

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.

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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.

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

6           (3) In addition, when marketing exclusivity is  
7           the reward for successful research and development  
8           efforts, companies have incentives to invest enor-  
9           mous sums in marketing of products, and in the de-  
10          velopment of medicines that do not offer significant  
11          incremental medicinal benefits over existing prod-  
12          ucts.

13          (4) According to the Food and Drug Adminis-  
14          tration, of the 1,284 new drug approvals from 1990  
15          to 2004, only 289, or 22.5 percent, were for “pri-  
16          ority” reviews (defined as a product that has “sig-  
17          nificant improvement compared to marketed prod-  
18          ucts in the treatment, diagnosis, or prevention of a  
19          disease”). Of these, only 183 (14.3 percent of the  
20          total) were new molecular entities classified as pri-  
21          ority products.

22          (5) Thus, there are important gaps in treat-  
23          ments for many severe illnesses.

24          (6) The existence of neglected diseases in other  
25          regions of the world leads to immense suffering and

1 death, undermines development, shrinks potential  
2 markets, and has long-term negative effects for  
3 United States security.

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

9 (8) Exclusive rights to market products are one  
10 way to reward successful product research and devel-  
11 opment, but not the only way. Prize funds are an-  
12 other way and have been used successfully to stimu-  
13 late inventions and solutions to difficult problems.

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

19 (10) Awards to pharmaceutical companies for  
20 successful product research and development can be  
21 targeted at products that improve health care out-  
22 comes, and can stimulate research and development  
23 in the areas of greatest need.

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

1 cines will lead to entry by generic manufacturers,  
2 and lower prices for prescription drugs. This will  
3 eliminate the need for price sensitive formularies,  
4 and reduce other barriers to access to new medi-  
5 cines.

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

11 (13) The combined cost to the Federal Govern-  
12 ment of purchases, reimbursements, and subsidies  
13 for medicines, including Federal outlays relating to  
14 Medicare, Medicaid, purchases of medicines by the  
15 Department of Defense and the Department of Vet-  
16 erans Affairs, and outlays related to the Federal  
17 Employees Health Benefits Program, is expected to  
18 exceed \$100,000,000,000 in 2007, and grow faster  
19 than the overall rate of growth in the Gross Domes-  
20 tic Product.

21 (14) The cost of total United States outlays for  
22 pharmaceutical drugs was more than  
23 \$274,000,000,000 in 2006, measured at manufac-  
24 turer's prices, an increase of more than 82 percent  
25 since 2000.

1           (15) The substitution of prize fund awards to  
2           companies for successful product research and devel-  
3           opment in place of marketing exclusivity for new  
4           medicines will lead to more competition, greater uti-  
5           lization of generic products, lower prices, and sav-  
6           ings to Federal, State and local governments, private  
7           employers and individual consumers of more than  
8           \$200,000,000,000 per year. Savings in governmental  
9           expenditures alone would be more than sufficient to  
10          fund the prize fund established through this legisla-  
11          tion.

12          (16) Basing the level of funding for innovation  
13          prizes on a share of Gross Domestic Product will en-  
14          sure a sustainable and forward looking commitment  
15          to stimulate innovation for new medicines.

16          (17) Current United States outlays on pharma-  
17          ceutical drugs are more than 2.2 percent of Gross  
18          Domestic Product.

19          (18) By funding innovation prizes at 0.6 per-  
20          cent of Gross Domestic Product, the United States  
21          will provide an incentive for innovation that would  
22          be more than \$80,000,000,000 in 2007, an amount  
23          that is more than 5 times the average rate of roy-  
24          alties for patent owners, and more than 4 times the  
25          level of private sector research and development

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 **SEC. 7. BOARD OF TRUSTEES FOR THE FUND.**

2 (a) ESTABLISHMENT.—There is hereby established  
3 (as a permanent, independent establishment in the execu-  
4 tive branch) a Board of Trustees for the Fund for Medical  
5 Innovation Prizes.

6 (b) MEMBERSHIP.—The Board shall be composed of  
7 13 members, including—

8 (1) the Administrator of the Centers for Medi-  
9 care & Medicaid Services;

10 (2) the Commissioner of Food and Drugs;

11 (3) the Director of the National Institutes of  
12 Health;

13 (4) the Director of the Centers for Disease  
14 Control and Prevention; and

15 (5) nine individuals to be appointed by the  
16 President, with the advice and consent of the Sen-  
17 ate, of which—

18 (A) three representatives of the business  
19 sector;

20 (B) three representatives of the private  
21 medical research and development sector, in-  
22 cluding at least one representative of the non-  
23 profit private medical research and development  
24 sector; and

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

1           representative of patients suffering from orphan  
2           diseases.

3           (c) TERMS.—

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

8           (2) TERMS OF INITIAL APPOINTEES.—As des-  
9           ignated by the President at the time of appointment,  
10          of the members first appointed to the Board under  
11          subsection (a)(5)—

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

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

16          (d) VACANCIES.—Any member of the Board ap-  
17          pointed to fill a vacancy occurring before the expiration  
18          of the term for which the member's predecessor was ap-  
19          pointed shall be appointed only for the remainder of that  
20          term. A member of the Board may serve after the expira-  
21          tion of that member's term until a successor has taken  
22          office.

23          (e) COMPENSATION AND TRAVEL EXPENSES.—

24                   (1) COMPENSATION.—Members of the Board  
25                   shall each be paid not less than the daily equivalent

1 of level IV of the Executive Schedule for each day  
2 (including travel time) during which they are en-  
3 gaged in the actual performance of the duties of the  
4 Board.

5 (2) TRAVEL EXPENSES.—Each member of the  
6 Board shall receive travel expenses, including per  
7 diem in lieu of subsistence, in accordance with appli-  
8 cable provisions under subchapter I of chapter 57 of  
9 title 5, United States Code.

10 (f) CHAIRPERSON; OFFICERS.—The members of the  
11 Board shall elect a Chairperson and any other officers of  
12 the Board. The Chairperson and any such officers shall  
13 be elected for a term of 2 years.

14 (g) STAFF.—The Board may appoint and fix the pay  
15 of such additional personnel as the Board considers appro-  
16 priate. The staff of the Board shall be appointed subject  
17 to the provisions of title 5, United States Code, governing  
18 appointments in the competitive service, and shall be paid  
19 in accordance with the provisions of chapter 51 and sub-  
20 chapter III of chapter 53 of such title relating to classi-  
21 fication and General Schedule pay rates.

22 (h) EXPERTS AND CONSULTANTS.—The Board may  
23 procure temporary and intermittent services under section  
24 3109(b) of title 5, United State Code.

1 **SEC. 8. POWERS AND DUTIES OF THE BOARD.**

2 (a) DUTIES.—The Board shall—

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

5 (2) submit a report to the Congress under sec-  
6 tion 14.

7 (b) POWERS OF BOARD.—

8 (1) HEARINGS AND SESSIONS.—

9 (A) IN GENERAL.—The Board may, for  
10 the purpose of carrying out this Act, hold hear-  
11 ings, sit and act at times and places, take testi-  
12 mony, and receive evidence as the Board con-  
13 siders appropriate.

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

18 (2) POLICIES AND PROCEDURES.—

19 (A) IN GENERAL.—Not later than 1 year  
20 after the initial members of the Board are ap-  
21 pointed under section 7(b)(5) and confirmed,  
22 the Board shall establish such policies and pro-  
23 cedures as may be appropriate to carry out this  
24 Act.

25 (B) MAJORITY VOTE.—The policies and  
26 procedures of the Board shall require that any

1 determination of the Board be made by not less  
2 than a majority vote of the members of the  
3 Board.

4 (C) ADMINISTRATIVE PROCEDURES.—The  
5 policies and procedures of the Board shall com-  
6 ply with subchapter II of chapter 5 of title 5,  
7 United States Code.

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

10 (i) comply with sections 552 and 552b  
11 of title 5, United States Code (commonly  
12 referred to as the “Freedom of Informa-  
13 tion Act” and the “Government in the  
14 Sunshine Act”, respectively); and

15 (ii) ensure that the proceedings and  
16 deliberations of the Board are transparent  
17 and are supported by a description of the  
18 methods, data sources, assumptions, out-  
19 comes, and related information that will  
20 allow the public to understand how the  
21 Board reaches its criteria-setting and  
22 award decisions.

23 (3) EXPERT ADVISORY COMMITTEES.—To as-  
24 sist the Board in carrying out this Act, the Board

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-

1       marily the poor in developing countries, indications  
2       for which orphan designation has been granted  
3       under section 526 of the Federal Food, Drug, and  
4       Cosmetic Act (21 U.S.C. 360bb), and global infec-  
5       tious diseases and and other global public health pri-  
6       orities.

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

11      **SEC. 14. REPORT TO CONGRESS.**

12       Not later than 1 year after the date of the enactment  
13      of this Act, the Board shall submit to Congress a report  
14      containing the findings, conclusions, and recommendations  
15      of the Board concerning the implementation and adminis-  
16      tration of this Act, including recommendations for such  
17      legislative and administrative action as the Board deter-  
18      mines to be appropriate.

19      **SEC. 15. FUNDING.**

20       (a) APPROPRIATIONS.—

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

1           (2) PROGRAM IMPLEMENTATION.—For fiscal  
2           year 2008 and each subsequent fiscal year, there is  
3           appropriated to the Fund, out of any funds in the  
4           Treasury not otherwise appropriated, an amount  
5           equal to the amount that is 0.6 percent of the gross  
6           domestic product of the United States for the pre-  
7           ceding fiscal year (as such amount is determined by  
8           the Secretary of Commerce).

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

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