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. 2. FINDINGS.

Congress makes the following findings:

(1) Current incentives for research and development for new medicines that involve market exclusivity lead to high prices.

(2) High prescription drug prices create hardships on patients, employers, and taxpayers who pay for medicines, as well as increasing restrictions on access to medicines, through limited availability of high priced medicines by health insurance plans.

(3) In addition, when marketing exclusivity is the reward for successful research and development efforts, companies have incentives to invest enormous sums in marketing of products, and in the development of medicines that do not offer significant incremental medicinal benefits over existing products.

(4) According to the Food and Drug Administration, of the 1,284 new drug approvals from 1990 to 2004, only 289, or 22.5 percent, were for ''priority'' reviews (defined as a product that has ''significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease''). Of these, only 183 (14.3 percent of the total) were new molecular entities classified as priority products.

(5) Thus, there are important gaps in treatments for many severe illnesses.

(6) 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.

(7) 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.

(8) Exclusive rights to market products are one way to reward successful product research and development, but not the only way. Prize funds are another way and have been used successfully to stimulate inventions and solutions to difficult problems.

(9) Awards to companies through a prize fund mechanism that reward successful product research and development can de-couple the reward for product research development from the price of the product.

(10) Awards to pharmaceutical companies for successful product research and development can be targeted at products that improve health care outcomes, and can stimulate research and development in the areas of greatest need.

(11) The implementation of a prize fund and the elimination of exclusive rights to sell new medi-

cines will lead to entry by generic manufacturers, and lower prices for prescription drugs. This will eliminate the need for price sensitive formularies, and reduce other barriers to access to new medicines.

(12) At present, generic products represent more than 63 percent of pharmaceutical prescriptions, but only 20 percent of the money spent on prescription drugs, for an average cost saving of 85 percent for generic prescriptions.

(13) The combined cost to the Federal Government of purchases, reimbursements, and subsidies for medicines, including Federal outlays relating to Medicare, Medicaid, purchases of medicines by the Department of Defense and the Department of Veterans Affairs, and outlays related to the Federal Employees Health Benefits Program, is expected to exceed $100,000,000,000 in 2007, and grow faster than the overall rate of growth in the Gross Domestic Product.

(14) The cost of total United States outlays for pharmaceutical drugs was more than $274,000,000,000 in 2006, measured at manufacturer's prices, an increase of more than 82 percent since 2000.

(15) The substitution of prize fund awards to companies for successful product research and development in place of marketing exclusivity for new medicines will lead to more competition, greater utilization of generic products, lower prices, and savings to Federal, State and local governments, private employers and individual consumers of more than $200,000,000,000 per year. Savings in governmental expenditures alone would be more than sufficient to fund the prize fund established through this legislation.

(16) Basing the level of funding for innovation prizes on a share of Gross Domestic Product will ensure a sustainable and forward looking commitment to stimulate innovation for new medicines.

(17) Current United States outlays on pharmaceutical drugs are more than 2.2 percent of Gross Domestic Product.

(18) By funding innovation prizes at 0.6 percent of Gross Domestic Product, the United States will provide an incentive for innovation that would be more than $80,000,000,000 in 2007, an amount that is more than 5 times the average rate of royalties for patent owners, and more than 4 times the level of private sector research and development

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

(19) The 2007 cost of the innovation prizes will be much lower than the $200,000,000,000 in reduced United States outlays for pharmaceutical drugs, it will vastly expand access to medicines, and it will ensure that future research and development for new medicines is targeted at treatments that improve health care outcomes and address public health priorities.

SEC. 3. PURPOSE.

It is the purpose of this Act to provide incentives to encourage entities to invest in research and development of new medicines through the 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. 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. 7. BOARD OF TRUSTEES FOR THE FUND.

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

(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; and

(5) nine individuals to be appointed by the President, with the advice and consent of the Senate, of which—

(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; and

(C) three representatives of consumer and patient interests, including at least one rep-

resentative of patients suffering from orphan diseases.

(c) 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 members shall be appointed for a term of 4 years; and

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

(d) 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.

(e) COMPENSATION AND TRAVEL EXPENSES.—

(1) COMPENSATION.—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 the duties of the Board.

(2) 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 a 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 such 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 AND DUTIES OF THE BOARD.

(a) 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.

(b) POWERS OF BOARD.—

(1) HEARINGS AND SESSIONS.—

(A) 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.

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

(2) POLICIES AND PROCEDURES.—

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

(B) 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.

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

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

(i) 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

(ii) 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 understand how the Board reaches its criteria-setting and award decisions.

(3) 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:

(A) Economic evaluation of therapeutic benefits.

(B) Business models and incentive structures for innovation.

(C) Research and development priorities.

(D) Orphan diseases.

(E) Financial control and auditing.

(4) 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 under this Act.

(5) 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 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.

SEC. 12. ARBITRATION.

In the case of a drug that is on the market on October 1, 2008, 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 under this Act 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 pri-

marily 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 Congress a report containing the findings, conclusions, and recommendations of the Board concerning the implementation and administration of this Act, including recommendations for such legislative and administrative action as the Board determines to be appropriate.

SEC. 15. FUNDING.

(a) APPROPRIATIONS.—

(1) START-UP COSTS.—For fiscal year 2008, there are authorized to be appropriated to the Fund, such sums as may be necessary to carry out this Act.

(2) PROGRAM IMPLEMENTATION.—For fiscal year 2008 and each subsequent fiscal year, there is appropriated to the Fund, out of any funds in the Treasury not otherwise appropriated, an amount equal to the amount that is 0.6 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 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.

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