

109TH CONGRESS
1ST SESSION

H. R. 2090

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 4, 2005

Mr. HINCHEY (for himself, Ms. DELAURO, and Mr. STUPAK) 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 2005”.

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 part 2, part 3, and part 4, all fees collected under such
 20 parts shall be deposited in the general fund of the Treas-
 21 ury.

22 “(b) DIRECT SPENDING.—

23 “(1) IN GENERAL.—Notwithstanding part 2,
 24 part 3, and part 4, amounts are available to the Sec-

1 retary for obligation in accordance with the fol-
2 lowing:

3 “(A) The amount specified in section
4 736(g)(3) for a fiscal year is, to the extent de-
5 scribed in section 736(g)(2)(A)(ii), available to
6 the Secretary for obligation solely for the proc-
7 ess for the review of human drug applications
8 (as defined in section 735).

9 “(B) The amount specified in section
10 738(h)(3) for a fiscal year is, to the extent de-
11 scribed in section 738(h)(2)(A)(ii), available to
12 the Secretary for obligation solely for the proc-
13 ess for the review of device applications (as de-
14 fined in section 737).

15 “(C) The amount specified in section
16 740(g)(3) for a fiscal year is, to the extent de-
17 scribed in section 740(g)(2)(A)(ii), available to
18 the Secretary for obligation solely for the proc-
19 ess for the review of animal drug applications
20 (as defined in section 739).

21 “(2) LIST OF MANDATORY APPROPRIATIONS.—
22 The program of spending established in paragraph
23 (1) shall be considered entitlement authority within
24 the meaning of section 250(17) of the Balanced
25 Budget and Emergency Deficit Control Act of 1985.

1 **“SEC. 740B. TERMINATION OF AUTHORITY FOR NEGOTIA-**
2 **TIONS WITH MANUFACTURERS ON USE OF**
3 **FEES.**

4 “(a) IN GENERAL.—With respect to persons from
5 whom fees are collected under part 2, part 3, or part 4:

6 “(1) Notwithstanding such parts, the following
7 applies on and after the date of the enactment of the
8 Food and Drug Administration Improvement Act of
9 2005:

10 “(A) The Secretary may not enter into
11 agreements with such persons on particular
12 uses of the fees, including agreements on prior-
13 ities, performance goals, or other commitments
14 relating to—

15 “(i) review times for human drug ap-
16 plications or supplements within the mean-
17 ing of part 2;

18 “(ii) review times for premarket appli-
19 cations, premarket reports, premarket noti-
20 fication submissions, or supplements within
21 the meaning of part 3; or

22 “(iii) review times for animal drug ap-
23 plications or supplements within the mean-
24 ing of part 4.

1 “(B) The Secretary may not otherwise ne-
2 gotiate understandings with such persons on
3 particular uses of the fees.

4 “(2) Notwithstanding such parts, the following
5 applies on and after October 1, 2005:

6 “(A) Any such agreement or under-
7 standing that was in effect on the day before
8 the date of the Food and Drug Administration
9 Improvement Act of 2005 is terminated, includ-
10 ing agreements or understandings pursuant to
11 letters referred to in section 502(4) of Public
12 Law 107–188 (116 Stat. 688), section 101(3)
13 of Public Law 107–250 (116 Stat. 1589), and
14 section 2(3) of Public Law 108–130 (117 Stat.
15 1361).

16 “(B) The Secretary is relieved of responsi-
17 bility for meeting any particular goals con-
18 cerning such review times that were established
19 in such letters.

20 “(b) RULES OF CONSTRUCTION.—Subsection (a)
21 may not be construed—

22 “(1) as affecting the responsibility of the Sec-
23 retary to work toward the general goal of admin-
24 istering this Act efficiently, including the review of

1 applications, reports, supplements and other submis-
2 sions referred to in subsection (a)(1)(A); or

3 “(2) as terminating requirements for the collec-
4 tion of fees under part 2, part 3, and part 4.”.

5 (b) APPLICABILITY.—Section 740A of the Federal
6 Food, Drug, and Cosmetic Act, as added by subsection
7 (a) of this section, applies with respect to fiscal year 2006
8 and subsequent fiscal years.

9 **SEC. 3. ESTABLISHMENT OF CENTER FOR POSTMARKET**
10 **DRUG SAFETY AND EFFECTIVENESS.**

11 (a) IN GENERAL.—Chapter V of the the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.)
13 is amended by inserting after section 505B the following
14 sections:

15 **“SEC. 505C. CENTER FOR POSTMARKET DRUG SAFETY AND**
16 **EFFECTIVENESS.**

17 “(a) ESTABLISHMENT.—Not later than 180 days
18 after the date of the enactment of the Food and Drug
19 Administration Improvement Act of 2005, the Secretary
20 shall establish within the Food and Drug Administration
21 a center to be known as the Center for Postmarket Drug
22 Safety and Effectiveness (referred to in this section as the
23 ‘Center’), which shall be headed by a director appointed
24 by the Secretary (without regard to the delegation to the
25 Commissioner of Food and Drugs under section

1 903(d)(2)). The Center shall be established as a separate
2 center at the organizational level immediately below the
3 Office of the Commissioner. The Director of the Center
4 shall report directly to the Commissioner.

5 “(b) DUTIES.—

6 “(1) IN GENERAL.—The Director of the Center
7 shall have the principal responsibility within the
8 Food and Drug Administration, below the Office of
9 the Commissioner, for assisting the Commissioner in
10 regulating approved drugs, other than with respect
11 to section 501. Such assistance includes assistance
12 with the following:

13 “(A) Administering enforcement authori-
14 ties under chapter III, including civil penalties
15 under section 303(f).

16 “(B) Administering section 502.

17 “(C) Administering requirements for stud-
18 ies that were required as conditions for the ap-
19 proval of applications under section 505 (which
20 studies are conducted after such approval).

21 “(D) Administering authorities under sec-
22 tions 505D and 505E.

23 “(E) Monitoring approved drugs to deter-
24 mine whether there are any issues regarding
25 safety and effectiveness.

1 “(F) With respect to issues identified
2 under subparagraph (E), taking action under
3 the provisions referred to in subparagraphs (A)
4 through (D), including as appropriate the fol-
5 lowing:

6 “(i) Establishing requirements for ad-
7 vertising under section 502(n).

8 “(ii) Establishing requirements for
9 modifications in labeling under section
10 502(x), including the specification of a
11 date by which the modifications are re-
12 quired to be made.

13 “(iii) Withdrawing the approval of
14 drugs under section 505(e).

15 “(iv) Requiring reports under section
16 505(k) on clinical experience with approved
17 drugs, including reports on the number of
18 individuals using the drugs as indicated by
19 sales of the drugs at retail and reports on
20 information possessed by manufacturers on
21 usage of the drugs.

22 “(v) Requiring notifications under sec-
23 tion 505D(a)(1) to eliminate unreasonable
24 risks of substantial harm to the public
25 health.

1 “(vi) Establishing restrictions under
2 section 505D(a)(2) to ensure the safe use
3 of approved drugs, including requirements
4 for—

5 “(I) the specific manner of ob-
6 taining the informed consent of pa-
7 tients to undergo treatment with the
8 drugs;

9 “(II) providing education to phy-
10 sicians;

11 “(III) providing education to pa-
12 tients; and

13 “(IV) the establishment of risk-
14 management plans by manufacturers.

15 “(vii) Requiring the conduct of studies
16 under section 505E.

17 “(2) TRANSFERS.—The Secretary shall transfer
18 to the Center all responsibilities for the matters re-
19 ferred to in paragraph (1) that, on the day before
20 the date of the enactment of the Food and Drug Ad-
21 ministration Improvement Act of 2005, were vested
22 in the Center for Drug Evaluation and Research and
23 the Center for Biologics Evaluation and Research.

24 “(c) INTERACTIONS WITH OTHER CENTERS.—

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

5 “(2) ACCESS TO INFORMATION.—The Secretary
6 shall ensure that the Director of the Center has full
7 access to all information possessed by the Food and
8 Drug Administration that relates to the safety and
9 effectiveness of approved drugs, including informa-
10 tion possessed by the Centers referred to in sub-
11 section (b)(2).

12 “(d) DEFINITION.—For purposes of this section, the
13 term ‘approved drug’ means a drug for which an approved
14 application under section 505 is in effect or for which a
15 biologics license under section 351 of the Public Health
16 Service Act is in effect.

17 “(e) FUNDING.—For the purpose of carrying out this
18 section, the Secretary shall make available for a fiscal
19 year, from the amount appropriated for the Food and
20 Drug Administration for such year, the following amount,
21 as applicable to such year:

22 “(1) For fiscal year 2006, \$100,000,000.

23 “(2) For fiscal year 2007, \$125,000,000.

24 “(3) For fiscal year 2008, \$150,000,000.

25 “(4) For fiscal year 2009, \$175,000,000.

1 “(5) For fiscal year 2010, \$200,000,000.

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

3 “(a) IN GENERAL.—Effective on and after the date
4 of the enactment of the Food and Drug Administration
5 Improvement Act of 2005, the Secretary has with respect
6 to approved drugs the same authorities as the Secretary
7 has with respect to devices under the following provisions:

8 “(1) Section 518(a) (relating to notifications to
9 eliminate an unreasonable risk of substantial harm
10 to the public health).

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

13 “(3) Section 520(h) (relating to making avail-
14 able to the public summaries of information respect-
15 ing safety and effectiveness).

16 “(b) DEFINITION.—For purposes of this section, the
17 term ‘approved drug’ has the meaning given such term
18 in section 505C(d).

19 **“SEC. 505E. POSTMARKET STUDIES REGARDING SAFETY OF**
20 **DRUGS.**

21 “(a) PHASE 4 STUDIES.—The Secretary may require
22 that the manufacturer of an approved drug conduct one
23 or more studies to confirm or refute an empirical or theo-
24 retical hypothesis of a significant safety issue with the
25 drug (whether raised with respect to the product directly

1 or with respect to the class of the product) that has been
2 identified pursuant to—

3 “(1) the MedWatch postmarket surveillance
4 system;

5 “(2) a clinical or epidemiological study;

6 “(3) the scientific literature;

7 “(4) a foreign government that regulates drugs
8 or devices;

9 “(5) an international organization concerned
10 with the safety or effectiveness of drugs or devices;
11 or

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

14 “(b) APPROVAL OF PROTOCOL; TIMEFRAME.—A
15 study under subsection (a) shall be conducted in accord-
16 ance with a protocol approved by the Secretary. In requir-
17 ing such a study, the Secretary shall specify a timeframe
18 for completing the study.

19 “(c) PUBLIC DISCLOSURE.—

20 “(1) INTERNET SITE.—Notwithstanding 506B,
21 the Secretary shall maintain on the Internet site of
22 the Food and Drug Administration a database that
23 provides information on each study required under
24 subsection (a), including a description of and the
25 reason for the study, the required completion date,

1 and whether the study has been completed. The Sec-
2 retary shall update the database not less frequently
3 than once each quarter.

4 “(2) FEDERAL REGISTER.—Not later than 30
5 days after first establishing the databank under
6 paragraph (1), the Secretary shall, with respect to
7 studies required under subsection (a), publish in the
8 Federal Register the same information as is included
9 in such database as of the date of such publication.
10 Thereafter, the Secretary shall publish in the Fed-
11 eral Register, not less frequently than once each
12 quarter, updates that reflect the updates made
13 under paragraph (1).

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

17 (b) CERTAIN STUDIES.—

18 (1) IN GENERAL.—With respect to section
19 505E(c) of the Federal Food, Drug, and Cosmetic
20 Act (as added by subsection (a) of this section), each
21 study described in paragraph (2) is deemed to be a
22 study to which such section applies.

23 (2) RELEVANT STUDIES.—For purposes of
24 paragraph (1), a study described in this paragraph
25 is a study that—

1 (A) relates to the safety or effectiveness of
2 a drug;

3 (B) was in progress as of the date of the
4 enactment of this Act; and

5 (C) was conducted pursuant to an agree-
6 ment that, or or after January 1, 2003, was en-
7 tered into with the Secretary of Health and
8 Human Services, acting through the Commis-
9 sioner of Food and Drugs.

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

11 Section 502 of the the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 352) is amended by adding at the
13 end the following:

14 “(x) If it is a drug and the Secretary deter-
15 mines that its labeling fails to provide information,
16 including specific wording, required by the Secretary
17 by order on the basis that the information is nec-
18 essary to ensure its safe and effective use.”.

19 **SEC. 5. ADDITIONAL ENFORCEMENT PROVISIONS.**

20 (a) POSTMARKET AUTHORITIES.—Section 502 of the
21 the Federal Food, Drug, and Cosmetic Act, as amended
22 by section 4 of this Act, is amended by adding at the end
23 the following:

1 “(y) If it is a drug with respect to which there is
2 a failure to comply with any requirement under section
3 505D or 505E.”.

4 (b) CIVIL PENALTIES FOR VIOLATIONS OF REQUIRE-
5 MENTS RELATING TO DRUGS.—Section 303(f) of the the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f))
7 is amended—

8 (1) by redesignating paragraphs (3) through
9 (5) as paragraphs (4) through (6), respectively;

10 (2) by inserting after paragraph (2) the fol-
11 lowing paragraph:

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

18 (3) in paragraph (4) (as so redesignated) by
19 striking “paragraph (1) or (2)” each place such
20 term appears and inserting “paragraph (1), (2), or
21 (3)”; and

22 (4) in paragraph (5) (as so redesignated), by
23 striking “paragraph (3)(A)” and inserting “para-
24 graph (4)(A)”; and

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

4 **SEC. 6. PREEMPTION.**

5 (a) IN GENERAL.—With respect to the issue of
6 whether a provision of chapter V of the Federal Food,
7 Drug, and Cosmetic Act or of section 351 of the Public
8 Health Service Act (or regulations or orders under such
9 a provision) supersedes the law of a State, the Secretary
10 of Health and Human Services (referred to in this section
11 as the “Secretary”) shall follow, without change, the inter-
12 pretation that was followed by the Food and Drug Admin-
13 istration in 1999, including the interpretation that such
14 Administration “does not believe that the evolution of
15 state tort law will cause the development of standards that
16 would be at odds with the agency’s regulations” and that
17 such regulations “establish minimal standards” but are
18 not intended to preclude the States from imposing addi-
19 tional requirements (63 FR 66384).

20 (b) PRODUCT LIABILITY CASES.—In the case of civil
21 actions regarding product liability that are brought in
22 State courts against manufacturers of drugs or devices,
23 policies of the Secretary required under subsection (a) in-
24 clude the policy that the Secretary cease intervening in

1 such actions to argue any interpretation contrary to such
2 subsection.

3 **SEC. 7. ADDITIONAL PROVISIONS.**

4 (a) REQUIREMENTS REGARDING MEMBERSHIP OF
5 ADVISORY COMMITTEES.—Subchapter A of chapter VII of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
7 et seq.) is amended by adding at the end the following
8 section:

9 **“SEC. 712. REQUIREMENTS REGARDING MEMBERSHIP OF**
10 **ADVISORY COMMITTEES.**

11 “(a) IN GENERAL.—Notwithstanding any other pro-
12 vision of law, the Secretary shall comply with the following
13 with respect to any meeting of an advisory committee con-
14 vened by the Secretary under this Act:

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

21 “(2) After compliance with paragraph (1), the
22 Secretary shall provide the public not fewer than 20
23 days to submit to the Secretary comments on the
24 proposed membership of the advisory committee.

1 “(3) The Secretary shall consider the public
2 comments to determine whether any adjustment to
3 the roster of the advisory committee is necessary to
4 make the committee fairly balanced.

5 “(4) Not later than three days before the start
6 of the meeting, the Secretary shall post on such
7 Internet site the final membership of the advisory
8 committee.

9 “(b) CONFLICTS OF INTEREST.—Notwithstanding
10 any other provision of law, a member of an advisory com-
11 mittee under this Act may not, with respect to service on
12 such committee, be granted an exemption under section
13 208(b) of title 18, United States Code (relating to per-
14 sonal financial interests).

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

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

19 “(2) The term ‘fairly balanced’ has the same
20 meaning as applies to such term under section
21 5(b)(2) of the Federal Advisory Committee Act.”.

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

1 **“SEC. 910. REQUIREMENT REGARDING INFORMED CON-**
2 **SENT FOR CERTAIN TREATMENTS.**

3 “With respect to the prescribing of a drug for a use
4 not included in the approved labeling for the drug under
5 section 505 or under section 351 of the Public Health
6 Service Act, the Secretary shall promulgate regulations re-
7 quiring that, before prescribing the drug—

8 “(1) the physician inform the patient that the
9 use for which the physician intends to prescribe the
10 drug has not been approved by the Food and Drug
11 Administration; and

12 “(2) the physician obtain from the patient an
13 acknowledgment of such fact and the consent of the
14 patient to use the drug for such use notwithstanding
15 such fact.”.

○