

110TH CONGRESS
1ST SESSION

S. 2210

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

OCTOBER 19, 2007

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 Act of 2007”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Current incentives for research and develop-
9 ment for new medicines that involve market exclu-
10 sivity lead to high prices.

1 spending that would be assigned to the United
2 States market, based upon the United States share
3 of global Gross National Product.

4 (19) The 2007 cost of the innovation prizes will
5 be much lower than the \$200,000,000,000 in re-
6 duced United States outlays for pharmaceutical
7 drugs, it will vastly expand access to medicines, and
8 it will ensure that future research and development
9 for new medicines is targeted at treatments that im-
10 prove health care outcomes and address public
11 health priorities.

12 **SEC. 3. PURPOSE.**

13 It is the purpose of this Act to provide incentives to
14 encourage entities to invest in research and development
15 of new medicines through the establishment of a Medical
16 Innovation Prize Fund and to enhance access to such
17 medicines by allowing any person in compliance with Food
18 and Drug Administration requirements to manufacture,
19 distribute, or sell an approved medicine.

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

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

7 (4) FUND.—The term “Fund” means the Fund
8 for Medical Innovation Prizes established under sec-
9 tion 6.

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

19 (a) IN GENERAL.—Notwithstanding title 35, United
20 States Code, relevant provisions of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including
22 amendments made by the Drug Price Competition and
23 Patent Term Restoration Act of 1984 (Public Law 98–
24 417; referred to as the “Hatch-Waxman Act”)), the Medi-
25 care Prescription Drug, Improvement, and Modernization

1 Act of 2003 (Public Law 108–173), and any other provi-
2 sion of law providing any patent right or exclusive mar-
3 keting period for any drug, biological product, or manufac-
4 turing process for a drug or biological product (such as
5 pediatric extensions under section 505A of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) or or-
7 phan drug marketing exclusivity under subchapter B of
8 chapter V of such Act (21 U.S.C. 360aa et seq.)), no per-
9 son shall have the right to exclusively manufacture, dis-
10 tribute, sell, or use a drug, a biological product, or a man-
11 ufacturing process for a drug or biological product in
12 interstate commerce, including the exclusive right to rely
13 on health registration data or the 30-month stay-of-effec-
14 tiveness period for Orange Book patents under section
15 505(j) of such Act (21 U.S.C. 355(j)).

16 (b) REMUNERATION.—A person that is eligible for
17 prize payments from the Fund as provided for in section
18 10 shall receive such payments—

19 (1) in lieu of any remuneration the person
20 would have otherwise received for the exclusive mar-
21 keting, distribution, sale, or use of a drug, biological
22 product, or manufacturing process for a drug or bio-
23 logical product but for the application of subsection
24 (a); and

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

6 (c) APPLICATION.—This section shall apply only with
7 respect to the marketing, distribution, sale, or use of a
8 drug, a biological product, or a manufacturing process for
9 a drug or biological product that occurs on or after Octo-
10 ber 1, 2007.

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

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

17 (b) AVAILABILITY OF FUNDS.—Amounts in the Fund
18 shall be available to the Board, subject to section 16(b),
19 for the purpose of carrying out this Act.

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

1 shall establish independent expert advisory commit-
2 tees, including committees on the following:

3 (A) Economic evaluation of therapeutic
4 benefits.

5 (B) Business models and incentive struc-
6 tures for innovation.

7 (C) Research and development priorities.

8 (D) Orphan diseases.

9 (E) Financial control and auditing.

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

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

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

19 (a) AWARD.—For fiscal year 2008, and each subse-
20 quent fiscal year, the Board shall award to persons de-
21 scribed in subsection (b) prize payments for medical inno-
22 vation relating to a drug, a biological product, or a new
23 manufacturing process for a drug or biological product.

24 (b) ELIGIBILITY.—To be eligible to receive a prize
25 payment under subsection (a) for medical innovation relat-

1 ing to a drug, a biological product, or a manufacturing
2 process, a person shall be—

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

6 (2) in the case of a manufacturing process, the
7 holder of the patent with respect to such process.

8 (c) CRITERIA.—The Board shall, by regulation, es-
9 tablish criteria for the selection of recipients, and for de-
10 termining the amount, of prize payments under this sec-
11 tion. Such criteria shall include consideration of the fol-
12 lowing:

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

19 (2) The incremental therapeutic benefit of the
20 drug, biological product, or manufacturing process
21 involved as compared to existing drugs, biological
22 products, and manufacturing processes available to
23 treat the same disease or condition, except that the
24 Board shall provide for cases where drugs, biological
25 products, or manufacturing processes are developed

1 at roughly the same time, so that the comparison is
2 to products that were not recently developed.

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

6 (A) current and emerging global infectious
7 diseases;

8 (B) severe illnesses with small client popu-
9 lations (such as indications for which orphan
10 designation has been granted under section 526
11 of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 360bb)); and

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

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

17 (d) REQUIREMENTS.—In awarding prize payments
18 under this section, the Board shall comply with the fol-
19 lowing:

20 (1) In cases where a new drug, biological prod-
21 uct, or manufacturing process offers an improve-
22 ment over an existing drug, biological product, or
23 manufacturing process and the new drug, biological
24 product, or manufacturing process competes with or
25 replaces the existing drug, biological product, or

1 manufacturing process, the Board shall continue to
2 make prize payments for the existing drug, biological
3 product, or manufacturing process to the degree that
4 the new drug, biological product, or manufacturing
5 process was based on or benefitted from the develop-
6 ment of the existing drug, biological product, or
7 manufacturing process.

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

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

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

21 (5) For every drug or biological product that
22 receives market clearance, the Board shall determine
23 whether and in what amount to award a prize pay-
24 ment for the drug or biological product not later
25 than the end of the fourth full calendar-year quarter

1 following the calendar-year quarter in which the
2 drug or biological product receives market clearance.

3 **SEC. 10. PRIZES FOR PRIORITY RESEARCH AND DEVELOP-**
4 **MENT.**

5 (a) **MINIMUM LEVELS OF FUNDING.**—For fiscal year
6 2008, and each subsequent fiscal year, the Board shall
7 establish and may periodically modify minimum levels of
8 funding under section 9 for priority research and develop-
9 ment.

10 (b) **INITIAL MINIMUM LEVELS.**—Of the amount ap-
11 propriated to the Fund for a fiscal year, the Board shall
12 use (subject to the establishment or modification of an ap-
13 plicable minimum level of funding under subsection (a))
14 not less than—

15 (1) 4 percent of such amount for global ne-
16 glected diseases;

17 (2) 10 percent of such amount for orphan
18 drugs; and

19 (3) 4 percent of such amount for global infec-
20 tious diseases and other global public health prior-
21 ities, including research on AIDS, AIDS vaccines,
22 and medicines for responding to bioterrorism.

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

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

3 (2) periodically recommend to the Board modi-
4 fications in the minimum levels of funding for prizes
5 for priority research and development under this sec-
6 tion.

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

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

12 (a) IN GENERAL.—A drug or biological product that
13 is on the market on October 1, 2007, shall remain eligible
14 for prize payments for not more than 10 fiscal years, con-
15 sistent with section 9(d)(3).

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

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

1 (1) of the amount appropriated to the Fund for
2 fiscal year 2008, not more than 90 percent of such
3 amount; and

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

9 **SEC. 12. ARBITRATION.**

10 In the case of a drug that is on the market on Octo-
11 ber 1, 2008, and subject to patents owned by a party other
12 than the person who first received market clearance for
13 the drug, the Board shall establish an arbitration proce-
14 dure to determine an equitable division of any prize pay-
15 ments under this Act among the patent owners and the
16 person who first received market clearance for the drug.

17 **SEC. 13. ANNUAL AUDITS BY GAO.**

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

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

24 (2) in addressing society’s medical needs, in-
25 cluding global neglected diseases that afflict pri-