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111TH CONGRESS
2D 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. HINCHEY introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Improvement Act of 2010''.

SEC. 2. FEES PAID BY MANUFACTURERS TO FOOD AND DRUG ADMINISTRATION; DEPOSIT IN GENERAL FUND OF TREASURY; DIRECT SPENDING.

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

''PART 6—MODIFICATIONS REGARDING USER-FEE PROGRAMS

''SEC. 743. DEPOSIT OF FEES IN GENERAL FUND OF TREASURY; DIRECT SPENDING.

''(a) DEPOSIT IN GENERAL FUND.—Notwithstanding any other provision of this Act related to the collection of fees related to drugs, devices, animal drugs, or generic animal drugs, all such fees collected under this Act shall be deposited in the general fund of the Treasury.

''(b) DIRECT SPENDING.—

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

fees, amounts are available to the Secretary for obligation in accordance with the following:

"(A) The amount authorized to be appropriated under section 736 for fees related to drugs is, to the extent described in section 736(g)(2)(A)(ii) (as in effect on September 30, 2010), available to the Secretary for obligation solely for the process for the review of human drug applications (within the meaning given to such term in section 735, as in effect on September 30, 2010).

"(B) The amount authorized to be appropriated under section 736A for fees relating to advisory review of prescription-drug television advertising is, to the extent described in section 736A(g)(2)(A)(ii) (as in effect on September 30, 2010), available to the Secretary for obligation solely for the process for the advisory review of prescription drug advertising (within the meaning given to such terms in section 736A, as in effect on September 30, 2010).

"(C) The amount authorized to be appropriated under section 736A–1 for fees relating to the regulation of advertisements for drugs

and devices is available to the Secretary for obligation solely for such regulation.

''(D) The amount authorized to be appropriated under this Act for fees related to devices is, to the extent described in section 738(h)(2)(A)(ii) (as in effect on September 30, 2010), available to the Secretary for obligation solely for the process for the review of device applications (within the meaning given to such terms in section 737, as in effect on September 30, 2010).

''(E) The amount authorized to be appropriated under this Act for fees related to animal drugs is, to the extent described in section 740(g)(2)(A)(ii) (as in effect on September 30, 2010), available to the Secretary for obligation solely for the process for the review of animal drug applications (within the meaning given to such terms in section 739, as in effect on September 30, 2010).

''(F) The amount authorized to be appropriated under this Act for fees related to generic new animal drugs is, to the extent described in section 741(g)(2)(A)(ii) (as in effect on September 30, 2010), available to the Sec-

retary for obligation solely for the process for the review of abbreviated applications for generic new animal drugs (within the meanings given to such terms in section 741, as in effect on September 30, 2010).

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

''SEC. 744. TERMINATION OF AUTHORITY FOR NEGOTIATIONS WITH MANUFACTURERS ON USE OF FEES.

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

''(1) On and after the date of the enactment of the Food and Drug Administration Improvement Act of 2010:

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

ities, performance goals, or other commitments relating to—

"(i) review times for human drug applications or supplements (within the meaning given to such terms in section 735, as in effect on September 30, 2010);

"(ii) review times for providing advisory comments on direct-to-consumer television advertisements (within the meaning given to such terms in section 736A, as in effect on September 30, 2010);

"(iii) review times for premarket applications, premarket reports, premarket notification submissions, or supplements (within the meaning given to such terms in section 737, as in effect on September 30, 2010);

"(iv) review times for animal drug applications or supplements (within the meaning given to such terms in section 739, as in effect on September 30, 2010); or

"(v) review times for abbreviated applications for a generic new animal drug or supplements thereto (within the meaning

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

''(B) The Secretary may not otherwise negotiate understandings with such persons on particular uses of the fees.

''(2) On and after October 1, 2010:

''(A) Any such agreement or understanding that was in effect on the day before the date of the Food and Drug Administration Improvement Act of 2010 is terminated, including agreements or understandings pursuant to letters referred to in section 502(4) of Public Law 107–188 (116 Stat. 688), section 101(3) of Public Law 107–250 (116 Stat. 1589), section 2(3) of Public Law 108–130 (117 Stat. 1361), and section 101(c) of Public Law 110–85 (121 Stat. 823).

''(B) The Secretary is relieved of responsibility for meeting any particular goals concerning such review times that were established in such letters.

''(b) RULES OF CONSTRUCTION.—Subsection (a) may not be construed—

''(1) as affecting the responsibility of the Secretary to work toward the general goal of admin-

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

''(2) as terminating requirements for the collection of fees under any other provision of this Act.''.

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

(c) MANAGEMENT STRATEGY TO ENSURE THE TIMELY REVIEW OF APPLICATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall submit to the Committees on Appropriations and Energy and Commerce of the House of Representatives and the Committees on Appropriations and Health, Education, Labor, and Pensions of the Senate a comprehensive review of the drug and device application and amendment process to identify ways to increase efficiency, reduce paperwork, speed analysis, and promote the quickest possible decision process designed to ensure the entry of safe, effective drugs and devices into the marketplace.

(2) CONSIDERATIONS.—In carrying out the review under paragraph (1), the Secretary shall consider a time-and-motion study to identify best practices in processing applications and ensure the consideration of safety issues.

(3) STAFF-TO-APPLICATION RATIO.—In carrying out the review under paragraph (1), not later than 180 days after the date of enactment of this Act, the Secretary shall submit to the committees referred to in such paragraph recommendations on an ideal staff-to-application ratio to address safety issues without slowing the decision process.

SEC. 3. ESTABLISHMENT OF CENTER FOR POSTMARKET DRUG, DEVICE, AND BIOLOGIC SAFETY AND EFFECTIVENESS.

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

"SEC. 505E. CENTER FOR POSTMARKET DRUG, DEVICE, AND BIOLOGIC SAFETY AND EFFECTIVENESS.

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

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

''(b) DUTIES.—

''(1) IN GENERAL.—Subject to paragraph (2), the Director of the Center shall have the principal responsibility within the Food and Drug Administration, below the Office of the Commissioner of Food and Drugs, for assisting the Commissioner in regulating approved drugs and devices. Such assistance includes the following:

''(A) Monitoring approved drugs to determine whether there are any issues regarding safety or effectiveness.

''(B) Administering section 502 (relating to misbranding).

''(C) Establishing and administering requirements for advertising under section 502(n) or 503(b).

"(D) Administering requirements for studies and clinical trials that were required as conditions for the approval of applications under section 505.

"(E) Withdrawing the approval of drugs under section 505(e).

"(F) Administering section 505(l)(2) (relating to action packages for approval).

"(G) Establishing and administering requirements for modifications in labeling under section 505(o)(4).

"(H) Administering authorities under sections 505(p) and 505–1 (relating to risk evaluation and mitigation strategies).

"(I) Administering section 505(r) (relating to postmarket drug safety information for patients and providers).

"(2) EXCLUSION.—The responsibility vested in the Director of the Center does not include review of any request for approval, licensure, or clearance of a new active ingredient, new indication, new dosage form, new dosing regimen, new route of administration, or any other new characteristic with respect to a previously approved, licensed, or cleared drug, biological product, or device.

''(3) TRANSFERS.—Not later than 1 year after the date of the enactment of this section, the Secretary shall transfer to the Center all responsibilities for the matters referred to in paragraph (1) that, on the day before the date of such transfer, were vested in the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, or the Center for Devices and Radiological Health Organization.

''(c) INTERACTIONS WITH OTHER CENTERS.—

''(1) CONSULTATION.—The Director of the Center shall carry out this section in consultation with the Directors of the Centers referred to in subsection (b)(3).

''(2) ACCESS TO INFORMATION.—The Secretary shall ensure that the Director of the Center has full access to all information possessed by the Food and Drug Administration that relates to the safety and effectiveness of approved drugs and devices, including information possessed by the Centers referred to in subsection (b)(3).

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

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

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

''(1) For fiscal year 2011, $150,000,000.

''(2) For fiscal year 2012, $175,000,000.

''(3) For fiscal year 2013, $200,000,000.

''(4) For fiscal year 2014, $225,000,000.

''(5) For fiscal year 2015, $250,000,000.''.

SEC. 4. STATEMENT FOR INCLUSION IN DIRECT-TO-CONSUMER ADVERTISEMENTS OF DRUGS.

(a) IN GENERAL.—Paragraph (3) of section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by striking ''published direct-to-consumer advertisements'' and inserting ''published or televised direct-to-consumer advertisements''.

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

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

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

SEC. 5. LIABILITY UNDER STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES.

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

''(e) NO EFFECT ON LIABILITY UNDER STATE LAW.—Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.''.

(b) EFFECTIVE DATE; APPLICABILITY.—The amendment made by subsection (a) shall—

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

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

SEC. 6. CLARITY IN DRUG LABELING.

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

and Human Services (in this section referred to as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall—

(1) complete a review of the Food and Drug Administration's regulations and guidance pertaining to the labeling of drugs and biological products; and

(2) revise such regulations and guidance as appropriate to improve the clarity and readability of such labeling.

(b) APPLICABILITY.—

(1) NEW PRODUCTS.—With respect to the labeling of any drug or biological product that is approved or licensed under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the day that is 1 year after the date of the enactment of this Act, the revised regulations and guidance under subsection (a)(2) shall apply as of the date of such approval or licensure.

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

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

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

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

(b) DEFINITION.—In this section, the term ''registry and results data bank'' has the meaning given to such term in section 402(j)(3)(B)(i) of the Public Health Service Act (42 U.S.C. 282(j)(3)(B)(i)).

SEC. 8. PROHIBITION AGAINST PARTICIPATION BY ADVISORY COMMITTEE MEMBERS WITH CONFLICTS OF INTEREST.

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

(1) in paragraph (2) of subsection (b), by striking '', so as to reduce'' and all that follows through the end of the paragraph and inserting a period;

(2) in subsection (c)—

(A) by amending the subsection heading to read as follows: ''PROHIBITION; INAPPLICABILITY OF WAIVERS'';

(B) in subparagraph (A) of paragraph (2), by striking ''Except as provided under subparagraph (B), a member'' and inserting ''A member'';

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

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

(D) by striking paragraph (3);

(3) in subsection (e)—

(A) in paragraph (1), by inserting ''and'' at the end;

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

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

(4) by striking subsection (f).

SEC. 9. FEES RELATING TO ADVERTISEMENTS FOR DRUGS AND DEVICES.

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

"SEC. 736A–1. FEES RELATING TO ADVERTISEMENTS FOR DRUGS AND DEVICES.

''(a) IN GENERAL.—Beginning with respect to fiscal year 2011, each person intending to publish or disseminate an advertisement for a drug or device during a fiscal year shall, prior to the advertisement's initial publication or dissemination during such fiscal year, pay a fee to the Secretary in the amount established under subsection (b).

''(b) FEE AMOUNTS.—

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

''(2) FEE SETTING.—The Secretary shall—

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

''(B) make such fees payable with respect to each distinct advertisement for a drug or device to be published or disseminated during the fiscal year; and

''(C) set the amount of such fees without regard to the number of times on which the advertisement is so published or disseminated.

''(3) LIMIT.—Notwithstanding paragraph (1), the fees under this section shall be retained in each fiscal year in an amount not to exceed the total costs for such fiscal year for the regulation of advertisements for drugs and devices.

''(c) DEFINITION.—In this section:

''(1) The term 'advertisement' shall be defined by the Secretary.

''(2) The term 'regulation of advertisements for drugs and devices'—

''(A) means any regulation of advertisements for drugs and devices by the Food and Drug Administration under this Act; and

''(B) notwithstanding subparagraph (A), excludes activities for which fees are assessed and collected under section 736A (relating to the process for the advisory review of prescription drug advertising).

''(d) COLLECTIONS AND APPROPRIATION ACTS.—

''(1) IN GENERAL.—The fees authorized by this section—

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

''(B) shall only be collected and available to defray the costs for such fiscal year for the regulation of advertisements of drugs and devices.

''(2) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2011 through 2015, there is authorized to be appropriated for the assessment, collection, and use of fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year.''.

SEC. 10. CERTAIN USES OF APPROVED DRUGS.

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

"SEC. 1011. REQUIREMENT REGARDING INFORMED CONSENT FOR CERTAIN TREATMENTS.

"With respect to the prescribing of a drug for a use not included in the approved labeling for the drug under section 505 or under section 351 of the Public Health Service Act, the Secretary shall promulgate regulations requiring that, before prescribing the drug—

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

"(2) the physician obtain from the patient an acknowledgment of such fact and the consent of the patient to use the drug for such use notwithstanding such fact.".

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