

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.

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

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.”.

○