

113TH CONGRESS  
1ST SESSION

# S. 627

To provide incentives for investment in research and development for new medicines, to enhance access to new medicines, and for other purposes.

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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 provide incentives for investment in research and development for new medicines, to enhance access to new medicines, 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  
5       Prize Fund Act”.

6       **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

8               (1) The development of new medicines and vac-  
9       cines is necessary to improve health care outcomes.

1           (2) Market exclusivity for new products is an  
2           expensive, inefficient, and unfair mechanism to re-  
3           ward investments in new products.

4           (3) By de-linking research and development in-  
5           centives from product prices, and by eliminating  
6           legal monopolies to sell products, it is possible to in-  
7           duce investments that are medically more important,  
8           procure products at low prices from competitive sup-  
9           pliers, radically lower pricing barriers for access to  
10          new medicines, reduce wasteful marketing and re-  
11          search and development activities, and dramatically  
12          lower the overall costs of acquiring innovation, while  
13          expanding access to that innovation.

14          (4) By funding innovation prizes at .55 percent  
15          of gross domestic product, the United States would  
16          provide more than \$86,000,000,000 in rewards for  
17          successful innovation in 2012.

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

21 **SEC. 3. PURPOSE.**

22          It is the purpose of this Act to provide incentives to  
23          encourage entities to invest in research and development  
24          of new medicines and to share knowledge, data, materials,  
25          and technology, through the establishment of a Medical

1 Innovation Prize Fund, while enhancing access to such  
2 medicines by eliminating legal monopolies on the manufac-  
3 ture, distribution, and sale of such medicines.

4 **SEC. 4. DEFINITIONS.**

5 In this Act:

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

10 (2) BOARD.—The term “Board” means the  
11 Board of Trustees for the Fund for Medical Innova-  
12 tion Prizes established under section 7.

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

16 (4) FUND.—The term “Fund” means the Fund  
17 for Medical Innovation Prizes established under sec-  
18 tion 6.

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

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 drug, biological product, or  
13 manufacturing process for a drug or biological product  
14 (such as pediatric extensions under section 505A of the  
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)  
16 or orphan drug marketing exclusivity under subchapter B  
17 of chapter V of such Act (21 U.S.C. 360aa et seq.)), no  
18 person shall have the right to exclusively manufacture, dis-  
19 tribute, sell, or use a drug, a biological product, or a man-  
20 ufacturing process for a drug or biological product in  
21 interstate commerce, including the exclusive right to rely  
22 on health registration data or the 30-month stay-of-effec-  
23 tiveness period for Orange Book patents under section  
24 505(j) of such Act (21 U.S.C. 355(j)).

1 (b) REMUNERATION.—A person that is eligible for  
2 prize payments from the Fund as provided for in sections  
3 9, 10, or 11 shall 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 drug, biological  
7 product, or manufacturing process for a drug or bio-  
8 logical product but for the application of subsection  
9 (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 drug, bio-  
13 logical product, or manufacturing process for a drug  
14 or biological product.

15 (c) APPLICATION.—This section shall apply only with  
16 respect to the marketing, distribution, sale, or use of a  
17 drug, a biological product, or a manufacturing process for  
18 a drug or biological product that occurs on or after Octo-  
19 ber 1, 2014.

20 **SEC. 6. FUND FOR MEDICAL INNOVATION PRIZES.**

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

1 (b) AVAILABILITY OF FUNDS.—Amounts in the Fund  
 2 shall be available to the Board, subject to section 17(c),  
 3 for the purpose of carrying out this Act.

4 (c) AMOUNTS CREDITED TO THE FUND.—The Sec-  
 5 retary of the Treasury shall credit to the Fund the interest  
 6 on, and the proceeds from sale or redemption of, obliga-  
 7 tions held in the Fund.

8 **SEC. 7. BOARD OF TRUSTEES FOR THE FUND.**

9 (a) ESTABLISHMENT.—There is hereby established  
 10 (as a permanent, independent establishment in the execu-  
 11 tive branch) a Board of Trustees for the Fund for Medical  
 12 Innovation Prizes.

13 (b) MEMBERSHIP.—The Board shall be composed of  
 14 13 members, including—

15 (1) the Administrator of the Centers for Medi-  
 16 care & Medicaid Services;

17 (2) the Commissioner of Food and Drugs;

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

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

22 (5) 9 individuals to be appointed by the Presi-  
 23 dent, with the advice and consent of the Senate, of  
 24 which—

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

3 (B) 2 shall be representatives of entities  
4 that provide health insurance and contribute to  
5 the co-funding of the Fund for Medical Innova-  
6 tion Prizes under section 17;

7 (C) 2 shall be representatives of the med-  
8 ical research and development sector, including  
9 at least 1 representative of the nonprofit private  
10 medical research and development sector; and

11 (D) 3 shall be representatives of consumer  
12 and patient interests, including at least one rep-  
13 resentative of patients suffering from orphan  
14 diseases.

15 (c) TERMS.—

16 (1) IN GENERAL.—Except as provided in para-  
17 graph (2), each member appointed to the Board  
18 under subsection (b)(5) shall be appointed for a  
19 term of 4 years.

20 (2) TERMS OF INITIAL APPOINTEES.—As des-  
21 ignated by the President at the time of appointment,  
22 of the members first appointed to the Board under  
23 subsection (b)(5)—

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

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

3 (d) VACANCIES.—Any member of the Board ap-  
4 pointed to fill a vacancy occurring before the expiration  
5 of the term for which the member's predecessor was ap-  
6 pointed shall be appointed only for the remainder of that  
7 term. A member of the Board may serve after the expira-  
8 tion of that member's term until a successor has taken  
9 office.

10 (e) COMPENSATION AND TRAVEL EXPENSES.—

11 (1) COMPENSATION.—Members of the Board  
12 shall each be paid not less than the daily equivalent  
13 of level IV of the Executive Schedule for each day  
14 (including travel time) during which they are en-  
15 gaged in the actual performance of the duties of the  
16 Board.

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

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

1 (g) STAFF.—The Board may appoint and fix the pay  
 2 of such additional personnel as the Board considers appro-  
 3 priate. The staff of the Board shall be appointed subject  
 4 to the provisions of title 5, United States Code, governing  
 5 appointments in the competitive service, and shall be paid  
 6 in accordance with the provisions of chapter 51 and sub-  
 7 chapter III of chapter 53 of such title relating to classi-  
 8 fication and General Schedule pay rates.

9 (h) EXPERTS AND CONSULTANTS.—The Board may  
 10 procure temporary and intermittent services under section  
 11 3109(b) of title 5, United States Code.

12 **SEC. 8. POWERS AND DUTIES OF THE BOARD.**

13 (a) DUTIES.—The Board shall—

14 (1) award prize payments for medical innova-  
 15 tion in accordance with this Act; and

16 (2) submit a report to the Congress under sec-  
 17 tion 16.

18 (b) POWERS OF BOARD.—

19 (1) HEARINGS AND SESSIONS.—

20 (A) IN GENERAL.—The Board may, for  
 21 the purpose of carrying out this Act, hold hear-  
 22 ings, sit and act at times and places, take testi-  
 23 mony, and receive evidence as the Board con-  
 24 siders appropriate.

1 (B) FIRST MEETING.—Not later than 30  
 2 days after the initial members of the Board are  
 3 appointed under section 7(b)(5) and confirmed,  
 4 the Board shall conduct its first meeting.

5 (2) POLICIES AND PROCEDURES.—

6 (A) IN GENERAL.—Not later than 1 year  
 7 after the initial members of the Board are ap-  
 8 pointed under section 7(b)(5) and confirmed,  
 9 the Board shall establish such policies and pro-  
 10 cedures as may be appropriate to carry out this  
 11 Act.

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

17 (C) ADMINISTRATIVE PROCEDURES.—The  
 18 policies and procedures of the Board shall com-  
 19 ply with subchapter II of chapter 5 of title 5,  
 20 United States Code.

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

23 (i) comply with sections 552 and 552b  
 24 of title 5, United States Code (commonly  
 25 referred to as the “Freedom of Informa-

tion 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, out-  
comes, 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 as-  
sist the Board in carrying out this Act, the Board  
shall establish independent expert advisory commit-  
tees, including committees on the following:

(A) Economic evaluation of therapeutic  
benefits.

(B) Business models and incentive struc-  
tures 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

1 the Board, take any action which the Board is au-  
 2 thorized to take under this Act.

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

7 **SEC. 9. PRIZE PAYMENTS FOR MEDICAL INNOVATION.**

8 (a) **AWARD.**—For fiscal year 2015, and each subse-  
 9 quent fiscal year, the Board shall award to persons de-  
 10 scribed in subsection (b) prize payments for medical inno-  
 11 vation relating to a drug, a biological product, or a new  
 12 manufacturing process for a drug or biological product.

13 (b) **ELIGIBILITY.**—To be eligible to receive a prize  
 14 payment under subsection (a) for medical innovation relat-  
 15 ing to a drug, a biological product, or a manufacturing  
 16 process, a person shall be—

17 (1) in the case of a drug or biological product,  
 18 the first person to receive market clearance with re-  
 19 spect to the drug or biological product;

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

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

1       (c) CRITERIA.—The Board shall, by regulation, es-  
2       tablish criteria for the selection of recipients, and for de-  
3       termining the amount, of prize payments under this sec-  
4       tion. Such criteria shall include consideration of the fol-  
5       lowing:

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

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

21             (3) The degree to which the drug, biological  
22      product, or manufacturing process involved address-  
23      es priority health care needs, including—

24                 (A) current and emerging global infectious  
25      diseases;

1 (B) severe illnesses with small client popu-  
2 lations (such as indications for which orphan  
3 designation has been granted under section 526  
4 of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 360bb)); and

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

8 (4) Improved efficiency of manufacturing proc-  
9 esses for drugs or biological processes.

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

15 (6) In the case of antibiotics or other products  
16 for which drug resistance is a significant public  
17 health problem, the expected life cycle benefits of the  
18 antibiotic or other product, with appropriate adjust-  
19 ments that reward the conservation of the resources,  
20 taking into account drug resistance that is related to  
21 use of the product.

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

1       (d) REQUIREMENTS.—In awarding prize payments  
2 under this section, the Board shall comply with the fol-  
3 lowing:

4           (1) In cases where a new drug, biological prod-  
5 uct, or manufacturing process offers an improve-  
6 ment over an existing drug, biological product, or  
7 manufacturing process and the new drug, biological  
8 product, or manufacturing process competes with or  
9 replaces the existing drug, biological product, or  
10 manufacturing process, the Board shall continue to  
11 make prize payments for the existing drug, biological  
12 product, or manufacturing process to the degree that  
13 the new drug, biological product, or manufacturing  
14 process was based on or benefitted from the develop-  
15 ment of the existing drug, biological product, or  
16 manufacturing process.

17           (2) The Board may not make prize payments  
18 based on the identity of the person who manufac-  
19 tures, distributes, sells, or uses the drug, biological  
20 product, or manufacturing process involved.

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

1           (4) For any fiscal year, the Board may not  
 2           award a prize payment for any single drug, biologi-  
 3           cal product, or manufacturing process in an amount  
 4           that exceeds 5 percent of the total amount appro-  
 5           priated to the Fund for that year.

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

13 **SEC. 10. PRIZES FOR PRIORITY RESEARCH AND DEVELOP-**  
 14 **MENT.**

15          (a) MINIMUM LEVELS OF FUNDING.—For fiscal year  
 16 2015, and each subsequent fiscal year, the Board shall  
 17 establish and may periodically modify minimum levels of  
 18 funding under section 9 for priority research and develop-  
 19 ment.

20          (b) INITIAL MINIMUM LEVELS.—Of the amount ap-  
 21 propriated to the Fund for a fiscal year, the Board shall  
 22 use (subject to the establishment or modification of an ap-  
 23 plicable minimum level of funding under subsection (a))  
 24 not less than—

1           (1) 4 percent of such amount for global ne-  
2       glected diseases;

3           (2) 10 percent of such amount for orphan dis-  
4       eases; and

5           (3) 4 percent of such amount for global infec-  
6       tious diseases and other global public health prior-  
7       ities, including research on AIDS, AIDS vaccines,  
8       and medicines for responding to bioterrorism.

9       (c) PUBLIC INPUT; RECOMMENDATIONS.—The advi-  
10   sory committee on research and development priorities (es-  
11   tablished pursuant to section 8(b)(3)) shall—

12           (1) solicit public input on research and develop-  
13       ment priorities; and

14           (2) periodically recommend to the Board modi-  
15       fications in the minimum levels of funding for prizes  
16       for priority research and development under this sec-  
17       tion.

18       (d) PROCEDURES.—The Board shall adopt proce-  
19   dures to establish and periodically modify minimum levels  
20   of funding under section 9 for priority research and devel-  
21   opment.

22   **SEC. 11. OPEN SOURCE DIVIDEND PRIZES.**

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

1 the Fund shall be dedicated to Open Source Dividend  
2 prizes.

3 (b) PROCEDURES.—

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

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

10 (B) reward the open, nondiscriminatory  
11 and royalty-free sharing of knowledge, data,  
12 materials, and technology that has contributed  
13 to the development of the new drugs, biological  
14 products, or manufacturing processes that are  
15 rewarded under sections 9 and 10;

16 (C) in the case of rewards for contributing  
17 to the development of new drugs, biological  
18 products, or manufacturing processes rewarded  
19 under sections 9 and 10, provide for a time-lim-  
20 ited period of nominations for persons or com-  
21 munities whose contributions were considered  
22 useful, including the evidence to support such  
23 nominations to describe the significance of the  
24 contribution; and

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

3 (2) PUBLIC AVAILABILITY OF NOMINATIONS.—

4 The nominations described in paragraph (1)(C), and  
 5 the evidence supporting such nominations, shall be  
 6 public. The public shall be allowed to provide com-  
 7 mentary and additional evidence on such nomina-  
 8 tions before awards are made.

9 **SEC. 12. COMPETITIVE INTERMEDIARIES FOR FUNDING IN-**  
 10 **TERIM TECHNOLOGIES.**

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

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

21 (c) RULES.—The Board of Trustees shall adopt rules  
 22 to ensure the transparency and accountability of any enti-  
 23 ties authorized to act as competitive intermediaries under  
 24 subsection (a).

1 **SEC. 13. SPECIAL TRANSITION RULES.**

2 (a) IN GENERAL.—A drug or biological product that  
3 is on the market on October 1, 2014, shall remain eligible  
4 for prize payments for not more than 10 fiscal years, con-  
5 sistent with section 9(d)(3).

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

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

15 (1) of the amount appropriated to the Fund for  
16 fiscal year 2015, not more than 90 percent of such  
17 amount; and

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

23 **SEC. 14. ARBITRATION.**

24 In the case of a drug that is on the market on Octo-  
25 ber 1, 2014, and subject to patents owned by a party other  
26 than the person who first received market clearance for

1 the drug, the Board shall establish an arbitration proce-  
2 dure to determine an equitable division of any prize pay-  
3 ments under this Act among the patent owners and the  
4 person who first received market clearance for the drug.

5 **SEC. 15. ANNUAL AUDITS BY GAO.**

6 (a) AUDITS.—The Comptroller General of the United  
7 States shall conduct an audit of the Board each fiscal year  
8 to determine the effectiveness of the Board—

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

13 (2) in addressing society’s medical needs, in-  
14 cluding global neglected diseases that afflict pri-  
15 marily the poor in developing countries, indications  
16 for which orphan designation has been granted  
17 under section 526 of the Federal Food, Drug, and  
18 Cosmetic Act (21 U.S.C. 360bb), and global infec-  
19 tious diseases and other global public health prior-  
20 ities.

21 (b) REPORTS.—The Comptroller General of the  
22 United States shall submit a report to the Congress each  
23 fiscal year on the results of each audit conducted under  
24 subsection (a).

1 **SEC. 16. REPORT TO CONGRESS.**

2 Not later than 1 year after the date of the enactment  
3 of this Act, the Board shall submit to Congress a report  
4 containing the findings, conclusions, and recommendations  
5 of the Board concerning the implementation and adminis-  
6 tration of this Act, including recommendations for such  
7 legislative and administrative action as the Board deter-  
8 mines to be appropriate.

9 **SEC. 17. FUNDING.**

10 (a) APPROPRIATIONS.—

11 (1) START-UP COSTS.—For fiscal year 2015,  
12 there are authorized to be appropriated to the Fund,  
13 such sums as may be necessary to carry out this  
14 Act.

15 (2) PROGRAM IMPLEMENTATION.—For fiscal  
16 year 2015 and each subsequent fiscal year, there is  
17 appropriated to the Fund, out of any funds in the  
18 Treasury not otherwise appropriated, an amount  
19 equal to the amount that is .55 percent of the gross  
20 domestic product of the United States for the pre-  
21 ceding fiscal year (as such amount is determined by  
22 the Secretary of Commerce).

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

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

3 **SEC. 18. IMPOSITION OF ANNUAL FEE ON HEALTH INSUR-**  
 4 **ANCE PROVIDERS.**

5 (a) IMPOSITION OF FEE.—

6 (1) IN GENERAL.—Each covered entity engaged  
 7 in the business of providing health insurance shall  
 8 pay to the Secretary not later than the annual pay-  
 9 ment date of each calendar year beginning after  
 10 2014 a fee in an amount determined under sub-  
 11 section (b).

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

17 (b) DETERMINATION OF FEE AMOUNT.—With re-  
 18 spect to each covered entity, the fee under this section for  
 19 any calendar year shall be equal to the amount determined  
 20 under section 17(a)(2), multiplied by the ratio of the cov-  
 21 ered entity’s net premiums written with respect to health  
 22 insurance for any United States health risk taken into ac-  
 23 count under subsection (c) during the preceding calendar  
 24 year, to—

1           (1) the sum of net premiums for all covered en-  
2       tities; and

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

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

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

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

21           (3) With respect to a covered entity's net pre-  
22       miums written during the calendar year that are  
23       \$50,000,000 or more, the percentage of net pre-  
24       miums written that are taken into account is 100  
25       percent.

1 (d) COVERED ENTITY.—

2 (1) IN GENERAL.—For purposes of this section,  
3 the term “covered entity” means any entity which  
4 provides health insurance for any United States  
5 health risk.

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

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