

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

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)”; and

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)”; and

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)”; and

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 “(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. 105. SAVINGS CLAUSE.**

11 Notwithstanding section 509 of the Prescription
12 Drug User Fee Amendments of 2002 (21 U.S.C. 379g
13 note), and notwithstanding the amendments made by this
14 title, part 2 of subchapter C of chapter VII of the Federal
15 Food, Drug, and Cosmetic Act, as in effect on the day
16 before the date of enactment of this title, shall continue
17 to be in effect with respect to human drug applications
18 and supplements (as defined in such part as of such day)
19 that on or after October 1, 2002, but before October 1,
20 2007, were accepted by the Food and Drug Administra-
21 tion for filing with respect to assessing and collecting any
22 fee required by such part for a fiscal year prior to fiscal
23 year 2008.

1 **SEC. 106. TECHNICAL AMENDMENTS.**

2 (a) Section 737 (21 U.S.C. 379i) is amended in the
3 matter preceding paragraph (1), by striking “subchapter”
4 and inserting “part”.

5 (b) Section 739 (21 U.S.C. 379j–11) is amended in
6 the matter preceding paragraph (1), by striking “sub-
7 chapter” 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 **SEC. 108. SUNSET DATE.**

16 Sections 735, 736, and 736A of the Federal Food,
17 Drug, and Cosmetic Act shall cease to be effective on Oc-
18 tober 1, 2012.

19 **TITLE II—DRUG SAFETY**

20 **SEC. 200. SHORT TITLE.**

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

1 **Subtitle A—Risk Evaluation and**
2 **Mitigation Strategies**

3 **SEC. 201. RISK EVALUATION.**

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

7 “(3) RISK IDENTIFICATION AND ASSESS-
8 MENT.—

9 “(A) ROUTINE ACTIVE SAFETY MONI-
10 TORING.—The Secretary shall facilitate a pub-
11 lic-private partnership to—

12 “(i) implement a routine active moni-
13 toring system for postmarket drug safety;
14 and

15 “(ii) focus postmarket studies under
16 subsection (o)(4)(A) and postapproval clin-
17 ical trials under subsection (o)(4)(B) more
18 effectively on cases for which reports under
19 paragraph (1) and other safety signal de-
20 tection is not sufficient to resolve whether
21 there is an elevated risk of a serious ad-
22 verse event associated with use of a drug.

23 “(B) PUBLIC-PRIVATE PARTNERSHIP.—
24 The public-private partnership described in sub-
25 paragraph (A) shall—

1 drug and other preapproval
2 trials;

3 “(bb) rare, serious drug side
4 effects; and

5 “(cc) the safety of use in do-
6 mestic populations not included
7 in the trials used to approve the
8 drug (such as older people, peo-
9 ple with comorbidities, pregnant
10 women, or children).

11 “(C) PUBLIC PROCESS FOR PRIORITY
12 QUESTIONS.—At least biannually, the Secretary
13 shall seek recommendations from appropriate
14 advisory committees to the Food and Drug Ad-
15 ministration on—

16 “(i) priority drug safety questions;
17 and

18 “(ii) mechanisms for answering such
19 questions, including through—

20 “(I) routine active safety moni-
21 toring; and

22 “(II) when such monitoring is
23 not sufficient, postmarket studies
24 under subsection (o)(4)(B) and post-

1 approval clinical trials under sub-
2 section (o)(4)(C).

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

10 “(E) PUBLIC AVAILABILITY OF ANAL-
11 YSES.—The Secretary shall make such analyses,
12 including the methods and results of such anal-
13 yses, available to the public for review and com-
14 ment.

15 “(F) OTHER APPROACHES.—The Secretary
16 shall develop, support, and participate in other
17 means to gather and analyze data and informa-
18 tion relevant to priority drug safety questions,
19 including existing means such as the Vaccine
20 Adverse Event Reporting System and the Vac-
21 cine Safety Datalink or successor databases.”.

22 (b) AUTHORIZATION OF APPROPRIATIONS.—There
23 are authorized to be appropriated to carry out this section
24 \$20,000,000 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) the last assessment of the
18 approved risk evaluation and mitiga-
19 tion strategy for the drug; or

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

23 “(I) the approval of such strat-
24 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;

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

15 “(iv) a postapproval study, including a
16 study under paragraph (4)(D); or

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

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

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

24 “(ii) may be symptomatically and
25 pathophysiologically related to an adverse

1 drug experience listed in the labeling of the
2 drug, but differs from such adverse drug
3 experience because of greater severity,
4 specificity, or prevalence.

5 “(3) REQUIRED ELEMENTS OF A RISK EVALUA-
6 TION AND MITIGATION STRATEGY.—The risk evalua-
7 tion and mitigation strategy for a drug shall re-
8 quire—

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

12 “(B) submission of reports for the drug as
13 required under subsection (k)(1);

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

16 “(D) a timetable for submission of assess-
17 ments of the strategy, that—

18 “(i) shall be no less frequently than
19 once annually for the first 3 years after
20 the drug is initially approved under sub-
21 section (c) or licensed under section 351 of
22 the Public Health Service Act, and at a
23 frequency specified in the strategy for sub-
24 sequent years;

1 “(ii) may be increased or reduced in
2 frequency as necessary as provided for in
3 paragraph (7)(B)(iv)(VI) ; and

4 “(iii) may be eliminated after the first
5 3 years if the Secretary determines that
6 serious risks of the drug have been ade-
7 quately identified and assessed and are
8 being adequately managed.

9 “(4) ADDITIONAL POTENTIAL EVALUATION
10 ELEMENTS OF A RISK EVALUATION AND MITIGATION
11 STRATEGY.—

12 “(A) RISK EVALUATION.—The Secretary
13 may require that the risk evaluation and miti-
14 gation strategy for a drug include 1 or more of
15 the additional evaluation elements described in
16 this paragraph, so long as the Secretary makes
17 the determination required with respect to each
18 additional included element.

19 “(B) POSTAPPROVAL STUDIES.—The risk
20 evaluation and mitigation strategy for a drug
21 may require that the applicant conduct an ap-
22 propriate postapproval study, such as a pro-
23 spective or retrospective observational study, of
24 the drug (which shall include a timeframe for
25 completing the study and reporting the results

1 to the Secretary), if the Secretary determines
2 that the reports under subsection (k)(1) and
3 routine active safety monitoring under sub-
4 section (k)(3) are not sufficient to—

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

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

13 “(C) POSTAPPROVAL CLINICAL TRIALS.—
14 The risk evaluation and mitigation strategy for
15 a drug may require that the applicant for a
16 drug for which there is no effective approved
17 application under subsection (j) as of the date
18 that the requirement is first imposed conduct
19 an appropriate postapproval clinical trial of the
20 drug (which shall include a timeframe for com-
21 pleting the clinical trial and reporting the re-
22 sults to the Secretary) to be included in the
23 clinical trial registry database and clinical trial
24 results database provided for under section
25 402(i) of the Public Health Service Act, if the

1 Secretary determines that the reports under
2 subsection (k)(1), routine active safety moni-
3 toring under subsection (k)(3), and a study or
4 studies under subparagraph (B) will likely be
5 inadequate to assess a signal of a serious risk
6 with use of the drug.

7 “(5) ADDITIONAL POTENTIAL COMMUNICATION
8 ELEMENTS OF A RISK EVALUATION AND MITIGATION
9 STRATEGY.—

10 “(A) RISK COMMUNICATION.—The Sec-
11 retary may require that the risk evaluation and
12 mitigation strategy for a drug include 1 or
13 more of the additional communication elements
14 described in this paragraph, so long as the Sec-
15 retary makes the determination required with
16 respect to each additional included element.

17 “(B) MEDGUIDE; PATIENT PACKAGE IN-
18 SERT.—The risk evaluation and mitigation
19 strategy for a drug may require that the appli-
20 cant develop for distribution to each patient
21 when the drug is dispensed—

22 “(i) a Medication Guide, as provided
23 for under part 208 of title 21, Code of
24 Federal Regulations (or any successor reg-
25 ulations); or

1 “(ii) a patient package insert, if the
2 Secretary determines that such insert may
3 help mitigate a serious risk listed in the la-
4 beling of the drug.

5 “(C) COMMUNICATION PLAN.—The risk
6 evaluation and mitigation strategy for a drug
7 may require that the applicant conduct a com-
8 munication plan to health care providers, if,
9 with respect to such drug, the Secretary deter-
10 mines that such plan may support implementa-
11 tion of an element of the strategy, such as a
12 label change. Such plan may include—

13 “(i) sending letters to health care pro-
14 viders;

15 “(ii) disseminating information about
16 the elements of the risk evaluation and
17 mitigation strategy to encourage implemen-
18 tation by health care providers of compo-
19 nents that apply to such health care pro-
20 viders, or to explain certain safety proto-
21 cols (such as medical monitoring by peri-
22 odic laboratory tests); or

23 “(iii) disseminating information to
24 health care providers through professional

1 societies about any serious risks of the
2 drug and any protocol to assure safe use.

3 “(D) PREREVIEW.—

4 “(i) IN GENERAL.—The risk evalua-
5 tion and mitigation strategy for a drug
6 may require that the applicant submit to
7 the Secretary advertisements of the drug
8 for prereview not later than 45 days before
9 dissemination of the advertisement, if the
10 Secretary determines that such prereview
11 is necessary to ensure compliance with sec-
12 tion 502(n) with respect to the inclusion of
13 a true statement in advertisements of in-
14 formation in brief summary relating to a
15 serious risk listed in the labeling of the
16 drug.

17 “(ii) SPECIFICATION OF ADVERTISE-
18 MENTS.—The Secretary may specify the
19 advertisements required to be submitted
20 under clause (i).

21 “(E) SPECIFIC DISCLOSURES.—

22 “(i) IN GENERAL.—The risk evalua-
23 tion and mitigation strategy for a drug
24 may require that the applicant include in

1 advertisements of the drug a specific dis-
2 closure—

3 “(I) of the date the drug was ap-
4 proved and that the existing informa-
5 tion may not have identified or al-
6 lowed for full assessment of all serious
7 risks of using the drug, if the Sec-
8 retary determines that such disclosure
9 is necessary to protect public health
10 and safety; or

11 “(II) about a serious risk listed
12 in the labeling of the drug or a pro-
13 tocol to ensure safe use described in
14 the labeling of the drug, if the Sec-
15 retary determines that such advertise-
16 ments lacking such disclosure would
17 be false or misleading.

18 “(ii) SPECIFICATION OF ADVERTISE-
19 MENTS.—The Secretary may specify the
20 advertisements required to include a spe-
21 cific disclosure under clause (i).

22 “(F) TEMPORARY MORATORIUM.—The risk
23 evaluation and mitigation strategy for a drug
24 may require that for a fixed period after initial
25 approval, not to exceed 2 years, the applicant

1 not issue or cause to be issued direct-to-con-
2 sumer advertisements of the drug, if the Sec-
3 retary determines that disclosure under sub-
4 paragraph (E)(i)(I) is inadequate to protect
5 public health and safety, and that such prohibi-
6 tion is necessary to protect public health and
7 safety while additional information about seri-
8 ous risks of the drug is collected under sub-
9 section (k). In making such determination, the
10 Secretary shall consider—

11 “(i) the number of patients who may
12 be treated with the drug;

13 “(ii) the seriousness of the condition
14 for which the drug will be used;

15 “(iii) the serious risks listed in the la-
16 beling of the drug;

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

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

1 “(iii) to the extent practicable, so as
2 to minimize the burden on the health care
3 delivery system—

4 “(I) conform with restrictions on
5 distribution or use for other drugs
6 with similar, serious risks; and

7 “(II) be designed to be compat-
8 ible with established distribution, pro-
9 curement, and dispensing systems for
10 drugs.

11 “(C) ELEMENTS TO PROTECT PATIENT
12 SAFETY.—The restrictions on distribution or
13 use described under subparagraph (A) shall in-
14 clude 1 or more goals to evaluate or mitigate a
15 serious risk listed in the labeling of the drug
16 and, to mitigate such risk, may require that—

17 “(i) health care providers that pre-
18 scribe the drug have particular training or
19 experience, or are specially certified;

20 “(ii) pharmacies, practitioners, or
21 health care settings that dispense the drug
22 are specially certified;

23 “(iii) the drug be dispensed to pa-
24 tients only in certain health care settings,
25 such as hospitals;

1 “(iv) the drug be dispensed to pa-
2 tients with evidence or other documenta-
3 tion of safe-use conditions, such as labora-
4 tory test results;

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

7 “(vi) each patient using the drug be
8 enrolled in a registry.

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

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

21 “(ii) work to improve implementation
22 of such elements by such persons.

23 “(E) EVALUATION OF RESTRICTIONS.—
24 The Secretary, through the Drug Safety and
25 Risk Management Advisory Committee (or suc-

1 cessor committee) of the Food and Drug Ad-
2 ministration, shall—

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

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

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

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

17 “(I) assure safe use of the drug;

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

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

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

1 “(I) issue, or modify current,
2 agency guidance about how to imple-
3 ment the requirements of this para-
4 graph; and

5 “(II) modify restrictions under
6 this paragraph as appropriate.

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

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

11 “(i) INITIAL APPROVAL.—An appli-
12 cant shall include a proposed risk evalua-
13 tion and mitigation strategy in an applica-
14 tion under subsection (b) or section 351 of
15 the Public Health Service Act for initial
16 approval of the drug.

17 “(ii) APPROVAL OF NEW INDICA-
18 TION.—If no risk evaluation and mitiga-
19 tion strategy for the drug is in effect under
20 this subsection and the drug may not be
21 dispensed without a prescription, the appli-
22 cant shall include a proposed risk evalua-
23 tion and mitigation strategy in an applica-
24 tion, including in a supplemental applica-

1 tion, seeking a new indication for such
2 drug.

3 “(iii) CONTENTS.—A proposed risk
4 evaluation and mitigation strategy—

5 “(I) shall include the minimal
6 elements required under paragraph
7 (3); and

8 “(II) may also include additional
9 elements as provided for under para-
10 graphs (4), (5), and (6).

11 “(B) ASSESSMENT AND MODIFICATION OF
12 A RISK EVALUATION AND MITIGATION STRAT-
13 EGY.—

14 “(i) VOLUNTARY ASSESSMENTS.—The
15 applicant may submit to the Secretary an
16 assessment of, and propose a modification
17 to, the approved risk evaluation and miti-
18 gation strategy for a drug at any time.

19 “(ii) REQUIRED ASSESSMENTS.—The
20 applicant shall submit an assessment of,
21 and may propose a modification to, the ap-
22 proved risk evaluation and mitigation
23 strategy for a drug—

24 “(I) when submitting an applica-
25 tion, including a supplemental appli-

1 cation, for a new indication under
2 subsection (b) or section 351 of the
3 Public Health Service Act, unless the
4 drug may be dispensed without a pre-
5 scription and the risk evaluation and
6 mitigation strategy for the drug in-
7 cludes only the elements under para-
8 graph (3);

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

12 “(III) within a time specified by
13 the Secretary, not to be less than 45
14 days, when ordered by the Secretary
15 (acting through the appropriate office
16 responsible for reviewing the drug and
17 the office responsible for postapproval
18 safety with respect to the drug), if the
19 Secretary determines that new safety
20 information indicates that an element
21 under paragraph (3) or (4) should be
22 modified or included in the strategy;

23 “(IV) within 90 days when or-
24 dered by the Secretary (acting
25 through such offices), if the Secretary

1 determines that new safety informa-
2 tion indicates that an element under
3 paragraph (6) should be modified or
4 added; or

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

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

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

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

22 “(iv) ASSESSMENT.—An assessment
23 of the approved risk evaluation and mitiga-
24 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 section 402(i) of the Public Health
3 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), (C), or (D) of
18 paragraph (3) or the addition, modifica-
19 tion, or removal of any element under
20 paragraph (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)(D), including to elimi-
16 nate assessments.

17 “(C) REVIEW.—The Secretary (acting
18 through the offices described in subparagraph
19 (B)(ii)) shall promptly review the proposed risk
20 evaluation and mitigation strategy for a drug
21 submitted under subparagraph (A), or an as-
22 sessment 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 (B)(ii)) shall initiate discussions of the pro-
4 posed risk evaluation and mitigation strategy
5 for a drug submitted under subparagraph (A),
6 or of an assessment of the approved risk eval-
7 uation and mitigation strategy for a drug sub-
8 mitted under subparagraph (B), with the appli-
9 cant 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 assessment is submitted
20 under subclause (II) or (III) of subpara-
21 graph (B)(ii), not later than 20 days after
22 such submission;

23 “(iii) if the assessment is submitted
24 under subparagraph (B)(i) or under sub-

1 paragraph (B)(ii)(IV), not later than 30
2 days after such submission; or

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

6 “(E) ACTION.—

7 “(i) IN GENERAL.—Unless the appli-
8 cant requests the dispute resolution proc-
9 ess as described under subparagraph (F)
10 or (G), the Secretary (acting through the
11 offices described in subparagraph (B)(ii))
12 shall approve and include the risk evalua-
13 tion and mitigation strategy for a drug, or
14 any modification to the strategy with—

15 “(I) the action letter on the ap-
16 plication, when a proposed strategy is
17 submitted under subparagraph (A) or
18 an assessment of the strategy is sub-
19 mitted under subparagraph (B)(ii)(I);
20 or

21 “(II) an order, which shall be
22 made public, issued not later than 50
23 days after the date discussions of such
24 modification begin under subpara-
25 graph (D), when an assessment of the

1 strategy is submitted under subpara-
2 graph (B)(i) or under subclause (II),
3 (III), (IV), or (V) of subparagraph
4 (B)(ii).

5 “(ii) INACTION.—An approved risk
6 evaluation and mitigation strategy shall re-
7 main in effect until the Secretary acts, if
8 the Secretary fails to act as provided under
9 clause (i).

10 “(F) DISPUTE RESOLUTION AT INITIAL
11 APPROVAL.—When a proposed risk evaluation
12 and mitigation strategy is submitted under sub-
13 paragraph (A)(i), the applicant shall use the
14 major dispute resolution procedures as set forth
15 in the letters described in section 735(a).

16 “(G) DISPUTE RESOLUTION IN ALL OTHER
17 CASES.—

18 “(i) REQUEST FOR REVIEW.—In any
19 case other than a submission under sub-
20 paragraph (A)(i), not earlier than 15 days,
21 and not later than 35 days, after discus-
22 sions under subparagraph (D) have begun,
23 the applicant may request in writing that
24 a dispute about the strategy be reviewed
25 by the Drug Safety Oversight Board.

1 “(ii) SCHEDULING REVIEW.—If the
2 applicant requests review under clause (i),
3 the Secretary—

4 “(I)(aa) shall schedule the dis-
5 pute for review at 1 of the next 2 reg-
6 ular meetings of the Drug Safety
7 Oversight Board, whichever meeting
8 date is more practicable; or

9 “(bb) may convene a special
10 meeting of the Drug Safety Oversight
11 Board to review the matter more
12 promptly, including to meet an action
13 deadline on an application (including
14 a supplemental application); and

15 “(II) shall give notice to the pub-
16 lic on the Internet website of the Food
17 and Drug Administration of—

18 “(aa) the nature of the dis-
19 pute; and

20 “(bb) the date on which the
21 Drug Safety Oversight Board
22 shall consider such dispute.

23 “(iii) AGREEMENT AFTER DISCUSSION
24 OR ADMINISTRATIVE APPEALS.—

1 “(I) FURTHER DISCUSSION OR
2 ADMINISTRATIVE APPEALS.—A re-
3 quest for review under clause (i) shall
4 not preclude—

5 “(aa) further discussions to
6 reach agreement on the risk eval-
7 uation and mitigation strategy;
8 or

9 “(bb) the use of administra-
10 tive appeals within the Food and
11 Drug Administration to reach
12 agreement on the strategy, in-
13 cluding the major dispute resolu-
14 tion procedures as set forth in
15 the letters described in section
16 735(a).

17 “(II) AGREEMENT TERMINATES
18 DISPUTE RESOLUTION.—At any time
19 before a decision and order is issued
20 under clause (vi), the Secretary and
21 the applicant may reach an agreement
22 on the risk evaluation and mitigation
23 strategy through further discussion or
24 administrative appeals, terminating
25 the dispute resolution process, and the

1 Secretary shall issue an action letter
2 or order, as appropriate, that de-
3 scribes the strategy.

4 “(iv) MEETING OF THE BOARD.—At
5 the meeting of the Drug Safety Oversight
6 Board described in clause (ii), the Board
7 shall—

8 “(I) hear from both parties; and

9 “(II) review the dispute.

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

16 “(vi) ACTION BY THE SECRETARY.—

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

1 “(aa) the action deadline for
2 the action letter on the applica-
3 tion; or

4 “(bb) 7 days after receiving
5 the recommendation of the Drug
6 Safety Oversight Board.

7 “(II) ORDER.—With respect to
8 an assessment of the risk evaluation
9 and mitigation strategy under sub-
10 paragraph (B)(i) or under subclause
11 (II), (III), (IV), or (V) of subpara-
12 graph (B)(ii), the Secretary shall
13 issue an order, which (with the rec-
14 ommendation of the Drug Safety
15 Oversight Board) shall be made pub-
16 lic, that resolves the dispute not later
17 than 7 days after receiving the rec-
18 ommendation of the Drug Safety
19 Oversight Board.

20 “(vii) INACTION.—An approved risk
21 evaluation and mitigation strategy shall re-
22 main in effect until the Secretary acts, if
23 the Secretary fails to act as provided for
24 under clause (vi).

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

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

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

24 “(ix) DISQUALIFICATION.—No indi-
25 vidual who is an employee of the Food and

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

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

19 “(H) USE OF ADVISORY COMMITTEES.—
20 The Secretary may convene a meeting of 1 or
21 more advisory committees of the Food and
22 Drug Administration to—

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

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

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

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

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

13 “(i) IN GENERAL.—When a concern
14 about a serious risk of a drug may be re-
15 lated to the pharmacological class of the
16 drug, the Secretary may defer assessments
17 of the approved risk evaluation and mitiga-
18 tion strategies for such drugs until the
19 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 may coordinate the timetable for
3 submission of assessments under paragraph
4 (3)(D), a study under paragraph (4)(B), or a
5 clinical trial under paragraph (4)(C), with ef-
6 forts to identify and assess the serious risks of
7 such drug by the marketing authorities of other
8 countries whose drug approval and risk man-
9 agement processes the Secretary deems com-
10 parable to the drug approval and risk manage-
11 ment processes of the United States.

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

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

1 of the approved risk evaluation and mitigation
2 strategy for the drug under this subsection is
3 not required.

4 “(8) DRUG SAFETY OVERSIGHT BOARD.—

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

7 “(B) COMPOSITION; MEETINGS.—The
8 Drug Safety Oversight Board shall—

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

13 “(ii) include representatives from of-
14 fices throughout the Food and Drug Ad-
15 ministration;

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

22 “(iv) meet at least monthly to provide
23 oversight and advice to the Secretary on
24 the management of important drug safety
25 issues.”.

1 **SEC. 203. ENFORCEMENT.**

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

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

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

12 “(2) comply with a requirement of such strat-
13 egy with respect to advertising as provided for under
14 subparagraph (D), (E), or (F) of paragraph (5) of
15 such section.”.

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

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

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

23 “(3) An applicant (as such term is used in sec-
24 tion 505(o)) who knowingly fails to comply with a
25 requirement of an approved risk evaluation and miti-
26 gation strategy under such section 505(o) shall be

1 subject to a civil money penalty of not less than
2 \$15,000 and not more than \$250,000 per violation,
3 and not to exceed \$1,000,000 for all such violations
4 adjudicated in a single proceeding.”;

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

7 (4) in paragraph (4), as so redesignated, by
8 striking “paragraph (1) or (2)” each place it ap-
9 pears and inserting “paragraph (1), (2), or (3)”;
10 and

11 (5) in paragraph (6), as so redesignated, by
12 striking “paragraph (4)” each place it appears and
13 inserting “paragraph (5)”.

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

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

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

20 “(D) RISK EVALUATION AND MITIGATION STRAT-
21 EGY.—A person that submits an application for a license
22 for a drug under this paragraph shall submit to the Sec-
23 retary as part of the application a proposed risk evaluation
24 and mitigation strategy as described under section 505(o)
25 of the Federal Food, Drug, and Cosmetic Act.”; and

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

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

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

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

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

20 “(D) RISK EVALUATION AND MITIGATION STRATEGY
21 REQUIREMENT.—

22 “(i) IN GENERAL.—A drug that is the subject
23 of an abbreviated new drug application under this
24 subsection shall be subject to only the following ele-
25 ments of the risk evaluation and mitigation strategy

1 required under subsection (o) for the applicable list-
2 ed drug:

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

5 “(II) Submission of reports, as required
6 under subsection (o)(3)(B) for the applicable
7 listed drug.

8 “(III) A Medication Guide or patient pack-
9 age insert, if required under subsection
10 (o)(5)(B) for the applicable listed drug.

11 “(IV) Prereview of advertising, if required
12 under subsection (o)(5)(D) for the applicable
13 listed drug.

14 “(V) Specific disclosures in advertising, if
15 required under subsection (o)(5)(E) for the ap-
16 plicable listed drug.

17 “(VI) A temporary moratorium on direct-
18 to-consumer advertising, if required under sub-
19 section (o)(5)(F) for the applicable listed drug.

20 “(VII) Restrictions on distribution or use,
21 if required under subsection (o)(6) for the ap-
22 plicable listed drug, except that such drug may
23 use a different, comparable aspect of such re-
24 strictions on distribution or use as are needed
25 to assure safe use of such drug if —

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

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

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

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

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

20 “(III) shall inform the applicant for a drug
21 approved under this subsection if the risk eval-
22 uation and mitigation strategy for the applica-
23 ble listed drug is modified; and

24 “(IV) in order to minimize the burden on
25 the health care delivery system of different re-

1 restrictions on distribution or use for the drug
2 approved under this subsection and the applica-
3 ble listed drug, may seek to negotiate a vol-
4 untary agreement with the owner of the patent,
5 method, or process for a license under which
6 the applicant for such drug may use an aspect
7 of the restrictions on distribution or use, if re-
8 quired under subsection (o)(6) for the applica-
9 ble listed drug, that is claimed by a patent that
10 has not expired or is a method or process that
11 as a trade secret is entitled to protection.”.

12 **SEC. 207. CONFORMING AMENDMENTS.**

13 Section 505(b)(1) of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 355(b)) is amended—

15 (1) in subparagraph (F), by striking “and”;

16 and

17 (2) in subparagraph (G), by striking the period
18 and inserting the following: “, and (H) a proposed
19 risk evaluation and mitigation strategy as described
20 under subsection (o).”.

21 **SEC. 208. RESOURCES.**

22 (a) **USER FEES.**—Subparagraph (F) of section
23 735(d)(6) of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 379g(d)(6)), as amended by section 103, is
25 amended—

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

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

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

6 “(iv) supporting routine active safety
7 monitoring under section 505(k)(3); and

8 “(v) reviewing and implementing risk
9 evaluation and mitigation strategies.”.

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

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

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

4 “(b) FEE REVENUE AMOUNTS.—

5 “(1) IN GENERAL.—Except”; and

6 (2) adding at the end the following:

7 “(2) ADDITIONAL FEE REVENUES FOR DRUG
8 SAFETY.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (C), in each of fiscal years 2008 through
11 2012, paragraph (1) shall be applied by sub-
12 stituting the amount determined under sub-
13 paragraph (B) for ‘\$392,783,000’.

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

17 “(i) \$392,783,000; plus

18 “(ii) the amount equal to—

19 “(I) \$70,000,000; minus

20 “(II) the amount equal to one-
21 fifth of the amount by which the ap-
22 propriations for salaries and expenses
23 of the Food and Drug Administration
24 for such fiscal year (excluding the
25 amount of fees appropriated for such

1 fiscal year) exceed the amount of ap-
2 propriations for the salaries and ex-
3 penses of the Food and Drug Admin-
4 istration for the fiscal year 2007 (ex-
5 cluding the amount of fees appro-
6 priated for such fiscal year), adjusted
7 as provided under subsection (c)(1).

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

12 “(C) LIMITATION.—This paragraph shall
13 not apply for any fiscal year if the amount de-
14 scribed under subparagraph (B)(ii) is less than
15 0.”.

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

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

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

10 (B) achieve interoperability within and
11 among the Centers of the Food and Drug Ad-
12 ministration and between the Food and Drug
13 Administration and product application spon-
14 sors; and

15 (C) utilize electronic health records;

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

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

1 (4) an assessment of additional resources need-
2 ed to so enhance the information technology assets
3 of the Food and Drug Administration.

4 **SEC. 209. DRUG LABELING.**

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

23 (b) POSTING UPON APPROVAL.—The Secretary shall
24 post in the repository under subsection (a) the approved
25 professional labeling and any required patient labeling of

1 a drug approved under such section 505 or licensed under
2 such section 351 not later than 21 days after the date
3 the drug is approved, including in a supplemental applica-
4 tion with respect to a labeling change.

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

13 (d) MEDICATION GUIDES.—Not later than the effec-
14 tive date of this subtitle, the Secretary, through the Com-
15 missioner of Food and Drugs, shall establish on the Inter-
16 net website for the repository under subsection (a), a link
17 to a list of each drug, whether approved under such sec-
18 tion 505 or licensed under such section 351, for which a
19 Medication Guide, as provided for under part 208 of title
20 21, Code of Federal Regulations (or any successor regula-
21 tions), is required.

22 **SEC. 210. EFFECTIVE DATE AND APPLICABILITY.**

23 (a) EFFECTIVE DATES.—

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

4 (2) USER FEES.—The amendments made by
5 subsections (a) through (c) of section 208 shall take
6 effect on October 1, 2007.

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

9 (1) IN GENERAL.—A drug that was approved
10 before the effective date of this subtitle shall be
11 deemed to have an approved risk evaluation and
12 mitigation strategy under section 505(o) of the Fed-
13 eral Food, Drug, and Cosmetic Act (as added by
14 this subtitle) if there are in effect on the effective
15 date of this subtitle restrictions on distribution or
16 use—

17 (A) required under section 314.520 or sec-
18 tion 601.42 of title 21, Code of Federal Regula-
19 tions; or

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

22 (2) RISK EVALUATION AND MITIGATION STRAT-
23 EGY.—The approved risk evaluation and mitigation
24 strategy deemed in effect for a drug under para-
25 graph (1) shall consist of the elements described in

1 subparagraphs (A) and (B) of paragraph (3) of such
2 section 505(o) and any other additional elements
3 under paragraphs (4), (5), and (6) in effect for such
4 drug on the effective date of this subtitle.

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

9 (A) that such drug is deemed to have an
10 approved risk evaluation and mitigation strat-
11 egy pursuant to such paragraph; and

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

18 (4) ENFORCEMENT ONLY AFTER ASSESSMENT
19 AND REVIEW.—Neither the Secretary nor the Attor-
20 ney General may seek to enforce a requirement of a
21 risk evaluation and mitigation strategy deemed in ef-
22 fect under paragraph (1) before the Secretary has
23 completed review of, and acted on, the first assess-
24 ment of such strategy under such section 505(o).

1 (c) OTHER DRUGS APPROVED BEFORE THE EFFEC-
2 TIVE DATE.—The Secretary, on a case-by-case basis, may
3 require the applicant for a drug approved before the effec-
4 tive date of this subtitle to which subsection (b) does not
5 apply to submit a proposed risk evaluation and mitigation
6 strategy in accordance with the timeframes provided for
7 in subclause (III), (IV), or (V), as applicable, of paragraph
8 (7)(B)(ii) of such section 505(o) if the Secretary deter-
9 mines that—

10 (1) an element described under paragraph
11 (3)(A) of such section 505(o) may require modifica-
12 tion; or

13 (2) a standard for adding an element described
14 in paragraph (4), (5), or (6) of such section 505(o)
15 that is not in effect with respect to such drug may
16 apply to such drug.

17 **Subtitle B—Reagan-Udall Founda-**
18 **tion for the Food and Drug Ad-**
19 **ministration**

20 **SEC. 211. THE REAGAN-UDALL FOUNDATION FOR THE**
21 **FOOD AND DRUG ADMINISTRATION.**

22 (a) IN GENERAL.—Chapter VII of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
24 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 sciences of developing, manufacturing, and evalu-
25 ating the safety and effectiveness of diagnostics, de-

1 vices, biologics, and drugs, and the safety of food,
2 food ingredients, and cosmetics;

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

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

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

22 “(5) recruit meeting participants and hold or
23 sponsor (in whole or in part) meetings as appro-
24 priate to further the goals and priorities established
25 under paragraph (2);

1 “(8) provide objective clinical and scientific in-
2 formation to the Food and Drug Administration
3 and, upon request, to other Federal agencies to as-
4 sist in agency determinations of how to ensure that
5 regulatory policy accommodates scientific advances;

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

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

11 “(d) BOARD OF DIRECTORS.—

12 “(1) ESTABLISHMENT.—

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

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

22 “(i) The Commissioner of Food and
23 Drugs.

24 “(ii) The Director of the National In-
25 stitutes of Health.

1 “(iii) The Director of the Centers for
2 Disease Control and Prevention.

3 “(iv) The Director of the Agency for
4 Healthcare Research and Quality.

5 “(C) APPOINTED MEMBERS.—

6 “(i) IN GENERAL.—The ex officio
7 members of the Board under subparagraph
8 (B) shall, by majority vote, appoint to the
9 Board 12 individuals, from a list of can-
10 didates to be provided, and updated as
11 necessary, by the National Academy of
12 Sciences. Of such appointed members—

13 “(I) 4 shall be representatives of
14 the general pharmaceutical, device,
15 food, cosmetic, and biotechnology in-
16 dustries;

17 “(II) 3 shall be representatives of
18 academic research organizations;

19 “(III) 2 shall be representatives
20 of Government agencies, including the
21 Food and Drug Administration and
22 the National Institutes of Health;

23 “(IV) 2 shall be representatives
24 of patient or consumer advocacy orga-
25 nizations; and

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

3 “(ii) REQUIREMENT.—The ex officio
4 members shall ensure the Board member-
5 ship includes individuals with expertise in
6 areas including the sciences of developing,
7 manufacturing, and evaluating the safety
8 and effectiveness of diagnostics, devices,
9 biologics, and drugs, and the safety of
10 food, food ingredients, and cosmetics.

11 “(D) INITIAL MEETING.—

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

18 “(I) incorporate the Foundation;

19 and

20 “(II) appoint the members of the
21 Board in accordance with subpara-
22 graph (C).

23 “(ii) SERVICE OF EX OFFICIO MEM-
24 BERS.—Upon the appointment of the
25 members of the Board under clause (i)(II),

1 the terms of service of the ex officio mem-
2 bers of the Board as members of the
3 Board shall terminate.

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

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

9 “(A) establish bylaws for the Foundation
10 that—

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

13 “(ii) establish policies for the selection
14 of the officers, employees, agents, and con-
15 tractors of the Foundation;

16 “(iii) establish policies, including eth-
17 ical standards, for the acceptance, sollicita-
18 tion, and disposition of donations and
19 grants to the Foundation and for the dis-
20 position of the assets of the Foundation;

21 “(iv) establish policies that would sub-
22 ject all employees of the Foundation to the
23 conflict of interest standards under section
24 208 of title 18, United States Code;

1 “(v) establish licensing, distribution,
2 and publication policies that support the
3 widest and least restrictive use by the pub-
4 lic of information and inventions developed
5 by the Foundation or with Foundation
6 funds to carry out the duties described in
7 paragraphs (6) and (7) of subsection (c);

8 “(vi) specify principles for the review
9 of proposals and awarding of grants and
10 contracts that include peer review and that
11 are consistent with those of the Founda-
12 tion for the National Institutes of Health,
13 to the extent determined practicable and
14 appropriate by the Board;

15 “(vii) specify a cap on administrative
16 expenses for recipients of a grant, con-
17 tract, or cooperative agreement from the
18 Foundation;

19 “(viii) establish policies for the execu-
20 tion of memoranda of understanding and
21 cooperative agreements between the Foun-
22 dation and other entities, including the
23 Food and Drug Administration;

24 “(ix) establish policies for funding
25 training fellowships, whether at the Foun-

1 dation or other academic or scientific insti-
2 tutions, for scientists, doctors, and other
3 professionals of the Food and Drug Ad-
4 ministration to foster greater under-
5 standing of and expertise in new scientific
6 tools, diagnostics, manufacturing tech-
7 niques, and potential barriers to trans-
8 lating basic research into clinical and regu-
9 latory practice;

10 “(x) specify a process for annual
11 Board review of the operations of the
12 Foundation; and

13 “(xi) establish specific duties of the
14 Executive Director;

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

17 “(C) evaluate the performance of the Exec-
18 utive Director; and

19 “(D) carry out any other necessary activi-
20 ties regarding the functioning of the Founda-
21 tion.

22 “(3) TERMS AND VACANCIES.—

23 “(A) TERM.—The term of office of each
24 member of the Board appointed under para-
25 graph (1)(C) shall be 4 years, except that the

1 terms of offices for the initial appointed mem-
2 bers of the Board shall expire on a staggered
3 basis as determined by the ex officio members.

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

6 “(i) shall not affect the power of the
7 remaining members to execute the duties
8 of the Board; and

9 “(ii) shall be filled by appointment by
10 the appointed members described in para-
11 graph (1)(C), from the list described in
12 such paragraph, by majority vote.

13 “(C) PARTIAL TERM.—If a member of the
14 Board does not serve the full term applicable
15 under subparagraph (A), the individual ap-
16 pointed under subparagraph (B) to fill the re-
17 sulting vacancy shall be appointed for the re-
18 mainder of the term of the predecessor of the
19 individual.

20 “(D) SERVING PAST TERM.—A member of
21 the Board may continue to serve after the expi-
22 ration of the term of the member until a suc-
23 cessor is appointed.

24 “(4) COMPENSATION.—Members of the Board
25 may not receive compensation for service on the

1 Board. Such members may be reimbursed for travel,
2 subsistence, and other necessary expenses incurred
3 in carrying out the duties of the Board, as set forth
4 in the bylaws issued by the Board.

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

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

12 “(g) EXECUTIVE DIRECTOR.—

13 “(1) IN GENERAL.—The Board shall appoint an
14 Executive Director who shall serve at the pleasure of
15 the Board. The Executive Director shall be respon-
16 sible for the day-to-day operations of the Foundation
17 and shall have such specific duties and responsibil-
18 ities as the Board shall prescribe.

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

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

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

3 “(2) hire, promote, compensate, and discharge
4 1 or more officers, employees, and agents, as may be
5 necessary, and define their duties;

6 “(3) prescribe the manner in which—

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

9 “(B) general operations of the Foundation
10 are to be conducted; and

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

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

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

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

23 “(7) enter into such other contracts, leases, co-
24 operative agreements, and other transactions as the

1 Board considers appropriate to conduct the activities
2 of the Foundation;

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

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

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

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

16 “(12) exercise other powers as set forth in this
17 section, and such other incidental powers as are nec-
18 essary to carry out its powers, duties, and functions
19 in accordance with this subchapter.

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

1 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
2 Government employees may serve on committees advisory
3 to the Foundation and otherwise cooperate with and assist
4 the Foundation in carrying out its functions, so long as
5 such employees do not direct or control Foundation activi-
6 ties.

7 “(k) DETAIL OF GOVERNMENT EMPLOYEES.—

8 “(1) DETAIL FROM FEDERAL AGENCIES.—Fed-
9 eral Government employees may be detailed from
10 Federal agencies with or without reimbursement to
11 those agencies to the Foundation at any time, and
12 such detail shall be without interruption or loss of
13 civil service status or privilege. Each such employee
14 shall abide by the statutory, regulatory, ethical, and
15 procedural standards applicable to the employees of
16 the agency from which such employee is detailed and
17 those of the Foundation.

18 “(2) VOLUNTARY SERVICE; ACCEPTANCE OF
19 FEDERAL EMPLOYEES.—The Executive Director of
20 the Foundation may accept the services of employees
21 detailed from Federal agencies with or without reim-
22 bursement to those agencies.

23 “(l) ANNUAL REPORTS.—

24 “(1) REPORTS TO FOUNDATION.—Any recipient
25 of a grant, contract, fellowship, memorandum of un-

1 derstanding, or cooperative agreement from the
2 Foundation under this section shall submit to the
3 Foundation a report on an annual basis for the du-
4 ration of such grant, contract, fellowship, memo-
5 randum of understanding, or cooperative agreement,
6 that describes the activities carried out under such
7 grant, contract, fellowship, memorandum of under-
8 standing, or cooperative agreement.

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

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

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

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

1 under section 770(1)(2) and by other recipients of grants,
2 contracts, memoranda of understanding, or cooperative
3 agreements into regulatory and product review activities
4 of the Food and Drug Administration.

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

12 **Subtitle C—Clinical Trials**

13 **SEC. 221. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-** 14 **ICAL TRIAL RESULTS DATABASE.**

15 (a) IN GENERAL.—Subsection (i) of section 402 of
16 the Public Health Service Act (42 U.S.C. 282), as amend-
17 ed by Public Law 109–482, is amended to read as follows:

18 “(i) CLINICAL TRIAL REGISTRY DATABASE; CLIN-
19 ICAL TRIAL RESULTS DATABASE.—

20 “(1) DEFINITIONS; REQUIREMENT.—

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

22 “(i) CLINICAL TRIAL INFORMATION.—
23 The term ‘clinical trial information’ means
24 those data elements that are necessary to
25 complete an entry in the clinical trial reg-

1 istry database under paragraph (2) or the
2 clinical trial results database under para-
3 graph (3), as applicable.

4 “(ii) COMPLETION DATE.—The term
5 ‘completion date’ means, with respect to a
6 clinical trial, the date on which the last pa-
7 tient enrolled in the clinical trial has com-
8 pleted his or her last medical visit of the
9 clinical trial, whether the clinical trial con-
10 cluded according to the prespecified pro-
11 tocol plan or was terminated.

12 “(iii) DRUG.—The term ‘drug’ means
13 a drug as defined in section 201(g) of the
14 Federal Food, Drug, and Cosmetic Act or
15 a biological product as defined in section
16 351 of this Act.

17 “(iv) RESPONSIBLE PARTY.—The
18 term ‘responsible party’, with respect to a
19 clinical trial of a drug, means the sponsor
20 of the clinical trial or the principal investi-
21 gator of such clinical trial if so designated
22 by such sponsor.

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

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

7 “(ii) other Federal agencies may iden-
8 tify the responsible party for an applicable
9 clinical trial.

10 “(2) CLINICAL TRIAL REGISTRY DATABASE.—

11 “(A) APPLICABLE CLINICAL TRIAL.—

12 “(i) IN GENERAL.—For purposes of
13 this paragraph the term ‘applicable clinical
14 trial’ means—

15 “(I) a therapeutic or
16 chemopreventive clinical trial to verify
17 the efficacy and establish appropriate
18 doses for the drug conducted before
19 the drug is approved under section
20 505 of the Federal Food, Drug, and
21 Cosmetic Act or licensed under section
22 351 of this Act;

23 “(II) a therapeutic or
24 chemopreventive confirmatory clinical
25 trial;

1 minister a clinical trial registry database in
2 accordance with this subsection (referred
3 to in this subsection as the ‘registry data-
4 base’). The Director of NIH shall ensure
5 that the registry database is made publicly
6 available through the Internet.

7 “(ii) CONTENT.—The Secretary shall
8 promulgate regulations for the submission
9 to the registry database of clinical trial in-
10 formation that—

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

15 “(II) includes the city, State, and
16 zip code for each clinical trial location;

17 “(III) if the drug is not approved
18 under section 505 of the Federal
19 Food, Drug, and Cosmetic Act or li-
20 censed under section 351 of this Act,
21 specifies whether or not there is ex-
22 panded access to the drug under sec-
23 tion 561 of the Federal Food, Drug,
24 and Cosmetic Act for those who do
25 not qualify for enrollment in the clin-

1 ical trial and how to obtain informa-
2 tion about such access; and

3 “(IV) requires the inclusion of
4 such other data elements to the reg-
5 istry database as appropriate.

6 “(C) FORMAT AND STRUCTURE.—

7 “(i) SEARCHABLE CATEGORIES.—The
8 Director of NIH shall ensure that the pub-
9 lic may search the entries in the registry
10 database by 1 or more of the following cri-
11 teria:

12 “(I) The indication being studied
13 in the clinical trial, using Medical
14 Subject Headers (MeSH) descriptors.

15 “(II) The safety issue being stud-
16 ied in the clinical trial.

17 “(III) The enrollment status of
18 the clinical trial.

19 “(IV) The sponsor of the clinical
20 trial.

21 “(ii) FORMAT.—The Director of the
22 NIH shall ensure that the registry data-
23 base is easily used by patients, and that
24 entries are easily compared.

1 “(D) DATA SUBMISSION.—The responsible
2 party for an applicable clinical trial shall submit
3 to the Director of NIH for inclusion in the reg-
4 istry database the clinical trial information de-
5 scribed in subparagraph (B)(ii).

6 “(E) TRUTHFUL CLINICAL TRIAL INFOR-
7 MATION.—

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

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

17 “(F) CHANGES IN CLINICAL TRIAL STA-
18 TUS.—

19 “(i) ENROLLMENT.—The responsible
20 party for an applicable 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 clinical trial shall

1 report to the Director of NIH that such
2 clinical trial is complete not later than 30
3 days after the completion date of the clin-
4 ical trial.

5 “(G) TIMING OF SUBMISSION.—The clin-
6 ical trial information for an applicable clinical
7 trial required to be submitted under this para-
8 graph shall be submitted not later than 14 days
9 after the first patient is enrolled in such clinical
10 trial.

11 “(3) CLINICAL TRIALS RESULTS DATABASE.—

12 “(A) APPLICABLE CLINICAL TRIAL.—

13 “(i) IN GENERAL.—For purposes of
14 this paragraph, the term ‘applicable clin-
15 ical trial’ means—

16 “(I) a clinical trial conducted be-
17 fore the drug is approved under sec-
18 tion 505 of the Federal Food, Drug,
19 and Cosmetic Act or licensed under
20 section 351 of this Act that is—

21 “(aa) a therapeutic or
22 chemopreventive confirmatory
23 clinical trial;

24 “(bb) a clinical trial for a
25 drug approved as a fast-track

1 product under section 506 of the
2 Federal Food, Drug, and Cos-
3 metic Act, if such clinical trial is
4 used to form the primary basis of
5 an efficacy claim for such drug;
6 or

7 “(cc) if required by the Sec-
8 retary under subparagraph
9 (G)(i), a clinical trial described in
10 paragraph (2)(A)(i)(I);

11 “(II) a clinical trial completed
12 after the drug is approved under such
13 section 505 or licensed under such
14 section 351; or

15 “(III) a pharmacokinetic study to
16 support a pediatric indication for the
17 drug.

18 “(ii) EXCEPTIONS.—

19 “(I) CERTAIN EXPLORATORY
20 TRIALS.—A clinical trial under clause
21 (i)(I) does not include an exploratory
22 clinical trial that is intended solely to
23 assess safety, solely to evaluate phar-
24 macokinetics, or solely to verify effi-
25 cacy.

1 “(v) The name of the drug that is the
2 subject of the clinical trial.

3 “(vi) Within the documents described
4 in subclauses (II) and (III) of subpara-
5 graph (D)(ii), the following information, as
6 applicable:

7 “(I) The sponsor of the clinical
8 trial.

9 “(II) Each financial sponsor of
10 the clinical trial.

11 “(D) CONTENTS.—

12 “(i) IN GENERAL.—The responsible
13 party for an applicable clinical trial shall
14 submit to the Director of NIH for inclu-
15 sion in the results database the clinical
16 trial information described in clause (ii).

17 “(ii) REQUIRED ELEMENTS.—In sub-
18 mitting clinical trial information for an ap-
19 plicable clinical trial to the Director of
20 NIH for inclusion in the results database,
21 the responsible party shall include, with re-
22 spect to such clinical trial, the following in-
23 formation:

1 “(I) The information described in
2 clauses (i) through (v) of subpara-
3 graph (C).

4 “(II) A non-promotional sum-
5 mary document that is written in non-
6 technical, understandable language for
7 patients that includes the following:

8 “(aa) The purpose of the
9 clinical trial.

10 “(bb) The sponsor of the
11 clinical trial.

12 “(cc) A point of contact for
13 information about the clinical
14 trial.

15 “(dd) A description of the
16 patient population tested in the
17 clinical trial.

18 “(ee) A general description
19 of the clinical trial and results,
20 including a description of and the
21 reasons for any changes in the
22 clinical trial design that occurred
23 since the date of submission of
24 clinical trial information for in-
25 clusion in the registry database

1 established under paragraph (2)
2 and a description of any signifi-
3 cant safety information.

4 “(III) A non-promotional sum-
5 mary document that is technical in
6 nature that includes the following:

7 “(aa) The purpose of the
8 clinical trial.

9 “(bb) The sponsor of the
10 clinical trial.

11 “(cc) Each financial sponsor
12 of the clinical trial.

13 “(dd) A point of contact for
14 scientific information about the
15 clinical trial.

16 “(ee) A description of the
17 patient population tested in the
18 clinical trial.

19 “(ff) A general description
20 of the clinical trial and results,
21 including a description of and the
22 reasons for any changes in the
23 clinical trial design that occurred
24 since the date of submission of
25 clinical trial information for the

1 clinical trial in the registry data-
2 base established under paragraph
3 (2).

4 “(gg) Summary data de-
5 scribing the results, including—

6 “(AA) whether the pri-
7 mary endpoint was achieved,
8 including relevant statistics;

9 “(BB) an assessment of
10 any secondary endpoints, if
11 applicable, including relevant
12 statistics; and

13 “(CC) any significant
14 safety information, including
15 a summary of the incidence
16 of serious adverse events ob-
17 served in the clinical trial
18 and a summary of the most
19 common adverse events ob-
20 served in the clinical trial
21 and the frequencies of such
22 events.

23 “(IV) A link to available peer-re-
24 viewed publications based on the re-
25 sults of the clinical trial.

1 “(V) The completion date of the
2 clinical trial.

3 “(VI) A link to the Internet web
4 posting of any adverse regulatory ac-
5 tions taken by the Food and Drug
6 Administration, such as a warning let-
7 ter, that was substantively based on
8 the clinical trial design, outcome, or
9 representation made by the applicant
10 about the design or outcome of the
11 clinical trial.

12 “(E) TIMING.—A responsible party shall
13 submit to the Director of NIH for inclusion in
14 the results database clinical trial information
15 for an applicable clinical trial not later than 1
16 year after the completion date of the clinical
17 trial as reported under paragraph (2)(F)(ii).

18 “(F) TRUTHFUL CLINICAL TRIAL INFOR-
19 MATION.—

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

24 “(ii) EFFECT.—Clause (i) shall not
25 have the effect of requiring clinical trial in-

1 formation with respect to an applicable
2 clinical trial to include information from
3 any source other than such clinical trial.

4 “(G) INCLUSION OF EARLIER-STAGE CLIN-
5 ICAL TRIALS.—

6 “(i) IN GENERAL.—The Secretary
7 may, subject to clause (ii), require through
8 rulemaking the submission of clinical trial
9 information for the clinical trials described
10 in paragraph (2)(A)(i)(I) to the Director of
11 NIH for inclusion in the results database.

12 “(ii) CONDITIONS FOR REQUIRING IN-
13 CLUSION OF EARLIER-STAGE TRIALS.—The
14 Secretary may promulgate regulations pur-
15 suant to clause (i) if—

16 “(I) the Comptroller General of
17 the United States has submitted to
18 the Secretary the report described
19 under clause (iii); and

20 “(II) such report recommends
21 the inclusion in the results database
22 of clinical trial information for the
23 clinical trials described under para-
24 graph (2)(A)(i)(I).

1 “(iii) STUDY BY GAO.—Not earlier
2 than 2 years after the results database has
3 been established, the Comptroller General
4 of the United States shall initiate a report
5 that—

6 “(I) evaluates the operation of
7 the database, including with respect to
8 cost, burden on drug sponsors and
9 agencies, and the value to patients
10 and health care providers of inclusion
11 in the results database of clinical trial
12 information with respect to clinical
13 trials described in paragraph
14 (2)(A)(i)(I);

15 “(II) recommends whether or not
16 clinical trial information for such clin-
17 ical trials should be included in the re-
18 sults database;

19 “(III) if the recommendation
20 under subclause (II) is to include the
21 clinical trial information for such clin-
22 ical trials in the results database, rec-
23 ommends whether such information
24 should be included in the same format
25 as the clinical trial information of

1 other applicable clinical trials, or if
2 modifications are necessary;

3 “(IV) provides recommendations
4 for any modifications described under
5 subclause (III); and

6 “(V) is submitted to the Com-
7 mittee on Health, Education, Labor,
8 and Pensions of the Senate, the Com-
9 mittee on Energy and Commerce of
10 the House of Representatives, and the
11 Secretary.

12 “(H) CHANGE IN REGULATORY STATUS.—
13 The responsible party for an applicable clinical
14 trial shall inform the Director of NIH of a
15 change in the regulatory status submitted
16 under subparagraph (C)(ii) of a drug that is
17 the subject of an applicable clinical trial within
18 30 days of such change, so that the Director
19 can update the results database accordingly.

20 “(I) PUBLIC AVAILABILITY OF RESULTS.—

21 “(i) PRE-APPROVAL STUDIES.—Ex-
22 cept as provided in clause (iv), with respect
23 to an applicable clinical trial that is com-
24 pleted before the drug is initially approved
25 under section 505 of the Federal Food,

1 Drug, and Cosmetic Act or initially li-
2 censed under section 351 of this Act, the
3 Director of NIH shall make publicly avail-
4 able on the results database the clinical
5 trial information submitted for such clin-
6 ical trial not later than 30 days after—

7 “(I) the drug is approved under
8 such section 505 or licensed under
9 such section 351; or

10 “(II) the Secretary issues a not
11 approvable letter for the drug under
12 such section 505 or such section 351.

13 “(ii) POST-APPROVAL STUDIES.—Ex-
14 cept as provided in clauses (iii) and (iv),
15 with respect to an applicable clinical trial
16 that is completed after the drug is initially
17 approved under such section 505 or ini-
18 tially licensed under such section 351, the
19 Director of NIH shall make publicly avail-
20 able on the results database the clinical
21 trial information submitted for such clin-
22 ical trial not later than 30 days after the
23 date of such submission.

24 “(iii) SEEKING APPROVAL OF A NEW
25 USE FOR THE DRUG.—

1 “(I) IN GENERAL.—If the manu-
2 facturer of the drug is the sponsor or
3 a financial sponsor of the applicable
4 clinical trial, and such manufacturer
5 certifies to the Director of NIH that
6 such manufacturer has filed, or will
7 file within 1 year, an application seek-
8 ing approval under such section 505
9 or licensing under such section 351
10 for the use studied in such clinical
11 trial (which use is not included in the
12 labeling of the approved drug), then
13 the Director of NIH shall make pub-
14 licly available on the results database
15 the clinical trial information sub-
16 mitted for such clinical trial on the
17 earlier of the date that is 30 days
18 after the date—

19 “(aa) the application is ap-
20 proved under such section 505 or
21 licensed such section 351;

22 “(bb) the Secretary issues a
23 not approvable letter for the ap-
24 plication under such section 505
25 or such section 351; or

1 “(cc) the application under
2 such section 505 or such section
3 351 is withdrawn.

4 “(II) LIMITATION ON CERTIFI-
5 CATION.—A manufacturer shall not
6 make a certification under subclause
7 (I) with respect to an applicable clin-
8 ical trial unless the manufacturer
9 makes such a certification with re-
10 spect to each applicable clinical trial
11 that is required to be submitted in an
12 application for approval of the use
13 studied in the clinical trial involved.

14 “(III) 2-YEAR LIMITATION.—The
15 clinical trial information subject to
16 subclause (I) shall be made publicly
17 available on the results database on
18 the date that is 2 years after the date
19 the certification referred to in sub-
20 clause (I) was made to the Director of
21 NIH, if a regulatory action referred to
22 in item (aa), (bb), or (cc) of subclause
23 (I) has not occurred by such date.

24 “(iv) SEEKING PUBLICATION.—

1 ical trial information was required to
2 be submitted to the Director of NIH
3 if the manuscript referred to in such
4 subclause has not been published by
5 such date.

6 “(J) VERIFICATION OF SUBMISSION PRIOR
7 TO PUBLIC AVAILABILITY.—In the case of clin-
8 ical trial information that is submitted under
9 this paragraph, but is not made publicly avail-
10 able pending either regulatory action or publica-
11 tion under clause (iii) or (iv) of subparagraph
12 (I), as applicable, the Director of NIH shall re-
13 spond to inquiries from other Federal agencies
14 and peer-reviewed journals to confirm that such
15 clinical trial information has been submitted
16 but has not yet been made publicly available on
17 the results database.

18 “(4) COORDINATION AND COMPLIANCE.—

19 “(A) CLINICAL TRIALS SUPPORTED BY
20 GRANTS FROM FEDERAL AGENCIES.—

21 “(i) IN GENERAL.—No Federal agen-
22 cy may release funds under a research
23 grant to a person who has not complied
24 with paragraphs (2) and (3) for any appli-

1 cable clinical trial for which such person is
2 the responsible party.

3 “(ii) GRANTS FROM CERTAIN FED-
4 ERAL AGENCIES.—If an applicable clinical
5 trial is funded in whole or in part by a
6 grant from the National Institutes of
7 Health, the Agency for Healthcare Re-
8 search and Quality, or the Department of
9 Veterans Affairs, any grant or progress re-
10 port forms required under such grant shall
11 include a certification that the responsible
12 party has made all required submissions to
13 the Director of NIH under paragraphs (2)
14 and (3).

15 “(iii) VERIFICATION BY FEDERAL
16 AGENCIES.—The heads of the agencies re-
17 ferred to in clause (ii), as applicable, shall
18 verify that the clinical trial information for
19 each applicable clinical trial for which a
20 grantee is the responsible party has been
21 submitted under paragraph (2) and (3), as
22 applicable, before releasing funding for a
23 grant to such grantee.

24 “(iv) NOTICE AND OPPORTUNITY TO
25 REMEDY.—If the head of an agency re-

1 ferred to in clause (ii), as applicable,
2 verifies that a grantee has not submitted
3 clinical trial information as described in
4 clause (iii), such agency head shall provide
5 notice to such grantee of such non-compli-
6 ance and allow such grantee 30 days to
7 correct such non-compliance and submit
8 the required clinical trial information.

9 “(v) CONSULTATION WITH OTHER
10 FEDERAL AGENCIES.—The Secretary
11 shall—

12 “(I) consult with other agencies
13 that conduct human studies in accord-
14 ance with part 46 of title 45, Code of
15 Federal Regulations (or any successor
16 regulations), to determine if any such
17 studies are applicable clinical trials
18 under paragraph (2) or (3); and

19 “(II) develop with such agencies
20 procedures comparable to those de-
21 scribed in clauses (ii), (iii), and (iv) to
22 ensure that clinical trial information
23 for such applicable clinical trials is
24 submitted under paragraphs (2) and
25 (3).

1 “(B) COORDINATION OF REGISTRY DATA-
2 BASE AND RESULTS DATABASE.—

3 “(i) IN GENERAL.—Each entry in the
4 registry database under paragraph (2)
5 shall include a link to the corresponding
6 entry in the results database under para-
7 graph (3).

8 “(ii) MISSING ENTRIES.—

9 “(I) IN GENERAL.—If, based on
10 a review of the entries in the registry
11 database under paragraph (2), the Di-
12 rector of NIH determines that a re-
13 sponsible party has failed to submit
14 required clinical trial information to
15 the results database under paragraph
16 (3), the Director of NIH shall inform
17 the responsible party involved of such
18 failure and permit the responsible
19 party to correct the failure within 30
20 days.

21 “(II) FAILURE TO CORRECT.—If
22 the responsible party does not correct
23 a failure to submit required clinical
24 trial information within the 30-day
25 period described under subclause (I),

1 the Director of NIH shall report such
2 non-compliance to the scientific peer
3 review committees of the Federal re-
4 search agencies and to the Office of
5 Human Research Protections.

6 “(III) PUBLIC NOTICE OF FAIL-
7 URE TO CORRECT.—The Director of
8 NIH shall include in the clinical trial
9 registry database entry and the clin-
10 ical trial results database entry for
11 each such clinical trial a notice of any
12 uncorrected failure to submit required
13 clinical trial information and shall
14 provide that the public may easily
15 search for such entries.

16 “(C) ACTION ON APPLICATIONS.—

17 “(i) VERIFICATION PRIOR TO FIL-
18 ING.—The Secretary, acting through the
19 Commissioner of Food and Drugs, shall
20 verify that the clinical trial information re-
21 quired under paragraphs (2) and (3) for
22 an applicable clinical trial is submitted
23 pursuant to such applicable paragraph—

24 “(I) when considering a drug for
25 an exemption under section 505(i) of

1 the Federal Food, Drug, and Cos-
2 metic Act, including as the drug pro-
3 gresses through the clinical trials de-
4 scribed under paragraph (2)(A)(i);
5 and

6 “(II) prior to filing an applica-
7 tion under section 505 of the Federal
8 Food, Drug, and Cosmetic Act or
9 under section 351 of this Act that in-
10 cludes information from such clinical
11 trial.

12 “(ii) NOTIFICATION.—If the respon-
13 sible party has not submitted such clinical
14 trial information, the Secretary shall notify
15 the applicant and the responsible party of
16 such non-compliance and require submis-
17 sion of such results within 30 days.

18 “(iii) REFUSAL TO FILE.—If the re-
19 sponsible party does not remedy such non-
20 compliance within 30 days of receipt of no-
21 tification under clause (ii), the Secretary
22 shall refuse to file such application.

23 “(D) CONTENT REVIEW.—

24 “(i) IN GENERAL.—To assure that the
25 summary documents described in para-

1 graph (3)(D) are non-promotional, and are
2 not false or misleading in any particular
3 under paragraph (3)(F), the Secretary
4 shall compare such documents to the re-
5 sults data of the clinical trial for a rep-
6 resentative sample of applicable clinical
7 trials by—

8 “(I) acting through the Commis-
9 sioner of Food and Drugs to examine
10 the results data for such clinical trials
11 submitted to Secretary when such
12 data are submitted—

13 “(aa) for review as part of
14 an application under section 505
15 of the Federal Food, Drug, and
16 Cosmetic Act or under section
17 351 of this Act; or

18 “(bb) in an annual status
19 report on the drug under such
20 application;

21 “(II) acting with the Federal
22 agency that funds such clinical trial in
23 whole or in part by a grant to exam-
24 ine the results data for such clinical
25 trials; and

1 “(III) acting through inspections
2 under section 704 of the Federal
3 Food, Drug, and Cosmetic Act to ex-
4 amine results data for such clinical
5 trials not described in subclause (I) or
6 (II).

7 “(ii) NOTICE OF NON-COMPLIANCE.—
8 If the Secretary determines that the clin-
9 ical trial information submitted in such a
10 summary document is promotional, or false
11 or misleading in any particular, the Sec-
12 retary shall notify the responsible party
13 and give such party an opportunity to rem-
14 edy such non-compliance by submitting the
15 required revised clinical trial information
16 within 30 days of such notification.

17 “(E) PENALTY FOR NON-COMPLIANCE.—In
18 determining whether to apply a penalty under
19 section 301(jj) of the Federal Food, Drug, and
20 Cosmetic Act, the Secretary, acting through the
21 Commissioner of Food and Drugs, shall con-
22 sider—

23 “(i) whether the responsible party
24 promptly corrects the non-compliance when
25 provided notice;

1 “(ii) whether the responsible party
2 has engaged in a pattern or practice of
3 non-compliance; and

4 “(iii) the extent to which the non-
5 compliance involved may have significantly
6 misled healthcare providers or patients
7 concerning the safety or effectiveness of
8 the drug involved.

9 “(5) LIMITATION ON DISCLOSURE OF CLINICAL
10 TRIAL INFORMATION.—Disclosure to the public of
11 clinical trial information submitted to the Director
12 of NIH under this subsection and requested under
13 section 552 of title 5, United States Code (com-
14 monly known as the Freedom of Information Act)
15 shall be made only as provided for under paragraphs
16 (2) and (3).

17 “(6) AUTHORIZATION OF APPROPRIATIONS.—
18 There are authorized to be appropriated to carry out
19 this subsection \$10,000,000 for each fiscal year.”.

20 (b) CONFORMING AMENDMENTS.—

21 (1) PROHIBITED ACTS.—Section 301 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 331), as amended by Public Law 109–462, is
24 amended by adding at the end the following:

1 “(jj)(1) The failure to submit clinical trial informa-
2 tion as required by section 402(i) of the Public Health
3 Service Act.

4 “(2) The submission of clinical trial information
5 under section 402(i) of the Public Health Service Act that
6 is promotional or false or misleading in any particular
7 under paragraph (2)(E) or (3)(F) of such section 402(i).”.

8 (2) NEW DRUGS.—

9 (A) INVESTIGATIONAL NEW DRUGS.—Sec-
10 tion 505(i) of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 355(i)) is amended—

12 (i) in paragraph (1)—

13 (I) in subparagraph (C), by strik-
14 ing “and” after the semicolon;

15 (II) in subparagraph (D), by
16 striking the period at the end and in-
17 serting “; and”; and

18 (III) by adding at the end the
19 following:

20 “(E) the submission to the Director of NIH of
21 clinical trial information for the clinical investigation
22 at issue required under section 402(i) of the Public
23 Health Service Act for inclusion in the registry data-
24 base and the results database described in such sec-
25 tion.”;

1 (ii) in paragraph (3)(B)—

2 (I) in clause (i), by striking “or”
3 after the semicolon;

4 (II) in clause (ii), by striking the
5 period at the end and inserting “; or”;
6 and

7 (III) by adding at the end the
8 following:

9 “(iii) clinical trial information for the clinical
10 investigation at issue was not submitted in compli-
11 ance with section 402(i) of the Public Health Service
12 Act.”; and

13 (iii) in paragraph (4), by adding at
14 the end the following: “The Secretary shall
15 update such regulations to require inclu-
16 sion in the informed consent form a state-
17 ment that clinical trial information for
18 such clinical investigation will be submitted
19 for inclusion in the registry database and
20 results database, as applicable, described
21 in section 402(i) of the Public Health
22 Service Act.”.

23 (B) REFUSAL TO APPROVE APPLICA-
24 TION.—Section 505(d) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
2 amended—

3 (i) in the first sentence, by inserting
4 after “or any particular;” the following:
5 “or (8) the applicant failed to submit the
6 clinical trial information for any applicable
7 clinical trial submitted as part of the appli-
8 cation to the Director of the National In-
9 stitutes of Health in compliance with sec-
10 tion 402(i) of the Public Health Service
11 Act;”; and

12 (ii) in the second sentence, by striking
13 “clauses (1) through (6)” and inserting
14 “paragraphs (1) through (8)”.

15 (c) GUIDANCE.—Not later than 180 days after the
16 date of enactment of this title, the Commissioner of Food
17 and Drugs, in consultation with the Director of the Na-
18 tional Institutes of Health, shall issue guidance to clarify
19 which clinical trials are applicable clinical trials (as de-
20 fined in section 402(i)(2) of the Public Health Service Act,
21 as amended by this section) and are required to be sub-
22 mitted for inclusion in the clinical trial registry database
23 described in such section 402(i)(2).

24 (d) PREEMPTION.—

1 (1) IN GENERAL.—No State or political subdivi-
2 sion of a State may establish or continue in effect
3 any requirement for the registration of clinical trials
4 or for the inclusion of information relating to the re-
5 sults of clinical trials in a database.

6 (2) RULE OF CONSTRUCTION.—The fact of sub-
7 mission of clinical trial information, if submitted in
8 compliance with section 402(i) of the Public Health
9 Service Act (as amended by this section), that re-
10 lates to a use of a drug not included in the official
11 labeling of the approved drug shall not be construed
12 by the Secretary or in any administrative or judicial
13 proceeding, as evidence of a new intended use of the
14 drug that is different from the intended use of the
15 drug set forth in the official labeling of the drug.
16 The availability of clinical trial information through
17 the databases under paragraphs (2) and (3) of such
18 section 402(i), if submitted in compliance with such
19 section 402(i), shall not be considered as labeling,
20 adulteration, or misbranding of the drug under the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 301 et seq.).

23 (e) EFFECTIVE DATES.—

24 (1) ESTABLISHMENT OF REGISTRY DATABASE
25 AND RESULTS DATABASE.—Not later than 1 year

1 after the date of enactment of this title, the Director
2 of NIH shall establish the registry database and the
3 results database of clinical trials of drugs in accord-
4 ance with section 402(i) of the Public Health Service
5 Act (as amended by subsection (a)).

6 (2) CLINICAL TRIALS INITIATED PRIOR TO OP-
7 ERATION OF REGISTRY DATABASE.—The responsible
8 party (as defined in such section 402(i)) for an ap-
9 plicable clinical trial under paragraph (2) of such
10 section 402(i) that is initiated after the date of en-
11 actment of this title and before the date such reg-
12 istry database is established under paragraph (1) of
13 this subsection, shall submit required clinical trial
14 information not later than 120 days after the date
15 such registry database is established.

16 (3) CLINICAL TRIALS INITIATED AFTER OPER-
17 ATION OF REGISTRY DATABASE.—The responsible
18 party (as defined in such section 402(i)) for an ap-
19 plicable clinical trial under paragraph (2) of such
20 section 402(i) that is initiated after the date such
21 registry database is established under paragraph (1)
22 of this subsection shall submit required clinical trial
23 information in accordance with such paragraph (2).

24 (4) TRIALS COMPLETED BEFORE OPERATION
25 OF RESULTS DATABASE.—

1 (A) IN GENERAL.—Paragraph (3) of such
2 section 402(i) shall take effect 90 days after
3 the date the results database is established
4 under paragraph (1) of this subsection with re-
5 spect to any applicable clinical trial (as defined
6 in such section 402(i)(3)) that—

7 (i) involves a drug to treat a serious
8 or life-threatening condition; and

9 (ii) is completed between the date of
10 enactment of this section and such date of
11 establishment under paragraph (1) of this
12 subsection.

13 (B) OTHER TRIALS.—Except as provided
14 in subparagraph (A), paragraph (3) of such
15 section 402(i) shall take effect 180 days after
16 the date that the results database is established
17 under paragraph (1) of this subsection with re-
18 spect to any applicable clinical trial (as defined
19 in such section 402(i)(3)) that is completed be-
20 tween the date of enactment of this title and
21 such date of establishment under paragraph
22 (1).

23 (C) TRIALS SUBMITTED IN AN APPLICA-
24 TION.—Except as provided in subparagraph

1 (A), paragraph (3) of such section 402(i) shall
2 take effect for any clinical trial if—

3 (i) data from such clinical trial is sub-
4 mitted in an application or supplement to
5 an application under section 505 of the
6 Food, Drug, and Cosmetic Act or under
7 section 351 of the Public Health Service
8 Act that—

9 (I) is submitted 180 days or
10 more after the date that the results
11 database is established under para-
12 graph (1) of this subsection; and

13 (II) contains data from an appli-
14 cable clinical trial; and

15 (ii) such clinical trial would otherwise
16 be an applicable clinical trial under such
17 paragraph (3) except for its date of com-
18 pletion.

19 (5) TRIALS COMPLETED AFTER ESTABLISH-
20 MENT OF RESULTS DATABASE.—Paragraph (3) of
21 such section 402(i) shall apply to any applicable
22 clinical trial that is completed after the date that the
23 results database is established under paragraph (1)
24 of this subsection.

1 (6) FUNDING RESTRICTIONS.—Subparagraph
2 (A) of paragraph (4) of such section 402(i) shall
3 take effect 210 days after the date that the clinical
4 trial registry database and the clinical trial results
5 database are established under paragraph (1) of this
6 subsection.

7 (7) STATUS OF CLINICALTRIALS.GOV
8 WEBSITE.—

9 (A) IN GENERAL.—After receiving public
10 comment and not later than 90 days after the
11 date of enactment of this title, the Secretary
12 shall publish in the Federal Register a notice
13 determining the more efficient approach to es-
14 tablishing the registry database described in
15 paragraph (2) of such section 402(i) and
16 whether such approach is—

17 (i) that such registry database should
18 expand and build upon the database de-
19 scribed in section 402(i) of the Public
20 Health Service Act (as in effect on the day
21 before the date of enactment of this title);
22 or

23 (ii) that such registry database should
24 supplant the database described in such

1 section 402(i) (as in effect on the day be-
2 fore the date of enactment of this title).

3 (B) CLINICALTRIALS.GOV SUPPLANTED.—

4 If the Secretary determines to apply the ap-
5 proach described under subparagraph (A)(ii),
6 the Secretary shall maintain an archive of the
7 database described in such section 402(i) (as in
8 effect on the day before the date of enactment
9 of this title) on the Internet website of the Na-
10 tional Library of Medicine.

11 **Subtitle D—Conflicts of Interest**

12 **SEC. 231. CONFLICTS OF INTEREST.**

13 (a) IN GENERAL.—Subchapter A of chapter VII of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
15 et seq.) is amended by inserting at the end the following:

16 **“SEC. 712. CONFLICTS OF INTEREST.**

17 “(a) DEFINITIONS.—For purposes of this section:

18 “(1) ADVISORY COMMITTEE.—The term ‘advi-
19 sory committee’ means an advisory committee under
20 the Federal Advisory Committee Act that provides
21 advice or recommendations to the Secretary regard-
22 ing activities of the Food and Drug Administration.

23 “(2) FINANCIAL INTEREST.—The term ‘finan-
24 cial interest’ means a financial interest under section
25 208(a) of title 18, United States Code.

1 “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

2 “(1) RECRUITMENT.—

3 “(A) IN GENERAL.—Given the importance
4 of advisory committees to the review process at
5 the Food and Drug Administration, the Sec-
6 retary shall carry out informational and recruit-
7 ment activities for purposes of recruiting indi-
8 viduals to serve as advisory committee mem-
9 bers. The Secretary shall seek input from pro-
10 fessional medical and scientific societies to de-
11 termine the most effective informational and re-
12 cruitment activities. The Secretary shall also
13 take into account the advisory committees with
14 the greatest number of vacancies.

15 “(B) RECRUITMENT ACTIVITIES.—The re-
16 cruitment activities under subparagraph (A)
17 may include—

18 “(i) advertising the process for becom-
19 ing an advisory committee member at med-
20 ical and scientific society conferences; and

21 “(ii) making widely available, includ-
22 ing by using existing electronic commu-
23 nications channels, the contact information
24 for the Food and Drug Administration

1 point of contact regarding advisory com-
2 mittee nominations.

3 “(2) SCREENING OF CANDIDATES.—The Sec-
4 retary shall ensure that each individual under con-
5 sideration for a term appointment to an advisory
6 committee disclose to the Secretary all information
7 related to, with respect to such individual—

8 “(A) current investments;

9 “(B) current and past employment;

10 “(C) current and past consulting relation-
11 ships;

12 “(D) current and past contracts and
13 grants; and

14 “(E) current patents or royalties.

15 “(3) DISCLOSURES NOT PUBLICLY AVAIL-
16 ABLE.—No disclosure required under paragraph (2)
17 shall be made available to the public by the Sec-
18 retary.

19 “(4) EVALUATION AND CRITERIA.—When con-
20 sidering a term appointment to an advisory com-
21 mittee, the Secretary shall review the expertise and
22 the disclosures under paragraph (2) of each indi-
23 vidual under consideration for the appointment, so
24 as to reduce the likelihood that an appointed indi-
25 vidual will later require a written determination as

1 referred to in section 208(b)(1) of title 18, United
2 States Code, a written certification as referred to in
3 section 208(b)(3) of title 18, United States Code, or
4 a waiver as referred to in subsection (c)(3) of this
5 section for service on the committee at a meeting of
6 the committee.

7 “(c) GRANTING AND DISCLOSURE OF WAIVERS.—

8 “(1) IN GENERAL.—Prior to a meeting of an
9 advisory committee regarding a particular matter
10 (as that term is used in section 208 of title 18,
11 United States Code), each member of the committee
12 shall disclose to the Secretary all financial interests
13 in accordance with subsection (b) of such section
14 208.

15 “(2) FINANCIAL GAIN OF ADVISORY COMMITTEE
16 MEMBER OR FAMILY MEMBER.—No member of an
17 advisory committee may vote with respect to any
18 matter considered by the advisory committee if such
19 member or an immediate family member of such
20 member could gain financially from the advice given
21 to the Secretary with respect to such matter.

22 “(3) WAIVER.—In addition to considerations
23 under section 208(b) of title 18, United States Code,
24 the Secretary may grant a waiver of a conflict of in-
25 terest requirement, including a requirement under

1 paragraph (2) of this subsection, if such waiver is
2 necessary to afford the advisory committee essential
3 expertise.

4 “(4) LIMITATION.—In no case may the Sec-
5 retary grant a waiver under paragraph (3) for a
6 member of an advisory committee if the scientific
7 work of such member is under consideration by the
8 committee.

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 a report to the
13 Inspector General of the Department of Health and
14 Human Services, the Committee on Appropriations and
15 the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate, and the Committee on Appropriations
17 and the Committee on Energy and Commerce of the
18 House of Representatives—

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, including
12 mechanisms to encourage the nomination of individ-
13 uals who are classified by the Food and Drug Ad-
14 ministration as academicians or practitioners for
15 service on an advisory committee.

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 DEVICE**
6 **USER FEES**

7 **SEC. 301. SENSE OF THE SENATE REGARDING MEDICAL DE-**
8 **VICE USER FEE REAUTHORIZATION.**

9 (a) FINDING.—The Senate finds that the Medical
10 Device User Fee and Modernization Act of 2002 (21
11 U.S.C. 301 note) is a valuable program for the review of
12 innovative medical technologies and it should be reauthor-
13 ized in a timely fashion.

14 (b) SENSE OF THE SENATE.—It is the sense of the
15 Senate that—

16 (1) user fees make possible the investments of
17 the Food and Drug Administration in information
18 technology infrastructure and human capital, more
19 comprehensive training for device reviewers, greater
20 use of experts in academia and the private sector,
21 enhanced project management, increased guidance
22 development, expanded participation in globalization
23 and standards setting activities, and increased inter-
24 action with industry, both before and during the ap-
25 plication review process;

1 (2) as medical device applications become pro-
2 gressively more complex, these investments will be-
3 come ever more necessary to keep up with perform-
4 ance goals that Food and Drug Administration has,
5 thus far, been successful in meeting, which are the
6 performance goals intended to speed promising new
7 technologies to patients;

8 (3) it is imperative that Food and Drug Admin-
9 istration review medical devices promptly and quick-
10 ly to speed both incremental and breakthrough inno-
11 vations to patients; and

12 (4) the Medical Device User Fee and Mod-
13 ernization Act of 2002 should be reauthorized quick-
14 ly in order to provide the program a sound financial
15 footing and to ensure timely and predictable review
16 of medical device applications.

17 **TITLE IV—PEDIATRIC MEDICAL**
18 **PRODUCTS**

19 **Subtitle A—Best Pharmaceuticals**
20 **for Children**

21 **SEC. 401. SHORT TITLE.**

22 This subtitle may be cited as the “Best Pharma-
23 ceuticals for Children Amendments of 2007”.

1 **SEC. 402. PEDIATRIC STUDIES OF DRUGS.**

2 (a) IN GENERAL.—Section 505A of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
4 amended—

5 (1) in subsection (a), by inserting before the pe-
6 riod at the end the following: “, and, at the discre-
7 tion of the Secretary, may include preclinical stud-
8 ies”;

9 (2) in subsection (b)—

10 (A) in paragraph (1)(A)(i), by striking
11 “(D)” both places it appears and inserting
12 “(E)”;

13 (B) in paragraph (1)(A)(ii), by striking
14 “(D)” and inserting “(E)”;

15 (C) by striking “(1)(A)(i)” and inserting
16 “(A)(i)(I)”;

17 (D) by striking “(ii) the” and inserting
18 “(II) the”;

19 (E) by striking “(B) if the drug is des-
20 ignated” and inserting “(ii) if the drug is des-
21 ignated”;

22 (F) by striking “(2)(A)” and inserting
23 “(B)(i)”;

24 (G) by striking “(i) a listed patent” and
25 inserting “(I) a listed patent”;

1 (H) by striking “(ii) a listed patent” and
2 inserting “(II) a listed patent”;

3 (I) by striking “(B) if the drug is the sub-
4 ject” and inserting “(ii) if the drug is the sub-
5 ject”;

6 (J) by striking “If” and all that follows
7 through “subsection (d)(3)” and inserting the
8 following:

9 “(1) IN GENERAL.—Except as provided in para-
10 graph (2), if, prior to approval of an application that
11 is submitted under section 505(b)(1), the Secretary
12 determines that information relating to the use of a
13 new drug in the pediatric population may produce
14 health benefits in that population, the Secretary
15 makes a written request for pediatric studies (which
16 shall include a timeframe for completing such stud-
17 ies), the applicant agrees to the request, such stud-
18 ies are completed using appropriate formulations for
19 each age group for which the study is requested
20 within any such timeframe and the reports thereof
21 are submitted and accepted in accordance with sub-
22 section (d)(3), and if the Secretary determines that
23 labeling changes are appropriate, such changes are
24 made within the timeframe requested by the Sec-
25 retary—”; and

1 (K) by adding at the end the following:

2 “(2) EXCEPTION.—The Secretary shall not ex-
3 tend the period referred to in paragraph (1)(A) or
4 any listed patent referred to in paragraph (1)(B)
5 later than 1 year prior to the expiration of such pe-
6 riod or such patent.”;

7 (3) in subsection (c)—

8 (A) in paragraph (1)(A)(i), by striking
9 “(D)” both places it appears and inserting
10 “(E)”;

11 (B) in paragraph (1)(A)(ii), by striking
12 “(D)” and inserting “(E)”;

13 (C) by striking “(1)(A)(i)” and inserting
14 “(A)(i)(I)”;

15 (D) by striking “(ii) the” and inserting
16 “(II) the”;

17 (E) by striking “(B) if the drug is des-
18 ignated” and inserting “(ii) if the drug is des-
19 ignated”;

20 (F) by striking “(2)(A)” and inserting
21 “(B)(i)”;

22 (G) by striking “(i) a listed patent” and
23 inserting “(I) a listed patent”;

24 (H) by striking “(ii) a listed patent” and
25 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 any listed patent referred to in paragraph (1)(B)
2 later than 1 year prior to the expiration of such pe-
3 riod or such patent.”;

4 (4) by striking subsection (d) and inserting the
5 following:

6 “(d) CONDUCT OF PEDIATRIC STUDIES.—

7 “(1) REQUEST FOR STUDIES.—

8 “(A) IN GENERAL.—The Secretary may,
9 after consultation with the sponsor of an appli-
10 cation for an investigational new drug under
11 section 505(i), the sponsor of an application for
12 a new drug under section 505(b)(1), or the
13 holder of an approved application for a drug
14 under section 505(b)(1), issue to the sponsor or
15 holder a written request for the conduct of pedi-
16 atric studies for such drug. Such request to
17 conduct pediatric studies shall be in writing and
18 shall include a timeframe for such studies and
19 a request to the sponsor or holder to propose
20 pediatric labeling resulting from such studies.

21 “(B) SINGLE WRITTEN REQUEST.—A sin-
22 gle written request—

23 “(i) may relate to more than 1 use of
24 a drug;

1 “(ii) may include uses that are both
2 approved and unapproved; and

3 “(iii) shall require that the study take
4 into account adequate representation of
5 children of ethnic and racial minorities.

6 “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-
7 IES.—

8 “(A) REQUEST AND RESPONSE.—

9 “(i) IN GENERAL.—If the Secretary
10 makes a written request for pediatric stud-
11 ies (including neonates, as appropriate)
12 under subsection (b) or (c), the applicant
13 or holder, not later than 180 days after re-
14 ceiving the written request, shall respond
15 to the Secretary as to the intention of the
16 applicant or holder to act on the request
17 by—

18 “(I) indicating when the pediatric
19 studies will be initiated, if the appli-
20 cant or holder agrees to the request;
21 or

22 “(II) indicating that the appli-
23 cant or holder does not agree to the
24 request and the reasons for declining
25 the request.

1 “(ii) DISAGREE WITH REQUEST.—If,
2 on or after the date of enactment of the
3 date of enactment Best Pharmaceuticals
4 for Children Amendments of 2007, the ap-
5 plicant or holder does not agree to the re-
6 quest on the grounds that it is not possible
7 to develop the appropriate pediatric formu-
8 lation, the applicant or holder shall submit
9 to the Secretary the reasons such pediatric
10 formulation 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 date of enactment Best Phar-
14 maceuticals for Children Amendments of 2007,
15 agrees to the request for such studies shall pro-
16 vide the Secretary, at the same time as submis-
17 sion of the reports of such studies, with all
18 postmarket adverse event reports regarding the
19 drug that is the subject of such studies and are
20 available 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 date of enactment Best
19 Pharmaceuticals for Children Amendments of 2007,
20 that the requirements of subsection (d) have been
21 met and that submissions and approvals under sub-
22 section (b)(2) or (j) of section 505 for a drug will
23 be subject to the provisions of this section. Such no-
24 tice shall be published not later than 30 days after
25 the date of the Secretary’s determination regarding

1 market exclusivity and shall include a copy of the
2 written request 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 date of enactment Best Pharmaceuticals for
7 Children Amendments of 2007, a pediatric formula-
8 tion was developed, studied, and found to be safe
9 and effective in the pediatric population (or specified
10 subpopulation) if the pediatric formulation for such
11 drug is not introduced onto the market within 1
12 year of the date that the Secretary publishes the no-
13 tice described in paragraph (1). Such notice identi-
14 fying such drug shall be published not later than 30
15 days after the date of the expiration of such 1 year
16 period.

17 “(f) INTERNAL REVIEW OF WRITTEN REQUESTS
18 AND PEDIATRIC STUDIES.—

19 “(1) INTERNAL REVIEW.—

20 “(A) IN GENERAL.—The Secretary shall
21 create an internal review committee to review
22 all written requests issued and all reports sub-
23 mitted on or after the date of enactment of the
24 date of enactment Best Pharmaceuticals for

1 Children Amendments of 2007, in accordance
2 with paragraphs (2) and (3).

3 “(B) MEMBERS.—The committee under
4 subparagraph (A) shall include individuals with
5 the following expertise:

6 “(i) Pediatrics.

7 “(ii) Biopharmacology.

8 “(iii) Statistics.

9 “(iv) Drugs and drug formulations.

10 “(v) Legal issues.

11 “(vi) Appropriate expertise pertaining
12 to the pediatric product under review.

13 “(vii) One or more experts from the
14 Office of Pediatric Therapeutics, including
15 an expert in pediatric ethics.

16 “(viii) Other individuals as designated
17 by the Secretary.

18 “(2) REVIEW OF WRITTEN REQUESTS.—All
19 written requests under this section shall be reviewed
20 and approved by the committee established under
21 paragraph (1) prior to being issued.

22 “(3) REVIEW OF PEDIATRIC STUDIES.—The
23 committee established under paragraph (1) shall re-
24 view all studies conducted pursuant to this section to

1 determine whether to accept or reject such reports
2 under subsection (d)(3).

3 “(4) TRACKING PEDIATRIC STUDIES AND LA-
4 BELING CHANGES.—The committee established
5 under paragraph (1) shall be responsible for track-
6 ing and making available to the public, in an easily
7 accessible manner, including through posting on the
8 website of the Food and Drug Administration—

9 “(A) the number of studies conducted
10 under this section;

11 “(B) the specific drugs and drug uses, in-
12 cluding labeled and off-labeled indications, stud-
13 ied under this section;

14 “(C) the types of studies conducted under
15 this section, including trial design, the number
16 of pediatric patients studied, and the number of
17 centers and countries involved;

18 “(D) the number of pediatric formulations
19 developed and the number of pediatric formula-
20 tions not developed and the reasons such for-
21 mulations were not developed;

22 “(E) the labeling changes made as a result
23 of studies conducted under this section;

24 “(F) an annual summary of labeling
25 changes made as a result of studies conducted

1 under this section for distribution pursuant to
2 subsection (k)(2); and

3 “(G) information regarding reports sub-
4 mitted on or after the date of enactment of the
5 date of enactment Best Pharmaceuticals for
6 Children Amendments of 2007.”;

7 (6) in subsection (g)—

8 (A) in paragraph (1)—

9 (i) by striking “(c)(1)(A)(ii)” and in-
10 sserting “(c)(1)(A)(i)(II)”;

11 (ii) by striking “(c)(2)” and inserting
12 “(c)(1)(B)”;

13 (B) in paragraph (2), by striking
14 “(c)(1)(B)” and inserting “(c)(1)(A)(ii)”;

15 (C) by redesignating paragraphs (1) and
16 (2) as subparagraphs (A) and (B), respectively;

17 (D) by striking “LIMITATIONS.—A drug”
18 and inserting “LIMITATIONS.—

19 “(1) IN GENERAL.—Notwithstanding subsection
20 (c)(2), a drug”;

21 (E) by adding at the end the following:

22 “(2) EXCLUSIVITY ADJUSTMENT.—

23 “(A) ADJUSTMENT.—With respect to any
24 drug, if the organization designated under sub-
25 paragraph (B) notifies the Secretary that the

1 combined annual gross sales for all drugs with
2 the same active moiety exceeded
3 \$1,000,000,000 in any calendar year prior to
4 the time the sponsor or holder agrees to a writ-
5 ten request pursuant to subsection (d)(2), then
6 each period of market exclusivity deemed or ex-
7 tended under subsection (b) or (c) shall be re-
8 duced by 3 months for such drug.

9 “(B) DESIGNATION.—The Secretary shall
10 designate an organization other than the Food
11 and Drug Administration to evaluate whether
12 the combined annual gross sales for all drugs
13 with the same active moiety exceeded
14 \$1,000,000,000 in a calendar year as described
15 in subparagraph (A). Prior to designating such
16 organization, the Secretary shall determine that
17 such organization is independent and is quali-
18 fied to evaluate the sales of pharmaceutical
19 products. The Secretary shall re-evaluate the
20 designation of such organization once every 3
21 years.

22 “(C) NOTIFICATION.—Once a year at a
23 time designated by the Secretary, the organiza-
24 tion designated under subparagraph (B) shall
25 notify the Food and Drug Administration of all

1 drugs with the same active moiety with com-
2 bined annual gross sales that exceed
3 \$1,000,000,000 during the previous calendar
4 year.”.

5 (7) in subsection (i)—

6 (A) in the heading, by striking “SUPPLE-
7 MENTS” and inserting “CHANGES”;

8 (B) in paragraph (1)—

9 (i) in the heading, by inserting “AP-
10 PPLICATIONS AND” after “PEDIATRIC”;

11 (ii) by inserting “application or” after
12 “Any”;

13 (iii) by striking “change pursuant to a
14 report on a pediatric study under” and in-
15 serting “change as a result of any pedi-
16 atric study conducted pursuant to”; and

17 (iv) by inserting “application or” after
18 “to be a priority”; and

19 (C) in paragraph (2)(A), by—

20 (i) striking “if the drug” and insert-
21 ing “if, on or after the date of enactment
22 of the date of enactment Best Pharma-
23 ceuticals for Children Amendments of
24 2007, the drug”; and

1 (ii) striking “an application with” and
2 all that follows through “on appropriate”
3 and inserting “the sponsor and the Sec-
4 retary have been unable to reach agree-
5 ment on appropriate”;

6 (8) by striking subsection (m);

7 (9) by redesignating subsections (j), (k), (l),
8 and (n), as subsections (k), (m), (o), and (q), respec-
9 tively;

10 (10) by inserting after subsection (i) the fol-
11 lowing:

12 “(j) OTHER LABELING CHANGES.—If, on or after the
13 date of enactment of the date of enactment Best Pharma-
14 ceuticals for Children Amendments of 2007, the Secretary
15 determines that a pediatric study conducted under this
16 section does not demonstrate that the drug that is the sub-
17 ject of the study is safe and effective in pediatric popu-
18 lations or subpopulations, the Secretary shall order the
19 label of such product to include information about the re-
20 sults of the study and a statement of the Secretary’s de-
21 termination.”;

22 (11) in subsection (k), as redesignated by para-
23 graph (9)—

24 (A) in paragraph (1)—

1 (i) by striking “a summary of the
2 medical and” and inserting “the medical,
3 statistical, and”; and

4 (ii) by striking “for the supplement”
5 and all that follows through the period and
6 inserting “under subsection (b) or (c).”;

7 (B) by redesignating paragraph (2) as
8 paragraph (3); and

9 (C) by inserting after paragraph (1) the
10 following:

11 “(2) DISSEMINATION OF INFORMATION RE-
12 GARDING LABELING CHANGES.—Beginning on the
13 date of enactment of the Best Pharmaceuticals for
14 Children Amendments of 2007, the Secretary shall
15 require that the sponsors of the studies that result
16 in labeling changes that are reflected in the annual
17 summary developed pursuant to subsection (f)(4)(F)
18 distribute, at least annually (or more frequently if
19 the Secretary determines that it would be beneficial
20 to the public health), such information to physicians
21 and other health care providers.”;

22 (12) by inserting after subsection (k), as redес-
23 igned by paragraph (9), the following:

24 “(l) ADVERSE EVENT REPORTING.—

1 “(1) REPORTING IN YEAR ONE.—Beginning on
2 the date of enactment of the Best Pharmaceuticals
3 for Children Amendments of 2007, during the 1-year
4 period beginning on the date a labeling change is
5 made pursuant to subsection (i), the Secretary shall
6 ensure that all adverse event reports that have been
7 received for such drug (regardless of when such re-
8 port was received) are referred to the Office of Pedi-
9 atric Therapeutics established under section 6 of the
10 Best Pharmaceuticals for Children Act (Public Law
11 107–109). In considering the report, the Director of
12 such Office shall provide for the review of the report
13 by the Pediatric Advisory Committee, including ob-
14 taining any recommendations of such Committee re-
15 garding whether the Secretary should take action
16 under this subtitle in response to such report.

17 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
18 lowing the 1-year period described in paragraph (1),
19 the Secretary shall, as appropriate, provide the Of-
20 fice of Pediatric Therapeutics with a report regard-
21 ing pediatric adverse events for a drug for which a
22 pediatric study was conducted under this section. In
23 considering the report, the Director of such Office
24 may provide for the review of the report by the Pedi-
25 atric Advisory Committee, including obtaining any

1 recommendation of such Committee regarding
2 whether the Secretary should take action in response
3 to such report.”;

4 (13) by inserting after subsection (m), as reded-
5 icated by paragraph (9), the following:

6 “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-
7 PLETED.—

8 “(1) IN GENERAL.—Beginning on the date of
9 enactment of the Best Pharmaceuticals for Children
10 Amendments of 2007, if pediatric studies have not
11 been completed under subsection (d) and if the Sec-
12 retary, through the committee established under
13 subsection (f), determines that there is a continuing
14 need for information relating to the use of the drug
15 in the pediatric population (including neonates, as
16 appropriate), the Secretary shall—

17 “(A) for drugs for which listed patents
18 have not expired, make a determination regard-
19 ing whether an assessment shall be required to
20 be submitted under section 505B; or

21 “(B) for drugs that have no listed patents
22 or have listed patents that have expired, deter-
23 mine whether there are funds available under
24 section 736 to award a grant to conduct the re-
25 quested studies pursuant to paragraph (2).

1 “(2) FUNDING OF STUDIES.—If, pursuant to
2 paragraph (1), the Secretary determines that there
3 are funds available under section 736 to award a
4 grant to conduct the requested pediatric studies,
5 then the Secretary shall issue a proposal to award
6 a grant to conduct the requested studies. If the Sec-
7 retary determines that funds are not available under
8 section 736, the Secretary shall refer the drug for
9 inclusion on the list established under section 409I
10 of the Public Health Service Act for the conduct of
11 studies.

12 “(3) PUBLIC NOTICE.—The Secretary shall give
13 the public notice of—

14 “(A) a decision under paragraph (1)(A)
15 not to require an assessment under section
16 505B and the basis for such decision;

17 “(B) the name of any drug, its manufac-
18 turer, and the indications to be studied pursu-
19 ant to a grant made under paragraph (2); and

20 “(C) any decision under paragraph (2) to
21 refer a drug for inclusion on the list established
22 under section 409I of the Public Health Service
23 Act.

24 “(4) EFFECT OF SUBSECTION.—Nothing in this
25 subsection alters or amends section 301(j) of this

1 Act or section 552 of title 5 or section 1905 of Title
2 18, United States Code.”;

3 (14) by inserting after subsection (o), as reded-
4 igned by paragraph (9), the following:

5 “(p) IOM STUDY.—Not later than 3 years after the
6 date of enactment of the Best Pharmaceuticals for Chil-
7 dren Amendments of 2007, the Secretary shall enter into
8 a contract with the Institute of Medicine to conduct a
9 study and report to Congress regarding the written re-
10 quests made and the studies conducted pursuant to this
11 section. The Institute of Medicine may devise an appro-
12 priate mechanism to review a representative sample of re-
13 quests made and studies conducted pursuant to this sec-
14 tion in order to conduct such study. Such study shall—

15 “(1) review such representative written requests
16 issued by the Secretary since 1997 under sub-
17 sections (b) and (c);

18 “(2) review and assess such representative pedi-
19 atric studies conducted under subsections (b) and (c)
20 since 1997 and labeling changes made as a result of
21 such studies; and

22 “(3) review the use of extrapolation for pedi-
23 atric subpopulations, the use of alternative endpoints
24 for pediatric populations, neonatal assessment tools,
25 and ethical issues in pediatric clinical trials.”; and

1 (15) in subsection (q), as redesignated by para-
2 graph (9)—

3 (A) striking “6-month period” and insert-
4 ing “3-month or 6-month period”;

5 (B) by striking “subsection (a)” and in-
6 serting “subsection (b)”; and

7 (C) by striking “2007” both places it ap-
8 pears and inserting “2012”.

9 (b) EFFECTIVE DATE.—Except as otherwise provided
10 in the amendments made by subsection (a), such amend-
11 ments shall apply to written requests under section 505A
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355a) made after the date of enactment of this subtitle.

14 **SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

15 Section 409I of the Public Health Service Act (42
16 U.S.C. 284m) is amended—

17 (1) by striking subsections (a) and (b) and in-
18 serting the following:

19 “(a) LIST OF PRIORITY ISSUES IN PEDIATRIC
20 THERAPEUTICS.—

21 “(1) IN GENERAL.—Not later than 1 year after
22 the date of enactment of the Best Pharmaceuticals
23 for Children Amendments of 2007, the Secretary,
24 acting through the Director of the National Insti-
25 tutes of Health and in consultation with the Com-

1 missioner of Food and Drugs and experts in pedi-
2 atric research, shall develop and publish a priority
3 list of needs in pediatric therapeutics, including
4 drugs or indications that require study. The list
5 shall be revised every 3 years.

6 “(2) CONSIDERATION OF AVAILABLE INFORMA-
7 TION.—In developing and prioritizing the list under
8 paragraph (1), the Secretary shall consider—

9 “(A) therapeutic gaps in pediatrics that
10 may include developmental pharmacology,
11 pharmacogenetic determinants of drug re-
12 sponse, metabolism of drugs and biologics in
13 children, and pediatric clinical trials;

14 “(B) particular pediatric diseases, dis-
15 orders or conditions where more complete
16 knowledge and testing of therapeutics, including
17 drugs and biologics, may be beneficial in pedi-
18 atric populations; and

19 “(C) the adequacy of necessary infrastruc-
20 ture to conduct pediatric pharmacological re-
21 search, including research networks and trained
22 pediatric investigators.

23 “(b) PEDIATRIC STUDIES AND RESEARCH.—The
24 Secretary, acting through the National Institutes of
25 Health, shall award funds to entities that have the exper-

1 tise to conduct pediatric clinical trials or other research
2 (including qualified universities, hospitals, laboratories,
3 contract research organizations, practice groups, federally
4 funded programs such as pediatric pharmacology research
5 units, other public or private institutions, or individuals)
6 to enable the entities to conduct the drug studies or other
7 research on the issues described in subsection (a). The
8 Secretary may use contracts, grants, or other appropriate
9 funding mechanisms to award funds under this sub-
10 section.”;

11 (2) in subsection (c)—

12 (A) in the heading, by striking “CON-
13 TRACTS” and inserting “PROPOSED PEDIATRIC
14 STUDY REQUESTS”;

15 (B) by striking paragraphs (4) and (12);

16 (C) by redesignating paragraphs (1), (2),
17 and (3), as paragraphs (2), (3), and (4);

18 (D) by inserting before paragraph (2), as
19 redesignated by subparagraph (C), the fol-
20 lowing:

21 “(1) SUBMISSION OF PROPOSED PEDIATRIC
22 STUDY REQUEST.—The Director of the National In-
23 stitutes of Health shall, as appropriate, submit pro-
24 posed pediatric study requests for consideration by
25 the Commissioner of Food and Drugs for pediatric

1 studies of a specific pediatric indication identified
2 under subsection (a). Such a proposed pediatric
3 study request shall be made in a manner equivalent
4 to a written request made under subsection (b) or
5 (c) of section 505A of the Federal Food, Drug, and
6 Cosmetic Act, including with respect to the informa-
7 tion provided on the pediatric studies to be con-
8 ducted pursuant to the request. The Director of the
9 National Institutes of Health may submit a pro-
10 posed pediatric study request for a drug for which—

11 “(A)(i) there is an approved application
12 under section 505(j) of the Federal Food,
13 Drug, and Cosmetic Act; or

14 “(ii) there is a submitted application that
15 could be approved under the criteria of section
16 505(j) of the Federal Food, Drug, and Cos-
17 metic Act; and

18 “(B) there is no patent protection or mar-
19 ket exclusivity protection for at least 1 form of
20 the drug under the Federal Food, Drug, and
21 Cosmetic Act; and

22 “(C) additional studies are needed to as-
23 sess the safety and effectiveness of the use of
24 the drug in the pediatric population.”;

1 (E) in paragraph (2), as redesignated by
2 subparagraph (C)—

3 (i) by inserting “based on the pro-
4 posed pediatric study request for the indi-
5 cation or indications submitted pursuant to
6 paragraph (1)” after “issue a written re-
7 quest”;

8 (ii) by striking “in the list described
9 in subsection (a)(1)(A) (except clause
10 (iv))” and inserting “under subsection
11 (a)”; and

12 (iii) by inserting “and using appro-
13 priate formulations for each age group for
14 which the study is requested” before the
15 period at the end;

16 (F) in paragraph (3), as redesignated by
17 subparagraph (C)—

18 (i) in the heading, by striking “CON-
19 TRACTS”;

20 (ii) by striking “paragraph (1)” and
21 inserting “paragraph (2)”;

22 (iii) by striking “or if a referral de-
23 scribed in subsection (a)(1)(A)(iv) is
24 made,”;

1 (iv) by striking “for contract pro-
2 posals” and inserting “for proposals”; and

3 (v) by inserting “in accordance with
4 subsection (b)” before the period at the
5 end;

6 (G) in paragraph (4), as redesignated by
7 subparagraph (C)—

8 (i) by striking “contract”; and

9 (ii) by striking “paragraph (2)” and
10 inserting “paragraph (3)”;

11 (H) in paragraph (5)—

12 (i) by striking the heading and insert-
13 ing “CONTRACTS, GRANTS, OR OTHER
14 FUNDING MECHANISMS”; and

15 (ii) by striking “A contract” and all
16 that follows through “is submitted” and
17 inserting “A contract, grant, or other
18 funding may be awarded under this section
19 only if a proposal is submitted”;

20 (I) in paragraph (6)(A)—

21 (i) by striking “a contract awarded”
22 and inserting “an award”; and

23 (ii) by inserting “, including a written
24 request if issued” after “with the study”;
25 and

1 (3) by inserting after subsection (c) the fol-
2 lowing:

3 “(d) DISSEMINATION OF PEDIATRIC INFORMA-
4 TION.—Not later than 1 year after the date of enactment
5 of the Best Pharmaceuticals for Children Amendments of
6 2007, the Secretary, acting through the Director of the
7 National Institutes of Health, shall study the feasibility
8 of establishing a compilation of information on pediatric
9 drug use and report the findings to Congress.”

10 “(e) AUTHORIZATION OF APPROPRIATIONS.—

11 “(1) IN GENERAL.—There are authorized to be
12 appropriated to carry out this section—

13 “(A) \$200,000,000 for fiscal year 2008;
14 and

15 “(B) such sums as are necessary for each
16 of the 4 succeeding fiscal years.

17 “(2) AVAILABILITY.—Any amount appropriated
18 under paragraph (1) shall remain available to carry
19 out this section until expended.”.

20 **SEC. 404. GAO REPORT.**

21 Not later than January 31, 2011, the Comptroller
22 General of the United States, in consultation with the Sec-
23 retary of Health and Human Services, shall submit to
24 Congress a report that addresses the effectiveness of sec-
25 tion 505A of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 355a) in ensuring that medicines used by chil-
2 dren are tested and properly labeled, including—

3 (1) the number and importance of drugs for
4 children that are being tested as a result of the
5 amendments made by this subtitle and the impor-
6 tance for children, health care providers, parents,
7 and others of labeling changes made as a result of
8 such testing;

9 (2) the number and importance of drugs for
10 children that are not being tested for their use not-
11 withstanding the provisions of this subtitle and the
12 amendments made by this subtitle, and possible rea-
13 sons for the lack of testing, including whether the
14 number of written requests declined by sponsors or
15 holders of drugs subject to section 505A(g)(2) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355a(g)(2)), has increased or decreased as a result
18 of the amendments made by this subtitle;

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 this subtitle, together with a description of
25 the outcomes of such process, including a description

1 of the disputes and the recommendations of the Pe-
2 diatric Advisory Committee;

3 (4) any recommendations for modifications to
4 the programs established under section 505A of the
5 Federal Food, Drug and Cosmetic Act (21 U.S.C.
6 355a) and section 409I of the Public Health Service
7 Act that the Secretary determines to be appropriate,
8 including a detailed rationale for each recommenda-
9 tion; and

10 (5)(A) the efforts made by the Secretary to in-
11 crease the number of studies conducted in the
12 neonate population; and

13 (B) the results of those efforts, including efforts
14 made to encourage the conduct of appropriate stud-
15 ies in neonates by companies with products that
16 have sufficient safety and other information to make
17 the conduct of the studies ethical and safe.

18 **SEC. 405. FEES RELATING TO DRUGS.**

19 Section 735(6) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 379g(6)) is amended by adding at
21 the end the following:

22 “(G) Activities relating to the support of
23 studies of drugs on pediatric populations under
24 section 505A(n)(1).”.

1 **SEC. 406. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

2 (a) INVESTMENT IN TOMORROW'S PEDIATRIC RE-
3 SEARCHERS.—Section 452G(2) of the Public Health Serv-
4 ice Act (42 U.S.C. 285g–10(2)) is amended by adding be-
5 fore the period at the end the following: “, including pedi-
6 atric pharmacological research”.

7 (b) PEDIATRIC RESEARCH LOAN REPAYMENT PRO-
8 GRAM.—Section 487F(a)(1) of the Public Health Service
9 Act (42 U.S.C. 288–6(a)(1)) is amended by inserting “in-
10 cluding pediatric pharmacological research,” after “pedi-
11 atric research,”.

12 **SEC. 407. FOUNDATION FOR THE NATIONAL INSTITUTES OF**
13 **HEALTH.**

14 Section 499(c)(1)(C) of the Public Health Service Act
15 (42 U.S.C. 290b(c)(1)(C)) is amended by striking “and
16 studies listed by the Secretary pursuant to section
17 409I(a)(1)(A) of the is Act and referred under section
18 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic
19 Act (21 U.S.C. 355(a)(d)(4)(C))”.

20 **SEC. 408. 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-
26 visory Committee Act (5 U.S.C. App.), the advisory com-

1 mittee shall continue to operate during the 5-year period
2 beginning on the date of enactment of the Best Pharma-
3 ceuticals for Children Amendments of 2007.”.

4 **SEC. 409. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**
5 **DRUGS ADVISORY COMMITTEE.**

6 Section 15 of the Best Pharmaceuticals for Children
7 Act (42 U.S.C. 284m note) is amended—

8 (1) in subsection (a)—

9 (A) in paragraph (1)—

10 (i) in subparagraph (B), by striking
11 “and” after the semicolon;

12 (ii) in subparagraph (C), by striking
13 the period at the end and inserting “;
14 and”; and

15 (iii) by adding at the end the fol-
16 lowing:

17 “(D) provide recommendations to the in-
18 ternal review committee created under section
19 505A(f) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 355a(f)) regarding the
21 implementation of amendments to sections
22 505A and 505B of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 355a and 355c)
24 with respect to the treatment of pediatric can-
25 cers.”; and

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

2 “(3) CONTINUATION OF OPERATION OF SUB-
3 COMMITTEE.—Notwithstanding section 14 of the
4 Federal Advisory Committee Act (5 U.S.C. App.),
5 the Subcommittee shall continue to operate during
6 the 5-year period beginning on the date of enact-
7 ment of the Best Pharmaceuticals for Children
8 Amendments of 2007.”; and

9 (2) in subsection (d), by striking “2003” and
10 inserting “2009”.

11 **SEC. 410. EFFECTIVE DATE AND LIMITATION FOR RULE RE-**
12 **LATING TO TOLL-FREE NUMBER FOR AD-**
13 **VERSE EVENTS ON LABELING FOR HUMAN**
14 **DRUG PRODUCTS.**

15 (a) IN GENERAL.—Notwithstanding subchapter II of
16 chapter 5, and chapter 7, of title 5, United States Code
17 (commonly known as the “Administrative Procedure Act”)
18 and any other provision of law, the proposed rule issued
19 by the Commissioner of Food and Drugs entitled “Toll-
20 Free Number for Reporting Adverse Events on Labeling
21 for Human Drug Products”, 69 Fed. Reg. 21778, (April
22 22, 2004) shall take effect on the date that is 60 days
23 after the date of enactment of this subtitle, unless such
24 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 shall submit to the Secretary docu-
2 mentation detailing why a pediatric formulation can-
3 not be developed, and, if the waiver is granted, the
4 applicant's submission shall promptly be made avail-
5 able to the public in an easily accessible manner, in-
6 cluding through posting on the website of the Food
7 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 the medical review that is collected as
15 part of the application under section 505
16 or section 351 of the Public Health Service
17 Act.”; and

18 (3) by striking paragraph (3) and inserting the
19 following:

20 “(3) DEFERRAL.—

21 “(A) IN GENERAL.—On the initiative of
22 the Secretary or at the request of the applicant,
23 the Secretary may defer submission of some or
24 all assessments required under paragraph (1)
25 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 Section 505B(b) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355c(b)) is amended—

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

7 “(1) IN GENERAL.—After providing notice in
8 the form of a letter, or a written request under sec-
9 tion 505A that was declined by the sponsor or hold-
10 er, and an opportunity for written response and a
11 meeting, which may include an advisory committee
12 meeting, the Secretary may (by order in the form of
13 a letter) require the sponsor or holder of an ap-
14 proved application for a drug under section 505 or
15 the holder of a license for a biological product under
16 section 351 of the Public Health Service Act (42
17 U.S.C. 262) to submit by a specified date the assess-
18 ments described in subsection (a)(2) and the written
19 request, as appropriate, if the Secretary finds that—

20 “(A)(i) the drug or biological product is
21 used for a substantial number of pediatric pa-
22 tients for the labeled indications; and

23 “(ii) adequate pediatric labeling could con-
24 fer a benefit on pediatric patients;

25 “(B) there is reason to believe that the
26 drug or biological product would represent a

1 meaningful therapeutic benefit over existing
2 therapies for pediatric patients for 1 or more of
3 the claimed indications; or

4 “(C) the absence of adequate pediatric la-
5 beling could pose a risk to pediatric patients.”;

6 (2) in paragraph (2)(C), by adding at the end
7 the following: “An applicant seeking either a partial
8 or full waiver shall submit to the Secretary docu-
9 mentation detailing why a pediatric formulation can-
10 not be developed, and, if the waiver is granted, the
11 applicant’s submission shall promptly be made avail-
12 able to the public in an easily accessible manner, in-
13 cluding through posting on the website of the Food
14 and Drug Administration.”; and

15 (3) by striking paragraph (3).

16 **SEC. 414. REVIEW OF PEDIATRIC ASSESSMENTS; ADVERSE**
17 **EVENT REPORTING; STRIKE OF SUNSET; LA-**
18 **BELING CHANGES; AND PEDIATRIC ASSESS-**
19 **MENTS.**

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

22 (1) by striking subsection (h);

23 (2) by redesignating subsection (f) as sub-
24 section (k);

1 (3) by redesignating subsection (g) as sub-
2 section (l); and

3 (4) by inserting after subsection (e) the fol-
4 lowing:

5 “(f) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS,
6 PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—

7 “(1) REVIEW.—The Secretary shall create an
8 internal committee to review all pediatric assessment
9 requests issued under this section, all pediatric as-
10 sessments conducted under this section, and all de-
11 ferral and waiver requests made pursuant to this
12 section. Such internal committee shall include indi-
13 viduals with the following expertise:

14 “(A) Pediatrics.

15 “(B) Biopharmacology.

16 “(C) Statistics.

17 “(D) Drugs and drug formulations.

18 “(E) Pediatric ethics.

19 “(F) Legal issues.

20 “(G) Appropriate expertise pertaining to
21 the pediatric product under review.

22 “(H) 1 or more experts from the Office of
23 Pediatric Therapeutics.

24 “(I) Other individuals as designated by the
25 Secretary.

1 “(2) REVIEW OF REQUESTS FOR PEDIATRIC AS-
2 SESSMENTS, DEFERRALS, AND WAIVERS.—All writ-
3 ten requests for a pediatric assessment issued pursu-
4 ant to this section and all requests for deferrals and
5 waivers from the requirement to conduct a pediatric
6 assessment under this section shall be reviewed and
7 approved by the committee established under para-
8 graph (1).

9 “(3) REVIEW OF ASSESSMENTS.—The com-
10 mittee established under paragraph (1) shall review
11 all assessments conducted under this section to de-
12 termine whether such assessments meet the require-
13 ments of this section.

14 “(4) TRACKING OF ASSESSMENTS AND LABEL-
15 ING CHANGES.—The committee established under
16 paragraph (1) is responsible for tracking and mak-
17 ing public in an easily accessible manner, including
18 through posting on the website of the Food and
19 Drug Administration—

20 “(A) the number of assessments conducted
21 under this section;

22 “(B) the specific drugs and drug uses as-
23 sessed under this section;

24 “(C) the types of assessments conducted
25 under this section, including trial design, the

1 number of pediatric patients studied, and the
2 number of centers and countries involved;

3 “(D) the total number of deferrals re-
4 quested and granted under this section, and, if
5 granted, the reasons for such deferrals, the
6 timeline for completion, and the number com-
7 pleted and pending by the specified date, as
8 outlined in subsection (a)(3);

9 “(E) the number of waivers requested and
10 granted under this section, and, if granted, the
11 reasons for the waivers;

12 “(F) the number of pediatric formulations
13 developed and the number of pediatric formula-
14 tions not developed and the reasons any such
15 formulations were not developed;

16 “(G) the labeling changes made as a result
17 of assessments conducted under this section;

18 “(H) an annual summary of labeling
19 changes made as a result of assessments con-
20 ducted under this section for distribution pursu-
21 ant to subsection (i)(2); and

22 “(I) an annual summary of the informa-
23 tion submitted pursuant to subsection
24 (a)(3)(B).

25 “(g) LABELING CHANGES.—

1 “(1) PRIORITY STATUS FOR PEDIATRIC SUP-
2 PLEMENT.—Any supplement to an application under
3 section 505 and section 351 of the Public Health
4 Service Act proposing a labeling change as a result
5 of any pediatric assessments conducted pursuant to
6 this section—

7 “(A) shall be considered a priority supple-
8 ment; and

9 “(B) shall be subject to the performance
10 goals established by the Commissioner for pri-
11 ority drugs.

12 “(2) DISPUTE RESOLUTION.—

13 “(A) REQUEST FOR LABELING CHANGE
14 AND FAILURE TO AGREE.—If the Commissioner
15 determines that a sponsor and the Commis-
16 sioner have been unable to reach agreement on
17 appropriate changes to the labeling for the drug
18 that is the subject of the application or supple-
19 ment, not later than 180 days after the date of
20 the submission of the application or supple-
21 ment—

22 “(i) the Commissioner shall request
23 that the sponsor make any labeling change
24 that the Commissioner determines to be
25 appropriate; and

1 “(ii) if the sponsor does not agree to
2 make a labeling change requested by the
3 Commissioner, the Commissioner shall
4 refer the matter to the Pediatric Advisory
5 Committee.

6 “(B) ACTION BY THE PEDIATRIC ADVISORY
7 COMMITTEE.—Not later than 90 days after re-
8 ceiving a referral under subparagraph (A)(ii),
9 the Pediatric Advisory Committee shall—

10 “(i) review the pediatric study reports;
11 and

12 “(ii) make a recommendation to the
13 Commissioner concerning appropriate la-
14 beling changes, if any.

15 “(C) CONSIDERATION OF RECOMMENDA-
16 TIONS.—The Commissioner shall consider the
17 recommendations of the Pediatric Advisory
18 Committee and, if appropriate, not later than
19 30 days after receiving the recommendation,
20 make a request to the sponsor of the applica-
21 tion or supplement to make any labeling
22 changes that the Commissioner determines to
23 be appropriate.

24 “(D) MISBRANDING.—If the sponsor, with-
25 in 30 days after receiving a request under sub-

1 paragraph (C), does not agree to make a label-
2 ing change requested by the Commissioner, the
3 Commissioner may deem the drug that is the
4 subject of the application or supplement to be
5 misbranded.

6 “(E) NO EFFECT ON AUTHORITY.—Noth-
7 ing in this subsection limits the authority of the
8 United States to bring an enforcement action
9 under this Act when a drug lacks appropriate
10 pediatric labeling. Neither course of action (the
11 Pediatric Advisory Committee process or an en-
12 forcement action referred to in the preceding
13 sentence) shall preclude, delay, or serve as the
14 basis to stay the other course of action.

15 “(3) OTHER LABELING CHANGES.—If the Sec-
16 retary makes a determination that a pediatric as-
17 sessment conducted under this section does not dem-
18 onstrate that the drug that is the subject of such as-
19 sessment is safe and effective in pediatric popu-
20 lations or subpopulations, the Secretary shall order
21 the label of such product to include information
22 about the results of the assessment and a statement
23 of the Secretary’s determination.

24 “(h) DISSEMINATION OF PEDIATRIC INFORMA-
25 TION.—

1 “(1) IN GENERAL.—Not later than 180 days
2 after the date of submission of a pediatric assess-
3 ment under this section, the Secretary shall make
4 available to the public in an easily accessible manner
5 the medical, statistical, and clinical pharmacology re-
6 views of such pediatric assessments and shall post
7 such assessments on the website of the Food and
8 Drug Administration.

9 “(2) DISSEMINATION OF INFORMATION RE-
10 GARDING LABELING CHANGES.—The Secretary shall
11 require that the sponsors of the assessments that re-
12 sult in labeling changes that are reflected in the an-
13 nual summary developed pursuant to subsection
14 (f)(4)(H) distribute such information to physicians
15 and other health care providers.

16 “(3) EFFECT OF SUBSECTION.—Nothing in this
17 subsection shall alter or amend section 301(j) of this
18 Act or section 552 of title 5, United States Code, or
19 section 1905 of title 18, United States Code.

20 “(i) ADVERSE EVENT REPORTING.—

21 “(1) REPORTING IN YEAR 1.—During the 1-
22 year period beginning on the date a labeling change
23 is made pursuant to subsection (g), the Secretary
24 shall ensure that all adverse event reports that have
25 been received for such drug (regardless of when such

1 report was received) are referred to the Office of Pe-
2 diatric Therapeutics. In considering the report, the
3 Director of such Office shall provide for the review
4 of the report by the Pediatric Advisory Committee,
5 including obtaining any recommendations of such
6 committee regarding whether the Secretary should
7 take action under this Act in response to such re-
8 port.

9 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
10 lowing the 1-year period described in paragraph (1),
11 the Secretary shall, as appropriate, provide the Of-
12 fice of Pediatric Therapeutics with a report regard-
13 ing pediatric adverse events for a drug for which a
14 pediatric study was conducted under this section. In
15 considering the report, the Director of such Office
16 may provide for the review of the report by the Pedi-
17 atric Advisory Committee, including obtaining any
18 recommendation of such Committee regarding
19 whether the Secretary should take action in response
20 to such report.”.

21 **SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.**

22 Section 505B(c) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355c) is amended—

24 (1) by striking “estimates” and inserting “de-
25 termines”; and

1 (2) by striking “would” and inserting “could”.

2 **SEC. 416. REPORTS.**

3 (a) IOM STUDY.—Section 505B of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355c), as amended
5 by section 414, is further amended by adding after sub-
6 section (l), the following:

7 “(m) INSTITUTE OF MEDICINE STUDY.—

8 “(1) IN GENERAL.—Not later than 3 years
9 after the date of enactment of the Pediatric Re-
10 search Improvement Act, the Secretary shall con-
11 tract with the Institute of Medicine to conduct a
12 study and report to Congress regarding the pediatric
13 studies conducted pursuant to this section since
14 1997.

15 “(2) CONTENT OF STUDY.—The study under
16 paragraph (1) shall review and assess—

17 “(A) pediatric studies conducted pursuant
18 to this section since 1997 and labeling changes
19 made as a result of such studies; and

20 “(B) the use of extrapolation for pediatric
21 subpopulations, the use of alternative endpoints
22 for pediatric populations, neonatal assessment
23 tools, number and type of pediatric adverse
24 events, and ethical issues in pediatric clinical
25 trials.

1 “(3) REPRESENTATIVE SAMPLE.—The Institute
2 of Medicine may devise an appropriate mechanism to
3 review a representative sample of studies conducted
4 pursuant to this section from each review division
5 within the Center for Drug Evaluation and Research
6 and the Center for Biologics Evaluation and Re-
7 search in order to make the required assessment.”.

8 (b) PREA REPORT.—The Pediatric Research Equity
9 Act of 2003 (Public Law 108–155) is amended by adding
10 at the end the following:

11 **“SEC. 5. REPORT.**

12 “Not later than September 1, 2010, the Comptroller
13 General of the United States, in consultation with the Sec-
14 retary of Health and Human Services, shall submit to
15 Congress a report that addresses the effectiveness of sec-
16 tion 505B of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355a) in ensuring that medicines used by chil-
18 dren are tested and properly labeled, including—

19 “(1) the number and importance of drugs for
20 children that are being tested as a result of this pro-
21 vision and the importance for children, health care
22 providers, parents, and others of labeling changes
23 made as a result of such testing;

24 “(2) the number and importance of drugs for
25 children that are not being tested for their use not-

1 withstanding the provisions of this Act, and possible
2 reasons for the lack of testing; and

3 “(3) the number of drugs for which testing is
4 being done and labeling changes required, including
5 the date labeling changes are made and which label-
6 ing changes required the use of the dispute resolu-
7 tion process established pursuant to the amendments
8 made by this Act, together with a description of the
9 outcomes of such process, including a description of
10 the disputes and the recommendations of the Pedi-
11 atric Advisory Committee.”.

12 **SEC. 417. TECHNICAL CORRECTIONS.**

13 Section 505B(a)(2)(B)(ii) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amend-
15 ed by striking “one” and inserting “1”.

16 **Subtitle C—Pediatric Medical**
17 **Devices**

18 **SEC. 421. SHORT TITLE.**

19 This subtitle may be cited as the “Pediatric Medical
20 Device Safety and Improvement Act of 2007”.

21 **SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.**

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

1 **“SEC. 515A. PEDIATRIC USES OF DEVICES.**

2 “(a) NEW DEVICES.—

3 “(1) IN GENERAL.—A person that submits to
4 the Secretary an application under section 520(m),
5 or an application (or supplement to an application)
6 or a product development protocol under section
7 515, shall include in the application or protocol the
8 information described in paragraph (2).

9 “(2) REQUIRED INFORMATION.—The applica-
10 tion or protocol described in paragraph (1) shall in-
11 clude, with respect to the device for which approval
12 is sought and if readily available—

13 “(A) a description of any pediatric sub-
14 populations that suffer from the disease or con-
15 dition that the device is intended to treat, diag-
16 nose, or cure; and

17 “(B) the number of affected pediatric pa-
18 tients.

19 “(3) ANNUAL REPORT.—Not later than 18
20 months after the date of enactment of this section,
21 and annually thereafter, the Secretary shall submit
22 to the Committee on Health, Education, Labor, and
23 Pensions of the Senate and the Committee on En-
24 ergy and Commerce of the House of Representatives
25 a report that includes—

1 “(A) the number of devices approved in the
2 year preceding the year in which the report is
3 submitted, for which there is a pediatric sub-
4 population that suffers from the disease or con-
5 dition that the device is intended to treat, diag-
6 nose, or cure;

7 “(B) the number of devices approved in
8 the year preceding the year in which the report
9 is submitted, labeled for use in pediatric pa-
10 tients;

11 “(C) the number of pediatric devices ap-
12 proved in the year preceding the year in which
13 the report is submitted, exempted from a fee
14 pursuant to section 738(a)(2)(B)(v); and

15 “(D) the review time for each device de-
16 scribed in subparagraphs (A), (B), and (C).

17 “(b) DETERMINATION OF PEDIATRIC EFFECTIVE-
18 NESS BASED ON SIMILAR COURSE OF DISEASE OR CONDI-
19 TION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

20 “(1) IN GENERAL.—If the course of the disease
21 or condition and the effects of the device are suffi-
22 ciently similar in adults and pediatric patients, the
23 Secretary may conclude that adult data may be used
24 to support a determination of a reasonable assur-

1 ance of effectiveness in pediatric populations, as ap-
2 propriate.

3 “(2) **EXTRAPOLATION BETWEEN SUBPOPULA-**
4 **TIONS.**—A study may not be needed in each pedi-
5 atric subpopulation if data from one subpopulation
6 can be extrapolated to another subpopulation.

7 “(c) **PEDIATRIC SUBPOPULATION.**—In this section,
8 the term ‘pediatric subpopulation’ has the meaning given
9 the term in section 520(m)(6)(E)(ii).”.

10 **SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EX-**
11 **EMPTION.**

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

15 (1) in paragraph (3), by striking “No” and in-
16 serting “Except as provided in paragraph (6), no”;

17 (2) in paragraph (5)—

18 (A) by inserting “, if the Secretary has
19 reason to believe that the requirements of para-
20 graph (6) are no longer met,” after “public
21 health”; and

22 (B) by adding at the end the following: “If
23 the person granted an exemption under para-
24 graph (2) fails to demonstrate continued com-
25 pliance with the requirements of this sub-

1 section, the Secretary may suspend or withdraw
2 the exemption from the effectiveness require-
3 ments of sections 514 and 515 for a humani-
4 tarian device only after providing notice and an
5 opportunity for an informal hearing.”;

6 (3) by striking paragraph (6) and inserting the
7 following:

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

12 “(i)(I) The device with respect to which the ex-
13 emption is granted is intended for the treatment or
14 diagnosis of a disease or condition that occurs in pe-
15 diatric patients or in a pediatric subpopulation, and
16 such device is labeled for use in pediatric patients or
17 in a pediatric subpopulation in which the disease or
18 condition occurs.

19 “(II) The device was not previously approved
20 under this subsection for the pediatric patients or
21 the pediatric subpopulation described in subclause
22 (I) prior to the date of enactment of the Pediatric
23 Medical Device Safety and Improvement Act of
24 2007.

1 “(ii) During any calendar year, the number of
2 such devices distributed during that year does not
3 exceed the annual distribution number specified by
4 the Secretary when the Secretary grants such ex-
5 emption. The annual distribution number shall be
6 based on the number of individuals affected by the
7 disease or condition that such device is intended to
8 treat, diagnose, or cure, and of that number, the
9 number of individuals likely to use the device, and
10 the number of devices reasonably necessary to treat
11 such individuals. In no case shall the annual dis-
12 tribution number exceed the number identified in
13 paragraph (2)(A).

14 “(iii) Such person immediately notifies the Sec-
15 retary if the number of such devices distributed dur-
16 ing any calendar year exceeds the annual distribu-
17 tion number referred to in clause (ii).

18 “(iv) The request for such exemption is sub-
19 mitted on or before October 1, 2013.

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

1 “(C) A person may petition the Secretary to modify
2 the annual distribution number specified by the Secretary
3 under subparagraph (A)(ii) with respect to a device if ad-
4 ditional information on the number of individuals affected
5 by the disease or condition arises, and the Secretary may
6 modify such number but in no case shall the annual dis-
7 tribution number exceed the number identified in para-
8 graph (2)(A).

9 “(D) If a person notifies the Secretary, or the Sec-
10 retary determines through an inspection under subpara-
11 graph (B), that the number of devices distributed during
12 any calendar year exceeds the annual distribution number,
13 as required under subparagraph (A)(iii), and modified
14 under subparagraph (C), if applicable, then the prohibi-
15 tion in paragraph (3) shall apply with respect to such per-
16 son for such device for any sales of such device after such
17 notification.

18 “(E)(i) In this subsection, the term ‘pediatric pa-
19 tients’ means patients who are 21 years of age or younger
20 at the time of the diagnosis or treatment.

21 “(ii) In this subsection, the term ‘pediatric sub-
22 population’ means 1 of the following populations:

23 “(I) Neonates.

24 “(II) Infants.

25 “(III) Children.

1 “(IV) Adolescents.”; and

2 (4) by adding at the end the following:

3 “(7) The Secretary shall refer any report of an ad-
4 verse event regarding a device for which the prohibition
5 under paragraph (3) does not apply pursuant to para-
6 graph (6)(A) that the Secretary receives to the Office of
7 Pediatric Therapeutics, established under section 6 of the
8 Best Pharmaceuticals for Children Act (Public Law 107–
9 109)). In considering the report, the Director of the Office
10 of Pediatric Therapeutics, in consultation with experts in
11 the Center for Devices and Radiological Health, shall pro-
12 vide for periodic review of the report by the Pediatric Ad-
13 visory Committee, including obtaining any recommenda-
14 tions of such committee regarding whether the Secretary
15 should take action under this Act in response to the re-
16 port.”.

17 (b) REPORT.—Not later than January 1, 2012, the
18 Comptroller General of the United States shall submit to
19 the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy and
21 Commerce of the House of Representatives a report on
22 the impact of allowing persons granted an exemption
23 under section 520(m)(2) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a
25 device to profit from such device pursuant to section

1 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amend-
2 ed by subsection (a)), including—

3 (1) an assessment of whether such section
4 520(m)(6) (as amended by subsection (a)) has in-
5 creased the availability of pediatric devices for condi-
6 tions that occur in small numbers of children, in-
7 cluding any increase or decrease in the number of—

8 (A) exemptions granted under such section
9 520(m)(2) for pediatric devices; and

10 (B) applications approved under section
11 515 of such Act (21 U.S.C. 360e) for devices
12 intended to treat, diagnose, or cure conditions
13 that occur in pediatric patients or for devices
14 labeled for use in a pediatric population;

15 (2) the conditions or diseases the pediatric de-
16 vices were intended to treat or diagnose and the esti-
17 mated size of the pediatric patient population for
18 each condition or disease;

19 (3) the costs of the pediatric devices, based on
20 a survey of children's hospitals;

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

23 (5) the impact, if any, of allowing profit on ac-
24 cess to such devices for patients;

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

3 (7) an estimate of the extent of the use of the
4 pediatric devices by both adults and pediatric popu-
5 lations for a condition or disease other than the con-
6 dition or disease on the label of such devices;

7 (8) recommendations of the Comptroller Gen-
8 eral of the United States regarding the effectiveness
9 of such section 520(m)(6) (as amended by sub-
10 section (a)) and whether any modifications to such
11 section 520(m)(6) (as amended by subsection (a))
12 should be made;

13 (9) existing obstacles to pediatric device devel-
14 opment; and

15 (10) an evaluation of the demonstration grants
16 described in section 5.

17 (c) GUIDANCE.—Not later than 180 days after the
18 date of enactment of this subtitle, the Commissioner of
19 Food and Drugs shall issue guidance for institutional re-
20 view committees on how to evaluate requests for approval
21 for devices for which a humanitarian device exemption
22 under section 520(m)(2) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

1 **SEC. 424. ENCOURAGING PEDIATRIC MEDICAL DEVICE RE-**
2 **SEARCH.**

3 (a) ACCESS TO FUNDING.—The Director of the Na-
4 tional Institutes of Health shall designate a contact point
5 or office at the National Institutes of Health to help
6 innovators and physicians access funding for pediatric
7 medical device development.

8 (b) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-
9 SEARCH.—

10 (1) IN GENERAL.—Not later than 180 days
11 after the date of enactment of this subtitle, the
12 Commissioner of Food and Drugs, in collaboration
13 with the Director of the National Institutes of
14 Health and the Director of the Agency for
15 Healthcare Research and Quality, shall submit to
16 the Committee on Health, Education, Labor, and
17 Pensions of the Senate and the Committee on En-
18 ergy and Commerce of the House of Representatives
19 a plan for expanding pediatric medical device re-
20 search and development. In developing such plan,
21 the Commissioner of Food and Drugs shall consult
22 with individuals and organizations with appropriate
23 expertise in pediatric medical devices.

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

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

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

7 (C) a research agenda for improving pedi-
8 atric medical device development and Food and
9 Drug Administration clearance or approval of
10 pediatric medical devices, and for evaluating the
11 short- and long-term safety and effectiveness of
12 pediatric medical devices.

13 **SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
14 **ATRIC DEVICE AVAILABILITY.**

15 (a) IN GENERAL.—

16 (1) REQUEST FOR PROPOSALS.—Not later than
17 90 days after the date of enactment of this subtitle,
18 the Secretary of Health and Human Services shall
19 issue a request for proposals for 1 or more grants
20 or contracts to nonprofit consortia for demonstration
21 projects to promote pediatric device development.

22 (2) DETERMINATION ON GRANTS OR CON-
23 TRACTS.—Not later than 180 days after the date the
24 Secretary of Health and Human Services issues a
25 request for proposals under paragraph (1), the Sec-

1 retary shall make a determination on the grants or
2 contracts under this section.

3 (b) APPLICATION.—A nonprofit consortium that de-
4 sires to receive a grant or contract under this section shall
5 submit an application to the Secretary of Health and
6 Human Services at such time, in such manner, and con-
7 taining such information as the Secretary may require.

8 (c) USE OF FUNDS.—A nonprofit consortium that re-
9 ceives a grant or contract under this section shall—

10 (1) encourage innovation by connecting quali-
11 fied individuals with pediatric device ideas with po-
12 tential manufacturers;

13 (2) mentor and manage pediatric device
14 projects through the development process, including
15 product identification, prototype design, device devel-
16 opment, and marketing;

17 (3) connect innovators and physicians to exist-
18 ing Federal resources, including resources from the
19 Food and Drug Administration, the National Insti-
20 tutes of Health, the Small Business Administration,
21 the Department of Energy, the Department of Edu-
22 cation, the National Science Foundation, the De-
23 partment of Veterans Affairs, the Agency for
24 Healthcare Research and Quality, and the National
25 Institute of Standards and Technology;

1 (4) assess the scientific and medical merit of
2 proposed pediatric device projects;

3 (5) assess business feasibility and provide busi-
4 ness advice;

5 (6) provide assistance with prototype develop-
6 ment; and

7 (7) provide assistance with postmarket needs,
8 including training, logistics, and reporting.

9 (d) COORDINATION.—

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

13 (A) coordinate with the National Institutes
14 of Health’s pediatric device contact point or of-
15 fice, designated under section 424; and

16 (B) provide to the National Institutes of
17 Health any identified pediatric device needs
18 that the consortium lacks sufficient capacity to
19 address or those needs in which the consortium
20 has been unable to stimulate manufacturer in-
21 terest.

22 (2) FOOD AND DRUG ADMINISTRATION.—Each
23 consortium that receives a grant or contract under
24 this section shall coordinate with the Commissioner
25 of Food and Drugs and device companies to facili-

1 tate the application for approval or clearance of de-
2 vices labeled for pediatric use.

3 (e) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section
5 \$6,000,000 for each of fiscal years 2008 through 2012.

6 **SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**
7 **PEUTICS AND PEDIATRIC ADVISORY COM-**
8 **MITTEE.**

9 (a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section
10 6(b) of the Best Pharmaceuticals for Children Act (21
11 U.S.C. 393a(b)) is amended by inserting “, including in-
12 creasing pediatric access to medical devices” after “pedi-
13 atric issues”.

14 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14
15 of the Best Pharmaceuticals for Children Act (42 U.S.C.
16 284m note) is amended—

17 (1) in subsection (a), by inserting “(including
18 drugs and biological products) and medical devices”
19 after “therapeutics”; and

20 (2) in subsection (b)—

21 (A) in paragraph (1), by inserting “(in-
22 cluding drugs and biological products) and med-
23 ical devices” after “therapeutics”; and

24 (B) in paragraph (2)—

1 (i) in subparagraph (A), by striking
2 “and 505B” and inserting “505B, 510(k),
3 515, and 520(m)”;

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

6 “(B) identification of research priorities re-
7 lated to therapeutics (including drugs and bio-
8 logical products) and medical devices for pedi-
9 atric populations and the need for additional
10 diagnostics and treatments for specific pediatric
11 diseases or conditions; and”;

12 (iii) in subparagraph (C), by inserting
13 “(including drugs and biological products)
14 and medical devices” after “therapeutics”.

15 **SEC. 427. STUDIES.**

16 (a) **POSTMARKET STUDIES.**—Section 522 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is
18 amended—

19 (1) in subsection (a)—

20 (A) by inserting “, or as a condition to ap-
21 proval of an application (or a supplement to an
22 application) or a product development protocol
23 under section 515 or as a condition to clearance
24 of a premarket notification under section

1 510(k),” after “The Secretary may by order”;
2 and

3 (B) by inserting “, that is expected to have
4 significant use in pediatric populations,” after
5 “health consequences”; and

6 (2) in subsection (b)—

7 (A) by striking “(b) SURVEILLANCE AP-
8 PROVAL.—Each” and inserting the following:

9 “(b) SURVEILLANCE APPROVAL.—
10 “(1) IN GENERAL.—Each”;

11 (B) by striking “The Secretary, in con-
12 sultation” and inserting “Except as provided in
13 paragraph (2), the Secretary, in consultation”;

14 (C) by striking “Any determination” and
15 inserting “Except as provided in paragraph (2),
16 any determination”; and

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

18 “(2) LONGER STUDIES FOR PEDIATRIC DE-
19 VICES.—The Secretary may by order require a pro-
20 spective surveillance period of more than 36 months
21 with respect to a device that is expected to have sig-
22 nificant use in pediatric populations if such period of
23 more than 36 months is necessary in order to assess
24 the impact of the device on growth and development,
25 or the effects of growth, development, activity level,

1 or other factors on the safety or efficacy of the de-
2 vice.”.

3 (b) DATABASE.—

4 (1) IN GENERAL.—

5 (A) ESTABLISHMENT.—The Secretary of
6 Health and Human Services, acting through the
7 Commissioner of Food and Drugs, shall estab-
8 lish a publicly accessible database of studies of
9 medical devices that includes all studies and
10 surveillance, described in paragraph (2)(A),
11 that were in progress on the date of enactment
12 of this subtitle or that began after such date.

13 (B) ACCESSIBILITY.—Information included
14 in the database under subparagraph (A) shall
15 be in language reasonably accessible and under-
16 stood by individuals without specific expertise in
17 the medical field.

18 (2) STUDIES AND SURVEILLANCE.—

19 (A) INCLUDED.—The database described
20 in paragraph (1) shall include—

21 (i) all postmarket surveillances or-
22 dered under section 522(a) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 360l(a)) or agreed to by the manufacturer;
25 and

1 (ii) all studies agreed to by the manu-
2 facturer of a medial device as part of—

3 (I) the premarket approval of
4 such device under section 515 of the
5 Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 360e);

7 (II) the clearance of a premarket
8 notification report under section
9 510(k) of such Act (21 U.S.C.
10 360(k)) with respect to such device; or

11 (III) the submission of an appli-
12 cation under section 520(m) of such
13 Act (21 U.S.C. 360j(m)) with respect
14 to such device.

15 (B) EXCLUDED.—The database described
16 in paragraph (1) shall not include any studies
17 with respect to a medical device that were com-
18 pleted prior to the initial approval of such de-
19 vice.

20 (3) CONTENTS OF STUDY AND SURVEIL-
21 LANCE.—For each study or surveillance included in
22 the database described in paragraph (1), the data-
23 base shall include—

24 (A) information on the status of the study
25 or surveillance;

1 (B) basic information about the study or
2 surveillance, including the purpose, the primary
3 and secondary outcomes, and the population
4 targeted;

5 (C) the expected completion date of the
6 study or surveillance;

7 (D) public health notifications, including
8 safety alerts; and

9 (E) any other information the Secretary of
10 Health and Human Services determines appro-
11 priate to protect the public health.

12 (4) ONCE COMPLETED OR TERMINATED.—In
13 addition to the information described in paragraph
14 (3), once a study or surveillance has been completed
15 or if a study or surveillance is terminated, the data-
16 base shall also include—

17 (A) the actual date of completion or termi-
18 nation;

19 (B) if the study or surveillance was termi-
20 nated, the reason for termination;

21 (C) if the study or surveillance was sub-
22 mitted but not accepted by the Food and Drug
23 Administration because the study or surveil-
24 lance did not meet the requirements for such

1 study or surveillance, an explanation of the rea-
2 sons and any follow-up action required;

3 (D) information about any labeling
4 changes made to the device as a result of the
5 study or surveillance findings;

6 (E) information about any other decisions
7 or actions of the Food and Drug Administra-
8 tion that result from the study or surveillance
9 findings;

10 (F) lay and technical summaries of the
11 study or surveillance results and key findings,
12 or an explanation as to why the results and key
13 findings do not warrant public availability;

14 (G) a link to any peer reviewed articles on
15 the study or surveillance; and

16 (H) any other information the Secretary of
17 Health and Human Services determines appro-
18 priate to protect the public health.

19 (5) PUBLIC ACCESS.—The database described
20 in paragraph (1) shall be—

21 (A) accessible to the general public; and

22 (B) easily searchable by multiple criteria,
23 including whether the study or surveillance in-
24 volves pediatric populations.

1 **SEC. 428. SEVERABILITY CLAUSE.**

2 If any provision of this Act, an amendment made this
3 Act, or the application of such provision or amendment
4 to any person or circumstance is held to be unconstitu-
5 tional, the remainder of this Act, the amendments made
6 by this Act, and the application of the provisions of such
7 to any person or circumstances shall not be affected there-
8 by.