

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 417

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 HOUSE OF REPRESENTATIVES

JANUARY 26, 2005

Mr. SANDERS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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 Act of 2005”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds as follows:

1           (1) Retail sales of prescription drugs totaled  
2           \$179.2 billion in 2003, up 10.7 percent over 2002  
3           and over 4 times as much as the amount spent in  
4           1990.

5           (2) Retail prescription prices, including both  
6           manufacturer price changes for existing drugs and  
7           changes in use to newer, higher-priced drugs, have  
8           increased an average of 7.4 percent a year from  
9           1993 to 2003, nearly triple the average inflation  
10          rate of 2.5 percent.

11          (3) United States spending for prescription  
12          drugs is projected to increase by 10.7 percent annu-  
13          ally between 2004 and 2013.

14          (4) From 1993 to 2003, the number of pre-  
15          scriptions purchased increased 70 percent (from 2.0  
16          billion to 3.4 billion), compared to a United States  
17          population growth of 13 percent. The average num-  
18          ber of prescriptions per capita increased from 7.8 to  
19          11.8.

20          (5) Prescription drug expenditures rose faster  
21          than overall national health spending from 1993 to  
22          2003.

23          (6) In 2003, prescription drugs accounted for  
24          11 percent of national health spending, but 23 per-  
25          cent of total out-of-pocket spending by patients.

1           (7) Consumers paid 30 percent of prescription  
2 drug costs in 2003—\$53.2 billion of the \$179.2 bil-  
3 lion spent on prescription medicines.

4           (8) Implementation of the new drug benefit in  
5 Medicare is likely to increase aggregate drug spend-  
6 ing.

7           (9) Retail sales of prescription drugs in the  
8 United States equaled approximately 1.5 percent of  
9 United States gross domestic product in 2003.

10          (10) High prices on medicines discourage em-  
11 ployers from providing health insurance coverage to  
12 workers.

13          (11) High prices on medicines lead to restric-  
14 tions on use because of price barriers and rationing  
15 by third parties that subsidize or insure purchases  
16 of medicines.

17          (12) In a 2003 survey, 37 percent of the unin-  
18 sured said they did not fill a prescription because of  
19 cost, compared to 13 percent of the insured.

20          (13) According to the Food and Drug Adminis-  
21 tration, from 1993 to 2002, approximately 70 per-  
22 cent of all new drugs approved did not offer signifi-  
23 cant therapeutic benefits over existing medicines.

24          (14) Drug prices are far higher in the United  
25 States than in any other developed country because

1 it is the only country that grants pharmaceutical  
2 companies a monopoly in the market, based on pat-  
3 ent protection, without any corresponding restriction  
4 on prices.

5 (15) Pharmaceutical manufacturers have dis-  
6 torted the quality of drug research in many in-  
7 stances, such as with the drug Celebrex. Often due  
8 to the influence of the funding source, drug research  
9 has been shown to suffer from concealed and dis-  
10 torted findings, bias, conflicts of interest, and se-  
11 crecy.

12 (16) There are important gaps in treatments  
13 for many severe illnesses.

14 (17) The existence of neglected diseases in  
15 other regions of the world leads to immense suf-  
16 fering and death, undermines development, shrinks  
17 potential markets, and has long-term negative ef-  
18 fects for United States security.

19 (18) Emerging diseases, viral mutations, and  
20 food-borne disease transmitted through international  
21 trade have negative effects on Americans and must  
22 be combated before they arrive on the Nation's  
23 shores.

1 **SEC. 3. PURPOSE.**

2       The purpose of this Act is to provide incentives to  
3 invest in research and development of new medicines by  
4 establishment of a Medical Innovation Prize Fund and to  
5 enhance access to such medicines by allowing any person  
6 in compliance with Food and Drug Administration re-  
7 quirements to manufacture, distribute, or sell an approved  
8 medicine.

9 **SEC. 4. ELIMINATION OF EXCLUSIVE RIGHTS TO MARKET**  
10 **DRUGS AND BIOLOGICAL PRODUCTS.**

11       (a) **NO RIGHT OF EXCLUSIVE MARKETING.**—No per-  
12 son shall have the right to exclusively manufacture, dis-  
13 tribute, sell, or use a drug, a biological product, or a man-  
14 ufacturing process for a drug or biological product in  
15 interstate commerce, notwithstanding title 35 of the  
16 United States Code, relevant provisions of the Federal  
17 Food, Drug, and Cosmetic Act, as amended by the Drug  
18 Price Competition and Patent Term Restoration Act of  
19 1984 (Public Law 98–417; 98 Stat. 1585; also referred  
20 to as the “Hatch-Waxman Act” ) and the Medicare Pre-  
21 scription Drug, Improvement, and Modernization Act of  
22 2003 (Public Law 108–173; 117 Stat. 2066), such as the  
23 exclusive rights to rely on health registration data or the  
24 30-month stay-of-effectiveness period for Orange Book  
25 patents, and any other provision of law providing any pat-  
26 ent right or exclusive marketing period for any drug, bio-

1 logical product, or manufacturing process for a drug or  
2 biological product, such as pediatric extensions or orphan  
3 drug marketing exclusivity.

4 (b) REMUNERATION.—A person eligible for prize pay-  
5 ments from the Fund for Medical Innovation Prizes under  
6 section 9 shall receive such payments—

7 (1) in lieu of any remuneration the person  
8 would have received (but for the operation of sub-  
9 section (a)) by reason of the exclusive marketing,  
10 distribution, sale, or use of the drug, biological prod-  
11 uct, or manufacturing process involved; and

12 (2) in addition to any remuneration the person  
13 receives by reason of the nonexclusive marketing,  
14 distribution, sale, or use of the drug, biological prod-  
15 uct, or marketing process.

16 (c) APPLICATION.—This section applies only with re-  
17 spect to the marketing, distribution, sale, or use of a drug,  
18 a biological product, or a marketing process that occurs  
19 on or after October 1, 2007.

20 **SEC. 5. 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, which  
24 shall consist of amounts appropriated to the Fund and  
25 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 16(b),  
3 for the purpose of carrying out this Act.

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

8 **SEC. 6. BOARD OF TRUSTEES FOR THE FUND FOR MEDICAL**  
9 **INNOVATION PRIZES.**

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

14 (b) DUTIES.—The Board shall—

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

17 (2) submit a report to the Congress under sec-  
18 tion 14.

19 **SEC. 7. MEMBERSHIP AND STAFF OF BOARD.**

20 (a) MEMBERSHIP.—The Board shall be composed of  
21 13 members as follows:

22 (1) The Administrator of the Centers for Medi-  
23 care & Medicaid Services.

24 (2) The Commissioner of Food and Drugs.

1           (3) The Director of the National Institutes of  
2 Health.

3           (4) The Director of the Centers for Disease  
4 Control and Prevention.

5           (5) Nine members, appointed by the President,  
6 with the advice and consent of the Senate, as fol-  
7 lows:

8                   (A) Three representatives of the business  
9 sector.

10                   (B) Three representatives of the private  
11 medical research and development sector, in-  
12 cluding at least one representative of the non-  
13 profit private medical research and development  
14 sector.

15                   (C) Three representatives of consumer and  
16 patient interests, including at least one rep-  
17 resentative of patients suffering from orphan  
18 diseases.

19           (b) TERMS.—

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

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



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

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

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

7 (c) 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 (d) BASIC PAY.—Members of the Board shall each  
15 be paid not less than the daily equivalent of level IV of  
16 the Executive Schedule for each day (including travel  
17 time) during which they are engaged in the actual per-  
18 formance of duties vested in the Board.

19 (e) TRAVEL EXPENSES.—Each member of the Board  
20 shall receive travel expenses, including per diem in lieu  
21 of subsistence, in accordance with applicable provisions  
22 under subchapter I of chapter 57 of title 5, United States  
23 Code.

24 (f) CHAIRPERSON; OFFICERS.—The members of the  
25 Board shall elect the Chairperson and any other officers

1 of the Board. The Chairperson and any such officers shall  
2 be elected for a term of 2 years.

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

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

14 **SEC. 8. POWERS OF BOARD.**

15 (a) HEARINGS AND SESSIONS.—

16 (1) IN GENERAL.—The Board may, for the pur-  
17 pose of carrying out this Act, hold hearings, sit and  
18 act at times and places, take testimony, and receive  
19 evidence as the Board considers appropriate.

20 (2) FIRST MEETING.—Not later than 30 days  
21 after the initial 9 members of the Board under sec-  
22 tion 7(a)(5) have been appointed and confirmed, the  
23 Board shall conduct its first meeting.

24 (b) POLICIES AND PROCEDURES.—

1           (1) IN GENERAL.—Not later than 1 year after  
2 the initial 9 members of the Board under section  
3 7(a)(5) have been appointed and confirmed, the  
4 Board shall establish such policies and procedures as  
5 may be appropriate to carry out this Act.

6           (2) MAJORITY VOTE.—The policies and proce-  
7 dures of the Board shall require that any determina-  
8 tion of the Board be made by not less than a major-  
9 ity vote of the members of the Board.

10          (3) ADMINISTRATIVE PROCEDURES.—The poli-  
11 cies and procedures of the Board shall comply with  
12 subchapter II of chapter 5 of title 5, United States  
13 Code.

14          (4) TRANSPARENCY.—The policies and proce-  
15 dures of the Board shall—

16           (A) comply with sections 552 and 552b of  
17 title 5, United States Code (commonly referred  
18 to as the “Freedom of Information Act” and  
19 the “Government in the Sunshine Act”, respec-  
20 tively); and

21           (B) ensure that the proceedings and delib-  
22 erations of the Board are transparent and are  
23 supported by a description of the methods, data  
24 sources, assumptions, outcomes, and related in-  
25 formation that will allow the public to under-

1 stand how the Board reaches its criteria-setting  
2 and award decisions.

3 (c) EXPERT ADVISORY COMMITTEES.—To assist the  
4 Board in carrying out this Act, the Board shall establish  
5 independent expert advisory committees, including com-  
6 mittees on the following:

7 (1) Economic evaluation of therapeutic benefits.

8 (2) Business models and incentive structures  
9 for innovation.

10 (3) Research and development priorities.

11 (4) Orphan diseases.

12 (5) Financial control and auditing.

13 (d) POWERS OF MEMBERS AND AGENTS.—Any mem-  
14 ber or agent of the Board may, if authorized by the Board,  
15 take any action which the Board is authorized to take by  
16 this Act.

17 (e) MAILS.—The Board may use the United States  
18 mails in the same manner and under the same conditions  
19 as other departments and agencies of the United States.

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

21 (a) AWARD.—For fiscal year 2007 and each subse-  
22 quent fiscal year, the Board shall award to persons de-  
23 scribed in subsection (b) prize payments for medical inno-  
24 vation relating to a drug, a biological product, or a new  
25 manufacturing process for a drug or biological product.

1 (b) ELIGIBILITY.—To be eligible to receive a prize  
2 payment under this section for medical innovation relating  
3 to a drug, a biological product, or a manufacturing proc-  
4 ess, a person shall be—

5 (1) in the case of a drug or biological product,  
6 the first person to receive market clearance; or

7 (2) in the case of a manufacturing process, the  
8 holder of the patent.

9 (c) CRITERIA.—The Board shall determine by regula-  
10 tion criteria for selecting recipients, and determining the  
11 amount, of prize payments under this section. Such cri-  
12 teria shall include consideration of the following:

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

18 (2) The incremental therapeutic benefit of a  
19 drug, biological product, or manufacturing process,  
20 compared to existing drugs, biological products, and  
21 manufacturing processes available to treat the same  
22 disease or condition.

23 (3) The degree to which the drug, biological  
24 product, or manufacturing process addresses priority  
25 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 (d) REQUIREMENTS.—In awarding prize payments  
13 under this section, the Board shall comply with the fol-  
14 lowing:

15 (1) In cases where a new drug, biological prod-  
16 uct, or manufacturing process offers an improve-  
17 ment over an existing drug, biological product, or  
18 manufacturing process and the new drug, biological  
19 product, or manufacturing process competes with or  
20 replaces the existing drug, biological product, or  
21 manufacturing process, the Board shall continue to  
22 make prize payments for the existing drug, biological  
23 product, or manufacturing process to the degree that  
24 the new drug, biological product, or manufacturing  
25 process was based on or benefited from the develop-

1       ment of the existing drug, biological product, or  
2       manufacturing process.

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

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

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

16              (5) For every drug or biological product that  
17      receives market clearance, the Board shall determine  
18      whether and in what amount to award a prize pay-  
19      ment for the drug or biological product not later  
20      than the end of the fourth full calendar-year quarter  
21      following the calendar-year quarter in which the  
22      drug or biological product receives market clearance.

1 **SEC. 10. PRIZES FOR PRIORITY RESEARCH AND DEVELOP-**  
2 **MENT.**

3 (a) **MINIMUM LEVELS OF FUNDING.**—For fiscal year  
4 2007 and each subsequent fiscal year, the Board shall es-  
5 tablish and may periodically modify minimum levels of  
6 funding under section 9 for priority research and develop-  
7 ment.

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

13 (1) 4 percent of such amount for global ne-  
14 glected diseases;

15 (2) 10 percent of such amount for orphan  
16 drugs; and

17 (3) 4 percent of such amount for global infec-  
18 tious diseases and other global public health prior-  
19 ities, including research on AIDS, AIDS vaccines,  
20 and medicines for responding to bioterrorism.

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

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



1           (2) periodically recommend to the Board  
2           changes in the minimum levels of funding for prizes  
3           for priority research and development.

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

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

9           (a) IN GENERAL.—A drug or biological product that  
10          is already on the market by October 1, 2007, shall remain  
11          eligible for prize payments for not more than 10 fiscal  
12          years, consistent with section 9(d)(3).

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

19          (c) MAXIMUM AMOUNT.—For drugs and biological  
20          products described in subsection (a), the Board may  
21          award—

22                 (1) of the amount appropriated to the Fund for  
23                 fiscal year 2007, not more than 90 percent of such  
24                 amount; and

1           (2) of the amount appropriated to the Fund for  
2           each of the succeeding 9 fiscal years, not more than  
3           a percentage of such amount that is 9 percent less  
4           than the percentage applicable to the preceding fis-  
5           cal year under this subsection.

6 **SEC. 12. ARBITRATION.**

7           In the case of a drug that is already on the market  
8           by October 1, 2007, and subject to patents owned by a  
9           party other than the person who first received market  
10          clearance for the drug, the Board shall establish an arbi-  
11          tration procedure to determine an equitable division of any  
12          prize payments among the patent owners and the person  
13          who first received market clearance for the drug.

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

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

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

21                 (2) in addressing society’s medical needs, in-  
22                 cluding global neglected diseases that afflict pri-  
23                 marily the poor in developing countries, indications  
24                 for which orphan designation has been granted  
25                 under section 526 of the Federal Food, Drug, and

1       Cosmetic Act (21 U.S.C. 360bb), and global infec-  
2       tious diseases and and other global public health pri-  
3       orities.

4       (b) REPORTS.—The Comptroller General of the  
5       United States shall submit a report to the Congress each  
6       fiscal year on the results of each audit conducted under  
7       subsection (a).

8       **SEC. 14. REPORT TO CONGRESS.**

9       Not later than 1 year after the date of the enactment  
10      of this Act, the Board shall submit to the Congress a re-  
11      port containing the findings, conclusions, and rec-  
12      ommendations of the Board regarding the implementation  
13      and administration of this Act, including recommenda-  
14      tions for such legislative and administrative action as the  
15      Board determines to be appropriate.

16      **SEC. 15. DEFINITIONS.**

17      In this Act:

18           (1) The term “biological product” has the  
19           meaning given to that term in section 351 of the  
20           Public Health Service Act (42 U.S.C. 262).

21           (2) The term “Board” means the Board of  
22           Trustees for the Fund for Medical Innovation Prizes  
23           established by section 6.

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

4           (4) The term “Fund” means the Fund for  
5 Medical Innovation Prizes established by section 5.

6           (5) The term “market clearance” means ap-  
7 proval of an application under section 505 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 355) or approval of a biologics license application  
10 under subsection (a) of section 351 of the Public  
11 Health Service Act (42 U.S.C. 262).

12 **SEC. 16. FUNDING.**

13           (a) APPROPRIATIONS.—

14           (1) START-UP COSTS.—For fiscal year 2006,  
15 there are authorized to be appropriated to the Fund  
16 for Medical Innovation Prizes such sums as may be  
17 necessary to carry out this Act.

18           (2) PROGRAM IMPLEMENTATION.—For fiscal  
19 year 2007 and each subsequent fiscal year, there is  
20 appropriated to the Fund for Medical Innovation  
21 Prizes, out of any funds in the Treasury not other-  
22 wise appropriated, an amount equal to the amount  
23 that is 0.5 percent of the gross domestic product of  
24 the United States for the preceding fiscal year (as

1       such amount is determined by the Secretary of Com-  
2       merce).

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

○