AMENDMENT NO._____ Calendar No._____

Purpose: To provide a complete substitute.

**IN THE SENATE OF THE UNITED STATES—110th Cong., 1st Sess.**

# S. 1082

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. KENNEDY (for himself and Mr. ENZI)

Viz:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Food and Drug Administration Revitalization Act''.

# TITLE I—PRESCRIPTION DRUG USER FEES

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

(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, whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

**SEC. 102. DRUG FEES.**

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

(1) by striking the section designation and all that follows through ''For purposes of this subchapter:'' and inserting the following:

**''SEC. 735. DRUG FEES.**

''(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety, as set forth in the goals identified for purposes of this subchapter in the letters from the Secretary 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.

''(b) 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 subsection (a) 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 human drug applications and supplements 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 sub-

mit 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 website of the Food and Drug Administration.

''(c) 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 human drug 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) 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.

"(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), 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.

''(d) DEFINITIONS.—For purposes of this part:'';

(2) in subsection (d)—

(A) in paragraph (1)—

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

(ii) by striking subparagraph (B);

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

(iv) in the matter following subparagraph (B), as so redesignated, by striking ''subparagraph (C)'' and inserting ''subparagraph (B)'';

(B) in paragraph (3)(C), by—

(i) striking ''the list'' and inserting ''the list (not including the discontinued section of such list)''; and

(ii) striking ''a list'' and inserting ''a list (not including the discontinued section of such a list)'';

(C) in paragraph (4), by inserting before the period at the end the following: ''(such as

capsules, tablets, and lyophilized products before reconstitution)'';

(D) by amending paragraph (6)(F) to read as follows:

''(F) In the case of drugs approved under human drug applications or supplements, postmarket safety activities, including—

''(i) collecting, developing, and reviewing safety information on approved drugs (including adverse event reports);

''(ii) developing and using improved adverse event data collection systems (including information technology systems); and

''(iii) developing and using improved analytical tools to assess potential safety problems (including by accessing external data bases).'';

(E) in paragraph (8)—

(i) by striking ''April of the preceding fiscal year'' and inserting ''October of the preceding fiscal year''; and

(ii) by striking ''April 1997'' and inserting ''October 1996'';

(F) by redesignating paragraph (9) as paragraph (10); and

(G) by inserting after paragraph (8) the following:

''(9) The term 'person' includes an affiliate thereof.''.

**SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking ''2003'' and inserting ''2008'';

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting ''OR WITHDRAWN BEFORE FILING'' after ''REFUND OF FEE IF APPLICATION REFUSED FOR FILING''; and

(ii) by inserting before the period at the end the following: ''or withdrawn without a waiver before filing'';

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

''(E) FEE FOR APPLICATION PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An application or supplement that has been refused for filing or that was withdrawn before filing, if filed under protest or resubmitted, shall be subject to the fee under subparagraph (A) (unless an exception under subparagraph (C) or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D).''; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (C)''; and

(B) by adding at the end the following:

''(C) SPECIAL RULES FOR COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a compounded positron emission tomography drug shall be subject under subparagraph (A) to one-

quarter of an annual establishment fee with respect to each such establishment identified in the application as producing compounded positron emission tomography drugs under the approved application.

''(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

''(I) the person is a not-for-profit medical center that has only 1 establishment for the production of compounded positron emission tomography drugs; and

''(II) at least 95 percent of the total number of doses of each compounded positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.''.

(b) FEE REVENUE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012: $392,783,000, plus an adjustment for workload on $354,893,000 of this amount. Such adjustment shall be made in accordance with the workload adjustment provisions in effect for fiscal year 2007, except that instead of commercial investigational new drug applications submitted to the Secretary, all commercial investigational new drug applications with a submission during the previous 12-month period shall be used in the determination. One-third of the revenue amount shall be derived from application fees, one-third from establishment fees, and one-third from product fees.''.

(c) ADJUSTMENTS TO FEES.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

(A) in the matter preceding subparagraph (A) by striking ''The revenues established in subsection (b)'' and inserting ''Beginning with

fiscal year 2009, the revenues established in subsection (b)'';

(B) in subparagraph (A) by striking ''or'' at the end;

(C) in subparagraph (B) by striking the period at the end and inserting '', or,'';

(D) by inserting after subparagraph (B) the following:

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.''; and

(E) in the matter following subparagraph (C) (as added by this paragraph), by striking ''fiscal year 2003'' and inserting ''fiscal year 2008''.

(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in the matter preceding subparagraph (A,) by striking ''2004'' and inserting ''2009'';

(B) in the first sentence of subparagraph (A)—

(i) by striking ‘‘, commercial investigational new drug applications’’ and inserting ‘‘(adjusted for changes in review activities)’’; and

(ii) by inserting before the period at the end ‘‘, and the change in the number of commercial investigational new drug applications with a submission during the previous 12-month period (adjusted for changes in review activities)’’;

(C) in subparagraph (B), by adding at the end the following new sentence: ‘‘Further, any adjustment for changes in review activities made in setting fees and fee revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would be absent the adjustment for changes in review activities.’’; and

(D) by adding at the end the following:

‘‘(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees for fiscal year 2009 and to make recommendations, if warranted, on future

changes in the methodology for calculating the adjustment for changes in review activity. After review of the recommendations by the independent accounting firm, the Secretary shall make appropriate changes to the workload adjustment methodology in setting fees for fiscal years 2010 through 2012. If the study is not conducted, no adjustment for changes in review activities shall be made after fiscal year 2009.''.

(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

(B) by inserting after paragraph (2) the following:

''(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Beginning in fiscal year 2010, the Secretary shall, before making the adjustments under paragraphs (1) and (2), reduce the fee amounts established in subsection (b), if actual costs paid for rent and rent-related expenses are less than $11,721,000. The reductions made under this paragraph, if any, shall not exceed the amounts by which costs fell

below $11,721,000, and shall not exceed $11,721,000 in any fiscal year.''.

(4) FINAL YEAR ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

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

(i) by striking ''2007'' each place it appears and inserting ''2012''; and

(ii) by striking ''2008'' and inserting ''2013''; and

(B) in paragraph (5), as redesignated by this subsection, by striking ''2002'' and inserting ''2007''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by—

(A) inserting ''to a person who is named as the applicant'' after ''The Secretary shall grant'';

(B) inserting ''to that person'' after ''a waiver from or a reduction of one or more fees assessed''; and

(C) striking ''finds'' and inserting ''determines'';

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

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

''(2) EVALUATION.—For the purpose of determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant and any affiliate of the applicant.''; and

(4) in paragraph (4), as redesignated by this subsection, in subparagraph (A), by inserting before the period at the end '', and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce''.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section such sums as are authorized to be assessed and collected under this section in each of fiscal years 2008 through 2012.''.

(2) OFFSET.—Section 736(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:

''(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, plus the amount estimated to be collected for fiscal year 2011, exceeds the amount of fees specified in aggregate in appropriation Acts for such 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.''.

(f) CONFORMING AMENDMENTS.—

(1) Section 736(a) (21 U.S.C. 379h(a)), as amended by this section, is amended—

(A) in paragraph (1)(A), by striking ''subsection (c)(4)'' each place it appears and inserting ''subsection (c)(5)'';

(B) in paragraph (2), by striking ''subsection (c)(4)'' and inserting ''subsection (c)(5)''; and

(C) in paragraph (3), by striking ''subsection (c)(4)'' and inserting ''subsection (c)(5)''.

(2) Section 736A(h)(3), as added by section 104 of this title, is amended by striking ''735(3)'' and inserting ''735(d)(3)''.

**SEC. 104. AUTHORITY TO ASSESS AND USE PRESCRIPTION DRUG ADVERTISING FEES.**

Chapter VII, subchapter C, part 2 (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following new section:

**''SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE ADVISORY REVIEW OF PRESCRIPTION DRUG ADVERTISING.**

''(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENT REVIEW FEES.—Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ADVISORY REVIEW FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each person that on or after October 1, 2007, submits a proposed direct-to-consumer television advertisement for advisory review by the Secretary prior to its initial public

dissemination shall be subject to a fee established under subsection (c)(3).

''(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A direct-to-consumer television advertisement that is required to be submitted to the Secretary prior to initial public dissemination shall not be assessed a fee unless the sponsor designates it as a submission for advisory review.

''(C) PAYMENT.—The fee required by subparagraph (A) shall be due no later than October 1 of the fiscal year in which the direct-to-consumer television advertisement shall be submitted to the Secretary for advisory review.

''(D) MODIFICATION OF ADVISORY REVIEW FEE.—

''(i) LATE PAYMENT.—If, on or before November 1 of the fiscal year in which the fees are due, a person has not paid all fees that were due and payable for advisory reviews identified in response to the Federal Register notice described in subsection (c)(3)(A), the fees shall be regarded as late. Such fees shall be due and payable 20 days before any direct-to-consumer tele-

vision advertisement is submitted by such person to the Secretary for advisory review. Notwithstanding any other provision of this section, such fees shall be due and payable for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3).

''(ii) LATE NOTICE OF SUBMISSION.—If any person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay a fee for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3). Fees under this subparagraph shall be due 20 days before the direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review.

''(E) LIMITS.—

"(i) IN GENERAL.—The payment of a fee under this paragraph for a fiscal year entitles the person that pays the fee to acceptance for advisory review by the Secretary of 1 direct-to-consumer television advertisement and acceptance of 1 resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over no more than 1 paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

"(ii) NO REFUND.—Except as provided by subsection (f), fees paid under this paragraph shall not be refunded.

"(iii) NO WAIVER, EXEMPTION, OR REDUCTION.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

"(iv) NON-TRANSFERABILITY.—The right to an advisory review is not transferable, except to a successor in interest.

''(2) OPERATING RESERVE FEE.—

''(A) IN GENERAL.—Each person that, on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to an operating reserve fee established under subsection (d)(2) only in the first fiscal year in which an advisory review fee is assessed.

''(B) PAYMENT.—Except as provided in subparagraph (C), the fee required by subparagraph (A) shall be due no later than October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1).

''(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person's participation in the Program, that person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(D)(ii). Fees required by this subparagraph shall be in

addition to the fees required under subparagraph (B), if any. Fees under this subparagraph shall be due 20 days before any direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review.

''(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsection (c).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

''(B) the total percentage change for the previous fiscal year in basic pay under the Gen-

eral Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

''(2) WORKLOAD ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of proposed direct-to-consumer

television advertisements for advisory review prior to initial broadcast.

"(B) DETERMINATION OF WORKLOAD ADJUSTMENT.—

"(i) IN GENERAL.—The workload adjustment under this paragraph for a fiscal year shall be determined by the Secretary—

"(I) based upon the number of direct-to-consumer television advertisements identified pursuant to paragraph (3)(A) for that fiscal year, excluding allowable previously paid carry over submissions; and

"(II) by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)).

"(ii) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register the fee revenues and fees

resulting from the adjustment and the supporting methodologies.

''(C) LIMITATION.—Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

''(3) ANNUAL FEE SETTING.—

''(A) NUMBER OF ADVERTISEMENTS.—The Secretary shall, 120 days before the start of each fiscal year, publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of direct-to-consumer television advertisements the person intends to submit for advisory review by the Secretary in the next fiscal year. Notification to the Secretary of the number of advertisements a person intends to submit for advisory review prior to initial broadcast shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. A person shall at the same time also notify the Secretary if such per-

son intends to use a paid submission from the previous fiscal year under subsection (a)(1)(E)(i). If such person does not so notify the Secretary, all submissions for advisory review shall be subject to advisory review fees.

''(B) ANNUAL FEE.—The Secretary shall, 60 days before the start of each fiscal year, establish, for the next fiscal year, the direct-to-consumer television advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under this subsection and the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions.

''(C) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b), the fee established

under subparagraph (B) for fiscal year 2008 may not be more than $83,000 per submission for advisory review.

''(D) ANNUAL FEE LIMIT.—Notwithstanding subsection (b), the fee established under subparagraph (B) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

''(E) LIMIT.—The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

''(d) OPERATING RESERVES.—

''(1) IN GENERAL.—The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the Program in the event the fees collected in any subsequent fiscal year pursuant to subsection (c)(3) do not generate the fee revenue amount established for that fiscal year.

''(2) FEE SETTING.—The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of direct-to-consumer television advertisements identified by that person pursuant to subsection (c)(3)(A) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year. In no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the Program in fiscal year 2008.

''(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves under this subsection only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsection (b) and the amount of fees collected for that fiscal year pursuant to subsection (a), or to pay costs of ending the Program if it is terminated pursuant to subsection (f) or if it is not reauthorized after fiscal year 2012.

''(4) REFUND OF OPERATING RESERVES.—Within 120 days of the end of fiscal year 2012, or if the Program is terminated pursuant to subsection (f), the Secretary, after setting aside sufficient oper-

ating reserve amounts to terminate the Program, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

''(e) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other law or regulation of the Secretary, a submission for advisory review of a direct-to-consumer television advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

''(f) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

''(1) FIRST FISCAL YEAR.—If on November 1, 2007, or 120 days after enactment of the Prescription Drug User Fee Amendments of 2007, whichever is later, the Secretary has received less than $11,250,000 in advisory review fees and operating reserve fees combined, the Program shall be terminated and all collected fees shall be refunded.

''(2) SUBSEQUENT FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of a fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years is less than $9,000,000, adjusted for inflation (in accordance with subsection (c)(1)), the Program shall be terminated, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the Program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the Program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and then unused advisory review fees from the relevant fiscal year.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and ex-

penses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by this section—

''(A) 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 be available for obligation only if appropriated budget authority continues to support at least the total combined number of full-time equivalent employees in the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, and the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch supported in fiscal year 2007.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section not less than $6,250,000 for each

of fiscal years 2008, 2009, 2010, 2011, and 2012, as adjusted to reflect adjustments in the total fee revenues made under this section, plus amounts collected for the reserve fund under subsection (d).

''(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year 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 collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'advisory review' means reviewing and providing advisory comments regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

''(2) The term 'carry over submission' means a submission for an advisory review for which a fee was paid in a fiscal year that is submitted for review in the following fiscal year.

''(3) The term 'direct-to-consumer television advertisement' means an advertisement for a prescrip-

tion drug product as defined in section 735(3) intended to be displayed on any television channel for less than 2 minutes.

''(4) The term 'person' includes an individual, a partnership, a corporation, and an association, and any affiliate thereof or successor in interest.

''(5) The term 'Program' means the Program to assess, collect, and use fees for the advisory review of prescription drug advertising established by this section.

''(6) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on proposed direct-to-consumer television advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the Program that are not necessary for the advisory review of direct-to-consumer television advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

''(7) The term 'resources allocated for the process for the advisory review of prescription drug advertising' means the expenses incurred in connection

with the process for the advisory review of prescription drug advertising for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

''(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

''(E) terminating the Program under subsection (f)(2), if necessary.

''(8) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been re-

vised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

''(9) The term 'submission for advisory review' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

**''SEC. 736B. SUNSET.**

''This part shall cease to be effective on October 1, 2012, except that subsection (b) of section 736 with respect to reports shall cease to be effective on January 31, 2013.''.

**SEC. 105. 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 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 Administra-

tion for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

**SEC. 106. TECHNICAL AMENDMENT.**

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

**SEC. 107. EFFECTIVE DATES.**

(a) IN GENERAL.—Except as provided in subsection (b), the amendments made by this title shall take effect October 1, 2007.

(b) EXCEPTION.—The amendment made by section 104 of this title shall take effect on the date of enactment of this title.

# TITLE II—DRUG SAFETY

**SEC. 200. SHORT TITLE.**

This title may be cited as the ''Enhancing Drug Safety and Innovation Act of 2007''.

## Subtitle A—Risk Evaluation and Mitigation Strategies

**SEC. 201. RISK EVALUATION.**

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(3) RISK IDENTIFICATION AND ASSESSMENT.—

''(A) ROUTINE ACTIVE SAFETY MONITORING.—The Secretary shall facilitate a public-private partnership to–

''(i) implement a routine active monitoring system for postmarket drug safety; and

''(ii) focus postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with use of a drug.

''(B) PUBLIC-PRIVATE PARTNERSHIP.—The public-private partnership described in subparagraph (A) shall—

''(i) develop a mechanism for the pooling of relevant data from Federal and private electronic health care population databases that—

''(I) includes, in aggregate—

"(aa) at least 25,000,000 patients by January 1, 2009; and

"(bb) at least 100,000,000 patients by January 1, 2012;

"(II) allows access to full-text medical records, where available;

"(III) takes into consideration the need for data completeness, coding, cleansing, and transmission;

"(IV) may, on a temporary or permanent basis, implement systems or products developed by private entities; and

"(V) complies with the requirements of the Health Insurance Portability and Accountability Act of 1996;

"(ii) support the routine and systematic collection and analysis of utilization and safety data from such pooled databases and from the Food and Drug Administration with respect to prescription drugs; and

"(iii) allow for prompt investigation of priority drug safety questions, including—

''(I) unresolved safety questions for drugs or classes of drugs; and

''(II) for a newly-approved drug—

''(aa) safety signals from clinical trials used to approve the drug and other preapproval trials;

''(bb) rare, serious drug side effects; and

''(cc) the safety of use in domestic populations not included in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children).

''(C) OTHER APPROACHES.—

''(i) IN GENERAL.—The Secretary shall develop, support, and participate in other approaches, including in other public-private partnerships, to gather and analyze data and information relevant to priority drug safety questions, including—

''(I) approaches that are complimentary to the routine active safety

monitoring described in subparagraphs (A) and (B), especially with respect to assessing the safety of use of a drug in domestic populations not included in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

''(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

''(ii) BEST PRACTICES.—With respect to such other approaches, the Secretary shall develop and implement best practices in epidemiology and the use of improved analytic tools.

''(D) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

"(i) priority drug safety questions; and

"(ii) mechanisms for answering such questions, including through—

"(I) routine active safety monitoring; and

"(II) when such monitoring is not sufficient, postmarket studies under subsection (o)(4)(B) and post-approval clinical trials under subsection (o)(4)(C).

"(E) ANALYSIS OF DRUG SAFETY DATA.—The Secretary shall engage independent private research groups, including through the Centers for Education and Research on Therapeutics provided for under section 905 of the Public Health Service Act, to conduct analyses of data relating to priority drug safety questions.

"(F) USE OF ANALYSES.—The Secretary shall provide the analyses described under subparagraph (E), including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

"(G) PUBLIC AVAILABILITY OF ANALYSES.—The Secretary shall make the analyses

described under subparagraph (E), including the methods and results of such analyses, available to the public for review and comment.

''(H) QUALIFIED ENTITIES.—

''(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

''(ii) QUALIFICATIONS.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity—

''(I) has the research capability and expertise to conduct and complete the activities under this subsection;

''(II) has in place an information technology infrastructure to support adverse event surveillance data and operational standards to provide security for such data;

''(III) has experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data;

''(IV) has an understanding of drug development and risk/benefit balancing in a clinical setting; and

''(V) has a significant business presence in the United States.

''(I) CONTRACT REQUIREMENTS.—Each contract with a qualified entity shall contain the following requirements:

''(i) ENSURING PRIVACY.—The qualified entity shall provide assurances that the entity will not use the data provided by the Secretary in a manner that violates—

''(I) the Federal regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (concerning the privacy of individually-identifiable beneficiary health information); or

''(II) sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information.

''(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

''(I) the qualified entity shall maintain the data related to the activities carried out under this subsection separate from the other components of the organization and establish appropriate security measures to maintain the confidentiality and privacy of such data; and

''(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

''(iii) TERMINATION OR NONRENEWAL.—If a contract under this subsection is terminated or not renewed, the following requirements shall apply:

''(I) CONFIDENTIALITY AND PRIVACY REGULATIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under

this subsection with respect to all data disclosed to the entity.

''(II) DISPOSITION OF DATA.—The entity shall return to the Secretary all data disclosed to the entity or, if returning the data is not practicable, destroy the data.

''(J) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (C).

''(K) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this subsection in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subsection will continue to be met.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $30,000,000 for each of fiscal years 2008 through 2012.

**SEC. 202. RISK EVALUATION AND MITIGATION STRATEGIES.**

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(o) RISK EVALUATION AND MITIGATION STRATEGY.—

''(1) IN GENERAL.—In the case of any drug subject to subsection (b) or to section 351 of the Public Health Service Act for which a risk evaluation and mitigation strategy is approved as provided for in this subsection, the applicant shall comply with the requirements of such strategy.

''(2) DEFINITIONS.—In this subsection:

''(A) ADVERSE DRUG EXPERIENCE.—The term 'adverse drug experience' means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

''(i) an adverse event occurring in the course of the use of the drug in professional practice;

''(ii) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

''(iii) an adverse event occurring from abuse of the drug;

''(iv) an adverse event occurring from withdrawal of the drug; and

''(v) any failure of expected pharmacological action of the drug.

''(B) NEW SAFETY INFORMATION.—The term 'new safety information' with respect to a drug means information about—

''(i) a serious risk or an unexpected serious risk with use of the drug that the Secretary has become aware of since the later of—

''(I) the date of initial approval of the drug under this section or initial licensure of the drug under section 351 of the Public Health Service Act; or

''(II) if applicable, the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

''(ii) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the later of—

''(I) the approval of such strategy; or

"(II) the last assessment of such strategy.

"(C) SERIOUS ADVERSE DRUG EXPERIENCE.—The term 'serious adverse drug experience' is an adverse drug experience that—

"(i) results in—

"(I) death;

"(II) the placement of the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

"(III) inpatient hospitalization or prolongation of existing hospitalization;

"(IV) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

"(V) a congenital anomaly or birth defect; or

"(ii) based on appropriate medical judgment, may jeopardize the patient and

may require a medical or surgical intervention to prevent an outcome described under clause (i).

''(D) SERIOUS RISK.—The term 'serious risk' means a risk of a serious adverse drug experience.

''(E) SIGNAL OF A SERIOUS RISK.—The term 'signal of a serious risk' means information related to a serious adverse drug experience derived from—

''(i) a clinical trial;

''(ii) adverse event reports under subsection (k)(1);

''(iii) routine active safety monitoring under subsection (k)(3);

''(iv) a postapproval study, including a study under paragraph (4)(B); or

''(v) peer-reviewed biomedical literature.

''(F) UNEXPECTED SERIOUS RISK.—The term 'unexpected serious risk' means a serious adverse drug experience that—

''(i) is not listed in the labeling of a drug; or

''(ii) may be symptomatically and pathophysiologically related to an adverse drug experience listed in the labeling of the drug, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

''(3) REQUIRED ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—If a risk evaluation and mitigation strategy for a drug is required, such strategy shall include—

''(A) the labeling for the drug for use by health care providers as approved under subsection (c);

''(B) a timetable for submission of assessments of the strategy, that—

''(i) for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act—

''(I) shall be no less frequently than 18 months and 3 years after the strategy is initially approved and at a

frequency specified in the strategy for subsequent years; and

''(II) may be eliminated after the first 3 years if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed;

''(ii) for any other drug, shall occur at a frequency determined by the Secretary; and

''(iii) may be increased or reduced in frequency as necessary as provided for in paragraph (7)(B)(iv)(VI).

''(4) ADDITIONAL POTENTIAL EVALUATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) RISK EVALUATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional evaluation elements described in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

''(B) POSTAPPROVAL STUDIES.—If the Secretary determines that the reports under subsection (k)(1) and routine active safety monitoring as available under subsection (k)(3) (including available other approaches under subsection (k)(3)(C)) are not sufficient to—

''(i) assess a signal of a serious risk with use of the drug; or

''(ii) identify unexpected serious risks in a domestic population who use the drug, including a population not included in trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children),

the risk evaluation and mitigation strategy for a drug may require that the applicant conduct an appropriate postapproval study, such as a prospective or retrospective observational study, of the drug (which shall include a timeframe specified by the Secretary for completing the study and reporting the results to the Secretary).

''(C) POSTAPPROVAL CLINICAL TRIALS.—If the Secretary determines that the reports under subsection (k)(1), routine active safety moni-

toring as available under subsection (k)(3) (including available other approaches under subsection (k)(3)(C)), and a study or studies under subparagraph (B) will likely be inadequate to assess a signal of a serious risk with use of the drug, and there is no effective approved application under subsection (j) as of the date that the requirement is first imposed, the risk evaluation and mitigation strategy for a drug may require that the applicant conduct an appropriate post-approval clinical trial of the drug (which shall include a timeframe specified by the Secretary for completing the clinical trial and reporting the results to the Secretary) to be included in the clinical trial registry data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act.

''(5) ADDITIONAL POTENTIAL COMMUNICATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) RISK COMMUNICATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional communication elements described in this paragraph, so long as the Sec-

retary makes the determination required with respect to each additional included element.

''(B) MEDGUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that the applicant develop for distribution to each patient when the drug is dispensed either or both of the following:

''(i) A Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations).

''(ii) A patient package insert, if the Secretary determines that such insert may help mitigate a serious risk listed in the labeling of the drug.

''(C) COMMUNICATION PLAN.—If the Secretary determines that a communication plan to health care providers may support implementation of an element of the risk evaluation and mitigation strategy for a drug, such as a labeling change, the strategy may require that the applicant conduct such a plan, which may include—

''(i) sending letters to health care providers;

''(ii) disseminating information about the elements of the strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests); or

''(iii) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use.

''(D) PREREVIEW.—

''(i) IN GENERAL.—If the Secretary determines that prereview of advertisements is necessary to ensure the inclusion of a true statement in such advertisements of information in brief summary relating to a serious risk listed in the labeling of the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant submit to the Secretary advertisements of the drug for prereview not

later than 45 days before dissemination of the advertisement

''(ii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to be submitted under clause (i).

''(E) SPECIFIC DISCLOSURES.—

''(i) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(ii) DATE OF APPROVAL.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and that the existing information may not have identified or allowed for full assessment of all serious risks of using the drug is necessary to pro-

tect public health and safety, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure

"(iii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to include a specific disclosure under clause (i) or (ii).

"(F) TEMPORARY MORATORIUM.—To the extent consistent with the Constitution, if the Secretary determines that disclosure under subparagraph (E)(ii) is inadequate to protect public health and safety, and that a prohibition of direct-to-consumer advertisements of the drug for a fixed period after initial approval of the drug, not to exceed 2 years, is necessary to protect public health and safety while additional information about serious risks of the drug is collected using the reports under subsection (k)(1) and the routine active safety monitoring as available under subsection (k)(3) (including available other approaches under subsection (k)(3)(C)), the risk evaluation and mitigation strategy for the drug may require that the applicant not issue or cause to be issued direct-

to-consumer advertisements of the drug for such fixed period. In making such determination, the Secretary shall consider—

''(i) the number of patients who may be treated with the drug;

''(ii) the seriousness of the condition for which the drug will be used;

''(iii) the serious risks listed in the labeling of the drug;

''(iv) the extent to which patients have access to other approved drugs in the pharmacological class of the drug and with the same intended use as the drug; and

''(v) the extent to which clinical trials used to approve the drug may not have identified serious risks that might occur among patients expected to be treated with the drug.

''(6) RESTRICTIONS ON DISTRIBUTION OR USE FOR DRUGS WITH UNUSUAL, SERIOUS RISKS.—

''(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and 1 or more communication elements under paragraph (5) to mitigate

a serious risk listed in the labeling of the drug, if the Secretary determines that the drug, which has been shown to be effective, can be safely used only if distribution or use of such drug is restricted, the Secretary may require as elements of the risk evaluation and mitigation strategy such restrictions on distribution or use as are needed to assure safe use of the drug.

''(B) LIMITS ON RESTRICTIONS TO ASSURE ACCESS AND MINIMIZE BURDEN.—Such restrictions under subparagraph (A) shall—

''(i) be commensurate with the specific, serious risk presented by the drug;

''(ii) not be unduly burdensome on patient access to the drug, considering in particular—

''(I) patients with serious or life-threatening diseases or conditions; and

''(II) patients (such as patients in rural areas) who have difficulty accessing health care; and

''(iii) to the extent practicable, so as to minimize the burden on the health care delivery system—

''(I) conform with restrictions on distribution or use for other drugs with similar, serious risks; and

''(II) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

''(C) ELEMENTS TO PROTECT PATIENT SAFETY.—The restrictions on distribution or use described under subparagraph (A) shall include 1 or more goals to evaluate or mitigate a serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

''(i) health care providers that prescribe the drug have particular training or experience, or are specially certified;

''(ii) pharmacies, practitioners, or health care settings that dispense the drug are specially certified;

''(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

''(iv) the drug be dispensed to patients with evidence or other documenta-

tion of safe-use conditions, such as laboratory test results;

''(v) each patient using the drug be subject to certain monitoring; or

''(vi) each patient using the drug be enrolled in a registry.

''(D) IMPLEMENTATION SYSTEM.—The restrictions on distribution or use described under subparagraph (A) that employ elements described in clauses (ii), (iii), or (iv) of subparagraph (C) may include a system through which the applicant is able to—

''(i) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

''(ii) work to improve implementation of such elements by such persons.

''(E) EVALUATION OF RESTRICTIONS.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration, shall—

''(i) seek input from patients, physicians, pharmacists, and other health care providers about how restrictions on distribution or use under this paragraph for 1 or more drugs may be standardized so as not to be—

''(I) unduly burdensome on patient access to the drug; and

''(II) to the extent practicable, minimize the burden on the health care delivery system;

''(ii) at least annually, evaluate, for 1 or more drugs, the restrictions on distribution or use of such drug to assess whether the restrictions—

''(I) assure safe use of the drug;

''(II) are not unduly burdensome on patient access to the drug; and

''(III) to the extent practicable, minimize the burden on the health care delivery system; and

''(iii) considering such input and evaluations—

''(I) issue, or modify current, agency guidance about how to imple-

ment the requirements of this paragraph; and

"(II) modify restrictions under this paragraph for 1 or more drugs as appropriate.

"(7) SUBMISSION AND REVIEW OF RISK EVALUATION AND MITIGATION STRATEGY.—

"(A) PROPOSED RISK EVALUATION AND MITIGATION STRATEGY.—

"(i) VOLUNTARY PROPOSAL.—An applicant may include a proposed risk evaluation and mitigation strategy for a drug in an application, including in a supplemental application, under subsection (b) or section 351 of the Public Health Service Act for the drug.

"(ii) REQUIRED PROPOSAL.—The applicant shall submit a proposed risk evaluation and mitigation strategy for a drug—

"(I) within a time specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through the appropriate office responsible for reviewing the drug and

the office responsible for postapproval safety with respect to the drug), if the Secretary determines that new safety information indicates that—

"(aa) the labeling of the drug should be changed; or

"(bb) an element under paragraph (4) or (5) should be included in a strategy for the drug; or

"(II) within 90 days when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety information indicates that an element under paragraph (6) should be included in a strategy for the drug.

"(iii) CONTENT OF ORDER.—An order under subclauses (I) or (II) of clause (ii) shall describe—

"(I) the new safety information with respect to the drug that warrants the proposal of a risk evaluation and mitigation strategy for the drug; and

"(II) whether and how the labeling of the drug should be changed and what elements under paragraphs (4), (5), or (6) should be included in a strategy for the drug.

"(iv) CONTENT OF PROPOSAL.—A proposed risk evaluation and mitigation strategy—

"(I) shall include a timetable as described under paragraph (3)(B); and

"(II) may also include additional elements as provided for under paragraphs (4), (5), and (6).

"(B) ASSESSMENT AND MODIFICATION OF A RISK EVALUATION AND MITIGATION STRATEGY.—

"(i) VOLUNTARY ASSESSMENTS.—If a risk evaluation and mitigation strategy for a drug is required, the applicant may submit to the Secretary an assessment of, and propose a modification to, such approved strategy for the drug at any time.

"(ii) REQUIRED ASSESSMENTS.—If a risk evaluation and mitigation strategy for

a drug is required, the application shall submit an assessment of, and may propose a modification to, such approved strategy for the drug—

"(I) when submitting an application, including a supplemental application, for a new indication under subsection (b) or section 351 of the Public Health Service Act;

"(II) when required by the strategy, as provided for in the timetable under paragraph (3)(B);

"(III) within a time specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through the offices described in subparagraph (A)(ii)(I)), if the Secretary determines that new safety information indicates that an element under paragraph (3) or (4) should be modified or included in the strategy;

"(IV) within 90 days when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety informa-

tion indicates that an element under paragraph (6) should be modified or added; or

''(V) within 15 days when ordered by the Secretary (acting through such offices), if the Secretary determines that there may be a cause for action by the Secretary under subsection (e).

''(iii) CONTENT OF ORDER.—An order under subclauses (III), (IV), or (V) of clause (ii) shall describe—

''(I) the new safety information with respect to the drug that warrants an assessment of the approved risk evaluation and mitigation strategy for the drug; and

''(II) whether and how such strategy should be modified because of such information.

''(iv) ASSESSMENT.—An assessment of the approved risk evaluation and mitigation strategy for a drug shall include—

''(I) a description of new safety information, if any, with respect to the drug;

''(II) whether and how to modify such strategy because of such information;

''(III) with respect to any post-approval study required under paragraph (4)(B) or otherwise undertaken by the applicant to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered; and

''(IV) with respect to any post-approval clinical trial required under paragraph (4)(C) or otherwise undertaken by the applicant to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information

with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act; and

''(V) with respect to any goal under paragraph (6) and considering input and evaluations, if applicable, under paragraph (6)(E), an assessment of how well the restrictions on distribution or use are meeting the goal or whether the goal or such restrictions should be modified.

''(v) MODIFICATION.—A modification (whether an enhancement or a reduction) to the approved risk evaluation and mitigation strategy for a drug may include the addition or modification of any element under subparagraph (A) or (B) of paragraph (3) or the addition, modification, or removal of any element under paragraph (4), (5), or (6), such as—

''(I) a labeling change, including the addition of a boxed warning;

''(II) adding a postapproval study or clinical trial requirement;

''(III) modifying a postapproval study or clinical trial requirement (such as a change in trial design due to legitimate difficulties recruiting participants);

''(IV) adding, modifying, or removing a restriction on advertising under subparagraph (D), (E), or (F) of paragraph (5);

''(V) adding, modifying, or removing a restriction on distribution or use under paragraph (6); or

''(VI) modifying the timetable for assessments of the strategy under paragraph (3)(B), including to eliminate assessments.

''(C) REVIEW.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall promptly review the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B).

''(D) DISCUSSION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall initiate discussions of the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A)(i), or of an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B), with the applicant to determine a strategy—

''(i) if the proposed strategy or assessment is submitted as part of an application (including a supplemental application) under subparagraph (A) or (B)(ii)(I), by the target date for communication of feedback from the review team to the applicant regarding proposed labeling and post-marketing study commitments, as set forth in the letters described in section 735(a);

''(ii) if the proposed strategy is submitted under subparagraph (A)(ii)(I) or the assessment is submitted under subclause (II) or (III) of subparagraph (B)(ii), not later than 20 days after such submission;

"(iii) if the proposed strategy is submitted under subparagraph (A)(ii)(II) or the assessment is submitted under subparagraph (B)(i) or under subparagraph (B)(ii)(IV), not later than 30 days after such submission; or

"(iv) if the assessment is submitted under subparagraph (B)(ii)(V), not later than 10 days after such submission.

"(E) ACTION.—

"(i) IN GENERAL.—Unless the applicant requests the dispute resolution process as described under subparagraph (F) or (G), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall approve and include the risk evaluation and mitigation strategy for a drug, or any modification to the strategy (including a timeframe for implementing such modification) with—

"(I) the action letter on the application, when a proposed strategy is submitted under subparagraph (A)(i) or an assessment of the strategy is

submitted under subparagraph (B)(ii)(I); or

''(II) an order, which shall be made public, issued not later than 50 days after the date discussions of such proposed strategy or modification begin under subparagraph (D), when a proposed strategy is submitted under subparagraph (A)(ii) or an assessment of the strategy is submitted under subparagraph (B)(i) or under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii).

''(ii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under clause (i).

''(F) DISPUTE RESOLUTION AT INITIAL APPROVAL.—When a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A)(i) and there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described in section 735(a).

''(G) DISPUTE RESOLUTION IN ALL OTHER CASES.—

''(i) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) and there is a dispute about the strategy, not earlier than 15 days, and not later than 35 days, after discussions under subparagraph (D) have begun, the applicant shall request in writing that the dispute be reviewed by the Drug Safety Oversight Board.

''(ii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

''(I)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

''(bb) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application);

"(II) shall give advance notice to the public through the Federal Register and on the Internet website of the Food and Drug Administration—

"(aa) that the drug is to be discussed by the Drug Safety Oversight Board; and

"(bb) the date on which the Drug Safety Oversight Board shall discuss such drug; and

"(III) shall apply section 301(j), section 552 of title 5, and section 1905 of title 18, United States Code, to any request for information about such review.

"(iii) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

"(I) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under clause (i) shall not preclude—

"(aa) further discussions to reach agreement on the risk evaluation and mitigation strategy; or

"(bb) the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including the major dispute resolution procedures as set forth in the letters described in section 735(a).

"(II) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under clause (vi), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) and the applicant may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

"(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight

Board described in clause (ii), the Board shall—

''(I) hear from both parties; and

''(II) review the dispute.

''(v) RECOMMENDATION OF THE BOARD.—Not later than 5 days after such meeting of the Drug Safety Oversight Board, the Board shall provide a written recommendation on resolving the dispute to the Secretary.

''(vi) ACTION BY THE SECRETARY.—

''(I) ACTION LETTER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(i) or to an assessment of the strategy submitted under subparagraph (B)(ii)(I), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

''(aa) the action deadline for the action letter on the application; or

''(bb) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(II) ORDER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(ii) or an assessment of the risk evaluation and mitigation strategy under subparagraph (B)(i) or under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii), the Secretary shall issue an order, which (with the recommendation of the Drug Safety Oversight Board) shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(vii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

''(viii) EFFECT ON ACTION DEADLINE.—With respect to the application or

supplemental application in which a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A)(i) or in which an assessment of the strategy is submitted under subparagraph (B)(ii)(I), the Secretary shall be considered to have met the action deadline for the action letter on such application if the applicant requests the dispute resolution process described in this subparagraph and if the Secretary—

''(I) has initiated the discussions described under subparagraph (D) by the target date referred to in subparagraph (D)(i); and

''(II) has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under clauses (ii), (v), and (vi), respectively.

''(ix) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who reviews a drug or who participated in an administra-

tive appeal under clause (iii)(I) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under clause (iv) to review a dispute about the risk evaluation and mitigation strategy for such drug.

''(x) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under clause (iv) of the Drug Safety Oversight Board.

''(H) USE OF ADVISORY COMMITTEES.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

''(i) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of

such drug or drugs is required to be submitted under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii);

''(ii) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

''(iii) with the consent of the applicant, review a dispute under subparagraph (G).

''(I) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

''(i) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has—

''(I) convened, after appropriate public notice, 1 or more public meetings to consider possible responses to such concern; or

''(II) gathered additional information or data about such concern.

''(ii) PUBLIC MEETINGS.—Such public meetings may include—

''(I) 1 or more meetings of the applicants for such drugs;

''(II) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under subparagraph (H); or

''(III) 1 or more workshops of scientific experts and other stakeholders.

''(iii) ACTION.—After considering the discussions from any meetings under clause (ii), the Secretary may—

''(I) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

''(II) seek public comment about such action; and

''(III) after seeking such comment, issue an order addressing such regulatory action.

"(J) INTERNATIONAL COORDINATION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may coordinate the timetable for submission of assessments under paragraph (3)(B), a study under paragraph (4)(B), or a clinical trial under paragraph (4)(C), with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States.

"(K) EFFECT.—Use of the processes described in subparagraphs (I) and (J) shall not delay action on an application or a supplement to an application for a drug.

"(L) NO EFFECT ON LABELING CHANGES THAT DO NOT REQUIRE PREAPPROVAL.—In the case of a labeling change to which section 314.70 of title 21, Code of Federal Regulations (or any successor regulation), applies for which the submission of a supplemental application is not required or for which distribution of the drug involved may commence upon the receipt

by the Secretary of a supplemental application for the change, the submission of an assessment of the approved risk evaluation and mitigation strategy for the drug under this subsection is not required.

''(8) DRUG SAFETY OVERSIGHT BOARD.—

''(A) IN GENERAL.—There is established a Drug Safety Oversight Board.

''(B) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

''(i) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

''(ii) include representatives from offices throughout the Food and Drug Administration (including the offices responsible for postapproval safety of drugs);

''(iii) include at least 1 representative each from the National Institutes of Health, the Department of Health and Human Services (other than the Food and Drug Administration), and the Veterans Health Administration; and

''(iv) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.''.

**SEC. 203. ENFORCEMENT.**

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a drug subject to an approved risk evaluation and mitigation strategy under section 505(o) and the applicant for such drug fails to—

''(1) make a labeling change required by such strategy after the Secretary has approved such strategy or completed review of, and acted on, an assessment of such strategy under paragraph (7) of such section; or

''(2) comply with a requirement of such strategy with respect to advertising as provided for under subparagraph (D), (E), or (F) of paragraph (5) of such section.''.

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively;

(2) by inserting after paragraph (2) the following:

''(3) An applicant (as such term is used in section 505(o)) who knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under such section 505(o) shall be subject to a civil money penalty of not less than $15,000 and not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.'';

(3) in paragraph (2)(C), by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)'';

(4) in paragraph (4), as so redesignated, by striking ''paragraph (1) or (2)'' each place it appears and inserting ''paragraph (1), (2), or (3)''; and

(5) in paragraph (6), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

**SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL PRODUCTS.**

Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(2), by adding at the end the following:

''(D) RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license for a drug under this paragraph may submit to the Secretary as part of the application a proposed risk evaluation and mitigation strategy as described under section 505(o) of the Federal Food, Drug, and Cosmetic Act.''; and

(2) in subsection (j), by inserting '', including the requirements under section 505(o) of such Act,'' after '', and Cosmetic Act''.

**SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.**

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: ''The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under subsection (o)(7)(B)(ii)(V).''.

**SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.**

Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended by adding at the end the following:

''(D) RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENT.—

''(i) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to only the following elements of the approved risk evaluation and mitigation strategy required under subsection (o) for the applicable listed drug:

''(I) Labeling, as required under subsection (o)(3)(A) for the applicable listed drug.

''(II) A Medication Guide or patient package insert, if required under subsection (o)(5)(B) for the applicable listed drug.

''(III) Prereview of advertising, if required under subsection (o)(5)(D) for the applicable listed drug.

''(IV) Specific disclosures in advertising, if required under subsection (o)(5)(E) for the applicable listed drug.

''(V) A temporary moratorium on direct-to-consumer advertising, if required under subsection (o)(5)(F) for the applicable listed drug.

''(VI) Restrictions on distribution or use, if required under subsection (o)(6) for the applicable listed drug, except that such drug may

use a different, comparable aspect of such restrictions on distribution or use as are needed to assure safe use of such drug if —

"(aa) the corresponding aspect of the restrictions on distribution or use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection; and

"(bb) the applicant certifies that it has sought a license for use of such aspect of the restrictions on distribution or use for the applicable listed drug.

"(ii) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under this subsection, the Secretary—

"(I) shall undertake any communication plan to health care providers required under section (o)(5)(C) for the applicable listed drug;

"(II) shall conduct, or contract for, any postapproval study required under subsection (o)(4)(B) for the applicable listed drug;

"(III) shall inform the applicant for a drug approved under this subsection if the approved

risk evaluation and mitigation strategy for the applicable listed drug is modified; and

''(IV) in order to minimize the burden on the health care delivery system of different restrictions on distribution or use for the drug approved under this subsection and the applicable listed drug, may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such drug may use an aspect of the restrictions on distribution or use, if required under subsection (o)(6) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.''.

**SEC. 207. RESOURCES.**

(a) USER FEES.—Subparagraph (F) of section 735(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(d)(6)), as amended by section 103, is amended—

(1) in clause (ii), by striking ''systems); and'' and inserting ''systems);''

(2) in clause (iii), by striking ''bases).'' and inserting ''bases); and''; and

(3) by adding at the end the following:

''(iv) reviewing, implementing, and ensuring compliance with risk evaluation and mitigation strategies.''.

(b) WORKLOAD ADJUSTMENT.—Subparagraph (A) of section 736(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(2)), as amended by section 103, is amended in the first sentence by striking ''and manufacturing changes submitted to the Secretary, and'' and inserting ''manufacturing changes, and assessments of risk evaluation and mitigation strategies submitted to the Secretary, uses of dispute resolution under the process for reviewing and assessing risk evaluation and mitigation strategies, and''.

(c) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—Section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), as amended by section 103, is amended by—

(1) striking the subsection designation and all that follows through ''.—Except'' and inserting the following:

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—Except''; and

(2) adding at the end the following:

''(2) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

"(A) IN GENERAL.—Subject to subparagraph (C), in each of fiscal years 2008 through 2012, paragraph (1) shall be applied by substituting the amount determined under subparagraph (B) for '$392,783,000'.

"(B) AMOUNT DETERMINED.—For any fiscal year 2008 through 2012, the amount determined under this subparagraph is the sum of—

"(i) $392,783,000; plus

"(ii) the amount equal to—

"(I) $50,000,000; minus

"(II) the amount equal to one-fifth of the amount by which the appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceed the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1).

In making the adjustment under subclause (II) for any fiscal year 2008 through 2012, subsection (c)(1) shall be applied by substituting '2007' for '2008'.

''(C) LIMITATION.—This paragraph shall not apply for any fiscal year if the amount described under subparagraph (B)(ii) is less than 0.''.

(d) STRATEGIC PLAN FOR INFORMATION TECHNOLOGY.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services (referred to in this subtitle as the ''Secretary'') shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology infrastructure, including systems for data collection, access to data in external health care databases, data mining capabilities, personnel, and personnel training programs, needed by the Food and Drug Administration to—

(A) comply with the requirements of this subtitle (and the amendments made by this subtitle);

(B) achieve interoperability within and among the Centers of the Food and Drug Administration and between the Food and Drug Administration and product application sponsors;

(C) utilize electronic health records; and

(D) implement routine active safety monitoring under section 505(k)(3) (including other approaches under subsection (C) of such section) of the Federal Food, Drug, and Cosmetic Act, as added by section 201 of this Act;

(2) an assessment of the extent to which the current information technology assets of the Food and Drug Administration are sufficient to meet the needs assessments under paragraph (1);

(3) a plan for enhancing the information technology assets of the Food and Drug Administration toward meeting the needs assessments under paragraph (1); and

(4) an assessment of additional resources needed to so enhance the information technology assets of the Food and Drug Administration.

**SEC. 208. DRUG LABELING.**

(a) ACCESSIBLE REPOSITORY OF DRUG LABELING.—Not later than the effective date of this subtitle, the Secretary, through the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, shall establish a searchable repository of structured, electronic product information, including the approved professional labeling and any required patient labeling of each drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) in order to improve patient safety through accessible product information, support initiatives to improve patient care by better management of health care information, and provide standards for drug information. Such repository shall be made publicly accessible on the Internet website of the National Library of Medicine and through a link on the homepage of the Internet website of the Food and Drug Administration.

(b) POSTING UPON APPROVAL.—The Secretary shall post in the repository under subsection (a) the approved professional labeling and any required patient labeling of a drug approved under such section 505 or licensed under such section 351 not later than 21 days after the date the drug is approved, including in a supplemental application with respect to a labeling change.

(c) REPORT.—The Secretary shall report annually to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the status of the repository under subsection (a), and on progress in posting structured electronic product information, including posting of information regarding drugs approved prior to the effective date of this subtitle.

(d) MEDICATION GUIDES.—Not later than the effective date of this subtitle, the Secretary, through the Commissioner of Food and Drugs, shall establish on the Internet website for the repository under subsection (a), a link to a list of each drug, whether approved under such section 505 or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required.

**SEC. 209. ACTION PACKAGE FOR APPROVAL.**

Section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by—

(1) redesignating paragraphs (1), (2), (3), (4), and (5) as subparagraphs (A), (B), (C), (D), and (E), respectively;

(2) striking ''(l) Safety and'' and inserting ''(l)(1) Safety and''; and

(3) adding at the end the following:

''(2) ACTION PACKAGE FOR APPROVAL.—

''(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet website of the Food and Drug Administration–

''(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

''(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

''(B) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

''(i) Documents generated by the Food and Drug Administration related to review of the application.

"(ii) Documents pertaining to the format and content of the application generated during drug development.

"(iii) Labeling submitted by the applicant.

"(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and how they were resolved, recommendation for action, and an explanation of any nonconcurrence with review conclusions.

"(v) If applicable, a separate review from a supervisor who does not concur with the summary review.

"(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

"(I) participated in the decision to approve the application; and

"(II) consents to have his or her name included in the package.

"(C) DISAGREEMENTS.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final. Disagreements by team leaders,

division directors, or office directors with any or all of the major conclusions of a reviewer shall be document in a separate review or in an addendum to the review.

''(D) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret or confidential commercial or financial information described in section 552(b)(4) of title 5, United States Code, unless the Secretary determines that such disclosure is necessary to protect the public health.''.

**SEC. 210. RISK COMMUNICATION.**

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

**''SEC. 566. ADVISORY COMMITTEE ON RISK COMMUNICATION.**

''(a) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the 'Advisory Committee on Risk Communication' (referred to in this section as the 'Committee').

''(b) DUTIES OF COMMITTEE.—The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

''(c) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

''(d) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this section.''.

**SEC. 211. REFERRAL TO ADVISORY COMMITTEE.**

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by this title, is further amended by adding at the end the following:

''(p) REFERRAL TO ADVISORY COMMITTEE.—

''(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which to has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

''(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described under such paragraph may occur within 1 year after approval of such a drug if—

''(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or

''(B) the Secretary determines that it would be beneficial to the public health.''.

**SEC. 212. RESPONSE TO THE INSTITUTE OF MEDICINE.**

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall issue a report responding to the 2006 report of the Institute of Medicine entitled ''The Future of Drug Safety—Promoting and Protecting the Health of the Public''.

(b) CONTENT OF REPORT.—The report issued by the Secretary of Health and Human Services under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described under such subsection; and

(2) an assessment of how the Food and Drug Administration has implemented—

(A) the recommendations described in such Institute of Medicine report; and

(B) the requirement under paragraph (7) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for post-approval safety with respect to the drug act together to assess, implement, and ensure compliance with the requirements of such section 505(o).

**SEC. 213. EFFECTIVE DATE AND APPLICABILITY.**

(a) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), this subtitle shall take effect 180 days after the date of enactment of this title.

(2) USER FEES.—The amendments made by subsections (a) through (c) of section 207 shall take effect on October 1, 2007.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall be deemed to have an approved risk evaluation and mitigation strategy under section 505(o) of the Fed-

eral Food, Drug, and Cosmetic Act (as added by this subtitle) if there are in effect on the effective date of this subtitle restrictions on distribution or use—

(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) RISK EVALUATION AND MITIGATION STRATEGY.—The approved risk evaluation and mitigation strategy deemed in effect for a drug under paragraph (1) shall consist of the elements described in subparagraphs (A) and (B) of paragraph (3) of such section 505(o) and any other additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(3) NOTIFICATION.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1)—

(A) that such drug is deemed to have an approved risk evaluation and mitigation strategy pursuant to such paragraph; and

(B) of the date, which, unless a safety issue with the drug arises, shall be no earlier than 6 months after the applicant is so notified, by which the applicant shall submit to the Secretary an assessment of such approved strategy under paragraph (7)(B) of such section 505(o).

(4) ENFORCEMENT ONLY AFTER ASSESSMENT AND REVIEW.—Neither the Secretary nor the Attorney General may seek to enforce a requirement of a risk evaluation and mitigation strategy deemed in effect under paragraph (1) before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505(o).

# Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

## SEC. 211. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

## "Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

### "SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.

"(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the 'Foundation') shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

"(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

"(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

"(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of

devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics;

''(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

''(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

''(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

''(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appro-

priate to further the goals and priorities established under paragraph (2);

''(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

''(7) ensure that—

''(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

''(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

''(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions

of the Foundation to further the goals and priorities established under paragraph (2);

''(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

''(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

''(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

''(d) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Commissioner of Food and Drugs.

''(ii) The Director of the National Institutes of Health.

''(iii) The Director of the Centers for Disease Control and Prevention.

''(iv) The Director of the Agency for Healthcare Research and Quality.

''(C) APPOINTED MEMBERS.—

''(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 12 individuals, from a list of candidates to be provided by the National Academy of Sciences. Of such appointed members—

''(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

''(II) 3 shall be representatives of academic research organizations;

''(III) 2 shall be representatives of Government agencies, including the

Food and Drug Administration and the National Institutes of Health;

''(IV) 2 shall be representatives of patient or consumer advocacy organizations; and

''(V) 1 shall be a representative of health care providers.

''(ii) REQUIREMENT.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

''(D) INITIAL MEETING.—

''(i) IN GENERAL.—Not later than 30 days after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

''(I) incorporate the Foundation; and

''(II) appoint the members of the Board in accordance with subparagraph (C).

''(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

''(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

''(2) DUTIES OF BOARD.—The Board shall—

''(A) establish bylaws for the Foundation that—

''(i) are published in the Federal Register and available for public comment;

''(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

''(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the dis-

position of the assets of the Foundation, including strict limits on the ability of donors to include stipulations or restrictions on the use of donated funds;

''(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

''(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

''(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health,

to the extent determined practicable and appropriate by the Board;

''(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

''(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

''(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

''(x) specify a process for annual Board review of the operations of the Foundation; and

"(xi) establish specific duties of the Executive Director;

"(B) prioritize and provide overall direction to the activities of the Foundation;

"(C) evaluate the performance of the Executive Director; and

"(D) carry out any other necessary activities regarding the functioning of the Foundation.

"(3) TERMS AND VACANCIES.—

"(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

"(B) VACANCY.—Any vacancy in the membership of the Board—

"(i) shall not affect the power of the remaining members to execute the duties of the Board; and

"(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner of Food and Drugs.

''(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(3) prescribe the manner in which—

''(A) real or personal property of the Foundation is acquired, held, and transferred;

''(B) general operations of the Foundation are to be conducted; and

''(C) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

''(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

''(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

''(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

''(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

''(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

''(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

''(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

''(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

''(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and

such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

''(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

''(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

''(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

''(l) ANNUAL REPORTS.—

''(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the du-

ration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

''(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

''(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

''(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

''(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

''(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treas-

ury are held in separate accounts from funds received from entities under subsection (i).

''(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).''.

(b) OTHER FOUNDATION PROVISIONS.—Chapter VII (21 U.S.C. 371 et seq.) (as amended by subsection (a)) is amended by adding at the end the following:

**''SEC. 771. LOCATION OF FOUNDATION.**

''The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

**''SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.**

''(a) IN GENERAL.—The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 770(l)(2).

''(b) REPORT TO CONGRESS.—Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 770(l)(2) and by other recipients of grants, contracts, memoranda of understanding, or cooperative

agreements into regulatory and product review activities of the Food and Drug Administration.

''(c) EXTRAMURAL GRANTS.—The provisions of this subchapter shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007.''.

(c) CONFORMING AMENDMENT.—Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) is amended by adding at the end the following: ''Any such fellowships and training programs under this section or under section 770(d)(2)(A)(ix) may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.''.

**SEC. 212. OFFICE OF THE CHIEF SCIENTIST.**

Chapter IX 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. 910. OFFICE OF THE CHIEF SCIENTIST.**

''(a) ESTABLISHMENT; APPOINTMENT.—The Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

''(b) DUTIES OF THE OFFICE.—The Office of the Chief Scientist shall—

''(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

''(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

''(3) develop and advocate for a budget to support intramural research;

''(4) develop a peer review process by which intramural research can be evaluated; and

''(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

''(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

''(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health.''.

# Subtitle C—Clinical Trials

**SEC. 221. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.**

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by—

(1) redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) inserting after subsection (i) the following:

''(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

''(1) DEFINITIONS; REQUIREMENT.—

''(A) DEFINITIONS.—In this subsection:

''(i) APPLICABLE DEVICE CLINICAL TRIAL.—The term 'applicable device clinical trial' means—

''(I) a prospective study of health outcomes comparing an intervention against a control in human subjects intended to support an application

under section 520(m) or 515, or a report under section 510(k), of the Federal Food, Drug, and Cosmetic Act (other than a limited study to gather essential information used to refine the device or design a pivotal trial and that is not intended to determine safety and effectiveness of a device); and

''(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act (as amended by the Pediatric Medical Device Safety and Improvement Act of 2007).

''(ii) APPLICABLE DRUG CLINICAL TRIAL.—

''(I) IN GENERAL.—The term 'applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

"(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the terms 'clinical investigation' and 'phase I' have the meaning given those terms in part 312.21 of title 21, Code of Federal Regulations.

"(iii) CLINICAL TRIAL INFORMATION.—The term 'clinical trial information' means those data elements that are necessary to complete an entry in the clinical trial registry data bank under paragraph (2).

"(iv) COMPLETION DATE.—The term 'completion date' means, with respect to an applicable drug clinical trial or an applicable device clinical trial, the date on which the last patient enrolled in the clinical trial has completed his or her last medical visit of the clinical trial, whether the clinical trial concluded according to the prespecified protocol plan or was terminated.

"(v) DEVICE.—The term 'device' means a device as defined in section

201(h) of the Federal Food, Drug, and Cosmetic Act.

''(vi) DRUG.—The term 'drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

''(vii) RESPONSIBLE PARTY.—The term 'responsible party', with respect to a clinical trial of a drug or device, means—

''(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulations)) or the principal investigator of such clinical trial if so designated by such sponsor; or

''(II) if no sponsor exists, the grantee, contractor, or awardee for a trial funded by a Federal agency or the principal investigator of such clinical trial if so designated by such grantee, contractor, or awardee.

''(B) REQUIREMENT.—The Secretary shall develop a mechanism by which—

''(i) the responsible party for each applicable drug clinical trial and applicable device clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2); and

''(ii) other Federal agencies may identify the responsible party for an applicable drug clinical trial or applicable device clinical trial.

''(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—

''(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(3)(A) (referred to in this subsection as the 'registry data bank'). The Director of NIH shall en-

sure that the registry data bank is made publicly available through the Internet.

''(ii) CONTENT.—Not later than 18 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, and after notice and comment, the Secretary shall promulgate regulations to expand the registry data bank to require the submission to the registry data bank of clinical trial information for applicable drug clinical trials and applicable device clinical trials that—

''(I) conforms to the International Clinical Trials Registry Platform trial registration data set of the World Health Organization;

''(II) includes the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed;

''(III) if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act,

specifies whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

''(IV) requires the inclusion of such other data elements to the registry data bank as appropriate; and

''(V) becomes effective 90 days after issuance of the final rule.

''(B) FORMAT AND STRUCTURE.—

''(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the registry data bank by 1 or more of the following criteria:

''(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

''(II) The treatment being studied in the clinical trial.

"(III) The location of the clinical trial.

"(IV) The age group studied in the clinical trial, including pediatric subpopulations.

"(V) The study phase of the clinical trial.

"(VI) The source of support for the clinical trial, which may be the National Institutes of Health or other Federal agency, a private industry source, or a university or other organization.

"(VII) The recruitment status of the clinical trial.

"(VIII) The National Clinical Trial number or other study identification of the clinical trial.

"(ii) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

"(C) DATA SUBMISSION.—The responsible party for an applicable drug clinical trial shall submit to the Director of NIH for inclusion in

the registry data bank the clinical trial information described in subparagraph (A)(ii).

''(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

''(E) CHANGES IN CLINICAL TRIAL STATUS.—

''(i) ENROLLMENT.—The responsible party for an applicable drug clinical trial or an applicable device clinical trial shall update the enrollment status not later than 30 days after the enrollment status of such clinical trial changes.

''(ii) COMPLETION.—The responsible party for an applicable drug clinical trial

or applicable device clinical trial shall report to the Director of NIH that such clinical trial is complete not later than 30 days after the completion date of the clinical trial.

''(F) TIMING OF SUBMISSION.—The clinical trial information for an applicable drug clinical trial or an applicable device clinical trial required to be submitted under this paragraph shall be submitted not later than 21 days after the first patient is enrolled in such clinical trial.

''(G) POSTING OF DATA.—

''(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of such submission.

''(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of clearance under section 510(k) of the Federal Food, Drug,

and Cosmetic Act, or approval under section 515 or section 520(m) of such Act, as applicable.

''(H) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit clinical trial information to the registry data bank in accordance with this subsection.

''(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

''(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

''(i) IN GENERAL.—Not later than 90 days after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

''(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(II) not later than 30 days after such information becomes publicly available, as applicable.

''(ii) REQUIRED INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) If an advisory committee considered at a meeting an applicable drug clinical trial or an applicable device clinical trial that is in the registry data bank, any posted Food and Drug Administration summary document regarding such applicable drug clinical trial or applicable clinical device trial.

"(bb) If an applicable drug clinical trial was conducted under section 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

"(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable drug clinical trial or applicable device clinical trial, respectively, if any.

"(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Food Drug and Cosmetic Act (as added by section 209 of the Enhancing Drug Safety and Innovation of 2007).

"(ee) For an applicable device clinical trial, in the case of a

premarket application, the detailed summary of information respecting the safety and effectiveness of a device required under section 520(h)(1) of the Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulations).

''(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) Medline citations to any publications regarding each applicable drug clinical trial and applicable device clinical trial.

''(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the Na-

tional Library of Medicine database of structured product labels, if available.

''(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include such links described in clause (ii) for data bank entries for clinical trials submitted to the database prior to enactment of the Enhancing Drug Safety and Innovation Act of 2007, as available.

''(B) FEASIBILITY STUDY.—The Director of NIH shall—

''(i) conduct a study to determine the best, validated methods of making the results of clinical trials publicly available after the approval of the drug that is the subject of an applicable drug clinical trial; and

''(ii) not later than 18 months after initiating such study, submit to the Secretary any findings and recommendations of such study.

''(C) NEGOTIATED RULEMAKING.—

''(i) IN GENERAL.—The Secretary shall establish a negotiated rulemaking

process pursuant to subchapter IV of chapter 5 of title 5, United States Code, to determine, for applicable drug clinical trials—

"(I) how to ensure quality and validate methods of expanding the registry data bank to include clinical trial results information for trials not within the scope of this Act;

"(II) the clinical trials of which the results information is appropriate for adding to the expanded registry data bank; and

"(III) the appropriate timing of the posting of such results information.

"(ii) TIME REQUIREMENT.—The process described in paragraph (1) shall be conducted in a timely manner to ensure that—

"(I) any recommendation for a proposed rule—

"(aa) is provided to the Secretary not later than 21 months after the date of the enactment

of the Enhancing Drug Safety and Innovation Act of 2007; and

''(bb) includes an assessment of the benefits and costs of the recommendation; and

''(II) a final rule is promulgated not later than 30 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, taking into account the recommendations under subclause (I) and the results of the feasibility study conducted under subparagraph (B).

''(iii) REPRESENTATION ON NEGOTIATED RULEMAKING COMMITTEE.—The negotiated rulemaking committee established by the Secretary pursuant to clause (i) shall include members representing—

''(I) the Food and Drug Administration;

''(II) the National Institutes of Health;

''(III) other Federal agencies as the Secretary determines appropriate;

"(IV) patient advocacy and health care provider groups;

"(V) the pharmaceutical industry;

"(VI) contract clinical research organizations;

"(VII) the International Committee of Medical Journal Editors;

"(VIII) other interested parties, including experts in privacy protection, pediatrics, health information technology, health literacy, communication, clinical trial design and implementation, and health care ethics.

"(iv) CONTENT OF REGULATIONS.—The regulations promulgated pursuant to clause (i) shall establish—

"(I) procedures to determine which clinical trials results information data elements shall be included in the registry data bank, taking into account the needs of different populations of users of the registry data bank;

"(II) a standard format for the submission of clinical trials results to the registry data bank;

"(III) a standard procedure for the submission of clinical trial results information, including the timing of submission and the timing of posting of results information, to the registry data bank, taking into account the possible impacts on publication of manuscripts based on the clinical trial;

"(IV) a standard procedure for the verification of clinical trial results information, including ensuring that free text data elements are non-promotional; and

"(V) an implementation plan for the prompt inclusion of clinical trials results information in the registry data bank.

"(D) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the consensus data elements set for reporting clinical trial results of the World Health

Organization when promulgating the regulations under subparagraph (C).

''(E) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

''(F) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable drug clinical trial or an applicable device clinical trial, upon a written request from the responsible person, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest, consistent with the protection of public health, or

in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

''(4) COORDINATION AND COMPLIANCE.—

''(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

''(i) IN GENERAL.—No Federal agency may release funds under a research grant to an awardee who has not complied with paragraph (2) for any applicable drug clinical trial or applicable device clinical trial for which such person is the responsible party.

''(ii) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable drug clinical trial or applicable device clinical trial is funded in whole or in part by a grant from the Food and Drug Administration, National Institutes of Health, the Agency for Healthcare Research and Quality, or the Department of Veterans Affairs, any grant or progress report forms re-

quired under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraph (2).

''(iii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (ii), as applicable, shall verify that the clinical trial information for each applicable drug clinical trial or applicable device clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

''(iv) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (ii), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (iii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

"(v) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

"(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such studies are applicable drug clinical trials or applicable device clinical trials under paragraph (1); and

"(II) develop with such agencies procedures comparable to those described in clauses (ii), (iii), and (iv) to ensure that clinical trial information for such applicable drug clinical trials and applicable device clinical trial is submitted under paragraph (2).

"(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section

351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

''(C) VERIFICATION OF SUBMISSION PRIOR TO POSTING.—In the case of clinical trial information that is submitted under paragraph (2), but is not made publicly available pending regulatory approval or clearance, as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed scientific journals to confirm that such clinical trial information has been submitted but has not yet been posted.

''(5) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, from any record or source other than the registry data bank expanded under

this subsection, information described in subparagraph (B).

''(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

''(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

''(ii) not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

''(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jj)(1) The failure to submit the certification required by section 402(j)(4)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

''(2) The submission of clinical trial information under section 402(j) of the Public Health Service Act that is promotional or false or misleading in any particular under paragraph (2) or (3) of such section 402(j).''.

(2) CIVIL MONEY PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)), as amended by section 203, is further amended by—

(A) redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7), respectively;

(B) inserting after paragraph (3) the following:

''(d) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for the first violation, and not more than $20,000 for each subsequent violation .'';

(C) in paragraph (2)(C), by striking ''paragraph (4)(A)'' and inserting ''paragraph (5)(A)'';

(D) in paragraph (5), as so redesignated, by striking ''paragraph (1), (2), or (3)'' each place it appears and inserting ''paragraph (1), (2), (3), or (4)''; and

(E) in paragraph (7), as so redesignated, by striking ''paragraph (5)'' each place it appears and inserting ''paragraph (6)''.

(3) NEW DRUGS.—

(A) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: ''The Secretary shall update such regulations to require inclusion in the informed consent form a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to section 402(j) of the Public Health Service Act.''.

(B) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(4)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.''.

(C) DEVICE REPORTS UNDER SECTION 510(k).—Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended by adding at the end the following:

''A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(4)(B) of such Act. Such certification shall not be considered an element of such notification.''.

(D) HUMANITARIAN DEVICE EXEMPTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended—

(i) in subparagraph (F), by striking ''; and'' and inserting a semicolon;

(ii) by redesignating subparagraph (G) as subparagraph (H); and

(iii) by inserting after subparagraph (F) the following:

''(G) the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application); and''.

(E) DEVICE PREMARKET APPROVAL APPLICATION.—Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period ''and such application shall include the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application)''.

(c) PREEMPTION.—

(1) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with section 402(j) of the Public Health Service Act (as added by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different

from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the data bank under such section 402(j), if submitted in compliance with such section 402(j), shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) TRANSITION RULE; EFFECTIVE DATE OF FUNDING RESTRICTIONS.—

(1) TRANSITION RULE FOR CLINICAL TRIALS INITIATED PRIOR TO EXPANSION OF REGISTRY DATA BANK.—The responsible party (as defined in section 402(j)(1) of the Federal Food, Drug, and Cosmetic Act (as added by this section)) for an applicable drug clinical trial or applicable device clinical trial (as defined under such section 402(j)(1)) that is initiated after the date of enactment of this subtitle and before the effective date of the regulations promulgated under paragraph (2) of such section 402(j), shall submit required clinical trial information under such section not later than 120 days after such effective date.

(2) FUNDING RESTRICTIONS.—Subparagraph (A) of paragraph (4) of such section 402(j) shall

take effect 210 days after the effective date of the regulations promulgated under paragraph (2) of such section 402(j).

(e) EFFECTIVE DATE.—Beginning 90 days after the date of enactment of this Act, the responsible party for an applicable drug clinical trial or an applicable device clinical trial (as that term is defined in such section 402(j)) that is initiated after the date of enactment of this Act and before the effective date of the regulations issued under paragraph (2)(A) of such subsection, shall submit clinical trial information under such paragraph (2).

# Subtitle D—Conflicts of Interest

**SEC. 231. CONFLICTS OF INTEREST.**

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

**"SEC. 712. CONFLICTS OF INTEREST.**

"(a) DEFINITIONS.—For purposes of this section:

"(1) ADVISORY COMMITTEE.—The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

''(2) FINANCIAL INTEREST.—The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

''(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

''(1) RECRUITMENT.—

''(A) IN GENERAL.—Given the importance of advisory committees to the review process at the Food and Drug Administration, the Secretary shall carry out informational and recruitment activities for purposes of recruiting individuals to serve as advisory committee members. The Secretary shall seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The Secretary shall also take into account the advisory committees with the greatest number of vacancies.

''(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

''(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

''(ii) making widely available, including by using existing electronic commu-

nications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

''(iii) developing a method through which an entity receiving National Institutes of Health funding can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

''(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(3) of this section

for service on the committee at a meeting of the committee.

''(c) GRANTING AND DISCLOSURE OF WAIVERS.—

''(1) IN GENERAL.—Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

''(2) FINANCIAL INTEREST OF ADVISORY COMMITTEE MEMBER OR FAMILY MEMBER.—No member of an advisory committee may vote with respect to any matter considered by the advisory committee if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

''(3) WAIVER.—The Secretary may grant a waiver of the prohibition in paragraph (2) if such waiver is necessary to afford the advisory committee essential expertise.

''(4) LIMITATION.—The Secretary may not grant a waiver under paragraph (3) for a member of an advisory committee when the member's own scientific work is involved.

''(5) DISCLOSURE OF WAIVER.—Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

''(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but in no case later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, re-

spectively)) on the Internet website of the Food and Drug Administration—

"(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

"(ii) the reasons of the Secretary for such determination, certification, or waiver.

"(B) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet website of the Food and Drug Administration, the information described in clauses

(i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

''(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(5) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

''(e) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Inspector General of the Department of Health and Human Services, the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

''(2) with respect to such year, the aggregate number of disclosures required under subsection

(c)(5) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

''(3) with respect to such year, the number of times the disclosures required under subsection (c)(5) occurred under subparagraph (B) of such subsection; and

''(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

''(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.''.

(b) CONFORMING AMENDMENT.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.

# TITLE III—MEDICAL DEVICES

**SEC. 301. SHORT TITLE; REFERENCES.**

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

(b) REFERENCES.—Except as otherwise specified, whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

## Subtitle A—Device User Fees

**SEC. 302. DEVICE FEES.**

Section 737 (21 U.S.C. 379i) is amended—

(1) by striking the section designation and all that follows through ''For purposes of this subchapter'' and inserting the following:

**''SEC. 737. DEVICE FEES.**

''(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part 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 this subchapter in the letters from the Secretary 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.

''(b) 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 subsection (a) 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, 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 website of the Food and Drug Administration.

''(c) 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) 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.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), 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.

''(d) DEFINITIONS.—For purposes of this part:'';

(2) by redesignating paragraphs (5), (6), (7), and (8), as paragraphs (7), (8), (9), and (11), respectively;

(3) in paragraph (4)—

(A) in subparagraph (A), by striking ''or an efficacy supplement,'' and inserting ''an efficacy supplement, or a 30-day notice,''; and

(B) by adding at the end the following:

''(F) The term '30-day notice' means a supplement to an approved premarket application or premarket report under section 515 that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.'';

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

''(5) 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.

''(6) The term 'annual fee for periodic reporting concerning a class III device' means the fee associated with reports imposed by a premarket application approval order (as described in section 814.82(a)(7) of title 21, Code of Federal Regulations), usually referred to as 'annual reports.' '';

(5) in paragraph (9), as redesignated by paragraph (2)—

(A) by striking ''April of'' and inserting ''October of''; and

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

(6) by inserting after paragraph (9), as redesignated by paragraph (2), the following:

''(10) The term 'person' includes an affiliate of such person.''; and

(7) by adding at the end the following:

''(12) The term 'establishment subject to a registration fee' means an establishment required to register with the Secretary under section 510 at which any of the following types of activities are conducted:

''(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 performs manufacturing operations on a single-use device.

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

''(13) The term 'establishment registration fee' means a fee assessed under section 738(a)(3) for the

registration of an establishment subject to a registration fee.

''(e) SUNSET.—This part shall cease to be effective on October 1, 2012, except that subsection (b) with respect to reports shall cease to be effective January 31, 2013.''.

**SEC. 303. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

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

(1) in subsection (a)—

(A) in paragraph (2)—

(i) in the header, by inserting '', AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE''after ''FEE'';

(ii) in subparagraph (A)—

(I) in clause (iii), by inserting ''75 percent of'' after ''a fee equal to'';

(II) in clause (iv), by striking ''21.5'' and inserting ''15'';

(III) in clause (v), by striking ''7.2'' and inserting ''7'';

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

(V) 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).'';

(VI) in clause (viii), as redesignated by subclause (IV)—

(aa) by striking ''1.42'' and inserting ''1.84''; and

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

(VII) by adding at the end 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, the annual fee shall be equal to 3.5 percent of the fee that applies under clause (i).'';

(iii) in subparagraph (C)—

(I) in the first sentence—

(aa) by striking ''or''; and

(bb) by striking ''except that'' and all that follows through the period and inserting '', 30-day notice, request for classification information, or periodic report concerning a class III device.''; and

(II) by striking the third sentence; and

(iv) in subparagraph (D)—

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

(II) by adding at the end the following:

''(iv) MODULAR APPLICATION WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for a modular application submitted under section 515(c)(4) that is withdrawn before a second module is submitted and before a first action on the first module. If the modular application is withdrawn after a second or subsequent module 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 modules submitted.

''(v) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.''; and

(B) by adding at the end 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 beginning with its registration for fiscal year 2008.

''(B) EXCEPTION FOR FEDERAL OR STATE GOVERNMENT ESTABLISHMENT.—No fee shall be required under subparagraph (A) for an establishment operated by a Federal or State government entity unless a device manufactured by the establishment is to be distributed commercially.

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

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

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), 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 Fee | $1,706 | $1,851 | $2,008 | $2,179 | $2,364''; |

(3) in subsection (c)—

(A) in paragraph (1), by striking the second sentence;

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

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

''(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT REGISTRATION FEE.—

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

"(B) PUBLICATION IN THE FEDERAL REGISTER.—The Secretary shall publish any determination with respect to any establishment reg-

istration fee adjustment made under subparagraph (A), and the rationale for such determination, in the Federal Register.''; and

(D) in paragraph (4)(A)—

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

(ii) by striking ''of fiscal year 2008'' and inserting ''of the next fiscal year'';

(4) in subsection (d)—

(A) in paragraph (1), by striking '', partners, and parent firms'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking '', partners, and parent firms'';

(ii) in subparagraph (B)—

(I) by striking ''An applicant shall'' and inserting the following:

''(i) IN GENERAL.—An applicant shall'';

(II) by striking ''The applicant shall support'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL

REVENUE SERVICE.—The applicant shall support'';

(III) by striking '', partners, and parent firms'' both places the term appears;

(IV) by striking ''partners, or parent firms, the'' and inserting ''the'';

(V) by striking '', partners, or parent firms, respectively''; and

(VI) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of the following:

''(I) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

''(II) A certification, in English, from the national taxing authority of

the country in which it is headquartered. Such certification shall provide the applicant's gross receipts and sales for the most recent year, in both the local currency and in United States dollars, the exchange rate used in making this conversion to dollars, and the dates during which these receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

''(III) Identical certifications shall be provided for each of the applicant's affiliates.

''(IV) A statement signed by the head of the applicant or its chief financial officer that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.''; and

(iii) in subparagraph (C)—

(I) by striking ''reduced rate of'' and inserting ''reduced rate of—''; and

(II) by striking ''38 percent'' and all that follows through the period and inserting the following:

''(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or a periodic report 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.'';

(5) in subsection (e)—

(A) in paragraph (1), by striking ''2004'' and inserting ''2008''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking '', partners, and parent firms'';

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

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant sub-

mits evidence that it qualifies for the lower fee rate.

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, the applicant shall certify that the applicant has no affiliates.

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the

definition under subparagraph (A) by submission of the following:

"(I) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

"(II) A certification, in English, from the national taxing authority of the country in which it is headquartered. Such certification shall provide the applicant's gross receipts and sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in making such conversion to dollars, and the dates during which such receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

"(III) Identical certifications shall be provided for each of the applicant's affiliates.

"(IV) A statement signed by the head of the applicant or its chief fi-

nancial officer that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.''; and

(iii) by striking subparagraph (C) and inserting the following:

''(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).'';

(6) by striking subsection (f) and inserting the following:

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) IN GENERAL.—A premarket application, premarket report, supplement, or premarket notification submission, 30-day notice, request for classification information, or periodic report concerning a class III device submitted by a person subject to fees under paragraphs (2) and (3) of subsection (a) shall be considered incomplete and shall not be accepted

by the Secretary until all fees owed by such person have been paid.

''(2) REGISTRATION INFORMATION.—Registration information submitted by an establishment subject to a registration fee under subsection (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until the registration fee owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment shall be deemed to have failed to register in accordance with section 510.'';

(7) in subsection (g)—

(A) 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 per-

cent 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

(B) in paragraph (2), by striking ''and premarket notification submissions, and'' and inserting ''premarket notification submissions, 30-day notices, requests for classification information, periodic reports concerning a class III device, and establishment registrations''; and

(8) in subsection (h), by striking paragraphs (3) and (4) and inserting the following:

''(3) AUTHORIZATION 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.

''(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 such 4 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. 304. 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, as in effect on the day before the date of 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. 305. EFFECTIVE DATE.**

The amendments made by this subtitle shall take effect on the date of the enactment of this subtitle.

# Subtitle B—Amendments Regarding Regulation of Medical Devices

**SEC. 311. 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 enactment of this subsection, the Secretary'' and inserting ''The Secretary'';

(2) 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 manufacturer 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).'';

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

''(6) A device establishment is eligible for inspections by persons accredited under paragraph (2) if the following conditions are met:

''(A) With respect to inspections to be conducted by an accredited person—

''(i) the owner or operator of the establishment submits to the Secretary a notice indicating the intent to use such a person to conduct the inspection, and the date on which the inspection is scheduled to begin; and

''(ii) the accredited person whom the establishment selects to conduct the inspection is listed on the Internet site of the Food and Drug Administration referred to in paragraph (4).

''(B) As requested by the Secretary, the establishment or the accredited person identified in the notice under subparagraph (A) provides information concerning the relationship

between the establishment and such accredited person.'';

(4) in paragraph (7)—

(A) by amending subparagraph (A) to read as follows:

''(B) 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, 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 new subparagraph:

''(F) The Secretary shall accept reports of audits assessing conformance with an appropriate quality systems standard set by the International Organization for Standardization (ISO) identified by the Secretary in public no-

tice for the purpose of setting risk-based inspectional priorities.''.

**SEC. 312. 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. 313. REGISTRATION.**

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 359(b)) is amended—

(1) by redesignating the existing text as paragraph (1), and indenting and relocating it appropriately;

(2) in paragraph (1), as so redesignated, by striking ''or a device or devices''; and

(3) by adding at the end the following new paragraph:

''(2) Between October 1 and 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. 359(i)(1)) is amended—

(1) by redesignating the existing text as subparagraph (A), and indenting and relocating it appropriately;

(2) in subparagraph (A), as so redesignated—

(A) by striking ''processing of a drug or a device that is imported'' and inserting ''processing of a drug that is imported'';

(B) by striking ''or device'' each place it appears; and

(3) by adding after such subparagraph (A) the following new subparagraph:

''(B) Between October 1 and December 31 of each year, any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary, 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 device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation.''.

**SEC. 314. 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), to read as follows:

''(2) Each person who registers with the Secretary under this section shall report to the Secretary (i) with regard to drugs, once during the month of June of each year and once during the month of December of each year, and (ii) with regard to devices, once each year between October 1 and December 31, the following information:''.

**SEC. 315. ELECTRONIC REGISTRATION AND LISTING.**

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

''(p)(1) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug, registrations under subsections

(b), (c), (d), and (i) of this section (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible, 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.

''(2) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.''.

# TITLE IV—PEDIATRIC MEDICAL PRODUCTS

## Subtitle A—Best Pharmaceuticals for Children

### SEC. 401. SHORT TITLE.

This subtitle may be cited as the ''Best Pharmaceuticals for Children Amendments of 2007''.

### SEC. 402. PEDIATRIC STUDIES OF DRUGS.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsection (a), by inserting before the period at the end the following: ", and, at the discretion of the Secretary, may include preclinical studies";

(2) in subsection (b)—

(A) in paragraph (1)(A)(i), by striking "(D)" both places it appears and inserting "(E)";

(B) in paragraph (1)(A)(ii), by striking "(D)" and inserting "(E)";

(C) by striking "(1)(A)(i)" and inserting "(A)(i)(I)";

(D) by striking "(ii) the" and inserting "(II) the";

(E) by striking "(B) if the drug is designated" and inserting "(ii) if the drug is designated";

(F) by striking "(2)(A)" and inserting "(B)(i)";

(G) by striking "(i) a listed patent" and inserting "(I) a listed patent";

(H) by striking "(ii) a listed patent" and inserting "(II) a listed patent";

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or in paragraph (1)(B) later than 9 months prior to the expiration of such period.'';

(3) in subsection (c)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or

in paragraph (1)(B) later than 9 months prior to the expiration of such period.'';

(4) by striking subsection (d) and inserting the following:

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) REQUEST FOR STUDIES.—

''(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In reaching an agreement regarding such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.

''(B) SINGLE WRITTEN REQUEST.—A single written request—

''(i) may relate to more than 1 use of a drug; and

''(ii) may include uses that are both approved and unapproved.

''(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

''(A) REQUEST AND RESPONSE.—

''(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

''(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

''(II) indicating that the applicant or holder does not agree to the request and the reasons for declining the request.

''(ii) DISAGREE WITH REQUEST.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

''(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

''(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accept-

ing or rejecting the reports shall be to determine, within the 180 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.'';

(5) by striking subsections (e) and (f) and inserting the following:

''(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

''(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclu-

sivity and shall include a copy of the written request made under subsection (b) or (c).

''(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within 1 year of the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such 1 year period.

''(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

''(1) INTERNAL REVIEW.—

''(A) IN GENERAL.—The Secretary shall create an internal review committee to review all written requests issued and all reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, in accordance with paragraphs (2) and (3).

''(B) MEMBERS.—The committee under subparagraph (A) shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(i) Pediatrics.

''(ii) Biopharmacology.

''(iii) Statistics.

''(iv) Drugs and drug formulations.

''(v) Legal issues.

''(vi) Appropriate expertise pertaining to the pediatric product under review.

''(vii) One or more experts from the Office of Pediatric Therapeutics, including an expert in pediatric ethics.

''(viii) Other individuals as designated by the Secretary.

''(2) REVIEW OF WRITTEN REQUESTS.—All written requests under this section shall be reviewed and approved by the committee established under paragraph (1) prior to being issued.

''(3) REVIEW OF PEDIATRIC STUDIES.—The committee established under paragraph (1) shall review all studies conducted pursuant to this section to determine whether to accept or reject such reports under subsection (d)(3).

''(4) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The committee established under paragraph (1) shall be responsible for tracking and making available to the public, in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

''(A) the number of studies conducted under this section;

''(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under this section;

''(C) the types of studies conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

''(E) the labeling changes made as a result of studies conducted under this section;

''(F) an annual summary of labeling changes made as a result of studies conducted under this section for distribution pursuant to subsection (k)(2); and

''(G) information regarding reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.'';

(6) in subsection (g)—

(A) in paragraph (1)—

(i) by striking ''(c)(1)(A)(ii)'' and inserting ''(c)(1)(A)(i)(II)''; and

(ii) by striking ''(c)(2)'' and inserting ''(c)(1)(B)'';

(B) in paragraph (2), by striking ''(c)(1)(B)'' and inserting ''(c)(1)(A)(ii)'';

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking ''LIMITATIONS.—A drug'' and inserting ''LIMITATIONS.—

''(1) IN GENERAL.—Notwithstanding subsection (c)(2), a drug''; and

(E) by adding at the end the following:

''(2) EXCLUSIVITY ADJUSTMENT.—

''(A) ADJUSTMENT.—

''(i) IN GENERAL.—With respect to any drug, if the organization designated under subparagraph (B) notifies the Secretary that the combined annual gross

sales for all drugs with the same active moiety exceeded $1,000,000,000 in any calendar year prior to the time the sponsor or holder agrees to the initial written request pursuant to subsection (d)(2), then each period of market exclusivity deemed or extended under subsection (b) or (c) shall be reduced by 3 months for such drug.

''(ii) DETERMINATION.—The determination under clause (i) of the combined annual gross sales shall be determined—

''(I) taking into account only those sales within the United States; and

''(II) taking into account only the sales of all drugs with the same active moiety of the sponsor or holder and its affiliates.

''(B) DESIGNATION.—The Secretary shall designate an organization other than the Food and Drug Administration to evaluate whether the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in a calendar year as described

in subparagraph (A). Prior to designating such organization, the Secretary shall determine that such organization is independent and is qualified to evaluate the sales of pharmaceutical products. The Secretary shall re-evaluate the designation of such organization once every 3 years.

''(C) NOTIFICATION.—Once a year at a time designated by the Secretary, the organization designated under subparagraph (B) shall notify the Food and Drug Administration of all drugs with the same active moiety with combined annual gross sales that exceed $1,000,000,000 during the previous calendar year.''.

(7) in subsection (i)—

(A) in the heading, by striking ''SUPPLEMENTS'' and inserting ''CHANGES'';

(B) in paragraph (1)—

(i) in the heading, by inserting ''APPLICATIONS AND'' after ''PEDIATRIC'';

(ii) by inserting ''application or'' after ''Any'';

(iii) by striking ''change pursuant to a report on a pediatric study under'' and in-

serting ''change as a result of any pediatric study conducted pursuant to''; and

(iv) by inserting ''application or'' after ''to be a priority''; and

(C) in paragraph (2)(A), by—

(i) striking ''If the Commissioner'' and inserting ''If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Commissioner''; and

(ii) striking ''an application with'' and all that follows through ''on appropriate'' and inserting ''the sponsor and the Commissioner have been unable to reach agreement on appropriate'';

(8) by striking subsection (m);

(9) by redesignating subsections (j), (k), (l), and (n), as subsections (k), (m), (o), and (p), respectively;

(10) by inserting after subsection (i) the following:

''(j) OTHER LABELING CHANGES.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary determines that a pediatric study conducted under this section does or does

not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.'';

(11) in subsection (k), as redesignated by paragraph (9)—

(A) in paragraph (1)—

(i) by striking ''a summary of the medical and'' and inserting ''the medical, statistical, and''; and

(ii) by striking ''for the supplement'' and all that follows through the period and inserting ''under subsection (b) or (c).'';

(B) by redesignating paragraph (2) as paragraph (3); and

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

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary shall require that the sponsors of the studies that result in labeling changes that are reflected in the annual

summary developed pursuant to subsection (f)(4)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.'';

(12) by inserting after subsection (k), as redesignated by paragraph (9), the following:

''(l) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, during the 1-year period beginning on the date a labeling change is made pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering such reports, the Director of such Office shall provide for the 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 section in response to such reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.'';

(13) by inserting after subsection (m), as redesignated by paragraph (9), the following:

''(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

''(1) IN GENERAL.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under subsection (f), determines that there is a con-

tinuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

"(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B. Prior to making such determination, the Secretary may take not more than 60 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate 1 or more of the pediatric studies of such drug referred to in the sentence preceding this paragraph and fund 1 or more of such studies in their entirety. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer such pediatric study or studies to the Foundation for the National Institutes for Health for the conduct of such study or studies.

"(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, determine whether there are funds available under section 736 to award a grant to con-

duct the requested studies pursuant to paragraph (2).

''(2) FUNDING OF STUDIES.—If, pursuant to paragraph (1), the Secretary determines that there are funds available under section 736 to award a grant to conduct the requested pediatric studies, then the Secretary shall issue a proposal to award a grant to conduct the requested studies. If the Secretary determines that funds are not available under section 736, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

''(3) PUBLIC NOTICE.—The Secretary shall give the public notice of—

''(A) a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision;

''(B) the name of any drug, its manufacturer, and the indications to be studied pursuant to a grant made under paragraph (2); and

''(C) any decision under paragraph (2) to refer a drug for inclusion on the list established under section 409I of the Public Health Service Act.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of Title 18, United States Code.'';

(14) in subsection (p), as redesignated by paragraph (9)—

(A) striking ''6-month period'' and inserting ''3-month or 6-month period'';

(B) by striking ''subsection (a)'' and inserting ''subsection (b)''; and

(C) by striking ''2007'' both places it appears and inserting ''2012''.

(b) EFFECTIVE DATE.—Except as otherwise provided in the amendments made by subsection (a), such amendments shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) made after the date of enactment of this subtitle.

**SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) by striking subsections (a) and (b) and inserting the following:

''(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every 3 years.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

''(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

''(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

''(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological re-

search, including research networks and trained pediatric investigators.

''(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.'';

(2) in subsection (c)—

(A) in the heading, by striking ''CONTRACTS'' and inserting ''PROPOSED PEDIATRIC STUDY REQUESTS'';

(B) by striking paragraphs (4) and (12);

(C) by redesignating paragraphs (1), (2), and (3), as paragraphs (2), (3), and (4);

(D) by inserting before paragraph (2), as redesignated by subparagraph (C), the following:

"(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

"(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

"(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; and

"(B) there is no patent protection or market exclusivity protection for at least 1 form of

the drug under the Federal Food, Drug, and Cosmetic Act; and

''(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.'';

(E) in paragraph (2), as redesignated by subparagraph (C)—

(i) by inserting ''based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1)'' after ''issue a written request'';

(ii) by striking ''in the list described in subsection (a)(1)(A) (except clause (iv))'' and inserting ''under subsection (a)''; and

(iii) by inserting ''and using appropriate formulations for each age group for which the study is requested'' before the period at the end;

(F) in paragraph (3), as redesignated by subparagraph (C)—

(i) in the heading, by striking ''CONTRACTS'';

(ii) by striking ''paragraph (1)'' and inserting ''paragraph (2)'';

(iii) by striking ''or if a referral described in subsection (a)(1)(A)(iv) is made,'';

(iv) by striking ''for contract proposals'' and inserting ''for proposals''; and

(v) by inserting ''in accordance with subsection (b)'' before the period at the end;

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

(i) by striking ''contract''; and

(ii) by striking ''paragraph (2)'' and inserting ''paragraph (3)'';

(H) in paragraph (5)—

(i) by striking the heading and inserting ''CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS''; and

(ii) by striking ''A contract'' and all that follows through ''is submitted'' and inserting ''A contract, grant, or other funding may be awarded under this section only if a proposal is submitted'';

(I) in paragraph (6)(A)—

(i) by striking ''a contract awarded'' and inserting ''an award''; and

(ii) by inserting '', including a written request if issued'' after ''with the study''; and

(3) by inserting after subsection (c) the following:

''(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.''

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(A) $200,000,000 for fiscal year 2008; and

''(B) such sums as are necessary for each of the 4 succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

**SEC. 404. REPORTS AND STUDIES.**

(a) GAO REPORT.—Not later than January 31, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of the amendments made by this subtitle and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this subtitle and the amendments made by this subtitle, and possible reasons for the lack of testing, including whether the number of written requests declined by sponsors or holders of drugs subject to section 505A(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)(2)), has increased or decreased as a result of the amendments made by this subtitle;

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this subtitle, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under section 505A of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

(b) IOM STUDY.—Not later than 3 years after the date of enactment of this subtitle, the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to such section in order to conduct such study. Such study shall—

(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c) of such section 505A;

(2) review and assess such representative pediatric studies conducted under such subsections (b) and (c) since 1997 and labeling changes made as a result of such studies; and

(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials.

**SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Serv-

ice Act (42 U.S.C. 285g–10(2)) is amended by adding before the period at the end the following: ", including pediatric pharmacological research".

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288–6(a)(1)) is amended by inserting "including pediatric pharmacological research," after "pediatric research,".

**SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.**

Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking "and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of the is Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)" and inserting "and studies for which the Secretary issues a certification under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(n)(1)(A))".

**SEC. 407. CONTINUATION OF OPERATION OF COMMITTEE.**

Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following:

"(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Ad-

visory Committee Act (5 U.S.C. App.), the advisory committee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''.

**SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.**

Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking ''and'' after the semicolon;

(ii) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(D) provide recommendations to the internal review committee created under section 505A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(f)) regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a and 355c)

with respect to the treatment of pediatric cancers.''; and

(B) by adding at the end the following:

''(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Subcommittee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''; and

(2) in subsection (d), by striking ''2003'' and inserting ''2009''.

**SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.**

(a) IN GENERAL.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the ''Administrative Procedure Act'') and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'', 69 Fed. Reg. 21778, (April 22, 2004) shall take effect on January 1, 2008, unless such Commissioner issues the final rule before such date.

(b) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule described under subsection (a), shall, notwithstanding section 17(a) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(1) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(3) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

# Subtitle B—Pediatric Research Improvement

**SEC. 411. SHORT TITLE.**

This subtitle may be cited as the ''Pediatric Research Improvement Act''.

**SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPOLATIONS, AND DEFERRALS.**

Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(1) in paragraph (4)(C), by adding at the end the following: ''An applicant seeking either a partial

or full waiver on this ground shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration'';

(2) in paragraph (2)(B), by adding at the end the following:

''(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 or section 351 of the Public Health Service Act.''; and

(3) by striking paragraph (3) and inserting the following:

''(3) DEFERRAL.—

''(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug

or issuance of the license for a biological product if—

''(i) the Secretary finds that—

''(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

''(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

''(III) there is another appropriate reason for deferral; and

''(ii) the applicant submits to the Secretary—

''(I) certification of the grounds for deferring the assessments;

''(II) a description of the planned or ongoing studies;

''(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

''(IV) a timeline for the completion of such studies.

"(B) ANNUAL REVIEW.—

"(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

"(I) Information detailing the progress made in conducting pediatric studies.

"(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

"(ii) PUBLIC AVAILABILITY.—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the website of the Food and Drug Administration.".

**SEC. 413. IMPROVING AVAILABILITY OF PEDIATRIC DATA FOR ALREADY MARKETED PRODUCTS.**

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

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

''(1) IN GENERAL.—After providing notice in the form of a letter, or a written request under section 505A that was declined by the sponsor or holder, and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) and the written request, as appropriate, if the Secretary finds that—

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

''(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

"(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

"(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.";

(2) in paragraph (2)(C), by adding at the end the following: "An applicant seeking either a partial or full waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration."; and

(3) by striking paragraph (3).

(b) EFFECT OF SECTION.—Nothing in this section alters or amends section 301(j) of the Federal Food, Drug, and Cosmetic Act or section 552 of title 5 or section 1905 of title 18, United States Code.

**SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESSMENTS; ADVERSE EVENT REPORTING; LABELING CHANGES; AND PEDIATRIC ASSESSMENTS.**

Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (h), by striking ''505A(n)'' and inserting ''505A(p)'';

(2) by redesignating subsection (f) as subsection (k);

(3) by redesignating subsection (g) as subsection (l); and

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

''(f) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS, PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—

''(1) REVIEW.—The Secretary shall create an internal committee to review all pediatric assessment requests issued under this section, all pediatric assessments conducted under this section, and all deferral and waiver requests made pursuant to this section. Such internal committee shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(A) Pediatrics.

''(B) Biopharmacology.

''(C) Statistics.

''(D) Drugs and drug formulations.

''(E) Pediatric ethics.

''(F) Legal issues.

''(G) Appropriate expertise pertaining to the pediatric product under review.

''(H) 1 or more experts from the Office of Pediatric Therapeutics.

''(I) Other individuals as designated by the Secretary.

''(2) REVIEW OF REQUESTS FOR PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—All written requests for a pediatric assessment issued pursuant to this section and all requests for deferrals and waivers from the requirement to conduct a pediatric assessment under this section shall be reviewed and approved by the committee established under paragraph (1).

''(3) REVIEW OF ASSESSMENTS.—The committee established under paragraph (1) shall review all assessments conducted under this section to determine whether such assessments meet the requirements of this section.

''(4) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The committee established under

paragraph (1) is responsible for tracking and making public in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

"(A) the number of assessments conducted under this section;

"(B) the specific drugs and drug uses assessed under this section;

"(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

"(D) the total number of deferrals requested and granted under this section, and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

"(E) the number of waivers requested and granted under this section, and, if granted, the reasons for the waivers;

"(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulations were not developed;

''(G) the labeling changes made as a result of assessments conducted under this section;

''(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (i)(2); and

''(I) an annual summary of the information submitted pursuant to subsection (a)(3)(B).

''(g) LABELING CHANGES.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENT.—Any supplement to an application under section 505 and section 351 of the Public Health Service Act proposing a labeling change as a result of any pediatric assessments conducted pursuant to this section—

''(A) shall be considered a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—

''(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that a sponsor and the Commis-

sioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—

"(i) the Commissioner shall request that the sponsor make any labeling change that the Commissioner determines to be appropriate; and

"(ii) if the sponsor does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

"(i) review the pediatric study reports; and

"(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

''(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

''(D) MISBRANDING.—If the sponsor, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded.

''(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

''(3) OTHER LABELING CHANGES.—If the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective, including whether such assessment results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the assessment and a statement of the Secretary's determination.

''(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments and shall post such assessments on the website of the Food and Drug Administration.

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—The Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the an-

nual summary developed pursuant to subsection (f)(4)(H) distribute such information to physicians and other health care providers.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.

''(i) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR 1.—During the 1-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the 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 such report.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics with all adverse event

reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such report.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.''.

**SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.**

Section 505B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) by striking ''estimates'' and inserting ''determines''; and

(2) by striking ''would'' and inserting ''could''.

**SEC. 416. REPORTS.**

(a) INSTITUTE OF MEDICINE STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Pediatric Research Improvement Act, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to section 505B of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997.

(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess—

(A) pediatric studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997 and labeling changes made as a result of such studies; and

(B) the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.

(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) from each review division within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in order to make the required assessment.

(b) PREA REPORT.—Not later than September 1, 2010, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of this provision and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of the Pediatric Research Equity Act of 2003 (Public Law 108–155), and possible reasons for the lack of testing; and

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by the Pediatric Research Equity Act of 2003 (Public Law 108–155), together with a description

of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee.

**SEC. 417. TECHNICAL CORRECTIONS.**

Section 505B(a)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amended by striking ''one'' and inserting ''1''.

# Subtitle C—Pediatric Medical Devices

**SEC. 421. SHORT TITLE.**

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

**SEC. 422. 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 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.—In this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).''.

**SEC. 423. 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.'';

(3) by striking paragraph (6) and inserting the following:

''(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 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, 2013.

''(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.''; and

(4) by adding at the end the following:

''(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 pro-

vide 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.''.

(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 the pediatric devices, based on a survey 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 425, 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 enactment of this subtitle, 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. 424. 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.''.

**SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.**

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of enactment of this subtitle, 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 424; 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—

(A) the effectiveness of activities conducted under subsection (c);

(B) the impact of activities conducted under subsection (c) on pediatric device development; and

(C) the status of pediatric device development 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. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.**

(a) IN GENERAL.—

(1) 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".

(2) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(A) IN GENERAL.—Not later than 270 days after the date of enactment of this subtitle, the Office of Pediatric Therapeutics, in collaboration with 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 Commissioner of Food and Drugs shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.

(B) CONTENTS.—The plan under subparagraph (A) shall include—

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

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

(iii) 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.

(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 bio-

logical products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and''; and

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

**SEC. 427. SURVEILLANCES.**

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

(1) 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 implanted in the human body for more than 1 year, or 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 of an application (or a supplement to an application) or a product development protocol under section 515 or as a condition to clearance of a premarket notification under section 510(k) only for 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

(2) 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 SURVEILLANCES 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 of the device.''.

**SEC. 428. 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.

Amend the title so as to read: ''To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.''.