the percentage of net pre-
 20 miums written that are taken into account is 100
 21 percent.

22 (d) COVERED ENTITY.—

23 (1) IN GENERAL.—For purposes of this section,
 24 the term “covered entity” means any entity which

1 provides health insurance for any United States
2 health risk.

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

5 **SEC. 14. DONOR INNOVATION PRIZE FUND.**

6 (a) IN GENERAL.—In order to further separate prod-
7 uct prices from research and development incentives and
8 to facilitate the supply of low-cost generic drugs for the
9 treatment of HIV/AIDS in developing countries, there is
10 established in the Treasury of the United States a “Donor
11 Innovation Prize Fund”.

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

14 (1) an amount set aside by the Secretary of
15 Health and Human Services that is equal to 10 per-
16 cent of the amount of money estimated by such Sec-
17 retary as the cost of qualifying treatments for HIV/
18 AIDS used by programs supported by the Presi-
19 dent’s Emergency Plan for AIDS Relief (commonly
20 referred to as “PEPFAR”) or other federally sup-
21 ported programs to fund the treatment of HIV/
22 AIDS in developing countries; and

23 (2) other amounts donated to the Fund as de-
24 scribed in subsection (d).

1 (c) USE OF FUNDS.—The Secretary of Health and
 2 Human Services (referred to in this section as the “Sec-
 3 retary”) shall use the funds from the Donor Innovation
 4 Prize Fund to reward the owners and developers of prod-
 5 ucts that permit open competition for products in devel-
 6 oping countries, either by not patenting products, pro-
 7 viding nondiscriminatory royalty-free open licenses to all
 8 patents and other intellectual property claims on at least
 9 a field of use for the treatment of HIV/AIDS in developing
 10 countries, or through licenses to the Medicine Patent Pool.

11 (d) ENCOURAGEMENT BY SECRETARY.—The Sec-
 12 retary shall encourage other donors and developing coun-
 13 try governments to contribute a similar fraction of drug
 14 purchase budgets to the Donor Innovation Prize Fund, in
 15 order to facilitate greater competition for generic drugs,
 16 while providing a sustainable source of rewards for innova-
 17 tion.

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

24 (f) TRANSPARENCY.—The Secretary shall adopt pro-
 25 cedures to ensure that the operation of the Donor Innova-

1 tion Prize Fund is transparent and supported by a de-
2 scription of the methods, data sources, assumptions, out-
3 comes, and related information that will allow the public
4 to understand how the Secretary reaches its criteria-set-
5 ting and award decisions.

