INDEX TO THE MEDICAL DEVICE PROVISIONS OF FDAAA

Medical Device User Fee Amendments of 2007

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H. R. 3580

One Hundred Tenth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the fourth day of January, two thousand and seven

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

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 Amendments Act of 2007".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Prescription Drug User Fee Amendments of 2007".

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the matter before paragraph (1), by striking "For purposes of this subchapter" and inserting "For purposes of this part";

(2) in paragraph (1)—

(A) in subparagraph (A), by striking "505(b)(1)," and inserting "505(b), or";

(B) by striking subparagraph (B);

(C) by redesignating subparagraph (C) as subparagraph (B); and

by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. 106. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by sections 102, 103, and 104 cease to be effective October 1, 2012.

(b) REPORTING REQUIREMENTS.—The amendment made by section 105 ceases to be effective January 31, 2013.

SEC. 107. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2007, regardless of the date of the enactment of this Act.

SEC. 108. SAVINGS CLAUSE.

Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 109. TECHNICAL AMENDMENT; CONFORMING AMENDMENT.

(a) Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1) by striking "subchapter" and inserting "part".

(b) Paragraph (11) of section 739 (21 U.S.C. 379j–11) is amended by striking "735(9)" and inserting "735(11)".

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Medical Device User Fee Amendments of 2007".

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy

and Commerce of the House of Representatives, as set forth in the Congressional Record.

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

Section 737 is amended—

(1) in the matter preceding paragraph (1), by striking "For purposes of this subchapter" and inserting "For purposes of this part";

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (8), (9), (10), and (12), respectively;

(3) by inserting after paragraph (4) the following:

"(5) The term '30-day notice' means a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

"(6) The term 'request for classification information' means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

"(7) The term 'annual fee', for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.";

(4) in paragraph (10), as so redesignated—

(A) by striking "April of the preceding fiscal year" and inserting "October of the preceding fiscal year"; and

(B) by striking "April 2002" and inserting "October 2001";

(5) by inserting after paragraph (10), as so amended, the following:

"(11) The term 'person' includes an affiliate thereof."; and

(6) by inserting after paragraph (12), as so redesignated, the following:

"(13) The term 'establishment subject to a registration fee' means an establishment that is required to register with the Secretary under section 510 and is one of the following types of establishments:

"(A) MANUFACTURER.—An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

"(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that, within the meaning of section 201(ll)(2)(A), performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

"(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.".

SEC. 212. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(A) in paragraph (1), by striking "Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002" and inserting "Beginning in fiscal year 2008"; and

(B) by amending the designation and heading of paragraph (2) to read as follows:

"(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—".

(2) FEE AMOUNTS.—Section 738(a)(2)(A) (21 U.S.C. 379j(a)(2)(A)) is amended—

(A) in clause (iii), by striking "a fee equal to the fee that applies" and inserting "a fee equal to 75 percent of the fee that applies";

(B) in clause (iv), by striking "21.5 percent" and inserting "15 percent";

(C) in clause (v), by striking "7.2 percent" and inserting "7 percent";

(D) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(E) by inserting after clause (v) the following:

"(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).";

(F) in clause (viii), as so redesignated—

(i) by striking "1.42 percent" and inserting "1.84 percent"; and

(ii) by striking ", subject to any adjustment under subsection (e)(2)(C)(ii)"; and

(G) by inserting after such clause (viii) the following:

"(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

"(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).".

(3) PAYMENT.—Section 738(a)(2)(C) (21 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

"(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.".

(4) REFUNDS.—Section 738(a)(2)(D) (21 U.S.C. 379j(a)(2)(D)) is amended—

(A) in clause (iii), by striking the last two sentences; and

(B) by adding after clause (iii) the following:

"(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted

under section 515(c)(4) that is withdrawn before a second portion is submitted and before a first action on the first portion.

"(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 515(c)(4) is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

"(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.".

(5) ANNUAL ESTABLISHMENT REGISTRATION FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amended by adding after paragraph (2) the following:

"(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

"(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

"(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.".

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384
Establishment Registration	$1,706	$1,851	$2,008	$2,179	$2,364.".

(c) ANNUAL FEE SETTING.—

(1) IN GENERAL.—Section 738(c) (21 U.S.C. 379j(c)(1)) is amended—

(A) in the subsection heading, by striking "Annual Fee Setting" and inserting "ANNUAL FEE SETTING"; and

(B) in paragraph (1), by striking the last sentence.

(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT FEE.—Section 738(c) (21 U.S.C. 379j(c)), as amended by paragraph (1), is further amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(B) by inserting after paragraph (1) the following:

"(2) ADJUSTMENT.—

"(A) IN GENERAL.—When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

"(B) PUBLICATION.—For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination."; and

(C) in paragraph (4), as redesignated by this paragraph, in subparagraph (A)—

(i) by striking "For fiscal years 2006 and 2007, the Secretary" and inserting "The Secretary"; and

(ii) by striking "for the first month of fiscal year 2008" and inserting "for the first month of the next fiscal year".

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 738(d)(1) (21 U.S.C. 379j(d)(1)) is amended—

(A) by striking ", partners, and parent firms"; and

(B) by striking "clauses (i) through (vi) of subsection (a)(2)(A)" and inserting "clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)".

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—Section 738(d)(2)(A) (21 U.S.C. 379j(d)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates."; and

(v) by adding at the end the following:

"(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.".

(3) REDUCED FEES.—Section 738(d)(2)(C) (21 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

"(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

"(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or periodic reporting concerning a class III device; and

"(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.".

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—Section 738(e)(1) (21 U.S.C. 379j(e)(1)) is amended—

(A) by striking "2004" and inserting "2008"; and

(B) by striking "(a)(2)(A)(vii)" and inserting "(a)(2)(A)(viii)".

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A) (21 U.S.C. 379j(e)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(B)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates."; and

(v) by adding at the end the following:

"(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.".

(3) REDUCED FEES.—Section 738(e)(2)(C) (21 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

"(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).".

(f) EFFECT OF FAILURE TO PAY FEES.—Section 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

"(f) EFFECT OF FAILURE TO PAY FEES.—

"(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

"(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.".

(g) CONDITIONS.—Section 738(g) (21 U.S.C. 379j(g)) is amended—

(1) by striking paragraph (1) and inserting the following:

"(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

"(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

"(B) fees were not assessed under subsection (a) for the previous fiscal year."; and

(2) by amending paragraph (2) to read as follows:

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.".

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(3) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $48,431,000 for fiscal year 2008;

"(B) $52,547,000 for fiscal year 2009;

"(C) $57,014,000 for fiscal year 2010;

"(D) $61,860,000 for fiscal year 2011; and

"(E) $67,118,000 for fiscal year 2012.".

(2) OFFSET.—Section 738(h)(4) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.".

SEC. 213. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 3 of subchapter C of chapter VII is amended by inserting after section 738 the following:

"SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) REPORTS.—

"(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

"(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

"(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

"(b) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization;

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. 214. SAVINGS CLAUSE.

Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and notwithstanding the amendments made by this subtitle, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS FOR POSTMARKET SAFETY INFORMATION.

For the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices, there are authorized to be appropriated to the Food and Drug Administration, in addition to the amounts authorized by other provisions of law for such purpose—

(1) $7,100,000 for fiscal year 2008;
(2) $7,455,000 for fiscal year 2009;
(3) $7,827,750 for fiscal year 2010;
(4) $8,219,138 for fiscal year 2011; and
(5) $8,630,094 for fiscal year 2012.

SEC. 216. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.

SEC. 217. SUNSET CLAUSE.

The amendments made by this subtitle cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act (regarding annual performance and financial reports) ceases to be effective January 31, 2013.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 221. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking "2007" and inserting "2012".

SEC. 222. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 360(b)) is amended—

(1) by striking "(b) On or before" and inserting "(b)(1) On or before";

(2) by striking "or a device or devices"; and

(3) by adding at the end the following:

"(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.".

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by striking "On or before December 31" and all that follows and inserting the following: "Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

"(A) upon first engaging in any such activity, immediately register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

"(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

"(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

"(ii) with respect to devices, register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.".

SEC. 223. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.

Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended, in the matter preceding subparagraph (A), by striking "Each person" and all that follows through "the following information:" and inserting "Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:".

SEC. 224. ELECTRONIC REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended to read as follows:

"(p) Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.".

SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) CONSIDERATION.—In determining the effectiveness of the premarket notification and classification authority under section 510(k) and subsections (f) and (i) of section 513 of the Federal Food, Drug, and Cosmetic Act, the study under subsection (a) shall consider the Secretary of Health and Human Services's evaluation of the respective intended uses and technologies of such devices, including the effectiveness of such Secretary's comparative assessment of technological characteristics such as device materials, principles of operations, and power sources.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.

(a) IN GENERAL.—Section 519 (21 U.S.C. 360i) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e) the following:

"Unique Device Identification System

"(f) The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.".

(b) CONFORMING AMENDMENT.—Section 303 (21 U.S.C. 333) is amended—

(1) by redesignating the subsection that follows subsection (e) as subsection (f); and

(2) in paragraph (1)(B)(ii) of subsection (f), as so redesignated, by striking "519(f)" and inserting "519(g)".

SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DEVICES.

Subparagraph (B) of section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended by striking "were to recur;" and inserting the following: "were to recur, which report under this subparagraph—

"(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

"(I) a class III device;

"(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

"(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer

or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

"(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

"(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)".

SEC. 228. INSPECTIONS BY ACCREDITED PERSONS.

Section 704(g) (21 U.S.C. 374(g)) is amended—

(1) in paragraph (1), by striking "Not later than one year after the date of the enactment of this subsection, the Secretary" and inserting "The Secretary";

(2) in paragraph (2), by—

(A) striking "Not later than 180 days after the date of enactment of this subsection, the Secretary" and inserting "The Secretary"; and

(B) striking the fifth sentence;

(3) in paragraph (3), by adding at the end the following:

"(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

"(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).";

(4) by amending paragraph (6) to read as follows:

"(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

"(i) The Secretary classified the results of the most recent inspection of the establishment as 'no action indicated' or 'voluntary action indicated'.

"(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

"(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

"(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

"(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

"(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

"(aa) at least 1 of such devices is marketed in the United States; and

"(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

"(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

"(I) denies clearance to participate as provided under subparagraph (C); or

"(II) makes a request under clause (ii).

"(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

"(I) compliance data for the establishment in accordance with clause (iii)(I); or

"(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

"(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

"(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

"(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues

a response that denies clearance to participate as provided under subparagraph (C).

"(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

"(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

"(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

"(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

"(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.";

(5) in paragraph (7)—

(A) in subparagraph (A), by striking "(A) Persons" and all that follows through the end and inserting the following: "(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary."; and

(B) by adding at the end the following:

"(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods."; and

(6) in paragraph (10)(C)(iii), by striking "based" and inserting "base".

SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING TO MEDICAL DEVICES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(1) the number of nosocomial infections attributable to new and reused medical devices; and

(2) the causes of such nosocomial infections, including the following:

(A) Reprocessed single-use devices.

(B) Handling of sterilized medical devices.

(C) In-hospital sterilization of medical devices.

(D) Health care professionals' practices for patient examination and treatment.

(E) Hospital-based policies and procedures for infection control and prevention.

(F) Hospital-based practices for handling of medical waste.

(G) Other causes.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

(c) DEFINITION.—In this section, the term "nosocomial infection" means an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital.

SEC. 230. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, "Ultraviolet radiation can cause skin cancer", or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing to determine consumer understanding of label warnings.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

SEC. 301. SHORT TITLE.

This title may be cited as the "Pediatric Medical Device Safety and Improvement Act of 2007".

SEC. 302. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

"SEC. 515A. PEDIATRIC USES OF DEVICES.

"(a) NEW DEVICES.—

"(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

"(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

"(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

"(B) the number of affected pediatric patients.

"(3) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

"(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

"(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

"(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

"(D) the review time for each device described in subparagraphs (A), (B), and (C).

"(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

"(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

"(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

"(c) PEDIATRIC SUBPOPULATION.—For purposes of this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).".

SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (3), by striking "No" and inserting "Except as provided in paragraph (6), no";

(2) in paragraph (5)—

(A) by inserting ", if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met," after "public health"; and

(B) by adding at the end the following: "If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing."; and

(3) by striking paragraph (6) and inserting after paragraph (5) the following new paragraphs:

"(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

"(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

"(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of the enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

"(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall

be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

"(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

"(iv) The request for such exemption is submitted on or before October 1, 2012.

"(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

"(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

"(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

"(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

"(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

"(I) Neonates.

"(II) Infants.

"(III) Children.

"(IV) Adolescents.

"(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

"(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee

of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.".

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 360e) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of purchasing pediatric devices, based on a representative sampling of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption;

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

(10) an evaluation of the demonstration grants described in section 305, which shall include an evaluation of the number of pediatric medical devices—

(A) that have been or are being studied in children; and

(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as amended by this Act) and any regulatory actions taken.

(c) GUIDANCE.—Not later than 180 days after the date of the enactment of this Act, the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian

device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.

(a) CONTACT POINT FOR AVAILABLE FUNDING.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking "and" after the semicolon at the end;

(2) in paragraph (22), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (22) the following:

"(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.".

(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Secretary of Health and Human Services shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.

(2) CONTENTS.—The plan under paragraph (1) shall include—

(A) the current status of federally funded pediatric medical device research;

(B) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(C) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects; and

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2008 through 2012.

SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting ", including increasing pediatric access to medical devices" after "pediatric issues".

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "and 505B" and inserting "505B, 510(k), 515, and 520(m)";

(ii) by striking subparagraph (B) and inserting the following:

"(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;"; and

(iii) in subparagraph (C), by inserting "(including drugs and biological products) and medical devices" after "therapeutics".

SEC. 307. POSTMARKET SURVEILLANCE.

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) by amending the section heading and designation to read as follows:

"SEC. 522. POSTMARKET SURVEILLANCE.";

(2) by striking subsection (a) and inserting the following:

"(a) POSTMARKET SURVEILLANCE.—

"(1) IN GENERAL.—

"(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

"(i) the failure of which would be reasonably likely to have serious adverse health consequences;

"(ii) that is expected to have significant use in pediatric populations; or

"(iii) that is intended to be—

"(I) implanted in the human body for more than 1 year; or

"(II) a life-sustaining or life-supporting device used outside a device user facility.

"(B) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

"(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act."; and

(3) in subsection (b)—

(A) by striking "(b) SURVEILLANCE APPROVAL.—Each" and inserting the following:

"(b) SURVEILLANCE APPROVAL.—

"(1) IN GENERAL.—Each";

(B) by striking "The Secretary, in consultation" and inserting "Except as provided in paragraph (2), the Secretary, in consultation";

(C) by striking "Any determination" and inserting "Except as provided in paragraph (2), any determination"; and

(D) by adding at the end the following:

"(2) LONGER SURVEILLANCE FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

"(c) DISPUTE RESOLUTION.—A manufacturer may request review under section 562 of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket surveillance order or condition shall not, because of noncompliance with such order or condition, be deemed in violation of section 301(q)(1)(C), adulterated under section 501(f)(1), misbranded under section 502(t)(3), or in violation of, as applicable, section 510(k) or section 515, unless deemed necessary to protect the public health.".

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

SEC. 401. SHORT TITLE.

This title may be cited as the "Pediatric Research Equity Act of 2007".

SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.

(a) IN GENERAL.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate

after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

"(4) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 365 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(c) PRIORITY REVIEW USER FEE.—

"(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

"(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

"(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351 of the Public Health Services Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

"(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.".

SEC. 1103. IMPROVING GENETIC TEST SAFETY AND QUALITY.

(a) REPORT.—If the Secretary's Advisory Committee on Genetics, Health, and Society does not complete and submit the Regulatory Oversight of Genetic/Genomic Testing Report & Action Recommendations to the Secretary of Health and Human Services (referred to in this section as the "Secretary") by July of 2008, the Secretary shall enter into a contract with the Institute of

Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetics, Health, and Society and other groups and shall be completed not later than 1 year after the date on which the Secretary entered into such contract.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring Federal efforts with respect to regulatory oversight of genetic tests to cease or be limited or delayed pending completion of the report by the Secretary's Advisory Committee on Genetics, Health, and Society or the Institute of Medicine.

SEC. 1104. NIH TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 319C–2(j)(3)(B), by striking "section 319C–1(h)" and inserting "section 319C–1(i)";

(2) in section 402(b)(4), by inserting "minority and other" after "reducing";

(3) in section 403(a)(4)(C)(iv)(III), by inserting "and postdoctoral training funded through research grants" before the semicolon;

(4) by designating the second section 403C (relating to the drug diethylstilbestrol) as section 403D; and

(5) in section 403C(a)—

(A) in the matter preceding paragraph (1)—

(i) by inserting "graduate students supported by the National Institutes of Health" after "with respect to"; and

(ii) by deleting "each degree-granting program";

(B) in paragraph (1), by inserting "such" after "percentage of"; and

(C) in paragraph (2), by inserting "(not including any leaves of absence)" after "average time".

SEC. 1105. SEVERABILITY CLAUSE.

If any provision of this Act, an amendment made this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.

Subtitle B—Antibiotic Access and Innovation

SEC. 1111. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS.

(a) DEFINITION.—In this section, the term "clinically susceptible concentrations" means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), through the Commissioner of Food and Drugs, shall identify (where such