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(Original Signature of Member)

109TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. SANDERS introduced the following bill; which was referred to the Committee on _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Innovation Prize Act of 2005''.

SEC. 2. FINDINGS.

The Congress finds as follows:

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

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

(3) United States spending for prescription drugs is projected to increase by 10.7 percent annually between 2004 and 2013.

(4) From 1993 to 2003, the number of prescriptions purchased increased 70 percent (from 2.0 billion to 3.4 billion), compared to a United States population growth of 13 percent. The average number of prescriptions per capita increased from 7.8 to 11.8.

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

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

(7) Consumers paid 30 percent of prescription drug costs in 2003 — $53.2 billion of the $179.2 billion spent on prescription medicines.

(8) Implementation of the new drug benefit in Medicare is likely to increase aggregate drug spending.

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

(10) High prices on medicines discourage employers from providing health insurance coverage to workers.

(11) High prices on medicines lead to restrictions on use because of price barriers and rationing by third parties that subsidize or insure purchases of medicines.

(12) In a 2003 survey, 37 percent of the uninsured said they did not fill a prescription because of cost, compared to 13 percent of the insured.

(13) According to the Food and Drug Administration, from 1993 to 2002, approximately 70 percent of all new drugs approved did not offer significant therapeutic benefits over existing medicines.

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

it is the only country that grants pharmaceutical companies a monopoly in the market, based on patent protection, without any corresponding restriction on prices.

(15) Pharmaceutical manufacturers have distorted the quality of drug research in many instances, such as with the drug Celebrex. Often due to the influence of the funding source, drug research has been shown to suffer from concealed and distorted findings, bias, conflicts of interest, and secrecy.

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

(17) The existence of neglected diseases in other regions of the world leads to immense suffering and death, undermines development, shrinks potential markets, and has long-term negative effects for United States security.

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

SEC. 3. PURPOSE.

The purpose of this Act is to provide incentives to invest in research and development of new medicines by establishment of a Medical Innovation Prize Fund and to enhance access to such medicines by allowing any person in compliance with Food and Drug Administration requirements to manufacture, distribute, or sell an approved medicine.

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

(a) NO RIGHT OF EXCLUSIVE MARKETING.—No person shall have the right to exclusively manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product in interstate commerce, notwithstanding title 35 of the United States Code, relevant provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; 98 Stat. 1585; also referred to as the ''Hatch-Waxman Act'') and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2066), such as the exclusive rights to rely on health registration data or the 30-month stay-of-effectiveness period for Orange Book patents, and any other provision of law providing any patent right or exclusive marketing period for any drug, bio-

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

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

(1) in lieu of any remuneration the person would have received (but for the operation of subsection (a)) by reason of the exclusive marketing, distribution, sale, or use of the drug, biological product, or manufacturing process involved; and

(2) in addition to any remuneration the person receives by reason of the nonexclusive marketing, distribution, sale, or use of the drug, biological product, or marketing process.

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

SEC. 5. FUND FOR MEDICAL INNOVATION PRIZES.

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

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

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

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

(a) ESTABLISHMENT.—There is hereby established (as a permanent, independent establishment in the executive branch) a Board of Trustees for the Fund for Medical Innovation Prizes.

(b) DUTIES.—The Board shall—

(1) award prize payments for medical innovation in accordance with this Act; and

(2) submit a report to the Congress under section 14.

SEC. 7. MEMBERSHIP AND STAFF OF BOARD.

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

(1) The Administrator of the Centers for Medicare & Medicaid Services.

(2) The Commissioner of Food and Drugs.

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

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

(5) Nine members, appointed by the President, with the advice and consent of the Senate, as follows:

(A) Three representatives of the business sector.

(B) Three representatives of the private medical research and development sector, including at least one representative of the nonprofit private medical research and development sector.

(C) Three representatives of consumer and patient interests, including at least one representative of patients suffering from orphan diseases.

(b) TERMS.—

(1) IN GENERAL.—Except as provided in paragraph (2), each member appointed to the Board under subsection (a)(5) shall be appointed for a term of 4 years.

(2) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment,

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

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

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

(c) VACANCIES.—Any member of the Board appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member of the Board may serve after the expiration of that member's term until a successor has taken office.

(d) BASIC PAY.—Members of the Board shall each be paid not less than the daily equivalent of level IV of the Executive Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Board.

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

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

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

(g) STAFF.—The Board may appoint and fix the pay of such additional personnel as the Board considers appropriate. The staff of the Board shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates.

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

SEC. 8. POWERS OF BOARD.

(a) HEARINGS AND SESSIONS.—

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

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

(b) POLICIES AND PROCEDURES.—

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

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

(3) ADMINISTRATIVE PROCEDURES.—The policies and procedures of the Board shall comply with subchapter II of chapter 5 of title 5, United States Code.

(4) TRANSPARENCY.—The policies and procedures of the Board shall—

(A) comply with sections 552 and 552b of title 5, United States Code (commonly referred to as the ''Freedom of Information Act'' and the ''Government in the Sunshine Act'', respectively); and

(B) ensure that the proceedings and deliberations of the Board are transparent and are supported by a description of the methods, data sources, assumptions, outcomes, and related information that will allow the public to under-

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

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

(1) Economic evaluation of therapeutic benefits.

(2) Business models and incentive structures for innovation.

(3) Research and development priorities.

(4) Orphan diseases.

(5) Financial control and auditing.

(d) POWERS OF MEMBERS AND AGENTS.—Any member or agent of the Board may, if authorized by the Board, take any action which the Board is authorized to take by this Act.

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

SEC. 9. PRIZE PAYMENTS FOR MEDICAL INNOVATION.

(a) AWARD.—For fiscal year 2007 and each subsequent fiscal year, the Board shall award to persons described in subsection (b) prize payments for medical innovation relating to a drug, a biological product, or a new manufacturing process for a drug or biological product.

(b) ELIGIBILITY.—To be eligible to receive a prize payment under this section for medical innovation relating to a drug, a biological product, or a manufacturing process, a person shall be—

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

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

(c) CRITERIA.—The Board shall determine by regulation criteria for selecting recipients, and determining the amount, of prize payments under this section. Such criteria shall include consideration of the following:

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

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

(3) The degree to which the drug, biological product, or manufacturing process addresses priority health care needs, including—

(A) current and emerging global infectious diseases;

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

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

(4) Improved efficiency of manufacturing processes for drugs or biological processes.

(d) REQUIREMENTS.—In awarding prize payments under this section, the Board shall comply with the following:

(1) In cases where a new drug, biological product, or manufacturing process offers an improvement over an existing drug, biological product, or manufacturing process and the new drug, biological product, or manufacturing process competes with or replaces the existing drug, biological product, or manufacturing process, the Board shall continue to make prize payments for the existing drug, biological product, or manufacturing process to the degree that the new drug, biological product, or manufacturing process was based on or benefited from the develop-

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

(2) The Board may not make prize payments based on the identity of the person who manufactures, distributes, sells, or uses the drug, biological product, or manufacturing process involved.

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

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

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

SEC. 10. PRIZES FOR PRIORITY RESEARCH AND DEVELOPMENT.

(a) MINIMUM LEVELS OF FUNDING.—For fiscal year 2007 and each subsequent fiscal year, the Board shall establish and may periodically modify minimum levels of funding under section 9 for priority research and development.

(b) INITIAL MINIMUM LEVELS.—Of the amount appropriated to the Fund for a fiscal year, the Board shall use (subject to establishment or modification of an applicable minimum level of funding under subsection (a)) not less than—

(1) 4 percent of such amount for global neglected diseases;

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

(3) 4 percent of such amount for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.

(c) PUBLIC INPUT; RECOMMENDATIONS.—The advisory committee on research and development priorities (established pursuant to section 8(c)) shall—

(1) solicit public input on research and development priorities; and

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

(d) PROCEDURES.—The Board shall adopt procedures to establish and periodically modify minimum levels of funding under section 9 for priority research and development.

SEC. 11. SPECIAL TRANSITION RULES.

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

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

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

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

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

SEC. 12. ARBITRATION.

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

SEC. 13. ANNUAL AUDITS BY GAO.

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

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

(2) in addressing society's medical needs, including global neglected diseases that afflict primarily the poor in developing countries, indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 360bb), and global infectious diseases and and other global public health priorities.

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

SEC. 14. REPORT TO CONGRESS.

Not later than 1 year after the date of the enactment of this Act, the Board shall submit to the Congress a report containing the findings, conclusions, and recommendations of the Board regarding the implementation and administration of this Act, including recommendations for such legislative and administrative action as the Board determines to be appropriate.

SEC. 15. DEFINITIONS.

In this Act:

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

(2) The term ''Board'' means the Board of Trustees for the Fund for Medical Innovation Prizes established by section 6.

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

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

(5) The term ''market clearance'' means approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 16. FUNDING.

(a) APPROPRIATIONS.—

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

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

such amount is determined by the Secretary of Commerce).

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