

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:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food and Drug Ad-
5 ministration Revitalization Act”.

1 **TITLE I—PRESCRIPTION DRUG**
2 **USER FEES**

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

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Prescription Drug User Fee Amendments of 2007”.

6 (b) **REFERENCES IN TITLE.**—Except as otherwise
7 specified, whenever in this title an amendment is ex-
8 pressed in terms of an amendment to a section or other
9 provision, the reference shall be considered to be made to
10 a section or other provision of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 301 et seq.).

12 **SEC. 102. DRUG FEES.**

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

14 (1) by striking the section designation and all
15 that follows through “For purposes of this sub-
16 chapter:” and inserting the following:

17 **“SEC. 735. DRUG FEES.**

18 “(a) **PURPOSE.**—It is the purpose of this part that
19 the fees authorized under this part be dedicated toward
20 expediting the drug development process, the process for
21 the review of human drug applications, and postmarket
22 drug safety, as set forth in the goals identified for pur-
23 poses of this subchapter in the letters from the Secretary
24 to the Chairman of the Committee on Health, Education,
25 Labor, and Pensions of the Senate and the Chairman of

1 the Committee on Energy and Commerce of the House
2 of Representatives, as set forth in the Congressional
3 Record.

4 “(b) REPORTS.—

5 “(1) PERFORMANCE REPORT.—For fiscal years
6 2008 through 2012, not later than 120 days after
7 the end of each fiscal year during which fees are col-
8 lected under this part, the Secretary shall prepare
9 and submit to the Committee on Health, Education,
10 Labor, and Pensions of the Senate and the Com-
11 mittee on Energy and Commerce of the House of
12 Representatives, a report concerning the progress of
13 the Food and Drug Administration in achieving the
14 goals identified in the letters described in subsection
15 (a) during such fiscal year and the future plans of
16 the Food and Drug Administration for meeting the
17 goals. The report for a fiscal year shall include infor-
18 mation on all previous cohorts for which the Sec-
19 retary has not given a complete response on all
20 human drug applications and supplements in the co-
21 hort.

22 “(2) FISCAL REPORT.—For fiscal years 2008
23 through 2012, not later than 120 days after the end
24 of each fiscal year during which fees are collected
25 under this part, the Secretary shall prepare and sub-

1 mit to the Committee on Health, Education, Labor,
2 and Pensions of the Senate and the Committee on
3 Energy and Commerce of the House of Representa-
4 tives, a report on the implementation of the author-
5 ity for such fees during such fiscal year and the use,
6 by the Food and Drug Administration, of the fees
7 collected during such fiscal year for which the report
8 is made.

9 “(3) PUBLIC AVAILABILITY.—The Secretary
10 shall make the reports required under paragraphs
11 (1) and (2) available to the public on the Internet
12 website of the Food and Drug Administration.

13 “(c) REAUTHORIZATION.—

14 “(1) CONSULTATION.—In developing rec-
15 ommendations to present to Congress with respect to
16 the goals, and plans for meeting the goals, for the
17 process for the review of human drug applications
18 for the first 5 fiscal years after fiscal year 2012, and
19 for the reauthorization of this part for such fiscal
20 years, the Secretary shall consult with—

21 “(A) the Committee on Energy and Com-
22 merce of the House of Representatives;

23 “(B) the Committee on Health, Education,
24 Labor, and Pensions of the Senate;

25 “(C) scientific and academic experts;

1 “(D) health care professionals;

2 “(E) representatives of patient and con-
3 sumer advocacy groups; and

4 “(F) the regulated industry.

5 “(2) PUBLIC REVIEW OF RECOMMENDA-
6 TIONS.—After negotiations with the regulated indus-
7 try, the Secretary shall—

8 “(A) present the recommendations devel-
9 oped under paragraph (1) to the Congressional
10 committees specified in such paragraph;

11 “(B) publish such recommendations in the
12 Federal Register;

13 “(C) provide for a period of 30 days for
14 the public to provide written comments on such
15 recommendations;

16 “(D) hold a meeting at which the public
17 may present its views on such recommenda-
18 tions; and

19 “(E) after consideration of such public
20 views and comments, revise such recommenda-
21 tions as necessary.

22 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
23 Not later than January 15, 2012, the Secretary
24 shall transmit to Congress the revised recommenda-
25 tions under paragraph (2), a summary of the views

1 and comments received under such paragraph, and
2 any changes made to the recommendations in re-
3 sponse to such views and comments.

4 “(d) DEFINITIONS.—For purposes of this part:”;

5 (2) in subsection (d)—

6 (A) in paragraph (1)—

7 (i) in subparagraph (A), by striking
8 “505(b)(1),” and inserting “505(b), or”;

9 (ii) by striking subparagraph (B);

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

12 (iv) in the matter following subpara-
13 graph (B), as so redesignated, by striking
14 “subparagraph (C)” and inserting “sub-
15 paragraph (B)”;

16 (B) in paragraph (3)(C), by—

17 (i) striking “the list” and inserting
18 “the list (not including the discontinued
19 section of such list)”;

20 (ii) striking “a list” and inserting “a
21 list (not including the discontinued section
22 of such a list)”;

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

1 capsules, tablets, and lyophilized products be-
2 fore reconstitution)”;

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

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

8 “(i) collecting, developing, and review-
9 ing safety information on approved drugs
10 (including adverse event reports);

11 “(ii) developing and using improved
12 adverse event data collection systems (in-
13 cluding information technology systems);
14 and

15 “(iii) developing and using improved
16 analytical tools to assess potential safety
17 problems (including by accessing external
18 data bases).”;

19 (E) in paragraph (8)—

20 (i) by striking “April of the preceding
21 fiscal year” and inserting “October of the
22 preceding fiscal year”; and

23 (ii) by striking “April 1997” and in-
24 serting “October 1996”;

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

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

5 “(9) The term ‘person’ includes an affiliate
6 thereof.”.

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

8 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
9 379h(a)) is amended—

10 (1) in the matter preceding paragraph (1), by
11 striking “2003” and inserting “2008”;

12 (2) in paragraph (1)—

13 (A) in subparagraph (D)—

14 (i) in the heading, by inserting “OR
15 WITHDRAWN BEFORE FILING” after “RE-
16 FUND OF FEE IF APPLICATION REFUSED
17 FOR FILING”; and

18 (ii) by inserting before the period at
19 the end the following: “or withdrawn with-
20 out a waiver before filing”;

21 (B) by redesignating subparagraphs (E)
22 and (F) as subparagraphs (F) and (G), respec-
23 tively; and

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

1 “(E) FEE FOR APPLICATION PREVIOUSLY
2 REFUSED FOR FILING OR WITHDRAWN BEFORE
3 FILING.—An application or supplement that
4 has been refused for filing or that was with-
5 drawn before filing, if filed under protest or re-
6 submitted, shall be subject to the fee under sub-
7 paragraph (A) (unless an exception under sub-
8 paragraph (C) or (F) applies or the fee is
9 waived or reduced under subsection (d)), with-
10 out regard to previous payment of such a fee
11 and the refund of 75 percent of that fee under
12 subparagraph (D).”; and

13 (3) in paragraph (2)—

14 (A) in subparagraph (A), by striking “sub-
15 paragraph (B)” and inserting “subparagraphs
16 (B) and (C)”; and

17 (B) by adding at the end the following:

18 “(C) SPECIAL RULES FOR COMPOUNDED
19 POSITRON EMISSION TOMOGRAPHY DRUGS.—

20 “(i) IN GENERAL.—Except as pro-
21 vided in clause (ii), each person who is
22 named as the applicant in an approved
23 human drug application for a compounded
24 positron emission tomography drug shall
25 be subject under subparagraph (A) to one-

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

6 “(ii) EXCEPTION FROM ANNUAL ES-
7 TABLISHMENT FEE.—Each person who is
8 named as the applicant in an application
9 described in clause (i) shall not be assessed
10 an annual establishment fee for a fiscal
11 year if the person certifies to the Sec-
12 retary, at a time specified by the Secretary
13 and using procedures specified by the Sec-
14 retary, that—

15 “(I) the person is a not-for-profit
16 medical center that has only 1 estab-
17 lishment for the production of com-
18 pounded positron emission tomog-
19 raphy drugs; and

20 “(II) at least 95 percent of the
21 total number of doses of each com-
22 pounded positron emission tomog-
23 raphy drug produced by such estab-
24 lishment during such fiscal year will
25 be used within the medical center.”.

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

3 “(b) FEE REVENUE AMOUNTS.—Except as provided
4 in subsections (c), (d), (f), and (g), fees under subsection
5 (a) shall be established to generate the following revenue
6 amounts, in each fiscal year beginning with fiscal year
7 2008 and continuing through fiscal year 2012:
8 \$392,783,000, plus an adjustment for workload on
9 \$354,893,000 of this amount. Such adjustment shall be
10 made in accordance with the workload adjustment provi-
11 sions in effect for fiscal year 2007, except that instead
12 of commercial investigational new drug applications sub-
13 mitted to the Secretary, all commercial investigational new
14 drug applications with a submission during the previous
15 12-month period shall be used in the determination. One-
16 third of the revenue amount shall be derived from applica-
17 tion fees, one-third from establishment fees, and one-third
18 from product fees.”.

19 (c) ADJUSTMENTS TO FEES.—

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

22 (A) in the matter preceding subparagraph

23 (A) by striking “The revenues established in
24 subsection (b)” and inserting “Beginning with

1 fiscal year 2009, the revenues established in
2 subsection (b)”;

3 (B) in subparagraph (A) by striking “or”
4 at the end;

5 (C) in subparagraph (B) by striking the
6 period at the end and inserting “, or,”;

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

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

15 (E) in the matter following subparagraph
16 (C) (as added by this paragraph), by striking
17 “fiscal year 2003” and inserting “fiscal year
18 2008”.

19 (2) WORKLOAD ADJUSTMENT.—Section
20 736(e)(2) (21 U.S.C. 379h(e)(2)) is amended—

21 (A) in the matter preceding subparagraph
22 (A,) by striking “2004” and inserting “2009”;

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

1 (i) by striking “, commercial inves-
2 tigational new drug applications” and in-
3 sserting “(adjusted for changes in review
4 activities)”;

5 (ii) by inserting before the period at
6 the end “, and the change in the number
7 of commercial investigational new drug ap-
8 plications with a submission during the
9 previous 12-month period (adjusted for
10 changes in review activities)”;

11 (C) in subparagraph (B), by adding at the
12 end the following new sentence: “Further, any
13 adjustment for changes in review activities
14 made in setting fees and fee revenue amounts
15 for fiscal year 2009 may not result in the total
16 workload adjustment being more than 2 per-
17 centage points higher than it would be absent
18 the adjustment for changes in review activi-
19 ties.”; and

20 (D) by adding at the end the following:

21 “(C) The Secretary shall contract with an
22 independent accounting firm to study the ad-
23 justment for changes in review activities applied
24 in setting fees for fiscal year 2009 and to make
25 recommendations, if warranted, on future

1 changes in the methodology for calculating the
2 adjustment for changes in review activity. After
3 review of the recommendations by the inde-
4 pendent accounting firm, the Secretary shall
5 make appropriate changes to the workload ad-
6 justment methodology in setting fees for fiscal
7 years 2010 through 2012. If the study is not
8 conducted, no adjustment for changes in review
9 activities shall be made after fiscal year 2009.”.

10 (3) RENT AND RENT-RELATED COST ADJUST-
11 MENT.—Section 736(c) (21 U.S.C. 379h(c)) is
12 amended—

13 (A) by redesignating paragraphs (3), (4),
14 and (5) as paragraphs (4), (5), and (6), respec-
15 tively; and

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

18 “(3) RENT AND RENT-RELATED COST ADJUST-
19 MENT.—Beginning in fiscal year 2010, the Secretary
20 shall, before making the adjustments under para-
21 graphs (1) and (2), reduce the fee amounts estab-
22 lished in subsection (b), if actual costs paid for rent
23 and rent-related expenses are less than \$11,721,000.
24 The reductions made under this paragraph, if any,
25 shall not exceed the amounts by which costs fell

1 below \$11,721,000, and shall not exceed
2 \$11,721,000 in any fiscal year.”.

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

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

7 (i) by striking “2007” each place it
8 appears and inserting “2012”; and

9 (ii) by striking “2008” and inserting
10 “2013”; and

11 (B) in paragraph (5), as redesignated by
12 this subsection, by striking “2002” and insert-
13 ing “2007”.

14 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
15 (21 U.S.C. 379h(d)) is amended—

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

18 (A) inserting “to a person who is named as
19 the applicant” after “The Secretary shall
20 grant”;

21 (B) inserting “to that person” after “a
22 waiver from or a reduction of one or more fees
23 assessed”; and

24 (C) striking “finds” and inserting “deter-
25 mines”;

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

3 (3) by inserting after paragraph (1) the fol-
4 lowing:

5 “(2) EVALUATION.—For the purpose of deter-
6 mining whether to grant a waiver or reduction of a
7 fee under paragraph (1), the Secretary shall con-
8 sider only the circumstances and assets of the appli-
9 cant and any affiliate of the applicant.”; and

10 (4) in paragraph (4), as redesignated by this
11 subsection, in subparagraph (A), by inserting before
12 the period at the end “, and that does not have a
13 drug product that has been approved under a human
14 drug application and introduced or delivered for in-
15 troduction into interstate commerce”.

16 (e) CREDITING AND AVAILABILITY OF FEES.—

17 (1) AUTHORIZATION OF APPROPRIATIONS.—
18 Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amend-
19 ed to read as follows:

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

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

3 “(4) OFFSET.—If the cumulative amount of
4 fees collected during fiscal years 2008, 2009, and
5 2010, plus the amount estimated to be collected for
6 fiscal year 2011, exceeds the amount of fees speci-
7 fied in aggregate in appropriation Acts for such fis-
8 cal years, the aggregate amount in excess shall be
9 credited to the appropriation account of the Food
10 and Drug Administration as provided in paragraph
11 (1), and shall be subtracted from the amount of fees
12 that would otherwise be authorized to be collected
13 under this section pursuant to appropriation Acts
14 for fiscal year 2012.”.

15 (f) CONFORMING AMENDMENTS.—

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

18 (A) in paragraph (1)(A), by striking “sub-
19 section (c)(4)” each place it appears and insert-
20 ing “subsection (c)(5)”;

21 (B) in paragraph (2), by striking “sub-
22 section (c)(4)” and inserting “subsection
23 (c)(5)”; and

1 (C) in paragraph (3), by striking “sub-
2 section (c)(4)” and inserting “subsection
3 (c)(5)”.

4 (2) Section 736A(h)(3), as added by section
5 104 of this title, is amended by striking “735(3)”
6 and inserting “735(d)(3)”.

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

9 Chapter VII, subchapter C, part 2 (21 U.S.C. 379g
10 et seq.) is amended by adding after section 736 the fol-
11 lowing new section:

12 **“SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE**
13 **ADVISORY REVIEW OF PRESCRIPTION DRUG**
14 **ADVERTISING.**

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

19 “(1) ADVISORY REVIEW FEE.—

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

1 dissemination shall be subject to a fee estab-
2 lished under subsection (c)(3).

3 “(B) EXCEPTION FOR REQUIRED SUBMIS-
4 SIONS.—A direct-to-consumer television adver-
5 tisement that is required to be submitted to the
6 Secretary prior to initial public dissemination
7 shall not be assessed a fee unless the sponsor
8 designates it as a submission for advisory re-
9 view.

10 “(C) PAYMENT.—The fee required by sub-
11 paragraph (A) shall be due no later than Octo-
12 ber 1 of the fiscal year in which the direct-to-
13 consumer television advertisement shall be sub-
14 mitted to the Secretary for advisory review.

15 “(D) MODIFICATION OF ADVISORY REVIEW
16 FEE.—

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

1 vision advertisement is submitted by such
2 person to the Secretary for advisory re-
3 view. Notwithstanding any other provision
4 of this section, such fees shall be due and
5 payable for each of those advisory reviews
6 in the amount of 150 percent of the advi-
7 sory review fee established for that fiscal
8 year pursuant to subsection (c)(3).

9 “(ii) LATE NOTICE OF SUBMISSION.—

10 If any person submits any direct-to-con-
11 sumer television advertisements for advi-
12 sory review that are in excess of the num-
13 ber identified by that person in response to
14 the Federal Register notice described in
15 subsection (c)(3)(A), that person must pay
16 a fee for each of those advisory reviews in
17 the amount of 150 percent of the advisory
18 review fee established for that fiscal year
19 pursuant to subsection (c)(3). Fees under
20 this subparagraph shall be due 20 days be-
21 fore the direct-to-consumer television ad-
22 vertisement is submitted by such person to
23 the Secretary for advisory review.

24 “(E) LIMITS.—

1 “(i) IN GENERAL.—The payment of a
2 fee under this paragraph for a fiscal year
3 entitles the person that pays the fee to ac-
4 ceptance for advisory review by the Sec-
5 retary of 1 direct-to-consumer television
6 advertisement and acceptance of 1 resub-
7 mission for advisory review of the same ad-
8 vertisement. The advertisement shall be
9 submitted for review in the fiscal year for
10 which the fee was assessed, except that a
11 person may carry over no more than 1
12 paid advisory review submission to the next
13 fiscal year. Resubmissions may be sub-
14 mitted without regard to the fiscal year of
15 the initial advisory review submission.

16 “(ii) NO REFUND.—Except as pro-
17 vided by subsection (f), fees paid under
18 this paragraph shall not be refunded.

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

23 “(iv) NON-TRANSFERABILITY.—The
24 right to an advisory review is not transfer-
25 able, except to a successor in interest.

1 “(2) OPERATING RESERVE FEE.—

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

8 “(B) PAYMENT.—Except as provided in
9 subparagraph (C), the fee required by subpara-
10 graph (A) shall be due no later than October 1
11 of the first fiscal year in which the person is re-
12 quired to pay an advisory review fee under
13 paragraph (1).

14 “(C) LATE NOTICE OF SUBMISSION.—If, in
15 the first fiscal year of a person’s participation
16 in the Program, that person submits any direct-
17 to-consumer television advertisements for advisory
18 review that are in excess of the number
19 identified by that person in response to the
20 Federal Register notice described in subsection
21 (c)(3)(A), that person must pay an operating
22 reserve fee for each of those advisory reviews
23 equal to the advisory review fee for each sub-
24 mission established under paragraph (1)(D)(ii).
25 Fees required by this subparagraph shall be in

1 addition to the fees required under subpara-
2 graph (B), if any. Fees under this subpara-
3 graph shall be due 20 days before any direct-
4 to-consumer television advertisement is sub-
5 mitted by such person to the Secretary for advi-
6 sory review.

7 “(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—
8 Fees under subsection (a)(1) shall be established to gen-
9 erate revenue amounts of \$6,250,000 for each of fiscal
10 years 2008 through 2012, as adjusted pursuant to sub-
11 section (c).

12 “(c) ADJUSTMENTS.—

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

18 “(A) the total percentage change that oc-
19 curred in the Consumer Price Index for all
20 urban consumers (all items; United States city
21 average), for the 12-month period ending June
22 30 preceding the fiscal year for which fees are
23 being established;

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

1 eral Schedule in accordance with section 5332
2 of title 5, as adjusted by any locality-based
3 comparability payment pursuant to section
4 5304 of such title for Federal employees sta-
5 tioned in the District of Columbia; or

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

12 The adjustment made each fiscal year by this sub-
13 section shall be added on a compounded basis to the
14 sum of all adjustments made each fiscal year after
15 fiscal year 2008 under this subsection.

16 “(2) WORKLOAD ADJUSTMENT.—

17 “(A) IN GENERAL.—Beginning with fiscal
18 year 2009, after the fee revenues established in
19 subsection (b) of this section are adjusted for a
20 fiscal year for inflation in accordance with para-
21 graph (1), the fee revenues shall be adjusted
22 further for such fiscal year to reflect changes in
23 the workload of the Secretary with respect to
24 the submission of proposed direct-to-consumer

1 television advertisements for advisory review
2 prior to initial broadcast.

3 “(B) DETERMINATION OF WORKLOAD AD-
4 JUSTMENT.—

5 “(i) IN GENERAL.—The workload ad-
6 justment under this paragraph for a fiscal
7 year shall be determined by the Sec-
8 retary—

9 “(I) based upon the number of
10 direct-to-consumer television adver-
11 tisements identified pursuant to para-
12 graph (3)(A) for that fiscal year, ex-
13 cluding allowable previously paid carry
14 over submissions; and

15 “(II) by multiplying the number
16 of such advertisements projected for
17 that fiscal year that exceeds 150 by
18 \$27,600 (adjusted each year begin-
19 ning with fiscal year 2009 for infla-
20 tion in accordance with paragraph
21 (1)).

22 “(ii) PUBLICATION IN FEDERAL REG-
23 ISTER.—The Secretary shall publish in the
24 Federal Register the fee revenues and fees

1 resulting from the adjustment and the sup-
2 porting methodologies.

3 “(C) LIMITATION.—Under no cir-
4 cumstances shall the adjustment result in fee
5 revenues for a fiscal year that are less than the
6 fee revenues established for the prior fiscal
7 year.

8 “(3) ANNUAL FEE SETTING.—

9 “(A) NUMBER OF ADVERTISEMENTS.—The
10 Secretary shall, 120 days before the start of
11 each fiscal year, publish a notice in the Federal
12 Register requesting any person to notify the
13 Secretary within 30 days of the number of di-
14 rect-to-consumer television advertisements the
15 person intends to submit for advisory review by
16 the Secretary in the next fiscal year. Notifica-
17 tion to the Secretary of the number of adver-
18 tisements a person intends to submit for advi-
19 sory review prior to initial broadcast shall be a
20 legally binding commitment by that person to
21 pay the annual advisory review fee for that
22 number of submissions on or before October 1
23 of the fiscal year in which the advertisement is
24 intended to be submitted. A person shall at the
25 same time also notify the Secretary if such per-

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

6 “(B) ANNUAL FEE.—The Secretary shall,
7 60 days before the start of each fiscal year, es-
8 tablish, for the next fiscal year, the direct-to-
9 consumer television advertisement advisory re-
10 view fee under subsection (a)(1), based on the
11 revenue amounts established under subsection
12 (b), the adjustments provided under this sub-
13 section and the number of direct-to-consumer
14 television advertisements identified pursuant to
15 subparagraph (A), excluding allowable pre-
16 viously paid carry over submissions. The annual
17 advisory review fee shall be established by divid-
18 ing the fee revenue for a fiscal year (as ad-
19 justed pursuant to this subsection) by the num-
20 ber of direct-to-consumer television advertise-
21 ments identified pursuant to subparagraph (A),
22 excluding allowable previously paid carry over
23 submissions.

24 “(C) FISCAL YEAR 2008 FEE LIMIT.—Not-
25 withstanding subsection (b), the fee established

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

4 “(D) ANNUAL FEE LIMIT.—Notwith-
5 standing subsection (b), the fee established
6 under subparagraph (B) for a fiscal year after
7 fiscal year 2008 may not be more than 50 per-
8 cent more than the fee established for the prior
9 fiscal year.

10 “(E) LIMIT.—The total amount of fees ob-
11 ligated for a fiscal year may not exceed the
12 total costs for such fiscal year for the resources
13 allocated for the process for the advisory review
14 of prescription drug advertising.

15 “(d) OPERATING RESERVES.—

16 “(1) IN GENERAL.—The Secretary shall estab-
17 lish in the Food and Drug Administration salaries
18 and expenses appropriation account without fiscal
19 year limitation a Direct-to-Consumer Advisory Re-
20 view Operating Reserve, of at least \$6,250,000 in
21 fiscal year 2008, to continue the Program in the
22 event the fees collected in any subsequent fiscal year
23 pursuant to subsection (c)(3) do not generate the fee
24 revenue amount established for that fiscal year.

1 “(2) FEE SETTING.—The Secretary shall estab-
2 lish the operating reserve fee under subsection
3 (a)(2)(A) for each person required to pay the fee by
4 multiplying the number of direct-to-consumer tele-
5 vision advertisements identified by that person pur-
6 suant to subsection (c)(3)(A) by the advisory review
7 fee established pursuant to subsection (c)(3) for that
8 fiscal year. In no case shall the operating reserve fee
9 assessed be less than the operating reserve fee as-
10 sessed if the person had first participated in the
11 Program in fiscal year 2008.

12 “(3) USE OF OPERATING RESERVE.—The Sec-
13 retary may use funds from the reserves under this
14 subsection only to the extent necessary in any fiscal
15 year to make up the difference between the fee rev-
16 enue amount established for that fiscal year under
17 subsection (b) and the amount of fees collected for
18 that fiscal year pursuant to subsection (a), or to pay
19 costs of ending the Program if it is terminated pur-
20 suant to subsection (f) or if it is not reauthorized
21 after fiscal year 2012.

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

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

8 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
9 standing any other law or regulation of the Secretary, a
10 submission for advisory review of a direct-to-consumer tel-
11 evision advertisement submitted by a person subject to
12 fees under subsection (a) shall be considered incomplete
13 and shall not be accepted for review by the Secretary until
14 all fees owed by such person under this section have been
15 paid.

16 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
17 GRAM.—

18 “(1) FIRST FISCAL YEAR.—If on November 1,
19 2007, or 120 days after enactment of the Prescrip-
20 tion Drug User Fee Amendments of 2007, whichever
21 is later, the Secretary has received less than
22 \$11,250,000 in advisory review fees and operating
23 reserve fees combined, the Program shall be termi-
24 nated and all collected fees shall be refunded.

1 “(2) SUBSEQUENT FISCAL YEARS.—Beginning
2 in fiscal year 2009, if, on November 1 of a fiscal
3 year, the combination of the operating reserves, an-
4 nual fee revenues from that fiscal year, and unobli-
5 gated fee revenues from prior fiscal years is less
6 than \$9,000,000, adjusted for inflation (in accord-
7 ance with subsection (c)(1)), the Program shall be
8 terminated, and the Secretary shall notify all partici-
9 pants, retain any money from the unused advisory
10 review fees and the operating reserves needed to ter-
11 minate the Program, and refund the remainder of
12 the unused fees and operating reserves. To the ex-
13 tent required to terminate the Program, the Sec-
14 retary shall first use unobligated advisory review fee
15 revenues from prior fiscal years, then the operating
16 reserves, and then unused advisory review fees from
17 the relevant fiscal year.

18 “(g) CREDITING AND AVAILABILITY OF FEES.—

19 “(1) IN GENERAL.—Fees authorized under sub-
20 section (a) shall be collected and available for obliga-
21 tion only to the extent and in the amount provided
22 in advance in appropriations Acts. Such fees are au-
23 thorized to remain available until expended. Such
24 sums as may be necessary may be transferred from
25 the Food and Drug Administration salaries and ex-

1 penses appropriation account without fiscal year lim-
2 itation to such appropriation account for salaries
3 and expenses with such fiscal year limitation. The
4 sums transferred shall be available solely for the
5 process for the advisory review of prescription drug
6 advertising.

7 “(2) COLLECTIONS AND APPROPRIATION
8 ACTS.—The fees authorized by this section—

9 “(A) shall be retained in each fiscal year in
10 an amount not to exceed the amount specified
11 in appropriation Acts, or otherwise made avail-
12 able for obligation for such fiscal year; and

13 “(B) shall be available for obligation only
14 if appropriated budget authority continues to
15 support at least the total combined number of
16 full-time equivalent employees in the Food and
17 Drug Administration, Center for Drug Evalua-
18 tion and Research, Division of Drug Marketing,
19 Advertising, and Communications, and the Cen-
20 ter for Biologics Evaluation and Research, Ad-
21 vertising and Promotional Labeling Branch
22 supported in fiscal year 2007.

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

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

5 “(4) OFFSET.—Any amount of fees collected
6 for a fiscal year under this section that exceeds the
7 amount of fees specified in appropriation Acts for
8 such fiscal year shall be credited to the appropria-
9 tion account of the Food and Drug Administration
10 as provided in paragraph (1), and shall be sub-
11 tracted from the amount of fees that would other-
12 wise be collected under this section pursuant to ap-
13 propriation Acts for a subsequent fiscal year.

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

15 “(1) The term ‘advisory review’ means review-
16 ing and providing advisory comments regarding com-
17 pliance of a proposed advertisement with the re-
18 quirements of this Act prior to its initial public dis-
19 semination.

20 “(2) The term ‘carry over submission’ means a
21 submission for an advisory review for which a fee
22 was paid in a fiscal year that is submitted for review
23 in the following fiscal year.

24 “(3) The term ‘direct-to-consumer television ad-
25 vertisement’ means an advertisement for a prescrip-

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

4 “(4) The term ‘person’ includes an individual,
5 a partnership, a corporation, and an association, and
6 any affiliate thereof or successor in interest.

7 “(5) The term ‘Program’ means the Program
8 to assess, collect, and use fees for the advisory re-
9 view of prescription drug advertising established by
10 this section.

11 “(6) The term ‘process for the advisory review
12 of prescription drug advertising’ means the activities
13 necessary to review and provide advisory comments
14 on proposed direct-to-consumer television advertise-
15 ments prior to public dissemination and, to the ex-
16 tent the Secretary has additional staff resources
17 available under the Program that are not necessary
18 for the advisory review of direct-to-consumer tele-
19 vision advertisements, the activities necessary to re-
20 view and provide advisory comments on other pro-
21 posed advertisements and promotional material prior
22 to public dissemination.

23 “(7) The term ‘resources allocated for the pro-
24 cess for the advisory review of prescription drug ad-
25 vertising’ means the expenses incurred in connection

1 with the process for the advisory review of prescrip-
2 tion drug advertising for—

3 “(A) officers and employees of the Food
4 and Drug Administration, contractors of the
5 Food and Drug Administration, advisory com-
6 mittees, and costs related to such officers, em-
7 ployees, and committees, and to contracts with
8 such contractors;

9 “(B) management of information, and the
10 acquisition, maintenance, and repair of com-
11 puter resources;

12 “(C) leasing, maintenance, renovation, and
13 repair of facilities and acquisition, maintenance,
14 and repair of fixtures, furniture, scientific
15 equipment, and other necessary materials and
16 supplies;

17 “(D) collection of fees under this section
18 and accounting for resources allocated for the
19 advisory review of prescription drug advertising;
20 and

21 “(E) terminating the Program under sub-
22 section (f)(2), if necessary.

23 “(8) The term ‘resubmission’ means a subse-
24 quent submission for advisory review of a direct-to-
25 consumer television advertisement that has been re-

1 vised in response to the Secretary’s comments on an
2 original submission. A resubmission may not intro-
3 duce significant new concepts or creative themes into
4 the television advertisement.

5 “(9) The term ‘submission for advisory review’
6 means an original submission of a direct-to-con-
7 sumer television advertisement for which the sponsor
8 voluntarily requests advisory comments before the
9 advertisement is publicly disseminated.

10 **“SEC. 736B. SUNSET.**

11 “‘This part shall cease to be effective on October 1,
12 2012, except that subsection (b) of section 736 with re-
13 spect to reports shall cease to be effective on January 31,
14 2013.’”.

15 **SEC. 105. SAVINGS CLAUSE.**

16 Notwithstanding section 509 of the Prescription
17 Drug User Fee Amendments of 2002 (21 U.S.C. 379g
18 note), and notwithstanding the amendments made by this
19 title, part 2 of subchapter C of chapter VII of the Federal
20 Food, Drug, and Cosmetic Act, as in effect on the day
21 before the date of enactment of this title, shall continue
22 to be in effect with respect to human drug applications
23 and supplements (as defined in such part as of such day)
24 that on or after October 1, 2002, but before October 1,
25 2007, were accepted by the Food and Drug Administra-

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

4 **SEC. 106. TECHNICAL AMENDMENT.**

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

8 **SEC. 107. EFFECTIVE DATES.**

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

12 (b) EXCEPTION.—The amendment made by section
13 104 of this title shall take effect on the date of enactment
14 of this title.

15 **TITLE II—DRUG SAFETY**

16 **SEC. 200. SHORT TITLE.**

17 This title may be cited as the “Enhancing Drug Safe-
18 ty and Innovation Act of 2007”.

19 **Subtitle A—Risk Evaluation and**
20 **Mitigation Strategies**

21 **SEC. 201. RISK EVALUATION.**

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

1 “(3) RISK IDENTIFICATION AND ASSESS-
2 MENT.—

3 “(A) ROUTINE ACTIVE SAFETY MONI-
4 TORING.—The Secretary shall facilitate a pub-
5 lic-private partnership to—

6 “(i) implement a routine active moni-
7 toring system for postmarket drug safety;
8 and

9 “(ii) focus postmarket studies under
10 subsection (o)(4)(B) and postapproval clin-
11 ical trials under subsection (o)(4)(C) more
12 effectively on cases for which reports under
13 paragraph (1) and other safety signal de-
14 tection is not sufficient to resolve whether
15 there is an elevated risk of a serious ad-
16 verse event associated with use of a drug.

17 “(B) PUBLIC-PRIVATE PARTNERSHIP.—
18 The public-private partnership described in sub-
19 paragraph (A) shall—

20 “(i) develop a mechanism for the pool-
21 ing of relevant data from Federal and pri-
22 vate electronic health care population data-
23 bases that—

24 “(I) includes, in aggregate—

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

3 “(bb) at least 100,000,000
4 patients by January 1, 2012;

5 “(II) allows access to full-text
6 medical records, where available;

7 “(III) takes into consideration
8 the need for data completeness, cod-
9 ing, cleansing, and transmission;

10 “(IV) may, on a temporary or
11 permanent basis, implement systems
12 or products developed by private enti-
13 ties; and

14 “(V) complies with the require-
15 ments of the Health Insurance Port-
16 ability and Accountability Act of
17 1996;

18 “(ii) support the routine and system-
19 atic collection and analysis of utilization
20 and safety data from such pooled data-
21 bases and from the Food and Drug Ad-
22 ministration with respect to prescription
23 drugs; and

24 “(iii) allow for prompt investigation of
25 priority drug safety questions, including—

1 “(I) unresolved safety questions
2 for drugs or classes of drugs; and

3 “(II) for a newly-approved
4 drug—

5 “(aa) safety signals from
6 clinical trials used to approve the
7 drug and other preapproval
8 trials;

9 “(bb) rare, serious drug side
10 effects; and

11 “(cc) the safety of use in do-
12 mestic populations not included
13 in the trials used to approve the
14 drug (such as older people, peo-
15 ple with comorbidities, pregnant
16 women, or children).

17 “(C) OTHER APPROACHES.—

18 “(i) IN GENERAL.—The Secretary
19 shall develop, support, and participate in
20 other approaches, including in other pub-
21 lic-private partnerships, to gather and ana-
22 lyze data and information relevant to pri-
23 ority drug safety questions, including—

24 “(I) approaches that are com-
25 plimentary to the routine active safety

1 monitoring described in subpara-
2 graphs (A) and (B), especially with
3 respect to assessing the safety of use
4 of a drug in domestic populations not
5 included in the trials used to approve
6 the drug (such as older people, people
7 with comorbidities, pregnant women,
8 or children); and

9 “(II) existing approaches such as
10 the Vaccine Adverse Event Reporting
11 System and the Vaccine Safety
12 Datalink or successor databases.

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

18 “(D) PUBLIC PROCESS FOR PRIORITY
19 QUESTIONS.—At least biannually, the Secretary
20 shall seek recommendations from the Drug
21 Safety and Risk Management Advisory Com-
22 mittee (or successor committee) and from other
23 advisory committees, as appropriate, to the
24 Food and Drug Administration on—

1 “(i) priority drug safety questions;

2 and

3 “(ii) mechanisms for answering such

4 questions, including through—

5 “(I) routine active safety moni-

6 toring; and

7 “(II) when such monitoring is

8 not sufficient, postmarket studies

9 under subsection (o)(4)(B) and post-

10 approval clinical trials under sub-

11 section (o)(4)(C).

12 “(E) ANALYSIS OF DRUG SAFETY DATA.—

13 The Secretary shall engage independent private

14 research groups, including through the Centers

15 for Education and Research on Therapeutics

16 provided for under section 905 of the Public

17 Health Service Act, to conduct analyses of data

18 relating to priority drug safety questions.

19 “(F) USE OF ANALYSES.—The Secretary

20 shall provide the analyses described under sub-

21 paragraph (E), including the methods and re-

22 sults of such analyses, about a drug to the

23 sponsor or sponsors of such drug.

24 “(G) PUBLIC AVAILABILITY OF ANAL-

25 YSES.—The Secretary shall make the analyses

1 described under subparagraph (E), including
2 the methods and results of such analyses, avail-
3 able to the public for review and comment.

4 “(H) QUALIFIED ENTITIES.—

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

10 “(ii) QUALIFICATIONS.—The Sec-
11 retary shall enter into a contract with an
12 entity under clause (i) only if the Secretary
13 determines that the entity—

14 “(I) has the research capability
15 and expertise to conduct and complete
16 the activities under this subsection;

17 “(II) has in place an information
18 technology infrastructure to support
19 adverse event surveillance data and
20 operational standards to provide secu-
21 rity for such data;

22 “(III) has experience with, and
23 expertise on, the development of drug
24 safety and effectiveness research using
25 electronic population data;

1 “(IV) has an understanding of
2 drug development and risk/benefit bal-
3 ancing in a clinical setting; and

4 “(V) has a significant business
5 presence in the United States.

6 “(I) CONTRACT REQUIREMENTS.—Each
7 contract with a qualified entity shall contain the
8 following requirements:

9 “(i) ENSURING PRIVACY.—The quali-
10 fied entity shall provide assurances that
11 the entity will not use the data provided by
12 the Secretary in a manner that violates—

13 “(I) the Federal regulations pro-
14 mulgated under section 264(c) of the
15 Health Insurance Portability and Ac-
16 countability Act of 1996 (concerning
17 the privacy of individually-identifiable
18 beneficiary health information); or

19 “(II) sections 552 or 552a of
20 title 5, United States Code, with re-
21 gard to the privacy of individually-
22 identifiable beneficiary health infor-
23 mation.

1 “(ii) COMPONENT OF ANOTHER ORGA-
2 NIZATION.—If a qualified entity is a com-
3 ponent of another organization—

4 “ (I) the qualified entity shall
5 maintain the data related to the ac-
6 tivities carried out under this sub-
7 section separate from the other com-
8 ponents of the organization and estab-
9 lish appropriate security measures to
10 maintain the confidentiality and pri-
11 vacy of such data; and

12 “ (II) the entity shall not make
13 an unauthorized disclosure of such
14 data to the other components of the
15 organization in breach of such con-
16 fidentiality and privacy requirement.

17 “(iii) TERMINATION OR NON-
18 RENEWAL.—If a contract under this sub-
19 section is terminated or not renewed, the
20 following requirements shall apply:

21 “ (I) CONFIDENTIALITY AND PRI-
22 VACY REGULATIONS.—The entity shall
23 continue to comply with the confiden-
24 tiality and privacy requirements under

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

3 “(II) DISPOSITION OF DATA.—
4 The entity shall return to the Sec-
5 retary all data disclosed to the entity
6 or, if returning the data is not prac-
7 ticable, destroy the data.

8 “(J) COMPETITIVE PROCEDURES.—The
9 Secretary shall use competitive procedures (as
10 defined in section 4(5) of the Federal Procure-
11 ment Policy Act) to enter into contracts under
12 subparagraph (C).

13 “(K) REVIEW OF CONTRACT IN THE
14 EVENT OF A MERGER OR ACQUISITION.—The
15 Secretary shall review the contract with a quali-
16 fied entity under this subsection in the event of
17 a merger or acquisition of the entity in order to
18 ensure that the requirements under this sub-
19 section will continue to be met.”.

20 (b) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated to carry out this section
22 \$30,000,000 for each of fiscal years 2008 through 2012.

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

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

5 “(o) RISK EVALUATION AND MITIGATION STRAT-
6 EGY.—

7 “(1) IN GENERAL.—In the case of any drug
8 subject to subsection (b) or to section 351 of the
9 Public Health Service Act for which a risk evalua-
10 tion and mitigation strategy is approved as provided
11 for in this subsection, the applicant shall comply
12 with the requirements of such strategy.

13 “(2) DEFINITIONS.—In this subsection:

14 “(A) ADVERSE DRUG EXPERIENCE.—The
15 term ‘adverse drug experience’ means any ad-
16 verse event associated with the use of a drug in
17 humans, whether or not considered drug re-
18 lated, including—

19 “(i) an adverse event occurring in the
20 course of the use of the drug in profes-
21 sional practice;

22 “(ii) an adverse event occurring from
23 an overdose of the drug, whether acci-
24 dental or intentional;

25 “(iii) an adverse event occurring from
26 abuse of the drug;

1 “(iv) an adverse event occurring from
2 withdrawal of the drug; and

3 “(v) any failure of expected pharma-
4 cological action of the drug.

5 “(B) NEW SAFETY INFORMATION.—The
6 term ‘new safety information’ with respect to a
7 drug means information about—

8 “(i) a serious risk or an unexpected
9 serious risk with use of the drug that the
10 Secretary has become aware of since the
11 later of—

12 “(I) the date of initial approval
13 of the drug under this section or ini-
14 tial licensure of the drug under sec-
15 tion 351 of the Public Health Service
16 Act; or

17 “(II) if applicable, the last as-
18 sessment of the approved risk evalua-
19 tion and mitigation strategy for the
20 drug; or

21 “(ii) the effectiveness of the approved
22 risk evaluation and mitigation strategy for
23 the drug obtained since the later of—

24 “(I) the approval of such strat-
25 egy; or

1 may require a medical or surgical interven-
2 tion to prevent an outcome described under
3 clause (i).

4 “(D) SERIOUS RISK.—The term ‘serious
5 risk’ means a risk of a serious adverse drug ex-
6 perience.

7 “(E) SIGNAL OF A SERIOUS RISK.—The
8 term ‘signal of a serious risk’ means informa-
9 tion related to a serious adverse drug experi-
10 ence derived from—

11 “(i) a clinical trial;

12 “(ii) adverse event reports under sub-
13 section (k)(1);

14 “(iii) routine active safety monitoring
15 under subsection (k)(3);

16 “(iv) a postapproval study, including a
17 study under paragraph (4)(B); or

18 “(v) peer-reviewed biomedical lit-
19 erature.

20 “(F) UNEXPECTED SERIOUS RISK.—The
21 term ‘unexpected serious risk’ means a serious
22 adverse drug experience that—

23 “(i) is not listed in the labeling of a
24 drug; or

1 “(ii) may be symptomatically and
2 pathophysiologically related to an adverse
3 drug experience listed in the labeling of the
4 drug, but differs from such adverse drug
5 experience because of greater severity,
6 specificity, or prevalence.

7 “(3) REQUIRED ELEMENTS OF A RISK EVALUA-
8 TION AND MITIGATION STRATEGY.—If a risk evalua-
9 tion and mitigation strategy for a drug is required,
10 such strategy shall include—

11 “(A) the labeling for the drug for use by
12 health care providers as approved under sub-
13 section (c);

14 “(B) a timetable for submission of assess-
15 ments of the strategy, that—

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

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

1 frequency specified in the strategy for
2 subsequent years; and

3 “(II) may be eliminated after the
4 first 3 years if the Secretary deter-
5 mines that serious risks of the drug
6 have been adequately identified and
7 assessed and are being adequately
8 managed;

9 “(ii) for any other drug, shall occur at
10 a frequency determined by the Secretary;
11 and

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

15 “(4) ADDITIONAL POTENTIAL EVALUATION
16 ELEMENTS OF A RISK EVALUATION AND MITIGATION
17 STRATEGY.—

18 “(A) RISK EVALUATION.—If a risk evalua-
19 tion and mitigation strategy for a drug is re-
20 quired, such strategy may include 1 or more of
21 the additional evaluation elements described in
22 this paragraph, so long as the Secretary makes
23 the determination required with respect to each
24 additional included element.

1 “(B) POSTAPPROVAL STUDIES.—If the
2 Secretary determines that the reports under
3 subsection (k)(1) and routine active safety mon-
4 itoring as available under subsection (k)(3) (in-
5 cluding available other approaches under sub-
6 section (k)(3)(C)) are not sufficient to—

7 “(i) assess a signal of a serious risk
8 with use of the drug; or

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

15 the risk evaluation and mitigation strategy for
16 a drug may require that the applicant conduct
17 an appropriate postapproval study, such as a
18 prospective or retrospective observational study,
19 of the drug (which shall include a timeframe
20 specified by the Secretary for completing the
21 study and reporting the results to the Sec-
22 retary).

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

1 toring as available under subsection (k)(3) (in-
2 cluding available other approaches under sub-
3 section (k)(3)(C)), and a study or studies under
4 subparagraph (B) will likely be inadequate to
5 assess a signal of a serious risk with use of the
6 drug, and there is no effective approved applica-
7 tion under subsection (j) as of the date that the
8 requirement is first imposed, the risk evaluation
9 and mitigation strategy for a drug may require
10 that the applicant conduct an appropriate post-
11 approval clinical trial of the drug (which shall
12 include a timeframe specified by the Secretary
13 for completing the clinical trial and reporting
14 the results to the Secretary) to be included in
15 the clinical trial registry data bank provided for
16 under subsections (i) and (j) of section 402 of
17 the Public Health Service Act.

18 “(5) ADDITIONAL POTENTIAL COMMUNICATION
19 ELEMENTS OF A RISK EVALUATION AND MITIGATION
20 STRATEGY.—

21 “(A) RISK COMMUNICATION.—If a risk
22 evaluation and mitigation strategy for a drug is
23 required, such strategy may include 1 or more
24 of the additional communication elements de-
25 scribed in this paragraph, so long as the Sec-

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

3 “(B) MEDGUIDE; PATIENT PACKAGE IN-
4 SERT.—The risk evaluation and mitigation
5 strategy for a drug may require that the appli-
6 cant develop for distribution to each patient
7 when the drug is dispensed either or both of the
8 following:

9 “(i) A Medication Guide, as provided
10 for under part 208 of title 21, Code of
11 Federal Regulations (or any successor reg-
12 ulations).

13 “(ii) A patient package insert, if the
14 Secretary determines that such insert may
15 help mitigate a serious risk listed in the la-
16 beling of the drug.

17 “(C) COMMUNICATION PLAN.—If the Sec-
18 retary determines that a communication plan to
19 health care providers may support implementa-
20 tion of an element of the risk evaluation and
21 mitigation strategy for a drug, such as a label-
22 ing change, the strategy may require that the
23 applicant conduct such a plan, which may in-
24 clude—

1 later than 45 days before dissemination of
2 the advertisement

3 “(ii) SPECIFICATION OF ADVERTISE-
4 MENTS.—The Secretary may specify the
5 advertisements required to be submitted
6 under clause (i).

7 “(E) SPECIFIC DISCLOSURES.—

8 “(i) SERIOUS RISK; SAFETY PRO-
9 TOCOL.—If the Secretary determines that
10 advertisements lacking a specific disclosure
11 about a serious risk listed in the labeling
12 of a drug or about a protocol to ensure
13 safe use described in the labeling of the
14 drug would be false or misleading, the risk
15 evaluation and mitigation strategy for the
16 drug may require that the applicant in-
17 clude in advertisements of the drug such
18 disclosure.

19 “(ii) DATE OF APPROVAL.—If the
20 Secretary determines that advertisements
21 lacking a specific disclosure of the date a
22 drug was approved and that the existing
23 information may not have identified or al-
24 lowed for full assessment of all serious
25 risks of using the drug is necessary to pro-

1 tect public health and safety, the risk eval-
2 uation and mitigation strategy for the drug
3 may require that the applicant include in
4 advertisements of the drug such disclosure

5 “(iii) SPECIFICATION OF ADVERTISE-
6 MENTS.—The Secretary may specify the
7 advertisements required to include a spe-
8 cific disclosure under clause (i) or (ii).

9 “(F) TEMPORARY MORATORIUM.—To the
10 extent consistent with the Constitution, if the
11 Secretary determines that disclosure under sub-
12 paragraph (E)(ii) is inadequate to protect pub-
13 lic health and safety, and that a prohibition of
14 direct-to-consumer advertisements of the drug
15 for a fixed period after initial approval of the
16 drug, not to exceed 2 years, is necessary to pro-
17 tect public health and safety while additional in-
18 formation about serious risks of the drug is col-
19 lected using the reports under subsection (k)(1)
20 and the routine active safety monitoring as
21 available under subsection (k)(3) (including
22 available other approaches under subsection
23 (k)(3)(C)), the risk evaluation and mitigation
24 strategy for the drug may require that the ap-
25 plicant not issue or cause to be issued direct-

1 to-consumer advertisements of the drug for
2 such fixed period. In making such determina-
3 tion, the Secretary shall consider—

4 “(i) the number of patients who may
5 be treated with the drug;

6 “(ii) the seriousness of the condition
7 for which the drug will be used;

8 “(iii) the serious risks listed in the la-
9 beling of the drug;

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

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

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

21 “(A) IN GENERAL.—When a risk evalua-
22 tion and mitigation strategy for a drug is re-
23 quired, and considering the adequacy of the la-
24 beling of the drug and 1 or more communica-
25 tion elements under paragraph (5) to mitigate

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

9 “(B) LIMITS ON RESTRICTIONS TO ASSURE
10 ACCESS AND MINIMIZE BURDEN.—Such restric-
11 tions under subparagraph (A) shall—

12 “(i) be commensurate with the spe-
13 cific, serious risk presented by the drug;

14 “(ii) not be unduly burdensome on pa-
15 tient access to the drug, considering in
16 particular—

17 “(I) patients with serious or life-
18 threatening diseases or conditions;

19 and

20 “(II) patients (such as patients
21 in rural areas) who have difficulty ac-
22 cessing health care; and

23 “(iii) to the extent practicable, so as
24 to minimize the burden on the health care
25 delivery system—

1 tion of safe-use conditions, such as labora-
2 tory test results;

3 “(v) each patient using the drug be
4 subject to certain monitoring; or

5 “(vi) each patient using the drug be
6 enrolled in a registry.

7 “(D) IMPLEMENTATION SYSTEM.—The re-
8 strictions on distribution or use described under
9 subparagraph (A) that employ elements de-
10 scribed in clauses (ii), (iii), or (iv) of subpara-
11 graph (C) may include a system through which
12 the applicant is able to—

13 “(i) monitor and evaluate implementa-
14 tion of such elements by health care pro-
15 viders, pharmacists, and other parties in
16 the health care system who are responsible
17 for implementing such elements; and

18 “(ii) work to improve implementation
19 of such elements by such persons.

20 “(E) EVALUATION OF RESTRICTIONS.—
21 The Secretary, through the Drug Safety and
22 Risk Management Advisory Committee (or suc-
23 cessor committee) of the Food and Drug Ad-
24 ministration, shall—

1 “(i) seek input from patients, physi-
2 cians, pharmacists, and other health care
3 providers about how restrictions on dis-
4 tribution or use under this paragraph for
5 1 or more drugs may be standardized so as
6 not to be—

7 “(I) unduly burdensome on pa-
8 tient access to the drug; and

9 “(II) to the extent practicable,
10 minimize the burden on the health
11 care delivery system;

12 “(ii) at least annually, evaluate, for 1
13 or more drugs, the restrictions on distribu-
14 tion or use of such drug to assess whether
15 the restrictions—

16 “(I) assure safe use of the drug;

17 “(II) are not unduly burdensome
18 on patient access to the drug; and

19 “(III) to the extent practicable,
20 minimize the burden on the health
21 care delivery system; and

22 “(iii) considering such input and eval-
23 uations—

24 “(I) issue, or modify current,
25 agency guidance about how to imple-

1 ment the requirements of this para-
2 graph; and

3 “**(II)** modify restrictions under
4 this paragraph for 1 or more drugs as
5 appropriate.

6 “**(7)** **SUBMISSION AND REVIEW OF RISK EVAL-**
7 **UATION AND MITIGATION STRATEGY.—**

8 “**(A)** **PROPOSED RISK EVALUATION AND**
9 **MITIGATION STRATEGY.—**

10 “**(i)** **VOLUNTARY PROPOSAL.—**An ap-
11 plicant may include a proposed risk evalua-
12 tion and mitigation strategy for a drug in
13 an application, including in a supplemental
14 application, under subsection (b) or section
15 351 of the Public Health Service Act for
16 the drug.

17 “**(ii)** **REQUIRED PROPOSAL.—**The ap-
18 plicant shall submit a proposed risk eval-
19 uation and mitigation strategy for a
20 drug—

21 “**(I)** within a time specified by
22 the Secretary, not to be less than 45
23 days, when ordered by the Secretary
24 (acting through the appropriate office
25 responsible for reviewing the drug and

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

5 “(aa) the labeling of the
6 drug should be changed; or

7 “(bb) an element under
8 paragraph (4) or (5) should be
9 included in a strategy for the
10 drug; or

11 “(II) within 90 days when or-
12 dered by the Secretary (acting
13 through such offices), if the Secretary
14 determines that new safety informa-
15 tion indicates that an element under
16 paragraph (6) should be included in a
17 strategy for the drug.

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

21 “(I) the new safety information
22 with respect to the drug that warrants
23 the proposal of a risk evaluation and
24 mitigation strategy for the drug; and

1 “(II) whether and how the label-
2 ing of the drug should be changed and
3 what elements under paragraphs (4),
4 (5), or (6) should be included in a
5 strategy for the drug.

6 “(iv) CONTENT OF PROPOSAL.—A
7 proposed risk evaluation and mitigation
8 strategy—

9 “(I) shall include a timetable as
10 described under paragraph (3)(B);
11 and

12 “(II) may also include additional
13 elements as provided for under para-
14 graphs (4), (5), and (6).

15 “(B) ASSESSMENT AND MODIFICATION OF
16 A RISK EVALUATION AND MITIGATION STRAT-
17 EGY.—

18 “(i) VOLUNTARY ASSESSMENTS.—If a
19 risk evaluation and mitigation strategy for
20 a drug is required, the applicant may sub-
21 mit to the Secretary an assessment of, and
22 propose a modification to, such approved
23 strategy for the drug at any time.

24 “(ii) REQUIRED ASSESSMENTS.—If a
25 risk evaluation and mitigation strategy for

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

5 “(I) when submitting an applica-
6 tion, including a supplemental appli-
7 cation, for a new indication under
8 subsection (b) or section 351 of the
9 Public Health Service Act;

10 “(II) when required by the strat-
11 egy, as provided for in the timetable
12 under paragraph (3)(B);

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

22 “(IV) within 90 days when or-
23 dered by the Secretary (acting
24 through such offices), if the Secretary
25 determines that new safety informa-

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

4 “(V) within 15 days when or-
5 dered by the Secretary (acting
6 through such offices), if the Secretary
7 determines that there may be a cause
8 for action by the Secretary under sub-
9 section (e).

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

13 “(I) the new safety information
14 with respect to the drug that warrants
15 an assessment of the approved risk
16 evaluation and mitigation strategy for
17 the drug; and

18 “(II) whether and how such
19 strategy should be modified because of
20 such information.

21 “(iv) ASSESSMENT.—An assessment
22 of the approved risk evaluation and mitiga-
23 tion strategy for a drug shall include—

1 “(I) a description of new safety
2 information, if any, with respect to
3 the drug;

4 “(II) whether and how to modify
5 such strategy because of such infor-
6 mation;

7 “(III) with respect to any post-
8 approval study required under para-
9 graph (4)(B) or otherwise undertaken
10 by the applicant to investigate a safe-
11 ty issue, the status of such study, in-
12 cluding whether any difficulties com-
13 pleting the study have been encoun-
14 tered; and

15 “(IV) with respect to any post-
16 approval clinical trial required under
17 paragraph (4)(C) or otherwise under-
18 taken by the applicant to investigate a
19 safety issue, the status of such clinical
20 trial, including whether enrollment
21 has begun, the number of participants
22 enrolled, the expected completion date,
23 whether any difficulties completing
24 the clinical trial have been encoun-
25 tered, and registration information

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

4 “(V) with respect to any goal
5 under paragraph (6) and considering
6 input and evaluations, if applicable,
7 under paragraph (6)(E), an assess-
8 ment of how well the restrictions on
9 distribution or use are meeting the
10 goal or whether the goal or such re-
11 strictions should be modified.

12 “(v) MODIFICATION.—A modification
13 (whether an enhancement or a reduction)
14 to the approved risk evaluation and mitiga-
15 tion strategy for a drug may include the
16 addition or modification of any element
17 under subparagraph (A) or (B) of para-
18 graph (3) or the addition, modification, or
19 removal of any element under paragraph
20 (4), (5), or (6), such as—

21 “(I) a labeling change, including
22 the addition of a boxed warning;

23 “(II) adding a postapproval
24 study or clinical trial requirement;

1 “(III) modifying a postapproval
2 study or clinical trial requirement
3 (such as a change in trial design due
4 to legitimate difficulties recruiting
5 participants);

6 “(IV) adding, modifying, or re-
7 moving a restriction on advertising
8 under subparagraph (D), (E), or (F)
9 of paragraph (5);

10 “(V) adding, modifying, or re-
11 moving a restriction on distribution or
12 use under paragraph (6); or

13 “(VI) modifying the timetable for
14 assessments of the strategy under
15 paragraph (3)(B), including to elimi-
16 nate assessments.

17 “(C) REVIEW.—The Secretary (acting
18 through the offices described in subparagraph
19 (A)(ii)(I)) shall promptly review the proposed
20 risk evaluation and mitigation strategy for a
21 drug submitted under subparagraph (A), or an
22 assessment of the approved risk evaluation and
23 mitigation strategy for a drug submitted under
24 subparagraph (B).

1 “(D) DISCUSSION.—The Secretary (acting
2 through the offices described in subparagraph
3 (A)(ii)(I)) shall initiate discussions of the pro-
4 posed risk evaluation and mitigation strategy
5 for a drug submitted under subparagraph
6 (A)(i), or of an assessment of the approved risk
7 evaluation and mitigation strategy for a drug
8 submitted under subparagraph (B), with the
9 applicant to determine a strategy—

10 “(i) if the proposed strategy or assess-
11 ment is submitted as part of an application
12 (including a supplemental application)
13 under subparagraph (A) or (B)(ii)(I), by
14 the target date for communication of feed-
15 back from the review team to the applicant
16 regarding proposed labeling and post-
17 marketing study commitments, as set forth
18 in the letters described in section 735(a);

19 “(ii) if the proposed strategy is sub-
20 mitted under subparagraph (A)(ii)(I) or
21 the assessment is submitted under sub-
22 clause (II) or (III) of subparagraph
23 (B)(ii), not later than 20 days after such
24 submission;

1 “(iii) if the proposed strategy is sub-
2 mitted under subparagraph (A)(ii)(II) or
3 the assessment is submitted under sub-
4 paragraph (B)(i) or under subparagraph
5 (B)(ii)(IV), not later than 30 days after
6 such submission; or

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

10 “(E) ACTION.—

11 “(i) IN GENERAL.—Unless the appli-
12 cant requests the dispute resolution proc-
13 ess as described under subparagraph (F)
14 or (G), the Secretary (acting through the
15 offices described in subparagraph
16 (A)(ii)(I)) shall approve and include the
17 risk evaluation and mitigation strategy for
18 a drug, or any modification to the strategy
19 (including a timeframe for implementing
20 such modification) with—

21 “(I) the action letter on the ap-
22 plication, when a proposed strategy is
23 submitted under subparagraph (A)(i)
24 or an assessment of the strategy is

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

3 “(II) an order, which shall be
4 made public, issued not later than 50
5 days after the date discussions of such
6 proposed strategy or modification
7 begin under subparagraph (D), when
8 a proposed strategy is submitted
9 under subparagraph (A)(ii) or an as-
10 sessment of the strategy is submitted
11 under subparagraph (B)(i) or under
12 subclause (II), (III), (IV), or (V) of
13 subparagraph (B)(ii).

14 “(ii) INACTION.—An approved risk
15 evaluation and mitigation strategy shall re-
16 main in effect until the Secretary acts, if
17 the Secretary fails to act as provided under
18 clause (i).

19 “(F) DISPUTE RESOLUTION AT INITIAL
20 APPROVAL.—When a proposed risk evaluation
21 and mitigation strategy is submitted under sub-
22 paragraph (A)(i) and there is a dispute about
23 the strategy, the applicant shall use the major
24 dispute resolution procedures as set forth in the
25 letters described in section 735(a).

1 “(G) DISPUTE RESOLUTION IN ALL OTHER
2 CASES.—

3 “(i) REQUEST FOR REVIEW.—In any
4 case other than a submission under sub-
5 paragraph (A)(i) and there is a dispute
6 about the strategy, not earlier than 15
7 days, and not later than 35 days, after dis-
8 cussions under subparagraph (D) have
9 begun, the applicant shall request in writ-
10 ing that the dispute be reviewed by the
11 Drug Safety Oversight Board.

12 “(ii) SCHEDULING REVIEW.—If the
13 applicant requests review under clause (i),
14 the Secretary—

15 “(I)(aa) shall schedule the dis-
16 pute for review at 1 of the next 2 reg-
17 ular meetings of the Drug Safety
18 Oversight Board, whichever meeting
19 date is more practicable; or

20 “(bb) may convene a special
21 meeting of the Drug Safety Oversight
22 Board to review the matter more
23 promptly, including to meet an action
24 deadline on an application (including
25 a supplemental application);

1 “(II) shall give advance notice to
2 the public through the Federal Reg-
3 ister and on the Internet website of
4 the Food and Drug Administration—

5 “(aa) that the drug is to be
6 discussed by the Drug Safety
7 Oversight Board; and

8 “(bb) the date on which the
9 Drug Safety Oversight Board
10 shall discuss such drug; and

11 “(III) shall apply section 301(j),
12 section 552 of title 5, and section
13 1905 of title 18, United States Code,
14 to any request for information about
15 such review.

16 “(iii) AGREEMENT AFTER DISCUSSION
17 OR ADMINISTRATIVE APPEALS.—

18 “(I) FURTHER DISCUSSION OR
19 ADMINISTRATIVE APPEALS.—A re-
20 quest for review under clause (i) shall
21 not preclude—

22 “(aa) further discussions to
23 reach agreement on the risk eval-
24 uation and mitigation strategy;
25 or

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

3 “(I) hear from both parties; and

4 “(II) review the dispute.

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

11 “(vi) ACTION BY THE SECRETARY.—

12 “(I) ACTION LETTER.—With re-
13 spect to a proposed risk evaluation
14 and mitigation strategy submitted
15 under subparagraph (A)(i) or to an
16 assessment of the strategy submitted
17 under subparagraph (B)(ii)(I), the
18 Secretary shall issue an action letter
19 that resolves the dispute not later
20 than the later of—

21 “(aa) the action deadline for
22 the action letter on the applica-
23 tion; or

1 supplemental application in which a pro-
2 posed risk evaluation and mitigation strat-
3 egy is submitted under subparagraph
4 (A)(i) or in which an assessment of the
5 strategy is submitted under subparagraph
6 (B)(ii)(I), the Secretary shall be considered
7 to have met the action deadline for the ac-
8 tion letter on such application if the appli-
9 cant requests the dispute resolution proc-
10 ess described in this subparagraph and if
11 the Secretary—

12 “(I) has initiated the discussions
13 described under subparagraph (D) by
14 the target date referred to in subpara-
15 graph (D)(i); and

16 “(II) has complied with the tim-
17 ing requirements of scheduling review
18 by the Drug Safety Oversight Board,
19 providing a written recommendation,
20 and issuing an action letter under
21 clauses (ii), (v), and (vi), respectively.

22 “(ix) DISQUALIFICATION.—No indi-
23 vidual who is an employee of the Food and
24 Drug Administration and who reviews a
25 drug or who participated in an administra-

1 tive appeal under clause (iii)(I) with re-
2 spect to such drug may serve on the Drug
3 Safety Oversight Board at a meeting under
4 clause (iv) to review a dispute about the
5 risk evaluation and mitigation strategy for
6 such drug.

7 “(x) ADDITIONAL EXPERTISE.—The
8 Drug Safety Oversight Board may add
9 members with relevant expertise from the
10 Food and Drug Administration, including
11 the Office of Pediatrics, the Office of
12 Women’s Health, or the Office of Rare
13 Diseases, or from other Federal public
14 health or health care agencies, for a meet-
15 ing under clause (iv) of the Drug Safety
16 Oversight Board.

17 “(H) USE OF ADVISORY COMMITTEES.—
18 The Secretary (acting through the offices de-
19 scribed in subparagraph (A)(ii)(I)) may convene
20 a meeting of 1 or more advisory committees of
21 the Food and Drug Administration to—

22 “(i) review a concern about the safety
23 of a drug or class of drugs, including be-
24 fore an assessment of the risk evaluation
25 and mitigation strategy or strategies of

1 such drug or drugs is required to be sub-
2 mitted under subclause (II), (III), (IV), or
3 (V) of subparagraph (B)(ii);

4 “(ii) review the risk evaluation and
5 mitigation strategy or strategies of a drug
6 or group of drugs; or

7 “(iii) with the consent of the appli-
8 cant, review a dispute under subparagraph
9 (G).

10 “(I) PROCESS FOR ADDRESSING DRUG
11 CLASS EFFECTS.—

12 “(i) IN GENERAL.—When a concern
13 about a serious risk of a drug may be re-
14 lated to the pharmacological class of the
15 drug, the Secretary (acting through the of-
16 fices described in subparagraph (A)(ii)(I))
17 may defer assessments of the approved
18 risk evaluation and mitigation strategies
19 for such drugs until the Secretary has—

20 “(I) convened, after appropriate
21 public notice, 1 or more public meet-
22 ings to consider possible responses to
23 such concern; or

24 “(II) gathered additional infor-
25 mation or data about such concern.

1 “(ii) PUBLIC MEETINGS.—Such public
2 meetings may include—

3 “(I) 1 or more meetings of the
4 applicants for such drugs;

5 “(II) 1 or more meetings of 1 or
6 more advisory committees of the Food
7 and Drug Administration, as provided
8 for under subparagraph (H); or

9 “(III) 1 or more workshops of
10 scientific experts and other stake-
11 holders.

12 “(iii) ACTION.—After considering the
13 discussions from any meetings under
14 clause (ii), the Secretary may—

15 “(I) announce in the Federal
16 Register a planned regulatory action,
17 including a modification to each risk
18 evaluation and mitigation strategy, for
19 drugs in the pharmacological class;

20 “(II) seek public comment about
21 such action; and

22 “(III) after seeking such com-
23 ment, issue an order addressing such
24 regulatory action.

1 “(J) INTERNATIONAL COORDINATION.—
2 The Secretary (acting through the offices de-
3 scribed in subparagraph (A)(ii)(I)) may coordi-
4 nate the timetable for submission of assess-
5 ments under paragraph (3)(B), a study under
6 paragraph (4)(B), or a clinical trial under para-
7 graph (4)(C), with efforts to identify and assess
8 the serious risks of such drug by the marketing
9 authorities of other countries whose drug ap-
10 proval and risk management processes the Sec-
11 retary deems comparable to the drug approval
12 and risk management processes of the United
13 States.

14 “(K) EFFECT.—Use of the processes de-
15 scribed in subparagraphs (I) and (J) shall not
16 delay action on an application or a supplement
17 to an application for a drug.

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

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

6 “(8) DRUG SAFETY OVERSIGHT BOARD.—

7 “(A) IN GENERAL.—There is established a
8 Drug Safety Oversight Board.

9 “(B) COMPOSITION; MEETINGS.—The
10 Drug Safety Oversight Board shall—

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

15 “(ii) include representatives from of-
16 fices throughout the Food and Drug Ad-
17 ministration (including the offices respon-
18 sible for postapproval safety of drugs);

19 “(iii) include at least 1 representative
20 each from the National Institutes of
21 Health, the Department of Health and
22 Human Services (other than the Food and
23 Drug Administration), and the Veterans
24 Health Administration; and

1 “(iv) meet at least monthly to provide
2 oversight and advice to the Secretary on
3 the management of important drug safety
4 issues.”.

5 **SEC. 203. ENFORCEMENT.**

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

9 “(x) If it is a drug subject to an approved risk evalua-
10 tion and mitigation strategy under section 505(o) and the
11 applicant for such drug fails to—

12 “(1) make a labeling change required by such
13 strategy after the Secretary has approved such strat-
14 egy or completed review of, and acted on, an assess-
15 ment of such strategy under paragraph (7) of such
16 section; or

17 “(2) comply with a requirement of such strat-
18 egy with respect to advertising as provided for under
19 subparagraph (D), (E), or (F) of paragraph (5) of
20 such section.”.

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

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

1 (2) by inserting after paragraph (2) the fol-
2 lowing:

3 “(3) An applicant (as such term is used in sec-
4 tion 505(o)) who knowingly fails to comply with a
5 requirement of an approved risk evaluation and miti-
6 gation strategy under such section 505(o) shall be
7 subject to a civil money penalty of not less than
8 \$15,000 and not more than \$250,000 per violation,
9 and not to exceed \$1,000,000 for all such violations
10 adjudicated in a single proceeding.”;

11 (3) in paragraph (2)(C), by striking “paragraph
12 (3)(A)” and inserting “paragraph (4)(A)”;

13 (4) in paragraph (4), as so redesignated, by
14 striking “paragraph (1) or (2)” each place it ap-
15 pears and inserting “paragraph (1), (2), or (3)”;
16 and

17 (5) in paragraph (6), as so redesignated, by
18 striking “paragraph (4)” each place it appears and
19 inserting “paragraph (5)”.

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

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

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

1 “(D) RISK EVALUATION AND MITIGATION STRAT-
2 EGY.—A person that submits an application for a license
3 for a drug under this paragraph may submit to the Sec-
4 retary as part of the application a proposed risk evaluation
5 and mitigation strategy as described under section 505(o)
6 of the Federal Food, Drug, and Cosmetic Act.”; and

7 (2) in subsection (j), by inserting “, including
8 the requirements under section 505(o) of such Act,”
9 after “, and Cosmetic Act”.

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

12 Section 505(e) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 355(e)) is amended by adding at
14 the end the following: “The Secretary may withdraw the
15 approval of an application submitted under this section,
16 or suspend the approval of such an application, as pro-
17 vided under this subsection, without first ordering the ap-
18 plicant to submit an assessment of the approved risk eval-
19 uation and mitigation strategy for the drug under sub-
20 section (o)(7)(B)(ii)(V).”.

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

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

1 “(D) RISK EVALUATION AND MITIGATION STRATEGY
2 REQUIREMENT.—

3 “(i) IN GENERAL.—A drug that is the subject
4 of an abbreviated new drug application under this
5 subsection shall be subject to only the following ele-
6 ments of the approved risk evaluation and mitigation
7 strategy required under subsection (o) for the appli-
8 cable listed drug:

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

11 “(II) A Medication Guide or patient pack-
12 age insert, if required under subsection
13 (o)(5)(B) for the applicable listed drug.

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

17 “(IV) Specific disclosures in advertising, if
18 required under subsection (o)(5)(E) for the ap-
19 plicable listed drug.

20 “(V) A temporary moratorium on direct-to-
21 consumer advertising, if required under sub-
22 section (o)(5)(F) for the applicable listed drug.

23 “(VI) Restrictions on distribution or use, if
24 required under subsection (o)(6) for the appli-
25 cable listed drug, except that such drug may

1 use a different, comparable aspect of such re-
2 strictions on distribution or use as are needed
3 to assure safe use of such drug if —

4 “(aa) the corresponding aspect of the
5 restrictions on distribution or use for the
6 applicable listed drug is claimed by a pat-
7 ent that has not expired or is a method or
8 process that as a trade secret is entitled to
9 protection; and

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

14 “(ii) ACTION BY SECRETARY.—For an applica-
15 ble listed drug for which a drug is approved under
16 this subsection, the Secretary—

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

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

23 “(III) shall inform the applicant for a drug
24 approved under this subsection if the approved

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

3 “(IV) in order to minimize the burden on
4 the health care delivery system of different re-
5 strictions on distribution or use for the drug
6 approved under this subsection and the applica-
7 ble listed drug, may seek to negotiate a vol-
8 untary agreement with the owner of the patent,
9 method, or process for a license under which
10 the applicant for such drug may use an aspect
11 of the restrictions on distribution or use, if re-
12 quired under subsection (o)(6) for the applica-
13 ble listed drug, that is claimed by a patent that
14 has not expired or is a method or process that
15 as a trade secret is entitled to protection.”.

16 **SEC. 207. RESOURCES.**

17 (a) USER FEES.—Subparagraph (F) of section
18 735(d)(6) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 379g(d)(6)), as amended by section 103, is
20 amended—

21 (1) in clause (ii), by striking “systems); and”
22 and inserting “systems);”

23 (2) in clause (iii), by striking “bases).” and in-
24 serting “bases); and”;

25 (3) by adding at the end the following:

1 “(iv) reviewing, implementing, and en-
2 suring compliance with risk evaluation and
3 mitigation strategies.”.

4 (b) WORKLOAD ADJUSTMENT.—Subparagraph (A) of
5 section 736(c)(2) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 379h(c)(2)), as amended by section
7 103, is amended in the first sentence by striking “and
8 manufacturing changes submitted to the Secretary, and”
9 and inserting “manufacturing changes, and assessments
10 of risk evaluation and mitigation strategies submitted to
11 the Secretary, uses of dispute resolution under the process
12 for reviewing and assessing risk evaluation and mitigation
13 strategies, and”.

14 (c) ADDITIONAL FEE REVENUES FOR DRUG SAFE-
15 TY.—Section 736 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 379h), as amended by section 103,
17 is amended by—

18 (1) striking the subsection designation and all
19 that follows through “.—Except” and inserting the
20 following:

21 “(b) FEE REVENUE AMOUNTS.—

22 “(1) IN GENERAL.—Except”; and

23 (2) adding at the end the following:

24 “(2) ADDITIONAL FEE REVENUES FOR DRUG
25 SAFETY.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (C), in each of fiscal years 2008 through
3 2012, paragraph (1) shall be applied by sub-
4 stituting the amount determined under sub-
5 paragraph (B) for ‘\$392,783,000’.

6 “(B) AMOUNT DETERMINED.—For any fis-
7 cal year 2008 through 2012, the amount deter-
8 mined under this subparagraph is the sum of—

9 “(i) \$392,783,000; plus

10 “(ii) the amount equal to—

11 “(I) \$50,000,000; minus

12 “(II) the amount equal to one-
13 fifth of the amount by which the ap-
14 propriations for salaries and expenses
15 of the Food and Drug Administration
16 for such fiscal year (excluding the
17 amount of fees appropriated for such
18 fiscal year) exceed the amount of ap-
19 propriations for the salaries and ex-
20 penses of the Food and Drug Admin-
21 istration for the fiscal year 2007 (ex-
22 cluding the amount of fees appro-
23 priated for such fiscal year), adjusted
24 as provided under subsection (c)(1).

1 In making the adjustment under subclause
2 (II) for any fiscal year 2008 through 2012,
3 subsection (c)(1) shall be applied by sub-
4 stituting ‘2007’ for ‘2008’.

5 “(C) LIMITATION.—This paragraph shall
6 not apply for any fiscal year if the amount de-
7 scribed under subparagraph (B)(ii) is less than
8 0.”.

9 (d) STRATEGIC PLAN FOR INFORMATION TECH-
10 NOLOGY.—Not later than 1 year after the date of enact-
11 ment of this title, the Secretary of Health and Human
12 Services (referred to in this subtitle as the “Secretary”)
13 shall submit to the Committee on Health, Education,
14 Labor, and Pensions and the Committee on Appropria-
15 tions of the Senate and the Committee on Energy and
16 Commerce and the Committee on Appropriations of the
17 House of Representatives, a strategic plan on information
18 technology that includes—

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

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

4 (B) achieve interoperability within and
5 among the Centers of the Food and Drug Ad-
6 ministration and between the Food and Drug
7 Administration and product application spon-
8 sors;

9 (C) utilize electronic health records; and

10 (D) implement routine active safety moni-
11 toring under section 505(k)(3) (including other
12 approaches under subsection (C) of such sec-
13 tion) of the Federal Food, Drug, and Cosmetic
14 Act, as added by section 201 of this Act;

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

19 (3) a plan for enhancing the information tech-
20 nology assets of the Food and Drug Administration
21 toward meeting the needs assessments under para-
22 graph (1); and

23 (4) an assessment of additional resources need-
24 ed to so enhance the information technology assets
25 of the Food and Drug Administration.

1 **SEC. 208. DRUG LABELING.**

2 (a) ACCESSIBLE REPOSITORY OF DRUG LABEL-
3 ING.—Not later than the effective date of this subtitle, the
4 Secretary, through the Commissioner of Food and Drugs,
5 and the Director of the National Institutes of Health, shall
6 establish a searchable repository of structured, electronic
7 product information, including the approved professional
8 labeling and any required patient labeling of each drug
9 approved under section 505 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355) or licensed under sec-
11 tion 351 of the Public Health Service Act (42 U.S.C. 262)
12 in order to improve patient safety through accessible prod-
13 uct information, support initiatives to improve patient care
14 by better management of health care information, and
15 provide standards for drug information. Such repository
16 shall be made publicly accessible on the Internet website
17 of the National Library of Medicine and through a link
18 on the homepage of the Internet website of the Food and
19 Drug Administration.

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

1 (c) REPORT.—The Secretary shall report annually to
2 the Committee on Health, Education, Labor and Pensions
3 of the Senate and the Committee on Energy and Com-
4 merce of the House of Representatives on the status of
5 the repository under subsection (a), and on progress in
6 posting structured electronic product information, includ-
7 ing posting of information regarding drugs approved prior
8 to the effective date of this subtitle.

9 (d) MEDICATION GUIDES.—Not later than the effec-
10 tive date of this subtitle, the Secretary, through the Com-
11 missioner of Food and Drugs, shall establish on the Inter-
12 net website for the repository under subsection (a), a link
13 to a list of each drug, whether approved under such sec-
14 tion 505 or licensed under such section 351, for which a
15 Medication Guide, as provided for under part 208 of title
16 21, Code of Federal Regulations (or any successor regula-
17 tions), is required.

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

19 Section 505(l) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 355(l)) is amended by—

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

24 (2) striking “(l) Safety and” and inserting
25 “(l)(1) Safety and”; and

1 (3) adding at the end the following:

2 “(2) ACTION PACKAGE FOR APPROVAL.—

3 “(A) ACTION PACKAGE.—The Secretary shall
4 publish the action package for approval of an appli-
5 cation under subsection (b) or section 351 of the
6 Public Health Service Act on the Internet website of
7 the Food and Drug Administration—

8 “(i) not later than 30 days after the date
9 of approval of such application for a drug no
10 active ingredient (including any ester or salt of
11 the active ingredient) of which has been ap-
12 proved in any other application under this sec-
13 tion or section 351 of the Public Health Service
14 Act; and

15 “(ii) not later than 30 days after the third
16 request for such action package for approval re-
17 ceived under section 552 of title 5, United
18 States Code, for any other drug.

19 “(B) CONTENTS.—An action package for ap-
20 proval of an application under subparagraph (A)
21 shall be dated and shall include the following:

22 “(i) Documents generated by the Food and
23 Drug Administration related to review of the
24 application.

1 “(ii) Documents pertaining to the format
2 and content of the application generated during
3 drug development.

4 “(iii) Labeling submitted by the applicant.

5 “(iv) A summary review that documents
6 conclusions from all reviewing disciplines about
7 the drug, noting any critical issues and dis-
8 agreements with the applicant and how they
9 were resolved, recommendation for action, and
10 an explanation of any nonconcurrence with re-
11 view conclusions.

12 “(v) If applicable, a separate review from
13 a supervisor who does not concur with the sum-
14 mary review.

15 “(vi) Identification by name of each officer
16 or employee of the Food and Drug Administra-
17 tion who—

18 “(I) participated in the decision to ap-
19 prove the application; and

20 “(II) consents to have his or her name
21 included in the package.

22 “(C) DISAGREEMENTS.—A scientific review of
23 an application is considered the work of the reviewer
24 and shall not be altered by management or the re-
25 viewer once final. Disagreements by team leaders,

1 division directors, or office directors with any or all
2 of the major conclusions of a reviewer shall be docu-
3 ment in a separate review or in an addendum to the
4 review.

5 “(D) CONFIDENTIAL INFORMATION.—This
6 paragraph does not authorize the disclosure of any
7 trade secret or confidential commercial or financial
8 information described in section 552(b)(4) of title 5,
9 United States Code, unless the Secretary determines
10 that such disclosure is necessary to protect the pub-
11 lic health.”.

12 **SEC. 210. RISK COMMUNICATION.**

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

16 **“SEC. 566. ADVISORY COMMITTEE ON RISK COMMUNICA-**
17 **TION.**

18 “(a) IN GENERAL.—The Secretary shall establish an
19 advisory committee to be known as the ‘Advisory Com-
20 mittee on Risk Communication’ (referred to in this section
21 as the ‘Committee’).

22 “(b) DUTIES OF COMMITTEE.—The Committee shall
23 advise the Commissioner on methods to effectively commu-
24 nicate risks associated with the products regulated by the
25 Food and Drug Administration.

1 “(c) MEMBERS.—The Secretary shall ensure that the
2 Committee is composed of experts on risk communication,
3 experts on the risks described in subsection (b), and rep-
4 resentatives of patient, consumer, and health professional
5 organizations.

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

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

10 Section 505 of the Federal Food, Drug, and Cosmetic
11 Act, as amended by this title, is further amended by add-
12 ing at the end the following:

13 “(p) REFERRAL TO ADVISORY COMMITTEE.—

14 “(1) IN GENERAL.—Prior to the approval of a
15 drug no active ingredient (including any ester or salt
16 of the active ingredient) of which to has been ap-
17 proved in any other application under this section or
18 section 351 of the Public Health Service Act, the
19 Secretary shall refer such drug to a Food and Drug
20 Administration advisory committee for review at a
21 meeting of such advisory committee.

22 “(2) EXCEPTION.—Notwithstanding paragraph
23 (1), an advisory committee review of a drug de-
24 scribed under such paragraph may occur within 1
25 year after approval of such a drug if—

1 “(A) the clinical trial that formed the pri-
2 mary basis of the safety and efficacy determina-
3 tion was halted by a drug safety monitoring
4 board or Institutional Review Board before its
5 scheduled completion due to early unanticipated
6 therapeutic results; or

7 “(B) the Secretary determines that it
8 would be beneficial to the public health.”.

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

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

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

19 (1) an update on the implementation by the
20 Food and Drug Administration of its plan to re-
21 spond to the Institute of Medicine report described
22 under such subsection; and

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

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

3 (B) the requirement under paragraph (7)
4 of section 505(o) of the Federal Food, Drug,
5 and Cosmetic Act (as added by this title), that
6 the appropriate office responsible for reviewing
7 a drug and the office responsible for post-
8 approval safety with respect to the drug act to-
9 gether to assess, implement, and ensure compli-
10 ance with the requirements of such section
11 505(o).

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

13 (a) EFFECTIVE DATES.—

14 (1) IN GENERAL.—Except as provided in para-
15 graph (2), this subtitle shall take effect 180 days
16 after the date of enactment of this title.

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

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

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

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

5 (A) required under section 314.520 or sec-
6 tion 601.42 of title 21, Code of Federal Regula-
7 tions; or

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

10 (2) RISK EVALUATION AND MITIGATION STRAT-
11 EGY.—The approved risk evaluation and mitigation
12 strategy deemed in effect for a drug under para-
13 graph (1) shall consist of the elements described in
14 subparagraphs (A) and (B) of paragraph (3) of such
15 section 505(o) and any other additional elements
16 under paragraphs (4), (5), and (6) in effect for such
17 drug on the effective date of this subtitle.

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

22 (A) that such drug is deemed to have an
23 approved risk evaluation and mitigation strat-
24 egy pursuant to such paragraph; and

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

7 (4) ENFORCEMENT ONLY AFTER ASSESSMENT
8 AND REVIEW.—Neither the Secretary nor the Attor-
9 ney General may seek to enforce a requirement of a
10 risk evaluation and mitigation strategy deemed in ef-
11 fect under paragraph (1) before the Secretary has
12 completed review of, and acted on, the first assess-
13 ment of such strategy under such section 505(o).

14 **Subtitle B—Reagan-Udall Founda-**
15 **tion for the Food and Drug Ad-**
16 **ministration**

17 **SEC. 211. THE REAGAN-UDALL FOUNDATION FOR THE**
18 **FOOD AND DRUG ADMINISTRATION.**

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

1 **“Subchapter I—Reagan-Udall Foundation for**
2 **the Food and Drug Administration**

3 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUN-**
4 **DATION.**

5 “(a) IN GENERAL.—A nonprofit corporation to be
6 known as the Reagan-Udall Foundation for the Food and
7 Drug Administration (referred to in this subchapter as the
8 ‘Foundation’) shall be established in accordance with this
9 section. The Foundation shall be headed by an Executive
10 Director, appointed by the members of the Board of Direc-
11 tors under subsection (e). The Foundation shall not be
12 an agency or instrumentality of the United States Govern-
13 ment.

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

19 “(c) DUTIES OF THE FOUNDATION.—The Founda-
20 tion shall—

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

1 devices, including diagnostics, biologics, and drugs,
2 and the safety of food, food ingredients, and cos-
3 metics;

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

6 “(3) in consultation with the Secretary, identify
7 existing and proposed Federal intramural and extra-
8 mural research and development programs relating
9 to the goals and priorities established under para-
10 graph (2), coordinate Foundation activities with
11 such programs, and minimize Foundation duplica-
12 tion of existing efforts;

13 “(4) award grants to, or enter into contracts,
14 memoranda of understanding, or cooperative agree-
15 ments with, scientists and entities, which may in-
16 clude the Food and Drug Administration, university
17 consortia, public-private partnerships, institutions of
18 higher education, entities described in section
19 501(c)(3) of the Internal Revenue Code (and exempt
20 from tax under section 501(a) of such Code), and
21 industry, to efficiently and effectively advance the
22 goals and priorities established under paragraph (2);

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

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

3 “(6) release and publish information and data
4 and, to the extent practicable, license, distribute,
5 and release material, reagents, and techniques to
6 maximize, promote, and coordinate the availability of
7 such material, reagents, and techniques for use by
8 the Food and Drug Administration, nonprofit orga-
9 nizations, and academic and industrial researchers
10 to further the goals and priorities established under
11 paragraph (2);

12 “(7) ensure that—

13 “(A) action is taken as necessary to obtain
14 patents for inventions developed by the Founda-
15 tion or with funds from the Foundation;

16 “(B) action is taken as necessary to enable
17 the licensing of inventions developed by the
18 Foundation or with funds from the Foundation;
19 and

20 “(C) executed licenses, memoranda of un-
21 derstanding, material transfer agreements, con-
22 tracts, and other such instruments, promote, to
23 the maximum extent practicable, the broadest
24 conversion to commercial and noncommercial
25 applications of licensed and patented inventions

1 of the Foundation to further the goals and pri-
2 orities established under paragraph (2);

3 “(8) provide objective clinical and scientific in-
4 formation to the Food and Drug Administration
5 and, upon request, to other Federal agencies to as-
6 sist in agency determinations of how to ensure that
7 regulatory policy accommodates scientific advances
8 and meets the agency’s public health mission;

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

11 “(10) carry out such other activities consistent
12 with the purposes of the Foundation as the Board
13 determines appropriate.

14 “(d) BOARD OF DIRECTORS.—

15 “(1) ESTABLISHMENT.—

16 “(A) IN GENERAL.—The Foundation shall
17 have a Board of Directors (referred to in this
18 subchapter as the ‘Board’), which shall be com-
19 posed of ex officio and appointed members in
20 accordance with this subsection. All appointed
21 members of the Board shall be voting members.

22 “(B) EX OFFICIO MEMBERS.—The ex offi-
23 cio members of the Board shall be the following
24 individuals or their designees:

1 “(i) The Commissioner of Food and
2 Drugs.

3 “(ii) The Director of the National In-
4 stitutes of Health.

5 “(iii) The Director of the Centers for
6 Disease Control and Prevention.

7 “(iv) The Director of the Agency for
8 Healthcare Research and Quality.

9 “(C) APPOINTED MEMBERS.—

10 “(i) IN GENERAL.—The ex officio
11 members of the Board under subparagraph
12 (B) shall, by majority vote, appoint to the
13 Board 12 individuals, from a list of can-
14 didates to be provided by the National
15 Academy of Sciences. Of such appointed
16 members—

17 “(I) 4 shall be representatives of
18 the general pharmaceutical, device,
19 food, cosmetic, and biotechnology in-
20 dustries;

21 “(II) 3 shall be representatives of
22 academic research organizations;

23 “(III) 2 shall be representatives
24 of Government agencies, including the

1 Food and Drug Administration and
2 the National Institutes of Health;

3 “(IV) 2 shall be representatives
4 of patient or consumer advocacy orga-
5 nizations; and

6 “(V) 1 shall be a representative
7 of health care providers.

8 “(ii) REQUIREMENT.—The ex officio
9 members shall ensure the Board member-
10 ship includes individuals with expertise in
11 areas including the sciences of developing,
12 manufacturing, and evaluating the safety
13 and effectiveness of devices, including
14 diagnostics, biologics, and drugs, and the
15 safety of food, food ingredients, and cos-
16 metics.

17 “(D) INITIAL MEETING.—

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

24 “(I) incorporate the Foundation;
25 and

1 “(II) appoint the members of the
2 Board in accordance with subpara-
3 graph (C).

4 “(ii) SERVICE OF EX OFFICIO MEM-
5 BERS.—Upon the appointment of the
6 members of the Board under clause (i)(II),
7 the terms of service of the ex officio mem-
8 bers of the Board as members of the
9 Board shall terminate.

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

14 “(2) DUTIES OF BOARD.—The Board shall—

15 “(A) establish bylaws for the Foundation
16 that—

17 “(i) are published in the Federal Reg-
18 ister and available for public comment;

19 “(ii) establish policies for the selection
20 of the officers, employees, agents, and con-
21 tractors of the Foundation;

22 “(iii) establish policies, including eth-
23 ical standards, for the acceptance, sollicita-
24 tion, and disposition of donations and
25 grants to the Foundation and for the dis-

1 position of the assets of the Foundation,
2 including strict limits on the ability of do-
3 nors to include stipulations or restrictions
4 on the use of donated funds;

5 “(iv) establish policies that would sub-
6 ject all employees, fellows, and trainees of
7 the Foundation to the conflict of interest
8 standards under section 208 of title 18,
9 United States Code;

10 “(v) establish licensing, distribution,
11 and publication policies that support the
12 widest and least restrictive use by the pub-
13 lic of information and inventions developed
14 by the Foundation or with Foundation
15 funds to carry out the duties described in
16 paragraphs (6) and (7) of subsection (c),
17 and may include charging cost-based fees
18 for published material produced by the
19 Foundation;

20 “(vi) specify principles for the review
21 of proposals and awarding of grants and
22 contracts that include peer review and that
23 are consistent with those of the Founda-
24 tion for the National Institutes of Health,

1 to the extent determined practicable and
2 appropriate by the Board;

3 “(vii) specify a cap on administrative
4 expenses for recipients of a grant, con-
5 tract, or cooperative agreement from the
6 Foundation;

7 “(viii) establish policies for the execu-
8 tion of memoranda of understanding and
9 cooperative agreements between the Foun-
10 dation and other entities, including the
11 Food and Drug Administration;

12 “(ix) establish policies for funding
13 training fellowships, whether at the Foun-
14 dation, academic or scientific institutions,
15 or the Food and Drug Administration, for
16 scientists, doctors, and other professionals
17 who are not employees of regulated indus-
18 try, to foster greater understanding of and
19 expertise in new scientific tools,
20 diagnostics, manufacturing techniques, and
21 potential barriers to translating basic re-
22 search into clinical and regulatory practice;

23 “(x) specify a process for annual
24 Board review of the operations of the
25 Foundation; and

1 “(xi) establish specific duties of the
2 Executive Director;

3 “(B) prioritize and provide overall direc-
4 tion to the activities of the Foundation;

5 “(C) evaluate the performance of the Exec-
6 utive Director; and

7 “(D) carry out any other necessary activi-
8 ties regarding the functioning of the Founda-
9 tion.

10 “(3) TERMS AND VACANCIES.—

11 “(A) TERM.—The term of office of each
12 member of the Board appointed under para-
13 graph (1)(C) shall be 4 years, except that the
14 terms of offices for the initial appointed mem-
15 bers of the Board shall expire on a staggered
16 basis as determined by the ex officio members.

17 “(B) VACANCY.—Any vacancy in the mem-
18 bership of the Board—

19 “(i) shall not affect the power of the
20 remaining members to execute the duties
21 of the Board; and

22 “(ii) shall be filled by appointment by
23 the appointed members described in para-
24 graph (1)(C) by majority vote.

1 “(C) PARTIAL TERM.—If a member of the
2 Board does not serve the full term applicable
3 under subparagraph (A), the individual ap-
4 pointed under subparagraph (B) to fill the re-
5 sulting vacancy shall be appointed for the re-
6 mainder of the term of the predecessor of the
7 individual.

8 “(D) SERVING PAST TERM.—A member of
9 the Board may continue to serve after the expi-
10 ration of the term of the member until a suc-
11 cessor is appointed.

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

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

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

25 “(g) EXECUTIVE DIRECTOR.—

1 “(1) IN GENERAL.—The Board shall appoint an
2 Executive Director who shall serve at the pleasure of
3 the Board. The Executive Director shall be respon-
4 sible for the day-to-day operations of the Foundation
5 and shall have such specific duties and responsibil-
6 ities as the Board shall prescribe.

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

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

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

16 “(2) hire, promote, compensate, and discharge
17 1 or more officers, employees, and agents, as may be
18 necessary, and define their duties;

19 “(3) prescribe the manner in which—

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

22 “(B) general operations of the Foundation
23 are to be conducted; and

24 “(C) the privileges granted to the Board
25 by law are exercised and enjoyed;

1 “(4) with the consent of the applicable executive
2 department or independent agency, use the informa-
3 tion, services, and facilities of such department or
4 agencies in carrying out this section;

5 “(5) enter into contracts with public and pri-
6 vate organizations for the writing, editing, printing,
7 and publishing of books and other material;

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

11 “(7) enter into such other contracts, leases, co-
12 operative agreements, and other transactions as the
13 Board considers appropriate to conduct the activities
14 of the Foundation;

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

18 “(9) take such action as may be necessary to
19 obtain patents and licenses for devices and proce-
20 dures developed by the Foundation and its employ-
21 ees;

22 “(10) sue and be sued in its corporate name,
23 and complain and defend in courts of competent ju-
24 risdiction;

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

4 “(12) exercise other powers as set forth in this
5 section, and such other incidental powers as are nec-
6 essary to carry out its powers, duties, and functions
7 in accordance with this subchapter.

8 “(i) ACCEPTANCE OF FUNDS FROM OTHER
9 SOURCES.—The Executive Director may solicit and accept
10 on behalf of the Foundation, any funds, gifts, grants, de-
11 vises, or bequests of real or personal property made to the
12 Foundation, including from private entities, for the pur-
13 poses of carrying out the duties of the Foundation.

14 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
15 Government employees may serve on committees advisory
16 to the Foundation and otherwise cooperate with and assist
17 the Foundation in carrying out its functions, so long as
18 such employees do not direct or control Foundation activi-
19 ties.

20 “(k) DETAIL OF GOVERNMENT EMPLOYEES; FEL-
21 LOWSHIPS.—

22 “(1) DETAIL FROM FEDERAL AGENCIES.—Fed-
23 eral Government employees may be detailed from
24 Federal agencies with or without reimbursement to
25 those agencies to the Foundation at any time, and

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

7 “(2) VOLUNTARY SERVICE; ACCEPTANCE OF
8 FEDERAL EMPLOYEES.—

9 “(A) FOUNDATION.—The Executive Direc-
10 tor of the Foundation may accept the services
11 of employees detailed from Federal agencies
12 with or without reimbursement to those agen-
13 cies.

14 “(B) FOOD AND DRUG ADMINISTRATION.—
15 The Commissioner may accept the uncompen-
16 sated services of Foundation fellows or trainees.
17 Such services shall be considered to be under-
18 taking an activity under contract with the Sec-
19 retary as described in section 708.

20 “(1) ANNUAL REPORTS.—

21 “(1) REPORTS TO FOUNDATION.—Any recipient
22 of a grant, contract, fellowship, memorandum of un-
23 derstanding, or cooperative agreement from the
24 Foundation under this section shall submit to the
25 Foundation a report on an annual basis for the du-

1 ration of such grant, contract, fellowship, memo-
2 randum of understanding, or cooperative agreement,
3 that describes the activities carried out under such
4 grant, contract, fellowship, memorandum of under-
5 standing, or cooperative agreement.

6 “(2) REPORT TO CONGRESS AND THE FDA.—
7 Beginning with fiscal year 2009, the Executive Di-
8 rector shall submit to Congress and the Commis-
9 sioner an annual report that—

10 “(A) describes the activities of the Foun-
11 dation and the progress of the Foundation in
12 furthering the goals and priorities established
13 under subsection (c)(2), including the practical
14 impact of the Foundation on regulated product
15 development;

16 “(B) provides a specific accounting of the
17 source and use of all funds used by the Foun-
18 dation to carry out such activities; and

19 “(C) provides information on how the re-
20 sults of Foundation activities could be incor-
21 porated into the regulatory and product review
22 activities of the Food and Drug Administration.

23 “(m) SEPARATION OF FUNDS.—The Executive Di-
24 rector shall ensure that the funds received from the Treas-

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

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

8 (b) OTHER FOUNDATION PROVISIONS.—Chapter VII
9 (21 U.S.C. 371 et seq.) (as amended by subsection (a))
10 is amended by adding at the end the following:

11 **“SEC. 771. LOCATION OF FOUNDATION.**

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

14 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
15 **TRATION.**

16 “(a) IN GENERAL.—The Commissioner shall receive
17 and assess the report submitted to the Commissioner by
18 the Executive Director of the Foundation under section
19 770(l)(2).

20 “(b) REPORT TO CONGRESS.—Beginning with fiscal
21 year 2009, the Commissioner shall submit to Congress an
22 annual report summarizing the incorporation of the infor-
23 mation provided by the Foundation in the report described
24 under section 770(l)(2) and by other recipients of grants,
25 contracts, memoranda of understanding, or cooperative

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

3 “(c) EXTRAMURAL GRANTS.—The provisions of this
4 subchapter shall have no effect on any grant, contract,
5 memorandum of understanding, or cooperative agreement
6 between the Food and Drug Administration and any other
7 entity entered into before, on, or after the date of enact-
8 ment of the Enhancing Drug Safety and Innovation Act
9 of 2007.”.

10 (c) CONFORMING AMENDMENT.—Section 742(b) of
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379l(b)) is amended by adding at the end the following:
13 “Any such fellowships and training programs under this
14 section or under section 770(d)(2)(A)(ix) may include pro-
15 vision by such scientists and physicians of services on a
16 voluntary and uncompensated basis, as the Secretary de-
17 termines appropriate. Such scientists and physicians shall
18 be subject to all legal and ethical requirements otherwise
19 applicable to officers or employees of the Department of
20 Health and Human Services.”.

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

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

1 **“SEC. 910. OFFICE OF THE CHIEF SCIENTIST.**

2 “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-
3 retary shall establish within the Office of the Commis-
4 sioner of Food and Drugs an office to be known as the
5 Office of the Chief Scientist. The Secretary shall appoint
6 a Chief Scientist to lead such Office.

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

9 “(1) oversee, coordinate, and ensure quality and
10 regulatory focus of the intramural research pro-
11 grams of the Food and Drug Administration;

12 “(2) track and, to the extent necessary, coordi-
13 nate intramural research awards made by each cen-
14 ter of the Administration or science-based office
15 within the Office of the Commissioner, and ensure
16 that there is no duplication of research efforts sup-
17 ported by the Reagan-Udall Foundation for the
18 Food and Drug Administration;

19 “(3) develop and advocate for a budget to sup-
20 port intramural research;

21 “(4) develop a peer review process by which in-
22 tramural research can be evaluated; and

23 “(5) identify and solicit intramural research
24 proposals from across the Food and Drug Adminis-
25 tration through an advisory board composed of em-
26 ployees of the Administration that shall include—

1 “(A) representatives of each of the centers
2 and the science-based offices within the Office
3 of the Commissioner; and

4 “(B) experts on trial design, epidemiology,
5 demographics, pharmacovigilance, basic science,
6 and public health.”.

7 **Subtitle C—Clinical Trials**

8 **SEC. 221. EXPANDED CLINICAL TRIAL REGISTRY DATA** 9 **BANK.**

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

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

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

15 “(j) EXPANDED CLINICAL TRIAL REGISTRY DATA
16 BANK.—

17 “(1) DEFINITIONS; REQUIREMENT.—

18 “(A) DEFINITIONS.—In this subsection:

19 “(i) APPLICABLE DEVICE CLINICAL
20 TRIAL.—The term ‘applicable device clin-
21 ical trial’ means—

22 “(I) a prospective study of health
23 outcomes comparing an intervention
24 against a control in human subjects
25 intended to support an application

1 under section 520(m) or 515, or a re-
2 port under section 510(k), of the Fed-
3 eral Food, Drug, and Cosmetic Act
4 (other than a limited study to gather
5 essential information used to refine
6 the device or design a pivotal trial and
7 that is not intended to determine safe-
8 ty and effectiveness of a device); and

9 “(II) a pediatric postmarket sur-
10 veillance as required under section
11 522 of the Federal Food, Drug, and
12 Cosmetic Act (as amended by the Pe-
13 diatric Medical Device Safety and Im-
14 provement Act of 2007).

15 “(ii) APPLICABLE DRUG CLINICAL
16 TRIAL.—

17 “(I) IN GENERAL.—The term
18 ‘applicable drug clinical trial’ means a
19 controlled clinical investigation, other
20 than a phase I clinical investigation,
21 of a product subject to section 505 of
22 the Federal Food, Drug, and Cos-
23 metic Act or to section 351 of this
24 Act.

1 “(II) CLINICAL INVESTIGA-
2 TION.—For purposes of subclause (I),
3 the terms ‘clinical investigation’ and
4 ‘phase I’ have the meaning given
5 those terms in part 312.21 of title 21,
6 Code of Federal Regulations.

7 “(iii) CLINICAL TRIAL INFORMA-
8 TION.—The term ‘clinical trial information’
9 means those data elements that are nec-
10 essary to complete an entry in the clinical
11 trial registry data bank under paragraph
12 (2).

13 “(iv) COMPLETION DATE.—The term
14 ‘completion date’ means, with respect to an
15 applicable drug clinical trial or an applica-
16 ble device clinical trial, the date on which
17 the last patient enrolled in the clinical trial
18 has completed his or her last medical visit
19 of the clinical trial, whether the clinical
20 trial concluded according to the
21 prespecified protocol plan or was termi-
22 nated.

23 “(v) DEVICE.—The term ‘device’
24 means a device as defined in section

1 201(h) of the Federal Food, Drug, and
2 Cosmetic Act.

3 “(vi) DRUG.—The term ‘drug’ means
4 a drug as defined in section 201(g) of the
5 Federal Food, Drug, and Cosmetic Act or
6 a biological product as defined in section
7 351 of this Act.

8 “(vii) RESPONSIBLE PARTY.—The
9 term ‘responsible party’, with respect to a
10 clinical trial of a drug or device, means—

11 “(I) the sponsor of the clinical
12 trial (as defined in section 50.3 of
13 title 21, Code of Federal Regulations
14 (or any successor regulations)) or the
15 principal investigator of such clinical
16 trial if so designated by such sponsor;
17 or

18 “(II) if no sponsor exists, the
19 grantee, contractor, or awardee for a
20 trial funded by a Federal agency or
21 the principal investigator of such clin-
22 ical trial if so designated by such
23 grantee, contractor, or awardee.

24 “(B) REQUIREMENT.—The Secretary shall
25 develop a mechanism by which—

1 “(i) the responsible party for each ap-
2 plicable drug clinical trial and applicable
3 device clinical trial shall submit the iden-
4 tity and contact information of such re-
5 sponsible party to the Secretary at the
6 time of submission of clinical trial informa-
7 tion under paragraph (2); and

8 “(ii) other Federal agencies may iden-
9 tify the responsible party for an applicable
10 drug clinical trial or applicable device clin-
11 ical trial.

12 “(2) EXPANSION OF CLINICAL TRIAL REGISTRY
13 DATA BANK WITH RESPECT TO CLINICAL TRIAL IN-
14 FORMATION.—

15 “(A) IN GENERAL.—

16 “(i) EXPANSION OF DATA BANK.—To
17 enhance patient enrollment and provide a
18 mechanism to track subsequent progress of
19 clinical trials, the Secretary, acting
20 through the Director of NIH, shall expand,
21 in accordance with this subsection, the
22 clinical trials registry of the data bank de-
23 scribed under subsection (i)(3)(A) (re-
24 ferred to in this subsection as the ‘registry
25 data bank’). The Director of NIH shall en-

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

3 “(ii) CONTENT.—Not later than 18
4 months after the date of enactment of the
5 Enhancing Drug Safety and Innovation
6 Act of 2007, and after notice and com-
7 ment, the Secretary shall promulgate regu-
8 lations to expand the registry data bank to
9 require the submission to the registry data
10 bank of clinical trial information for appli-
11 cable drug clinical trials and applicable de-
12 vice clinical trials that—

13 “(I) conforms to the Inter-
14 national Clinical Trials Registry Plat-
15 form trial registration data set of the
16 World Health Organization;

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

22 “(III) if the drug is not approved
23 under section 505 of the Federal
24 Food, Drug, and Cosmetic Act or li-
25 censed under section 351 of this Act,

1 specifies whether or not there is ex-
2 panded access to the drug under sec-
3 tion 561 of the Federal Food, Drug,
4 and Cosmetic Act for those who do
5 not qualify for enrollment in the clin-
6 ical trial and how to obtain informa-
7 tion about such access;

8 “(IV) requires the inclusion of
9 such other data elements to the reg-
10 istry data bank as appropriate; and

11 “(V) becomes effective 90 days
12 after issuance of the final rule.

13 “(B) FORMAT AND STRUCTURE.—

14 “(i) SEARCHABLE CATEGORIES.—The
15 Director of NIH shall ensure that the pub-
16 lic may search the entries in the registry
17 data bank by 1 or more of the following
18 criteria:

19 “(I) The disease or condition
20 being studied in the clinical trial,
21 using Medical Subject Headers
22 (MeSH) descriptors.

23 “(II) The treatment being stud-
24 ied in the clinical trial.

1 “(III) The location of the clinical
2 trial.

3 “(IV) The age group studied in
4 the clinical trial, including pediatric
5 subpopulations.

6 “(V) The study phase of the clin-
7 ical trial.

8 “(VI) The source of support for
9 the clinical trial, which may be the
10 National Institutes of Health or other
11 Federal agency, a private industry
12 source, or a university or other orga-
13 nization.

14 “(VII) The recruitment status of
15 the clinical trial.

16 “(VIII) The National Clinical
17 Trial number or other study identi-
18 fication of the clinical trial.

19 “(ii) **FORMAT.**—The Director of the
20 NIH shall ensure that the registry data
21 bank is easily used by the public, and that
22 entries are easily compared.

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

1 the registry data bank the clinical trial informa-
2 tion described in subparagraph (A)(ii).

3 “(D) TRUTHFUL CLINICAL TRIAL INFOR-
4 MATION.—

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

9 “(ii) EFFECT.—Clause (i) shall not
10 have the effect of requiring clinical trial in-
11 formation with respect to an applicable
12 drug clinical trial or an applicable device
13 clinical trial to include information from
14 any source other than such clinical trial in-
15 volved.

16 “(E) CHANGES IN CLINICAL TRIAL STA-
17 TUS.—

18 “(i) ENROLLMENT.—The responsible
19 party for an applicable drug clinical trial
20 or an applicable device clinical trial shall
21 update the enrollment status not later than
22 30 days after the enrollment status of such
23 clinical trial changes.

24 “(ii) COMPLETION.—The responsible
25 party for an applicable drug clinical trial

1 or applicable device clinical trial shall re-
2 port to the Director of NIH that such clin-
3 ical trial is complete not later than 30 days
4 after the completion date of the clinical
5 trial.

6 “(F) TIMING OF SUBMISSION.—The clin-
7 ical trial information for an applicable drug
8 clinical trial or an applicable device clinical trial
9 required to be submitted under this paragraph
10 shall be submitted not later than 21 days after
11 the first patient is enrolled in such clinical trial.

12 “(G) POSTING OF DATA.—

13 “(i) APPLICABLE DRUG CLINICAL
14 TRIAL.—The Director of NIH shall ensure
15 that clinical trial information for an appli-
16 cable drug clinical trial submitted in ac-
17 cordance with this paragraph is posted
18 publicly within 30 days of such submission.

19 “(ii) APPLICABLE DEVICE CLINICAL
20 TRIAL.—The Director of NIH shall ensure
21 that clinical trial information for an appli-
22 cable device clinical trial submitted in ac-
23 cordance with this paragraph is posted
24 publicly within 30 days of clearance under
25 section 510(k) of the Federal Food, Drug,

1 and Cosmetic Act, or approval under sec-
2 tion 515 or section 520(m) of such Act, as
3 applicable.

4 “(H) VOLUNTARY SUBMISSIONS.—A re-
5 sponsible party for a clinical trial that is not an
6 applicable drug clinical trial or an applicable de-
7 vice clinical trial may submit clinical trial infor-
8 mation to the registry data bank in accordance
9 with this subsection.

10 “(3) EXPANSION OF REGISTRY DATA BANK TO
11 INCLUDE RESULTS OF CLINICAL TRIALS.—

12 “(A) LINKING REGISTRY DATA BANK TO
13 EXISTING RESULTS.—

14 “(i) IN GENERAL.—Not later than 90
15 days after the date of enactment of the
16 Enhancing Drug Safety and Innovation
17 Act of 2007, for those clinical trials that
18 form the primary basis of an efficacy claim
19 or are conducted after the drug involved is
20 approved or after the device involved is
21 cleared or approved, the Secretary shall en-
22 sure that the registry data bank includes
23 links to results information for such clin-
24 ical trial—

1 “(I) not earlier than 30 days
2 after the date of the approval of the
3 drug involved or clearance or approval
4 of the device involved; or

5 “(II) not later than 30 days after
6 such information becomes publicly
7 available, as applicable.

8 “(ii) REQUIRED INFORMATION.—The
9 Secretary shall ensure that the registry
10 data bank includes links to the following
11 information:

12 “(I) FDA INFORMATION.—The
13 Secretary shall ensure that the reg-
14 istry data bank includes links to the
15 following information:

16 “(aa) If an advisory com-
17 mittee considered at a meeting
18 an applicable drug clinical trial
19 or an applicable device clinical
20 trial that is in the registry data
21 bank, any posted Food and Drug
22 Administration summary docu-
23 ment regarding such applicable
24 drug clinical trial or applicable
25 clinical device trial.

1 “(bb) If an applicable drug
2 clinical trial was conducted under
3 section 505B of the Federal
4 Food, Drug, and Cosmetic Act, a
5 link to the posted Food and Drug
6 Administration assessment of the
7 results of such trial.

8 “(cc) Food and Drug Ad-
9 ministration public health
10 advisories regarding the drug or
11 device that is the subject of the
12 applicable drug clinical trial or
13 applicable device clinical trial, re-
14 spectively, if any.

15 “(dd) For an applicable
16 drug clinical trial, the Food and
17 Drug Administration action
18 package for approval document
19 required under section 505(l)(2)
20 of the Food Drug and Cosmetic
21 Act (as added by section 209 of
22 the Enhancing Drug Safety and
23 Innovation of 2007).

24 “(ee) For an applicable de-
25 vice clinical trial, in the case of a

1 premarket application, the de-
2 tailed summary of information
3 respecting the safety and effec-
4 tiveness of a device required
5 under section 520(h)(1) of the
6 Federal Food, Drug, and Cos-
7 metic Act, or, in the case of a re-
8 port under section 510(k) of such
9 Act, the section 510(k) summary
10 of the safety and effectiveness
11 data required under section
12 807.95(d) of title 21, Code of
13 Federal Regulations (or any suc-
14 cessor regulations).

15 “(II) NIH INFORMATION.—The
16 Secretary shall ensure that the reg-
17 istry data bank includes links to the
18 following information:

19 “(aa) Medline citations to
20 any publications regarding each
21 applicable drug clinical trial and
22 applicable device clinical trial.

23 “(bb) The entry for the drug
24 that is the subject of an applica-
25 ble drug clinical trial in the Na-

1 process pursuant to subchapter IV of chap-
2 ter 5 of title 5, United States Code, to de-
3 termine, for applicable drug clinical
4 trials—

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

10 “(II) the clinical trials of which
11 the results information is appropriate
12 for adding to the expanded registry
13 data bank; and

14 “(III) the appropriate timing of
15 the posting of such results informa-
16 tion.

17 “(ii) TIME REQUIREMENT.—The proc-
18 ess described in paragraph (1) shall be
19 conducted in a timely manner to ensure
20 that—

21 “(I) any recommendation for a
22 proposed rule—

23 “(aa) is provided to the Sec-
24 retary not later than 21 months
25 after the date of the enactment

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

3 “(bb) includes an assess-
4 ment of the benefits and costs of
5 the recommendation; and

6 “(II) a final rule is promulgated
7 not later than 30 months after the
8 date of the enactment of the Enhanc-
9 ing Drug Safety and Innovation Act
10 of 2007, taking into account the rec-
11 ommendations under subclause (I)
12 and the results of the feasibility study
13 conducted under subparagraph (B).

14 “(iii) REPRESENTATION ON NEGO-
15 TIATED RULEMAKING COMMITTEE.—The
16 negotiated rulemaking committee estab-
17 lished by the Secretary pursuant to clause
18 (i) shall include members representing—

19 “(I) the Food and Drug Adminis-
20 tration;

21 “(II) the National Institutes of
22 Health;

23 “(III) other Federal agencies as
24 the Secretary determines appropriate;

1 “(IV) patient advocacy and
2 health care provider groups;

3 “(V) the pharmaceutical indus-
4 try;

5 “(VI) contract clinical research
6 organizations;

7 “(VII) the International Com-
8 mittee of Medical Journal Editors;

9 “(VIII) other interested parties,
10 including experts in privacy protec-
11 tion, pediatrics, health information
12 technology, health literacy, commu-
13 nication, clinical trial design and im-
14 plementation, and health care ethics.

15 “(iv) CONTENT OF REGULATIONS.—
16 The regulations promulgated pursuant to
17 clause (i) shall establish—

18 “(I) procedures to determine
19 which clinical trials results informa-
20 tion data elements shall be included in
21 the registry data bank, taking into ac-
22 count the needs of different popu-
23 lations of users of the registry data
24 bank;

1 “(II) a standard format for the
2 submission of clinical trials results to
3 the registry data bank;

4 “(III) a standard procedure for
5 the submission of clinical trial results
6 information, including the timing of
7 submission and the timing of posting
8 of results information, to the registry
9 data bank, taking into account the
10 possible impacts on publication of
11 manuscripts based on the clinical
12 trial;

13 “(IV) a standard procedure for
14 the verification of clinical trial results
15 information, including ensuring that
16 free text data elements are non-pro-
17 motional; and

18 “(V) an implementation plan for
19 the prompt inclusion of clinical trials
20 results information in the registry
21 data bank.

22 “(D) CONSIDERATION OF WORLD HEALTH
23 ORGANIZATION DATA SET.—The Secretary shall
24 consider the consensus data elements set for re-
25 porting clinical trial results of the World Health

1 Organization when promulgating the regula-
2 tions under subparagraph (C).

3 “(E) TRUTHFUL CLINICAL TRIAL INFOR-
4 MATION.—

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

9 “(ii) EFFECT.—Clause (i) shall not
10 have the effect of requiring clinical trial in-
11 formation with respect to an applicable
12 drug clinical trial or an applicable device
13 clinical trial to include information from
14 any source other than such clinical trial in-
15 volved.

16 “(F) WAIVERS REGARDING CERTAIN CLIN-
17 ICAL TRIAL RESULTS.—The Secretary may
18 waive any applicable requirements of this para-
19 graph for an applicable drug clinical trial or an
20 applicable device clinical trial, upon a written
21 request from the responsible person, if the Sec-
22 retary determines that extraordinary cir-
23 cumstances justify the waiver and that pro-
24 viding the waiver is in the public interest, con-
25 sistent with the protection of public health, or

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

7 “(4) COORDINATION AND COMPLIANCE.—

8 “(A) CLINICAL TRIALS SUPPORTED BY
9 GRANTS FROM FEDERAL AGENCIES.—

10 “(i) IN GENERAL.—No Federal agen-
11 cy may release funds under a research
12 grant to an awardee who has not complied
13 with paragraph (2) for any applicable drug
14 clinical trial or applicable device clinical
15 trial for which such person is the respon-
16 sible party.

17 “(ii) GRANTS FROM CERTAIN FED-
18 ERAL AGENCIES.—If an applicable drug
19 clinical trial or applicable device clinical
20 trial is funded in whole or in part by a
21 grant from the Food and Drug Adminis-
22 tration, National Institutes of Health, the
23 Agency for Healthcare Research and Qual-
24 ity, or the Department of Veterans Affairs,
25 any grant or progress report forms re-

1 required under such grant shall include a
2 certification that the responsible party has
3 made all required submissions to the Di-
4 rector of NIH under paragraph (2).

5 “(iii) VERIFICATION BY FEDERAL
6 AGENCIES.—The heads of the agencies re-
7 ferred to in clause (ii), as applicable, shall
8 verify that the clinical trial information for
9 each applicable drug clinical trial or appli-
10 cable device clinical trial for which a grant-
11 ee is the responsible party has been sub-
12 mitted under paragraph (2) before releas-
13 ing any remaining funding for a grant or
14 funding for a future grant to such grantee.

15 “(iv) NOTICE AND OPPORTUNITY TO
16 REMEDY.—If the head of an agency re-
17 ferred to in clause (ii), as applicable,
18 verifies that a grantee has not submitted
19 clinical trial information as described in
20 clause (iii), such agency head shall provide
21 notice to such grantee of such non-compli-
22 ance and allow such grantee 30 days to
23 correct such non-compliance and submit
24 the required clinical trial information.

1 “(v) CONSULTATION WITH OTHER
2 FEDERAL AGENCIES.—The Secretary
3 shall—

4 “(I) consult with other agencies
5 that conduct research involving
6 human subjects in accordance with
7 any section of part 46 of title 45,
8 Code of Federal Regulations (or any
9 successor regulations), to determine if
10 any such studies are applicable drug
11 clinical trials or applicable device clin-
12 ical trials under paragraph (1); and

13 “(II) develop with such agencies
14 procedures comparable to those de-
15 scribed in clauses (ii), (iii), and (iv) to
16 ensure that clinical trial information
17 for such applicable drug clinical trials
18 and applicable device clinical trial is
19 submitted under paragraph (2).

20 “(B) CERTIFICATION TO ACCOMPANY
21 DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUB-
22 MISSIONS.—At the time of submission of an ap-
23 plication under section 505 of the Federal
24 Food, Drug, and Cosmetic Act, section 515 of
25 such Act, section 520(m) of such Act, or section

1 351 of this Act, or submission of a report under
2 section 510(k) of such Act, such application or
3 submission shall be accompanied by a certifi-
4 cation that all applicable requirements of this
5 subsection have been met. Where available, such
6 certification shall include the appropriate Na-
7 tional Clinical Trial control numbers.

8 “(C) VERIFICATION OF SUBMISSION PRIOR
9 TO POSTING.—In the case of clinical trial infor-
10 mation that is submitted under paragraph (2),
11 but is not made publicly available pending regu-
12 latory approval or clearance, as applicable, the
13 Director of NIH shall respond to inquiries from
14 other Federal agencies and peer-reviewed sci-
15 entific journals to confirm that such clinical
16 trial information has been submitted but has
17 not yet been posted.

18 “(5) LIMITATION ON DISCLOSURE OF CLINICAL
19 TRIAL INFORMATION.—

20 “(A) IN GENERAL.—Nothing in this sub-
21 section (or under section 552 of title 5, United
22 States Code) shall require the Secretary to pub-
23 licly disclose, from any record or source other
24 than the registry data bank expanded under

1 this subsection, information described in sub-
2 paragraph (B).

3 “(B) INFORMATION DESCRIBED.—Infor-
4 mation described in this subparagraph is—

5 “(i) information submitted to the Di-
6 rector of NIH under this subsection, or in-
7 formation of the same general nature as
8 (or integrally associated with) the informa-
9 tion so submitted; and

10 “(ii) not otherwise publicly available,
11 including because it is protected from dis-
12 closure under section 552 of title 5, United
13 States Code.

14 “(6) AUTHORIZATION OF APPROPRIATIONS.—
15 There are authorized to be appropriated to carry out
16 this subsection \$10,000,000 for each fiscal year.”.

17 (b) CONFORMING AMENDMENTS.—

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

21 “(jj)(1) The failure to submit the certification re-
22 quired by section 402(j)(4)(B) of the Public Health Serv-
23 ice Act, or knowingly submitting a false certification under
24 such section.

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

5 (2) CIVIL MONEY PENALTIES.—Section 303(f)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 333(f)), as amended by section 203, is fur-
8 ther amended by—

9 (A) redesignating paragraphs (4), (5), and
10 (6) as paragraphs (5), (6), and (7), respec-
11 tively;

12 (B) inserting after paragraph (3) the fol-
13 lowing:

14 “(d) Any person who violates section 301(jj) shall be
15 subject to a civil monetary penalty of not more than
16 \$10,000 for the first violation, and not more than \$20,000
17 for each subsequent violation .”;

18 (C) in paragraph (2)(C), by striking
19 “paragraph (4)(A)” and inserting “paragraph
20 (5)(A)”;

21 (D) in paragraph (5), as so redesignated,
22 by striking “paragraph (1), (2), or (3)” each
23 place it appears and inserting “paragraph (1),
24 (2), (3), or (4)”;

1 (E) in paragraph (7), as so redesignated,
2 by striking “paragraph (5)” each place it ap-
3 pears and inserting “paragraph (6)”.

4 (3) NEW DRUGS.—

5 (A) INVESTIGATIONAL NEW DRUGS.—Sec-
6 tion 505(i) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355(i)) is amended in
8 paragraph (4), by adding at the end the fol-
9 lowing: “The Secretary shall update such regu-
10 lations to require inclusion in the informed con-
11 sent form a statement that clinical trial infor-
12 mation for such clinical investigation has been
13 or will be submitted for inclusion in the registry
14 data bank pursuant to section 402(j) of the
15 Public Health Service Act.”.

16 (B) NEW DRUG APPLICATIONS.—Section
17 505(b) of the Federal, Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(b)) is amended by
19 adding at the end the following:

20 “(6) An application submitted under this sub-
21 section shall be accompanied by the certification re-
22 quired under section 402(j)(4)(B) of the Public
23 Health Service Act. Such certification shall not be
24 considered an element of such application.”.

1 (C) DEVICE REPORTS UNDER SECTION
2 510(k).—Section 510(k) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360(k)) is
4 amended by adding at the end the following:
5 “A notification submitted under this subsection that con-
6 tains clinical trial data for an applicable device clinical
7 trial (as defined in section 402(j)(1) of the Public Health
8 Service Act) shall be accompanied by the certification re-
9 quired under section 402(j)(4)(B) of such Act. Such cer-
10 tification shall not be considered an element of such notifi-
11 cation.”.

12 (D) HUMANITARIAN DEVICE EXEMP-
13 TION.—Section 515(c) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is
15 amended—

16 (i) in subparagraph (F), by striking “;
17 and” and inserting a semicolon;

18 (ii) by redesignating subparagraph
19 (G) as subparagraph (H); and

20 (iii) by inserting after subparagraph
21 (F) the following:

22 “(G) the certification required under sec-
23 tion 402(j)(4)(B) of the Public Health Service
24 Act (which shall not be considered an element
25 of such application); and”.

1 (E) DEVICE PREMARKET APPROVAL APPLI-
2 CATION.—Section 520(m)(2) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 360e(c)) is amended in the first sentence in the
5 matter following subparagraph (C), by inserting
6 at the end before the period “and such applica-
7 tion shall include the certification required
8 under section 402(j)(4)(B) of the Public Health
9 Service Act (which shall not be considered an
10 element of such application)”.

11 (c) PREEMPTION.—

12 (1) IN GENERAL.—No State or political subdivi-
13 sion of a State may establish or continue in effect
14 any requirement for the registration of clinical trials
15 or for the inclusion of information relating to the re-
16 sults of clinical trials in a database.

17 (2) RULE OF CONSTRUCTION.—The fact of sub-
18 mission of clinical trial information, if submitted in
19 compliance with section 402(j) of the Public Health
20 Service Act (as added by this section), that relates
21 to a use of a drug or device not included in the offi-
22 cial labeling of the approved drug or device shall not
23 be construed by the Secretary or in any administra-
24 tive or judicial proceeding, as evidence of a new in-
25 tended use of the drug or device that is different

1 from the intended use of the drug or device set forth
2 in the official labeling of the drug or device. The
3 availability of clinical trial information through the
4 data bank under such section 402(j), if submitted in
5 compliance with such section 402(j), shall not be
6 considered as labeling, adulteration, or misbranding
7 of the drug or device under the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 301 et seq.).

9 (d) TRANSITION RULE; EFFECTIVE DATE OF FUND-
10 ING RESTRICTIONS.—

11 (1) TRANSITION RULE FOR CLINICAL TRIALS
12 INITIATED PRIOR TO EXPANSION OF REGISTRY DATA
13 BANK.—The responsible party (as defined in section
14 402(j)(1) of the Federal Food, Drug, and Cosmetic
15 Act (as added by this section)) for an applicable
16 drug clinical trial or applicable device clinical trial
17 (as defined under such section 402(j)(1)) that is ini-
18 tiated after the date of enactment of this subtitle
19 and before the effective date of the regulations pro-
20 mulgated under paragraph (2) of such section
21 402(j), shall submit required clinical trial informa-
22 tion under such section not later than 120 days
23 after such effective date.

24 (2) FUNDING RESTRICTIONS.—Subparagraph
25 (A) of paragraph (4) of such section 402(j) shall

1 take effect 210 days after the effective date of the
2 regulations promulgated under paragraph (2) of
3 such section 402(j).

4 (e) EFFECTIVE DATE.—Beginning 90 days after the
5 date of enactment of this Act, the responsible party for
6 an applicable drug clinical trial or an applicable device
7 clinical trial (as that term is defined in such section
8 402(j)) that is initiated after the date of enactment of this
9 Act and before the effective date of the regulations issued
10 under paragraph (2)(A) of such subsection, shall submit
11 clinical trial information under such paragraph (2).

12 **Subtitle D—Conflicts of Interest**

13 **SEC. 231. CONFLICTS OF INTEREST.**

14 (a) IN GENERAL.—Subchapter A of chapter VII of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
16 et seq.) is amended by inserting at the end the following:

17 **“SEC. 712. CONFLICTS OF INTEREST.**

18 “(a) DEFINITIONS.—For purposes of this section:

19 “(1) ADVISORY COMMITTEE.—The term ‘advi-
20 sory committee’ means an advisory committee under
21 the Federal Advisory Committee Act that provides
22 advice or recommendations to the Secretary regard-
23 ing activities of the Food and Drug Administration.

1 nications channels, the contact information
2 for the Food and Drug Administration
3 point of contact regarding advisory com-
4 mittee nominations; and

5 “(iii) developing a method through
6 which an entity receiving National Insti-
7 tutes of Health funding can identify a per-
8 son who the Food and Drug Administra-
9 tion can contact regarding the nomination
10 of individuals to serve on advisory commit-
11 tees.

12 “(2) EVALUATION AND CRITERIA.—When con-
13 sidering a term appointment to an advisory com-
14 mittee, the Secretary shall review the expertise of
15 the individual and the financial disclosure report
16 filed by the individual pursuant to the Ethics in
17 Government Act of 1978 for each individual under
18 consideration for the appointment, so as to reduce
19 the likelihood that an appointed individual will later
20 require a written determination as referred to in sec-
21 tion 208(b)(1) of title 18, United States Code, a
22 written certification as referred to in section
23 208(b)(3) of title 18, United States Code, or a waiv-
24 er as referred to in subsection (c)(3) of this section

1 for service on the committee at a meeting of the
2 committee.

3 “(c) GRANTING AND DISCLOSURE OF WAIVERS.—

4 “(1) IN GENERAL.—Prior to a meeting of an
5 advisory committee regarding a ‘particular matter’
6 (as that term is used in section 208 of title 18,
7 United States Code), each member of the committee
8 who is a full-time Government employee or special
9 Government employee shall disclose to the Secretary
10 financial interests in accordance with subsection (b)
11 of such section 208.

12 “(2) FINANCIAL INTEREST OF ADVISORY COM-
13 MITTEE MEMBER OR FAMILY MEMBER.—No member
14 of an advisory committee may vote with respect to
15 any matter considered by the advisory committee if
16 such member (or an immediate family member of
17 such member) has a financial interest that could be
18 affected by the advice given to the Secretary with re-
19 spect to such matter, excluding interests exempted
20 in regulations issued by the Director of the Office of
21 Government Ethics as too remote or inconsequential
22 to affect the integrity of the services of the Govern-
23 ment officers or employees to which such regulations
24 apply.

1 “(3) WAIVER.—The Secretary may grant a
2 waiver of the prohibition in paragraph (2) if such
3 waiver is necessary to afford the advisory committee
4 essential expertise.

5 “(4) LIMITATION.—The Secretary may not
6 grant a waiver under paragraph (3) for a member
7 of an advisory committee when the member’s own
8 scientific work is involved.

9 “(5) DISCLOSURE OF WAIVER.—Notwith-
10 standing section 107(a)(2) of the Ethics in Govern-
11 ment Act (5 U.S.C. App.), the following shall apply:

12 “(A) 15 OR MORE DAYS IN ADVANCE.—As
13 soon as practicable, but in no case later than
14 15 days prior to a meeting of an advisory com-
15 mittee to which a written determination as re-
16 ferred to in section 208(b)(1) of title 18, United
17 States Code, a written certification as referred
18 to in section 208(b)(3) of title 18, United
19 States Code, or a waiver as referred to in para-
20 graph (3) applies, the Secretary shall disclose
21 (other than information exempted from disclo-
22 sure under section 552 of title 5, United States
23 Code, and section 552a of title 5, United States
24 Code (popularly known as the Freedom of In-
25 formation Act and the Privacy Act of 1974, re-

1 spectively)) on the Internet website of the Food
2 and Drug Administration—

3 “(i) the type, nature, and magnitude
4 of the financial interests of the advisory
5 committee member to which such deter-
6 mination, certification, or waiver applies;
7 and

8 “(ii) the reasons of the Secretary for
9 such determination, certification, or waiv-
10 er.

11 “(B) LESS THAN 30 DAYS IN ADVANCE.—

12 In the case of a financial interest that becomes
13 known to the Secretary less than 30 days prior
14 to a meeting of an advisory committee to which
15 a written determination as referred to in section
16 208(b)(1) of title 18, United States Code, a
17 written certification as referred to in section
18 208(b)(3) of title 18, United States Code, or a
19 waiver as referred to in paragraph (3) applies,
20 the Secretary shall disclose (other than infor-
21 mation exempted from disclosure under section
22 552 of title 5, United States Code, and section
23 552a of title 5, United States Code) on the
24 Internet website of the Food and Drug Admin-
25 istration, the information described in clauses

1 (i) and (ii) of subparagraph (A) as soon as
2 practicable after the Secretary makes such de-
3 termination, certification, or waiver, but in no
4 case later than the date of such meeting.

5 “(d) PUBLIC RECORD.—The Secretary shall ensure
6 that the public record and transcript of each meeting of
7 an advisory committee includes the disclosure required
8 under subsection (c)(5) (other than information exempted
9 from disclosure under section 552 of title 5, United States
10 Code, and section 552a of title 5, United States Code).

11 “(e) ANNUAL REPORT.—Not later than February 1
12 of each year, the Secretary shall submit to the Inspector
13 General of the Department of Health and Human Serv-
14 ices, the Committee on Appropriations and the Committee
15 on Health, Education, Labor, and Pensions of the Senate,
16 and the Committee on Appropriations and the Committee
17 on Energy and Commerce of the House of Representatives
18 a report that describes—

19 “(1) with respect to the fiscal year that ended
20 on September 30 of the previous year, the number
21 of vacancies on each advisory committee, the number
22 of nominees received for each committee, and the
23 number of such nominees willing to serve;

24 “(2) with respect to such year, the aggregate
25 number of disclosures required under subsection

1 (c)(5) for each meeting of each advisory committee
2 and the percentage of individuals to whom such dis-
3 closures did not apply who served on such committee
4 for each such meeting;

5 “(3) with respect to such year, the number of
6 times the disclosures required under subsection
7 (c)(5) occurred under subparagraph (B) of such sub-
8 section; and

9 “(4) how the Secretary plans to reduce the
10 number of vacancies reported under paragraph (1)
11 during the fiscal year following such year, and mech-
12 anisms to encourage the nomination of individuals
13 for service on an advisory committee, including those
14 who are classified by the Food and Drug Adminis-
15 tration as academicians or practitioners.

16 “(f) PERIODIC REVIEW OF GUIDANCE.—Not less
17 than once every 5 years, the Secretary shall review guid-
18 ance of the Food and Drug Administration regarding con-
19 flict of interest waiver determinations with respect to advi-
20 sory committees and update such guidance as necessary.”.

21 (b) CONFORMING AMENDMENT.—Section 505(n) of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(n)) is amended by—

24 (1) striking paragraph (4); and

1 (2) redesignating paragraphs (5), (6), (7), and
2 (8) as paragraphs (4), (5), (6), and (7), respectively.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall take effect on October 1, 2007.

5 **TITLE III—MEDICAL DEVICES**

6 **SEC. 301. SHORT TITLE; REFERENCES.**

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

9 (b) REFERENCES.—Except as otherwise specified,
10 whenever in this title an amendment is expressed in terms
11 of an amendment to a section or other provision, the ref-
12 erence shall be considered to be made to a section or other
13 provision of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 301 et seq.).

15 **Subtitle A—Device User Fees**

16 **SEC. 302. DEVICE FEES.**

17 Section 737 (21 U.S.C. 379i) is amended—

18 (1) by striking the section designation and all
19 that follows through “For purposes of this sub-
20 chapter” and inserting the following:

21 **“SEC. 737. DEVICE FEES.**

22 “(a) PURPOSE.—It is the purpose of this part that
23 the fees authorized under this part be dedicated toward
24 expediting the process for the review of device applications
25 and for assuring the safety and effectiveness of devices,

1 as set forth in the goals identified for purposes of this
2 subchapter in the letters from the Secretary to the Chair-
3 man of the Committee on Health, Education, Labor, and
4 Pensions of the Senate and the Chairman of the Com-
5 mittee on Energy and Commerce of the House of Rep-
6 resentatives, as set forth in the Congressional Record.

7 “(b) REPORTS.—

8 “(1) PERFORMANCE REPORT.—For fiscal years
9 2008 through 2012, not later than 120 days after
10 the end of each fiscal year during which fees are col-
11 lected under this part, the Secretary shall prepare
12 and submit to the Committee on Health, Education,
13 Labor, and Pensions of the Senate and the Com-
14 mittee on Energy and Commerce of the House of
15 Representatives, a report concerning the progress of
16 the Food and Drug Administration in achieving the
17 goals identified in the letters described in subsection
18 (a) during such fiscal year and the future plans of
19 the Food and Drug Administration for meeting the
20 goals. The report for a fiscal year shall include infor-
21 mation on all previous cohorts for which the Sec-
22 retary has not given a complete response on all de-
23 vice premarket applications, supplements, and pre-
24 market notifications in the cohort.

1 “(2) FISCAL REPORT.—For fiscal years 2008
2 through 2012, not later than 120 days after the end
3 of each fiscal year during which fees are collected
4 under this part, the Secretary shall prepare and sub-
5 mit to the Committee on Health, Education, Labor,
6 and Pensions of the Senate and the Committee on
7 Energy and Commerce of the House of Representa-
8 tives, a report on the implementation of the author-
9 ity for such fees during such fiscal year and the use,
10 by the Food and Drug Administration, of the fees
11 collected during such fiscal year for which the report
12 is made.

13 “(3) PUBLIC AVAILABILITY.—The Secretary
14 shall make the reports required under paragraphs
15 (1) and (2) available to the public on the Internet
16 website of the Food and Drug Administration.

17 “(c) REAUTHORIZATION.—

18 “(1) CONSULTATION.—In developing rec-
19 ommendations to present to Congress with respect to
20 the goals, and plans for meeting the goals, for the
21 process for the review of device applications for the
22 first 5 fiscal years after fiscal year 2012, and for the
23 reauthorization of this part for such fiscal years, the
24 Secretary shall consult with—

1 “(A) the Committee on Energy and Com-
2 merce of the House of Representatives;

3 “(B) the Committee on Health, Education,
4 Labor, and Pensions of the Senate;

5 “(C) scientific and academic experts;

6 “(D) health care professionals;

7 “(E) representatives of patient and con-
8 sumer advocacy groups; and

9 “(F) the regulated industry.

10 “(2) PUBLIC REVIEW OF RECOMMENDA-
11 TIONS.—After negotiations with the regulated indus-
12 try, the Secretary shall—

13 “(A) present the recommendations devel-
14 oped under paragraph (1) to the Congressional
15 committees specified in such paragraph;

16 “(B) publish such recommendations in the
17 Federal Register;

18 “(C) provide for a period of 30 days for
19 the public to provide written comments on such
20 recommendations;

21 “(D) hold a meeting at which the public
22 may present its views on such recommenda-
23 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2012, the Secretary
6 shall transmit to Congress the revised recommenda-
7 tions under paragraph (2), a summary of the views
8 and comments received under such paragraph, and
9 any changes made to the recommendations in re-
10 sponse to such views and comments.

11 “(d) DEFINITIONS.—For purposes of this part:”;

12 (2) by redesignating paragraphs (5), (6), (7),
13 and (8), as paragraphs (7), (8), (9), and (11), re-
14 spectively;

15 (3) in paragraph (4)—

16 (A) in subparagraph (A), by striking “or
17 an efficacy supplement,” and inserting “an effi-
18 cacy supplement, or a 30-day notice,”; and

19 (B) by adding at the end the following:

20 “(F) The term ‘30-day notice’ means a supple-
21 ment to an approved premarket application or pre-
22 market report under section 515 that is limited to
23 a request to make modifications to manufacturing
24 procedures or methods of manufacture affecting the
25 safety and effectiveness of the device.”;

1 (4) by inserting after paragraph (4) the fol-
2 lowing:

3 “(5) The term ‘request for classification infor-
4 mation’ means a request made under section 513(g)
5 for information respecting the class in which a de-
6 vice has been classified or the requirements applica-
7 ble to a device.

8 “(6) The term ‘annual fee for periodic reporting
9 concerning a class III device’ means the fee associ-
10 ated with reports imposed by a premarket applica-
11 tion approval order (as described in section
12 814.82(a)(7) of title 21, Code of Federal Regula-
13 tions), usually referred to as ‘annual reports.’”;

14 (5) in paragraph (9), as redesignated by para-
15 graph (2)—

16 (A) by striking “April of” and inserting
17 “October of”; and

18 (B) by striking “April 2002” and inserting
19 “October 2001”;

20 (6) by inserting after paragraph (9), as redesign-
21 ated by paragraph (2), the following:

22 “(10) The term ‘person’ includes an affiliate of
23 such person.”; and

24 (7) by adding at the end the following:

1 “(12) The term ‘establishment subject to a reg-
2 istration fee’ means an establishment required to
3 register with the Secretary under section 510 at
4 which any of the following types of activities are
5 conducted:

6 “(A) MANUFACTURER.—An establishment
7 that makes by any means any article that is a
8 device including an establishment that sterilizes
9 or otherwise makes such article for or on behalf
10 of a specification developer or any other person.

11 “(B) SINGLE-USE DEVICE REPROC-
12 ESSOR.—An establishment that performs manu-
13 facturing operations on a single-use device.

14 “(C) SPECIFICATION DEVELOPER.—An es-
15 tablishment that develops specifications for a
16 device that is distributed under the establish-
17 ment’s name but that performs no manufac-
18 turing, including establishments that, in addi-
19 tion to developing specifications, arrange for the
20 manufacturing of devices labeled with another
21 establishment’s name by a contract manufac-
22 turer.

23 “(13) The term ‘establishment registration fee’
24 means a fee assessed under section 738(a)(3) for the

1 registration of an establishment subject to a reg-
2 istration fee.

3 “(e) SUNSET.—This part shall cease to be effective
4 on October 1, 2012, except that subsection (b) with re-
5 spect to reports shall cease to be effective January 31,
6 2013.”.

7 **SEC. 303. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

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

9 (1) in subsection (a)—

10 (A) in paragraph (2)—

11 (i) in the header, by inserting “, AND
12 ANNUAL FEE FOR PERIODIC REPORTING
13 CONCERNING A CLASS III DEVICE” after
14 “FEE”;

15 (ii) in subparagraph (A)—

16 (I) in clause (iii), by inserting
17 “75 percent of” after “a fee equal
18 to”;

19 (II) in clause (iv), by striking
20 “21.5” and inserting “15”;

21 (III) in clause (v), by striking
22 “7.2” and inserting “7”;

23 (IV) by redesignating clauses (vi)
24 and (vii) as clauses (vii) and (viii), re-
25 spectively;

1 (V) by inserting after clause (v)
2 the following:

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

6 (VI) in clause (viii), as redesign-
7 nated by subclause (IV)—

8 (aa) by striking “1.42” and
9 inserting “1.84”; and

10 (bb) by striking “, subject to
11 any adjustment under subsection
12 (e)(2)(C)(ii)”;

13 (VII) by adding at the end the
14 following:

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

18 “(x) For periodic reporting concerning
19 a class III device, the annual fee shall be
20 equal to 3.5 percent of the fee that applies
21 under clause (i).”;

22 (iii) in subparagraph (C)—

23 (I) in the first sentence—

24 (aa) by striking “or”; and

1 (bb) by striking “except
2 that” and all that follows
3 through the period and inserting
4 “, 30-day notice, request for clas-
5 sification information, or periodic
6 report concerning a class III de-
7 vice.”; and

8 (II) by striking the third sen-
9 tence; and

10 (iv) in subparagraph (D)—

11 (I) in clause (iii), by striking the
12 last two sentences; and

13 (II) by adding at the end the fol-
14 lowing:

15 “(iv) MODULAR APPLICATION WITH-
16 DRAWN BEFORE FIRST ACTION.—The Sec-
17 retary shall refund 75 percent of the appli-
18 cation fee paid for a modular application
19 submitted under section 515(c)(4) that is
20 withdrawn before a second module is sub-
21 mitted and before a first action on the first
22 module. If the modular application is with-
23 drawn after a second or subsequent module
24 is submitted but before any first action,
25 the Secretary may return a portion of the

1 fee. The amount of refund, if any, shall be
2 based on the level of effort already ex-
3 pended on the review of the modules sub-
4 mitted.

5 “(v) SOLE DISCRETION TO REFUND.—
6 The Secretary shall have sole discretion to
7 refund a fee or portion of the fee under
8 this subparagraph. A determination by the
9 Secretary concerning a refund under this
10 paragraph shall not be reviewable.”; and

11 (B) by adding at the end the following:

12 “(3) ANNUAL ESTABLISHMENT REGISTRATION
13 FEE.—

14 “(A) IN GENERAL.—Except as provided in
15 subparagraph (B), each establishment subject
16 to a registration fee shall be subject to a fee for
17 each initial or annual registration beginning
18 with its registration for fiscal year 2008.

19 “(B) EXCEPTION FOR FEDERAL OR STATE
20 GOVERNMENT ESTABLISHMENT.—No fee shall
21 be required under subparagraph (A) for an es-
22 tablishment operated by a Federal or State gov-
23 ernment entity unless a device manufactured by
24 the establishment is to be distributed commer-
25 cially.

1 “(C) PAYMENT.—The annual establish-
 2 ment registration fee shall be due once each fis-
 3 cal year, upon the initial registration of the es-
 4 tablishment or upon the annual registration
 5 under section 510.”;

6 (2) by striking subsection (b) and inserting the
 7 following:

8 “(b) FEE AMOUNTS.—Except as provided in sub-
 9 sections (c), (d), and (e), the fees under subsection (a)
 10 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 Ap- plication	\$185,000	\$200,725	\$217,787	\$236,298	\$256,384
Establishment Registration Fee	\$1,706	\$1,851	\$2,008	\$2,179	\$2,364”;

11 (3) in subsection (c)—

12 (A) in paragraph (1), by striking the sec-
 13 ond sentence;

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

16 (C) by inserting after paragraph (1) the
 17 following:

18 “(2) ADJUSTMENT OF ANNUAL ESTABLISH-
 19 MENT REGISTRATION FEE.—

1 “(A) IN GENERAL.—When setting the fees
2 for fiscal year 2010, the Secretary may increase
3 the establishment registration fee specified in
4 subsection (b) only if the Secretary estimates
5 that the number of establishments submitting
6 fees for fiscal year 2009 is less than 12,250.
7 The percent increase shall be the percent by
8 which the estimate of establishments submitting
9 fees in fiscal year 2009 is less than 12,750, but
10 in no case shall the percent increase be more
11 than 8.5 percent over the amount for such fee
12 specified in subsection (b) for fiscal year 2010.
13 If the Secretary makes any adjustment to the
14 establishment registration fee for fiscal year
15 2010, then the establishment registration fee
16 for fiscal years 2011 and 2012 under sub-
17 section (b) shall be adjusted as follows: the fee
18 for fiscal year 2011 shall be equal to the ad-
19 justed fee for fiscal year 2010, increased by 8.5
20 percent, and the fee for fiscal year 2012 shall
21 be equal to the adjusted fee for fiscal year
22 2011, increased by 8.5 percent.

23 “(B) PUBLICATION IN THE FEDERAL REG-
24 ISTER.—The Secretary shall publish any deter-
25 mination with respect to any establishment reg-

1 REVENUE SERVICE.—The applicant shall
2 support”;

3 (III) by striking “, partners, and
4 parent firms” both places the term
5 appears;

6 (IV) by striking “partners, or
7 parent firms, the” and inserting
8 “the”;

9 (V) by striking “, partners, or
10 parent firms, respectively”; and

11 (VI) by adding at the end the fol-
12 lowing:

13 “(iii) FIRMS NOT SUBMITTING TAX
14 RETURNS TO THE UNITED STATES INTER-
15 NAL REVENUE SERVICE.—The applicant
16 shall support its claim that it meets the
17 definition under subparagraph (A) by sub-
18 mission of the following:

19 “(I) A signed certification, in
20 such form as the Secretary may direct
21 through a notice published in the Fed-
22 eral Register, that the applicant meets
23 the criteria for a small business.

24 “(II) A certification, in English,
25 from the national taxing authority of

1 the country in which it is
2 headquartered. Such certification shall
3 provide the applicant's gross receipts
4 and sales for the most recent year, in
5 both the local currency and in United
6 States dollars, the exchange rate used
7 in making this conversion to dollars,
8 and the dates during which these re-
9 ceipts and sales were collected, and it
10 shall bear the official seal of the na-
11 tional taxing authority.

12 “(III) Identical certifications
13 shall be provided for each of the appli-
14 cant's affiliates.

15 “(IV) A statement signed by the
16 head of the applicant or its chief fi-
17 nancial officer that it has submitted
18 certifications for all of its affiliates, or
19 that it had no affiliates, whichever is
20 applicable.”; and

21 (iii) in subparagraph (C)—

22 (I) by striking “reduced rate of”
23 and inserting “reduced rate of—”;
24 and

1 (II) by striking “38 percent” and
2 all that follows through the period and
3 inserting the following:

4 “(i) 25 percent of the fee established
5 under such subsection for a premarket ap-
6 plication, a premarket report, a supple-
7 ment, or a periodic report concerning a
8 class III device; and

9 “(ii) 50 percent of the fee established
10 under such subsection for a 30-day notice
11 or a request for classification informa-
12 tion.”;

13 (5) in subsection (e)—

14 (A) in paragraph (1), by striking “2004”
15 and inserting “2008”; and

16 (B) in paragraph (2)—

17 (i) in subparagraph (A), by striking “,
18 partners, and parent firms”;

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

21 “(B) EVIDENCE OF QUALIFICATION.—

22 “(i) IN GENERAL.—An applicant shall
23 pay the higher fees established by the Sec-
24 retary each year unless the applicant sub-

1 mits evidence that it qualifies for the lower
2 fee rate.

3 “(ii) FIRMS SUBMITTING TAX RE-
4 TURNS TO THE UNITED STATES INTERNAL
5 REVENUE SERVICE.—The applicant shall
6 support its claim that it meets the defini-
7 tion under subparagraph (A) by submis-
8 sion of a copy of its most recent Federal
9 income tax return for a taxable year, and
10 a copy of such returns of its affiliates,
11 which show an amount of gross sales or re-
12 cepts that is less than the maximum es-
13 tablished in subparagraph (A). The appli-
14 cant, and each of such affiliates, shall cer-
15 tify that the information provided is a true
16 and accurate copy of the actual tax forms
17 they submitted to the Internal Revenue
18 Service. If no tax forms are submitted for
19 affiliates, the applicant shall certify that
20 the applicant has no affiliates.

21 “(iii) FIRMS NOT SUBMITTING TAX
22 RETURNS TO THE UNITED STATES INTER-
23 NAL REVENUE SERVICE.—The applicant
24 shall support its claim that it meets the

1 definition under subparagraph (A) by sub-
2 mission of the following:

3 “(I) A signed certification, in
4 such form as the Secretary may direct
5 through a notice published in the Fed-
6 eral Register, that the applicant meets
7 the criteria for a small business.

8 “(II) A certification, in English,
9 from the national taxing authority of
10 the country in which it is
11 headquartered. Such certification shall
12 provide the applicant’s gross receipts
13 and sales for the most recent year, in
14 both the local currency and in United
15 States dollars, and the exchange rate
16 used in making such conversion to
17 dollars, and the dates during which
18 such receipts and sales were collected,
19 and it shall bear the official seal of
20 the national taxing authority.

21 “(III) Identical certifications
22 shall be provided for each of the appli-
23 cant’s affiliates.

24 “(IV) A statement signed by the
25 head of the applicant or its chief fi-

1 nancial officer that it has submitted
2 certifications for all of its affiliates, or
3 that it had no affiliates, whichever is
4 applicable.”; and

5 (iii) by striking subparagraph (C) and
6 inserting the following:

7 “(C) **REDUCED FEES.**—For fiscal year
8 2008 and each subsequent fiscal year, where
9 the Secretary finds that the applicant involved
10 meets the definition under subparagraph (A),
11 the fee for a premarket notification submission
12 may be paid at 50 percent of the fee that ap-
13 plies under subsection (a)(2)(A)(viii) and as es-
14 tablished under subsection (c)(1).”;

15 (6) by striking subsection (f) and inserting the
16 following:

17 “(f) **EFFECT OF FAILURE TO PAY FEES.**—

18 “(1) **IN GENERAL.**—A premarket application,
19 premarket report, supplement, or premarket notifi-
20 cation submission, 30-day notice, request for classi-
21 fication information, or periodic report concerning a
22 class III device submitted by a person subject to fees
23 under paragraphs (2) and (3) of subsection (a) shall
24 be considered incomplete and shall not be accepted

1 by the Secretary until all fees owed by such person
2 have been paid.

3 “(2) REGISTRATION INFORMATION.—Registra-
4 tion information submitted by an establishment sub-
5 ject to a registration fee under subsection (a)(3)
6 shall be considered incomplete and shall not be ac-
7 cepted by the Secretary until the registration fee
8 owed for the establishment has been paid. Until the
9 fee is paid and the registration is complete, the es-
10 tablishment shall be deemed to have failed to reg-
11 ister in accordance with section 510.”;

12 (7) in subsection (g)—

13 (A) by striking paragraph (1) and insert-
14 ing the following:

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

23 “(A) the amount so appropriated for the
24 fiscal year, excluding the amount of fees appro-
25 priated for the fiscal year, is more than 1 per-

1 cent less than \$205,720,000 multiplied by the
2 adjustment factor applicable to such fiscal year;
3 or

4 “(B) fees were not assessed under sub-
5 section (a) for the previous fiscal year.”; and

6 (B) in paragraph (2), by striking “and
7 premarket notification submissions, and” and
8 inserting “premarket notification submissions,
9 30-day notices, requests for classification infor-
10 mation, periodic reports concerning a class III
11 device, and establishment registrations”; and

12 (8) in subsection (h), by striking paragraphs
13 (3) and (4) and inserting the following:

14 “(3) AUTHORIZATION OF APPROPRIATIONS.—
15 There are authorized to be appropriated for fees
16 under this section—

17 “(A) \$48,431,000 for fiscal year 2008;

18 “(B) \$52,547,000 for fiscal year 2009;

19 “(C) \$57,014,000 for fiscal year 2010;

20 “(D) \$61,860,000 for fiscal year 2011;

21 and

22 “(E) \$67,118,000 for fiscal year 2012.

23 “(4) OFFSET.—If the cumulative amount of
24 fees collected during fiscal years 2008, 2009, and
25 2010, added to the amount estimated to be collected

1 for fiscal year 2011 (which estimate shall be based
2 upon the amount of fees received by the Secretary
3 through June 30, 2011), exceeds the amount of fees
4 specified in aggregate in paragraph (3) for such 4
5 fiscal years, the aggregate amount in excess shall be
6 credited to the appropriation account of the Food
7 and Drug Administration as provided in paragraph
8 (1), and shall be subtracted from the amount of fees
9 that would otherwise be authorized to be collected
10 under this section pursuant to appropriation Acts
11 for fiscal year 2012.”.

12 **SEC. 304. SAVINGS CLAUSE.**

13 Notwithstanding section 107 of the Medical Device
14 User Fee and Modernization Act of 2002 (Public Law
15 107–250), and notwithstanding the amendments made by
16 this subtitle, part 3 of subchapter C of chapter VII of the
17 Federal Food, Drug, and Cosmetic Act, as in effect on
18 the day before the date of enactment of this subtitle, shall
19 continue to be in effect with respect to premarket applica-
20 tions, premarket reports, premarket notification submis-
21 sions, and supplements (as defined in such part as of such
22 day) that on or after October 1, 2002, but before October
23 1, 2007, were accepted by the Food and Drug Administra-
24 tion for filing with respect to assessing and collecting any

1 fee required by such part for a fiscal year prior to fiscal
2 year 2008.

3 **SEC. 305. EFFECTIVE DATE.**

4 The amendments made by this subtitle shall take ef-
5 fect on the date of the enactment of this subtitle.

6 **Subtitle B—Amendments Regarding**
7 **Regulation of Medical De-**
8 **vices**

9 **SEC. 311. INSPECTIONS BY ACCREDITED PERSONS.**

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

11 (1) in paragraph (1) by striking “not later than
12 one year after the date of enactment of this sub-
13 section, the Secretary” and inserting “The Sec-
14 retary”;

15 (2) in paragraph (3) by adding at the end the
16 following:

17 “(F) Such person shall notify the Sec-
18 retary of any withdrawal, suspension, restric-
19 tion, or expiration of certificate of conformance
20 with the quality systems standard referred to in
21 paragraph (7) for any manufacturer that such
22 person inspects under this subsection not later
23 than 30 days after such withdrawal, suspension,
24 restriction, or expiration.

1 “(G) Such person may conduct audits to
2 establish conformance with the quality systems
3 standard referred to in paragraph (7).”;

4 (3) by amending paragraph (6) to read as fol-
5 lows:

6 “(6) A device establishment is eligible for in-
7 spections by persons accredited under paragraph (2)
8 if the following conditions are met:

9 “(A) With respect to inspections to be con-
10 ducted by an accredited person—

11 “(i) the owner or operator of the es-
12 tablishment submits to the Secretary a no-
13 tice indicating the intent to use such a per-
14 son to conduct the inspection, and the date
15 on which the inspection is scheduled to
16 begin; and

17 “(ii) the accredited person whom the
18 establishment selects to conduct the in-
19 spection is listed on the Internet site of the
20 Food and Drug Administration referred to
21 in paragraph (4).

22 “(B) As requested by the Secretary, the
23 establishment or the accredited person identi-
24 fied in the notice under subparagraph (A) pro-
25 vides information concerning the relationship

1 between the establishment and such accredited
2 person.”;

3 (4) in paragraph (7)—

4 (A) by amending subparagraph (A) to read
5 as follows:

6 “(B) Persons accredited under paragraph
7 (2) to conduct inspections shall record in writ-
8 ing their inspection observations and shall
9 present the observations to the device establish-
10 ment’s designated representative and describe
11 each observation. Additionally, such accredited
12 person shall prepare an inspection report in a
13 form and manner designated by the Secretary,
14 taking into consideration the goals of inter-
15 national harmonization of quality systems
16 standards. Any official classification of the in-
17 spection shall be determined by the Secretary.”;
18 and

19 (B) by adding at the end the following new
20 subparagraph:

21 “(F) The Secretary shall accept reports of
22 audits assessing conformance with an appro-
23 priate quality systems standard set by the
24 International Organization for Standardization
25 (ISO) identified by the Secretary in public no-

1 tice for the purpose of setting risk-based
2 inspectional priorities.”.

3 **SEC. 312. EXTENSION OF AUTHORITY FOR THIRD PARTY**
4 **REVIEW OF PREMARKET NOTIFICATION.**

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

7 **SEC. 313. REGISTRATION.**

8 (a) ANNUAL REGISTRATION OF PRODUCERS OF
9 DRUGS AND DEVICES.—Section 510(b) (21 U.S.C.
10 359(b)) is amended—

11 (1) by redesignating the existing text as para-
12 graph (1), and indenting and relocating it appro-
13 priately;

14 (2) in paragraph (1), as so redesignated, by
15 striking “or a device or devices”; and

16 (3) by adding at the end the following new
17 paragraph:

18 “(2) Between October 1 and December 31 of
19 each year every person who owns or operates any es-
20 tablishment in any State engaged in the manufac-
21 ture, preparation, propagation, compounding, or
22 processing of a device or devices shall register with
23 the Secretary his name, places of business, and all
24 such establishments.”.

1 (b) REGISTRATION OF FOREIGN ESTABLISH-
2 MENTS.—Section 510(i)(1) (21 U.S.C. 359(i)(1)) is
3 amended—

4 (1) by redesignating the existing text as sub-
5 paragraph (A), and indenting and relocating it ap-
6 propriately;

7 (2) in subparagraph (A), as so redesignated—

8 (A) by striking “processing of a drug or a
9 device that is imported” and inserting “proc-
10 essing of a drug that is imported”;

11 (B) by striking “or device” each place it
12 appears; and

13 (3) by adding after such subparagraph (A) the
14 following new subparagraph:

15 “(B) Between October 1 and December 31
16 of each year, any establishment within any for-
17 eign country engaged in the manufacture, prep-
18 aration, propagation, compounding, or proc-
19 essing of a device that is imported or offered
20 for import into the United States shall, through
21 electronic means in accordance with the criteria
22 of the Secretary, register with the Secretary the
23 name and place of business of the establish-
24 ment, the name of the United States agent for
25 the establishment, the name of each importer of

1 such device in the United States that is known
2 to the establishment, and the name of each per-
3 son who imports or offers for import such de-
4 vice to the United States for purposes of impor-
5 tation.”.

6 **SEC. 314. FILING OF LISTS OF DRUGS AND DEVICES MANU-**
7 **FACTURED PREPARED, PROPAGATED AND**
8 **COMPOUNDED BY REGISTRANTS; STATE-**
9 **MENTS; ACCOMPANYING DISCLOSURES.**

10 Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended,
11 in the matter preceding subparagraph (A), to read as fol-
12 lows:

13 “(2) Each person who registers with the Sec-
14 retary under this section shall report to the Sec-
15 retary (i) with regard to drugs, once during the
16 month of June of each year and once during the
17 month of December of each year, and (ii) with re-
18 gard to devices, once each year between October 1
19 and December 31, the following information:”.

20 **SEC. 315. ELECTRONIC REGISTRATION AND LISTING.**

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

23 “(p)(1) With regard to any establishment engaged in
24 the manufacture, preparation, propagation, compounding,
25 or processing of a drug, registrations under subsections

1 (b), (c), (d), and (i) of this section (including the submis-
2 sion of updated information) shall be submitted to the
3 Secretary by electronic means, upon a finding by the Sec-
4 retary that the electronic receipt of such registrations is
5 feasible, unless the Secretary grants a request for waiver
6 of such requirement because use of electronic means is not
7 reasonable for the person requesting such waiver.

8 “(2) With regard to any establishment engaged in the
9 manufacture, preparation, propagation, compounding, or
10 processing of a device, the registration and listing infor-
11 mation required by this section shall be submitted to the
12 Secretary by electronic means, unless the Secretary grants
13 a waiver because electronic registration and listing is not
14 reasonable for the person requesting such waiver.”.

15 **TITLE IV—PEDIATRIC MEDICAL** 16 **PRODUCTS**

17 **Subtitle A—Best Pharmaceuticals** 18 **for Children**

19 **SEC. 401. SHORT TITLE.**

20 This subtitle may be cited as the “Best Pharma-
21 ceuticals for Children Amendments of 2007”.

22 **SEC. 402. PEDIATRIC STUDIES OF DRUGS.**

23 (a) IN GENERAL.—Section 505A of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
25 amended—

1 (1) in subsection (a), by inserting before the pe-
2 riod at the end the following: “, and, at the discre-
3 tion of the Secretary, may include preclinical stud-
4 ies”;

5 (2) in subsection (b)—

6 (A) in paragraph (1)(A)(i), by striking
7 “(D)” both places it appears and inserting
8 “(E)”;

9 (B) in paragraph (1)(A)(ii), by striking
10 “(D)” and inserting “(E)”;

11 (C) by striking “(1)(A)(i)” and inserting
12 “(A)(i)(I)”;

13 (D) by striking “(ii) the” and inserting
14 “(II) the”;

15 (E) by striking “(B) if the drug is des-
16 ignated” and inserting “(ii) if the drug is des-
17 ignated”;

18 (F) by striking “(2)(A)” and inserting
19 “(B)(i)”;

20 (G) by striking “(i) a listed patent” and
21 inserting “(I) a listed patent”;

22 (H) by striking “(ii) a listed patent” and
23 inserting “(II) a listed patent”;

1 (I) by striking “(B) if the drug is the sub-
2 ject” and inserting “(ii) if the drug is the sub-
3 ject”;

4 (J) by striking “If” and all that follows
5 through “subsection (d)(3)” and inserting the
6 following:

7 “(1) IN GENERAL.—Except as provided in para-
8 graph (2), if, prior to approval of an application that
9 is submitted under section 505(b)(1), the Secretary
10 determines that information relating to the use of a
11 new drug in the pediatric population may produce
12 health benefits in that population, the Secretary
13 makes a written request for pediatric studies (which
14 shall include a timeframe for completing such stud-
15 ies), the applicant agrees to the request, such stud-
16 ies are completed using appropriate formulations for
17 each age group for which the study is requested
18 within any such timeframe and the reports thereof
19 are submitted and accepted in accordance with sub-
20 section (d)(3), and if the Secretary determines that
21 labeling changes are appropriate, such changes are
22 made within the timeframe requested by the Sec-
23 retary—”;

24 (K) by adding at the end the following:

1 “(2) EXCEPTION.—The Secretary shall not ex-
2 tend the period referred to in paragraph (1)(A) or
3 in paragraph (1)(B) later than 9 months prior to
4 the expiration of such period.”;

5 (3) in subsection (c)—

6 (A) in paragraph (1)(A)(i), by striking
7 “(D)” both places it appears and inserting
8 “(E)”;

9 (B) in paragraph (1)(A)(ii), by striking
10 “(D)” and inserting “(E)”;

11 (C) by striking “(1)(A)(i)” and inserting
12 “(A)(i)(I)”;

13 (D) by striking “(ii) the” and inserting
14 “(II) the”;

15 (E) by striking “(B) if the drug is des-
16 ignated” and inserting “(ii) if the drug is des-
17 ignated”;

18 (F) by striking “(2)(A)” and inserting
19 “(B)(i)”;

20 (G) by striking “(i) a listed patent” and
21 inserting “(I) a listed patent”;

22 (H) by striking “(ii) a listed patent” and
23 inserting “(II) a listed patent”;

1 (I) by striking “(B) if the drug is the sub-
2 ject” and inserting “(ii) if the drug is the sub-
3 ject”;

4 (J) by striking “If” and all that follows
5 through “subsection (d)(3)” and inserting the
6 following:

7 “(1) IN GENERAL.—Except as provided in para-
8 graph (2), if the Secretary determines that informa-
9 tion relating to the use of an approved drug in the
10 pediatric population may produce health benefits in
11 that population and makes a written request to the
12 holder of an approved application under section
13 505(b)(1) for pediatric studies (which shall include
14 a timeframe for completing such studies), the holder
15 agrees to the request, such studies are completed
16 using appropriate formulations for each age group
17 for which the study is requested within any such
18 timeframe and the reports thereof are submitted and
19 accepted in accordance with subsection (d)(3), and if
20 the Secretary determines that labeling changes are
21 appropriate, such changes are made within the time-
22 frame requested by the Secretary—”; and

23 (K) by adding at the end the following:

24 “(2) EXCEPTION.—The Secretary shall not ex-
25 tend the period referred to in paragraph (1)(A) or

1 in paragraph (1)(B) later than 9 months prior to
2 the expiration of such period.”;

3 (4) by striking subsection (d) and inserting the
4 following:

5 “(d) CONDUCT OF PEDIATRIC STUDIES.—

6 “(1) REQUEST FOR STUDIES.—

7 “(A) IN GENERAL.—The Secretary may,
8 after consultation with the sponsor of an appli-
9 cation for an investigational new drug under
10 section 505(i), the sponsor of an application for
11 a new drug under section 505(b)(1), or the
12 holder of an approved application for a drug
13 under section 505(b)(1), issue to the sponsor or
14 holder a written request for the conduct of pedi-
15 atric studies for such drug. In reaching an
16 agreement regarding such request, the Sec-
17 retary shall take into account adequate rep-
18 resentation of children of ethnic and racial mi-
19 norities. Such request to conduct pediatric stud-
20 ies shall be in writing and shall include a time-
21 frame for such studies and a request to the
22 sponsor or holder to propose pediatric labeling
23 resulting from such studies.

24 “(B) SINGLE WRITTEN REQUEST.—A sin-
25 gle written request—

1 “(i) may relate to more than 1 use of
2 a drug; and

3 “(ii) may include uses that are both
4 approved and unapproved.

5 “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-
6 IES.—

7 “(A) REQUEST AND RESPONSE.—

8 “(i) IN GENERAL.—If the Secretary
9 makes a written request for pediatric stud-
10 ies (including neonates, as appropriate)
11 under subsection (b) or (c), the applicant
12 or holder, not later than 180 days after re-
13 ceiving the written request, shall respond
14 to the Secretary as to the intention of the
15 applicant or holder to act on the request
16 by—

17 “(I) indicating when the pediatric
18 studies will be initiated, if the appli-
19 cant or holder agrees to the request;
20 or

21 “(II) indicating that the appli-
22 cant or holder does not agree to the
23 request and the reasons for declining
24 the request.

1 “(ii) DISAGREE WITH REQUEST.—If,
2 on or after the date of enactment of the
3 Best Pharmaceuticals for Children Amend-
4 ments of 2007, the applicant or holder
5 does not agree to the request on the
6 grounds that it is not possible to develop
7 the appropriate pediatric formulation, the
8 applicant or holder shall submit to the Sec-
9 retary the reasons such pediatric formula-
10 tion cannot be developed.

11 “(B) ADVERSE EVENT REPORTS.—An ap-
12 plicant or holder that, on or after the date of
13 enactment of the Best Pharmaceuticals for
14 Children Amendments of 2007, agrees to the
15 request for such studies shall provide the Sec-
16 retary, at the same time as submission of the
17 reports of such studies, with all postmarket ad-
18 verse event reports regarding the drug that is
19 the subject of such studies and are available
20 prior to submission of such reports.

21 “(3) MEETING THE STUDIES REQUIREMENT.—
22 Not later than 180 days after the submission of the
23 reports of the studies, the Secretary shall accept or
24 reject such reports and so notify the sponsor or
25 holder. The Secretary’s only responsibility in accept-

1 ing or rejecting the reports shall be to determine,
2 within the 180 days, whether the studies fairly re-
3 spond to the written request, have been conducted in
4 accordance with commonly accepted scientific prin-
5 ciples and protocols, and have been reported in ac-
6 cordance with the requirements of the Secretary for
7 filing.

8 “(4) EFFECT OF SUBSECTION.—Nothing in this
9 subsection alters or amends section 301(j) of this
10 Act or section 552 of title 5 or section 1905 of title
11 18, United States Code.”;

12 (5) by striking subsections (e) and (f) and in-
13 serting the following:

14 “(e) NOTICE OF DETERMINATIONS ON STUDIES RE-
15 QUIREMENT.—

16 “(1) IN GENERAL.—The Secretary shall publish
17 a notice of any determination, made on or after the
18 date of enactment of the Best Pharmaceuticals for
19 Children Amendments of 2007, that the require-
20 ments of subsection (d) have been met and that sub-
21 missions and approvals under subsection (b)(2) or
22 (j) of section 505 for a drug will be subject to the
23 provisions of this section. Such notice shall be pub-
24 lished not later than 30 days after the date of the
25 Secretary’s determination regarding market exclu-

1 sivity and shall include a copy of the written request
2 made under subsection (b) or (c).

3 “(2) IDENTIFICATION OF CERTAIN DRUGS.—

4 The Secretary shall publish a notice identifying any
5 drug for which, on or after the date of enactment of
6 the Best Pharmaceuticals for Children Amendments
7 of 2007, a pediatric formulation was developed,
8 studied, and found to be safe and effective in the pe-
9 diatric population (or specified subpopulation) if the
10 pediatric formulation for such drug is not introduced
11 onto the market within 1 year of the date that the
12 Secretary publishes the notice described in para-
13 graph (1). Such notice identifying such drug shall be
14 published not later than 30 days after the date of
15 the expiration of such 1 year period.

16 “(f) INTERNAL REVIEW OF WRITTEN REQUESTS
17 AND PEDIATRIC STUDIES.—

18 “(1) INTERNAL REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall
20 create an internal review committee to review
21 all written requests issued and all reports sub-
22 mitted on or after the date of enactment of the
23 Best Pharmaceuticals for Children Amendments
24 of 2007, in accordance with paragraphs (2) and
25 (3).

1 “(B) MEMBERS.—The committee under
2 subparagraph (A) shall include individuals, each
3 of whom is an employee of the Food and Drug
4 Administration, with the following expertise:

5 “(i) Pediatrics.

6 “(ii) Biopharmacology.

7 “(iii) Statistics.

8 “(iv) Drugs and drug formulations.

9 “(v) Legal issues.

10 “(vi) Appropriate expertise pertaining
11 to the pediatric product under review.

12 “(vii) One or more experts from the
13 Office of Pediatric Therapeutics, including
14 an expert in pediatric ethics.

15 “(viii) Other individuals as designated
16 by the Secretary.

17 “(2) REVIEW OF WRITTEN REQUESTS.—All
18 written requests under this section shall be reviewed
19 and approved by the committee established under
20 paragraph (1) prior to being issued.

21 “(3) REVIEW OF PEDIATRIC STUDIES.—The
22 committee established under paragraph (1) shall re-
23 view all studies conducted pursuant to this section to
24 determine whether to accept or reject such reports
25 under subsection (d)(3).

1 “(4) TRACKING PEDIATRIC STUDIES AND LA-
2 BELING CHANGES.—The committee established
3 under paragraph (1) shall be responsible for track-
4 ing and making available to the public, in an easily
5 accessible manner, including through posting on the
6 website of the Food and Drug Administration—

7 “(A) the number of studies conducted
8 under this section;

9 “(B) the specific drugs and drug uses, in-
10 cluding labeled and off-labeled indications, stud-
11 ied under this section;

12 “(C) the types of studies conducted under
13 this section, including trial design, the number
14 of pediatric patients studied, and the number of
15 centers and countries involved;

16 “(D) the number of pediatric formulations
17 developed and the number of pediatric formula-
18 tions not developed and the reasons such for-
19 mulations were not developed;

20 “(E) the labeling changes made as a result
21 of studies conducted under this section;

22 “(F) an annual summary of labeling
23 changes made as a result of studies conducted
24 under this section for distribution pursuant to
25 subsection (k)(2); and

1 “(G) information regarding reports sub-
2 mitted on or after the date of enactment of the
3 Best Pharmaceuticals for Children Amendments
4 of 2007.”;

5 (6) in subsection (g)—

6 (A) in paragraph (1)—

7 (i) by striking “(c)(1)(A)(ii)” and in-
8 sserting “(c)(1)(A)(i)(II)”;

9 (ii) by striking “(c)(2)” and inserting
10 “(c)(1)(B)”;

11 (B) in paragraph (2), by striking
12 “(c)(1)(B)” and inserting “(c)(1)(A)(ii)”;

13 (C) by redesignating paragraphs (1) and
14 (2) as subparagraphs (A) and (B), respectively;

15 (D) by striking “LIMITATIONS.—A drug”
16 and inserting “LIMITATIONS.—

17 “(1) IN GENERAL.—Notwithstanding subsection
18 (c)(2), a drug”;

19 (E) by adding at the end the following:

20 “(2) EXCLUSIVITY ADJUSTMENT.—

21 “(A) ADJUSTMENT.—

22 “(i) IN GENERAL.—With respect to
23 any drug, if the organization designated
24 under subparagraph (B) notifies the Sec-
25 retary that the combined annual gross

1 sales for all drugs with the same active
2 moiety exceeded \$1,000,000,000 in any
3 calendar year prior to the time the sponsor
4 or holder agrees to the initial written re-
5 quest pursuant to subsection (d)(2), then
6 each period of market exclusivity deemed
7 or extended under subsection (b) or (c)
8 shall be reduced by 3 months for such
9 drug.

10 “(ii) DETERMINATION.—The deter-
11 mination under clause (i) of the combined
12 annual gross sales shall be determined—

13 “(I) taking into account only
14 those sales within the United States;
15 and

16 “(II) taking into account only the
17 sales of all drugs with the same active
18 moiety of the sponsor or holder and
19 its affiliates.

20 “(B) DESIGNATION.—The Secretary shall
21 designate an organization other than the Food
22 and Drug Administration to evaluate whether
23 the combined annual gross sales for all drugs
24 with the same active moiety exceeded
25 \$1,000,000,000 in a calendar year as described

1 in subparagraph (A). Prior to designating such
2 organization, the Secretary shall determine that
3 such organization is independent and is quali-
4 fied to evaluate the sales of pharmaceutical
5 products. The Secretary shall re-evaluate the
6 designation of such organization once every 3
7 years.

8 “(C) NOTIFICATION.—Once a year at a
9 time designated by the Secretary, the organiza-
10 tion designated under subparagraph (B) shall
11 notify the Food and Drug Administration of all
12 drugs with the same active moiety with com-
13 bined annual gross sales that exceed
14 \$1,000,000,000 during the previous calendar
15 year.”.

16 (7) in subsection (i)—

17 (A) in the heading, by striking “SUPPLE-
18 MENTS” and inserting “CHANGES”;

19 (B) in paragraph (1)—

20 (i) in the heading, by inserting “AP-
21 PPLICATIONS AND” after “PEDIATRIC”;

22 (ii) by inserting “application or” after
23 “Any”;

24 (iii) by striking “change pursuant to a
25 report on a pediatric study under” and in-

1 serting “change as a result of any pedi-
2 atric study conducted pursuant to”; and

3 (iv) by inserting “application or” after
4 “to be a priority”; and

5 (C) in paragraph (2)(A), by—

6 (i) striking “If the Commissioner”
7 and inserting “If, on or after the date of
8 enactment of the Best Pharmaceuticals for
9 Children Amendments of 2007, the Com-
10 missioner”; and

11 (ii) striking “an application with” and
12 all that follows through “on appropriate”
13 and inserting “the sponsor and the Com-
14 missioner have been unable to reach agree-
15 ment on appropriate”;

16 (8) by striking subsection (m);

17 (9) by redesignating subsections (j), (k), (l),
18 and (n), as subsections (k), (m), (o), and (p), respec-
19 tively;

20 (10) by inserting after subsection (i) the fol-
21 lowing:

22 “(j) OTHER LABELING CHANGES.—If, on or after the
23 date of enactment of the Best Pharmaceuticals for Chil-
24 dren Amendments of 2007, the Secretary determines that
25 a pediatric study conducted under this section does or does

1 not demonstrate that the drug that is the subject of the
2 study is safe and effective, including whether such study
3 results are inconclusive, in pediatric populations or sub-
4 populations, the Secretary shall order the labeling of such
5 product to include information about the results of the
6 study and a statement of the Secretary's determination.”;

7 (11) in subsection (k), as redesignated by para-
8 graph (9)—

9 (A) in paragraph (1)—

10 (i) by striking “a summary of the
11 medical and” and inserting “the medical,
12 statistical, and”; and

13 (ii) by striking “for the supplement”
14 and all that follows through the period and
15 inserting “under subsection (b) or (c).”;

16 (B) by redesignating paragraph (2) as
17 paragraph (3); and

18 (C) by inserting after paragraph (1) the
19 following:

20 “(2) DISSEMINATION OF INFORMATION RE-
21 GARDING LABELING CHANGES.—Beginning on the
22 date of enactment of the Best Pharmaceuticals for
23 Children Amendments of 2007, the Secretary shall
24 require that the sponsors of the studies that result
25 in labeling changes that are reflected in the annual

1 summary developed pursuant to subsection (f)(4)(F)
2 distribute, at least annually (or more frequently if
3 the Secretary determines that it would be beneficial
4 to the public health), such information to physicians
5 and other health care providers.”;

6 (12) by inserting after subsection (k), as reded-
7 igned by paragraph (9), the following:

8 “(1) ADVERSE EVENT REPORTING.—

9 “(1) REPORTING IN YEAR ONE.—Beginning on
10 the date of enactment of the Best Pharmaceuticals
11 for Children Amendments of 2007, during the 1-year
12 period beginning on the date a labeling change is
13 made pursuant to subsection (i), the Secretary shall
14 ensure that all adverse event reports that have been
15 received for such drug (regardless of when such re-
16 port was received) are referred to the Office of Pedi-
17 atric Therapeutics established under section 6 of the
18 Best Pharmaceuticals for Children Act (Public Law
19 107–109). In considering such reports, the Director
20 of such Office shall provide for the review of the re-
21 port by the Pediatric Advisory Committee, including
22 obtaining any recommendations of such Committee
23 regarding whether the Secretary should take action
24 under this section in response to such reports.

1 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
2 lowing the 1-year period described in paragraph (1),
3 the Secretary shall, as appropriate, refer to the Of-
4 fice of Pediatric Therapeutics all pediatric adverse
5 event reports for a drug for which a pediatric study
6 was conducted under this section. In considering
7 such reports, the Director of such Office may pro-
8 vide for the review of such reports by the Pediatric
9 Advisory Committee, including obtaining any rec-
10 ommendation of such Committee regarding whether
11 the Secretary should take action in response to such
12 reports.

13 “(3) EFFECT.—The requirements of this sub-
14 section shall supplement, not supplant, other review
15 of such adverse event reports by the Secretary.”;

16 (13) by inserting after subsection (m), as reded-
17 esignated by paragraph (9), the following:

18 “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-
19 PLETED.—

20 “(1) IN GENERAL.—Beginning on the date of
21 enactment of the Best Pharmaceuticals for Children
22 Amendments of 2007, if pediatric studies of a drug
23 have not been completed under subsection (d) and if
24 the Secretary, through the committee established
25 under subsection (f), determines that there is a con-

1 tinuing need for information relating to the use of
2 the drug in the pediatric population (including neo-
3 nates, as appropriate), the Secretary shall carry out
4 the following:

5 “(A) For a drug for which a listed patent
6 has not expired, make a determination regard-
7 ing whether an assessment shall be required to
8 be submitted under section 505B. Prior to mak-
9 ing such determination, the Secretary may take
10 not more than 60 days to certify whether the
11 Foundation for the National Institutes of
12 Health has sufficient funding at the time of
13 such certification to initiate 1 or more of the
14 pediatric studies of such drug referred to in the
15 sentence preceding this paragraph and fund 1
16 or more of such studies in their entirety. Only
17 if the Secretary makes such certification in the
18 affirmative, the Secretary shall refer such pedi-
19 atric study or studies to the Foundation for the
20 National Institutes for Health for the conduct
21 of such study or studies.

22 “(B) For a drug that has no listed patents
23 or has 1 or more listed patents that have ex-
24 pired, determine whether there are funds avail-
25 able under section 736 to award a grant to con-

1 duct the requested studies pursuant to para-
2 graph (2).

3 “(2) FUNDING OF STUDIES.—If, pursuant to
4 paragraph (1), the Secretary determines that there
5 are funds available under section 736 to award a
6 grant to conduct the requested pediatric studies,
7 then the Secretary shall issue a proposal to award
8 a grant to conduct the requested studies. If the Sec-
9 retary determines that funds are not available under
10 section 736, the Secretary shall refer the drug for
11 inclusion on the list established under section 409I
12 of the Public Health Service Act for the conduct of
13 studies.

14 “(3) PUBLIC NOTICE.—The Secretary shall give
15 the public notice of—

16 “(A) a decision under paragraph (1)(A)
17 not to require an assessment under section
18 505B and the basis for such decision;

19 “(B) the name of any drug, its manufac-
20 turer, and the indications to be studied pursu-
21 ant to a grant made under paragraph (2); and

22 “(C) any decision under paragraph (2) to
23 refer a drug for inclusion on the list established
24 under section 409I of the Public Health Service
25 Act.

1 “(4) EFFECT OF SUBSECTION.—Nothing in this
2 subsection alters or amends section 301(j) of this
3 Act or section 552 of title 5 or section 1905 of Title
4 18, United States Code.”;

5 (14) in subsection (p), as redesignated by para-
6 graph (9)—

7 (A) striking “6-month period” and insert-
8 ing “3-month or 6-month period”;

9 (B) by striking “subsection (a)” and in-
10 sserting “subsection (b)”; and

11 (C) by striking “2007” both places it ap-
12 pears and inserting “2012”.

13 (b) EFFECTIVE DATE.—Except as otherwise provided
14 in the amendments made by subsection (a), such amend-
15 ments shall apply to written requests under section 505A
16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355a) made after the date of enactment of this subtitle.

18 **SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

19 Section 409I of the Public Health Service Act (42
20 U.S.C. 284m) is amended—

21 (1) by striking subsections (a) and (b) and in-
22 sserting the following:

23 “(a) LIST OF PRIORITY ISSUES IN PEDIATRIC
24 THERAPEUTICS.—

1 “(1) IN GENERAL.—Not later than 1 year after
2 the date of enactment of the Best Pharmaceuticals
3 for Children Amendments of 2007, the Secretary,
4 acting through the Director of the National Insti-
5 tutes of Health and in consultation with the Com-
6 missioner of Food and Drugs and experts in pedi-
7 atric research, shall develop and publish a priority
8 list of needs in pediatric therapeutics, including
9 drugs or indications that require study. The list
10 shall be revised every 3 years.

11 “(2) CONSIDERATION OF AVAILABLE INFORMA-
12 TION.—In developing and prioritizing the list under
13 paragraph (1), the Secretary shall consider—

14 “(A) therapeutic gaps in pediatrics that
15 may include developmental pharmacology,
16 pharmacogenetic determinants of drug re-
17 sponse, metabolism of drugs and biologics in
18 children, and pediatric clinical trials;

19 “(B) particular pediatric diseases, dis-
20 orders or conditions where more complete
21 knowledge and testing of therapeutics, including
22 drugs and biologics, may be beneficial in pedi-
23 atric populations; and

24 “(C) the adequacy of necessary infrastruc-
25 ture to conduct pediatric pharmacological re-

1 search, including research networks and trained
2 pediatric investigators.

3 “(b) PEDIATRIC STUDIES AND RESEARCH.—The
4 Secretary, acting through the National Institutes of
5 Health, shall award funds to entities that have the exper-
6 tise to conduct pediatric clinical trials or other research
7 (including qualified universities, hospitals, laboratories,
8 contract research organizations, practice groups, federally
9 funded programs such as pediatric pharmacology research
10 units, other public or private institutions, or individuals)
11 to enable the entities to conduct the drug studies or other
12 research on the issues described in subsection (a). The
13 Secretary may use contracts, grants, or other appropriate
14 funding mechanisms to award funds under this sub-
15 section.”;

16 (2) in subsection (c)—

17 (A) in the heading, by striking “CON-
18 TRACTS” and inserting “PROPOSED PEDIATRIC
19 STUDY REQUESTS”;

20 (B) by striking paragraphs (4) and (12);

21 (C) by redesignating paragraphs (1), (2),
22 and (3), as paragraphs (2), (3), and (4);

23 (D) by inserting before paragraph (2), as
24 redesignated by subparagraph (C), the fol-
25 lowing:

1 “(1) SUBMISSION OF PROPOSED PEDIATRIC
2 STUDY REQUEST.—The Director of the National In-
3 stitutes of Health shall, as appropriate, submit pro-
4 posed pediatric study requests for consideration by
5 the Commissioner of Food and Drugs for pediatric
6 studies of a specific pediatric indication identified
7 under subsection (a). Such a proposed pediatric
8 study request shall be made in a manner equivalent
9 to a written request made under subsection (b) or
10 (c) of section 505A of the Federal Food, Drug, and
11 Cosmetic Act, including with respect to the informa-
12 tion provided on the pediatric studies to be con-
13 ducted pursuant to the request. The Director of the
14 National Institutes of Health may submit a pro-
15 posed pediatric study request for a drug for which—

16 “(A)(i) there is an approved application
17 under section 505(j) of the Federal Food,
18 Drug, and Cosmetic Act; or

19 “(ii) there is a submitted application that
20 could be approved under the criteria of section
21 505(j) of the Federal Food, Drug, and Cos-
22 metic Act; and

23 “(B) there is no patent protection or mar-
24 ket exclusivity protection for at least 1 form of

1 the drug under the Federal Food, Drug, and
2 Cosmetic Act; and

3 “(C) additional studies are needed to as-
4 sess the safety and effectiveness of the use of
5 the drug in the pediatric population.”;

6 (E) in paragraph (2), as redesignated by
7 subparagraph (C)—

8 (i) by inserting “based on the pro-
9 posed pediatric study request for the indi-
10 cation or indications submitted pursuant to
11 paragraph (1)” after “issue a written re-
12 quest”;

13 (ii) by striking “in the list described
14 in subsection (a)(1)(A) (except clause
15 (iv))” and inserting “under subsection
16 (a)”;

17 (iii) by inserting “and using appro-
18 priate formulations for each age group for
19 which the study is requested” before the
20 period at the end;

21 (F) in paragraph (3), as redesignated by
22 subparagraph (C)—

23 (i) in the heading, by striking “CON-
24 TRACTS”;

1 (ii) by striking “paragraph (1)” and
2 inserting “paragraph (2)”;

3 (iii) by striking “or if a referral de-
4 scribed in subsection (a)(1)(A)(iv) is
5 made,”;

6 (iv) by striking “for contract pro-
7 posals” and inserting “for proposals”; and

8 (v) by inserting “in accordance with
9 subsection (b)” before the period at the
10 end;

11 (G) in paragraph (4), as redesignated by
12 subparagraph (C)—

13 (i) by striking “contract”; and

14 (ii) by striking “paragraph (2)” and
15 inserting “paragraph (3)”;

16 (H) in paragraph (5)—

17 (i) by striking the heading and insert-
18 ing “CONTRACTS, GRANTS, OR OTHER
19 FUNDING MECHANISMS”; and

20 (ii) by striking “A contract” and all
21 that follows through “is submitted” and
22 inserting “A contract, grant, or other
23 funding may be awarded under this section
24 only if a proposal is submitted”;

25 (I) in paragraph (6)(A)—

1 (i) by striking “a contract awarded”
2 and inserting “an award”; and

3 (ii) by inserting “, including a written
4 request if issued” after “with the study”;
5 and

6 (3) by inserting after subsection (c) the fol-
7 lowing:

8 “(d) DISSEMINATION OF PEDIATRIC INFORMA-
9 TION.—Not later than 1 year after the date of enactment
10 of the Best Pharmaceuticals for Children Amendments of
11 2007, the Secretary, acting through the Director of the
12 National Institutes of Health, shall study the feasibility
13 of establishing a compilation of information on pediatric
14 drug use and report the findings to Congress.”

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—

16 “(1) IN GENERAL.—There are authorized to be
17 appropriated to carry out this section—

18 “(A) \$200,000,000 for fiscal year 2008;

19 and

20 “(B) such sums as are necessary for each
21 of the 4 succeeding fiscal years.

22 “(2) AVAILABILITY.—Any amount appropriated
23 under paragraph (1) shall remain available to carry
24 out this section until expended.”.

1 **SEC. 404. REPORTS AND STUDIES.**

2 (a) GAO REPORT.—Not later than January 31,
3 2011, the Comptroller General of the United States, in
4 consultation with the Secretary of Health and Human
5 Services, shall submit to Congress a report that addresses
6 the effectiveness of section 505A of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring
8 that medicines used by children are tested and properly
9 labeled, including—

10 (1) the number and importance of drugs for
11 children that are being tested as a result of the
12 amendments made by this subtitle and the impor-
13 tance for children, health care providers, parents,
14 and others of labeling changes made as a result of
15 such testing;

16 (2) the number and importance of drugs for
17 children that are not being tested for their use not-
18 withstanding the provisions of this subtitle and the
19 amendments made by this subtitle, and possible rea-
20 sons for the lack of testing, including whether the
21 number of written requests declined by sponsors or
22 holders of drugs subject to section 505A(g)(2) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 355a(g)(2)), has increased or decreased as a result
25 of the amendments made by this subtitle;

1 (3) the number of drugs for which testing is
2 being done and labeling changes required, including
3 the date labeling changes are made and which label-
4 ing changes required the use of the dispute resolu-
5 tion process established pursuant to the amendments
6 made by this subtitle, together with a description of
7 the outcomes of such process, including a description
8 of the disputes and the recommendations of the Pe-
9 diatric Advisory Committee;

10 (4) any recommendations for modifications to
11 the programs established under section 505A of the
12 Federal Food, Drug and Cosmetic Act (21 U.S.C.
13 355a) and section 409I of the Public Health Service
14 Act that the Secretary determines to be appropriate,
15 including a detailed rationale for each recommenda-
16 tion; and

17 (5)(A) the efforts made by the Secretary to in-
18 crease the number of studies conducted in the
19 neonate population; and

20 (B) the results of those efforts, including efforts
21 made to encourage the conduct of appropriate stud-
22 ies in neonates by companies with products that
23 have sufficient safety and other information to make
24 the conduct of the studies ethical and safe.

1 (b) IOM STUDY.—Not later than 3 years after the
2 date of enactment of this subtitle, the Secretary of Health
3 and Human Services shall enter into a contract with the
4 Institute of Medicine to conduct a study and report to
5 Congress regarding the written requests made and the
6 studies conducted pursuant to section 505A of the Federal
7 Food, Drug, and Cosmetic Act. The Institute of Medicine
8 may devise an appropriate mechanism to review a rep-
9 resentative sample of requests made and studies conducted
10 pursuant to such section in order to conduct such study.

11 Such study shall—

12 (1) review such representative written requests
13 issued by the Secretary since 1997 under sub-
14 sections (b) and (c) of such section 505A;

15 (2) review and assess such representative pedi-
16 atric studies conducted under such subsections (b)
17 and (c) since 1997 and labeling changes made as a
18 result of such studies; and

19 (3) review the use of extrapolation for pediatric
20 subpopulations, the use of alternative endpoints for
21 pediatric populations, neonatal assessment tools, and
22 ethical issues in pediatric clinical trials.

23 **SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

24 (a) INVESTMENT IN TOMORROW'S PEDIATRIC RE-
25 SEARCHERS.—Section 452G(2) of the Public Health Serv-

1 ice Act (42 U.S.C. 285g–10(2)) is amended by adding be-
2 fore the period at the end the following: “, including pedi-
3 atric pharmacological research”.

4 (b) PEDIATRIC RESEARCH LOAN REPAYMENT PRO-
5 GRAM.—Section 487F(a)(1) of the Public Health Service
6 Act (42 U.S.C. 288–6(a)(1)) is amended by inserting “in-
7 cluding pediatric pharmacological research,” after “pedi-
8 atric research,”.

9 **SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTES OF**
10 **HEALTH.**

11 Section 499(c)(1)(C) of the Public Health Service Act
12 (42 U.S.C. 290b(e)(1)(C)) is amended by striking “and
13 studies listed by the Secretary pursuant to section
14 409I(a)(1)(A) of the is Act and referred under section
15 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic
16 Act (21 U.S.C. 355(a)(d)(4)(C))” and inserting “and stud-
17 ies for which the Secretary issues a certification under sec-
18 tion 505A(n)(1)(A) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355a(n)(1)(A))”.

20 **SEC. 407. CONTINUATION OF OPERATION OF COMMITTEE.**

21 Section 14 of the Best Pharmaceuticals for Children
22 Act (42 U.S.C. 284m note) is amended by adding at the
23 end the following:

24 “(d) CONTINUATION OF OPERATION OF COM-
25 MITTEE.—Notwithstanding section 14 of the Federal Ad-

1 visory Committee Act (5 U.S.C. App.), the advisory com-
2 mittee shall continue to operate during the 5-year period
3 beginning on the date of enactment of the Best Pharma-
4 ceuticals for Children Amendments of 2007.”.

5 **SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**
6 **DRUGS ADVISORY COMMITTEE.**

7 Section 15 of the Best Pharmaceuticals for Children
8 Act (42 U.S.C. 284m note) is amended—

9 (1) in subsection (a)—

10 (A) in paragraph (1)—

11 (i) in subparagraph (B), by striking
12 “and” after the semicolon;

13 (ii) in subparagraph (C), by striking
14 the period at the end and inserting “;
15 and”; and

16 (iii) by adding at the end the fol-
17 lowing:

18 “(D) provide recommendations to the in-
19 ternal review committee created under section
20 505A(f) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 355a(f)) regarding the
22 implementation of amendments to sections
23 505A and 505B of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355a and 355c)

1 with respect to the treatment of pediatric can-
2 cers.”; and

3 (B) by adding at the end the following:

4 “(3) CONTINUATION OF OPERATION OF SUB-
5 COMMITTEE.—Notwithstanding section 14 of the
6 Federal Advisory Committee Act (5 U.S.C. App.),
7 the Subcommittee shall continue to operate during
8 the 5-year period beginning on the date of enact-
9 ment of the Best Pharmaceuticals for Children
10 Amendments of 2007.”; and

11 (2) in subsection (d), by striking “2003” and
12 inserting “2009”.

13 **SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RE-**
14 **LATING TO TOLL-FREE NUMBER FOR AD-**
15 **VERSE EVENTS ON LABELING FOR HUMAN**
16 **DRUG PRODUCTS.**

17 (a) IN GENERAL.—Notwithstanding subchapter II of
18 chapter 5, and chapter 7, of title 5, United States Code
19 (commonly known as the “Administrative Procedure Act”)
20 and any other provision of law, the proposed rule issued
21 by the Commissioner of Food and Drugs entitled “Toll-
22 Free Number for Reporting Adverse Events on Labeling
23 for Human Drug Products”, 69 Fed. Reg. 21778, (April
24 22, 2004) shall take effect on January 1, 2008, unless
25 such Commissioner issues the final rule before such date.

1 (b) LIMITATION.—The proposed rule that takes ef-
2 fect under subsection (a), or the final rule described under
3 subsection (a), shall, notwithstanding section 17(a) of the
4 Best Pharmaceuticals for Children Act (21 U.S.C.
5 355b(a)), not apply to a drug—

6 (1) for which an application is approved under
7 section 505 of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355);

9 (2) that is not described under section
10 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

11 (3) the packaging of which includes a toll-free
12 number through which consumers can report com-
13 plaints to the manufacturer or distributor of the
14 drug.

15 **Subtitle B—Pediatric Research** 16 **Improvement**

17 **SEC. 411. SHORT TITLE.**

18 This subtitle may be cited as the “Pediatric Research
19 Improvement Act”.

20 **SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPOLATIONS,** 21 **AND DEFERRALS.**

22 Section 505B(a) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355c(a)) is amended—

24 (1) in paragraph (4)(C), by adding at the end
25 the following: “An applicant seeking either a partial

1 or full waiver on this ground shall submit to the
2 Secretary documentation detailing why a pediatric
3 formulation cannot be developed, and, if the waiver
4 is granted, the applicant's submission shall promptly
5 be made available to the public in an easily acces-
6 sible manner, including through posting on the
7 website of the Food and Drug Administration”;

8 (2) in paragraph (2)(B), by adding at the end
9 the following:

10 “(iii) INFORMATION ON EXTRAPO-
11 LATION.—A brief documentation of the sci-
12 entific data supporting the conclusion
13 under clauses (i) and (ii) shall be included
14 in any pertinent reviews for the application
15 under section 505 or section 351 of the
16 Public Health Service Act.”; and

17 (3) by striking paragraph (3) and inserting the
18 following:

19 “(3) DEFERRAL.—

20 “(A) IN GENERAL.—On the initiative of
21 the Secretary or at the request of the applicant,
22 the Secretary may defer submission of some or
23 all assessments required under paragraph (1)
24 until a specified date after approval of the drug

1 or issuance of the license for a biological prod-
2 uct if—

3 “(i) the Secretary finds that—

4 “(I) the drug or biological prod-
5 uct is ready for approval for use in
6 adults before pediatric studies are
7 complete;

8 “(II) pediatric studies should be
9 delayed until additional safety or ef-
10 fectiveness data have been collected;
11 or

12 “(III) there is another appro-
13 priate reason for deferral; and

14 “(ii) the applicant submits to the Sec-
15 retary—

16 “(I) certification of the grounds
17 for deferring the assessments;

18 “(II) a description of the planned
19 or ongoing studies;

20 “(III) evidence that the studies
21 are being conducted or will be con-
22 ducted with due diligence and at the
23 earliest possible time; and

24 “(IV) a timeline for the comple-
25 tion of such studies.

1 “(B) ANNUAL REVIEW.—

2 “(i) IN GENERAL.—On an annual
3 basis following the approval of a deferral
4 under subparagraph (A), the applicant
5 shall submit to the Secretary the following
6 information:

7 “(I) Information detailing the
8 progress made in conducting pediatric
9 studies.

10 “(II) If no progress has been
11 made in conducting such studies, evi-
12 dence and documentation that such
13 studies will be conducted with due
14 diligence and at the earliest possible
15 time.

16 “(ii) PUBLIC AVAILABILITY.—The in-
17 formation submitted through the annual
18 review under clause (i) shall promptly be
19 made available to the public in an easily
20 accessible manner, including through the
21 website of the Food and Drug Administra-
22 tion.”.

1 **SEC. 413. IMPROVING AVAILABILITY OF PEDIATRIC DATA**
2 **FOR ALREADY MARKETED PRODUCTS.**

3 (a) IN GENERAL.—Section 505B(b) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355c(b)) is
5 amended—

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

8 “(1) IN GENERAL.—After providing notice in
9 the form of a letter, or a written request under sec-
10 tion 505A that was declined by the sponsor or hold-
11 er, and an opportunity for written response and a
12 meeting, which may include an advisory committee
13 meeting, the Secretary may (by order in the form of
14 a letter) require the sponsor or holder of an ap-
15 proved application for a drug under section 505 or
16 the holder of a license for a biological product under
17 section 351 of the Public Health Service Act (42
18 U.S.C. 262) to submit by a specified date the assess-
19 ments described in subsection (a)(2) and the written
20 request, as appropriate, if the Secretary finds that—

21 “(A)(i) the drug or biological product is
22 used for a substantial number of pediatric pa-
23 tients for the labeled indications; and

24 “(ii) adequate pediatric labeling could con-
25 fer a benefit on pediatric patients;

1 “(B) there is reason to believe that the
2 drug or biological product would represent a
3 meaningful therapeutic benefit over existing
4 therapies for pediatric patients for 1 or more of
5 the claimed indications; or

6 “(C) the absence of adequate pediatric la-
7 beling could pose a risk to pediatric patients.”;

8 (2) in paragraph (2)(C), by adding at the end
9 the following: “An applicant seeking either a partial
10 or full waiver shall submit to the Secretary docu-
11 mentation detailing why a pediatric formulation can-
12 not be developed, and, if the waiver is granted, the
13 applicant’s submission shall promptly be made avail-
14 able to the public in an easily accessible manner, in-
15 cluding through posting on the website of the Food
16 and Drug Administration.”; and

17 (3) by striking paragraph (3).

18 (b) EFFECT OF SECTION.—Nothing in this section
19 alters or amends section 301(j) of the Federal Food,
20 Drug, and Cosmetic Act or section 552 of title 5 or section
21 1905 of title 18, United States Code.

1 **SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESSMENTS;**
2 **ADVERSE EVENT REPORTING; LABELING**
3 **CHANGES; AND PEDIATRIC ASSESSMENTS.**

4 Section 505B of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355c) is amended—

6 (1) in subsection (h), by striking “505A(n)”
7 and inserting “505A(p)”;

8 (2) by redesignating subsection (f) as sub-
9 section (k);

10 (3) by redesignating subsection (g) as sub-
11 section (l); and

12 (4) by inserting after subsection (e) the fol-
13 lowing:

14 “(f) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS,
15 PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—

16 “(1) REVIEW.—The Secretary shall create an
17 internal committee to review all pediatric assessment
18 requests issued under this section, all pediatric as-
19 sessments conducted under this section, and all de-
20 ferral and waiver requests made pursuant to this
21 section. Such internal committee shall include indi-
22 viduals, each of whom is an employee of the Food
23 and Drug Administration, with the following exper-
24 tise:

25 “(A) Pediatrics.

26 “(B) Biopharmacology.

1 “(C) Statistics.

2 “(D) Drugs and drug formulations.

3 “(E) Pediatric ethics.

4 “(F) Legal issues.

5 “(G) Appropriate expertise pertaining to
6 the pediatric product under review.

7 “(H) 1 or more experts from the Office of
8 Pediatric Therapeutics.

9 “(I) Other individuals as designated by the
10 Secretary.

11 “(2) REVIEW OF REQUESTS FOR PEDIATRIC AS-
12 SESSMENTS, DEFERRALS, AND WAIVERS.—All writ-
13 ten requests for a pediatric assessment issued pursu-
14 ant to this section and all requests for deferrals and
15 waivers from the requirement to conduct a pediatric
16 assessment under this section shall be reviewed and
17 approved by the committee established under para-
18 graph (1).

19 “(3) REVIEW OF ASSESSMENTS.—The com-
20 mittee established under paragraph (1) shall review
21 all assessments conducted under this section to de-
22 termine whether such assessments meet the require-
23 ments of this section.

24 “(4) TRACKING OF ASSESSMENTS AND LABEL-
25 ING CHANGES.—The committee established under

1 paragraph (1) is responsible for tracking and mak-
2 ing public in an easily accessible manner, including
3 through posting on the website of the Food and
4 Drug Administration—

5 “(A) the number of assessments conducted
6 under this section;

7 “(B) the specific drugs and drug uses as-
8 sessed under this section;

9 “(C) the types of assessments conducted
10 under this section, including trial design, the
11 number of pediatric patients studied, and the
12 number of centers and countries involved;

13 “(D) the total number of deferrals re-
14 quested and granted under this section, and, if
15 granted, the reasons for such deferrals, the
16 timeline for completion, and the number com-
17 pleted and pending by the specified date, as
18 outlined in subsection (a)(3);

19 “(E) the number of waivers requested and
20 granted under this section, and, if granted, the
21 reasons for the waivers;

22 “(F) the number of pediatric formulations
23 developed and the number of pediatric formula-
24 tions not developed and the reasons any such
25 formulations were not developed;

1 “(G) the labeling changes made as a result
2 of assessments conducted under this section;

3 “(H) an annual summary of labeling
4 changes made as a result of assessments con-
5 ducted under this section for distribution pursu-
6 ant to subsection (i)(2); and

7 “(I) an annual summary of the informa-
8 tion submitted pursuant to subsection
9 (a)(3)(B).

10 “(g) LABELING CHANGES.—

11 “(1) PRIORITY STATUS FOR PEDIATRIC SUP-
12 PLEMENT.—Any supplement to an application under
13 section 505 and section 351 of the Public Health
14 Service Act proposing a labeling change as a result
15 of any pediatric assessments conducted pursuant to
16 this section—

17 “(A) shall be considered a priority supple-
18 ment; and

19 “(B) shall be subject to the performance
20 goals established by the Commissioner for pri-
21 ority drugs.

22 “(2) DISPUTE RESOLUTION.—

23 “(A) REQUEST FOR LABELING CHANGE
24 AND FAILURE TO AGREE.—If the Commissioner
25 determines that a sponsor and the Commis-

1 sioner have been unable to reach agreement on
2 appropriate changes to the labeling for the drug
3 that is the subject of the application or supple-
4 ment, not later than 180 days after the date of
5 the submission of the application or supple-
6 ment—

7 “(i) the Commissioner shall request
8 that the sponsor make any labeling change
9 that the Commissioner determines to be
10 appropriate; and

11 “(ii) if the sponsor does not agree to
12 make a labeling change requested by the
13 Commissioner, the Commissioner shall
14 refer the matter to the Pediatric Advisory
15 Committee.

16 “(B) ACTION BY THE PEDIATRIC ADVISORY
17 COMMITTEE.—Not later than 90 days after re-
18 ceiving a referral under subparagraph (A)(ii),
19 the Pediatric Advisory Committee shall—

20 “(i) review the pediatric study reports;
21 and

22 “(ii) make a recommendation to the
23 Commissioner concerning appropriate la-
24 beling changes, if any.

1 “(C) CONSIDERATION OF RECOMMENDA-
2 TIONS.—The Commissioner shall consider the
3 recommendations of the Pediatric Advisory
4 Committee and, if appropriate, not later than
5 30 days after receiving the recommendation,
6 make a request to the sponsor of the applica-
7 tion or supplement to make any labeling
8 changes that the Commissioner determines to
9 be appropriate.

10 “(D) MISBRANDING.—If the sponsor, with-
11 in 30 days after receiving a request under sub-
12 paragraph (C), does not agree to make a label-
13 ing change requested by the Commissioner, the
14 Commissioner may deem the drug that is the
15 subject of the application or supplement to be
16 misbranded.

17 “(E) NO EFFECT ON AUTHORITY.—Noth-
18 ing in this subsection limits the authority of the
19 United States to bring an enforcement action
20 under this Act when a drug lacks appropriate
21 pediatric labeling. Neither course of action (the
22 Pediatric Advisory Committee process or an en-
23 forcement action referred to in the preceding
24 sentence) shall preclude, delay, or serve as the
25 basis to stay the other course of action.

1 “(3) OTHER LABELING CHANGES.—If the Sec-
2 retary makes a determination that a pediatric as-
3 sessment conducted under this section does or does
4 not demonstrate that the drug that is the subject of
5 such assessment is safe and effective, including
6 whether such assessment results are inconclusive, in
7 pediatric populations or subpopulations, the Sec-
8 retary shall order the labeling of such product to in-
9 clude information about the results of the assess-
10 ment and a statement of the Secretary’s determina-
11 tion.

12 “(h) DISSEMINATION OF PEDIATRIC INFORMA-
13 TION.—

14 “(1) IN GENERAL.—Not later than 180 days
15 after the date of submission of a pediatric assess-
16 ment under this section, the Secretary shall make
17 available to the public in an easily accessible manner
18 the medical, statistical, and clinical pharmacology re-
19 views of such pediatric assessments and shall post
20 such assessments on the website of the Food and
21 Drug Administration.

22 “(2) DISSEMINATION OF INFORMATION RE-
23 GARDING LABELING CHANGES.—The Secretary shall
24 require that the sponsors of the assessments that re-
25 sult in labeling changes that are reflected in the an-

1 nual summary developed pursuant to subsection
2 (f)(4)(H) distribute such information to physicians
3 and other health care providers.

4 “(3) EFFECT OF SUBSECTION.—Nothing in this
5 subsection shall alter or amend section 301(j) of this
6 Act or section 552 of title 5, United States Code, or
7 section 1905 of title 18, United States Code.

8 “(i) ADVERSE EVENT REPORTING.—

9 “(1) REPORTING IN YEAR 1.—During the 1-
10 year period beginning on the date a labeling change
11 is made pursuant to subsection (g), the Secretary
12 shall ensure that all adverse event reports that have
13 been received for such drug (regardless of when such
14 report was received) are referred to the Office of Pe-
15 diatric Therapeutics. In considering such reports,
16 the Director of such Office shall provide for the re-
17 view of the report by the Pediatric Advisory Com-
18 mittee, including obtaining any recommendations of
19 such committee regarding whether the Secretary
20 should take action under this Act in response to
21 such report.

22 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
23 lowing the 1-year period described in paragraph (1),
24 the Secretary shall, as appropriate, refer to the Of-
25 fice of Pediatric Therapeutics with all adverse event

1 reports for a drug for which a pediatric study was
2 conducted under this section. In considering such re-
3 ports, the Director of such Office may provide for
4 the review of such reports by the Pediatric Advisory
5 Committee, including obtaining any recommendation
6 of such Committee regarding whether the Secretary
7 should take action in response to such report.

8 “(3) EFFECT.—The requirements of this sub-
9 section shall supplement, not supplant, other review
10 of such adverse event reports by the Secretary.”.

11 **SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.**

12 Section 505B(e) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 355e) is amended—

14 (1) by striking “estimates” and inserting “de-
15 termines”; and

16 (2) by striking “would” and inserting “could”.

17 **SEC. 416. REPORTS.**

18 (a) INSTITUTE OF MEDICINE STUDY.—

19 (1) IN GENERAL.—Not later than 3 years after
20 the date of enactment of the Pediatric Research Im-
21 provement Act, the Secretary shall contract with the
22 Institute of Medicine to conduct a study and report
23 to Congress regarding the pediatric studies con-
24 ducted pursuant to section 505B of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 355c)
2 since 1997.

3 (2) CONTENT OF STUDY.—The study under
4 paragraph (1) shall review and assess—

5 (A) pediatric studies conducted pursuant
6 to section 505B of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355c) since 1997 and
8 labeling changes made as a result of such stud-
9 ies; and

10 (B) the use of extrapolation for pediatric
11 subpopulations, the use of alternative endpoints
12 for pediatric populations, neonatal assessment
13 tools, number and type of pediatric adverse
14 events, and ethical issues in pediatric clinical
15 trials.

16 (3) REPRESENTATIVE SAMPLE.—The Institute
17 of Medicine may devise an appropriate mechanism to
18 review a representative sample of studies conducted
19 pursuant to section 505B of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355c) from each
21 review division within the Center for Drug Evalua-
22 tion and Research and the Center for Biologics
23 Evaluation and Research in order to make the re-
24 quired assessment.

1 (b) PREA REPORT.—Not later than September 1,
2 2010, the Comptroller General of the United States, in
3 consultation with the Secretary of Health and Human
4 Services, shall submit to Congress a report that addresses
5 the effectiveness of section 505B of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring
7 that medicines used by children are tested and properly
8 labeled, including—

9 (1) the number and importance of drugs for
10 children that are being tested as a result of this pro-
11 vision and the importance for children, health care
12 providers, parents, and others of labeling changes
13 made as a result of such testing;

14 (2) the number and importance of drugs for
15 children that are not being tested for their use not-
16 withstanding the provisions of the Pediatric Re-
17 search Equity Act of 2003 (Public Law 108–155),
18 and possible reasons for the lack of testing; and

19 (3) the number of drugs for which testing is
20 being done and labeling changes required, including
21 the date labeling changes are made and which label-
22 ing changes required the use of the dispute resolu-
23 tion process established pursuant to the amendments
24 made by the Pediatric Research Equity Act of 2003
25 (Public Law 108–155), together with a description

1 of the outcomes of such process, including a descrip-
2 tion of the disputes and the recommendations of the
3 Pediatric Advisory Committee.

4 **SEC. 417. TECHNICAL CORRECTIONS.**

5 Section 505B(a)(2)(B)(ii) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amend-
7 ed by striking “one” and inserting “1”.

8 **Subtitle C—Pediatric Medical**
9 **Devices**

10 **SEC. 421. SHORT TITLE.**

11 This subtitle may be cited as the “Pediatric Medical
12 Device Safety and Improvement Act of 2007”.

13 **SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.**

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

17 **“SEC. 515A. PEDIATRIC USES OF DEVICES.**

18 “(a) NEW DEVICES.—

19 “(1) IN GENERAL.—A person that submits to
20 the Secretary an application under section 520(m),
21 or an application (or supplement to an application)
22 or a product development protocol under section
23 515, shall include in the application or protocol the
24 information described in paragraph (2).

1 “(2) REQUIRED INFORMATION.—The applica-
2 tion or protocol described in paragraph (1) shall in-
3 clude, with respect to the device for which approval
4 is sought and if readily available—

5 “(A) a description of any pediatric sub-
6 populations that suffer from the disease or con-
7 dition that the device is intended to treat, diag-
8 nose, or cure; and

9 “(B) the number of affected pediatric pa-
10 tients.

11 “(3) ANNUAL REPORT.—Not later than 18
12 months after the date of enactment of this section,
13 and annually thereafter, the Secretary shall submit
14 to the Committee on Health, Education, Labor, and
15 Pensions of the Senate and the Committee on En-
16 ergy and Commerce of the House of Representatives
17 a report that includes—

18 “(A) the number of devices approved in the
19 year preceding the year in which the report is
20 submitted, for which there is a pediatric sub-
21 population that suffers from the disease or con-
22 dition that the device is intended to treat, diag-
23 nose, or cure;

24 “(B) the number of devices approved in
25 the year preceding the year in which the report

1 is submitted, labeled for use in pediatric pa-
2 tients;

3 “(C) the number of pediatric devices ap-
4 proved in the year preceding the year in which
5 the report is submitted, exempted from a fee
6 pursuant to section 738(a)(2)(B)(v); and

7 “(D) the review time for each device de-
8 scribed in subparagraphs (A), (B), and (C).

9 “(b) DETERMINATION OF PEDIATRIC EFFECTIVE-
10 NESS BASED ON SIMILAR COURSE OF DISEASE OR CONDI-
11 TION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

12 “(1) IN GENERAL.—If the course of the disease
13 or condition and the effects of the device are suffi-
14 ciently similar in adults and pediatric patients, the
15 Secretary may conclude that adult data may be used
16 to support a determination of a reasonable assur-
17 ance of effectiveness in pediatric populations, as ap-
18 propriate.

19 “(2) EXTRAPOLATION BETWEEN SUBPOPULA-
20 TIONS.—A study may not be needed in each pedi-
21 atric subpopulation if data from one subpopulation
22 can be extrapolated to another subpopulation.

23 “(c) PEDIATRIC SUBPOPULATION.—In this section,
24 the term ‘pediatric subpopulation’ has the meaning given
25 the term in section 520(m)(6)(E)(ii).”

1 **SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EX-**
2 **EMPTION.**

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

6 (1) in paragraph (3), by striking “No” and in-
7 serting “Except as provided in paragraph (6), no”;

8 (2) in paragraph (5)—

9 (A) by inserting “, if the Secretary has
10 reason to believe that the requirements of para-
11 graph (6) are no longer met,” after “public
12 health”; and

13 (B) by adding at the end the following: “If
14 the person granted an exemption under para-
15 graph (2) fails to demonstrate continued com-
16 pliance with the requirements of this sub-
17 section, the Secretary may suspend or withdraw
18 the exemption from the effectiveness require-
19 ments of sections 514 and 515 for a humani-
20 tarian device only after providing notice and an
21 opportunity for an informal hearing.”;

22 (3) by striking paragraph (6) and inserting the
23 following:

24 “(6)(A) Except as provided in subparagraph (D), the
25 prohibition in paragraph (3) shall not apply with respect

1 to a person granted an exemption under paragraph (2)
2 if each of the following conditions apply:

3 “(i)(I) The device with respect to which the ex-
4 emption is granted is intended for the treatment or
5 diagnosis of a disease or condition that occurs in pe-
6 diatric patients or in a pediatric subpopulation, and
7 such device is labeled for use in pediatric patients or
8 in a pediatric subpopulation in which the disease or
9 condition occurs.

10 “(II) The device was not previously approved
11 under this subsection for the pediatric patients or
12 the pediatric subpopulation described in subclause
13 (I) prior to the date of enactment of the Pediatric
14 Medical Device Safety and Improvement Act of
15 2007.

16 “(ii) During any calendar year, the number of
17 such devices distributed during that year does not
18 exceed the annual distribution number specified by
19 the Secretary when the Secretary grants such ex-
20 emption. The annual distribution number shall be
21 based on the number of individuals affected by the
22 disease or condition that such device is intended to
23 treat, diagnose, or cure, and of that number, the
24 number of individuals likely to use the device, and
25 the number of devices reasonably necessary to treat

1 such individuals. In no case shall the annual dis-
2 tribution number exceed the number identified in
3 paragraph (2)(A).

4 “(iii) Such person immediately notifies the Sec-
5 retary if the number of such devices distributed dur-
6 ing any calendar year exceeds the annual distribu-
7 tion number referred to in clause (ii).

8 “(iv) The request for such exemption is sub-
9 mitted on or before October 1, 2013.

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

15 “(C) A person may petition the Secretary to modify
16 the annual distribution number specified by the Secretary
17 under subparagraph (A)(ii) with respect to a device if ad-
18 ditional information on the number of individuals affected
19 by the disease or condition arises, and the Secretary may
20 modify such number but in no case shall the annual dis-
21 tribution number exceed the number identified in para-
22 graph (2)(A).

23 “(D) If a person notifies the Secretary, or the Sec-
24 retary determines through an inspection under subpara-
25 graph (B), that the number of devices distributed during

1 any calendar year exceeds the annual distribution number,
2 as required under subparagraph (A)(iii), and modified
3 under subparagraph (C), if applicable, then the prohibi-
4 tion in paragraph (3) shall apply with respect to such per-
5 son for such device for any sales of such device after such
6 notification.

7 “(E)(i) In this subsection, the term ‘pediatric pa-
8 tients’ means patients who are 21 years of age or younger
9 at the time of the diagnosis or treatment.

10 “(ii) In this subsection, the term ‘pediatric sub-
11 population’ means 1 of the following populations:

12 “(I) Neonates.

13 “(II) Infants.

14 “(III) Children.

15 “(IV) Adolescents.”; and

16 (4) by adding at the end the following:

17 “(7) The Secretary shall refer any report of an ad-
18 verse event regarding a device for which the prohibition
19 under paragraph (3) does not apply pursuant to para-
20 graph (6)(A) that the Secretary receives to the Office of
21 Pediatric Therapeutics, established under section 6 of the
22 Best Pharmaceuticals for Children Act (Public Law 107–
23 109)). In considering the report, the Director of the Office
24 of Pediatric Therapeutics, in consultation with experts in
25 the Center for Devices and Radiological Health, shall pro-

1 vide for periodic review of the report by the Pediatric Ad-
2 visory Committee, including obtaining any recommenda-
3 tions of such committee regarding whether the Secretary
4 should take action under this Act in response to the re-
5 port.”.

6 (b) REPORT.—Not later than January 1, 2012, the
7 Comptroller General of the United States shall submit to
8 the Committee on Health, Education, Labor, and Pen-
9 sions of the Senate and the Committee on Energy and
10 Commerce of the House of Representatives a report on
11 the impact of allowing persons granted an exemption
12 under section 520(m)(2) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a
14 device to profit from such device pursuant to section
15 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amend-
16 ed by subsection (a)), including—

17 (1) an assessment of whether such section
18 520(m)(6) (as amended by subsection (a)) has in-
19 creased the availability of pediatric devices for condi-
20 tions that occur in small numbers of children, in-
21 cluding any increase or decrease in the number of—

22 (A) exemptions granted under such section
23 520(m)(2) for pediatric devices; and

24 (B) applications approved under section
25 515 of such Act (21 U.S.C. 360e) for devices

1 intended to treat, diagnose, or cure conditions
2 that occur in pediatric patients or for devices
3 labeled for use in a pediatric population;

4 (2) the conditions or diseases the pediatric de-
5 vices were intended to treat or diagnose and the esti-
6 mated size of the pediatric patient population for
7 each condition or disease;

8 (3) the costs of the pediatric devices, based on
9 a survey of children's hospitals;

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

12 (5) the impact, if any, of allowing profit on ac-
13 cess to such devices for patients;

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

16 (7) an estimate of the extent of the use of the
17 pediatric devices by both adults and pediatric popu-
18 lations for a condition or disease other than the con-
19 dition or disease on the label of such devices;

20 (8) recommendations of the Comptroller Gen-
21 eral of the United States regarding the effectiveness
22 of such section 520(m)(6) (as amended by sub-
23 section (a)) and whether any modifications to such
24 section 520(m)(6) (as amended by subsection (a))
25 should be made;

1 (9) existing obstacles to pediatric device devel-
2 opment; and

3 (10) an evaluation of the demonstration grants
4 described in section 425, which shall include an eval-
5 uation of the number of pediatric medical devices—

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

8 (B) that have been submitted to the Food
9 and Drug Administration for approval, clear-
10 ance, or review under such section 520(m) (as
11 amended by this Act) and any regulatory ac-
12 tions taken.

13 (c) GUIDANCE.—Not later than 180 days after the
14 date of enactment of this subtitle, the Commissioner of
15 Food and Drugs shall issue guidance for institutional re-
16 view committees on how to evaluate requests for approval
17 for devices for which a humanitarian device exemption
18 under section 520(m)(2) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

20 **SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.**

21 Section 402(b) of the Public Health Service Act (42
22 U.S.C. 282(b)) is amended—

23 (1) in paragraph (21), by striking “and” after
24 the semicolon at the end;

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

3 (3) by inserting after paragraph (22) the fol-
4 lowing:

5 “(23) shall designate a contact point or office
6 to help innovators and physicians identify sources of
7 funding available for pediatric medical device devel-
8 opment.”.

9 **SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
10 **ATRIC DEVICE AVAILABILITY.**

11 (a) IN GENERAL.—

12 (1) REQUEST FOR PROPOSALS.—Not later than
13 90 days after the date of enactment of this subtitle,
14 the Secretary of Health and Human Services shall
15 issue a request for proposals for 1 or more grants
16 or contracts to nonprofit consortia for demonstration
17 projects to promote pediatric device development.

18 (2) DETERMINATION ON GRANTS OR CON-
19 TRACTS.—Not later than 180 days after the date the
20 Secretary of Health and Human Services issues a
21 request for proposals under paragraph (1), the Sec-
22 retary shall make a determination on the grants or
23 contracts under this section.

24 (b) APPLICATION.—A nonprofit consortium that de-
25 sires to receive a grant or contract under this section shall

1 submit an application to the Secretary of Health and
2 Human Services at such time, in such manner, and con-
3 taining such information as the Secretary may require.

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

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

11 (2) mentoring and managing pediatric device
12 projects through the development process, including
13 product identification, prototype design, device devel-
14 opment, and marketing;

15 (3) connecting innovators and physicians to ex-
16 isting Federal and non-Federal resources, including
17 resources from the Food and Drug Administration,
18 the National Institutes of Health, the Small Busi-
19 ness Administration, the Department of Energy, the
20 Department of Education, the National Science
21 Foundation, the Department of Veterans Affairs,
22 the Agency for Healthcare Research and Quality,
23 and the National Institute of Standards and Tech-
24 nology;

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

3 (5) providing assistance and advice as needed
4 on business development, personnel training, proto-
5 type development, postmarket needs, and other ac-
6 tivities consistent with the purposes of this section.

7 (d) COORDINATION.—

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

11 (A) coordinate with the National Institutes
12 of Health’s pediatric device contact point or of-
13 fice, designated under section 424; and

14 (B) provide to the National Institutes of
15 Health any identified pediatric device needs
16 that the consortium lacks sufficient capacity to
17 address or those needs in which the consortium
18 has been unable to stimulate manufacturer in-
19 terest.

20 (2) FOOD AND DRUG ADMINISTRATION.—Each
21 consortium that receives a grant or contract under
22 this section shall coordinate with the Commissioner
23 of Food and Drugs and device companies to facili-
24 tate the application for approval or clearance of de-
25 vices labeled for pediatric use.

1 (3) EFFECTIVENESS AND OUTCOMES.—Each
2 consortium that receives a grant or contract under
3 this section shall annually report to the Secretary of
4 Health and Human Services on—

5 (A) the effectiveness of activities conducted
6 under subsection (c);

7 (B) the impact of activities conducted
8 under subsection (c) on pediatric device devel-
9 opment; and

10 (C) the status of pediatric device develop-
11 ment that has been facilitated by the consor-
12 tium.

13 (e) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated to carry out this section
15 \$6,000,000 for each of fiscal years 2008 through 2012.

16 **SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**
17 **PEUTICS AND PEDIATRIC ADVISORY COM-**
18 **MITTEE.**

19 (a) IN GENERAL.—

20 (1) OFFICE OF PEDIATRIC THERAPEUTICS.—
21 Section 6(b) of the Best Pharmaceuticals for Chil-
22 dren Act (21 U.S.C. 393a(b)) is amended by insert-
23 ing “, including increasing pediatric access to med-
24 ical devices” after “pediatric issues”.

1 (2) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-
2 SEARCH.—

3 (A) IN GENERAL.—Not later than 270
4 days after the date of enactment of this sub-
5 title, the Office of Pediatric Therapeutics, in
6 collaboration with the Director of the National
7 Institutes of Health and the Director of the
8 Agency for Healthcare Research and Quality,
9 shall submit to the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate and
11 the Committee on Energy and Commerce of the
12 House of Representatives a plan for expanding
13 pediatric medical device research and develop-
14 ment. In developing such plan, the Commis-
15 sioner of Food and Drugs shall consult with in-
16 dividuals and organizations with appropriate ex-
17 pertise in pediatric medical devices.

18 (B) CONTENTS.—The plan under subpara-
19 graph (A) shall include—

20 (i) the current status of federally
21 funded pediatric medical device research;

22 (ii) any gaps in such research, which
23 may include a survey of pediatric medical
24 providers regarding unmet pediatric med-
25 ical device needs, as needed; and

1 (iii) a research agenda for improving
2 pediatric medical device development and
3 Food and Drug Administration clearance
4 or approval of pediatric medical devices,
5 and for evaluating the short- and long-
6 term safety and effectiveness of pediatric
7 medical devices.

8 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14
9 of the Best Pharmaceuticals for Children Act (42 U.S.C.
10 284m note) is amended—

11 (1) in subsection (a), by inserting “(including
12 drugs and biological products) and medical devices”
13 after “therapeutics”; and

14 (2) in subsection (b)—

15 (A) in paragraph (1), by inserting “(in-
16 cluding drugs and biological products) and med-
17 ical devices” after “therapeutics”; and

18 (B) in paragraph (2)—

19 (i) in subparagraph (A), by striking
20 “and 505B” and inserting “505B, 510(k),
21 515, and 520(m)”;

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

24 “(B) identification of research priorities re-
25 lated to therapeutics (including drugs and bio-

1 “(iii) that is intended to be implanted
2 in the human body for more than 1 year,
3 or a life sustaining or life supporting de-
4 vice used outside a device user facility.

5 “(B) CONDITION.—The Secretary may
6 order a postmarket surveillance under subpara-
7 graph (A) as a condition to approval of an ap-
8 plication (or a supplement to an application) or
9 a product development protocol under section
10 515 or as a condition to clearance of a pre-
11 market notification under section 510(k) only
12 for a device described in subparagraph (A)(ii).

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

17 (2) in subsection (b)—

18 (A) by striking “(b) SURVEILLANCE AP-
19 PROVAL.—Each” and inserting the following:

20 “(b) SURVEILLANCE APPROVAL.—

21 “(1) IN GENERAL.—Each”;

22 (B) by striking “The Secretary, in con-
23 sultation” and inserting “Except as provided in
24 paragraph (2), the Secretary, in consultation”;

1 (C) by striking “Any determination” and
2 inserting “Except as provided in paragraph (2),
3 any determination”; and

4 (D) by adding at the end the following:

5 “(2) LONGER SURVEILLANCES FOR PEDIATRIC
6 DEVICES.—The Secretary may by order require a
7 prospective surveillance period of more than 36
8 months with respect to a device that is expected to
9 have significant use in pediatric populations if such
10 period of more than 36 months is necessary in order
11 to assess the impact of the device on growth and de-
12 velopment, or the effects of growth, development, ac-
13 tivity level, or other factors on the safety of the de-
14 vice.”.

15 **SEC. 428. SEVERABILITY CLAUSE.**

16 If any provision of this Act, an amendment made this
17 Act, or the application of such provision or amendment
18 to any person or circumstance is held to be unconstitu-
19 tional, the remainder of this Act, the amendments made
20 by this Act, and the application of the provisions of such
21 to any person or circumstances shall not be affected there-
22 by.

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.”.