This is not an idea we are proposing, it is a law—a law to protect the integrity of the advisory committees and the drugs and medical devices which are sold across America.

I urge my colleagues to support this amendment.

Mr. KENNEDY. Mr. President, the FDA has a new policy, a new procedure out there.

Basically, what the Durbin amendment says is, one size fits all. That concept has been rejected by the Europeans, rejected by the Canadians, and basically rejected by the Institute of Medicine. In this life science century, researchers who are looking at cancer drugs may be examining 15 different components. Are we going to say that if a conflict exists with one of those components that they meet the Durbin amendment standard. This would exclude some of the most knowledgeable people in this country from participating in the review of breakthrough drugs.

The FDA says they have adopted transparency. Everyone in the Senate is going to know who sits on the advisory committees. There is a financial limitation of $50,000 at the FDA now. Everyone is going to know the existence of any conflicts. It is a new day out there. We have now have transparency, but virtually everyone who understands that we are in the life science century says we have to have the best scientific minds at the table, and so the Institute of Medicine said: Don't go with a one-size-fits-all, which the Durbin amendment does.

The PRESIDING OFFICER. All time has expired.

The question is on agreeing to amendment No. 1034. The yeas and nays have been ordered.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 47, nays 47, as follows:

[Rollcall Vote No. 156 Leg.]

YEAS—47

Akaka	Collins	Lautenberg
Baucus	Conrad	Leahy
Bayh	Dorgan	Levin
Biden	Durbin	Lieberman
Bingaman	Feingold	Lincoln
Boxer	Feinstein	McCaskill
Brown	Grassley	Menendez
Cantwell	Harkin	Mikulski
Cardin	Inouye	Murray
Carper	Klobuchar	Nelson (FL)
Casey	Kohl	Obama
Clinton	Landrieu	Pryor
Reed	Schumer	Webb
Reid	Snowe	Whitehouse
Salazar	Stabenow	Wyden
Sanders	Tester	

NAYS—47

Alexander	Dole	Martinez
Allard	Domenici	McConnell
Bennett	Ensign	Murkowski
Bond	Enzi	Nelson (NE)
Bunning	Graham	Rockefeller
Burr	Gregg	Sessions
Byrd	Hagel	Shelby
Chambliss	Hatch	Smith
Coburn	Hutchison	Specter
Cochran	Inhofe	Stevens
Coleman	Isakson	Sununu
Corker	Kennedy	Thomas
Cornyn	Kerry	Thune
Craig	Kyl	Voinovich
DeMint	Lott	Warner
Dodd	Lugar	

NOT VOTING—6

Brownback	Johnson	Roberts
Crapo	McCain	Vitter

The amendment (No. 1034) was rejected.

The PRESIDING OFFICER. Under the previous order, the committee substitute amendment, as modified and amended, is agreed to, the motion to reconsider is considered made and laid upon the table, and the cloture motion on the bill is withdrawn.

Under the previous order, the clerk will read the bill for the third time.

The bill was ordered to be engrossed for a third reading and was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill, as modified and amended, pass?

Mr. KENNEDY. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 93, nays 1, as follows:

[Rollcall Vote No. 157 Leg.]

YEAS—93

Akaka	Casey	Ensign
Alexander	Chambliss	Enzi
Allard	Clinton	Feingold
Baucus	Coburn	Feinstein
Bayh	Cochran	Graham
Bennett	Coleman	Grassley
Biden	Collins	Gregg
Bingaman	Conrad	Hagel
Bond	Corker	Harkin
Boxer	Cornyn	Hatch
Brown	Craig	Hutchison
Bunning	DeMint	Inhofe
Burr	Dodd	Inouye
Byrd	Dole	Isakson
Cantwell	Domenici	Kennedy
Cardin	Dorgan	Kerry
Carper	Durbin	Klobuchar
Kohl	Mikulski	Smith
Kyl	Murkowski	Snowe
Landrieu	Murray	Specter
Lautenberg	Nelson (FL)	Stabenow
Leahy	Nelson (NE)	Stevens
Levin	Obama	Sununu
Lieberman	Pryor	Tester
Lincoln	Reed	Thomas
Lott	Reid	Thune
Lugar	Rockefeller	Voinovich
Martinez	Salazar	Warner
McCaskill	Schumer	Webb
McConnell	Sessions	Whitehouse
Menendez	Shelby	Wyden

NAYS—1

Sanders

NOT VOTING—6

Brownback	Johnson	Roberts
Crapo	McCain	Vitter

The bill (S. 1082) as modified and amended, was passed, as follows:

S. 1082

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Administration 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 part 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 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 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 of such person.".

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-fifth 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 with 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 with 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 not 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 television 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 not 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 General 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 paragraph 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, as part of the notice described in paragraph (1), the fee revenues and fees resulting from the adjustment made under this paragraph and the supporting methodologies.

"(C) LIMITATION.—Under no circumstances shall the adjustment made under this paragraph 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 person 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 operating 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 expenses 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 prescription 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 '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.

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

"(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 revised 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 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. 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. ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.

(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) ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.—

"(A) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—The Secretary shall, not later than 2 years after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, act in collaboration with academic institutions and private entities to—

"(i) establish minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and

"(ii) establish, through partnerships, a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources, with the goals of including, in aggregate—

"(I) at least 25,000,000 patients by July 1, 2010; and

"(II) at least 100,000,000 patients by July 1, 2012.

"(B) DATA COLLECTION ACTIVITIES.—

"(i) IN GENERAL.—The Secretary shall, not later than 1 year after the establishment of the minimum standards and the identification and analysis system under subparagraph (A), establish and maintain an active surveillance infrastructure—

"(I) to collect and report data for pharmaceutical postmarket risk identification and analysis, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; and

"(II) that includes, in addition to the collection and monitoring (in a standardized form) of data on all serious adverse drug experiences (as defined in subsection (o)(2)(C)) required to be submitted to the Secretary under paragraph (1), and those events voluntarily submitted from patients, providers, and drug, when appropriate, procedures to—

"(aa) provide for adverse event surveillance by collecting and monitoring Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

"(bb) provide for adverse event surveillance by collecting and monitoring private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data);

"(cc) provide for adverse event surveillance by monitoring standardized electronic health records, as available;

"(dd) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

"(ee) enable the program to identify certain trends and patterns with respect to data reported to the program;

"(ff) enable the program to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, laboratory data, and other information determined appropriate, which may include data on comparative national adverse event trends; and

"(gg) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

"(ii) TIMELINESS OF REPORTING.—The procedures developed under clause (i) shall ensure that such data are collected, monitored, and reported in a timely, routine, and automatic manner, taking into consideration the need for data completeness, coding, cleansing, and transmission.

"(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active surveillance infrastructure by the date described under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

"(iv) COMPLEMENTARY APPROACHES.—To the extent the active surveillance infrastructure established under clause (i) is not sufficient to gather data and information relevant to priority drug safety questions, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

"(I) approaches that are complementary 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.

"(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

"(C) RISK IDENTIFICATION AND ANALYSIS.—

"(i) PURPOSE.—To carry out this paragraph, the Secretary shall establish collaborations with other Government, academic, and private entities, including the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for the risk identification and analysis of the data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary, in order to—

"(I) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

"(II) provide the Secretary with routine access to expertise to study advanced drug safety data; and

"(III) enhance the ability of the Secretary to make timely assessments based on drug safety data.

"(ii) 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—

"(aa) routine active surveillance under subparagraph (B); and

"(bb) when such surveillance is not sufficient, postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C).

"(iii) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

"(I) IN GENERAL.—Not later than 180 days after the date of the establishment of the active surveillance infrastructure under subparagraph (B), the Secretary shall establish and implement procedures under which the Secretary may routinely collaborate with a qualified entity to—

"(aa) clean, classify, or aggregate data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary;

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

"(AA) unresolved safety questions for drugs or classes of drugs; and

"(BB) for a newly-approved drug: safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and 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);

"(cc) perform advanced research and analysis on identified drug safety risks;

"(dd) convene an expert advisory committee to oversee the establishment of standards for the ethical and scientific uses for, and communication of, postmarketing data collected under subparagraph (B), including advising on the development of effective research methods for the study of drug safety questions;

"(ee) 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 the use of a drug; and

"(ff) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

"(II) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in subclause (I) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

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

"(v) 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) QUALIFICATION.—The Secretary shall enter into a contract with an entity under subclause (I) only if the Secretary determines that the entity—

"(aa) has the research capability and expertise to conduct and complete the activities under this paragraph;

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

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

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

"(ee) has a significant business presence in the United States.

"(vi) 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—

"(aa) the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; or

"(bb) 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—

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

"(bb) 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 with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

"(aa) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

"(bb) 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.

"(vii) 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 clause (v).

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

"(D) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and provide for the coordination of the activities of private entities, professional associations, or other entities that may have sources of surveillance data.".

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by this section for which funds are made available under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), there are authorized to be appropriated to carry out the amendment made by this section, in addition to such funds, $25,000,000 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 surveillance 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) is 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—