

112TH CONGRESS
1ST SESSION

S. 1137

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

IN THE SENATE OF THE UNITED STATES

MAY 26, 2011

Mr. SANDERS introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 \$80,000,000,000 in rewards for
17 successful innovation in 2011.

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

21 (6) By providing 5 percent of the prize fund re-
22 wards to those who provide open access to knowl-
23 edge, data, materials, and technologies, new open
24 source business models will induce greater access to
25 useful knowledge, data, materials, and technologies.

1 **SEC. 3. PURPOSE.**

2 It is the purpose of this Act to provide incentives to
3 encourage entities to invest in research and development
4 of new medicines and to share knowledge, data, materials,
5 and technology, through the establishment of a Medical
6 Innovation Prize Fund, while enhancing access to such
7 medicines by eliminating legal monopolies on the manufac-
8 ture, distribution, and sale of such medicines.

9 **SEC. 4. DEFINITIONS.**

10 In this Act:

11 (1) **BIOLOGICAL PRODUCT.**—The term “biologi-
12 cal product” has the meaning given such term in
13 section 351 of the Public Health Service Act (42
14 U.S.C. 262).

15 (2) **BOARD.**—The term “Board” means the
16 Board of Trustees for the Fund for Medical Innova-
17 tion Prizes established under section 7.

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

21 (4) **FUND.**—The term “Fund” means the Fund
22 for Medical Innovation Prizes established under sec-
23 tion 6.

24 (5) **MARKET CLEARANCE.**—The term “market
25 clearance” means the approval of an application
26 under section 505 of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 355) or the approval of a
2 biologics license application under subsection (a) of
3 section 351 of the Public Health Service Act (42
4 U.S.C. 262).

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

7 (a) IN GENERAL.—Notwithstanding title 35, United
8 States Code, relevant provisions of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including
10 amendments made by the Drug Price Competition and
11 Patent Term Restoration Act of 1984 (Public Law 98–
12 417; commonly referred to as the “Hatch-Waxman Act”)),
13 the Medicare Prescription Drug, Improvement, and Mod-
14 ernization Act of 2003 (Public Law 108–173), and any
15 other provision of law providing any patent right or exclu-
16 sive marketing period for any drug, biological product, or
17 manufacturing process for a drug or biological product
18 (such as pediatric extensions under section 505A of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)
20 or orphan drug marketing exclusivity under subchapter B
21 of chapter V of such Act (21 U.S.C. 360aa et seq.)), no
22 person shall have the right to exclusively manufacture, dis-
23 tribute, sell, or use a drug, a biological product, or a man-
24 ufacturing process for a drug or biological product in
25 interstate commerce, including the exclusive right to rely

1 on health registration data or the 30-month stay-of-effectiveness period for Orange Book patents under section
2 tiveness period for Orange Book patents under section
3 505(j) of such Act (21 U.S.C. 355(j)).

4 (b) REMUNERATION.—A person that is eligible for
5 prize payments from the Fund as provided for in sections
6 9, 10, or 11 shall receive such payments—

7 (1) in lieu of any remuneration the person
8 would have otherwise received for the exclusive mar-
9 keting, distribution, sale, or use of a drug, biological
10 product, or manufacturing process for a drug or bio-
11 logical product but for the application of subsection
12 (a); and

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

18 (c) APPLICATION.—This section shall apply only with
19 respect to the marketing, distribution, sale, or use of a
20 drug, a biological product, or a manufacturing process for
21 a drug or biological product that occurs on or after Octo-
22 ber 1, 2012.

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

24 (a) ESTABLISHMENT.—There is hereby established in
25 the Treasury of the United States a revolving fund to be

1 known as the “Fund for Medical Innovation Prizes”,
2 which shall consist of amounts appropriated to the Fund
3 and amounts credited to the Fund under subsection (c).

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

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

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

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

16 (b) MEMBERSHIP.—The Board shall be composed of
17 13 members, including—

18 (1) the Administrator of the Centers for Medi-
19 care & Medicaid Services;

20 (2) the Commissioner of Food and Drugs;

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

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

1 (5) 9 individuals to be appointed by the Presi-
2 dent, with the advice and consent of the Senate, of
3 which—

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

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

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

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

18 (c) TERMS.—

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

23 (2) TERMS OF INITIAL APPOINTEES.—As des-
24 ignated by the President at the time of appointment,

1 of the members first appointed to the Board under
2 subsection (b)(5)—

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

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

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

14 (e) COMPENSATION AND TRAVEL EXPENSES.—

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

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

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

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

13 (h) EXPERTS AND CONSULTANTS.—The Board may
14 procure temporary and intermittent services under section
15 3109(b) of title 5, United State Code.

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

17 (a) DUTIES.—The Board shall—

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

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

22 (b) POWERS OF BOARD.—

23 (1) HEARINGS AND SESSIONS.—

24 (A) IN GENERAL.—The Board may, for
25 the purpose of carrying out this Act, hold hear-

1 ings, sit and act at times and places, take testi-
2 mony, and receive evidence as the Board con-
3 siders appropriate.

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

8 (2) POLICIES AND PROCEDURES.—

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

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

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

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

1 (i) comply with sections 552 and 552b
2 of title 5, United States Code (commonly
3 referred to as the “Freedom of Informa-
4 tion Act” and the “Government in the
5 Sunshine Act”, respectively); and

6 (ii) ensure that the proceedings and
7 deliberations of the Board are transparent
8 and are supported by a description of the
9 methods, data sources, assumptions, out-
10 comes, and related information that will
11 allow the public to understand how the
12 Board reaches its criteria-setting and
13 award decisions.

14 (3) EXPERT ADVISORY COMMITTEES.—To as-
15 sist the Board in carrying out this Act, the Board
16 shall establish independent expert advisory commit-
17 tees, including committees on the following:

18 (A) Economic evaluation of therapeutic
19 benefits.

20 (B) Business models and incentive struc-
21 tures for innovation.

22 (C) Research and development priorities.

23 (D) Orphan diseases.

24 (E) Financial control and auditing.

25 (F) Open source biomedical science.

1 (4) POWERS OF MEMBERS AND AGENTS.—Any
2 member or agent of the Board may, if authorized by
3 the Board, take any action which the Board is au-
4 thorized to take under this Act.

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

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

10 (a) AWARD.—For fiscal year 2013, and each subse-
11 quent fiscal year, the Board shall award to persons de-
12 scribed in subsection (b) prize payments for medical inno-
13 vation relating to a drug, a biological product, or a new
14 manufacturing process for a drug or biological product.

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

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

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

24 (3) in the case of open source contributions, the
25 persons or communities that openly shared knowl-

1 edge, data, materials, and technology on a royalty-
2 free and nondiscriminatory basis.

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

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

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

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

1 (A) current and emerging global infectious
2 diseases;

3 (B) severe illnesses with small client popu-
4 lations (such as indications for which orphan
5 designation has been granted under section 526
6 of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 360bb)); and

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

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

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

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

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

4 (d) REQUIREMENTS.—In awarding prize payments
5 under this section, the Board shall comply with the fol-
6 lowing:

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

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

24 (3) The Board may award prize payments for
25 a drug, a biological product, or a manufacturing

1 process for not more than 10 fiscal years, regardless
2 of the term of any related patents.

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

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

15 **SEC. 10. PRIZES FOR PRIORITY RESEARCH AND DEVELOP-**
16 **MENT.**

17 (a) **MINIMUM LEVELS OF FUNDING.**—For fiscal year
18 2013, and each subsequent fiscal year, the Board shall
19 establish and may periodically modify minimum levels of
20 funding under section 9 for priority research and develop-
21 ment.

22 (b) **INITIAL MINIMUM LEVELS.**—Of the amount ap-
23 propriated to the Fund for a fiscal year, the Board shall
24 use (subject to the establishment or modification of an ap-

1 plicable minimum level of funding under subsection (a))
2 not less than—

3 (1) 4 percent of such amount for global ne-
4 glected diseases;

5 (2) 10 percent of such amount for orphan dis-
6 eases; and

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

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

14 (1) solicit public input on research and develop-
15 ment priorities; and

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

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

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

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

7 (b) PROCEDURES.—

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

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

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

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

1 nominations to describe the significance of the
 2 contribution; and

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

5 (2) PUBLIC AVAILABILITY OF NOMINATIONS.—

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

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

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

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

23 (c) RULES.—The Board of Trustees shall adopt rules
 24 to ensure the transparency and accountability of any enti-

1 ties authorized to act as competitive intermediaries under
2 subsection (a).

3 **SEC. 13. SPECIAL TRANSITION RULES.**

4 (a) IN GENERAL.—A drug or biological product that
5 is on the market on October 1, 2012, shall remain eligible
6 for prize payments for not more than 10 fiscal years, con-
7 sistent with section 9(d)(3).

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

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

17 (1) of the amount appropriated to the Fund for
18 fiscal year 2013, not more than 90 percent of such
19 amount; and

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

1 **SEC. 14. ARBITRATION.**

2 In the case of a drug that is on the market on Octo-
3 ber 1, 2012, and subject to patents owned by a party other
4 than the person who first received market clearance for
5 the drug, the Board shall establish an arbitration proce-
6 dure to determine an equitable division of any prize pay-
7 ments under this Act among the patent owners and the
8 person who first received market clearance for the drug.

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

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

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

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

25 (b) REPORTS.—The Comptroller General of the
26 United States shall submit a report to the Congress each

1 fiscal year on the results of each audit conducted under
2 subsection (a).

3 **SEC. 16. REPORT TO CONGRESS.**

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

11 **SEC. 17. FUNDING.**

12 (a) APPROPRIATIONS.—

13 (1) START-UP COSTS.—For fiscal year 2013,
14 there are authorized to be appropriated to the Fund,
15 such sums as may be necessary to carry out this
16 Act.

17 (2) PROGRAM IMPLEMENTATION.—For fiscal
18 year 2013 and each subsequent fiscal year, there is
19 appropriated to the Fund, out of any funds in the
20 Treasury not otherwise appropriated, an amount
21 equal to the amount that is .55 percent of the gross
22 domestic product of the United States for the pre-
23 ceding fiscal year (as such amount is determined by
24 the Secretary of Commerce).

1 (b) AVAILABILITY.—Funds appropriated to the Fund
 2 for a fiscal year shall remain available for expenditure in
 3 accordance with this Act until the end of the 3-year period
 4 beginning on October 1 of such fiscal year. Any such funds
 5 that are unexpended at the end of such period shall revert
 6 to the Treasury.

7 **SEC. 18. IMPOSITION OF ANNUAL FEE ON HEALTH INSUR-**
 8 **ANCE PROVIDERS.**

9 (a) IMPOSITION OF FEE.—

10 (1) IN GENERAL.—Each covered entity engaged
 11 in the business of providing health insurance shall
 12 pay to the Secretary not later than the annual pay-
 13 ment date of each calendar year beginning after
 14 2012 a fee in an amount determined under sub-
 15 section (b).

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

21 (b) DETERMINATION OF FEE AMOUNT.—With re-
 22 spect to each covered entity, the fee under this section for
 23 any calendar year shall be equal to the amount determined
 24 under section 17(a)(2), multiplied by the ratio of the cov-
 25 ered entity’s net premiums written with respect to health

1 insurance for any United States health risk taken into ac-
2 count under subsection (c) during the preceding calendar
3 year, to—

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

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

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

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

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

24 (3) With respect to a covered entity's net pre-
25 miums written during the calendar year that are

1 \$50,000,000 or more, the percentage of net pre-
2 miums written that are taken into account is 100
3 percent.

4 (d) COVERED ENTITY.—

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

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

○