

111TH CONGRESS
2^D SESSION

H. R. 4816

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

MARCH 10, 2010

Mr. HINCHAY 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 2010”.

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 6—MODIFICATIONS REGARDING USER-FEE**
15 **PROGRAMS**

16 **“SEC. 743. DEPOSIT OF FEES IN GENERAL FUND OF TREAS-**
17 **URY; 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, animal drugs, or generic
21 animal drugs, all such fees collected under this Act shall
22 be deposited in the general 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 section 736 for fees related to
5 drugs is, to the extent described in section
6 736(g)(2)(A)(ii) (as in effect on September 30,
7 2010), 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, 2010).

12 “(B) The amount authorized to be appro-
13 priated under section 736A for fees relating to
14 advisory review of prescription-drug television
15 advertising is, to the extent described in section
16 736A(g)(2)(A)(ii) (as in effect on September
17 30, 2010), available to the Secretary for obliga-
18 tion solely for the process for the advisory re-
19 view of prescription drug advertising (within the
20 meaning given to such terms in section 736A,
21 as in effect on September 30, 2010).

22 “(C) The amount authorized to be appro-
23 priated under section 736A–1 for fees relating
24 to the regulation of advertisements for drugs

1 and devices is available to the Secretary for ob-
2 ligation solely for such regulation.

3 “(D) The amount authorized to be appro-
4 priated under this Act for fees related to de-
5 vices is, to the extent described in section
6 738(h)(2)(A)(ii) (as in effect on September 30,
7 2010), available to the Secretary for obligation
8 solely for the process for the review of device
9 applications (within the meaning given to such
10 terms in section 737, as in effect on September
11 30, 2010).

12 “(E) The amount authorized to be appro-
13 priated under this Act for fees related to animal
14 drugs is, to the extent described in section
15 740(g)(2)(A)(ii) (as in effect on September 30,
16 2010), available to the Secretary for obligation
17 solely for the process for the review of animal
18 drug applications (within the meaning given to
19 such terms in section 739, as in effect on Sep-
20 tember 30, 2010).

21 “(F) The amount authorized to be appro-
22 priated under this Act for fees related to ge-
23 neric new animal drugs is, to the extent de-
24 scribed in section 741(g)(2)(A)(ii) (as in effect
25 on September 30, 2010), available to the Sec-

1 retary for obligation solely for the process for
2 the review of abbreviated applications for ge-
3 neric new animal drugs (within the meanings
4 given to such terms in section 741, as in effect
5 on September 30, 2010).

6 “(2) LIST OF MANDATORY APPROPRIATIONS.—

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

11 **“SEC. 744. TERMINATION OF AUTHORITY FOR NEGOTIA-**
12 **TIONS WITH MANUFACTURERS ON USE OF**
13 **FEES.**

14 “(a) IN GENERAL.—With respect to persons from
15 whom fees related to drugs, devices, animal drugs, or ge-
16 neric animal drugs are collected under this Act and not-
17 withstanding any other provision of this Act related to the
18 collection of such fees:

19 “(1) On and after the date of the enactment of
20 the Food and Drug Administration Improvement
21 Act of 2010:

22 “(A) The Secretary may not enter into
23 agreements with such persons on particular
24 uses of the fees, including agreements on prior-

1 ities, performance goals, or other commitments
2 relating to—

3 “(i) review times for human drug ap-
4 plications or supplements (within the
5 meaning given to such terms in section
6 735, as in effect on September 30, 2010);

7 “(ii) review times for providing advi-
8 sory comments on direct-to-consumer tele-
9 vision advertisements (within the meaning
10 given to such terms in section 736A, as in
11 effect on September 30, 2010);

12 “(iii) review times for premarket ap-
13 plications, premarket reports, premarket
14 notification submissions, or supplements
15 (within the meaning given to such terms in
16 section 737, as in effect on September 30,
17 2010);

18 “(iv) review times for animal drug ap-
19 plications or supplements (within the
20 meaning given to such terms in section
21 739, as in effect on September 30, 2010);

22 or

23 “(v) review times for abbreviated ap-
24 plications for a generic new animal drug or
25 supplements thereto (within the meaning

1 given to such terms in section 741, as in
2 effect on September 30, 2010).

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

6 “(2) On and after October 1, 2010:

7 “(A) Any such agreement or under-
8 standing that was in effect on the day before
9 the date of the Food and Drug Administration
10 Improvement Act of 2010 is terminated, includ-
11 ing agreements or understandings pursuant to
12 letters referred to in section 502(4) of Public
13 Law 107–188 (116 Stat. 688), section 101(3)
14 of Public Law 107–250 (116 Stat. 1589), sec-
15 tion 2(3) of Public Law 108–130 (117 Stat.
16 1361), and section 101(c) of Public Law 110–
17 85 (121 Stat. 823).

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

22 “(b) RULES OF CONSTRUCTION.—Subsection (a)
23 may not be construed—

24 “(1) as affecting the responsibility of the Sec-
25 retary to work toward the general goal of admin-

1 istering this Act efficiently, including the review of
2 applications, reports, supplements and other submis-
3 sions referred to in subsection (a)(1)(A); or

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

6 (b) APPLICABILITY.—Section 743 of the Federal
7 Food, Drug, and Cosmetic Act, as added by subsection
8 (a) of this section, applies with respect to fiscal year 2011
9 and subsequent fiscal years.

10 (c) MANAGEMENT STRATEGY TO ENSURE THE TIME-
11 LY REVIEW OF APPLICATIONS.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services (in this subsection referred to as
14 the “Secretary”) shall submit to the Committees on
15 Appropriations and Energy and Commerce of the
16 House of Representatives and the Committees on
17 Appropriations and Health, Education, Labor, and
18 Pensions of the Senate a comprehensive review of
19 the drug and device application and amendment
20 process to identify ways to increase efficiency, re-
21 duce paperwork, speed analysis, and promote the
22 quickest possible decision process designed to ensure
23 the entry of safe, effective drugs and devices into the
24 marketplace.

1 (2) CONSIDERATIONS.—In carrying out the re-
2 view under paragraph (1), the Secretary shall con-
3 sider a time-and-motion study to identify best prac-
4 tices in processing applications and ensure the con-
5 sideration of safety issues.

6 (3) STAFF-TO-APPLICATION RATIO.—In car-
7 rying out the review under paragraph (1), not later
8 than 180 days after the date of enactment of this
9 Act, the Secretary shall submit to the committees re-
10 ferred to in such paragraph recommendations on an
11 ideal staff-to-application ratio to address safety
12 issues without slowing the decision process.

13 **SEC. 3. ESTABLISHMENT OF CENTER FOR POSTMARKET**
14 **DRUG, DEVICE, AND BIOLOGIC SAFETY AND**
15 **EFFECTIVENESS.**

16 Chapter V of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 351 et seq.) is amended by inserting after
18 section 505D the following:

19 **“SEC. 505E. CENTER FOR POSTMARKET DRUG, DEVICE, AND**
20 **BIOLOGIC SAFETY AND EFFECTIVENESS.**

21 “(a) ESTABLISHMENT.—Not later than 180 days
22 after the date of the enactment of the Food and Drug
23 Administration Improvement Act of 2010, the Secretary
24 shall establish within the Food and Drug Administration
25 a center to be known as the Center for Postmarket Drug,

1 Device, and Biologic Safety and Effectiveness (referred to
2 in this section as the ‘Center’), which shall be headed by
3 a director appointed by the Commissioner of Food and
4 Drugs in consultation with the Secretary (without regard
5 to the delegation to the Commissioner under section
6 1003(d)(2)). The Center shall be established as a separate
7 center at the organizational level immediately below the
8 Office of the Commissioner. The Director of the Center
9 shall report directly to the Commissioner.

10 “(b) DUTIES.—

11 “(1) IN GENERAL.—Subject to paragraph (2),
12 the Director of the Center shall have the principal
13 responsibility within the Food and Drug Administra-
14 tion, below the Office of the Commissioner of Food
15 and Drugs, for assisting the Commissioner in regu-
16 lating approved drugs and devices. Such assistance
17 includes the following:

18 “(A) Monitoring approved drugs to deter-
19 mine whether there are any issues regarding
20 safety or effectiveness.

21 “(B) Administering section 502 (relating
22 to misbranding).

23 “(C) Establishing and administering re-
24 quirements for advertising under section 502(n)
25 or 503(b).

1 “(D) Administering requirements for stud-
2 ies and clinical trials that were required as con-
3 ditions for the approval of applications under
4 section 505.

5 “(E) Withdrawing the approval of drugs
6 under section 505(e).

7 “(F) Administering section 505(l)(2) (re-
8 lating to action packages for approval).

9 “(G) Establishing and administering re-
10 quirements for modifications in labeling under
11 section 505(o)(4).

12 “(H) Administering authorities under sec-
13 tions 505(p) and 505–1 (relating to risk evalua-
14 tion and mitigation strategies).

15 “(I) Administering section 505(r) (relating
16 to postmarket drug safety information for pa-
17 tients and providers).

18 “(2) EXCLUSION.—The responsibility vested in
19 the Director of the Center does not include review
20 of any request for approval, licensure, or clearance
21 of a new active ingredient, new indication, new dos-
22 age form, new dosing regimen, new route of adminis-
23 tration, or any other new characteristic with respect
24 to a previously approved, licensed, or cleared drug,
25 biological product, or device.

1 “(3) TRANSFERS.—Not later than 1 year after
2 the date of the enactment of this section, the Sec-
3 retary shall transfer to the Center all responsibilities
4 for the matters referred to in paragraph (1) that, on
5 the day before the date of such transfer, were vested
6 in the Center for Drug Evaluation and Research, the
7 Center for Biologics Evaluation and Research, or the
8 Center for Devices and Radiological Health Organi-
9 zation.

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)(3).

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 and devices, includ-
20 ing information possessed by the Centers referred to
21 in subsection (b)(3).

22 “(d) DEFINITION.—For purposes of this section, the
23 term ‘approved drugs and devices’ includes a drug for
24 which an approved application under section 505 of this
25 Act is in effect, a biological product for which a biologics

1 license under section 351 of the Public Health Service Act
2 is in effect, or a device for which a clearance or approved
3 application under section 510(k) or 515 of this Act is in
4 effect.

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

10 “(1) For fiscal year 2011, \$150,000,000.

11 “(2) For fiscal year 2012, \$175,000,000.

12 “(3) For fiscal year 2013, \$200,000,000.

13 “(4) For fiscal year 2014, \$225,000,000.

14 “(5) For fiscal year 2015, \$250,000,000.”.

15 **SEC. 4. STATEMENT FOR INCLUSION IN DIRECT-TO-CON-**
16 **SUMER ADVERTISEMENTS OF DRUGS.**

17 (a) IN GENERAL.—Paragraph (3) of section 502(n)
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 352(n)) is amended by striking “published direct-to-con-
20 sumer advertisements” and inserting “published or tele-
21 vised direct-to-consumer advertisements”.

22 (b) EFFECTIVE DATE.—The requirements of section
23 502(n)(3) of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 352(n)(3)) applicable to televised direct-to-con-
25 sumer advertisements, as added by subsection (a), take

1 effect on the date that is 180 days after the date of the
2 enactment of this Act.

3 (c) REGULATIONS.—Not later than the date that is
4 180 days after the date of the enactment of this Act, the
5 Secretary of Health and Human Services shall promulgate
6 final regulations to implement such requirements.

7 **SEC. 5. LIABILITY UNDER STATE AND LOCAL REQUIRE-**
8 **MENTS RESPECTING DEVICES.**

9 (a) AMENDMENT.—Section 521 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by
11 adding at the end the following:

12 “(c) NO EFFECT ON LIABILITY UNDER STATE
13 LAW.—Nothing in this section shall be construed to mod-
14 ify or otherwise affect any action for damages or the liabil-
15 ity of any person under the law of any State.”.

16 (b) EFFECTIVE DATE; APPLICABILITY.—The amend-
17 ment made by subsection (a) shall—

18 (1) take effect as if included in the enactment
19 of the Medical Device Amendments of 1976 (Public
20 Law 94–295); and

21 (2) apply to any civil action pending or filed on
22 or after the date of enactment of this Act.

23 **SEC. 6. CLARITY IN DRUG LABELING.**

24 (a) IN GENERAL.—Not later than 1 year after the
25 date of the enactment of this Act, the Secretary of Health

1 and Human Services (in this section referred to as the
2 “Secretary”), acting through the Commissioner of Food
3 and Drugs, shall—

4 (1) complete a review of the Food and Drug
5 Administration’s regulations and guidance per-
6 taining to the labeling of drugs and biological prod-
7 ucts; and

8 (2) revise such regulations and guidance as ap-
9 propriate to improve the clarity and readability of
10 such labeling.

11 (b) APPLICABILITY.—

12 (1) NEW PRODUCTS.—With respect to the label-
13 ing of any drug or biological product that is ap-
14 proved or licensed under section 505 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
16 section 351 of the Public Health Service Act (42
17 U.S.C. 262) on or after the day that is 1 year after
18 the date of the enactment of this Act, the revised
19 regulations and guidance under subsection (a)(2)
20 shall apply as of the date of such approval or licen-
21 sure.

22 (2) EXISTING PRODUCTS.—With respect to any
23 drug or biological product that was so approved or
24 licensed before such day, the revised regulations and

1 guidance under subsection (a)(2) shall apply as soon
2 as the Secretary determines practicable.

3 **SEC. 7. DISCLOSURE OF CLINICAL TRIAL ADVERSE EVENTS**
4 **ON FDA WEB SITE.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services, acting through the Commissioner of
7 Food and Drugs, shall make all clinical trial adverse
8 events included in the registry and results data bank of
9 the National Institutes of Health publicly available on the
10 Web site of the Food and Drug Administration.

11 (b) DEFINITION.—In this section, the term “registry
12 and results data bank” has the meaning given to such
13 term in section 402(j)(3)(B)(i) of the Public Health Serv-
14 ice Act (42 U.S.C. 282(j)(3)(B)(i)).

15 **SEC. 8. PROHIBITION AGAINST PARTICIPATION BY ADVI-**
16 **SORY COMMITTEE MEMBERS WITH CON-**
17 **FLICTS OF INTEREST.**

18 Section 712 of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 379d–1) is amended—

20 (1) in paragraph (2) of subsection (b), by strik-
21 ing “, so as to reduce” and all that follows through
22 the end of the paragraph and inserting a period;

23 (2) in subsection (c)—

1 (A) by amending the subsection heading to
2 read as follows: “PROHIBITION; INAPPLICA-
3 BILITY OF WAIVERS”;

4 (B) in subparagraph (A) of paragraph (2),
5 by striking “Except as provided under subpara-
6 graph (B), a member” and inserting “A mem-
7 ber”;

8 (C) by striking subparagraphs (B) and (C)
9 of paragraph (2) and inserting the following:

10 “(B) INAPPLICABILITY OF WAIVERS.—A
11 member of an advisory committee under this
12 Act may not, with respect to service on such
13 committee, be granted a written determination
14 as referred to in section 208(b)(1) of title 18,
15 United States Code, or a written certification as
16 referred to in section 208(b)(3) of title 18,
17 United States Code.”; and

18 (D) by striking paragraph (3);

19 (3) in subsection (e)—

20 (A) in paragraph (1), by inserting “and”
21 at the end;

22 (B) by striking paragraphs (2) and (3);
23 and

24 (C) by redesignating paragraph (4) as
25 paragraph (2); and

1 (4) by striking subsection (f).

2 **SEC. 9. FEES RELATING TO ADVERTISEMENTS FOR DRUGS**
3 **AND DEVICES.**

4 Part 2 of subchapter C of chapter VII (21 U.S.C.
5 379g et seq.) is amended by inserting after section 736A
6 the following:

7 **“SEC. 736A-1. FEES RELATING TO ADVERTISEMENTS FOR**
8 **DRUGS AND DEVICES.**

9 “(a) IN GENERAL.—Beginning with respect to fiscal
10 year 2011, each person intending to publish or dissemi-
11 nate an advertisement for a drug or device during a fiscal
12 year shall, prior to the advertisement’s initial publication
13 or dissemination during such fiscal year, pay a fee to the
14 Secretary in the amount established under subsection (b).

15 “(b) FEE AMOUNTS.—

16 “(1) TOTAL REVENUE AMOUNTS.—For each of
17 fiscal years 2011 through 2015, the Secretary shall
18 establish fees under subsection (a) to generate a
19 total revenue amount equal to \$4,000,000, except
20 that such amount shall be adjusted for each of fiscal
21 years 2012 through 2015 to reflect inflation.

22 “(2) FEE SETTING.—The Secretary shall—

23 “(A) set the amount of fees to be assessed
24 and collected under this section before the start
25 of the relevant fiscal year;

1 “(B) make such fees payable with respect
2 to each distinct advertisement for a drug or de-
3 vice to be published or disseminated during the
4 fiscal year; and

5 “(C) set the amount of such fees without
6 regard to the number of times on which the ad-
7 vertisement is so published or disseminated.

8 “(3) LIMIT.—Notwithstanding paragraph (1),
9 the fees under this section shall be retained in each
10 fiscal year in an amount not to exceed the total costs
11 for such fiscal year for the regulation of advertise-
12 ments for drugs and devices.

13 “(c) DEFINITION.—In this section:

14 “(1) The term ‘advertisement’ shall be defined
15 by the Secretary.

16 “(2) The term ‘regulation of advertisements for
17 drugs and devices’—

18 “(A) means any regulation of advertise-
19 ments for drugs and devices by the Food and
20 Drug Administration under this Act; and

21 “(B) notwithstanding subparagraph (A),
22 excludes activities for which fees are assessed
23 and collected under section 736A (relating to
24 the process for the advisory review of prescrip-
25 tion drug advertising).

1 “(d) COLLECTIONS AND APPROPRIATION ACTS.—

2 “(1) IN GENERAL.—The fees authorized by this
3 section—

4 “(A) notwithstanding subsection (b)(1),
5 shall be retained in each fiscal year in an
6 amount not to exceed the amount specified in
7 appropriation Acts, or otherwise made available
8 for obligation, for such fiscal year; and

9 “(B) shall only be collected and available
10 to defray the costs for such fiscal year for the
11 regulation of advertisements of drugs and de-
12 vices.

13 “(2) AUTHORIZATION OF APPROPRIATIONS.—
14 For each of fiscal years 2011 through 2015, there
15 is authorized to be appropriated for the assessment,
16 collection, and use of fees under this section an
17 amount equal to the total revenue amount deter-
18 mined under subsection (b) for the fiscal year.”.

19 **SEC. 10. CERTAIN USES OF APPROVED DRUGS.**

20 Chapter X of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 391 et seq.) is amended by adding at the
22 end the following:

1 **“SEC. 1011. 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.”.

○