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

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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.

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 2007''.

SEC. 4. DEFINITIONS.

In this Act:

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

(2) BOARD.—The term ''Board'' means the Board of Trustees for the Fund for Medical Innovation Prizes established under section 7.

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

(4) FUND.—The term ''Fund'' means the Fund for Medical Innovation Prizes established under section 6.

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

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

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

Act of 2003 (Public Law 108–173), and any other provision of law providing any patent right or exclusive marketing period for any drug, biological product, or manufacturing process for a drug or biological product (such as pediatric extensions under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) or orphan drug marketing exclusivity under subchapter B of chapter V of such Act (21 U.S.C. 360aa et seq.)), 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, including the exclusive right to rely on health registration data or the 30-month stay-of-effectiveness period for Orange Book patents under section 505(j) of such Act (21 U.S.C. 355(j)).

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

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

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

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

SEC. 6. 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 THE 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. 9. PRIZE PAYMENTS FOR MEDICAL INNOVATION.

(a) AWARD.—For fiscal year 2008, 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 subsection (a) for medical innovation relat-

ing 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 with respect to the drug or biological product; or

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

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

(1) The number of patients who would benefit from the drug, biological product, or manufacturing process involved, 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 the drug, biological product, or manufacturing process involved as compared to existing drugs, biological products, and manufacturing processes available to treat the same disease or condition, except that the Board shall provide for cases where drugs, biological products, or manufacturing processes are developed

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

(3) The degree to which the drug, biological product, or manufacturing process involved 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 benefitted from the development 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 2008, 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 the 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(b)(3)) shall—

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

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

(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 on the market on 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.—With respect to drugs and biological products described in subsection (a), the Board may award—

(1) of the amount appropriated to the Fund for fiscal year 2008, 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 equal to 9 percent less the percentage applicable to the preceding fiscal year under this subsection.