

110TH CONGRESS  
1ST SESSION

# H. R. 2273

To amend the Federal Food, Drug, and Cosmetic Act to provide for the deposit in the general fund of the Treasury of fees that are collected from manufacturers of drugs and devices under chapter VII of such Act, to terminate the authority of the Food and Drug Administration to negotiate with the manufacturers on particular uses of the fees, to establish a Center for Postmarket Drug Safety and Effectiveness, to establish additional authorities to ensure the safe and effective use of drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 10, 2007

Mr. HINCHEY (for himself, Mr. STUPAK, and Mr. GRIJALVA) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the deposit in the general fund of the Treasury of fees that are collected from manufacturers of drugs and devices under chapter VII of such Act, to terminate the authority of the Food and Drug Administration to negotiate with the manufacturers on particular uses of the fees, to establish a Center for Postmarket Drug Safety and Effectiveness, to establish additional authorities to ensure the safe and effective use of drugs, 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 “Food and Drug Ad-  
5 ministration Improvement Act of 2007”.

6 **SEC. 2. FEES PAID BY MANUFACTURERS TO FOOD AND**  
7 **DRUG ADMINISTRATION; DEPOSIT IN GEN-**  
8 **ERAL FUND OF TREASURY; DIRECT SPEND-**  
9 **ING.**

10 (a) IN GENERAL.—Subchapter C of chapter VII of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 379f et seq.) is amended by adding at the end the fol-  
13 lowing part:

14 **“PART 5—MODIFICATIONS REGARDING USER-FEE**  
15 **PROGRAMS**

16 **“SEC. 740A. DEPOSIT OF FEES IN GENERAL FUND OF**  
17 **TREASURY; DIRECT SPENDING.**

18 “(a) DEPOSIT IN GENERAL FUND.—Notwithstanding  
19 any other provision of this Act related to the collection  
20 of fees related to drugs, devices, or animal drugs, all such  
21 fees collected under this Act shall be deposited in the gen-  
22 eral fund of the Treasury.

23 “(b) DIRECT SPENDING.—

24 “(1) IN GENERAL.—Notwithstanding any other  
25 provision of this Act related to the collection of such

1 fees, amounts are available to the Secretary for obli-  
2 gation in accordance with the following:

3 “(A) The amount authorized to be appro-  
4 priated under this Act for fees related to drugs  
5 is, to the extent described in section  
6 736(g)(2)(A)(ii) (as in effect on September 30,  
7 2007), available to the Secretary for obligation  
8 solely for the process for the review of human  
9 drug applications (within the meaning given to  
10 such term in section 735, as in effect on Sep-  
11 tember 30, 2007).

12 “(B) The amount authorized to be appro-  
13 priated under this Act for fees related to de-  
14 vices is, to the extent described in section  
15 738(h)(2)(A)(ii) (as in effect on September 30,  
16 2007), available to the Secretary for obligation  
17 solely for the process for the review of device  
18 applications (within the meaning given to such  
19 terms in section 737, as in effect on September  
20 30, 2007).

21 “(C) The amount authorized to be appro-  
22 priated under this Act for fees related to animal  
23 drugs is, to the extent described in section  
24 740(g)(2)(A)(ii) (as in effect on September 30,  
25 2007), available to the Secretary for obligation

1 solely for the process for the review of animal  
2 drug applications (within the meaning given to  
3 such terms in section 739, as in effect on Sep-  
4 tember 30, 2007).

5 “(2) LIST OF MANDATORY APPROPRIATIONS.—

6 The program of spending established in paragraph  
7 (1) shall be considered entitlement authority within  
8 the meaning of section 250(17) of the Balanced  
9 Budget and Emergency Deficit Control Act of 1985.

10 **“SEC. 740B. TERMINATION OF AUTHORITY FOR NEGOTIA-**  
11 **TIONS WITH MANUFACTURERS ON USE OF**  
12 **FEES.**

13 “(a) IN GENERAL.—With respect to persons from  
14 whom fees related to drugs, devices, or animal drugs are  
15 collected under this Act and notwithstanding any other  
16 provision of this Act related to the collection of such fees:

17 “(1) On and after the date of the enactment of  
18 the Food and Drug Administration Improvement  
19 Act of 2007:

20 “(A) The Secretary may not enter into  
21 agreements with such persons on particular  
22 uses of the fees, including agreements on prior-  
23 ities, performance goals, or other commitments  
24 relating to—

1 “(i) review times for human drug ap-  
2 plications or supplements (within the  
3 meaning given to such terms in section  
4 735, as in effect on September 30, 2007);

5 “(ii) review times for premarket appli-  
6 cations, premarket reports, premarket noti-  
7 fication submissions, or supplements (with-  
8 in the meaning given to such terms in sec-  
9 tion 737, as in effect on September 30,  
10 2007); or

11 “(iii) review times for animal drug ap-  
12 plications or supplements (within the  
13 meaning given to such terms in section  
14 739, as in effect on September 30, 2007).

15 “(B) The Secretary may not otherwise ne-  
16 gotiate understandings with such persons on  
17 particular uses of the fees.

18 “(2) On and after October 1, 2007:

19 “(A) Any such agreement or under-  
20 standing that was in effect on the day before  
21 the date of the Food and Drug Administration  
22 Improvement Act of 2007 is terminated, includ-  
23 ing agreements or understandings pursuant to  
24 letters referred to in section 502(4) of Public  
25 Law 107–188 (116 Stat. 688), section 101(3)

1 of Public Law 107–250 (116 Stat. 1589), and  
2 section 2(3) of Public Law 108–130 (117 Stat.  
3 1361).

4 “(B) The Secretary is relieved of responsi-  
5 bility for meeting any particular goals con-  
6 cerning such review times that were established  
7 in such letters.

8 “(b) RULES OF CONSTRUCTION.—Subsection (a)  
9 may not be construed—

10 “(1) as affecting the responsibility of the Sec-  
11 retary to work toward the general goal of admin-  
12 istering this Act efficiently, including the review of  
13 applications, reports, supplements and other submis-  
14 sions referred to in subsection (a)(1)(A); or

15 “(2) as terminating requirements for the collec-  
16 tion of fees under any other provision of this Act.”.

17 (b) APPLICABILITY.—Section 740A of the Federal  
18 Food, Drug, and Cosmetic Act, as added by subsection  
19 (a) of this section, applies with respect to fiscal year 2008  
20 and subsequent fiscal years.

21 **SEC. 3. ESTABLISHMENT OF CENTER FOR POSTMARKET**  
22 **DRUG SAFETY AND EFFECTIVENESS.**

23 (a) IN GENERAL.—Chapter V of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
25 ed by inserting after section 505B the following sections:

1 **“SEC. 505C. CENTER FOR POSTMARKET DRUG SAFETY AND**  
2 **EFFECTIVENESS.**

3 “(a) ESTABLISHMENT.—Not later than 180 days  
4 after the date of the enactment of the Food and Drug  
5 Administration Improvement Act of 2007, the Secretary  
6 shall establish within the Food and Drug Administration  
7 a center to be known as the Center for Postmarket Drug  
8 Safety and Effectiveness (referred to in this section as the  
9 ‘Center’), which shall be headed by a director appointed  
10 by the Secretary (without regard to the delegation to the  
11 Commissioner of Food and Drugs under section  
12 903(d)(2)). The Center shall be established as a separate  
13 center at the organizational level immediately below the  
14 Office of the Commissioner. The Director of the Center  
15 shall report directly to the Commissioner.

16 “(b) DUTIES.—

17 “(1) IN GENERAL.—The Director of the Center  
18 shall have the principal responsibility within the  
19 Food and Drug Administration, below the Office of  
20 the Commissioner, for assisting the Commissioner in  
21 regulating approved drugs, other than with respect  
22 to section 501. Such assistance includes assistance  
23 with the following:

24 “(A) Administering enforcement authori-  
25 ties under chapter III, including civil penalties  
26 under section 303(f).

1 “(B) Administering section 502.

2 “(C) Administering requirements for stud-  
3 ies that were required as conditions for the ap-  
4 proval of applications under section 505 (which  
5 studies are conducted after such approval).

6 “(D) Administering authorities under sec-  
7 tions 505D and 505E.

8 “(E) Monitoring approved drugs to deter-  
9 mine whether there are any issues regarding  
10 safety and effectiveness.

11 “(F) With respect to issues identified  
12 under subparagraph (E), taking action under  
13 the provisions referred to in subparagraphs (A)  
14 through (D), including as appropriate the fol-  
15 lowing:

16 “(i) Establishing requirements for ad-  
17 vertising under section 502(n).

18 “(ii) Establishing requirements for  
19 modifications in labeling under section  
20 502(x), including the specification of a  
21 date by which the modifications are re-  
22 quired to be made.

23 “(iii) Withdrawing the approval of  
24 drugs under section 505(e).

1           “(iv) Requiring reports under section  
2           505(k) on clinical experience with approved  
3           drugs, including reports on the number of  
4           individuals using the drugs as indicated by  
5           sales of the drugs at retail and reports on  
6           information possessed by manufacturers on  
7           usage of the drugs.

8           “(v) Requiring notifications under sec-  
9           tion 505D(a)(1) to eliminate unreasonable  
10          risks of substantial harm to the public  
11          health.

12          “(vi) Establishing restrictions under  
13          section 505D(a)(2) to ensure the safe use  
14          of approved drugs, including requirements  
15          for—

16                 “(I) the specific manner of ob-  
17                 taining the informed consent of pa-  
18                 tients to undergo treatment with the  
19                 drugs;

20                 “(II) providing education to phy-  
21                 sicians;

22                 “(III) providing education to pa-  
23                 tients; and

24                 “(IV) the establishment of risk-  
25                 management plans by manufacturers.

1                   “(vii) Requiring the conduct of studies  
2                   under section 505E.

3                   “(2) TRANSFERS.—The Secretary shall transfer  
4                   to the Center all responsibilities for the matters re-  
5                   ferred to in paragraph (1) that, on the day before  
6                   the date of the enactment of the Food and Drug Ad-  
7                   ministration Improvement Act of 2007, were vested  
8                   in the Center for Drug Evaluation and Research and  
9                   the Center for Biologics Evaluation and Research.

10                  “(c) INTERACTIONS WITH OTHER CENTERS.—

11                  “(1) CONSULTATION.—The Director of the  
12                  Center shall carry out this section in consultation  
13                  with the Directors of the Centers referred to in sub-  
14                  section (b)(2).

15                  “(2) ACCESS TO INFORMATION.—The Secretary  
16                  shall ensure that the Director of the Center has full  
17                  access to all information possessed by the Food and  
18                  Drug Administration that relates to the safety and  
19                  effectiveness of approved drugs, including informa-  
20                  tion possessed by the Centers referred to in sub-  
21                  section (b)(2).

22                  “(d) DEFINITION.—For purposes of this section, the  
23                  term ‘approved drug’ means a drug for which an approved  
24                  application under section 505 is in effect or for which a

1 biologics license under section 351 of the Public Health  
2 Service Act is in effect.

3 “(e) FUNDING.—For the purpose of carrying out this  
4 section, the Secretary shall make available for a fiscal  
5 year, from the amount appropriated for the Food and  
6 Drug Administration for such year, the following amount,  
7 as applicable to such year:

8 “(1) For fiscal year 2008, \$100,000,000.

9 “(2) For fiscal year 2009, \$125,000,000.

10 “(3) For fiscal year 2010, \$150,000,000.

11 “(4) For fiscal year 2011, \$175,000,000.

12 “(5) For fiscal year 2012, \$200,000,000.

13 **“SEC. 505D. CERTAIN POSTMARKET AUTHORITIES.**

14 “(a) IN GENERAL.—Effective on and after the date  
15 of the enactment of the Food and Drug Administration  
16 Improvement Act of 2007, the Secretary has with respect  
17 to approved drugs the same authorities as the Secretary  
18 has with respect to devices under the following provisions:

19 “(1) Section 518(a) (relating to notifications to  
20 eliminate an unreasonable risk of substantial harm  
21 to the public health).

22 “(2) Section 520(e)(1)(B) (relating to restric-  
23 tions on sale, distribution, or use).



1           “(6) such other sources as the Secretary deter-  
2           mines to be appropriate.

3           “(b) APPROVAL OF PROTOCOL; TIMEFRAME.—A  
4           study under subsection (a) shall be conducted in accord-  
5           ance with a protocol approved by the Secretary. In requir-  
6           ing such a study, the Secretary shall specify a timeframe  
7           for completing the study.

8           “(c) PUBLIC DISCLOSURE.—

9           “(1) INTERNET SITE.—Notwithstanding section  
10          506B, the Secretary shall maintain on the Internet  
11          site of the Food and Drug Administration a data-  
12          base that provides information on each study re-  
13          quired under subsection (a), including a description  
14          of and the reason for the study, the required comple-  
15          tion date, and whether the study has been com-  
16          pleted. The Secretary shall update the database not  
17          less frequently than once each quarter.

18          “(2) FEDERAL REGISTER.—Not later than 30  
19          days after first establishing the database under  
20          paragraph (1), the Secretary shall, with respect to  
21          studies required under subsection (a), publish in the  
22          Federal Register the same information as is included  
23          in such database as of the date of such publication.  
24          Thereafter, the Secretary shall publish in the Fed-  
25          eral Register, not less frequently than once each

1 quarter, updates that reflect the updates made  
2 under paragraph (1).

3 “(d) DEFINITION.—For purposes of this section, the  
4 term ‘approved drug’ has the meaning given such term  
5 in section 505C(d).”.

6 (b) CERTAIN STUDIES.—

7 (1) IN GENERAL.—With respect to section  
8 505E(c) of the Federal Food, Drug, and Cosmetic  
9 Act (as added by subsection (a) of this section), each  
10 study described in paragraph (2) is deemed to be a  
11 study to which such section applies.

12 (2) RELEVANT STUDIES.—For purposes of  
13 paragraph (1), a study described in this paragraph  
14 is a study that—

15 (A) relates to the safety or effectiveness of  
16 a drug;

17 (B) was in progress as of the date of the  
18 enactment of this Act; and

19 (C) was conducted pursuant to an agree-  
20 ment that, on or after January 1, 2003, was  
21 entered into with the Secretary of Health and  
22 Human Services, acting through the Commis-  
23 sioner of Food and Drugs.

1 **SEC. 4. ORDER REGARDING POSTMARKET LABELING.**

2 Section 502 of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 352) is amended by adding at the end the  
4 following:

5 “(y) If it is a drug and the Secretary deter-  
6 mines that its labeling fails to provide information,  
7 including specific wording, required by the Secretary  
8 by order on the basis that the information is nec-  
9 essary to ensure its safe and effective use.”.

10 **SEC. 5. ADDITIONAL ENFORCEMENT PROVISIONS.**

11 (a) **POSTMARKET AUTHORITIES.**—Section 502 of the  
12 Federal Food, Drug, and Cosmetic Act, as amended by  
13 section 4 of this Act, is amended by adding at the end  
14 the following:

15 “(y) If it is a drug with respect to which there is  
16 a failure to comply with any requirement under section  
17 505D or 505E.”.

18 (b) **CIVIL PENALTIES FOR VIOLATIONS OF REQUIRE-**  
19 **MENTS RELATING TO DRUGS.**—Section 303(f) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is  
21 amended—

22 (1) by redesignating paragraphs (3) through  
23 (5) as paragraphs (4) through (6), respectively;

24 (2) by inserting after paragraph (2) the fol-  
25 lowing paragraph:

1           “(3) Any person who violates a requirement of  
2           this Act which relates to drugs shall be liable to the  
3           United States for a civil penalty in an amount not  
4           exceeding \$50,000 per day for each such violation,  
5           not to exceed \$50,000,000 for all such violations ad-  
6           judicated in a single proceeding.”;

7           (3) in paragraph (4) (as so redesignated) by  
8           striking “paragraph (1) or (2)” each place such  
9           term appears and inserting “paragraph (1), (2), or  
10          (3)”;

11          (4) in paragraph (5) (as so redesignated), by  
12          striking “paragraph (3)(A)” and inserting “para-  
13          graph (4)(A)”;

14          (5) in paragraph (6) (as so redesignated), by  
15          striking “paragraph (4)” each place such term ap-  
16          pears and inserting “paragraph (5)”.

17 **SEC. 6. PREEMPTION.**

18          (a) IN GENERAL.—With respect to the issue of  
19          whether a provision of chapter V of the Federal Food,  
20          Drug, and Cosmetic Act or of section 351 of the Public  
21          Health Service Act (or regulations or orders under such  
22          a provision) supersedes the law of a State, the Secretary  
23          of Health and Human Services (referred to in this section  
24          as the “Secretary”) shall follow, without change, the inter-  
25          pretation that was followed by the Food and Drug Admin-

1 istration in 1999, including the interpretation that such  
2 Administration “does not believe that the evolution of  
3 state tort law will cause the development of standards that  
4 would be at odds with the agency’s regulations” and that  
5 such regulations “establish minimal standards” but are  
6 not intended to preclude the States from imposing addi-  
7 tional requirements (63 FR 66384).

8 (b) **PRODUCT LIABILITY CASES.**—In the case of civil  
9 actions regarding product liability that are brought in  
10 State courts against manufacturers of drugs or devices,  
11 policies of the Secretary required under subsection (a) in-  
12 clude the policy that the Secretary cease intervening in  
13 such actions to argue any interpretation contrary to such  
14 subsection.

15 **SEC. 7. ADDITIONAL PROVISIONS.**

16 (a) **REQUIREMENTS REGARDING MEMBERSHIP OF**  
17 **ADVISORY COMMITTEES.**—Subchapter A of chapter VII of  
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371  
19 et seq.) is amended by adding at the end the following  
20 section:

21 **“SEC. 712. REQUIREMENTS REGARDING MEMBERSHIP OF**  
22 **ADVISORY COMMITTEES.**

23 “(a) **IN GENERAL.**—Notwithstanding any other pro-  
24 vision of law, the Secretary shall comply with the following

1 with respect to any meeting of an advisory committee con-  
2 vened by the Secretary under this Act:

3           “(1) Not later than 30 days before such meet-  
4 ing, the Secretary shall post on the Internet site of  
5 the Food and Drug Administration the agenda for  
6 the meeting and the tentative list of all proposed ad-  
7 visory committee members, together with a short bi-  
8 ography of each such prospective member.

9           “(2) After compliance with paragraph (1), the  
10 Secretary shall provide the public not fewer than 20  
11 days to submit to the Secretary comments on the  
12 proposed membership of the advisory committee.

13           “(3) The Secretary shall consider the public  
14 comments to determine whether any adjustment to  
15 the roster of the advisory committee is necessary to  
16 make the committee fairly balanced.

17           “(4) Not later than three days before the start  
18 of the meeting, the Secretary shall post on such  
19 Internet site the final membership of the advisory  
20 committee.

21           “(b) CONFLICTS OF INTEREST.—Notwithstanding  
22 any other provision of law, a member of an advisory com-  
23 mittee under this Act may not, with respect to service on  
24 such committee, be granted an exemption under section

1 208(b) of title 18, United States Code (relating to per-  
2 sonal financial interests).

3 “(c) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘advisory committee’ has the  
5 same meaning given such term in section 3(2) of the  
6 Federal Advisory Committee Act.

7 “(2) The term ‘fairly balanced’ has the same  
8 meaning as applies to such term under section  
9 5(b)(2) of the Federal Advisory Committee Act.”.

10 (b) CERTAIN USES OF APPROVED DRUGS.—Chapter  
11 IX of the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 391 et seq.) is amended by adding at the end the  
13 following section:

14 **“SEC. 910. REQUIREMENT REGARDING INFORMED CON-**  
15 **SENT FOR CERTAIN TREATMENTS.**

16 “With respect to the prescribing of a drug for a use  
17 not included in the approved labeling for the drug under  
18 section 505 or under section 351 of the Public Health  
19 Service Act, the Secretary shall promulgate regulations re-  
20 quiring that, before prescribing the drug—

21 “(1) the physician inform the patient that the  
22 use for which the physician intends to prescribe the  
23 drug has not been approved by the Food and Drug  
24 Administration; and

1           “(2) the physician obtain from the patient an  
2           acknowledgment of such fact and the consent of the  
3           patient to use the drug for such use notwithstanding  
4           such fact.”.

○