

Calendar No. 270

110TH CONGRESS
1ST SESSION**H. R. 2900**

IN THE SENATE OF THE UNITED STATES

JULY 16, 2007

Received; read twice and placed on the calendar

AN ACT

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food and Drug Ad-
5 ministration Amendments Act of 2007”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

- Sec. 101. Short title; references in title.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Fees relating to advisory review of prescription-drug television advertising.
- Sec. 105. Reauthorization; reporting requirements.
- Sec. 106. Sunset dates.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

- Sec. 201. Short title; references in title.

Subtitle A—Fees Related to Medical Devices

- Sec. 211. Definitions.
- Sec. 212. Authority to assess and use device fees.
- Sec. 213. Annual reports.
- Sec. 214. Consultation.
- Sec. 215. Additional authorization of appropriations for postmarket safety information.
- Sec. 216. Effective date.
- Sec. 217. Sunset clause.

Subtitle B—Amendments Regarding Regulation of Medical Devices

- Sec. 221. Extension of authority for third party review of premarket notification.
- Sec. 222. Registration.
- Sec. 223. Filing of lists of drugs and devices manufactured, prepared, propagated, and compounded by registrants; statements; accompanying disclosures.
- Sec. 224. Electronic registration and listing.
- Sec. 225. Report by Government Accountability Office.
- Sec. 226. Unique device identification system.
- Sec. 227. Frequency of reporting for certain devices.
- Sec. 228. Inspections by accredited persons.
- Sec. 229. Study of nosocomial infections relating to medical devices.

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

- Sec. 301. Short title.
- Sec. 302. Tracking pediatric device approvals.
- Sec. 303. Modification to humanitarian device exemption.
- Sec. 304. Encouraging pediatric medical device research.
- Sec. 305. Demonstration grants for improving pediatric device availability.
- Sec. 306. Amendments to office of pediatric therapeutics and pediatric advisory committee.
- Sec. 307. Postmarket Studies.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

- Sec. 401. Short title.
- Sec. 402. Reauthorization of Pediatric Research Equity Act.
- Sec. 403. Government Accountability Office report.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

Sec. 501. Short title.

Sec. 502. Reauthorization of Best Pharmaceuticals for Children Act.

TITLE VI—REAGAN-UDALL FOUNDATION

Sec. 601. The Reagan-Udall Foundation for the Food and Drug Administration.

Sec. 602. Office of the Chief Scientist.

Sec. 603. Critical path public-private partnerships.

TITLE VII—CONFLICTS OF INTEREST

Sec. 701. Conflicts of interest.

TITLE VIII—CLINICAL TRIAL DATABASES

Sec. 801. Clinical trial registry database and clinical trial results database.

Sec. 802. Study by Government Accountability Office.

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

Sec. 901. Postmarket studies and clinical trials regarding human drugs; risk evaluation and mitigation strategies.

Sec. 902. Enforcement.

Sec. 903. No effect on withdrawal or suspension of approval.

Sec. 904. Benefit-risk assessments.

Sec. 905. Postmarket risk identification and analysis system for active surveillance and assessment.

Sec. 907. Statement for inclusion in direct-to-consumer advertisements of drugs.

Sec. 908. Clinical trial guidance for antibiotic drugs.

Sec. 909. Prohibition against food to which drugs or biological products have been added.

Sec. 910. Assuring pharmaceutical safety.

Sec. 911. Orphan antibiotic drugs.

Sec. 912. Citizen petitions and petitions for stay of agency action.

Sec. 913. Authorization of appropriations.

Sec. 914. Effective date and applicability.

1 **TITLE I—PRESCRIPTION DRUG** 2 **USER FEE AMENDMENTS OF 2007**

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 ACT.—Except as otherwise spec-
7 ified, amendments made by this title to a section or other
8 provision of law are amendments to such section or other

1 provision of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 301 et seq.).

3 **SEC. 102. DEFINITIONS.**

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

5 (1) in paragraph (1)—

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

8 (B) by striking subparagraph (B); and

9 (C) by redesignating subparagraph (C) as
10 subparagraph (B);

11 (2) in paragraph (3)(C)—

12 (A) by striking “505(j)(7)(A)” and insert-
13 ing “505(j)(7)(A) (not including the discon-
14 tinued section of such list),”; and

15 (B) by inserting before the period “(not in-
16 cluding the discontinued section of such list)”;

17 (3) in paragraph (4), by inserting before the pe-
18 riod at the end the following: “(such as capsules,
19 tablets, or lyophilized products before reconstitu-
20 tion)”;

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

23 “(F) Postmarket safety activities with re-
24 spect to drugs approved under human drug ap-

1 plications or supplements, including the fol-
2 lowing activities:

3 “(i) Collecting, developing, and re-
4 viewing safety information on approved
5 drugs, including adverse event reports.

6 “(ii) Developing and using improved
7 adverse-event data-collection systems, in-
8 cluding information technology systems.

9 “(iii) Developing and using improved
10 analytical tools to assess potential safety
11 problems, including access to external data
12 bases.

13 “(iv) Implementing and enforcing sec-
14 tion 505(o) (relating to postapproval stud-
15 ies and clinical trials and labeling changes)
16 and section 505(p) (relating to risk evalua-
17 tion and mitigation strategies).

18 “(v) Preparing and making publicly
19 available (including on the website of the
20 Food and Drug Administration) a sum-
21 mary analysis of the adverse drug reaction
22 reports received for recently approved
23 drugs, including identification of any new
24 risks not previously identified, potential
25 new risks, or known risks reported in un-

1 usual number not previously identified
2 within 18 months of the drug's initial mar-
3 keting or after exposure of 10,000 individ-
4 uals to the drug, whichever is later.

5 “(vi) Conducting regular, bi-weekly
6 screening of the Adverse Event Reporting
7 System database and developing a report
8 every 15 days on any new safety concerns.

9 “(vii) Ensuring that the reports avail-
10 able to the public under the Adverse Event
11 Reporting System are updated at least
12 every 6 months.

13 “(viii) Reporting to the Congress on—

14 “(I) the recommendations re-
15 ceived in consultations with, and re-
16 ports from, the Office of Surveillance
17 and Epidemiology within the Food
18 and Drug Administration on
19 postmarket safety activities;

20 “(II) a description of the actions
21 taken on those recommendations; and

22 “(III) if no action is taken, or a
23 different action is taken relative to the
24 action recommended by the Office of
25 Surveillance and Epidemiology, an ex-

1 planation of why no action or a dif-
2 ferent action was taken.

3 “(ix) On an annual basis, reviewing
4 the entire backlog of postmarket safety
5 commitments to determine which commit-
6 ments require revision or should be elimi-
7 nated, reporting to the Congress on these
8 determinations, and assigning start dates
9 and estimated completion dates for such
10 commitments.

11 “(x) Developing postmarket safety
12 performance measures, including those list-
13 ed in clauses (v) through (ix), that are as
14 measurable and rigorous as the ones al-
15 ready developed for premarket review.”;

16 (5) in paragraph (8)—

17 (A) by striking “April of the preceding fis-
18 cal year” and inserting “October of the pre-
19 ceding fiscal year”; and

20 (B) by striking “April 1997” and inserting
21 “October 1996”;

22 (6) by redesignating paragraph (9) as para-
23 graph (11); and

24 (7) by inserting after paragraph (8) the fol-
25 lowing paragraphs:

1 “(9) The term ‘person’ includes an affiliate
2 thereof.

3 “(10) The term ‘active’, with respect to a com-
4 mercial investigational new drug application, means
5 such an application to which information was sub-
6 mitted during the relevant period.”.

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 FUSED FOR FILING”; and

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

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

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

1 “(E) FEES FOR APPLICATIONS PRE-
2 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
3 BEFORE FILING.—A human drug application or
4 supplement that was submitted but was refused
5 for filing, or was withdrawn before being ac-
6 cepted or refused for filing, shall be subject to
7 the full fee under subparagraph (A) upon being
8 resubmitted or filed over protest, unless the fee
9 is waived or reduced under subsection (d).”;
10 and

11 (3) in paragraph (2)—

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

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

16 “(C) SPECIAL RULES FOR POSITRON EMIS-
17 SION TOMOGRAPHY DRUGS.—

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

1 application as producing positron emission
2 tomography drugs under the approved ap-
3 plication.

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

13 “(I) the person is a not-for-profit
14 medical center that has only 1 estab-
15 lishment for the production of
16 positron emission tomography drugs;
17 and

18 “(II) at least 95 percent of the
19 total number of doses of each positron
20 emission tomography drug produced
21 by such establishment during such fis-
22 cal year will be used within the med-
23 ical center.

24 “(iii) DEFINITION.—For purposes of
25 this subparagraph, the term ‘positron

1 emission tomography drug’ has the mean-
2 ing given to the term ‘compounded
3 positron emission tomography drug’ in sec-
4 tion 201(ii), except that subparagraph
5 (1)(B) of such section shall not apply.”.

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

8 “(b) FEE REVENUE AMOUNTS.—

9 “(1) IN GENERAL.—For each of the fiscal years
10 2008 through 2012, fees under subsection (a) shall,
11 except as provided in subsections (c), (d), (f), and
12 (g), be established to generate a total revenue
13 amount under such subsection that is equal to the
14 sum of—

15 “(A) \$392,783,000; and

16 “(B) an amount equal to the modified
17 workload adjustment factor for fiscal year 2007
18 (as determined under paragraph (3)).

19 “(2) TYPES OF FEES.—Of the total revenue
20 amount determined for a fiscal year under para-
21 graph (1)—

22 “(A) one-third shall be derived from fees
23 under subsection (a)(1) (relating to human
24 drug applications and supplements);

1 “(B) one-third shall be derived from fees
2 under subsection (a)(2) (relating to prescription
3 drug establishments); and

4 “(C) one-third shall be derived from fees
5 under subsection (a)(3) (relating to prescription
6 drug products).

7 “(3) MODIFIED WORKLOAD ADJUSTMENT FAC-
8 TOR FOR FISCAL YEAR 2007.—For purposes of
9 paragraph (1)(B), the Secretary shall determine the
10 modified workload adjustment factor by determining
11 the dollar amount that results from applying the
12 methodology that was in effect under subsection
13 (c)(2) for fiscal year 2007 to the amount
14 \$354,893,000, except that, with respect to the por-
15 tion of such determination that is based on the
16 change in the total number of commercial investiga-
17 tional new drug applications, the Secretary shall
18 count the number of such applications that were ac-
19 tive during the most recent 12-month period for
20 which data on such submissions is available.

21 “(4) ADDITIONAL FEE REVENUES FOR DRUG
22 SAFETY.—

23 “(A) IN GENERAL.—For each of the fiscal
24 years 2008 through 2012, paragraph (1)(A)
25 shall, subject to subparagraph (C), be applied

1 by substituting the amount determined under
2 subparagraph (B) for ‘\$392,783,000’.

3 “(B) AMOUNT DETERMINED.—For each of
4 the fiscal years 2008 through 2012, the amount
5 determined under this subparagraph is the sum
6 of—

7 “(i) \$392,783,000; plus

8 “(ii) an amount equal to—

9 “(I)(aa) for fiscal year 2008,
10 \$25,000,000;

11 “(bb) for fiscal year 2009,
12 \$35,000,000;

13 “(cc) for fiscal year 2010,
14 \$45,000,000;

15 “(dd) for fiscal year 2011,
16 \$55,000,000; and

17 “(ee) for fiscal year 2012,
18 \$65,000,000; minus

19 “(II) the amount equal to the ex-
20 cess amount in item (bb), provided
21 that—

22 “(aa) the amount of the
23 total appropriation for the Food
24 and Drug Administration for
25 such fiscal year (excluding the

1 amount of fees appropriated for
2 such fiscal year) exceeds the
3 amount of the total appropriation
4 for the Food and Drug Adminis-
5 tration for fiscal year 2007 (ex-
6 cluding the amount of fees appro-
7 priated for such fiscal year), ad-
8 justed as provided under sub-
9 section (c)(1); and

10 “(bb) the amount of the
11 total appropriations for the proc-
12 ess of human drug review at the
13 Food and Drug Administration
14 for such fiscal year (excluding
15 the amount of fees appropriated
16 for such fiscal year) exceeds the
17 amount of appropriations for the
18 process of human drug review at
19 the Food and Drug Administra-
20 tion for fiscal year 2007 (exclud-
21 ing the amount of fees appro-
22 priated for such fiscal year), ad-
23 justed as provided under sub-
24 section (c)(1).

1 In making the adjustment under sub-
 2 clause (II) for any of fiscal years
 3 2008 through 2012, subsection (c)(1)
 4 shall be applied by substituting ‘2007’
 5 for ‘2008’.

6 “(C) LIMITATION.—This paragraph shall
 7 not apply for any fiscal year if the amount de-
 8 scribed under subparagraph (B)(ii) is less than
 9 0.”.

10 (c) ADJUSTMENTS TO FEES.—

11 (1) INFLATION ADJUSTMENT.—Section
 12 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

13 (A) in the matter preceding subparagraph
 14 (A), by striking “The revenues established in
 15 subsection (b)” and inserting “For fiscal year
 16 2009 and subsequent fiscal years, the revenues
 17 established in subsection (b)”;

18 (B) in subparagraph (A), by striking “or”
 19 at the end;

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

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

24 “(C) the average annual change in the
 25 cost, per full-time equivalent position of the

Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.”; and

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

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

(A) in the matter preceding subparagraph (A), by striking “Beginning with fiscal year 2004,” and inserting “For fiscal year 2009 and subsequent fiscal years,”;

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

(i) by striking “human drug applications,” and inserting “human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph),”;

(ii) by striking “commercial investigational new drug applications,”; and

1 (iii) by inserting before the period the
2 following: “, and the change in the total
3 number of active commercial investiga-
4 tional new drug applications (adjusted for
5 changes in review activities, as so de-
6 scribed) during the most recent 12-month
7 period for which data on such submissions
8 is available”;

9 (C) in subparagraph (B), by adding at the
10 end the following: “Any adjustment for changes
11 in review activities made in setting fees and rev-
12 enue amounts for fiscal year 2009 may not re-
13 sult in the total workload adjustment being
14 more than 2 percentage points higher than it
15 would have been in the absence of the adjust-
16 ment for changes in review activities.”; and

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

18 “(C) The Secretary shall contract with an
19 independent accounting firm to study the ad-
20 justment for changes in review activities applied
21 in setting fees and revenue amounts for fiscal
22 year 2009 and to make recommendations, if
23 warranted, for future changes in the method-
24 ology for calculating the adjustment. After re-
25 view of the recommendations, the Secretary

1 shall, if warranted, make appropriate changes
2 to the methodology, and the changes shall be ef-
3 fective for each of the fiscal years 2010 through
4 2012. The Secretary shall not make any adjust-
5 ment for changes in review activities for any
6 fiscal year after 2009 unless such study has
7 been completed.”.

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

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

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

16 “(3) RENT AND RENT-RELATED COST ADJUST-
17 MENT.—For fiscal year 2010 and each subsequent
18 fiscal year, the Secretary shall, before making ad-
19 justments under paragraphs (1) and (2), decrease
20 the fee revenue amount established in subsection (b)
21 if actual costs paid for rent and rent-related ex-
22 penses for the preceding fiscal year are less than es-
23 timates made for such year in fiscal year 2006. Any
24 reduction made under this paragraph shall not ex-
25 ceed the amount by which such costs fall below the

1 estimates made in fiscal year 2006 for such fiscal
2 year, and shall not exceed \$11,721,000 for any fiscal
3 year.”.

4 (4) FINAL YEAR ADJUSTMENT.—Section 736(c)
5 (21 U.S.C. 379h(c)) is amended—

6 (A) in paragraph (4) (as redesignated by
7 paragraph (3)(A))—

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

10 (ii) by striking “paragraphs (1) and
11 (2)” and inserting “paragraphs (1), (2),
12 and (3)”;

13 (iii) by striking “2008” and inserting
14 “2013”; and

15 (B) in paragraph (5) (as so redesignated),
16 by striking “2002” and inserting “2007”.

17 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
18 (21 U.S.C. 379h(d)) is amended—

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

21 (A) by inserting after “The Secretary shall
22 grant” the following: “to a person who is
23 named as the applicant in a human drug appli-
24 cation”; and

1 (B) by inserting “to that person” after
2 “one or more fees assessed”;

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

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

7 “(2) CONSIDERATIONS.—In determining wheth-
8 er to grant a waiver or reduction of a fee under
9 paragraph (1), the Secretary shall consider only the
10 circumstances and assets of the applicant involved
11 and any affiliate of the applicant.”; and

12 (4) in paragraph (4) (as redesignated by para-
13 graph (2)), in subparagraph (A), by inserting before
14 the period the following: “, and that does not have
15 a drug product that has been approved under a
16 human drug application and introduced or delivered
17 for introduction into interstate commerce”.

18 (e) CREDITING AND AVAILABILITY OF FEES.—

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

22 “(3) AUTHORIZATION OF APPROPRIATIONS.—
23 For each of the fiscal years 2008 through 2012,
24 there is authorized to be appropriated for fees under
25 this section an amount equal to the total revenue

1 amount determined under subsection (b) for the fis-
2 cal year, as adjusted or otherwise affected under
3 subsection (c) and paragraph (4) of this sub-
4 section.”.

5 (2) OFFSET.—Section 736(g)(4) (21 U.S.C.
6 379h(g)(4)) is amended to read as follows:

7 “(4) OFFSET.—If the sum of the cumulative
8 amount of fees collected under this section for the
9 fiscal years 2008 through 2010 and the amount of
10 fees estimated to be collected under this section for
11 fiscal year 2011 exceeds the cumulative amount ap-
12 propriated under paragraph (3) for the fiscal years
13 2008 through 2011, the excess shall be credited to
14 the appropriation account of the Food and Drug Ad-
15 ministration as provided in paragraph (1), and shall
16 be subtracted from the amount of fees that would
17 otherwise be authorized to be collected under this
18 section pursuant to appropriation Acts for fiscal
19 year 2012.”.

20 (f) EXEMPTION FOR ORPHAN DRUGS.—Section 736
21 (21 U.S.C. 379h) is further amended by adding at the
22 end the following:

23 “(k) ORPHAN DRUGS.—A drug designated under sec-
24 tion 526 for a rare disease or condition and approved
25 under section 505 or under section 351 of the Public

1 Health Service Act shall be exempt from product and facil-
2 ity fees under this section, provided that the drug meets
3 all of the following:

4 “(1) The drug had United States sales in the
5 previous year of less than \$25,000,000 for the active
6 moiety, for all indications, dosage forms, and
7 strengths for which the drug is approved and for
8 any off-label uses.

9 “(2) The drug meets the public health require-
10 ments contained in this Act as such requirements
11 are applied to requests for waivers for product and
12 facility fees.

13 “(3) The drug is owned or licensed and mar-
14 keted by a company that had less than
15 \$100,000,000 in gross worldwide revenue during the
16 previous year.”.

17 (g) CONFORMING AMENDMENT.—Section 736(a) (21
18 U.S.C. 379h(a)) is amended in paragraphs (1)(A)(i),
19 (1)(A)(ii), (2)(A), and (3)(A) by striking “(c)(4)” each
20 place such term appears and inserting “(c)(5)”.

21 **SEC. 104. FEES RELATING TO ADVISORY REVIEW OF PRE-**
22 **SCRIPTION-DRUG TELEVISION ADVERTISING.**

23 Part 2 of subchapter C of chapter VII (21 U.S.C.
24 379g et seq.) is amended by adding after section 736 the
25 following:

1 **“SEC. 736A. FEES RELATING TO ADVISORY REVIEW OF PRE-**
2 **SCRIPTION-DRUG TELEVISION ADVERTISING.**

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

7 “(1) ADVISORY REVIEW FEE.—

8 “(A) IN GENERAL.—With respect to a pro-
9 posed direct-to-consumer television advertise-
10 ment (referred to in this section as a ‘DTC ad-
11 vertisement’), each person that on or after Oc-
12 tober 1, 2007, submits such an advertisement
13 for advisory review by the Secretary prior to its
14 initial public broadcast (referred to in this sec-
15 tion as ‘prebroadcast advisory review’) shall, ex-
16 cept as provided in subparagraph (B), be sub-
17 ject to a fee established under subsection (c)(3).

18 “(B) EXCEPTION FOR REQUIRED SUBMIS-
19 SIONS.—A DTC advertisement that is required
20 under section 502(n) to be submitted to the
21 Secretary prior to initial public broadcast is not
22 subject to a fee under subparagraph (A) unless
23 the sponsor designates the submission as a sub-
24 mission for prebroadcast advisory review.

25 “(C) NOTICE TO SECRETARY OF NUMBER
26 OF ADVERTISEMENTS.—Not later than June 1

1 of each fiscal year, the Secretary shall publish
2 a notice in the Federal Register requesting any
3 person to notify the Secretary within 30 days of
4 the number of DTC advertisements the person
5 intends to submit for prebroadcast advisory re-
6 view in the next fiscal year.

7 “(D) PAYMENT.—

8 “(i) IN GENERAL.—The fee required
9 by subparagraph (A) (referred to in this
10 section as ‘an advisory review fee’) shall be
11 due not later than October 1 of the fiscal
12 year in which the DTC advertisement in-
13 volved is intended be submitted for
14 prebroadcast advisory review, subject to
15 subparagraph (F)(i).

16 “(ii) EFFECT OF SUBMISSION.—Noti-
17 fication of the Secretary under subpara-
18 graph (C) of the number of DTC adver-
19 tisements a person intends to submit for
20 prebroadcast advisory review is a legally
21 binding commitment by that person to pay
22 the annual advisory review fee for that
23 number of submissions on or before Octo-
24 ber 1 of the fiscal year in which the adver-
25 tisement is intended to be submitted.

1 “(iii) NOTICE REGARDING CARRYOVER
2 SUBMISSIONS.—In making a notification
3 under subparagraph (C), the person in-
4 volved shall in addition notify the Sec-
5 retary if under subparagraph (F)(i) the
6 person intends to submit a DTC advertise-
7 ment for which the advisory review fee has
8 already been paid. If the person does not
9 so notify the Secretary, each DTC adver-
10 tisement submitted by the person for
11 prebroadcast advisory review in the fiscal
12 year involved shall be subject to the advi-
13 sory review fee.

14 “(E) MODIFICATION OF ADVISORY REVIEW
15 FEE.—

16 “(i) LATE PAYMENT.—If a person has
17 submitted a notification under subpara-
18 graph (C) with respect to a fiscal year and
19 has not paid all advisory review fees due
20 under subparagraph (D) on or before No-
21 vember 1 of such fiscal year, the fees are
22 regarded as late and a revised due date
23 and an increase in the amount of fees ap-
24 plies in accordance with this clause, not-
25 withstanding any other provision of this

1 section. For such person, the advisory re-
2 view fee for each DTC advertisement sub-
3 mitted in such fiscal year for prebroadcast
4 advisory review shall be due and payable
5 20 days before the advertisement is sub-
6 mitted to the Secretary, and each such fee
7 shall be revised to be equal to 150 percent
8 of the fee that otherwise would have ap-
9 plied pursuant to subsection (c)(3).

10 “(ii) EXCEEDING IDENTIFIED NUM-
11 BER OF SUBMISSIONS.—If a person sub-
12 mits a number of DTC ads for
13 prebroadcast advisory review in a fiscal
14 year that exceeds the number identified by
15 the person under subparagraph (C), a re-
16 vised due date and an increase in the
17 amount of fees applies under this clause
18 for each submission in excess of such num-
19 ber, notwithstanding any other provision of
20 this section. For each such DTC ad, the
21 advisory review fee shall be due and pay-
22 able 20 days before the advertisement is
23 submitted to the Secretary, and the fee
24 shall be revised to be equal to 150 percent

1 of the fee that otherwise would have ap-
2 plied pursuant to subsection (c)(3).

3 “(F) LIMITS.—

4 “(i) SUBMISSIONS.—For each advi-
5 sory review fee paid by a person for a fis-
6 cal year, the person is entitled to accept-
7 ance for advisory review by the Secretary
8 of one DTC advertisement and acceptance
9 of one resubmission for advisory review of
10 the same advertisement. The advertisement
11 shall be submitted for review in the fiscal
12 year for which the fee was assessed, except
13 that a person may carry over not more
14 than one paid advisory review submission
15 to the next fiscal year. Resubmissions may
16 be submitted without regard to the fiscal
17 year of the initial advisory review submis-
18 sion.

19 “(ii) NO REFUNDS.—Except as pro-
20 vided by subsection (f), fees paid under
21 subparagraph (A) shall not be refunded.

22 “(iii) NO WAIVERS, EXEMPTIONS, OR
23 REDUCTIONS.—The Secretary shall not
24 grant a waiver, exemption, or reduction of
25 any fees due or payable under this section.

1 “(iv) RIGHT TO ADVISORY REVIEW
2 NOT TRANSFERABLE.—The right to an ad-
3 visory review under this paragraph is not
4 transferable, except to a successor in inter-
5 est.

6 “(2) OPERATING RESERVE FEE.—

7 “(A) IN GENERAL.—Each person that on
8 or after October 1, 2007, is assessed an advi-
9 sory review fee under paragraph (1) shall be
10 subject to fee established under subsection
11 (d)(2) referred to in this section as an ‘oper-
12 ating reserve fee’ for the first fiscal year in
13 which an advisory review fee is assessed to such
14 person. The person is not subject to an oper-
15 ating reserve fee for any other fiscal year.

16 “(B) PAYMENT.—Except as provided in
17 subparagraph (C), the operating reserve fee
18 shall be due no later than October 1 of the first
19 fiscal year in which the person is required to
20 pay an advisory review fee under paragraph (1).

21 “(C) LATE NOTICE OF SUBMISSION.—If, in
22 the first fiscal year of a person’s participation
23 in the program under this section, that person
24 submits any DTC advertisements for
25 prebroadcast advisory review that are in excess

1 of the number identified by that person in re-
2 sponse to the Federal Register notice described
3 in subsection (a)(1)(C), that person shall pay
4 an operating reserve fee for each of those advi-
5 sory reviews equal to the advisory review fee for
6 each submission established under paragraph
7 (1)(D)(ii). Fees required by this subparagraph
8 shall be in addition to any fees required by sub-
9 paragraph (A). Fees under this subparagraph
10 shall be due 20 days before any DTC advertise-
11 ment is submitted by such person to the Sec-
12 retary for prebroadcast advisory review.

13 “(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—
14 Fees under subsection (a)(1) shall be established to gen-
15 erate revenue amounts of \$6,250,000 for each of fiscal
16 years 2008 through 2012, as adjusted pursuant to sub-
17 sections (c) and (g)(4).

18 “(c) ADJUSTMENTS.—

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

24 “(A) the total percentage change that oc-
25 curred in the Consumer Price Index for all

1 urban consumers (all items; U.S. city average),
2 for the 12-month period ending June 30 pre-
3 ceding the fiscal year for which fees are being
4 established;

5 “(B) the total percentage change for the
6 previous fiscal year in basic pay under the Gen-
7 eral Schedule in accordance with section 5332
8 of title 5, United States Code, as adjusted by
9 any locality-based comparability payment pur-
10 suant to section 5304 of such title for Federal
11 employees stationed in the District of Columbia;
12 or

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

19 The adjustment made each fiscal year by this sub-
20 section will be added on a compounded basis to the
21 sum of all adjustments made each fiscal year after
22 fiscal year 2008 under this subsection.

23 “(2) WORKLOAD ADJUSTMENT.—Beginning
24 with fiscal year 2009, after the fee revenues estab-
25 lished in subsection (b) are adjusted for a fiscal year

1 for inflation in accordance with paragraph (1), the
2 fee revenues shall be adjusted further for such fiscal
3 year to reflect changes in the workload of the Sec-
4 retary with respect to the submission of DTC adver-
5 tisements for advisory review prior to initial broad-
6 cast. With respect to such adjustment:

7 “(A) The adjustment shall be determined
8 by the Secretary based upon the number of
9 DTC advertisements identified pursuant to sub-
10 section (a)(1)(C) for the upcoming fiscal year,
11 excluding allowable previously paid carry over
12 submissions. The adjustment shall be deter-
13 mined by multiplying the number of such adver-
14 tisements projected for that fiscal year that ex-
15 ceeds 150 by \$27,600 (adjusted each year be-
16 ginning with fiscal year 2009 for inflation in
17 accordance with paragraph (1)). The Secretary
18 shall publish in the Federal Register the fee
19 revenues and fees resulting from the adjust-
20 ment and the supporting methodologies.

21 “(B) Under no circumstances shall the ad-
22 justment result in fee revenues for a fiscal year
23 that are less than the fee revenues established
24 for the prior fiscal year.

1 “(3) ANNUAL FEE SETTING FOR ADVISORY RE-
2 VIEW.—

3 “(A) IN GENERAL.—Not later than August
4 1 of each fiscal year, the Secretary shall estab-
5 lish for the next fiscal year the DTC advertise-
6 ment advisory review fee under subsection
7 (a)(1), based on the revenue amounts estab-
8 lished under subsection (b), the adjustments
9 provided under paragraphs (1) and (2), and the
10 number of DTC advertisements identified pur-
11 suant to subsection (a)(1)(C), excluding allow-
12 able previously-paid carry over submissions.
13 The annual advisory review fee shall be estab-
14 lished by dividing the fee revenue for a fiscal
15 year (as adjusted pursuant to this subsection)
16 by the number of DTC advertisements so iden-
17 tified, excluding allowable previously-paid carry
18 over submissions.

19 “(B) FISCAL YEAR 2008 FEE LIMIT.—Not-
20 withstanding subsection (b) and the adjust-
21 ments pursuant to this subsection, the fee es-
22 tablished under subparagraph (A) for fiscal
23 year 2008 may not be more than \$83,000 per
24 submission for advisory review.

1 “(C) ANNUAL FEE LIMIT.—Notwith-
2 standing subsection (b) and the adjustments
3 pursuant to this subsection, the fee established
4 under subparagraph (A) for a fiscal year after
5 fiscal year 2008 may not be more than 50 per-
6 cent more than the fee established for the prior
7 fiscal year.

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

13 “(d) OPERATING RESERVES.—

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

24 “(2) FEE SETTING.—The Secretary shall estab-
25 lish the operating reserve fee under subsection

1 (a)(2)(A) for each person required to pay the fee by
2 multiplying the number of DTC advertisements iden-
3 tified by that person pursuant to subsection
4 (a)(1)(C) by the advisory review fee established pur-
5 suant to subsection (c)(3) for that fiscal year, except
6 that in no case shall the operating reserve fee as-
7 sessed be less than the operating reserve fee as-
8 sessed if the person had first participated in the pro-
9 gram under this section in fiscal year 2008.

10 “(3) USE OF OPERATING RESERVE.—The Sec-
11 retary may use funds from the reserves only to the
12 extent necessary in any fiscal year to make up the
13 difference between the fee revenue amount estab-
14 lished for that fiscal year under subsections (b) and
15 (c) and the amount of fees actually collected for that
16 fiscal year pursuant to subsection (a)(1), or to pay
17 costs of ending the program under this section if it
18 is terminated pursuant to subsection (f) or not reau-
19 thorized beyond fiscal year 2012.

20 “(4) REFUND OF OPERATING RESERVES.—
21 Within 120 days of the end of fiscal year 2012, or
22 if the program under this section ends early pursu-
23 ant to subsection (f), the Secretary, after setting
24 aside sufficient operating reserve amounts to termi-
25 nate the program under this section, shall refund all

1 amounts remaining in the operating reserve on a pro
2 rata basis to each person that paid an operating re-
3 serve fee assessment. In no event shall the refund to
4 any person exceed the total amount of operating re-
5 serve fees paid by such person pursuant to sub-
6 section (a)(2).

7 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
8 standing any other requirement, a submission for
9 prebroadcast advisory review of a DTC advertisement sub-
10 mitted by a person subject to fees under subsection (a)
11 shall be considered incomplete and shall not be accepted
12 for review by the Secretary until all fees owed by such
13 person under this section have been paid.

14 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
15 GRAM.—

16 “(1) INITIAL FUNDING.—If on November 1,
17 2007, or 120 days after enactment of this provision,
18 whichever is later, the Secretary has not received at
19 least \$11,250,000 in advisory review fees and oper-
20 ating reserve fees combined, the program under this
21 section shall not commence and all collected fees
22 shall be refunded.

23 “(2) LATER FISCAL YEARS.—Beginning in fis-
24 cal year 2009, if, on November 1 of the fiscal year,
25 the combination of the operating reserves, annual fee

1 revenues from that fiscal year, and unobligated fee
2 revenues from prior fiscal years falls below
3 \$9,000,000, adjusted for inflation (as described in
4 subsection (c)(1)), the program under this section
5 shall cease to exist, and the Secretary shall notify all
6 participants, retain any money from the unused ad-
7 visory review fees and the operating reserves needed
8 to close down the program under this section, and
9 refund the remainder of the unused fees and oper-
10 ating reserves. To the extent required to close down
11 the program under this section, the Secretary shall
12 first use unobligated advisory review fee revenues
13 from prior fiscal years, then the operating reserves,
14 and finally, unused advisory review fees from the rel-
15 evant fiscal year.

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

17 “(1) IN GENERAL.—Fees authorized under sub-
18 section (a) of this section shall be collected and
19 available for obligation only to the extent and in the
20 amount provided in advance in appropriations Acts.
21 Such fees are authorized to remain available until
22 expended. Such sums as may be necessary may be
23 transferred from the Food and Drug Administration
24 salaries and expenses appropriation account without
25 fiscal year limitation to such appropriation account

1 for salaries and expenses with such fiscal year limi-
2 tation. The sums transferred shall be available solely
3 for the process for the advisory review of prescrip-
4 tion drug advertising.

5 “(2) COLLECTIONS AND APPROPRIATION
6 ACTS.—

7 “(A) IN GENERAL.—The fees authorized
8 by this section—

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

14 “(ii) shall be available for obligation
15 only if the amounts appropriated as budget
16 authority for such fiscal year are sufficient
17 to support a number of full-time equivalent
18 review employees that is not fewer than the
19 number of such employees supported in fis-
20 cal year 2007.

21 “(B) REVIEW EMPLOYEES.—For purposes
22 of subparagraph (A)(ii), the term ‘full-time
23 equivalent review employees’ means the total
24 combined number of full-time equivalent em-
25 ployees in—

1 “(i) the Center for Drug Evaluation
2 and Research, Division of Drug Marketing,
3 Advertising, and Communications, Food
4 and Drug Administration; and

5 “(ii) the Center for Biologics Evalua-
6 tion and Research, Advertising and Pro-
7 motional Labeling Branch, Food and Drug
8 Administration.

9 “(3) AUTHORIZATION OF APPROPRIATIONS.—

10 For each of the fiscal years 2008 through 2012,
11 there is authorized to be appropriated for fees under
12 this section an amount equal to the total revenue
13 amount determined under subsection (b) for the fis-
14 cal year, as adjusted pursuant to subsection (c) and
15 paragraph (4) of this subsection, plus amounts col-
16 lected for the reserve fund under subsection (d).

17 “(4) OFFSET.—Any amount of fees collected
18 for a fiscal year under this section that exceeds the
19 amount of fees specified in appropriation Acts for
20 such fiscal year shall be credited to the appropria-
21 tion account of the Food and Drug Administration
22 as provided in paragraph (1), and shall be sub-
23 tracted from the amount of fees that would other-
24 wise be collected under this section pursuant to ap-
25 propriation Acts for a subsequent fiscal year.

1 “(h) DEFINITIONS.—For purposes of this sub-
2 chapter:

3 “(1) The term ‘advisory review’ means review-
4 ing and providing advisory comments on a proposed
5 advertisement prior to its initial public broadcast.

6 “(2) The term ‘advisory review fee’ has the
7 meaning indicated for such term in subsection
8 (a)(1)(D).

9 “(3) The term ‘carry over submission’ means a
10 submission for an advisory review for which a fee
11 was paid in one fiscal year that is submitted for re-
12 view in the following fiscal year.

13 “(4) The term ‘direct-to-consumer television ad-
14 vertisement’ means an advertisement for a prescrip-
15 tion drug product as defined in section 735(3) in-
16 tended to be displayed on any television channel for
17 less than 3 minutes.

18 “(5) The term ‘DTC advertisement’ has the
19 meaning indicated for such term in subsection
20 (a)(1)(A).

21 “(6) The term ‘operating reserve fee’ has the
22 meaning indicated for such term in subsection
23 (a)(2)(A).

1 “(7) The term ‘person’ includes an individual,
2 partnership, corporation, and association, and any
3 affiliate thereof or successor in interest.

4 “(8) The term ‘prebroadcast advisory review’
5 has the meaning indicated for such term in sub-
6 section (a)(1)(A).

7 “(9) The term ‘process for the advisory review
8 of prescription drug advertising’ means the activities
9 necessary to review and provide advisory comments
10 on DTC advertisements prior to public broadcast
11 and, to the extent the Secretary has additional staff
12 resources available under the program under this
13 section that are not necessary for the advisory re-
14 view of DTC advertisements, the activities necessary
15 to review and provide advisory comments on other
16 proposed advertisements and promotional material
17 prior to public broadcast.

18 “(10) The term ‘resources allocated for the
19 process for the advisory review of prescription drug
20 advertising’ means the expenses incurred in connec-
21 tion with the process for the advisory review of pre-
22 scription drug advertising for—

23 “(A) officers and employees of the Food
24 and Drug Administration, contractors of the
25 Food and Drug Administration, advisory com-

1 mittees, and costs related to such officers, em-
2 ployees, and committees, and to contracts with
3 such contractors;

4 “(B) management of information, and the
5 acquisition, maintenance, and repair of com-
6 puter resources;

7 “(C) leasing, maintenance, renovation, and
8 repair of facilities and acquisition, maintenance,
9 and repair of fixtures, furniture, scientific
10 equipment, and other necessary materials and
11 supplies;

12 “(D) collection of fees under this section
13 and accounting for resources allocated for the
14 advisory review of prescription drug advertising;
15 and

16 “(E) closing down the program under this
17 section pursuant to subsection (f)(2) if that be-
18 comes necessary.

19 “(11) The term ‘resubmission’ means a subse-
20 quent submission for advisory review of a direct-to-
21 consumer television advertisement that has been re-
22 vised in response to the Secretary’s comments on an
23 original submission. A resubmission may not intro-
24 duce significant new concepts or creative themes into
25 the television advertisement.

1 “(12) The term ‘submission for advisory review’
2 means an original submission of a direct-to-con-
3 sumer television advertisement for which the sponsor
4 voluntarily requests advisory comments before the
5 advertisement is publicly disseminated.”.

6 **SEC. 105. REAUTHORIZATION; REPORTING REQUIREMENTS.**

7 (a) **PERFORMANCE REPORT.**—Beginning with fiscal
8 year 2008, not later than 120 days after the end of each
9 fiscal year for which fees are collected under part 2 of
10 subchapter C of chapter VII of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary
12 of Health and Human Services (referred to in this section
13 as the “Secretary”) shall prepare and submit to the Com-
14 mittee on Energy and Commerce of the House of Rep-
15 resentatives and the Committee on Health, Education,
16 Labor, and Pensions of the Senate a report concerning
17 the progress of the Food and Drug Administration in
18 achieving the goals identified in the letters described in
19 section 502(4) of the Prescription Drug User Fee Amend-
20 ments of 2002 (Subtitle A of title V of Public Law 107–
21 188) during such fiscal year and the future plans of the
22 Food and Drug Administration for meeting the goals.

23 (b) **FISCAL REPORT.**—Beginning with fiscal year
24 2008, not later than 120 days after the end of each fiscal
25 year for which fees are collected under the part described

1 in subsection (a), the Secretary shall prepare and submit
2 to the Committee on Energy and Commerce of the House
3 of Representatives and the Committee on Health, Edu-
4 cation, Labor, and Pensions of the Senate a report on the
5 implementation of the authority for such fees during such
6 fiscal year and the use, by the Food and Drug Administra-
7 tion, of the fees collected for such fiscal year.

8 (c) REAUTHORIZATION.—

9 (1) CONSULTATION.—In developing rec-
10 ommendations to present to the Congress with re-
11 spect to the goals, and plans for meeting the goals,
12 for the process for the review of human drug appli-
13 cations for the first 5 fiscal years after fiscal year
14 2012, and for the reauthorization of this part for
15 such fiscal years, the Secretary shall consult with—

16 (A) the Committee on Energy and Com-
17 merce of the House of Representatives;

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

20 (C) scientific and academic experts;

21 (D) health care professionals;

22 (E) representatives of patient and con-
23 sumer advocacy groups; and

24 (F) the regulated industry.

1 (2) PUBLIC REVIEW OF RECOMMENDATIONS.—

2 After negotiations with the regulated industry and
3 representatives of patient and consumer advocacy
4 groups, the Secretary shall—

5 (A) present the recommendations devel-
6 oped under paragraph (1) to the congressional
7 committees specified in such paragraph;

8 (B) publish such recommendations in the
9 Federal Register;

10 (C) provide for a period of 30 days for the
11 public to provide written comments on such rec-
12 ommendations;

13 (D) hold a meeting at which the public
14 may present its views on such recommenda-
15 tions; and

16 (E) after consideration of such public
17 views and comments, revise such recommenda-
18 tions as necessary.

19 (3) TRANSMITTAL OF RECOMMENDATIONS.—

20 Not later than January 15, 2012, the Secretary
21 shall transmit to Congress the revised recommenda-
22 tions under paragraph (2), a summary of the views
23 and comments received under such paragraph, and
24 any changes made to the recommendations in re-
25 sponse to such views and comments.

1 (4) PUBLIC AVAILABILITY OF MINUTES.—Be-
2 fore presenting the recommendations developed
3 under paragraphs (1) and (2) to the Congress, the
4 Secretary shall make publicly available, on the public
5 website of the Food and Drug Administration, the
6 minutes of all negotiations conducted under para-
7 graph (1) or (2), as applicable, between the Food
8 and Drug Administration and the regulated industry
9 and representatives of patient and consumer advo-
10 cacy groups.

11 **SEC. 106. SUNSET DATES.**

12 The amendments made by sections 102, 103, and 104
13 cease to be effective October 1, 2012.

14 **TITLE II—MEDICAL DEVICE**
15 **USER FEE AMENDMENTS OF 2007**

16 **SEC. 201. SHORT TITLE; REFERENCES IN TITLE.**

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

19 (b) REFERENCES IN ACT.—Except as otherwise spec-
20 ified, amendments made by this title to a section or other
21 provision of law are amendments to such section or other
22 provision of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 301 et seq.).

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

Section 737 (21 U.S.C. 379i) is amended—

(1) in paragraph (4)—

(A) in subparagraph (A), by striking “or an efficacy supplement,” and inserting “an efficacy supplement, or a 30-day notice,”; and

(B) by adding after subparagraph (E) the following:

“(F) The term ‘30-day notice’ means a supplement to an approved premarket application or premarket report under section 515 that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.”;

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (7), (8), (9), and (11), respectively;

(3) by inserting after paragraph (4), as amended by paragraph (1) of this section, the following:

“(5) The term ‘request for classification information’ means a request made under section 513(g) for information respecting the class in which a de-

1 vice has been classified or the requirements applica-
2 ble to a device.

3 “(6) The term ‘annual fee’, with respect to peri-
4 odic reporting concerning a class III device, means
5 the annual fee associated with periodic reports re-
6 quired by a PMA approval order (as described in
7 section 814.82(a)(7) of title 21, Code of Federal
8 Regulations (or any successor regulation)).”;

9 (4) in paragraph (9), as so redesignated—

10 (A) by striking “April of the preceding fis-
11 cal year” and inserting “October of the pre-
12 ceding fiscal year”; and

13 (B) by striking “April 2002” and inserting
14 “October 2001”;

15 (5) by inserting after paragraph (9), as so
16 amended, the following:

17 “(10) The term ‘person’ includes an affiliate
18 thereof.”; and

19 (6) by inserting after paragraph (11), as redес-
20 ignated by paragraph (2) of this section, the fol-
21 lowing:

22 “(12) The term ‘establishment subject to reg-
23 istration’ means an establishment that is required to
24 register with the Secretary under section 510 and is
25 one of the following types of establishments:

1 “(A) MANUFACTURER.—An establishment
 2 that makes by any means any article that is a
 3 device, as defined in section 201(h), including
 4 an establishment that sterilizes or otherwise
 5 makes such article for or on behalf of a speci-
 6 fication developer or any other person.

7 “(B) SINGLE-USE DEVICE REPROC-
 8 ESSOR.—An establishment that performs manu-
 9 facturing operations on a single-use device.

10 “(C) SPECIFICATION DEVELOPER.—An es-
 11 tablishment that develops specifications for a
 12 device that is distributed under the establish-
 13 ment’s name but which performs no manufac-
 14 turing, including an establishment that, in addi-
 15 tion to developing specifications, also arranges
 16 for the manufacturing of devices labeled with
 17 another establishment’s name by a contract
 18 manufacturer.”.

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

20 (a) TYPES OF FEES.—

21 (1) IN GENERAL.—The designation and heading
 22 of paragraph (2) of section 738(a) (21 U.S.C.
 23 379j(a)(2)) are amended to read as follows:

24 “(2) PREMARKET APPLICATION, PREMARKET
 25 REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND

1 ANNUAL FEE FOR PERIODIC REPORTING CON-
2 CERNING A CLASS III DEVICE.—”.

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

5 (A) in clause (iii), by striking “a fee equal
6 to the fee that applies” and inserting “a fee
7 equal to 75 percent of the fee that applies”;

8 (B) in clause (iv), by striking “21.5 per-
9 cent” and inserting “15 percent”;

10 (C) in clause (v), by striking “7.2 percent”
11 and inserting “7 percent”;

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

14 (E) by inserting after clause (v), as
15 amended by this paragraph, the following:

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

19 (F) in clause (viii), as so redesignated, by
20 striking “1.42 percent” and inserting “1.84
21 percent”; and

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

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

4 “(x) For periodic reporting concerning
5 a class III device, the annual fee shall be
6 equal to 3.5 percent of the fee that applies
7 under clause (i).”.

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

10 “(C) PAYMENT.—The fee required by sub-
11 paragraph (A) shall be due upon submission of
12 the premarket application, premarket report,
13 supplement, premarket notification submission,
14 30-day notice, request for classification infor-
15 mation, or periodic reporting concerning a class
16 III device. Applicants submitting portions of
17 applications pursuant to section 515(c)(3) shall
18 pay such fees upon submission of the first por-
19 tion of such applications.”.

20 (4) REFUNDS.—Section 738(a)(2)(D) (21
21 U.S.C. 379j(a)(2)(D)) is amended by adding after
22 clause (iii) the following:

23 “(iv) MODULAR APPLICATIONS WITH-
24 DRAWN BEFORE FIRST ACTION.—The Sec-
25 retary shall refund 75 percent of the appli-

1 cation fee paid for a modular application
 2 submitted under section 515(c)(4) that is
 3 withdrawn before a second module is sub-
 4 mitted and before a first action on the first
 5 module. If the modular application is with-
 6 drawn after a second or subsequent module
 7 is submitted but before any first action,
 8 the Secretary may return a portion of the
 9 fee. The amount of refund, if any, shall be
 10 based on the level of effort already ex-
 11 pended on the review of the modules sub-
 12 mitted.”.

13 (5) ANNUAL ESTABLISHMENT REGISTRATION
 14 FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amend-
 15 ed by adding after paragraph (2) the following:

16 “(3) ANNUAL ESTABLISHMENT REGISTRATION
 17 FEE.—

18 “(A) IN GENERAL.—Except as provided in
 19 subparagraph (B), each establishment subject
 20 to registration shall be subject to a fee for each
 21 initial or annual registration under section 510
 22 beginning with its registration for fiscal year
 23 2008.

24 “(B) EXCEPTION.—No fee shall be re-
 25 quired under subparagraph (A) for an estab-

lishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

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

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

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

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

(c) ANNUAL FEE SETTING.—

1 (1) IN GENERAL.—Section 738(c) (21 U.S.C.
2 379j(c)(1)) is amended—

3 (A) in the subsection heading, by striking
4 “Annual Fee Setting” and inserting “ANNUAL
5 FEE SETTING”; and

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

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

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

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

15 “(2) ADJUSTMENT.—

16 “(A) IN GENERAL.—When setting fees for
17 fiscal year 2010, the Secretary may increase the
18 fee under subsection (a)(3)(A) (applicable to es-
19 tablishments subject to registration) only if the
20 Secretary estimates that the number of estab-
21 lishments submitting fees for fiscal year 2009 is
22 less than 12,250. The percentage increase shall
23 be the percentage by which the estimate of es-
24 tablishments submitting fees in fiscal year 2009
25 is less than 12,750, but in no case may the per-

1 centage increase be more than 8.5 percent over
2 that specified in subsection (b) for fiscal year
3 2010. If the Secretary makes any adjustment to
4 the fee under subsection (a)(3)(A) for fiscal
5 year 2010, then such fee for fiscal years 2011
6 and 2012 shall be adjusted so that such fee for
7 fiscal year 2011 is equal to the adjusted fee for
8 fiscal year 2010 increased by 8.5 percent, and
9 such fee for fiscal year 2012 is equal to the ad-
10 justed fee for fiscal year 2011 increased by 8.5
11 percent.

12 “(B) PUBLICATION.—For any adjustment
13 made under subparagraph (A), the Secretary
14 shall publish in the Federal Register the Sec-
15 retary’s determination to make the adjustment
16 and the rationale for the determination.”; and

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

19 (i) by striking “For fiscal years 2006
20 and 2007, the Secretary” and inserting
21 “The Secretary”; and

22 (ii) by striking “for the first month of
23 fiscal year 2008” and inserting “for the
24 first month of the next fiscal year”.

1 (d) SMALL BUSINESSES; FEE WAIVER AND FEE RE-
 2 Duction REGARDING PREMARKET APPROVAL.—

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

5 (A) by striking “, partners, and parent
 6 firms”; and

7 (B) by striking “clauses (i) through (vi) of
 8 subsection (a)(2)(A)” and inserting “clauses (i)
 9 through (v) and clauses (vii), (ix), and (x) of
 10 subsection (a)(2)(A)”.

11 (2) RULES RELATING TO PREMARKET AP-
 12 PROVAL FEES.—

13 (A) DEFINITION.—Section 738(d)(2)(A)
 14 (21 U.S.C. 379j(d)(2)(A)) is amended by strik-
 15 ing “, partners, and parent firms”.

16 (B) EVIDENCE OF QUALIFICATION.—Sec-
 17 tion 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is
 18 amended—

19 (i) by striking “(B) EVIDENCE OF
 20 QUALIFICATION.—An applicant” and in-
 21 serting the following:

22 “(B) EVIDENCE OF QUALIFICATION.—

23 “(i) IN GENERAL.—An applicant”;

1 (ii) by striking “The applicant shall
2 support its claim” and inserting the fol-
3 lowing:

4 “(ii) FIRMS SUBMITTING TAX RE-
5 TURNS TO THE UNITED STATES INTERNAL
6 REVENUE SERVICE.—The applicant shall
7 support its claim”;

8 (iii) by striking “, partners, and par-
9 ent firms” each place it appears;

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

14 (v) by adding at the end the following:

15 “(iii) FIRMS NOT SUBMITTING TAX
16 RETURNS TO THE UNITED STATES INTER-
17 NAL REVENUE SERVICE.—In the case of an
18 applicant that has not previously submitted
19 a Federal income tax return, the applicant
20 and each of its affiliates shall demonstrate
21 that it meets the definition under subpara-
22 graph (A) by submission of a signed cer-
23 tification, in such form as the Secretary
24 may direct through a notice published in
25 the Federal Register, that the applicant or

1 affiliate meets the criteria for a small busi-
2 ness and a certification, in English, from
3 the national taxing authority of the coun-
4 try in which the applicant or, if applicable,
5 affiliate is headquartered. The certification
6 from such taxing authority shall bear the
7 official seal of such taxing authority and
8 shall provide the applicant's or affiliate's
9 gross receipts and sales for the most recent
10 year in both the local currency of such
11 country and in United States dollars, the
12 exchange rate used in converting such local
13 currency to dollars, and the dates during
14 which these receipts and sales were col-
15 lected. The applicant shall also submit a
16 statement signed by the head of the appli-
17 cant's firm or by its chief financial officer
18 that the applicant has submitted certifi-
19 cations for all of its affiliates, or that the
20 applicant has no affiliates."

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

23 "(C) REDUCED FEES.—Where the Sec-
24 retary finds that the applicant involved meets
25 the definition under subparagraph (A), the fees

established under subsection (c)(1) may be paid
at a reduced rate of—

“(i) 25 percent of the fee established
under such subsection for a premarket ap-
plication, a premarket report, a supple-
ment (other than a 30-day notice), or peri-
odic reporting concerning a class III de-
vice; and

“(ii) 50 percent of the fee established
under such subsection for a 30-day notice
or a request for classification informa-
tion.”.

(e) SMALL BUSINESSES; FEE REDUCTION REGARD-
ING PREMARKET NOTIFICATION SUBMISSIONS.—

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

(A) by striking “2004” and inserting
“2008”; and

(B) by striking “(a)(2)(A)(vii)” and insert-
ing “(a)(2)(A)(viii)”.

(2) RULES RELATING TO PREMARKET NOTIFI-
CATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A)
(21 U.S.C. 379j(e)(2)(A)) is amended by strik-
ing “, partners, and parent firms”.

1 (B) EVIDENCE OF QUALIFICATION.—Sec-
2 tion 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(A)) is
3 amended—

4 (i) by striking “(B) EVIDENCE OF
5 QUALIFICATION.—An applicant” and in-
6 serting the following:

7 “(B) EVIDENCE OF QUALIFICATION.—

8 “(i) IN GENERAL.—An applicant”;

9 (ii) by striking “The applicant shall
10 support its claim” and inserting the fol-
11 lowing:

12 “(ii) FIRMS SUBMITTING TAX RE-
13 TURNS TO THE UNITED STATES INTERNAL
14 REVENUE SERVICE.—The applicant shall
15 support its claim”;

16 (iii) by striking “, partners, and par-
17 ent firms” each place it appears;

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

22 (v) by adding at the end the following:

23 “(iii) FIRMS NOT SUBMITTING TAX
24 RETURNS TO THE UNITED STATES INTER-
25 NAL REVENUE SERVICE.—In the case of an

1 applicant that has not previously submitted
2 a Federal income tax return, the applicant
3 and each of its affiliates shall demonstrate
4 that it meets the definition under subpara-
5 graph (A) by submission of a signed cer-
6 tification, in such form as the Secretary
7 may direct through a notice published in
8 the Federal Register, that the applicant or
9 affiliate meets the criteria for a small busi-
10 ness and a certification, in English, from
11 the national taxing authority of the coun-
12 try in which the applicant or, if applicable,
13 affiliate is headquartered. The certification
14 from such taxing authority shall bear the
15 official seal of such taxing authority and
16 shall provide the applicant's or affiliate's
17 gross receipts and sales for the most recent
18 year in both the local currency of such
19 country and in United States dollars, the
20 exchange rate used in converting such local
21 currency to dollars, and the dates during
22 which these receipts and sales were col-
23 lected. The applicant shall also submit a
24 statement signed by the head of the appli-
25 cant's firm or by its chief financial officer

1 that the applicant has submitted certifi-
2 cations for all of its affiliates, or that the
3 applicant has no affiliates.”.

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

6 “(C) REDUCED FEES.—For fiscal year
7 2008 and each subsequent fiscal year, where
8 the Secretary finds that the applicant involved
9 meets the definition under subparagraph (A),
10 the fee for a premarket notification submission
11 may be paid at 50 percent of the fee that ap-
12 plies under subsection (a)(2)(A)(viii), and as es-
13 tablished under subsection (c)(1).”.

14 (f) EFFECT OF FAILURE TO PAY FEES.—Section
15 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

16 “(f) EFFECT OF FAILURE TO PAY FEES.—

17 “(1) NO ACCEPTANCE OF SUBMISSIONS.—A
18 premarket application, premarket report, supple-
19 ment, premarket notification submission, 30-day no-
20 tice, request for classification information, or peri-
21 odic reporting concerning a class III device sub-
22 mitted by a person subject to fees under subsection
23 (a)(2) and (a)(3) shall be considered incomplete and
24 shall not be accepted by the Secretary until all fees
25 owed by such person have been paid.

1 “(2) NO REGISTRATION.—Registration informa-
2 tion submitted under section 510 by an establish-
3 ment subject to registration shall be considered in-
4 complete and shall not be accepted by the Secretary
5 until the registration fee under subsection (a)(3)
6 owed for the establishment has been paid. Until the
7 fee is paid and the registration is complete, the es-
8 tablishment is deemed to have failed to register in
9 accordance with section 510.”.

10 (g) CONDITIONS.—Section 738(g) (21 U.S.C.
11 379j(g)) is amended—

12 (1) in paragraph (1)(D)—

13 (A) in the matter preceding clause (i), by
14 striking “For fiscal year 2007” and inserting
15 “For fiscal year 2007 and for each subsequent
16 year”;

17 (B) in clause (i), by striking “applicable to
18 fiscal year 2007” and inserting “applicable to
19 such fiscal year”; and

20 (C) in clause (ii)—

21 (i) by striking “subparagraph (C)”
22 and inserting “this subparagraph”; and

23 (ii) by striking “for fiscal year 2006”
24 and inserting “for the previous fiscal
25 year”; and

1 (2) by amending paragraph (2) to read as fol-
2 lows:

3 “(2) AUTHORITY.—If the Secretary does not
4 assess fees under subsection (a) during any portion
5 of a fiscal year because of subparagraph (C) or (D)
6 of paragraph (1) and if at a later date in such fiscal
7 year the Secretary may assess such fees, the Sec-
8 retary may assess and collect such fees, without any
9 modification in the rate for premarket applications,
10 supplements, premarket reports, premarket notifica-
11 tion submissions, 30-day notices, requests for classi-
12 fication information, periodic reporting concerning a
13 class III device, and establishment registrations at
14 any time in such fiscal year, notwithstanding the
15 provisions of subsection (a) relating to the date fees
16 are to be paid.”.

17 (h) CREDITING AND AVAILABILITY OF FEES.—

18 (1) AUTHORIZATION OF APPROPRIATIONS.—
19 Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amend-
20 ed to read as follows:

21 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—
22 There are authorized to be appropriated for fees
23 under this section—

24 “(A) \$48,431,000 for fiscal year 2008;

25 “(B) \$52,547,000 for fiscal year 2009;

1 “(C) \$57,014,000 for fiscal year 2010;
2 “(D) \$61,860,000 for fiscal year 2011;
3 and
4 “(E) \$67,118,000 for fiscal year 2012.”.

5 (2) OFFSET.—Section 738(h)(4) (21 U.S.C.
6 379j(h)(3)) is amended to read as follows:

7 “(4) OFFSET.—If the cumulative amount of
8 fees collected during fiscal years 2008, 2009, and
9 2010, added to the amount estimated to be collected
10 for fiscal year 2011, which estimate shall be based
11 upon the amount of fees received by the Secretary
12 through June 30, 2011, exceeds the amount of fees
13 specified in aggregate in paragraph (3) for these
14 four fiscal years, the aggregate amount in excess
15 shall be credited to the appropriation account of the
16 Food and Drug Administration as provided in para-
17 graph (1), and shall be subtracted from the amount
18 of fees that would otherwise be authorized to be col-
19 lected under this section pursuant to appropriation
20 Acts for fiscal year 2012.”.

21 **SEC. 213. ANNUAL REPORTS.**

22 Beginning with fiscal year 2008, the Secretary shall
23 prepare and submit to the Committee on Energy and
24 Commerce of the House of Representatives and the Com-

1 mittee on Health, Education, Labor, and Pensions of the
2 Senate a report concerning—

3 (1) the progress of the Food and Drug Admin-
4 istration in achieving the goals identified in the let-
5 ters from the Secretary of Health and Human Serv-
6 ices to the Committee on Energy and Commerce of
7 the House of Representatives and the Committee on
8 Health, Education, Labor, and Pensions of the Sen-
9 ate, as set forth in the Congressional Record during
10 such fiscal year, and the future plans of the Food
11 and Drug Administration for meeting the goals, not
12 later than 60 days after the end of each fiscal year
13 during which fees are collected under part 3 of chap-
14 ter VII of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 379i et seq.); and

16 (2) the implementation of the authority for
17 such fees during such fiscal year, and the use, by
18 the Food and Drug Administration, of the fees col-
19 lected during such fiscal year (including a descrip-
20 tion of the use of such fees for postmarket safety ac-
21 tivities), not later than 120 days after the end of
22 each fiscal year during which fees are collected
23 under the medical device user-fee program reauthor-
24 ized by this title.

1 **SEC. 214. CONSULTATION.**

2 (a) IN GENERAL.—In developing recommendations to
3 the Congress for the goals and plans for meeting the goals
4 for the process for the review of medical device applica-
5 tions for fiscal years after fiscal year 2012, and for the
6 reauthorization of sections 737 and 738 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379i, 379j),
8 the Secretary of Health and Human Services (referred to
9 in this section as the “Secretary”) shall consult with the
10 Committee on Energy and Commerce of the House of
11 Representatives, the Committee on Health, Education,
12 Labor, and Pensions of the Senate, appropriate scientific
13 and academic experts, health care professionals, represent-
14 atives of patient and consumer advocacy groups, and the
15 regulated industry.

16 (b) RECOMMENDATIONS.—The Secretary shall pub-
17 lish in the Federal Register recommendations under sub-
18 section (a), after negotiations with the regulated industry
19 and patient and consumer advocacy groups; shall present
20 such recommendations to the congressional committees
21 specified in such subsection; shall hold a meeting at which
22 the public may present its views on such recommenda-
23 tions; and shall provide for a period of 30 days for the
24 public to provide written comments on such recommenda-
25 tions.

1 **SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIA-**
2 **TIONS FOR POSTMARKET SAFETY INFORMA-**
3 **TION.**

4 For the purpose of collecting, developing, reviewing,
5 and evaluating postmarket safety information on medical
6 devices, there are authorized to be appropriated to the
7 Food and Drug Administration, in addition to the
8 amounts authorized by other provisions of law for such
9 purpose, \$7,100,000 for fiscal year 2008, and for each of
10 the fiscal years 2009 through 2012, \$7,100,000 increased
11 by the amount necessary to offset the effects of inflation
12 occurring after October 1, 2007.

13 **SEC. 216. EFFECTIVE DATE.**

14 The amendments made by this title shall take effect
15 on the date of the enactment of this title, except that fees
16 shall be assessed for all premarket applications, premarket
17 reports, supplements, and premarket notification submis-
18 sions received on or after October 1, 2007, regardless of
19 the date of enactment.

20 **SEC. 217. SUNSET CLAUSE.**

21 The amendments made by this title cease to be effec-
22 tive October 1, 2012, except that section 213 (regarding
23 annual reports) ceases to be effective January 31, 2013.

1 **Subtitle B—Amendments Regarding**
2 **Regulation of Medical De-**
3 **vices**

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

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

8 **SEC. 222. REGISTRATION.**

9 (a) ANNUAL REGISTRATION OF PRODUCERS OF
10 DRUGS AND DEVICES.—Section 510(b) (21 U.S.C.
11 360(b)) is amended—

12 (1) by striking “On or before” and inserting

13 “(1) On or before”;

14 (2) by striking “or a device or devices”; and

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

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

23 (b) REGISTRATION OF FOREIGN ESTABLISH-
24 MENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is
25 amended by striking “On or before December 31” and all

1 that follows and inserting the following: “Any establish-
2 ment within any foreign country engaged in the manufac-
3 ture, preparation, propagation, compounding, or proc-
4 essing of a drug or device that is imported or offered for
5 import into the United States shall, through electronic
6 means in accordance with the criteria of the Secretary—

7 “(A) upon first engaging in any such activity,
8 immediately register with the Secretary the name
9 and place of business of the establishment, the name
10 of the United States agent for the establishment, the
11 name of each importer of such drug or device in the
12 United States that is known to the establishment,
13 and the name of each person who imports or offers
14 for import such drug or device to the United States
15 for purposes of importation; and

16 “(B) each establishment subject to the require-
17 ments of subparagraph (A) shall thereafter—

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

21 “(ii) with respect to devices, register with
22 the Secretary during the period beginning on
23 October 1 and ending on December 31 of each
24 year.”.

1 **SEC. 223. FILING OF LISTS OF DRUGS AND DEVICES MANU-**
2 **FACTURED, PREPARED, PROPAGATED, AND**
3 **COMPOUNDED BY REGISTRANTS; STATE-**
4 **MENTS; ACCOMPANYING DISCLOSURES.**

5 Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended,
6 in the matter preceding subparagraph (A), by striking
7 “Each person” and all that follows through “the following
8 information:” and inserting “Each person who registers
9 with the Secretary under this section shall report to the
10 Secretary, with regard to drugs once during the month
11 of June of each year and once during the month of Decem-
12 ber of each year, and with regard to devices once each
13 year during the period beginning on October 1 and ending
14 on December 31, the following information:”.

15 **SEC. 224. ELECTRONIC REGISTRATION AND LISTING.**

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

18 “(p)(1) Registrations and listings under this section
19 (including the submission of updated information) shall be
20 submitted to the Secretary by electronic means unless the
21 Secretary grants a request for waiver of such requirement
22 because use of electronic means is not reasonable for the
23 person requesting such waiver.

24 “(2) With regard to any establishment engaged in the
25 manufacture, preparation, propagation, compounding, or
26 processing of a device, the registration and listing infor-

1 mation required by this section shall be submitted to the
2 Secretary by electronic means, unless the Secretary grants
3 a waiver because electronic registration and listing is not
4 reasonable for the person requesting such waiver.”.

5 **SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OF-**
6 **FICE.**

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

13 (b) CONSIDERATION.—In determining the effective-
14 ness of the premarket notification and classification au-
15 thority under section 510(k) and subsections (f) and (i)
16 of section 513, the study under subsection (a) shall con-
17 sider the Secretary’s evaluation of the respective intended
18 uses and technologies of such devices, including the effec-
19 tiveness of the Secretary’s comparative assessment of
20 technological characteristics such as device materials,
21 principles of operations, and power sources.

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

1 **SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.**

2 Section 519 (21 U.S.C. 360i) is amended—

3 (1) by redesignating subsection (f) as sub-
4 section (g); and

5 (2) by inserting after subsection (e) the fol-
6 lowing:

7 “Unique Device Identification System

8 “(f) The Secretary shall promulgate regulations es-
9 tablishing a unique device identification system for med-
10 ical devices requiring the labeling of devices to bear a
11 unique identifier.”.

12 **SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DE-**
13 **VICES.**

14 Subparagraph (B) of section 519(a)(1) (21 U.S.C.
15 360i(a)(1)) is amended by striking “were to recur;” and
16 inserting the following: “were to recur, which report under
17 this subparagraph—

18 “(i) shall be submitted in accordance
19 with part 803 of title 21, Code of Federal
20 Regulations (or successor regulations), if
21 the device involved is—

22 “(I) a class III device;

23 “(II) a class II device that is per-
24 manently implantable, is life sup-
25 porting, or is life sustaining; or

1 “(III) a type of device that the
2 Secretary has by regulation deter-
3 mined should be subject to such part
4 803 in order to protect the public
5 health; or

6 “(ii) shall, if the device is not subject
7 to clause (i), be submitted in accordance
8 with criteria established by the Secretary
9 for reports made pursuant to this clause,
10 which criteria shall require the reports to
11 be in summary form and made on a quar-
12 terly basis;”.

13 **SEC. 228. INSPECTIONS BY ACCREDITED PERSONS.**

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

15 (1) in paragraph (1), by striking “Not later
16 than one year after the date of the enactment of this
17 subsection, the Secretary” and inserting “The Sec-
18 retary”;

19 (2) in paragraph (2), by—

20 (A) striking “Not later than 180 days
21 after the date of enactment of this subsection,
22 the Secretary” and inserting “The Secretary”;
23 and

24 (B) striking the fifth sentence;

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

3 “(F) Such person shall notify the Secretary of
4 any withdrawal, suspension, restriction, or expiration
5 of certificate of conformance with the quality sys-
6 tems standard referred to in paragraph (7) for any
7 device establishment that such person inspects under
8 this subsection not later than 30 days after such
9 withdrawal, suspension, restriction, or expiration.

10 “(G) Such person may conduct audits to estab-
11 lish conformance with the quality systems standard
12 referred to in paragraph (7).”;

13 (4) by amending paragraph (6) to read as fol-
14 lows:

15 “(6)(A) Subject to subparagraphs (B) and (C), a de-
16 vice establishment is eligible for inspection by persons ac-
17 credited under paragraph (2) if the following conditions
18 are met:

19 “(i) The Secretary classified the results of the
20 most recent inspection of the establishment as ‘no
21 action indicated’ or ‘voluntary action indicated’.

22 “(ii) With respect to inspections of the estab-
23 lishment to be conducted by an accredited person,
24 the owner or operator of the establishment submits
25 to the Secretary a notice that—

1 “(I) provides the date of the last inspection
2 of the establishment by the Secretary and the
3 classification of that inspection;

4 “(II) states the intention of the owner or
5 operator to use an accredited person to conduct
6 inspections of the establishment;

7 “(III) identifies the particular accredited
8 person the owner or operator intends to select
9 to conduct such inspections; and

10 “(IV) includes a certification that, with re-
11 spect to the devices that are manufactured, pre-
12 pared, propagated, compounded, or processed in
13 the establishment—

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

16 “(bb) at least 1 of such devices is
17 marketed, or is intended to be marketed,
18 in 1 or more foreign countries, 1 of which
19 countries certifies, accredits, or otherwise
20 recognizes the person accredited under
21 paragraph (2) and identified under sub-
22 clause (III) as a person authorized to con-
23 duct inspections of device establishments.

24 “(B)(i) Except with respect to the requirement of
25 subparagraph (A)(i), a device establishment is deemed to

1 have clearance to participate in the program and to use
2 the accredited person identified in the notice under sub-
3 paragraph (A)(ii) for inspections of the establishment un-
4 less the Secretary, not later than 30 days after receiving
5 such notice, issues a response that—

6 “(I) denies clearance to participate as provided
7 under subparagraph (C); or

8 “(II) makes a request under clause (ii).

9 “(ii) The Secretary may request from the owner or
10 operator of a device establishment in response to the no-
11 tice under subparagraph (a)(ii) with respect to the estab-
12 lishment, or from the particular accredited person identi-
13 fied in such notice—

14 “(I) compliance data for the establishment in
15 accordance with clause (iii)(I); or

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

20 The owner or operator of the establishment, or such ac-
21 credited person, as the case may be, shall respond to such
22 a request not later than 60 days after receiving such re-
23 quest.

24 “(iii)(I) The compliance data to be submitted by the
25 owner or operation of a device establishment in response

1 to a request under clause (ii)(I) are data describing wheth-
2 er the quality controls of the establishment have been suf-
3 ficient for ensuring consistent compliance with current
4 good manufacturing practice within the meaning of section
5 501(h) and with other applicable provisions of this Act.
6 Such data shall include complete reports of inspectional
7 findings regarding good manufacturing practice or other
8 quality control audits that, during the preceding 2-year
9 period, were conducted at the establishment by persons
10 other than the owner or operator of the establishment, to-
11 gether with all other compliance data the Secretary deems
12 necessary. Data under the preceding sentence shall dem-
13 onstrate to the Secretary whether the establishment has
14 facilitated consistent compliance by promptly correcting
15 any compliance problems identified in such inspections.

16 “(II) A request to an accredited person under clause
17 (ii)(II) may not seek any information that is not required
18 to be maintained by such person in records under sub-
19 section (f)(1).

20 “(iv) A device establishment is deemed to have clear-
21 ance to participate in the program and to use the accred-
22 ited person identified in the notice under subparagraph
23 (A)(ii) for inspections of the establishment unless the Sec-
24 retary, not later than 60 days after receiving the informa-
25 tion requested under clause (ii), issues a response that de-

1 nies clearance to participate as provided under subpara-
2 graph (C).

3 “(C)(i) The Secretary may deny clearance to a device
4 establishment if the Secretary has evidence that the cer-
5 tification under subparagraph (A)(ii)(IV) is untrue and
6 the Secretary provides to the owner or operator of the es-
7 tablishment a statement summarizing such evidence.

8 “(ii) The Secretary may deny clearance to a device
9 establishment if the Secretary determines that the estab-
10 lishment has failed to demonstrate consistent compliance
11 for purposes of subparagraph (B)(iii)(I) and the Secretary
12 provides to the owner or operator of the establishment a
13 statement of the reasons for such determination.

14 “(iii)(I) The Secretary may reject the selection of the
15 accredited person identified in the notice under subpara-
16 graph (A)(ii) if the Secretary provides to the owner or op-
17 erator of the establishment a statement of the reasons for
18 such rejection. Reasons for the rejection may include that
19 the establishment or the accredited person, as the case
20 may be, has failed to fully respond to the request, or that
21 the Secretary has concerns regarding the relationship be-
22 tween the establishment and such accredited person.

23 “(II) If the Secretary rejects the selection of an ac-
24 credited person by the owner or operator of a device estab-
25 lishment, the owner or operator may make an additional

1 selection of an accredited person by submitting to the Sec-
2 retary a notice that identifies the additional selection.
3 Clauses (i) and (ii) of subparagraph (B), and subclause
4 (I) of this clause, apply to the selection of an accredited
5 person through a notice under the preceding sentence in
6 the same manner and to the same extent as such provi-
7 sions apply to a selection of an accredited person through
8 a notice under subparagraph (A)(ii).

9 “(iv) In the case of a device establishment that is de-
10 nied clearance under clause (i) or (ii) or with respect to
11 which the selection of the accredited person is rejected
12 under clause (iii), the Secretary shall designate a person
13 to review the statement of reasons, or statement summa-
14 rizing such evidence, as the case may be, of the Secretary
15 under such clause if, during the 30-day period beginning
16 on the date on which the owner or operator of the estab-
17 lishment receives such statement, the owner or operator
18 requests the review. The review shall commence not later
19 than 30 days after the owner or operator requests the re-
20 view, unless the Secretary and the owner or operator oth-
21 erwise agree.”;

22 (5) in paragraph (7)—

23 (A) in subparagraph (A), by striking “(A)
24 Persons” and all that follows through the end
25 and inserting the following: “(A) Persons ac-

1 credited under paragraph (2) to conduct inspec-
2 tions shall record in writing their inspection ob-
3 servations and shall present the observations to
4 the device establishment's designated represent-
5 ative and describe each observation. Addition-
6 ally, such accredited person shall prepare an in-
7 spection report in a form and manner des-
8 igned by the Secretary to conduct inspections,
9 taking into consideration the goals of inter-
10 national harmonization of quality systems
11 standards. Any official classification of the in-
12 spection shall be determined by the Secretary.”;
13 and

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

15 “(F) For the purpose of setting risk-based
16 inspectional priorities, the Secretary shall accept voluntary
17 submissions of reports of audits assessing conformance
18 with appropriate quality systems standards set by the
19 International Organization for Standardization (ISO) and
20 identified by the Secretary in public notice. If the owner
21 or operator of an establishment elects to submit audit re-
22 ports under this subparagraph, the owner or operator shall
23 submit all such audit reports with respect to the establish-
24 ment during the preceding 2-year periods.”; and

1 (6) in paragraph (10)(C)(iii), by striking
2 “based” and inserting “base”.

3 **SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING**
4 **TO MEDICAL DEVICES.**

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

7 (1) the number of nosocomial infections attrib-
8 utable to new and reused medical devices; and

9 (2) the causes of such nosocomial infections, in-
10 cluding the following:

11 (A) Reprocessed single use devices.

12 (B) Handling of sterilized medical devices.

13 (C) In-hospital sterilization of medical de-
14 vices.

15 (D) Health care professionals’ practices for
16 patient examination and treatment.

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

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

21 (G) Other causes.

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

1 (c) DEFINITION.—In this section, the term
2 “nosocomial infection” means an infection that is acquired
3 while an individual is a patient at a hospital and was nei-
4 ther present nor incubating in the patient prior to receiv-
5 ing services in the hospital.

6 **TITLE III—PEDIATRIC MEDICAL**
7 **DEVICE SAFETY AND IM-**
8 **PROVEMENT ACT OF 2007**

9 **SEC. 301. SHORT TITLE.**

10 This title may be cited as the “Pediatric Medical De-
11 vice Safety and Improvement Act of 2007”.

12 **SEC. 302. TRACKING PEDIATRIC DEVICE APPROVALS.**

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

16 **“SEC. 515A. PEDIATRIC USES OF DEVICES.**

17 “(a) NEW DEVICES.—

18 “(1) IN GENERAL.—A person that submits to
19 the Secretary an application under section 520(m),
20 or an application (or supplement to an application)
21 or a product development protocol under section
22 515, shall include in the application or protocol the
23 information described in paragraph (2).

24 “(2) REQUIRED INFORMATION.—The applica-
25 tion or protocol described in paragraph (1) shall in-

1 clude, with respect to the device for which approval
2 is sought and if readily available—

3 “(A) a description of any pediatric sub-
4 populations that suffer from the disease or con-
5 dition that the device is intended to treat, diag-
6 nose, or cure; and

7 “(B) the number of affected pediatric pa-
8 tients.

9 “(3) ANNUAL REPORT.—Not later than 18
10 months after the date of enactment of this section,
11 and annually thereafter, the Secretary shall submit
12 to the Committee on Health, Education, Labor, and
13 Pensions of the Senate and the Committee on En-
14 ergy and Commerce of the House of Representatives
15 a report that includes—

16 “(A) the number of devices approved in the
17 year preceding the year in which the report is
18 submitted, for which there is a pediatric sub-
19 population that suffers from the disease or con-
20 dition that the device is intended to treat, diag-
21 nose, or cure;

22 “(B) the number of devices approved in
23 the year preceding the year in which the report
24 is submitted, labeled for use in pediatric pa-
25 tients;

1 “(C) the number of pediatric devices ap-
2 proved in the year preceding the year in which
3 the report is submitted, exempted from a fee
4 pursuant to section 738(a)(2)(B)(v); and

5 “(D) the review time for each device de-
6 scribed in subparagraphs (A), (B), and (C).

7 “(b) DETERMINATION OF PEDIATRIC EFFECTIVE-
8 NESS BASED ON SIMILAR COURSE OF DISEASE OR CONDI-
9 TION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

10 “(1) IN GENERAL.—If the course of the disease
11 or condition and the effects of the device are suffi-
12 ciently similar in adults and pediatric patients, the
13 Secretary may conclude that adult data may be used
14 to support a determination of a reasonable assur-
15 ance of effectiveness in pediatric populations, as ap-
16 propriate.

17 “(2) EXTRAPOLATION BETWEEN SUBPOPULA-
18 TIONS.—A study may not be needed in each pedi-
19 atric subpopulation if data from one subpopulation
20 can be extrapolated to another subpopulation.

21 “(c) PEDIATRIC SUBPOPULATION.—For purposes of
22 this section, the term ‘pediatric subpopulation’ has the
23 meaning given the term in section 520(m)(6)(E)(ii).”.

1 **SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EX-**
2 **EMPTION.**

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

6 (1) in paragraph (3), by striking “No” and in-
7 serting “Except as provided in paragraph (6), no”;

8 (2) in paragraph (5)—

9 (A) by inserting “, if the Secretary has
10 reason to believe that the requirements of para-
11 graph (6) are no longer met,” after “public
12 health”; and

13 (B) by adding at the end the following: “If
14 the person granted an exemption under para-
15 graph (2) fails to demonstrate continued com-
16 pliance with the requirements of this sub-
17 section, the Secretary may suspend or withdraw
18 the exemption from the effectiveness require-
19 ments of sections 514 and 515 for a humani-
20 tarian device only after providing notice and an
21 opportunity for an informal hearing.”; and

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

24 “(6)(A) Except as provided in subparagraph (D), the
25 prohibition in paragraph (3) shall not apply with respect

1 to a person granted an exemption under paragraph (2)
2 if each of the following conditions apply:

3 “(i)(I) The device with respect to which the ex-
4 emption is granted is intended for the treatment or
5 diagnosis of a disease or condition that occurs in pe-
6 diatric patients or in a pediatric subpopulation, and
7 such device is labeled for use in pediatric patients or
8 in a pediatric subpopulation in which the disease or
9 condition occurs.

10 “(II) The device was not previously approved
11 under this subsection for the pediatric patients or
12 the pediatric subpopulation described in subclause
13 (I) prior to the date of enactment of the Pediatric
14 Medical Device Safety and Improvement Act of
15 2007.

16 “(ii) During any calendar year, the number of
17 such devices distributed during that year does not
18 exceed the annual distribution number specified by
19 the Secretary when the Secretary grants such ex-
20 emption. The annual distribution number shall be
21 based on the number of individuals affected by the
22 disease or condition that such device is intended to
23 treat, diagnose, or cure, and of that number, the
24 number of individuals likely to use the device, and
25 the number of devices reasonably necessary to treat

1 such individuals. In no case shall the annual dis-
2 tribution number exceed the number identified in
3 paragraph (2)(A).

4 “(iii) Such person immediately notifies the Sec-
5 retary if the number of such devices distributed dur-
6 ing any calendar year exceeds the annual distribu-
7 tion number referred to in clause (ii).

8 “(iv) The request for such exemption is sub-
9 mitted on or before October 1, 2013.

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

15 “(C) A person may petition the Secretary to modify
16 the annual distribution number specified by the Secretary
17 under subparagraph (A)(ii) with respect to a device if ad-
18 ditional information on the number of individuals affected
19 by the disease or condition arises, and the Secretary may
20 modify such number but in no case shall the annual dis-
21 tribution number exceed the number identified in para-
22 graph (2)(A).

23 “(D) If a person notifies the Secretary, or the Sec-
24 retary determines through an inspection under subpara-
25 graph (B), that the number of devices distributed during

1 any calendar year exceeds the annual distribution number,
2 as required under subparagraph (A)(iii), and modified
3 under subparagraph (C), if applicable, then the prohibi-
4 tion in paragraph (3) shall apply with respect to such per-
5 son for such device for any sales of such device after such
6 notification.

7 “(E)(i) In this subsection, the term ‘pediatric pa-
8 tients’ means patients who are 21 years of age or younger
9 at the time of the diagnosis or treatment.

10 “(ii) In this subsection, the term ‘pediatric sub-
11 population’ means 1 of the following populations:

12 “(I) Neonates.

13 “(II) Infants.

14 “(III) Children.

15 “(IV) Adolescents.

16 “(7) The Secretary shall refer any report of an ad-
17 verse event regarding a device for which the prohibition
18 under paragraph (3) does not apply pursuant to para-
19 graph (6)(A) that the Secretary receives to the Office of
20 Pediatric Therapeutics, established under section 6 of the
21 Best Pharmaceuticals for Children Act (Public Law 107–
22 109). In considering the report, the Director of the Office
23 of Pediatric Therapeutics, in consultation with experts in
24 the Center for Devices and Radiological Health, shall pro-
25 vide for periodic review of the report by the Pediatric Ad-

1 visory Committee, including obtaining any recommenda-
2 tions of such committee regarding whether the Secretary
3 should take action under this Act in response to the re-
4 port.

5 “(8) In consultation with the Office of Pediatric
6 Therapeutics and the Center for Devices and Radiological
7 Health, the Secretary shall provide for an annual review
8 by the Pediatric Advisory Committee of all devices de-
9 scribed in paragraph (6) to ensure that the exemption
10 under paragraph (2) remains appropriate for the pediatric
11 populations for which it is granted.”.

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

23 (1) an assessment of whether such section
24 520(m)(6) (as amended by subsection (a)) has in-
25 creased the availability of pediatric devices for condi-

1 tions that occur in small numbers of children, in-
2 cluding any increase or decrease in the number of—

3 (A) exemptions granted under such section
4 520(m)(2) for pediatric devices; and

5 (B) applications approved under section
6 515 of such Act (21 U.S.C. 360e) for devices
7 intended to treat, diagnose, or cure conditions
8 that occur in pediatric patients or for devices
9 labeled for use in a pediatric population;

10 (2) the conditions or diseases the pediatric de-
11 vices were intended to treat or diagnose and the esti-
12 mated size of the pediatric patient population for
13 each condition or disease;

14 (3) the costs of the pediatric devices, based on
15 a survey of children's hospitals;

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

18 (5) the impact, if any, of allowing profit on ac-
19 cess to such devices for patients;

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

22 (7) an estimate of the extent of the use of the
23 pediatric devices by both adults and pediatric popu-
24 lations for a condition or disease other than the con-
25 dition or disease on the label of such devices;

(10) an evaluation of the demonstration grants described in section 305.

18 SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RE-
19 SEARCH.

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1 (b) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-
2 SEARCH.—

3 (1) IN GENERAL.—Not later than 180 days
4 after the date of enactment of this Act, the Commis-
5 sioner of Food and Drugs, in collaboration with the
6 Director of the National Institutes of Health and the
7 Director of the Agency for Healthcare Research and
8 Quality, shall submit to the Committee on Health,
9 Education, Labor, and Pensions of the Senate and
10 the Committee on Energy and Commerce of the
11 House of Representatives a plan for expanding pedi-
12 atric medical device research and development. In
13 developing such plan, the Commissioner of Food and
14 Drugs shall consult with individuals and organiza-
15 tions with appropriate expertise in pediatric medical
16 devices.

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

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

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

1 (C) a research agenda for improving pedi-
2 atric medical device development and Food and
3 Drug Administration clearance or approval of
4 pediatric medical devices, and for evaluating the
5 short- and long-term safety and effectiveness of
6 pediatric medical devices.

7 **SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
8 **ATRIC DEVICE AVAILABILITY.**

9 (a) IN GENERAL.—

10 (1) REQUEST FOR PROPOSALS.—Not later than
11 90 days after the date of enactment of this Act, the
12 Secretary of Health and Human Services shall issue
13 a request for proposals for 1 or more grants or con-
14 tracts to nonprofit consortia for demonstration
15 projects to promote pediatric device development.

16 (2) DETERMINATION ON GRANTS OR CON-
17 TRACTS.—Not later than 180 days after the date the
18 Secretary of Health and Human Services issues a
19 request for proposals under paragraph (1), the Sec-
20 retary shall make a determination on the grants or
21 contracts under this section.

22 (b) APPLICATION.—A nonprofit consortium that de-
23 sires to receive a grant or contract under this section shall
24 submit an application to the Secretary of Health and

1 Human Services at such time, in such manner, and con-
2 taining such information as the Secretary may require.

3 (c) USE OF FUNDS.—A nonprofit consortium that re-
4 ceives a grant or contract under this section shall—

5 (1) encourage innovation by connecting quali-
6 fied individuals with pediatric device ideas with po-
7 tential manufacturers;

8 (2) mentor and manage pediatric device
9 projects through the development process, including
10 product identification, prototype design, device devel-
11 opment, and marketing;

12 (3) connect innovators and physicians to exist-
13 ing Federal resources, including resources from the
14 Food and Drug Administration, the National Insti-
15 tutes of Health, the Small Business Administration,
16 the Department of Energy, the Department of Edu-
17 cation, the National Science Foundation, the De-
18 partment of Veterans Affairs, the Agency for
19 Healthcare Research and Quality, and the National
20 Institute of Standards and Technology;

21 (4) assess the scientific and medical merit of
22 proposed pediatric device projects;

23 (5) assess business feasibility and provide busi-
24 ness advice;

1 (6) provide assistance with prototype develop-
2 ment; and

3 (7) provide assistance with postmarket needs,
4 including training, logistics, and reporting.

5 (d) COORDINATION.—

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

9 (A) coordinate with the National Institutes
10 of Health’s pediatric device contact point or of-
11 fice, designated under section 304; and

12 (B) provide to the National Institutes of
13 Health any identified pediatric device needs
14 that the consortium lacks sufficient capacity to
15 address or those needs in which the consortium
16 has been unable to stimulate manufacturer in-
17 terest.

18 (2) FOOD AND DRUG ADMINISTRATION.—Each
19 consortium that receives a grant or contract under
20 this section shall coordinate with the Commissioner
21 of Food and Drugs and device companies to facili-
22 tate the application for approval or clearance of de-
23 vices labeled for pediatric use.

1 (e) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated to carry out this section
 3 \$6,000,000 for each of fiscal years 2008 through 2012.

4 **SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**
 5 **PEUTICS AND PEDIATRIC ADVISORY COM-**
 6 **MITTEE.**

7 (a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section
 8 6(b) of the Best Pharmaceuticals for Children Act (21
 9 U.S.C. 393a(b)) is amended by inserting “, including in-
 10 creasing pediatric access to medical devices” after “pedi-
 11 atric issues”.

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

15 (1) in subsection (a), by inserting “(including
 16 drugs and biological products) and medical devices”
 17 after “therapeutics”; and

18 (2) in subsection (b)—

19 (A) in paragraph (1), by inserting “(in-
 20 cluding drugs and biological products) and med-
 21 ical devices” after “therapeutics”; and

22 (B) in paragraph (2)—

23 (i) in subparagraph (A), by striking
 24 “and 505B” and inserting “505B, 510(k),
 25 515, and 520(m)”;

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

3 “(B) identification of research priorities re-
4 lated to therapeutics (including drugs and bio-
5 logical products) and medical devices for pedi-
6 atric populations and the need for additional
7 diagnostics and treatments for specific pediatric
8 diseases or conditions;”; and

9 (iii) in subparagraph (C), by inserting
10 “(including drugs and biological products)
11 and medical devices” after “therapeutics”.

12 **SEC. 307. POSTMARKET STUDIES.**

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

15 (1) in subsection (a)—

16 (A) by inserting “, or as a condition to ap-
17 proval of an application (or a supplement to an
18 application) or a product development protocol
19 under section 515 or as a condition to clearance
20 of a premarket notification under section
21 510(k), for a pediatric population or pediatric
22 subpopulation,” after “The Secretary may by
23 order”; and

24 (B) by inserting “, or that is indicated for
25 pediatric populations or subpopulations or is ex-

1 pected to have significant use in pediatric popu-
 2 lations,” after “health consequences”; and
 3 (2) in subsection (b)—

4 (A) by striking “(b) SURVEILLANCE AP-
 5 PROVAL.—Each” and inserting the following:

6 “(b) SURVEILLANCE APPROVAL.—

7 “(1) IN GENERAL.—Each”;

8 (B) by striking “The Secretary, in con-
 9 sultation” and inserting “Except as provided in
 10 paragraph (2), the Secretary, in consultation”;

11 (C) by striking “Any determination” and
 12 inserting “Except as provided in paragraph (2),
 13 any determination”; and

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

15 “(2) LONGER STUDIES FOR PEDIATRIC DE-
 16 VICES.—The Secretary may by order require a pro-
 17 spective surveillance period of more than 36 months
 18 with respect to a device that is expected to have sig-
 19 nificant use in pediatric populations if such period of
 20 more than 36 months is necessary in order to assess
 21 the impact of the device on growth and development,
 22 or the effects of growth, development, activity level,
 23 or other factors on the safety or efficacy of the de-
 24 vice.

1 “(c) DISPUTE RESOLUTION.—A manufacturer may
 2 request review under section 562 of any order or condition
 3 requiring postmarket surveillance under this section. Dur-
 4 ing the pendency of such review, the device subject to such
 5 a postmarket surveillance order or condition shall not be
 6 deemed misbranded under section 502(t) or otherwise in
 7 violation of such order or condition or a related require-
 8 ment of this Act unless deemed necessary to protect the
 9 public health.”.

10 **TITLE IV—PEDIATRIC** 11 **RESEARCH EQUITY ACT OF 2007**

12 **SEC. 401. SHORT TITLE.**

13 This title may be cited as the “Pediatric Research
 14 Equity Act of 2007”.

15 **SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQ-** 16 **UITY ACT.**

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

20 **“SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS** 21 **AND BIOLOGICAL PRODUCTS.**

22 “(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

23 “(1) IN GENERAL.—A person that submits, on
 24 or after the date of enactment of the Pediatric Re-

1 search Equity Act of 2007, an application (or sup-
2 plement to an application)—

3 “(A) under section 505 for a new active in-
4 gredient, new indication, new dosage form, new
5 dosing regimen, or new route of administration,
6 or

7 “(B) under section 351 of the Public
8 Health Service Act (42 U.S.C. 262) for a new
9 active ingredient, new indication, new dosage
10 form, new dosing regimen, or new route of ad-
11 ministration,

12 shall submit with the application the assessments de-
13 scribed in paragraph (2).

14 “(2) ASSESSMENTS.—

15 “(A) IN GENERAL.—The assessments re-
16 ferred to in paragraph (1) shall contain data,
17 gathered using appropriate formulations for
18 each age group for which the assessment is re-
19 quired, that are adequate—

20 “(i) to assess the safety and effective-
21 ness of the drug or the biological product
22 for the claimed indications in all relevant
23 pediatric subpopulations; and

24 “(ii) to support dosing and adminis-
25 tration for each pediatric subpopulation for

1 which the drug or the biological product is
2 safe and effective.

3 “(B) SIMILAR COURSE OF DISEASE OR
4 SIMILAR EFFECT OF DRUG OR BIOLOGICAL
5 PRODUCT.—

6 “(i) IN GENERAL.—If the course of
7 the disease and the effects of the drug are
8 sufficiently similar in adults and pediatric
9 patients, the Secretary may conclude that
10 pediatric effectiveness can be extrapolated
11 from adequate and well-controlled studies
12 in adults, usually supplemented with other
13 information obtained in pediatric patients,
14 such as pharmacokinetic studies.

15 “(ii) EXTRAPOLATION BETWEEN AGE
16 GROUPS.—A study may not be needed in
17 each pediatric age group if data from one
18 age group can be extrapolated to another
19 age group.

20 “(iii) INFORMATION ON EXTRAPO-
21 LATION.—A brief documentation of the sci-
22 entific data supporting the conclusion
23 under clauses (i) and (ii) shall be included
24 in the medical review that is collected as
25 part of the application under section 505

1 of this Act or section 351 of the Public
2 Health Service Act (42 U.S.C. 262).

3 “(3) DEFERRAL.—

4 “(A) IN GENERAL.—On the initiative of
5 the Secretary or at the request of the applicant,
6 the Secretary may defer submission of some or
7 all assessments required under paragraph (1)
8 until a specified date after approval of the drug
9 or issuance of the license for a biological prod-
10 uct if—

11 “(i) the Secretary finds that—

12 “(I) the drug or biological prod-
13 uct is ready for approval for use in
14 adults before pediatric studies are
15 complete;

16 “(II) pediatric studies should be
17 delayed until additional safety or ef-
18 fectiveness data have been collected;
19 or

20 “(III) there is another appro-
21 priate reason for deferral; and

22 “(ii) the applicant submits to the Sec-
23 retary—

24 “(I) certification of the grounds
25 for deferring the assessments;

1 “(II) a description of the planned
2 or ongoing studies;

3 “(III) evidence that the studies
4 are being conducted or will be con-
5 ducted with due diligence and at the
6 earliest possible time; and

7 “(IV) a timeline for the comple-
8 tion of such studies.

9 “(B) ANNUAL REVIEW.—

10 “(i) IN GENERAL.—On an annual
11 basis following the approval of a deferral
12 under subparagraph (A), the applicant
13 shall submit to the Secretary the following
14 information:

15 “(I) Information detailing the
16 progress made in conducting pediatric
17 studies.

18 “(II) If no progress has been
19 made in conducting such studies, evi-
20 dence and documentation that such
21 studies will be conducted with due
22 diligence and at the earliest possible
23 time.

24 “(ii) PUBLIC AVAILABILITY.—The in-
25 formation submitted through the annual

1 review under clause (i) shall promptly be
2 made available to the public in an easily
3 accessible manner, including through the
4 website of the Food and Drug Administra-
5 tion.

6 “(4) WAIVERS.—

7 “(A) FULL WAIVER.—On the initiative of
8 the Secretary or at the request of an applicant,
9 the Secretary shall grant a full waiver, as ap-
10 propriate, of the requirement to submit assess-
11 ments for a drug or biological product under
12 this subsection if the applicant certifies and the
13 Secretary finds that—

14 “(i) necessary studies are impossible
15 or highly impracticable (because, for exam-
16 ple, the number of patients is so small or
17 the patients are geographically dispersed);

18 “(ii) there is evidence strongly sug-
19 gesting that the drug or biological product
20 would be ineffective or unsafe in all pedi-
21 atric age groups; or

22 “(iii) The drug or biological product—

23 “(I) does not represent a mean-
24 ingful therapeutic benefit over existing
25 therapies for pediatric patients; and

1 “(II) is not likely to be used in a
2 substantial number of pediatric pa-
3 tients.

4 “(B) PARTIAL WAIVER.—On the initiative
5 of the Secretary or at the request of an appli-
6 cant, the Secretary shall grant a partial waiver,
7 as appropriate, of the requirement to submit as-
8 sessments for a drug or biological product
9 under this subsection with respect to a specific
10 pediatric age group if the applicant certifies
11 and the Secretary finds that—

12 “(i) necessary studies are impossible
13 or highly impracticable (because, for exam-
14 ple, the number of patients in that age
15 group is so small or patients in that age
16 group are geographically dispersed);

17 “(ii) there is evidence strongly sug-
18 gesting that the drug or biological product
19 would be ineffective or unsafe in that age
20 group;

21 “(iii) the drug or biological product—

22 “(I) does not represent a mean-
23 ingful therapeutic benefit over existing
24 therapies for pediatric patients in that
25 age group; and

1 “(II) is not likely to be used by
2 a substantial number of pediatric pa-
3 tients in that age group; or

4 “(iv) the applicant can demonstrate
5 that reasonable attempts to produce a pe-
6 diatric formulation necessary for that age
7 group have failed.

8 “(C) PEDIATRIC FORMULATION NOT POS-
9 SIBLE.—If a waiver is granted on the ground
10 that it is not possible to develop a pediatric for-
11 mulation, the waiver shall cover only the pedi-
12 atric groups requiring that formulation. An ap-
13 plicant seeking either a full or partial waiver
14 shall submit to the Secretary documentation de-
15 tailing why a pediatric formulation cannot be
16 developed and, if the waiver is granted, the ap-
17 plicant’s submission shall promptly be made
18 available to the public in an easily accessible
19 manner, including through posting on the
20 website of the Food and Drug Administration.

21 “(D) LABELING REQUIREMENT.—If the
22 Secretary grants a full or partial waiver because
23 there is evidence that a drug or biological prod-
24 uct would be ineffective or unsafe in pediatric
25 populations, the information shall be included

1 in the labeling for the drug or biological prod-
2 uct.

3 “(b) MARKETED DRUGS AND BIOLOGICAL PROD-
4 UCTS.—

5 “(1) IN GENERAL.—Beginning on the date of
6 enactment of the Pediatric Research Equity Act of
7 2007, after providing notice in the form of a letter
8 and an opportunity for written response and a meet-
9 ing, which may include an advisory committee meet-
10 ing, the Secretary may (by order in the form of a
11 letter) require the sponsor or holder of an approved
12 application for a drug under section 505 or the hold-
13 er of a license for a biological product under section
14 351 of the Public Health Service Act to submit by
15 a specified date the assessments described in sub-
16 section (a)(2), if the Secretary finds that—

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

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

22 “(B) there is reason to believe that the
23 drug or biological product would represent a
24 meaningful therapeutic benefit over existing

1 therapies for pediatric patients for 1 or more of
2 the claimed indications; or

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

5 “(2) WAIVERS.—

6 “(A) FULL WAIVER.—At the request of an
7 applicant, the Secretary shall grant a full waiv-
8 er, as appropriate, of the requirement to submit
9 assessments under this subsection if the appli-
10 cant certifies and the Secretary finds that—

11 “(i) necessary studies are impossible
12 or highly impracticable (because, for exam-
13 ple, the number of patients in that age
14 group is so small or patients in that age
15 group are geographically dispersed); or

16 “(ii) there is evidence strongly sug-
17 gesting that the drug or biological product
18 would be ineffective or unsafe in all pedi-
19 atric age groups.

20 “(B) PARTIAL WAIVER.—At the request of
21 an applicant, the Secretary shall grant a partial
22 waiver, as appropriate, of the requirement to
23 submit assessments under this subsection with
24 respect to a specific pediatric age group if the

1 applicant certifies and the Secretary finds
2 that—

3 “(i) necessary studies are impossible
4 or highly impracticable (because, for exam-
5 ple, the number of patients in that age
6 group is so small or patients in that age
7 group are geographically dispersed);

8 “(ii) there is evidence strongly sug-
9 gesting that the drug or biological product
10 would be ineffective or unsafe in that age
11 group;

12 “(iii)(I) the drug or biological prod-
13 uct—

14 “(aa) does not represent a mean-
15 ingful therapeutic benefit over existing
16 therapies for pediatric patients in that
17 age group; and

18 “(bb) is not likely to be used in
19 a substantial number of pediatric pa-
20 tients in that age group; and

21 “(II) the absence of adequate labeling
22 could not pose significant risks to pediatric
23 patients; or

24 “(iv) the applicant can demonstrate
25 that reasonable attempts to produce a pe-

1 diatric formulation necessary for that age
2 group have failed.

3 “(C) PEDIATRIC FORMULATION NOT POS-
4 SIBLE.—If a waiver is granted on the ground
5 that it is not possible to develop a pediatric for-
6 mulation, the waiver shall cover only the pedi-
7 atric groups requiring that formulation. An ap-
8 plicant seeking either a full or partial waiver
9 shall submit to the Secretary documentation de-
10 tailing why a pediatric formulation cannot be
11 developed and, if the waiver is granted, the ap-
12 plicant’s submission shall promptly be made
13 available to the public in an easily accessible
14 manner, including through posting on the
15 website of the Food and Drug Administration.

16 “(D) LABELING REQUIREMENT.—If the
17 Secretary grants a full or partial waiver because
18 there is evidence that a drug or biological prod-
19 uct would be ineffective or unsafe in pediatric
20 populations, the information shall be included
21 in the labeling for the drug or biological prod-
22 uct.

23 “(c) MEANINGFUL THERAPEUTIC BENEFIT.—For
24 the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I)
25 of subsection (a) and paragraphs (1)(B)(I) and

1 (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological
2 product shall be considered to represent a meaningful
3 therapeutic benefit over existing therapies if the Secretary
4 determines that—

5 “(1) if approved, the drug or biological product
6 could represent an improvement in the treatment,
7 diagnosis, or prevention of a disease, compared with
8 marketed products adequately labeled for that use in
9 the relevant pediatric population; or

10 “(2) the drug or biological product is in a class
11 of products or for an indication for which there is
12 a need for additional options.

13 “(d) SUBMISSION OF ASSESSMENTS.—If a person
14 fails to submit an assessment described in subsection
15 (a)(2), or a request for approval of a pediatric formulation
16 described in subsection (a) or (b), in accordance with ap-
17 plicable provisions of subsections (a) and (b)—

18 “(1) the drug or biological product that is the
19 subject of the assessment or request may be consid-
20 ered misbranded solely because of that failure and
21 subject to relevant enforcement action (except that
22 the drug or biological product shall not be subject to
23 action under section 303); but

24 “(2) the failure to submit the assessment or re-
25 quest shall not be the basis for a proceeding—

1 “(A) to withdraw approval for a drug
2 under section 505(e); or

3 “(B) to revoke the license for a biological
4 product under section 351 of the Public Health
5 Service Act.

6 “(e) MEETINGS.—Before and during the investiga-
7 tional process for a new drug or biological product, the
8 Secretary shall meet at appropriate times with the sponsor
9 of the new drug or biological product to discuss—

10 “(1) information that the sponsor submits on
11 plans and timelines for pediatric studies; or

12 “(2) any planned request by the sponsor for
13 waiver or deferral of pediatric studies.

14 “(f) REVIEW OF PEDIATRIC PLANS, DEFERRALS,
15 AND WAIVERS.—

16 “(1) REVIEW.—Beginning not later than 30
17 days after the date of enactment of the Pediatric
18 Research Equity Act of 2007, the Secretary shall
19 utilize an internal committee to provide consultation
20 to reviewing divisions on all pediatric plans and as-
21 sessments prior to approval of an application or sup-
22 plement for which a pediatric assessment is required
23 under this section and all deferral and waiver re-
24 quests granted pursuant to this section. Such inter-
25 nal committee shall include employees of the Food

1 and Drug Administration, with expertise in pedi-
2 atrics (including representation from the Office of Pe-
3 diatric Therapeutics), biopharmacology, statistics,
4 chemistry, legal issues, pediatric ethics, and the ap-
5 propriate expertise pertaining to the pediatric prod-
6 uct under review, and other individuals designated
7 by the Secretary.

8 “(2) ACTIVITY BY COMMITTEE.—The committee
9 referred to in paragraph (1) may operate using ap-
10 propriate members of such committee and need not
11 convene all members of the committee.

12 “(3) DOCUMENTATION OF COMMITTEE AC-
13 TION.—For each drug or biological product, the
14 committee referred to in paragraph (1) shall docu-
15 ment, for each activity described in paragraph (4),
16 which members of the committee participated in
17 such activity.

18 “(4) REVIEW OF PEDIATRIC PLANS, DEFERRALS
19 AND WAIVERS.—Consultation on pediatric plans and
20 assessments by the internal committee pursuant to
21 this section shall occur prior to approval of an appli-
22 cation or supplement for which a pediatric assess-
23 ment is required under this section. The internal
24 committee shall review all requests for deferrals and
25 waivers from the requirement to submit a pediatric

1 assessment granted under this section and shall pro-
2 vide recommendations as needed to reviewing divi-
3 sions.

4 “(5) RETROSPECTIVE REVIEW OF PEDIATRIC
5 PLANS, DEFERRALS AND WAIVERS.—Within one year
6 after enactment of the Pediatric Research Equity
7 Act of 2007, the committee shall conduct a retro-
8 spective review and analysis of a representative sam-
9 ple of assessments submitted and deferrals and
10 waivers approved under this section since enactment
11 of the Pediatric Research Equity Act of 2003. Such
12 review shall include an analysis of the quality and
13 consistency of pediatric information in pediatric as-
14 sessments and the appropriateness of waivers and
15 deferrals granted. Based on such review, the Sec-
16 retary shall issue recommendations to the review di-
17 visions for improvements and initiate guidance to in-
18 dustry related to the scope of pediatric studies re-
19 quired under this section.

20 “(6) TRACKING OF ASSESSMENTS AND LABEL-
21 ING CHANGES.—Beginning on the date of enactment
22 of the Pediatric Research Equity Act of 2007, the
23 Secretary shall track and make available to the pub-
24 lic in an easily accessible manner, including through

1 posting on the website of the Food and Drug Ad-
2 ministration—

3 “(A) the number of assessments conducted
4 under this section;

5 “(B) the specific drugs and biological prod-
6 ucts and their uses assessed under this section;

7 “(C) the types of assessments conducted
8 under this section, including trial design, the
9 number of pediatric patients studied, and the
10 number of centers and countries involved;

11 “(D) the total number of deferrals re-
12 quested and granted under this section and, if
13 granted, the reasons for such deferrals, the
14 timeline for completion, and the number com-
15 pleted and pending by the specified date, as
16 outlined in subsection (a)(3);

17 “(E) the number of waivers requested and
18 granted under this section and, if granted, the
19 reasons for the waivers;

20 “(F) the number of pediatric formulations
21 developed and the number of pediatric formula-
22 tions not developed and the reasons any such
23 formulation was not developed;

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

1 “(H) an annual summary of labeling
2 changes made as a result of assessments con-
3 ducted under this section for distribution pursu-
4 ant to subsection (h)(2); and

5 “(I) an annual summary of information
6 submitted pursuant to subsection (a)(3)(B).

7 “(7) COMMITTEE.—The committee utilized
8 under paragraph (1) shall be the committee estab-
9 lished under section 505A(f)(1).

10 “(g) LABELING CHANGES.—

11 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-
12 CATIONS.—Any supplement to an application under
13 section 505 and section 351 of the Public Health
14 Service Act proposing a labeling change as a result
15 of any pediatric assessments conducted pursuant to
16 this section—

17 “(A) shall be considered a priority applica-
18 tion or supplement; and

19 “(B) shall be subject to the performance
20 goals established by the Commissioner for pri-
21 ority drugs.

22 “(2) DISPUTE RESOLUTION.—

23 “(A) REQUEST FOR LABELING CHANGE
24 AND FAILURE TO AGREE.—If, on or after the
25 date of enactment of the Pediatric Research

1 Equity Act of 2007, the Commissioner deter-
2 mines that a sponsor and the Commissioner
3 have been unable to reach agreement on appro-
4 priate changes to the labeling for the drug that
5 is the subject of the application or supplement,
6 not later than 180 days after the date of the
7 submission of the application or supplement—

8 “(i) the Commissioner shall request
9 that the sponsor of the application make
10 any labeling change that the Commissioner
11 determines to be appropriate; and

12 “(ii) if the sponsor does not agree
13 within 30 days after the Commissioner’s
14 request to make a labeling change re-
15 quested by the Commissioner, the Commis-
16 sioner shall refer the matter to the Pedi-
17 atric Advisory Committee.

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

22 “(i) review the pediatric study reports;
23 and

1 “(ii) make a recommendation to the
2 Commissioner concerning appropriate la-
3 beling changes, if any.

4 “(C) CONSIDERATION OF RECOMMENDA-
5 TIONS.—The Commissioner shall consider the
6 recommendations of the Pediatric Advisory
7 Committee and, if appropriate, not later than
8 30 days after receiving the recommendation,
9 make a request to the sponsor of the applica-
10 tion to make any labeling changes that the
11 Commissioner determines to be appropriate.

12 “(D) MISBRANDING.—If the sponsor of the
13 application, within 30 days after receiving a re-
14 quest under subparagraph (C), does not agree
15 to make a labeling change requested by the
16 Commissioner, the Commissioner may deem the
17 drug that is the subject of the application to be
18 misbranded.

19 “(E) NO EFFECT ON AUTHORITY.—Noth-
20 ing in this subsection limits the authority of the
21 United States to bring an enforcement action
22 under this Act when a drug lacks appropriate
23 pediatric labeling. Neither course of action (the
24 Pediatric Advisory Committee process or an en-
25 forcement action referred to in the preceding

1 sentence) shall preclude, delay, or serve as the
2 basis to stay the other course of action.

3 “(3) OTHER LABELING CHANGES.—If, on or
4 after the date of enactment of the Pediatric Re-
5 search Equity Act of 2007, the Secretary makes a
6 determination that a pediatric assessment conducted
7 under this section does or does not demonstrate that
8 the drug that is the subject of such assessment is
9 safe and effective in pediatric populations or sub-
10 populations, including whether such assessment re-
11 sults are inconclusive, the Secretary shall order the
12 label of such product to include information about
13 the results of the assessment and a statement of the
14 Secretary’s determination.

15 “(h) DISSEMINATION OF PEDIATRIC INFORMA-
16 TION.—

17 “(1) IN GENERAL.—Not later than 180 days
18 after the date of submission of a pediatric assess-
19 ment under this section, the Secretary shall make
20 available to the public in an easily accessible manner
21 the medical, statistical, and clinical pharmacology re-
22 views of such pediatric assessments, and shall post
23 such assessments on the website of the Food and
24 Drug Administration.

1 “(2) DISSEMINATION OF INFORMATION RE-
2 GARDING LABELING CHANGES.—Beginning on the
3 date of enactment of the Pediatric Research Equity
4 Act of 2007, the Secretary shall require that the
5 sponsors of the assessments that result in labeling
6 changes that are reflected in the annual summary
7 developed pursuant to subsection (f)(6)(H) dis-
8 tribute such information to physicians and other
9 health care providers.

10 “(3) EFFECT OF SUBSECTION.—Nothing in this
11 subsection shall alter or amend Section 301(j) of
12 this Act or section 552 of title 5 or section 1905 of
13 title 18, United States Code.

14 “(i) ADVERSE EVENT REPORTING.—

15 “(1) REPORTING IN YEAR ONE.—Beginning on
16 the date of enactment of the Pediatric Research Eq-
17 uity Act of 2007, during the one-year period begin-
18 ning on the date a labeling change is made pursuant
19 to subsection (g), the Secretary shall ensure that all
20 adverse event reports that have been received for
21 such drug (regardless of when such report was re-
22 ceived) are referred to the Office of Pediatric Thera-
23 peutics. In considering the report, the Director of
24 such Office shall provide for the review of the report
25 by the Pediatric Advisory Committee, including ob-

1 taining any recommendations of such committee re-
2 garding whether the Secretary should take action
3 under this Act in response to such report.

4 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
5 lowing the one-year period described in paragraph
6 (1), the Secretary shall, as appropriate, refer to the
7 Office of Pediatric Therapeutics all pediatric adverse
8 event reports for a drug for which a pediatric study
9 was conducted under this section. In considering the
10 report, the Director of such Office may provide for
11 the review of the report by the Pediatric Advisory
12 Committee, including obtaining any recommendation
13 of such Committee regarding whether the Secretary
14 should take action in response to such report.

15 “(3) EFFECT.—The requirements of this sub-
16 section shall supplement, not supplant, other review
17 of such adverse event reports by the Secretary.

18 “(j) SCOPE OF AUTHORITY.—Nothing in this section
19 provides to the Secretary any authority to require a pedi-
20 atric assessment of any drug or biological product, or any
21 assessment regarding other populations or uses of a drug
22 or biological product, other than the pediatric assessments
23 described in this section.

24 “(k) ORPHAN DRUGS.—Unless the Secretary re-
25 quires otherwise by regulation, this section does not apply

1 to any drug for an indication for which orphan designation
2 has been granted under section 526.

3 “(l) INSTITUTE OF MEDICINE STUDY.—

4 “(1) IN GENERAL.—Not later than three years
5 after the date of the enactment of the Pediatric Re-
6 search Equity Act of 2007, the Secretary shall con-
7 tract with the Institute of Medicine to conduct a
8 study and report to Congress regarding the pediatric
9 studies conducted pursuant to this section since
10 1997 and labeling changes made as a result of such
11 studies.

12 “(2) CONTENT OF STUDY.—The study under
13 paragraph (1) shall review and assess the use of ex-
14 trapolation for pediatric subpopulations, the use of
15 alternative endpoints for pediatric populations, neo-
16 natal assessment tools, the number and type of pedi-
17 atric adverse events, and ethical issues in pediatric
18 clinical trials.

19 “(3) REPRESENTATIVE SAMPLE.—The Institute
20 of Medicine may devise an appropriate mechanism to
21 review a representative sample of studies conducted
22 pursuant to this section from each review division
23 within the Center for Drug Evaluation and Research
24 in order to make the requested assessment.”.

1 (b) APPLICABILITY.—The amendment made in sub-
2 section (a) applies to assessments required under section
3 505B on or after the date of enactment of this Act.

4 **SEC. 403. GOVERNMENT ACCOUNTABILITY OFFICE RE-**
5 **PORT.**

6 Not later than September 1, 2011, the Comptroller
7 General of the United States, in consultation with the Sec-
8 retary of Health and Human Services, shall submit to the
9 Congress a report that addresses the effectiveness of sec-
10 tions 505A and 505B of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355a, 355c) and section 409I of the
12 Public Health Service Act (42 U.S.C. 284m) in ensuring
13 that medicines used by children are tested and properly
14 labeled. Such report shall include—

15 (1) the number and importance of drugs and
16 biological products for children that are being tested
17 as a result of the amendments made by this title and
18 title V and the importance for children, health care
19 providers, parents, and others of labeling changes
20 made as a result of such testing;

21 (2) the number and importance of drugs and
22 biological products for children that are not being
23 tested for their use notwithstanding the provisions of
24 this title and title V and possible reasons for the
25 lack of testing, including whether the number of

1 written requests declined by sponsors or holders of
2 drugs subject to section 505A(g)(2) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 355a(g)(2)) has increased or decreased as a result of
5 the amendments made by this title;

6 (3) the number of drugs and biological products
7 for which testing is being done and labeling changes
8 required, including the date labeling changes are
9 made and which labeling changes required the use of
10 the dispute resolution process established pursuant
11 to the amendments made by this title, together with
12 a description of the outcomes of such process, in-
13 cluding a description of the disputes and the rec-
14 ommendations of the Pediatric Advisory Committee;

15 (4) any recommendations for modifications to
16 the programs established under sections 505A and
17 505B of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 355a) and section 409I of the Public
19 Health Service Act (42 U.S.C. 284m) that the Sec-
20 retary determines to be appropriate, including a de-
21 tailed rationale for each recommendation; and

22 (5)(A) the efforts made by the Secretary to in-
23 crease the number of studies conducted in the
24 neonate population; and

1 (B) the results of those efforts, including efforts
2 made to encourage the conduct of appropriate stud-
3 ies in neonates by companies with products that
4 have sufficient safety and other information to make
5 the conduct of the studies ethical and safe.

6 **TITLE V—BEST PHARMA-**
7 **CEUTICALS FOR CHILDREN**
8 **ACT OF 2007**

9 **SEC. 501. SHORT TITLE.**

10 This title may be cited as the “Best Pharmaceuticals
11 for Children Act of 2007”.

12 **SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS**
13 **FOR CHILDREN ACT.**

14 (a) PEDIATRIC STUDIES OF DRUGS.—

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

18 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

19 “(a) DEFINITIONS.—As used in this section, the term
20 ‘pediatric studies’ or ‘studies’ means at least one clinical
21 investigation (that, at the Secretary’s discretion, may in-
22 clude pharmacokinetic studies) in pediatric age groups (in-
23 cluding neonates in appropriate cases) in which a drug
24 is anticipated to be used, and at the discretion of the Sec-
25 retary, may include preclinical studies.

1 “(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

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

19 “(A)(i)(I) the period referred to in sub-
20 section (c)(3)(E)(ii) of section 505, and in sub-
21 section (j)(5)(F)(ii) of such section, is deemed
22 to be five years and six months rather than five
23 years, and the references in subsections
24 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to
25 four years, to forty-eight months, and to seven

1 and one-half years are deemed to be four and
2 one-half years, fifty-four months, and eight
3 years, respectively; or

4 “(II) the period referred to in clauses (iii)
5 and (iv) of subsection (c)(3)(E) of such section,
6 and in clauses (iii) and (iv) of subsection
7 (j)(5)(F) of such section, is deemed to be three
8 years and six months rather than three years;
9 and

10 “(ii) if the drug is designated under sec-
11 tion 526 for a rare disease or condition, the pe-
12 riod referred to in section 527(a) is deemed to
13 be seven years and six months rather than
14 seven years; and

15 “(B)(i) if the drug is the subject of—

16 “(I) a listed patent for which a certifi-
17 cation has been submitted under sub-
18 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
19 section 505 and for which pediatric studies
20 were submitted prior to the expiration of
21 the patent (including any patent exten-
22 sions); or

23 “(II) a listed patent for which a cer-
24 tification has been submitted under sub-

1 sections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)
2 of section 505,
3 the period during which an application may not
4 be approved under section 505(c)(3) or section
5 505(j)(5)(B) shall be extended by a period of
6 six months after the date the patent expires (in-
7 cluding any patent extensions); or

8 “(ii) if the drug is the subject of a listed
9 patent for which a certification has been sub-
10 mitted under subsection (b)(2)(A)(iv) or
11 (j)(2)(A)(vii)(IV) of section 505, and in the pat-
12 ent infringement litigation resulting from the
13 certification the court determines that the pat-
14 ent is valid and would be infringed, the period
15 during which an application may not be ap-
16 proved under section 505(c)(3) or section
17 505(j)(5)(B) shall be extended by a period of
18 six months after the date the patent expires (in-
19 cluding any patent extensions).

20 “(2) EXCEPTION.—The Secretary shall not ex-
21 tend the period referred to in paragraph (1)(A) or
22 (1)(B) if the determination is made later than one
23 year prior to the expiration of such period.

24 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-
25 KETED DRUGS.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), if the Secretary determines that informa-
3 tion relating to the use of an approved drug in the
4 pediatric population may produce health benefits in
5 that population and makes a written request to the
6 holder of an approved application under section
7 505(b)(1) for pediatric studies (which shall include
8 a timeframe for completing such studies), the holder
9 agrees to the request, such studies are completed
10 using appropriate formulations for each age group
11 for which the study is requested within any such
12 timeframe and the reports thereof are submitted and
13 accepted in accordance with subsection (d)(3), and if
14 the Secretary determines that labeling changes are
15 appropriate and such changes are approved within
16 the timeframe requested by the Secretary—

17 “(A)(i)(I) the period referred to in sub-
18 section (c)(3)(E)(ii) of section 505, and in sub-
19 section (j)(5)(F)(ii) of such section, is deemed
20 to be five years and six months rather than five
21 years, and the references in subsections
22 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to
23 four years, to forty-eight months, and to seven
24 and one-half years are deemed to be four and

1 one-half years, fifty-four months, and eight
2 years, respectively; or

3 “(II) the period referred to in clauses (iii)
4 and (iv) of subsection (c)(3)(D) of such section,
5 and in clauses (iii) and (iv) of subsection
6 (j)(5)(F) of such section, is deemed to be three
7 years and six months rather than three years;
8 and

9 “(ii) if the drug is designated under sec-
10 tion 526 for a rare disease or condition, the pe-
11 riod referred to in section 527(a) is deemed to
12 be seven years and six months rather than
13 seven years; and

14 “(B)(i) if the drug is the subject of—

15 “(I) a listed patent for which a certifi-
16 cation has been submitted under sub-
17 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
18 section 505 and for which pediatric studies
19 were submitted prior to the expiration of
20 the patent (including any patent exten-
21 sions); or

22 “(II) a listed patent for which a cer-
23 tification has been submitted under sub-
24 section (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)
25 of section 505,

1 the period during which an application may not
2 be approved under section 505(c)(3) or section
3 505(j)(5)(B)(ii) shall be extended by a period of
4 six months after the date the patent expires (in-
5 cluding any patent extensions); or

6 “(ii) if the drug is the subject of a listed
7 patent for which a certification has been sub-
8 mitted under subsection (b)(2)(A)(iv) or
9 (j)(2)(A)(vii)(IV) of section 505, and in the pat-
10 ent infringement litigation resulting from the
11 certification the court determines that the pat-
12 ent is valid and would be infringed, the period
13 during which an application may not be ap-
14 proved under section 505(c)(3) or section
15 505(j)(5)(B) shall be extended by a period of
16 six months after the date the patent expires (in-
17 cluding any patent extensions)

18 “(2) EXCEPTION.—The Secretary shall not ex-
19 tend the period referred to in paragraph (1)(A) or
20 (1)(B) if the determination is made later than one
21 year prior to the expiration of such period.

22 “(d) CONDUCT OF PEDIATRIC STUDIES.—

23 “(1) REQUEST FOR STUDIES.—

24 “(A) IN GENERAL.—The Secretary may,
25 after consultation with the sponsor of an appli-

1 cation for an investigational new drug under
2 section 505(i), the sponsor of an application for
3 a new drug under section 505(b)(1), or the
4 holder of an approved application for a drug
5 under section 505(b)(1) issue to the sponsor or
6 holder a written request for the conduct of pedi-
7atric studies for such drug. In issuing such re-
8quest, the Secretary shall take into account
9adequate representation of children of ethnic
10and racial minorities. Such request to conduct
11pediatric studies shall be in writing and shall
12include a timeframe for such studies and a re-
13quest to the sponsor or holder to propose pedi-
14atric labeling resulting from such studies.

15 “(B) SINGLE WRITTEN REQUEST.—A sin-
16gle written request—

17 “(i) may relate to more than one use
18 of a drug; and

19 “(ii) may include uses that are both
20 approved and unapproved.

21 “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-
22IES.—

23 “(A) REQUEST AND RESPONSE.—

24 “(i) IN GENERAL.—If the Secretary
25 makes a written request for pediatric stud-

1 ies (including neonates, as appropriate)
2 under subsection (b) or (c), the applicant
3 or holder, not later than 180 days after re-
4 ceiving the written request, shall respond
5 to the Secretary as to the intention of the
6 applicant or holder to act on the request
7 by—

8 “(I) indicating when the pediatric
9 studies will be initiated, if the appli-
10 cant or holder agrees to the request;
11 or

12 “(II) indicating that the appli-
13 cant or holder does not agree to the
14 request and stating the reasons for
15 declining the request.

16 “(ii) DISAGREE WITH REQUEST.—If,
17 on or after the date of the enactment of
18 the Best Pharmaceuticals for Children Act
19 of 2007, the applicant or holder does not
20 agree to the request on the grounds that it
21 is not possible to develop the appropriate
22 pediatric formulation, the applicant or
23 holder shall submit to the Secretary the
24 reasons such pediatric formulation cannot
25 be developed.

1 “(B) ADVERSE EVENT REPORTS.—An ap-
2 plicant or holder that, on or after the date of
3 the enactment of the Best Pharmaceuticals for
4 Children Act of 2007, agrees to the request for
5 such studies shall provide the Secretary, at the
6 same time as the submission of the reports of
7 such studies, with all postmarket adverse event
8 reports regarding the drug that is the subject
9 of such studies and are available prior to sub-
10 mission of such reports.

11 “(3) MEETING THE STUDIES REQUIREMENT.—
12 Not later than 180 days after the submission of the
13 reports of the studies, the Secretary shall accept or
14 reject such reports and so notify the sponsor or
15 holder. The Secretary’s only responsibility in accept-
16 ing or rejecting the reports shall be to determine,
17 within the 180-day period, whether the studies fairly
18 respond to the written request, have been conducted
19 in accordance with commonly accepted scientific
20 principles and protocols, and have been reported in
21 accordance with the requirements of the Secretary
22 for filing.

23 “(4) EFFECT OF SUBSECTION.—Nothing in this
24 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 “(e) NOTICE OF DETERMINATIONS ON STUDIES RE-
4 QUIREMENT.—

5 “(1) IN GENERAL.—The Secretary shall publish
6 a notice of any determination, made on or after the
7 date of the enactment of the Best Pharmaceuticals
8 for Children Act of 2007, that the requirements of
9 subsection (d) have been met and that submissions
10 and approvals under subsection (b)(2) or (j) of sec-
11 tion 505 for a drug will be subject to the provisions
12 of this section. Such notice shall be published not
13 later than 30 days after the date of the Secretary’s
14 determination regarding market exclusivity and shall
15 include a copy of the written request made under
16 subsection (b) or (c).

17 “(2) IDENTIFICATION OF CERTAIN DRUGS.—
18 The Secretary shall publish a notice identifying any
19 drug for which, on or after the date of the enact-
20 ment of the Best Pharmaceuticals for Children Act
21 of 2007, a pediatric formulation was developed,
22 studied, and found to be safe and effective in the pe-
23 diatric population (or specified subpopulation) if the
24 pediatric formulation for such drug is not introduced
25 onto the market within one year after the date that

1 the Secretary publishes the notice described in para-
2 graph (1). Such notice identifying such drug shall be
3 published not later than 30 days after the date of
4 the expiration of such one year period.

5 “(f) INTERNAL REVIEW OF WRITTEN REQUESTS
6 AND PEDIATRIC STUDIES.—

7 “(1) INTERNAL REVIEW.—

8 “(A) IN GENERAL.—The Secretary shall
9 establish an internal review committee to review
10 all written requests issued on or after the date
11 of the enactment of the Best Pharmaceuticals
12 for Children Act of 2007, in accordance with
13 paragraph (2).

14 “(B) MEMBERS.—The committee estab-
15 lished under subparagraph (A) shall include in-
16 dividuals with expertise in pediatrics, biophar-
17 macology, statistics, drugs and drug formula-
18 tions, legal issues, pediatric ethics, the appro-
19 priate expertise, such as expertise in child and
20 adolescent psychiatry, pertaining to the pedi-
21 atric product under review, one or more experts
22 from the Office of Pediatric Therapeutics, and
23 other individuals designated by the Secretary.

24 “(2) REVIEW OF WRITTEN REQUESTS.—The
25 committee established under paragraph (1) shall re-

1 view all written requests issued pursuant to this sec-
2 tion prior to being issued.

3 “(3) TRACKING PEDIATRIC STUDIES AND LA-
4 BELING CHANGES.—The Secretary shall track and
5 make available to the public, in an easily accessible
6 manner, including through posting on the website of
7 the Food and Drug Administration—

8 “(A) the number of studies conducted
9 under this section and under section 409I of
10 the Public Health Service Act;

11 “(B) the specific drugs and biological prod-
12 ucts and their uses, including labeled and off-
13 labeled indications, studied under such sections;

14 “(C) the types of studies conducted under
15 such sections, including trial design, the num-
16 ber of pediatric patients studied, and the num-
17 ber of 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 such sections;

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

1 under such sections for distribution pursuant to
2 subsection (k)(2); and

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

7 “(4) COMMITTEE.—The committee established
8 under paragraph (1) shall be the committee utilized
9 under section 505B(f)(1).

10 “(g) LIMITATIONS.—Notwithstanding subsection
11 (c)(2), a drug to which the six-month period under sub-
12 section (b) or (c) has already been applied—

13 “(1) may receive an additional six-month period
14 under subsection (c)(1)(A)(i)(II) for a supplemental
15 application if all other requirements under this sec-
16 tion are satisfied; and

17 “(2) may not receive any additional such period
18 under subsection (c)(1)(A)(ii).

19 “(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-
20 QUIREMENTS.—Notwithstanding any other provision of
21 law, if any pediatric study is required by a provision of
22 law (including a regulation) other than this section and
23 such study meets the completeness, timeliness, and other
24 requirements of this section, such study shall be deemed

1 to satisfy the requirement for market exclusivity pursuant
2 to this section.

3 “(i) LABELING CHANGES.—

4 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-
5 CATIONS AND SUPPLEMENTS.—Any application or
6 supplement to an application under section 505 pro-
7 posing a labeling change as a result of any pediatric
8 study conducted pursuant to this section—

9 “(A) shall be considered to be a priority
10 application or supplement; and

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

14 “(2) DISPUTE RESOLUTION.—

15 “(A) REQUEST FOR LABELING CHANGE
16 AND FAILURE TO AGREE.—If, on or after the
17 date of the enactment of the Best Pharma-
18 ceuticals for Children Act of 2007, the Commis-
19 sioner determines that the sponsor and the
20 Commissioner have been unable to reach agree-
21 ment on appropriate changes to the labeling for
22 the drug that is the subject of the application,
23 not later than 180 days after the date of sub-
24 mission of the application—

1 “(i) the Commissioner shall request
2 that the sponsor of the application make
3 any labeling change that the Commissioner
4 determines to be appropriate; and

5 “(ii) if the sponsor of the application
6 does not agree within 30 days after the
7 Commissioner’s request to make a labeling
8 change requested by the Commissioner, the
9 Commissioner shall refer the matter to the
10 Pediatric Advisory Committee.

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

15 “(i) review the pediatric study reports;
16 and

17 “(ii) make a recommendation to the
18 Commissioner concerning appropriate la-
19 beling changes, if any.

20 “(C) CONSIDERATION OF RECOMMENDA-
21 TIONS.—The Commissioner shall consider the
22 recommendations of the Pediatric Advisory
23 Committee and, if appropriate, not later than
24 30 days after receiving the recommendation,
25 make a request to the sponsor of the applica-

1 tion to make any labeling change that the Com-
2 missioner determines to be appropriate.

3 “(D) MISBRANDING.—If the sponsor of the
4 application, within 30 days after receiving a re-
5 quest under subparagraph (C), does not agree
6 to make a labeling change requested by the
7 Commissioner, the Commissioner may deem the
8 drug that is the subject of the application to be
9 misbranded.

10 “(E) NO EFFECT ON AUTHORITY.—Noth-
11 ing in this subsection limits the authority of the
12 United States to bring an enforcement action
13 under this Act when a drug lacks appropriate
14 pediatric labeling. Neither course of action (the
15 Pediatric Advisory Committee process or an en-
16 forcement action referred to in the preceding
17 sentence) shall preclude, delay, or serve as the
18 basis to stay the other course of action.

19 “(j) OTHER LABELING CHANGES.—If, on or after the
20 date of the enactment of the Best Pharmaceuticals for
21 Children Act of 2007, the Secretary determines that a pe-
22 diatric study conducted under this section does or does
23 not demonstrate that the drug that is the subject of the
24 study is safe and effective in pediatric populations or sub-
25 populations, including whether such study results are in-

1 conclusive, the Secretary shall order the labeling of such
2 product to include information about the results of the
3 study and a statement of the Secretary's determination.

4 “(k) DISSEMINATION OF PEDIATRIC INFORMA-
5 TION.—

6 “(1) IN GENERAL.—Not later than 180 days
7 after the date of submission of a report on a pedi-
8 atric study under this section, the Secretary shall
9 make available to the public the medical, statistical,
10 and clinical pharmacology reviews of pediatric stud-
11 ies conducted under subsection (b) or (c).

12 “(2) DISSEMINATION OF INFORMATION RE-
13 GARDING LABELING CHANGES.—Beginning on the
14 date of the enactment of the Best Pharmaceuticals
15 for Children Act of 2007, the Secretary shall include
16 as a requirement of a written request that the spon-
17 sors of the studies that result in labeling changes
18 that are reflected in the annual summary developed
19 pursuant to subsection (f)(3)(F) distribute, at least
20 annually (or more frequently if the Secretary deter-
21 mines that it would be beneficial to the public
22 health), such information to physicians and other
23 health care providers.

24 “(3) 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 “(l) ADVERSE EVENT REPORTING.—

4 “(1) REPORTING IN YEAR ONE.—Beginning on
5 the date of the enactment of the Best Pharma-
6 ceuticals for Children Act of 2007, during the one-
7 year period beginning on the date a labeling change
8 is approved pursuant to subsection (i), the Secretary
9 shall ensure that all adverse event reports that have
10 been received for such drug (regardless of when such
11 report was received) are referred to the Office of Pe-
12 diatric Therapeutics established under section 6 of
13 the Best Pharmaceuticals for Children Act (Public
14 Law 107–109). In considering the reports, the Di-
15 rector of such Office shall provide for the review of
16 the reports by the Pediatric Advisory Committee, in-
17 cluding obtaining any recommendations of such
18 Committee regarding whether the Secretary should
19 take action under this Act in response to such re-
20 ports.

21 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
22 lowing the one-year period described in paragraph
23 (1), the Secretary shall, as appropriate, refer to the
24 Office of Pediatric Therapeutics all pediatric adverse
25 event reports for a drug for which a pediatric study

1 was conducted under this section. In considering
2 such reports, the Director of such Office may pro-
3 vide for the review of such reports by the Pediatric
4 Advisory Committee, including obtaining any rec-
5 ommendation of such Committee regarding whether
6 the Secretary should take action in response to such
7 reports.

8 “(3) EFFECT.—The requirements of this sub-
9 section shall supplement, not supplant, other review
10 of such adverse event reports by the Secretary.

11 “(m) CLARIFICATION OF INTERACTION OF MARKET
12 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-
13 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL
14 OF A DRUG UNDER SECTION 505(j).—If a 180-day period
15 under section 505(j)(5)(B)(iv) overlaps with a 6-month ex-
16 clusivity period under this section, so that the applicant
17 for approval of a drug under section 505(j) entitled to the
18 180-day period under that section loses a portion of the
19 180-day period to which the applicant is entitled for the
20 drug, the 180-day period shall be extended from—

21 “(1) the date on which the 180-day period
22 would have expired by the number of days of the
23 overlap, if the 180-day period would, but for the ap-
24 plication of this subsection, expire after the 6-month
25 exclusivity period; or

1 “(2) the date on which the 6-month exclusivity
2 period expires, by the number of days of the overlap
3 if the 180-day period would, but for the application
4 of this subsection, expire during the six-month exclu-
5 sivity period.

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

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

17 “(A) for a drug 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 a drug that has no listed patents
22 or has 1 or more listed patents that have ex-
23 pired, determine whether there are funds avail-
24 able under section 736 to award a grant to con-

1 duct the requested studies pursuant to para-
2 graph (2).

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

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

16 “(A) a decision under paragraph (1)(A)
17 not to require an assessment under section
18 505B and the basis for such decision;

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

22 “(C) any decision under paragraph (2) to
23 include a drug on the list established under sec-
24 tion 409I of the Public Health Service Act.

1 “(4) EFFECT OF SUBSECTION.—Nothing in this
2 subsection alters or amends section 301(j) of this
3 Act or section 552 of title 5 or section 1905 of title
4 18, United States Code.

5 “(o) PROMPT APPROVAL OF DRUGS UNDER SECTION
6 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LA-
7 BELING.—

8 “(1) GENERAL RULE.—A drug for which an ap-
9 plication has been submitted or approved under sec-
10 tion 505(j) shall not be considered ineligible for ap-
11 proval under that section or misbranded under sec-
12 tion 502 on the basis that the labeling of the drug
13 omits a pediatric indication or any other aspect of
14 labeling pertaining to pediatric use when the omitted
15 indication or other aspect is protected by patent or
16 by exclusivity under clause (iii) or (iv) of section
17 505(j)(5)(F).

18 “(2) LABELING.—Notwithstanding clauses (iii)
19 and (iv) of section 505(j)(5)(F), the Secretary may
20 require that the labeling of a drug approved under
21 section 505(j) that omits a pediatric indication or
22 other aspect of labeling as described in paragraph
23 (1) include—

24 “(A) a statement that, because of mar-
25 keting exclusivity for a manufacturer—

1 “(i) the drug is not labeled for pedi-
2 atric use; or

3 “(ii) in the case of a drug for which
4 there is an additional pediatric use not re-
5 ferred to in paragraph (1), the drug is not
6 labeled for the pediatric use under para-
7 graph (1); and

8 “(B) a statement of any appropriate pedi-
9 atric contraindications, warnings, or pre-
10 cautions that the Secretary considers necessary.

11 “(3) PRESERVATION OF PEDIATRIC EXCLU-
12 SIVITY AND OTHER PROVISIONS.—This subsection
13 does not affect—

14 “(A) the availability or scope of exclusivity
15 under this section;

16 “(B) the availability or scope of exclusivity
17 under section 505 for pediatric formulations;

18 “(C) the question of the eligibility for ap-
19 proval of any application under section 505(j)
20 that omits any other conditions of approval en-
21 titled to exclusivity under clause (iii) or (iv) of
22 section 505(j)(5)(F); or

23 “(D) except as expressly provided in para-
24 graphs (1) and (2), the operation of section
25 505.

1 “(p) INSTITUTE OF MEDICINE STUDY.—Not later
2 than 3 years after the date of the enactment of the Best
3 Pharmaceuticals for Children Act of 2007, the Secretary
4 shall enter into a contract with the Institute of Medicine
5 to conduct a study and report to Congress regarding the
6 written requests made and the studies conducted pursuant
7 to this section. The Institute of Medicine may devise an
8 appropriate mechanism to review a representative sample
9 of requests made and studies conducted pursuant to this
10 section in order to conduct such study. Such study shall—

11 “(1) review such representative written requests
12 issued by the Secretary since 1997 under sub-
13 sections (b) and (c);

14 “(2) review and assess such representative pedi-
15 atric studies conducted under subsections (b) and (c)
16 since 1997 and labeling changes made as a result of
17 such studies;

18 “(3) review the use of extrapolation for pedi-
19 atric subpopulations, the use of alternative endpoints
20 for pediatric populations, neonatal assessment tools,
21 and ethical issues in pediatric clinical trials; and

22 “(4) make recommendations regarding appro-
23 priate incentives for encouraging pediatric studies of
24 biologics.

1 “(q) SUNSET.—A drug may not receive any 6-month
2 period under subsection (b) or (c) unless—

3 “(1) on or before October 1, 2012, the Sec-
4 retary makes a written request for pediatric studies
5 of the drug;

6 “(2) on or before October 1, 2012, an applica-
7 tion for the drug is accepted for filing under section
8 505(b); and

9 “(3) all requirements of this section are met.”.

10 (2) EFFECTIVE DATE.—The amendment made
11 by this subsection shall apply to written requests
12 under section 505A of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355a) made after the date
14 of the enactment of this Act.

15 (b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—
16 Section 409I of the Public Health Service Act (42 U.S.C.
17 284m) is amended to read as follows:

18 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

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

21 “(1) IN GENERAL.—Not later than one year
22 after the date of the enactment of the Best Pharma-
23 ceuticals for Children Act 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 three 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 subsection.

10 “(c) PROCESS FOR PROPOSED PEDIATRIC STUDY
11 REQUESTS AND LABELING CHANGES.—

12 “(1) SUBMISSION OF PROPOSED PEDIATRIC
13 STUDY REQUEST.—The Director of the National In-
14 stitutes of Health shall, as appropriate, submit pro-
15 posed pediatric study requests for consideration by
16 the Commissioner of Food and Drugs for pediatric
17 studies of a specific pediatric indication identified
18 under subsection (a). Such a proposed pediatric
19 study request shall be made in a manner equivalent
20 to a written request made under subsection (b) or
21 (c) of section 505A of the Federal Food, Drug, and
22 Cosmetic Act, including with respect to the informa-
23 tion provided on the pediatric studies to be con-
24 ducted pursuant to the request. The Director of the

1 National Institutes of Health may submit a pro-
2 posed pediatric study request for a drug for which—

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

6 “(ii) there is a submitted application that
7 could be approved under the criteria of such
8 section; and

9 “(B) there is no patent protection or mar-
10 ket exclusivity protection for at least one form
11 of the drug under the Federal Food, Drug, and
12 Cosmetic Act; and

13 “(C) additional studies are needed to as-
14 sess the safety and effectiveness of the use of
15 the drug in the pediatric population.

16 “(2) WRITTEN REQUEST TO HOLDERS OF AP-
17 PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-
18 SIVITY.—The Commissioner of Food and Drugs, in
19 consultation with the Director of the National Insti-
20 tutes of Health, may issue a written request based
21 on the proposed pediatric study request for the indi-
22 cation or indications submitted pursuant to para-
23 graph (1) (which shall include a timeframe for nego-
24 tiations for an agreement) for pediatric studies con-
25 cerning a drug identified under subsection (a) to all

1 holders of an approved application for the drug
2 under section 505 of the Federal Food, Drug, and
3 Cosmetic Act. Such a written request shall be made
4 in a manner equivalent to the manner in which a
5 written request is made under subsection (b) or (c)
6 of section 505A of such Act, including with respect
7 to information provided on the pediatric studies to
8 be conducted pursuant to the request and using ap-
9 propriate formulations for each age group for which
10 the study is requested.

11 “(3) REQUESTS FOR PROPOSALS.—If the Com-
12 missioner of Food and Drugs does not receive a re-
13 sponse to a written request issued under paragraph
14 (2) not later than 30 days after the date on which
15 a request was issued, the Secretary, acting through
16 the Director of the National Institutes of Health and
17 in consultation with the Commissioner of Food and
18 Drugs, shall publish a request for proposals to con-
19 duct the pediatric studies described in the written
20 request in accordance with subsection (b).

21 “(4) DISQUALIFICATION.—A holder that re-
22 ceives a first right of refusal shall not be entitled to
23 respond to a request for proposals under paragraph
24 (3).

1 “(5) CONTRACTS, GRANTS, OR OTHER FUNDING
2 MECHANISMS.—A contract, grant, or other funding
3 may be awarded under this section only if a proposal
4 is submitted to the Secretary in such form and man-
5 ner, and containing such agreements, assurances,
6 and information as the Secretary determines to be
7 necessary to carry out this section.

8 “(6) REPORTING OF STUDIES.—

9 “(A) IN GENERAL.—On completion of a
10 pediatric study in accordance with an award
11 under this section, a report concerning the
12 study shall be submitted to the Director of the
13 National Institutes of Health and the Commis-
14 sioner of Food and Drugs. The report shall in-
15 clude all data generated in connection with the
16 study, including a written request if issued.

17 “(B) AVAILABILITY OF REPORTS.—Each
18 report submitted under subparagraph (A) shall
19 be considered to be in the public domain (sub-
20 ject to section 505A(d)(4) of the Federal Food,
21 Drug, and Cosmetic Act) and shall be assigned
22 a docket number by the Commissioner of Food
23 and Drugs. An interested person may submit
24 written comments concerning such pediatric
25 studies to the Commissioner of Food and

1 Drugs, and the written comments shall become
2 part of the docket file with respect to each of
3 the drugs.

4 “(C) ACTION BY COMMISSIONER.—The
5 Commissioner of Food and Drugs shall take ap-
6 propriate action in response to the reports sub-
7 mitted under subparagraph (A) in accordance
8 with paragraph (7).

9 “(7) REQUESTS FOR LABELING CHANGE.—Dur-
10 ing the 180-day period after the date on which a re-
11 port is submitted under paragraph (6)(A), the Com-
12 missioner of Food and Drugs shall—

13 “(A) review the report and such other data
14 as are available concerning the safe and effec-
15 tive use in the pediatric population of the drug
16 studied;

17 “(B) negotiate with the holders of ap-
18 proved applications for the drug studied for any
19 labeling changes that the Commissioner of Food
20 and Drugs determines to be appropriate and re-
21 quests the holders to make; and

22 “(C)(i) place in the public docket file a
23 copy of the report and of any requested labeling
24 changes; and

1 “(ii) publish in the Federal Register and
2 through a posting on the website of the Food
3 and Drug Administration a summary of the re-
4 port and a copy of any requested labeling
5 changes.

6 “(8) DISPUTE RESOLUTION.—

7 “(A) REFERRAL TO PEDIATRIC ADVISORY
8 COMMITTEE.—If, not later than the end of the
9 180-day period specified in paragraph (7), the
10 holder of an approved application for the drug
11 involved does not agree to any labeling change
12 requested by the Commissioner of Food and
13 Drugs under that paragraph, the Commissioner
14 of Food and Drugs shall refer the request to
15 the Pediatric Advisory Committee.

16 “(B) ACTION BY THE PEDIATRIC ADVISORY
17 COMMITTEE.—Not later than 90 days after re-
18 ceiving a referral under subparagraph (A), the
19 Pediatric Advisory Committee shall—

20 “(i) review the available information
21 on the safe and effective use of the drug
22 in the pediatric population, including study
23 reports submitted under this section; and

1 “(ii) make a recommendation to the
2 Commissioner of Food and Drugs as to ap-
3 propriate labeling changes, if any.

4 “(9) FDA DETERMINATION.—Not later than 30
5 days after receiving a recommendation from the Pe-
6 diatric Advisory Committee under paragraph
7 (8)(B)(ii) with respect to a drug, the Commissioner
8 of Food and Drugs shall consider the recommenda-
9 tion and, if appropriate, make a request to the hold-
10 ers of approved applications for the drug to make
11 any labeling change that the Commissioner of Food
12 and Drugs determines to be appropriate.

13 “(10) FAILURE TO AGREE.—If a holder of an
14 approved application for a drug, within 30 days
15 after receiving a request to make a labeling change
16 under paragraph (9), does not agree to make a re-
17 quested labeling change, the Commissioner of Food
18 and Drugs may deem the drug to be misbranded
19 under the Federal Food, Drug, and Cosmetic Act.

20 “(11) NO EFFECT ON AUTHORITY.—Nothing in
21 this subsection limits the authority of the United
22 States to bring an enforcement action under the
23 Federal Food, Drug, and Cosmetic Act when a drug
24 lacks appropriate pediatric labeling. Neither course
25 of action (the Pediatric Advisory Committee process

1 or an enforcement action referred to in the pre-
2 ceding sentence) shall preclude, delay, or serve as
3 the basis to stay the other course of action.

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

11 “(e) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

21 (c) FEES RELATING TO DRUGS.—Section 735(6) of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 379(6)) is amended by adding at the end the following
24 new subparagraph:

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

4 (d) FOUNDATION FOR THE NATIONAL INSTITUTES
5 OF HEALTH.—Section 499(c)(1)(C) of the Public Health
6 Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by
7 striking “and studies listed by the Secretary pursuant to
8 section 409I(a)(1)(A) of this Act and referred under sec-
9 tion 505A(d)(4)(C) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 355(a)(d)(4)(C))”.

11 (e) CONTINUATION OF OPERATION OF COM-
12 MITTEE.—Section 14 of the Best Pharmaceuticals for
13 Children Act (42 U.S.C. 284m note) is amended by adding
14 at the end the following new subsection:

15 “(d) CONTINUATION OF OPERATION OF COM-
16 MITTEE.—Notwithstanding section 14 of the Federal Ad-
17 visory Committee Act, the advisory committee shall con-
18 tinue to operate during the five-year period beginning on
19 the date of the enactment of the Best Pharmaceuticals for
20 Children Act of 2007.”.

21 (f) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
22 DRUGS ADVISORY COMMITTEE.—Section 15 of the Best
23 Pharmaceuticals for Children Act (42 U.S.C. 284m note)
24 is amended—

25 (1) in subsection (a)—

1 (A) in paragraph (1)—

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

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

7 (iii) by adding at the end the fol-
8 lowing new subparagraph:

9 “(D) provide recommendations to the in-
10 ternal review committee created under section
11 505A(f) of the Federal Food, Drug, and Cos-
12 metic Act regarding the implementation of
13 amendments to sections 505A and 505B of the
14 Federal Food, Drug, and Cosmetic Act with re-
15 spect to the treatment of pediatric cancers.”;
16 and

17 (B) by adding at the end the following new
18 paragraph:

19 “(3) CONTINUATION OF OPERATION OF SUB-
20 COMMITTEE.—Notwithstanding section 14 of the
21 Federal Advisory Committee Act, the Subcommittee
22 shall continue to operate during the five-year period
23 beginning on the date of the enactment of the Best
24 Pharmaceuticals for Children Act of 2007.”; and

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

3 (g) EFFECTIVE DATE AND LIMITATION FOR RULE
4 RELATING TO TOLL-FREE NUMBER FOR ADVERSE
5 EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

6 (1) IN GENERAL.—Notwithstanding subchapter
7 II of chapter 5, and chapter 7, of title 5, United
8 States Code (commonly known as the “Administra-
9 tive Procedure Act”) and any other provision of law,
10 the proposed rule issued by the Commissioner of
11 Food and Drugs entitled “Toll-Free Number for Re-
12 porting Adverse Events on Labeling for Human
13 Drug Products,” 69 Fed. Reg. 21778, (April 22,
14 2004) shall take effect on January 1, 2008, unless
15 such Commissioner issues the final rule before such
16 date.

17 (2) LIMITATION.—The proposed rule that takes
18 effect under subsection (a), or the final rule de-
19 scribed under subsection (a), shall, notwithstanding
20 section 17(a) of the Best Pharmaceuticals for Chil-
21 dren Act (21 U.S.C. 355b(a)), not apply to a drug—

22 (A) for which an application is approved
23 under section 505 of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355);

1 (B) that is not described under section
 2 503(b)(1) of such Act (21 U.S.C. 353(b)(1));
 3 and

4 (C) the packaging of which includes a toll-
 5 free number through which consumers can re-
 6 port complaints to the manufacturer or dis-
 7 tributor of the drug.

8 **TITLE VI—REAGAN-UDALL** 9 **FOUNDATION**

10 **SEC. 601. THE REAGAN-UDALL FOUNDATION FOR THE** 11 **FOOD AND DRUG ADMINISTRATION.**

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

15 **“Subchapter I—Reagan-Udall Foundation for** 16 **the Food and Drug Administration**

17 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUN-** 18 **DATION.**

19 “(a) IN GENERAL.—A nonprofit corporation to be
 20 known as the Reagan-Udall Foundation for the Food and
 21 Drug Administration (referred to in this subchapter as the
 22 ‘Foundation’) shall be established in accordance with this
 23 section. The Foundation shall be headed by an Executive
 24 Director, appointed by the members of the Board of Direc-
 25 tors under subsection (e). The Foundation shall not be

1 an agency or instrumentality of the United States Govern-
2 ment.

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

8 “(c) DUTIES OF THE FOUNDATION.—The Founda-
9 tion shall—

10 “(1) taking into consideration the Critical Path
11 reports and priorities published by the Food and
12 Drug Administration, identify unmet needs in the
13 development, manufacture, and evaluation of the
14 safety and effectiveness, including postapproval, of
15 devices, including diagnostics, biologics, and drugs,
16 and the safety of food, food ingredients, and cos-
17 metics, and including the incorporation of more sen-
18 sitive and predictive tools and devices to measure
19 safety;

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

22 “(3) in consultation with the Secretary, identify
23 existing and proposed Federal intramural and extra-
24 mural research and development programs relating
25 to the goals and priorities established under para-

1 graph (2), coordinate Foundation activities with
2 such programs, and minimize Foundation duplication of existing efforts;
3

4 “(4) award grants to, or enter into contracts,
5 memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university
6 consortia, public-private partnerships, institutions of
7 higher education, entities described in section
8 501(c)(3) of the Internal Revenue Code (and exempt
9 from tax under section 501(a) of such Code), and
10 industry, to efficiently and effectively advance the
11 goals and priorities established under paragraph (2);
12

13 “(5) recruit meeting participants and hold or
14 sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established
15 under paragraph (2);
16

17 “(6) release and publish information and data
18 and, to the extent practicable, license, distribute,
19 and release material, reagents, and techniques to
20 maximize, promote, and coordinate the availability of
21 such material, reagents, and techniques for use by
22 the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers
23
24

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

3 “(7) ensure that—

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

7 “(B) action is taken as necessary to enable
8 the licensing of inventions developed by the
9 Foundation or with funds from the Foundation;
10 and

11 “(C) executed licenses, memoranda of un-
12 derstanding, material transfer agreements, con-
13 tracts, and other such instruments, promote, to
14 the maximum extent practicable, the broadest
15 conversion to commercial and noncommercial
16 applications of licensed and patented inventions
17 of the Foundation to further the goals and pri-
18 orities established under paragraph (2);

19 “(8) provide objective clinical and scientific in-
20 formation to the Food and Drug Administration
21 and, upon request, to other Federal agencies to as-
22 sist in agency determinations of how to ensure that
23 regulatory policy accommodates scientific advances
24 and meets the agency’s public health mission;

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

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

6 “(d) BOARD OF DIRECTORS.—

7 “(1) ESTABLISHMENT.—

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

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

17 “(i) The Commissioner.

18 “(ii) The Director of the National In-
19 stitutes of Health.

20 “(iii) The Director of the Centers for
21 Disease Control and Prevention.

22 “(iv) The Director of the Agency for
23 Healthcare Research and Quality.

24 “(C) APPOINTED MEMBERS.—

1 “(i) IN GENERAL.—The ex officio
2 members of the Board under subparagraph
3 (B) shall, by majority vote, appoint to the
4 Board 12 individuals, from a list of can-
5 didates to be provided by the National
6 Academy of Sciences. Of such appointed
7 members—

8 “(I) 4 shall be representatives of
9 the general pharmaceutical, device,
10 food, cosmetic, and biotechnology in-
11 dustries;

12 “(II) 3 shall be representatives of
13 academic research organizations;

14 “(III) 2 shall be representatives
15 of Government agencies, including the
16 Food and Drug Administration and
17 the National Institutes of Health;

18 “(IV) 2 shall be representatives
19 of patient or consumer advocacy orga-
20 nizations; and

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

23 “(ii) REQUIREMENT.—The ex officio
24 members shall ensure the Board member-
25 ship includes individuals with expertise in

1 areas including the sciences of developing,
2 manufacturing, and evaluating the safety
3 and effectiveness of devices, including
4 diagnostics, biologics, and drugs, and the
5 safety of food, food ingredients, and cos-
6 metics.

7 “(D) INITIAL MEETING.—

8 “(i) IN GENERAL.—Not later than 30
9 days after the date of the enactment of
10 this Act, the Secretary shall convene a
11 meeting of the ex officio members of the
12 Board to—

13 “(I) incorporate the Foundation;

14 and

15 “(II) appoint the members of the
16 Board in accordance with subpara-
17 graph (C).

18 “(ii) SERVICE OF EX OFFICIO MEM-
19 BERS.—Upon the appointment of the
20 members of the Board under clause (i)(II),
21 the terms of service of the ex officio mem-
22 bers of the Board as members of the
23 Board shall terminate.

24 “(iii) CHAIR.—The ex officio members
25 of the Board under subparagraph (B) shall

1 designate an appointed member of the
2 Board to serve as the Chair of the Board.

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

4 “(A) establish bylaws for the Foundation
5 that—

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

8 “(ii) establish policies for the selection
9 of the officers, employees, agents, and con-
10 tractors of the Foundation;

11 “(iii) establish policies, including eth-
12 ical standards, for the acceptance, sollicita-
13 tion, and disposition of donations and
14 grants to the Foundation and for the dis-
15 position of the assets of the Foundation,
16 including appropriate limits on the ability
17 of donors to designate, by stipulation or re-
18 striction, the use or recipient of donated
19 funds;

20 “(iv) establish policies that would sub-
21 ject all employees, fellows, and trainees of
22 the Foundation to the conflict of interest
23 standards under section 208 of title 18,
24 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 and may include charging cost-based fees
9 for published material produced by the
10 Foundation;

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

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

22 “(viii) establish policies for the execu-
23 tion of memoranda of understanding and
24 cooperative agreements between the Foun-

1 dation and other entities, including the
2 Food and Drug Administration;

3 “(ix) establish policies for funding
4 training fellowships, whether at the Foun-
5 dation, academic or scientific institutions,
6 or the Food and Drug Administration, for
7 scientists, doctors, and other professionals
8 who are not employees of regulated indus-
9 try, to foster greater understanding of and
10 expertise in new scientific tools,
11 diagnostics, manufacturing techniques, and
12 potential barriers to translating basic re-
13 search into clinical and regulatory practice;

14 “(x) specify a process for annual
15 Board review of the operations of the
16 Foundation; and

17 “(xi) establish specific duties of the
18 Executive Director;

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

21 “(C) evaluate the performance of the Exec-
22 utive Director; and

23 “(D) carry out any other necessary activi-
24 ties regarding the functioning of the Founda-
25 tion.

1 “(3) TERMS AND VACANCIES.—

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

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

10 “(i) shall not affect the power of the
11 remaining members to execute the duties
12 of the Board; and

13 “(ii) shall be filled by appointment by
14 the appointed members described in para-
15 graph (1)(C) by majority vote.

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

23 “(D) SERVING PAST TERM.—A member of
24 the Board may continue to serve after the expi-

1 ration of the term of the member until a suc-
2 cessor is appointed.

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

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

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

16 “(g) EXECUTIVE DIRECTOR.—

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

23 “(2) COMPENSATION.—The compensation of
24 the Executive Director shall be fixed by the Board

1 but shall not be greater than the compensation of
2 the Commissioner.

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

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

8 “(2) hire, promote, compensate, and discharge
9 1 or more officers, employees, and agents, as may be
10 necessary, and define their duties;

11 “(3) prescribe the manner in which—

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

14 “(B) general operations of the Foundation
15 are to be conducted; and

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

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

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

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

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

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

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

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

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

21 “(12) exercise other powers as set forth in this
22 section, and such other incidental powers as are nec-
23 essary to carry out its powers, duties, and functions
24 in accordance with this subchapter.

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

7 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
8 Government employees may serve on committees advisory
9 to the Foundation and otherwise cooperate with and assist
10 the Foundation in carrying out its functions, so long as
11 such employees do not direct or control Foundation activi-
12 ties.

13 “(k) DETAIL OF GOVERNMENT EMPLOYEES; FEL-
14 LOWSHIPS.—

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

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

3 “(A) FOUNDATION.—The Executive Direc-
4 tor of the Foundation may accept the services
5 of employees detailed from Federal agencies
6 with or without reimbursement to those agen-
7 cies.

8 “(B) FOOD AND DRUG ADMINISTRATION.—
9 The Commissioner may accept the uncompen-
10 sated services of Foundation fellows or trainees.
11 Such services shall be considered to be under-
12 taking an activity under contract with the Sec-
13 retary as described in section 708.

14 “(1) ANNUAL REPORTS.—

15 “(1) REPORTS TO FOUNDATION.—Any recipient
16 of a grant, contract, fellowship, memorandum of un-
17 derstanding, or cooperative agreement from the
18 Foundation under this section shall submit to the
19 Foundation a report on an annual basis for the du-
20 ration of such grant, contract, fellowship, memo-
21 randum of understanding, or cooperative agreement,
22 that describes the activities carried out under such
23 grant, contract, fellowship, memorandum of under-
24 standing, or cooperative agreement.

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

5 “(A) describes the activities of the Foun-
6 dation and the progress of the Foundation in
7 furthering the goals and priorities established
8 under subsection (c)(2), including the practical
9 impact of the Foundation on regulated product
10 development;

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

14 “(C) provides information on how the re-
15 sults of Foundation activities could be incor-
16 porated into the regulatory and product review
17 activities of the Food and Drug Administration.

18 “(m) SEPARATION OF FUNDS.—The Executive Di-
19 rector shall ensure that the funds received from the Treas-
20 ury are held in separate accounts from funds received
21 from entities under subsection (i).

22 “(n) FUNDING.—From amounts appropriated to the
23 Food and Drug Administration for each fiscal year, the
24 Commissioner shall transfer not less than \$500,000 and

1 not more than \$1,250,000, to the Foundation to carry out
2 subsections (a), (b), and (d) through (m).”.

3 (b) OTHER FOUNDATION PROVISIONS.—Chapter VII
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 371 et seq.) (as amended by subsection (a)) is amended
6 by adding at the end the following:

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

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

10 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
11 **TRATION.**

12 “(a) IN GENERAL.—The Commissioner shall receive
13 and assess the report submitted to the Commissioner by
14 the Executive Director of the Foundation under section
15 770(l)(2).

16 “(b) REPORT TO CONGRESS.—Beginning with fiscal
17 year 2009, the Commissioner shall submit to Congress an
18 annual report summarizing the incorporation of the infor-
19 mation provided by the Foundation in the report described
20 under section 770(l)(2) and by other recipients of grants,
21 contracts, memoranda of understanding, or cooperative
22 agreements into regulatory and product review activities
23 of the Food and Drug Administration.

24 “(c) EXTRAMURAL GRANTS.—The provisions of this
25 subchapter shall have no effect on any grant, contract,

1 memorandum of understanding, or cooperative agreement
2 between the Food and Drug Administration and any other
3 entity entered into before, on, or after the date of enact-
4 ment of this subchapter.”.

5 (c) CONFORMING AMENDMENT.—Section 742(b) of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 379l(b)) is amended by adding at the end the following:
8 “Any such fellowships and training programs under this
9 section or under section 770(d)(2)(A)(ix) may include pro-
10 vision by such scientists and physicians of services on a
11 voluntary and uncompensated basis, as the Secretary de-
12 termines appropriate. Such scientists and physicians shall
13 be subject to all legal and ethical requirements otherwise
14 applicable to officers or employees of the Department of
15 Health and Human Services.”.

16 **SEC. 602. OFFICE OF THE CHIEF SCIENTIST.**

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

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

21 “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-
22 retary shall establish within the Office of the Commis-
23 sioner an office to be known as the Office of the Chief
24 Scientist. The Secretary shall appoint a Chief Scientist to
25 lead such Office.

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

3 “(1) oversee, coordinate, and ensure quality and
4 regulatory focus of the intramural research pro-
5 grams of the Food and Drug Administration;

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

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

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

17 “(5) identify and solicit intramural research
18 proposals from across the Food and Drug Adminis-
19 tration through an advisory board composed of em-
20 ployees of the Administration that shall include—

21 “(A) representatives of each of the centers
22 and the science-based offices within the Office
23 of the Commissioner; and

1 “(B) experts on trial design, epidemiology,
2 demographics, pharmacovigilance, basic science,
3 and public health.”.

4 **SEC. 603. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.**

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

8 **“SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNER-**
9 **SHIPS.**

10 “(a) ESTABLISHMENT.—The Secretary, acting
11 through the Commissioner of Food and Drugs, shall enter
12 into collaborative agreements, to be known as Critical
13 Path Public-Private Partnerships, with one or more eligi-
14 ble entities to implement the Critical Path Initiative of the
15 Food and Drug Administration by developing innovative,
16 collaborative projects in research, education, and outreach
17 for the purpose of fostering medical product innovation,
18 enabling the acceleration of medical product development,
19 and enhancing medical product safety.

20 “(b) ELIGIBLE ENTITY.—In this section, the term
21 ‘eligible entity’ means an entity that meets each of the
22 following:

23 “(1) The entity is—

1 “(A) an institution of higher education (as
2 such term is defined in section 101 of the High-
3 er Education Act of 1965); or

4 “(B) an organization described in section
5 501(c)(3) of the Internal Revenue Code of 1986
6 and exempt from tax under section 501(a) of
7 such Code.

8 “(2) The entity has experienced personnel and
9 clinical and other technical expertise in the bio-
10 medical sciences.

11 “(3) The entity demonstrates to the Secretary’s
12 satisfaction that the entity is capable of—

13 “(A) developing and critically evaluating
14 tools, methods, and processes—

15 “(i) to increase efficiency, predict-
16 ability, and productivity of medical product
17 development; and

18 “(ii) to more accurately identify the
19 benefits and risks of new and existing med-
20 ical products;

21 “(B) establishing partnerships, consortia,
22 and collaborations with health care practitioners
23 and other providers of health care goods or
24 services; pharmacists; pharmacy benefit man-
25 agers and purchasers; health maintenance orga-

1 nizations and other managed health care orga-
2 nizations; health care insurers; government
3 agencies; patients and consumers; manufactur-
4 ers of prescription drugs, biological products,
5 diagnostic technologies, and devices; and aca-
6 demic scientists; and

7 “(C) securing funding for the projects of a
8 Critical Path Public-Private Partnership from
9 Federal and nonfederal governmental sources,
10 foundations, and private individuals.

11 “(c) FUNDING.—The Secretary may not enter into
12 a collaborative agreement under subsection (a) unless the
13 eligible entity involved provides an assurance that the enti-
14 ty will not accept funding for a Critical Path Public-Pri-
15 vate Partnership project from any organization that man-
16 ufactures or distributes products regulated by the Food
17 and Drug Administration unless—

18 “(1) the entity accepts such funding for such
19 project from 2 or more such organizations; and

20 “(2) the entity provides assurances in its agree-
21 ment with the Food and Drug Administration that
22 the results of the Critical Path Public-Private Part-
23 nership project will not be influenced by any source
24 of funding.

1 “(d) ANNUAL REPORT.—Not later than 18 months
2 after the date of the enactment of this section, and annu-
3 ally thereafter, the Secretary, in collaboration with the
4 parties to each Critical Path Public-Private Partnership,
5 shall submit a report to the Committee on Health, Edu-
6 cation, Labor, and Pensions of the Senate and the Com-
7 mittee on Energy and Commerce of the House of Rep-
8 resentatives—

9 “(1) reviewing the operations and activities of
10 the Partnerships in the previous year; and

11 “(2) addressing such other issues relating to
12 this section as the Secretary determines to be appro-
13 priate.

14 “(e) DEFINITION.—In this section, the term ‘medical
15 product’ includes a drug, a biological product, a device,
16 and any combination of such products.

17 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
18 carry out this section, there are authorized to be appro-
19 priated \$5,000,000 for fiscal year 2008 and such sums
20 as may be necessary for each of fiscal years 2009 through
21 2012.”.

TITLE VII—CONFLICTS OF INTEREST

SEC. 701. CONFLICTS OF INTEREST.

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

“SEC. 712. CONFLICTS OF INTEREST.

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

“(1) ADVISORY COMMITTEE.—The term ‘advisory committee’ means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

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

“(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

“(1) RECRUITMENT.—

“(A) IN GENERAL.—Given the importance of advisory committees to the review process at the Food and Drug Administration, the Secretary, through the Office of Women’s Health, the Office of Orphan Product Development, the Office of Pediatric Therapeutics, and other offices within the Food and Drug Administration

1 with relevant expertise, shall develop and imple-
2 ment strategies on effective outreach to poten-
3 tial members of advisory committees at univer-
4 sities, colleges, other academic research centers,
5 professional and medical societies, and patient
6 and consumer groups. The Secretary shall seek
7 input from professional medical and scientific
8 societies to determine the most effective infor-
9 mational and recruitment activities. The Sec-
10 retary shall also take into account the advisory
11 committees with the greatest number of vacan-
12 cies.

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

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

19 “(ii) making widely available, includ-
20 ing by using existing electronic commu-
21 nications channels, the contact information
22 for the Food and Drug Administration
23 point of contact regarding advisory com-
24 mittee nominations; and

1 “(iii) developing a method through
2 which an entity receiving funding from the
3 National Institutes of Health, the Agency
4 for Healthcare Research and Quality, the
5 Centers for Disease Control and Preven-
6 tion, or the Veterans Health Administra-
7 tion can identify a person who the Food
8 and Drug Administration can contact re-
9 garding the nomination of individuals to
10 serve on advisory committees.

11 “(2) EVALUATION AND CRITERIA.—When con-
12 sidering a term appointment to an advisory com-
13 mittee, the Secretary shall review the expertise of
14 the individual and the financial disclosure report
15 filed by the individual pursuant to the Ethics in
16 Government Act of 1978 for each individual under
17 consideration for the appointment, so as to reduce
18 the likelihood that an appointed individual will later
19 require a written determination as referred to in sec-
20 tion 208(b)(1) of title 18, United States Code, a
21 written certification as referred to in section
22 208(b)(3) of title 18, United States Code, or a waiv-
23 er as referred to in subsection (c)(3) of this section
24 for service on the committee at a meeting of the
25 committee.

1 “(3) PARTICIPATION OF GUEST EXPERT WITH
2 FINANCIAL INTEREST.—Notwithstanding any other
3 provision of this section, an individual with a finan-
4 cial interest with respect to any matter considered
5 by an advisory committee may be allowed to partici-
6 pate in a meeting of an advisory committee as a
7 guest expert if the Secretary determines that the in-
8 dividual has particular expertise required for the
9 meeting. An individual participating as a guest ex-
10 pert may provide information and expert opinion,
11 but shall not participate in the discussion or voting
12 by the members of the advisory committee.

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

14 “(1) IN GENERAL.—Prior to a meeting of an
15 advisory committee regarding a ‘particular matter’
16 (as that term is used in section 208 of title 18,
17 United States Code), each member of the committee
18 who is a full-time Government employee or special
19 Government employee shall disclose to the Secretary
20 financial interests in accordance with subsection (b)
21 of such section 208.

22 “(2) FINANCIAL INTEREST OF ADVISORY COM-
23 MITTEE MEMBER OR FAMILY MEMBER.—No member
24 of an advisory committee may vote with respect to
25 any matter considered by the advisory committee if

1 such member (or an immediate family member of
2 such member) has a financial interest that could be
3 affected by the advice given to the Secretary with re-
4 spect to such matter, excluding interests exempted
5 in regulations issued by the Director of the Office of
6 Government Ethics as too remote or inconsequential
7 to affect the integrity of the services of the Govern-
8 ment officers or employees to which such regulations
9 apply.

10 “(3) WAIVER.—The Secretary may grant a
11 waiver of the prohibition in paragraph (2) if such
12 waiver is necessary to afford the advisory committee
13 essential expertise.

14 “(4) LIMITATIONS.—

15 “(A) ONE WAIVER PER COMMITTEE MEET-
16 ING.—Notwithstanding any other provision of
17 this section, with respect to each advisory com-
18 mittee, the Secretary shall not grant more than
19 1 waiver under paragraph (3) per committee
20 meeting.

21 “(B) SCIENTIFIC WORK.—The Secretary
22 may not grant a waiver under paragraph (3)
23 for a member of an advisory committee when
24 the member’s own scientific work is involved.

1 “(5) DISCLOSURE OF WAIVER.—Notwith-
2 standing section 107(a)(2) of the Ethics in Govern-
3 ment Act (5 U.S.C. App.), the following shall apply:

4 “(A) 15 OR MORE DAYS IN ADVANCE.—As
5 soon as practicable, but in no case later than
6 15 days prior to a meeting of an advisory com-
7 mittee to which a written determination as re-
8 ferred to in section 208(b)(1) of title 18, United
9 States Code, a written certification as referred
10 to in section 208(b)(3) of title 18, United
11 States Code, or a waiver as referred to in para-
12 graph (3) applies, the Secretary shall disclose
13 (other than information exempted from disclo-
14 sure under section 552 of title 5, United States
15 Code, and section 552a of title 5, United States
16 Code (popularly known as the Freedom of In-
17 formation Act and the Privacy Act of 1974, re-
18 spectively)) on the Internet website of the Food
19 and Drug Administration—

20 “(i) the type, nature, and magnitude
21 of the financial interests of the advisory
22 committee member to which such deter-
23 mination, certification, or waiver applies;
24 and

1 “(ii) the reasons of the Secretary for
2 such determination, certification, or waiv-
3 er.

4 “(B) LESS THAN 30 DAYS IN ADVANCE.—

5 In the case of a financial interest that becomes
6 known to the Secretary less than 30 days prior
7 to a meeting of an advisory committee to which
8 a written determination as referred to in section
9 208(b)(1) of title 18, United States Code, a
10 written certification as referred to in section
11 208(b)(3) of title 18, United States Code, or a
12 waiver as referred to in paragraph (3) applies,
13 the Secretary shall disclose (other than infor-
14 mation exempted from disclosure under section
15 552 of title 5, United States Code, and section
16 552a of title 5, United States Code) on the
17 Internet website of the Food and Drug Admin-
18 istration, the information described in clauses
19 (i) and (ii) of subparagraph (A) as soon as
20 practicable after the Secretary makes such de-
21 termination, certification, or waiver, but in no
22 case later than the date of such meeting.

23 “(d) PUBLIC RECORD.—The Secretary shall ensure
24 that the public record and transcript of each meeting of
25 an advisory committee includes the disclosure required

1 under subsection (c)(5) (other than information exempted
2 from disclosure under section 552 of title 5, United States
3 Code, and section 552a of title 5, United States Code).

4 “(e) ANNUAL REPORT.—Not later than February 1
5 of each year, the Secretary shall submit to the Committee
6 on Appropriations and the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate, and the Com-
8 mittee on Appropriations and the Committee on Energy
9 and Commerce of the House of Representatives a report
10 that describes—

11 “(1) with respect to the fiscal year that ended
12 on September 30 of the previous year, the number
13 of vacancies on each advisory committee, the number
14 of nominees received for each committee, and the
15 number of such nominees willing to serve;

16 “(2) with respect to such year, the aggregate
17 number of disclosures required under subsection
18 (c)(5) for each meeting of each advisory committee
19 and the percentage of individuals to whom such dis-
20 closures did not apply who served on such committee
21 for each such meeting;

22 “(3) with respect to such year, the number of
23 times the disclosures required under subsection
24 (c)(5) occurred under subparagraph (B) of such sub-
25 section; and

1 “(4) how the Secretary plans to reduce the
2 number of vacancies reported under paragraph (1)
3 during the fiscal year following such year, and mech-
4 anisms to encourage the nomination of individuals
5 for service on an advisory committee, including those
6 who are classified by the Food and Drug Adminis-
7 tration as academicians or practitioners.

8 “(f) PERIODIC REVIEW OF GUIDANCE.—Not less
9 than once every 5 years, the Secretary shall review guid-
10 ance of the Food and Drug Administration regarding con-
11 flict of interest waiver determinations with respect to advi-
12 sory committees and update such guidance as necessary.”.

13 (b) CONFORMING AMENDMENT.—Section 505(n) of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355(n)) is amended—

16 (1) by striking paragraph (4); and

17 (2) by redesignating paragraphs (5), (6), (7),
18 and (8) as paragraphs (4), (5), (6), and (7), respec-
19 tively.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall take effect on October 1, 2007.

1 **TITLE VIII—CLINICAL TRIAL**
2 **DATABASES**

3 **SEC. 801. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-**
4 **ICAL TRIAL RESULTS DATABASE.**

5 (a) IN GENERAL.—Title IV of the Public Health
6 Service Act (42 U.S.C. 281 et seq.) is amended—

7 (1) in section 402, by striking subsection (i);

8 and

9 (2) by inserting after section 492B the fol-
10 lowing new section:

11 **“SEC. 492C. CLINICAL TRIAL REGISTRY DATABASE; CLIN-**
12 **ICAL TRIAL RESULTS DATABASE.**

13 “(a) DEFINITIONS.—In this section:

14 “(1) APPLICABLE CLINICAL TRIAL.—The term
15 ‘applicable clinical trial’—

16 “(A) means a clinical trial that is con-
17 ducted to test the safety or effectiveness (in-
18 cluding comparative effectiveness) of a drug or
19 device (irrespective of whether the clinical trial
20 is federally or privately funded, and whether the
21 clinical trial involves an approved or unap-
22 proved drug or device);

23 “(B) includes such a clinical trial that is
24 conducted outside of the United States if—

1 “(i) there is an application or pre-
2 market notification pending before the
3 Food and Drug Administration for ap-
4 proval or clearance of the drug or device
5 involved under section 505, 510(k), or 515
6 of the Federal Food, Drug, and Cosmetic
7 Act or section 351 of this Act; or

8 “(ii) the drug or device involved is so
9 approved or cleared; and

10 “(C) notwithstanding subparagraphs (A)
11 and (B), excludes—

12 “(i) a clinical trial to determine the
13 safety of a use of a drug that is designed
14 solely to detect major toxicities in the drug
15 or to investigate pharmacokinetics, unless
16 the clinical trial is designed to investigate
17 pharmacokinetics in a special population or
18 populations; and

19 “(ii) a small clinical trial to determine
20 the feasibility of a device, or a clinical trial
21 to test prototype devices where the primary
22 focus is feasibility.

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

1 ical trial registry database under subsection (b) or
2 the clinical trial results database under subsection
3 (c), as applicable.

4 “(3) COMPLETION DATE.—The term ‘comple-
5 tion date’ means the date of the final collection of
6 data from subjects in the clinical trial for the pri-
7 mary and secondary outcomes to be examined in the
8 trial.

9 “(4) DEVICE.—The term ‘device’ has the mean-
10 ing given to that term in section 201(h) of the Fed-
11 eral Food, Drug, and Cosmetic Act.

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

16 “(6) RESPONSIBLE PARTY.—The term ‘respon-
17 sible party’, with respect to an applicable clinical
18 trial, means—

19 “(A) the primary sponsor (as defined in
20 the International Clinical Trials Registry Plat-
21 form trial registration data set of the World
22 Health Organization) of the clinical trial; or

23 “(B) the principal investigator of such clin-
24 ical trial if so designated by such sponsor, so
25 long as the principal investigator is responsible

1 for conducting the trial, has access to and con-
2 trol over the data, has the right to publish the
3 results of the trial, and has the responsibility to
4 meet all of the requirements under this section
5 that are applicable to responsible parties.

6 “(b) CLINICAL TRIALS REGISTRY DATABASE.—

7 “(1) ESTABLISHMENT.—To enhance patient en-
8 rollment and provide a mechanism to track subse-
9 quent progress of clinical trials, the Secretary, act-
10 ing through the Director of NIH, shall establish and
11 administer a clinical trial registry database in ac-
12 cordance with this section (referred to in this section
13 as the ‘registry database’). The Director of NIH
14 shall ensure that the registry database is made pub-
15 licly available through the Internet.

16 “(2) CONTENT.—The Secretary shall promul-
17 gate regulations for the submission to the registry
18 database of clinical trial information that—

19 “(A) conforms to the International Clinical
20 Trials Registry Platform trial registration data
21 set of the World Health Organization;

22 “(B) includes the city, State, and zip code
23 for each clinical trial location or a toll free
24 number through which such location informa-
25 tion may be accessed;

1 “(C) includes a statement of the estimated
2 completion date for the clinical trial;

3 “(D) includes the identity and contact in-
4 formation of the responsible party;

5 “(E) if the drug is not approved under sec-
6 tion 505 of the Federal Food, Drug, and Cos-
7 metic Act or licensed under section 351 of this
8 Act, or the device is not cleared under section
9 510(k) or approved under section 515 of the
10 Federal Food, Drug, and Cosmetic Act, speci-
11 fies whether or not there is expanded access to
12 the drug or device under section 561 of the
13 Federal Food, Drug, and Cosmetic Act for
14 those who do not qualify for enrollment in the
15 clinical trial and how to obtain information
16 about such access;

17 “(F) includes, with respect to any indi-
18 vidual who is not an employee of the responsible
19 party for the clinical trial or of the manufac-
20 turer of the drug or device involved, information
21 on whether the responsible party or manufac-
22 turer has entered into any agreement with such
23 individual that restricts in any manner the abil-
24 ity of the individual—

1 “(i) to discuss the results of the trial
2 at a scientific meeting or any other public
3 or private forum; or

4 “(ii) to publish the results of the trial,
5 or a description or discussion of the results
6 of the trial, in a scientific or academic
7 journal; and

8 “(G) requires the inclusion of such other
9 data elements to the registry database as ap-
10 propriate.

11 “(3) FORMAT AND STRUCTURE.—

12 “(A) SEARCHABLE CATEGORIES.—The Di-
13 rector of NIH shall ensure that the public may
14 search the entries in the registry database by 1
15 or more of the following criteria:

16 “(i) The indication being studied in
17 the clinical trial, using Medical Subject
18 Headers (MeSH) descriptors.

19 “(ii) The safety issue being studied in
20 the clinical trial.

21 “(iii) The enrollment status of the
22 clinical trial.

23 “(iv) The sponsor of the clinical trial.

24 “(B) FORMAT.—The Director of the NIH
25 shall ensure that the registry database is easily

1 used by patients, and that entries are easily
2 compared.

3 “(4) DATA SUBMISSION.—The responsible party
4 for an applicable clinical trial shall submit to the Di-
5 rector of NIH for inclusion in the registry database
6 the clinical trial information described in paragraph
7 (2).

8 “(5) TRUTHFUL CLINICAL TRIAL INFORMA-
9 TION.—

10 “(A) IN GENERAL.—The clinical trial in-
11 formation submitted by a responsible party
12 under this subsection shall not be false or mis-
13 leading.

14 “(B) EFFECT.—Subparagraph (A) shall
15 not have the effect of requiring clinical trial in-
16 formation to include information from any
17 source other than the clinical trial involved.

18 “(6) TIMING OF SUBMISSION.—Except as pro-
19 vided in paragraph (7), the clinical trial information
20 for a clinical trial required to be submitted under
21 this subsection shall be submitted not later than 14
22 days after the first patient is enrolled in such clin-
23 ical trial.

24 “(7) UPDATES.—The responsible party for an
25 applicable clinical trial shall submit to the Director

1 of NIH for inclusion in the registry database peri-
2 odic updates to reflect changes to the clinical trial
3 information submitted under this subsection. Such
4 updates—

5 “(A) shall be provided not less than once
6 every 6 months until information on the results
7 of the trial is submitted under subsection (c);

8 “(B) shall include identification of the
9 dates of any such changes;

10 “(C) not later than 30 days after the en-
11 rollment status of such clinical trial changes,
12 shall include an update of the enrollment sta-
13 tus; and

14 “(D) not later than 30 days after the com-
15 pletion date of the clinical trial, shall include a
16 report to the Director that such clinical trial is
17 complete.

18 “(8) APPLICABILITY OF DEVICE TRIALS.—In
19 the case of an applicable clinical trial regarding a
20 device, the responsible person for the trial shall sub-
21 mit to the Director of NIH the clinical trial informa-
22 tion as required in paragraph (4), but the Director
23 may not make the information publicly available
24 through the registry database until the device is ap-
25 proved or cleared (as the case may be).

1 “(c) CLINICAL TRIALS RESULTS DATABASE.—

2 “(1) ESTABLISHMENT.—To ensure that results
3 of clinical trials are made public and that patients
4 and providers have current information regarding
5 the results of clinical trials, the Secretary, acting
6 through the Director of NIH, shall establish and ad-
7 minister a clinical trial results database in accord-
8 ance with this section (referred to in this section as
9 the ‘results database’). The Director of NIH shall
10 ensure that the results database is made publicly
11 available through the Internet.

12 “(2) SEARCHABLE CATEGORIES.—The Director
13 of NIH shall ensure that the public may search the
14 entries in the results database by 1 or more of the
15 following:

16 “(A) The indication studied in the clinical
17 trial, using Medical Subject Headers (MeSH)
18 descriptors.

19 “(B) The safety issue studied in the clin-
20 ical trial.

21 “(C) Whether an application for the tested
22 indication is approved, pending approval, with-
23 drawn, or not submitted.

24 “(D) The phase of the clinical trial.

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

3 “(F) Within the documents described in
4 clauses (i) and (ii) of paragraph (3)(B), the fol-
5 lowing information, as applicable:

6 “(i) The sponsor of the clinical trial.

7 “(ii) Each financial sponsor of the
8 clinical trial.

9 “(3) CONTENTS.—

10 “(A) IN GENERAL.—The responsible party
11 for an applicable clinical trial shall submit to
12 the Director of NIH for inclusion in the results
13 database the clinical trial information described
14 in subparagraph (B).

15 “(B) REQUIRED ELEMENTS.—In submit-
16 ting clinical trial information for a clinical trial
17 to the Director of NIH for inclusion in the re-
18 sults database, the responsible party shall in-
19 clude, with respect to such clinical trial, the fol-
20 lowing information:

21 “(i) The information described in sub-
22 paragraphs (A) through (E) of subsection
23 (b)(2).

1 “(ii) A summary that is written in
2 non-technical, understandable language for
3 patients that includes the following:

4 “(I) The purpose of the clinical
5 trial.

6 “(II) The sponsor of the clinical
7 trial.

8 “(III) A point of contact for in-
9 formation about the clinical trial.

10 “(IV) A description of the patient
11 population tested in the clinical trial.

12 “(V) A general description of the
13 clinical trial and results, including a
14 description of and the reasons for any
15 changes in the clinical trial design
16 that occurred since the date of sub-
17 mission of clinical trial information
18 for inclusion in the registry database
19 established under subsection (b) and a
20 description of any significant safety
21 information.

22 “(iii) A summary that is technical in
23 nature that includes the following:

24 “(I) The purpose of the clinical
25 trial.

1 “(II) The sponsor of the clinical
2 trial.

3 “(III) Each financial sponsor of
4 the clinical trial.

5 “(IV) A point of contact for sci-
6 entific information about the clinical
7 trial.

8 “(V) A description of the patient
9 population tested in the clinical trial.

10 “(VI) A general description of
11 the clinical trial and results, including
12 a description of and the reasons for
13 any changes in the clinical trial design
14 that occurred since the date of sub-
15 mission of clinical trial information
16 for the clinical trial in the registry
17 database established under subsection
18 (b).

19 “(VII) Summary data describing
20 the results, including—

21 “(aa) whether the primary
22 endpoint was achieved, including
23 relevant statistics;

24 “(bb) an assessment of any
25 secondary endpoints, if applica-

1 ble, including relevant statistics;
2 and

3 “(cc) any significant safety
4 information, including a sum-
5 mary of the incidence of serious
6 adverse events observed in the
7 clinical trial and a summary of
8 the most common adverse events
9 observed in the clinical trial and
10 the frequencies of such events.

11 “(iv) With respect to the group of
12 subjects receiving the drug or device in-
13 volved, and each comparison group of sub-
14 jects, the percentage of individuals who
15 ceased participation as subjects and the
16 reasons for ceasing participation.

17 “(v) With respect to an individual who
18 is not an employee of the responsible party
19 for the clinical trial or of the manufacturer
20 of the drug or device involved, information
21 (to the extent not submitted under sub-
22 section (b)(2)(F)) on any agreement that
23 the responsible party or manufacturer has
24 entered into with such individual that re-

1 stricts in any manner the ability of the in-
2 dividual—

3 “(I) to discuss the results of the
4 trial at a scientific meeting or any
5 other public or private forum; or

6 “(II) to publish the results of the
7 trial, or a description or discussion of
8 the results of the trial, in a scientific
9 or academic journal.

10 “(vi) The completion date of the clin-
11 ical trial.

12 “(vii) A link to the Internet web post-
13 ing of any adverse regulatory actions taken
14 by the Food and Drug Administration,
15 such as a warning letter, that was sub-
16 stantively based on the clinical trial design,
17 outcome, or representation made by the
18 applicant about the design or outcome of
19 the clinical trial.

20 “(C) LINKS IN DATABASE.—The Director
21 of NIH shall ensure that the results database
22 includes the following:

23 “(i) Links to Medline citations to pub-
24 lications reporting results from each appli-

1 cable drug clinical trial and applicable de-
2 vice clinical trial.

3 “(ii) Links to the entry for the prod-
4 uct that is the subject of an applicable
5 drug clinical trial in the National Library
6 of Medicine database of structured product
7 labels, if available.

8 “(iii) Links described in clauses (i)
9 and (ii) for data bank entries for clinical
10 trials submitted to the data bank prior to
11 enactment of this section, as available.

12 “(4) TIMING.—

13 “(A) IN GENERAL.—Except as provided in
14 subparagraphs (B) and (C), a responsible party
15 shall submit to the Director of NIH for inclu-
16 sion in the results database clinical trial infor-
17 mation for an applicable clinical trial not later
18 than 1 year after the earlier of—

19 “(i) the estimated completion date of
20 the trial, as submitted under subsection
21 (b)(2); or

22 “(ii) the actual date of the completion,
23 or termination before completion, of the
24 trial, as applicable.

1 “(B) EXTENSIONS.—The Director of NIH
2 may provide an extension of the deadline for
3 submission of clinical trial information under
4 subparagraph (A) if the responsible party for
5 the trial submits to the Director a written re-
6 quest that demonstrates good cause for the ex-
7 tension and provides an estimate of the date on
8 which the information will be submitted. The
9 Director of NIH may grant more than one such
10 extension for the clinical trial involved.

11 “(C) UPDATES.—The responsible party for
12 an applicable clinical trial shall submit to the
13 Director of NIH for inclusion in the results
14 database periodic updates to reflect changes in
15 the clinical trial information submitted under
16 this subsection. Such updates—

17 “(i) shall be provided not less fre-
18 quently than once every 6 months during
19 the 10-year period beginning on the date
20 on which information is due under sub-
21 paragraph (A);

22 “(ii) shall identify the dates on which
23 the changes were made; and

24 “(iii) shall include, not later than 30
25 days after any change in the regulatory

1 status of the drug or device involved, an
2 update informing the Director of NIH of
3 such change.

4 “(5) TRUTHFUL CLINICAL TRIAL INFORMA-
5 TION.—

6 “(A) IN GENERAL.—The clinical trial in-
7 formation submitted by a responsible party
8 under this subsection shall not be false or mis-
9 leading in any particular.

10 “(B) EFFECT.—Subparagraph (A) shall
11 not have the effect of requiring clinical trial in-
12 formation with respect to a clinical trial to in-
13 clude information from any source other than
14 such clinical trial.

15 “(6) PUBLIC AVAILABILITY OF RESULTS.—

16 “(A) PRE-APPROVAL STUDIES.—Except as
17 provided in subparagraph (E), with respect to
18 an applicable clinical trial that is completed be-
19 fore the drug is initially approved under section
20 505 of the Federal Food, Drug, and Cosmetic
21 Act or initially licensed under section 351 of
22 this Act, or the device is initially cleared under
23 section 510(k) or approved under section 515 of
24 the Federal Food, Drug, and Cosmetic Act, the
25 Director of NIH shall make publicly available

1 on the results database the clinical trial infor-
2 mation submitted for such clinical trial not
3 later than 30 days after—

4 “(i) the drug or device is approved
5 under such section 505, licensed under
6 such section 351, cleared under such sec-
7 tion 510(k), or approved under such sec-
8 tion 515, as applicable; or

9 “(ii) the Secretary issues a not ap-
10 provable letter or a not substantially equiv-
11 alent letter for the drug or device under
12 such section 505, 351, 510(k), or 515, as
13 applicable.

14 “(B) MEDICAL AND CLINICAL PHARMA-
15 COLOGY REVIEWS OF PRE-APPROVAL STUD-
16 IES.—Not later than 90 days after the date ap-
17 plicable under clause (i) or (ii) of subparagraph
18 (A) with respect to an applicable clinical trial,
19 the Director of NIH shall make publicly avail-
20 able on the results database a summary of the
21 available medical and clinical pharmacology re-
22 views conducted by the Food and Drug Admin-
23 istration for such trial.

24 “(C) POST-APPROVAL STUDIES.—Except
25 as provided in subparagraphs (D) and (E), with

1 respect to an applicable clinical trial that is
2 completed after the drug is initially approved
3 under such section 505 or licensed under such
4 section 351, or the device is initially cleared
5 under such section 510(k) or approved under
6 such section 515, the Director of NIH shall
7 make publicly available on the results database
8 the clinical trial information submitted for such
9 clinical trial not later than 30 days after the
10 date of such submission.

11 “(D) SEEKING APPROVAL OF A NEW USE
12 FOR THE DRUG OR DEVICE.—

13 “(i) IN GENERAL.—If the manufac-
14 turer of the drug or device is the sponsor
15 or a financial sponsor of an applicable clin-
16 ical trial, and such manufacturer certifies
17 to the Director of NIH that such manufac-
18 turer has filed, or will file within 1 year,
19 an application seeking approval under such
20 section 505, licensing under such section
21 351, clearance under such section 510(k),
22 or approval under such section 515 for the
23 use studied in such clinical trial (which use
24 is not included in the labeling of the ap-
25 proved drug or device), then the Director

1 of NIH shall make publicly available on
2 the results database the clinical trial infor-
3 mation submitted for such clinical trial on
4 the earlier of the date that is 30 days after
5 the date—

6 “(I) the new use of the drug or
7 device is approved under such section
8 505, licensed under such section 351,
9 cleared under such section 510(k), or
10 approved under such section 515;

11 “(II) the Secretary issues a not
12 approvable letter or a not substan-
13 tially equivalent letter for the new use
14 of the drug or device under such sec-
15 tion 505, 351, 510(k), or 515; or

16 “(III) the application or pre-
17 market notification under such section
18 505, 351, 510(k), or 515 is with-
19 drawn.

20 “(ii) LIMITATION ON CERTIFI-
21 CATION.—If a manufacturer makes a cer-
22 tification under clause (i) with respect to a
23 clinical trial, the manufacturer shall make
24 such a certification with respect to each
25 applicable clinical trial that is required to

1 be submitted in an application for approval
2 of the use studied in the clinical trial.

3 “(iii) 2-YEAR LIMITATION.—The clin-
4 ical trial information subject to clause (i)
5 shall be made publicly available on the re-
6 sults database on the date that is 2 years
7 after the date the certification referred to
8 in clause (i) was made to the Director of
9 NIH, if a regulatory action referred to in
10 subclause (I), (II), or (III) of clause (i) has
11 not occurred by such date.

12 “(iv) MEDICAL AND CLINICAL PHAR-
13 MACOLOGY REVIEWS.—Not later than 90
14 days after the date applicable under sub-
15 clause (I), (II), or (III) of clause (i) or
16 clause (iii) with respect to an applicable
17 clinical trial, the Director of NIH shall
18 make publicly available on the results data-
19 base a summary of the available medical
20 and clinical pharmacology reviews con-
21 ducted by the Food and Drug Administra-
22 tion for such trial.

23 “(E) SEEKING PUBLICATION.—

24 “(i) IN GENERAL.—If the principal in-
25 vestigator of an applicable clinical trial is

1 seeking publication in a peer-reviewed bio-
2 medical journal of a manuscript based on
3 the results of the clinical trial and the re-
4 sponsible party so certifies to the Director
5 of NIH—

6 “(I) the responsible party shall
7 notify the Director of NIH of the pub-
8 lication date of such manuscript not
9 later than 15 days after such date;
10 and

11 “(II) the Director of NIH shall
12 make publicly available on the results
13 database the clinical trial information
14 submitted for such clinical trial on the
15 date that is 30 days after the publica-
16 tion date of such manuscript.

17 “(ii) LIMITATIONS.—The clinical trial
18 information subject to clause (i)—

19 “(I) shall be made publicly avail-
20 able on the results database on the
21 date that is 2 years after the date
22 that the clinical trial information was
23 required to be submitted to the Direc-
24 tor of NIH if the manuscript referred

1 to in such clause has not been pub-
2 lished by such date; and

3 “(II) shall not be required to be
4 made publicly available under section
5 552 of title 5, United States Code
6 (commonly known as the ‘Freedom of
7 Information Act’), prior to the date
8 applicable to such clinical trial infor-
9 mation under this subparagraph.

10 “(7) VERIFICATION OF SUBMISSION PRIOR TO
11 PUBLIC AVAILABILITY.—In the case of clinical trial
12 information that is submitted under this subsection,
13 but is not made publicly available pending either
14 regulatory action or publication under subparagraph
15 (D) or (E) of paragraph (6), as applicable, the Di-
16 rector of NIH shall respond to inquiries from other
17 Federal agencies and peer-reviewed journals to con-
18 firm that such clinical trial information has been
19 submitted but has not yet been made publicly avail-
20 able on the results database.

21 “(d) UPDATES; TRACKING OF CHANGES IN SUB-
22 MITTED INFORMATION.—The Director of NIH shall en-
23 sure that updates submitted to the Director under sub-
24 sections (b)(7) and (c)(4) do not result in the removal
25 from the registry database or the results database of the

1 original submissions or of any preceding updates, and that
2 information in such databases is presented in a manner
3 that enables users to readily access each original submis-
4 sion and to track the changes made by the updates.

5 “(e) COORDINATION AND COMPLIANCE.—

6 “(1) CONSULTATION WITH OTHER FEDERAL
7 AGENCIES.—The Secretary shall—

8 “(A) consult with other agencies that con-
9 duct human studies in accordance with part 46
10 of title 45, Code of Federal Regulations (or any
11 successor regulations), to determine if any such
12 studies are applicable clinical trials; and

13 “(B) develop with such agencies appro-
14 priate procedures to ensure that clinical trial in-
15 formation for such applicable clinical trials is
16 submitted under subsection (b) and (c).

17 “(2) COORDINATION OF REGISTRY DATABASE
18 AND RESULTS DATABASE.—

19 “(A) IN GENERAL.—Each entry in the reg-
20 istry database under subsection (b) or the re-
21 sults database under subsection (c) shall in-
22 clude a link to the corresponding entry in the
23 results database or the registry database, re-
24 spectively.

25 “(B) MISSING ENTRIES.—

1 “(i) IN GENERAL.—If, based on a re-
2 view of the entries in the registry database
3 under subsection (b), the Director of NIH
4 determines that a responsible party has
5 failed to submit required clinical trial in-
6 formation to the results database under
7 subsection (c), the Director of NIH shall
8 inform the responsible party involved of
9 such failure and permit the responsible
10 party to correct the failure within 30 days.

11 “(ii) FAILURE TO CORRECT.—If the
12 responsible party does not correct a failure
13 to submit required clinical trial informa-
14 tion within the 30-day period described
15 under clause (i), the Director of NIH shall
16 report such noncompliance to the scientific
17 peer review committees of the Federal re-
18 search agencies and to the Office of
19 Human Research Protections.

20 “(iii) PUBLIC NOTICE OF FAILURE TO
21 CORRECT.—The Director of NIH shall in-
22 clude in the clinical trial registry database
23 entry and the clinical trial results database
24 entry for each applicable clinical trial a no-
25 tice of any uncorrected failure to submit

1 required clinical trial information and shall
2 provide that the public may easily search
3 for such entries.

4 “(3) ACTION ON APPLICATIONS.—

5 “(A) VERIFICATION PRIOR TO FILING.—

6 The Secretary, acting through the Commis-
7 sioner of Food and Drugs, shall verify that the
8 clinical trial information required under sub-
9 sections (b) and (c) for an applicable clinical
10 trial is submitted pursuant to such subsections,
11 as applicable—

12 “(i) when considering a drug or device
13 for an exemption under section 505(i) or
14 section 520(g) of the Federal Food, Drug,
15 and Cosmetic Act; and

16 “(ii) prior to filing an application or
17 premarket notification under section 505,
18 510(k), or 515 of the Federal Food, Drug,
19 and Cosmetic Act or section 351 of this
20 Act, that includes information from such
21 clinical trial.

22 “(B) NOTIFICATION.—If the Secretary de-
23 termines under subparagraph (A) that clinical
24 trial information has not been submitted as re-
25 quired by subsection (b) or (c), the Secretary

1 shall notify the applicant and the responsible
2 party of such noncompliance and require sub-
3 mission of such information within 30 days.

4 “(C) REFUSAL TO FILE.—If the respon-
5 sible party does not remedy such noncompliance
6 within 30 days of receipt of notification under
7 subparagraph (B), the Secretary shall refuse to
8 file, approve, or clear such application or pre-
9 market notification.

10 “(4) CONTENT REVIEW.—

11 “(A) IN GENERAL.—To ensure that the
12 summary documents described in subsection
13 (c)(3) are non-promotional, and are not false or
14 misleading in any particular under subsection
15 (c)(5), the Secretary shall compare such docu-
16 ments to the results data of the clinical trial for
17 a representative sample of applicable clinical
18 trials by—

19 “(i) acting through the Commissioner
20 of Food and Drugs to examine the results
21 data for such clinical trials submitted to
22 Secretary when such data are submitted—

23 “(I) for review as part of an ap-
24 plication under section 505 or 515 of
25 the Federal Food, Drug, and Cos-

1 metetic Act or under section 351 of this
2 Act or a premarket notification under
3 section 510(k) of the Federal Food,
4 Drug, and Cosmetic Act; or

5 “(II) in an annual status report
6 on the drug or device under such ap-
7 plication;

8 “(ii) acting with the Federal agency
9 that funds such clinical trial in whole or in
10 part by a grant to examine the results data
11 for such clinical trials; and

12 “(iii) acting through inspections under
13 section 704 of the Federal Food, Drug,
14 and Cosmetic Act to examine results data
15 for such clinical trials not described in
16 clause (i) or (ii).

17 “(B) NOTICE OF NONCOMPLIANCE.—If the
18 Secretary determines that the clinical trial in-
19 formation submitted in such a summary docu-
20 ment is false or misleading in any particular,
21 the Secretary shall notify the responsible party
22 and give such party an opportunity to remedy
23 such noncompliance by submitting the required
24 revised clinical trial information within 30 days
25 of such notification.

1 “(f) PENALTIES FOR NONCOMPLIANCE.—

2 “(1) IN GENERAL.—The following acts and the
3 causing thereof are unlawful:

4 “(A) The failure to submit clinical trial in-
5 formation as required by this section.

6 “(B) The submission of clinical trial infor-
7 mation under this section that is false or mis-
8 leading in any particular in violation of sub-
9 section (b)(5) or (c)(5).

10 “(2) CERTAIN PENALTIES.—Section 303(a) of
11 the Federal Food, Drug, and Cosmetic Act applies
12 with respect to a violation of paragraph (1) to the
13 same extent and in the same manner as such section
14 303(a) applies with respect to a violation of section
15 301 of such Act.

16 “(3) CONSIDERATIONS.—In determining wheth-
17 er to apply a penalty under paragraph (2) or under
18 paragraph (4) for a violation described in paragraph
19 (1), the Secretary, acting through the Commissioner
20 of Food and Drugs, shall consider—

21 “(A) whether the responsible party
22 promptly corrects the noncompliance when pro-
23 vided notice;

1 “(B) whether the responsible party has en-
2 gaged in a pattern or practice of noncompli-
3 ance; and

4 “(C) the extent to which the noncompli-
5 ance involved may have significantly misled
6 health care providers or patients concerning the
7 safety or effectiveness of the drug involved.

8 “(4) CIVIL PENALTIES.—

9 “(A) IN GENERAL.—A person is subject to
10 a civil penalty in accordance with this para-
11 graph if the person commits a violation de-
12 scribed in paragraph (1) and fails to correct the
13 violation by the end of the 30-day period de-
14 scribed in subparagraph (B).

15 “(B) NOTIFICATION.—If a person is in vio-
16 lation of paragraph (1), the Secretary shall no-
17 tify the person of such noncompliance and give
18 the person a 30-day period to correct such vio-
19 lation before imposing a civil penalty under this
20 paragraph.

21 “(C) AMOUNT OF PENALTY.—The amount
22 of a civil penalty under this subsection shall be
23 not more than a total of \$15,000 for all viola-
24 tions adjudicated in a single proceeding in the
25 case of an individual, and not more than

1 \$10,000 per day until the violation is corrected
2 in the case of any other person, except that if
3 the person is a nonprofit entity the penalty may
4 not exceed a total of \$15,000 for all violations
5 adjudicated in a single proceeding.

6 “(D) PROCEDURES.—The provisions of
7 paragraphs (4) through (6) of section 303(f) of
8 the Federal Food, Drug, and Cosmetic Act
9 apply to the imposition of a penalty under this
10 subsection to the same extent and in the same
11 manner as such provisions apply to a penalty
12 imposed under such section 303(f).

13 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated to carry out this section
15 \$10,000,000 for each fiscal year.”.

16 (b) CONFORMING AMENDMENTS.—

17 (1) INVESTIGATIONAL NEW DRUGS.—Section
18 505(i) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 355(i)) is amended—

20 (A) in paragraph (1)—

21 (i) in subparagraph (C), by striking
22 “and” after the semicolon;

23 (ii) in subparagraph (D)—

24 (I) by aligning the indentation of
25 such subparagraph with the indenta-

1 tion of subparagraphs (A), (B), and
2 (C); and

3 (II) by striking the period at the
4 end and inserting “; and”; and

5 (iii) by adding at the end the fol-
6 lowing:

7 “(E) the submission to the Director of NIH of
8 clinical trial information for the clinical investigation
9 at issue required under section 492C of the Public
10 Health Service Act for inclusion in the registry data-
11 base and the results database described in such sec-
12 tion.”;

13 (B) in paragraph (3)(B)—

14 (i) in clause (i), by striking “or” after
15 the semicolon;

16 (ii) in clause (ii), by striking the pe-
17 riod at the end and inserting “; or”; and

18 (iii) by adding at the end the fol-
19 lowing:

20 “(iii) clinical trial information for the clinical
21 investigation at issue was not submitted in compli-
22 ance with section 492C of the Public Health Service
23 Act.”; and

24 (C) in paragraph (4), by adding at the end
25 the following: “The Secretary shall update such

1 regulations to require inclusion in the informed
2 consent form a statement that clinical trial in-
3 formation for such clinical investigation will be
4 submitted for inclusion in the registry database
5 and results database, as applicable, described in
6 section 492C of the Public Health Service
7 Act.”.

8 (2) REFUSAL TO APPROVE NEW DRUG APPLICA-
9 TION.—Section 505(d) of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355(d)) is amended—

11 (A) in the first sentence, by inserting after
12 “in any particular;” the following: “or (8) the
13 applicant failed to submit the clinical trial in-
14 formation for any applicable clinical trial as re-
15 quired by section 492C of the Public Health
16 Service Act;”; and

17 (B) in the second sentence, by striking
18 “clauses (1) through (6)” and inserting “para-
19 graphs (1) through (8)”.

20 (3) INVESTIGATIONAL NEW DEVICES.—Sub-
21 paragraph (B) of section 520(g)(2) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C.
23 360j(g)(2)) is amended—

24 (A) by redesignating clause (iii) as clause
25 (iv); and

1 (B) by inserting after clause (ii) the fol-
2 lowing:

3 “(iii) A requirement that the person applying
4 for an exemption for a device assure that such per-
5 son is in compliance with the requirements of section
6 492C of the Public Health Service Act for the sub-
7 mission of clinical trial information for inclusion in
8 the registry database and the results database de-
9 scribed in such section.”.

10 (4) REFUSAL TO CLEAR NEW DEVICE PRE-
11 MARKET NOTIFICATION REPORT.—Subsection (k) of
12 section 510 of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 360) is amended—

14 (A) in paragraph (1), by striking “and” at
15 the end; and

16 (B) in paragraph (2), by striking the pe-
17 riod at the end and inserting “, and”; and

18 (C) by adding at the end the following:

19 “(3) action taken by such person to comply
20 with requirements under section 492C of the Public
21 Health Service Act for the submission of clinical
22 trial information for inclusion in the registry data-
23 base and the results database described in such sec-
24 tion.”.

1 (5) REFUSAL TO APPROVE NEW DEVICE APPLI-
2 CATION.—Paragraph (2) of section 515(d) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 360e(d)) is amended—

5 (A) in subparagraph (D), by striking “or”
6 at the end;

7 (B) in subparagraph (E), by striking the
8 period at the end and inserting “; or”; and

9 (C) by inserting after subparagraph (E)
10 the following:

11 “(F) the applicant is in violation of the require-
12 ments under section 492C of the Public Health
13 Service Act for the submission of clinical trial infor-
14 mation for inclusion in the registry database or the
15 results database described in such section.”.

16 (c) GUIDANCE.—Not later than 180 days after the
17 date of the enactment of this Act, the Commissioner of
18 Food and Drugs, in consultation with the Director of the
19 National Institutes of Health, shall issue guidance to clar-
20 ify which clinical trials are applicable clinical trials (as de-
21 fined in section 492C of the Public Health Service Act,
22 as amended by this section) and required to be submitted
23 for inclusion in the clinical trial registry database de-
24 scribed in such section.

25 (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 any requirement for the inclusion of information
5 relating to the results 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 492C of the Public Health
9 Service Act (as amended by this section), that re-
10 lates to a use of a drug or device not included in the
11 official labeling of the approved drug or device shall
12 not be construed by the Secretary or in any adminis-
13 trative or judicial proceeding, as evidence of a new
14 intended use of the drug or device that is different
15 from the intended use of the drug or device set forth
16 in the official labeling of the drug or device. The
17 availability of clinical trial information through the
18 databases under subsections (b) and (c) of such sec-
19 tion 492C, if submitted in compliance with such sec-
20 tion 492C, shall not be considered as labeling, adul-
21 teration, or misbranding of the drug or device under
22 the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 301 et seq.).

24 (e) EFFECTIVE DATES.—

1 (1) ESTABLISHMENT OF REGISTRY DATABASE
2 AND RESULTS DATABASE.—Not later than 1 year
3 after the date of the enactment of this Act, the Di-
4 rector of NIH shall establish the registry database
5 and the results database of clinical trials of drugs
6 and devices in accordance with section 492C of the
7 Public Health Service Act (as amended by sub-
8 section (a)).

9 (2) CLINICAL TRIALS INITIATED PRIOR TO OP-
10 ERATION OF REGISTRY DATABASE.—The responsible
11 party (as defined in such section 492C) for an appli-
12 cable clinical trial (as defined in such section 492C)
13 that is initiated after the date of the enactment of
14 this Act and before the date such registry database
15 is established under paragraph (1) of this sub-
16 section, shall submit required clinical trial informa-
17 tion not later than 120 days after the date such reg-
18 istry database is established.

19 (3) CLINICAL TRIALS INITIATED AFTER OPER-
20 ATION OF REGISTRY DATABASE.—The responsible
21 party (as defined in such section 492C) for an appli-
22 cable clinical trial (as defined in such section 492C)
23 that is initiated after the date such registry database
24 is established under paragraph (1) of this subsection

1 shall submit required clinical trial information in ac-
2 cordance with subsection (b) of such section 492C.

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

5 (A) IN GENERAL.—Subsection (c) of such
6 section 492C shall take effect 90 days after the
7 date the results database is established under
8 paragraph (1) of this subsection with respect to
9 any applicable clinical trial (as defined in such
10 section 492C) that—

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

13 (ii) is completed between the date of
14 the enactment of this Act and such date of
15 establishment under paragraph (1) of this
16 subsection.

17 (B) OTHER TRIALS.—Except as provided
18 in subparagraph (A), subsection (c) of such sec-
19 tion 492C shall take effect 180 days after the
20 date that the results database is established
21 under paragraph (1) of this subsection with re-
22 spect to any applicable clinical trial that is com-
23 pleted between the date of the enactment of this
24 Act and such date of establishment under para-
25 graph (1).

1 (5) TRIALS COMPLETED AFTER ESTABLISH-
2 MENT OF RESULTS DATABASE.—Subsection (c) of
3 such section 492C shall apply to any clinical trial
4 that is completed after the date that the results
5 database is established under paragraph (1) of this
6 subsection.

7 (6) RETROACTIVITY OF DATABASE.—

8 (A) VOLUNTARY SUBMISSIONS.—The Sec-
9 retary of Health and Human Services (referred
10 to in this paragraph as the “Secretary”) shall
11 establish procedures and mechanisms to allow
12 for the voluntary submission to the Secretary—

13 (i) of clinical trial information for in-
14 clusion in the registry database (as defined
15 in such section 492C) on applicable clinical
16 trials (as defined in such section 492C)
17 initiated before the date of the enactment
18 of this Act; and

19 (ii) of clinical trial information for in-
20 clusion in the results database (as defined
21 in such section 492C) on applicable clinical
22 trials (as defined in such section 492C)
23 completed before the date of the enactment
24 of this Act.

1 (B) REQUIRED SUBMISSIONS.—Notwith-
2 standing the preceding paragraphs of this sub-
3 section, in any case in which the Secretary de-
4 termines that submission of clinical trial infor-
5 mation for an applicable clinical trial (as de-
6 fined in such section 492C) described in clause
7 (i) or (ii) of subparagraph (A) is in the interest
8 of the public health—

9 (i) the Secretary may require that
10 such information be submitted to the Sec-
11 retary in accordance with such section
12 492C; and

13 (ii) failure to comply with such a re-
14 quirement shall be treated as a violation of
15 the corresponding requirement of such sec-
16 tion 492C.

17 (7) STATUS OF CLINICALTRIALS.GOV
18 WEBSITE.—

19 (A) IN GENERAL.—After receiving public
20 comment and not later than 90 days after the
21 date of the enactment of this Act, the Secretary
22 shall publish in the Federal Register a notice
23 determining the more efficient approach to es-
24 tablishing the registry database described in

subsection (b) of such section 492C and whether such approach is—

(i) that such registry database should expand and build upon the data bank described in section 402(i) of the Public Health Service Act (as in effect on the day before the date of the enactment of this Act); or

(ii) that such registry database should supplant the data bank described in such section 402(i) (as in effect on the day before the date of the enactment of this Act).

(B) CLINICALTRIALS.GOV SUPPLANTED.—

If the Secretary determines to apply the approach described under subparagraph (A)(ii), the Secretary shall maintain an archive of the data bank described in such section 402(i) (as in effect on the day before the date of the enactment of this Act) on the Internet website of the National Library of Medicine.

SEC. 802. STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine whether information on the trials registry and database is consid-

1 ered promotional and to evaluate the implementation of
2 this database.

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

7 **TITLE IX—ENHANCED AUTHORI-**
8 **TIES** **REGARDING**
9 **POSTMARKET SAFETY OF**
10 **DRUGS**

11 **SEC. 901. POSTMARKET STUDIES AND CLINICAL TRIALS RE-**
12 **GARDING HUMAN DRUGS; RISK EVALUATION**
13 **AND MITIGATION STRATEGIES.**

14 (a) IN GENERAL.—Section 505 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by
16 adding at the end the following subsections:

17 “(c) POSTMARKET STUDIES AND CLINICAL TRIALS;
18 LABELING.—

19 “(1) IN GENERAL.—A responsible person may
20 not introduce or deliver for introduction into inter-
21 state commerce the new drug involved if the person
22 is in violation of a requirement established under
23 paragraph (3) or (4) with respect to the drug.

24 “(2) DEFINITIONS.—For purposes of this sub-
25 section:

1 “(A) RESPONSIBLE PERSON.—The term
2 ‘responsible person’ means a person who—

3 “(i) has submitted to the Secretary a
4 covered application that is pending; or

5 “(ii) is the holder of an approved cov-
6 ered application.

7 “(B) COVERED APPLICATION.—The term
8 ‘covered application’ means—

9 “(i) an application under subsection
10 (b) for a drug that is subject to section
11 503(b); and

12 “(ii) an application under section 351
13 of the Public Health Service Act.

14 “(C) NEW SAFETY INFORMATION; SERIOUS
15 RISK.—The terms ‘new safety information’, ‘se-
16 rious risk’, and ‘signal of a serious risk’ have
17 the meanings given such terms in section 505–
18 1(b).

19 “(3) STUDIES AND CLINICAL TRIALS.—

20 “(A) IN GENERAL.—For any or all of the
21 purposes specified in subparagraph (B), the
22 Secretary may, subject to subparagraph (C), re-
23 quire a responsible person for a drug to conduct
24 a postapproval study or studies of the drug, or
25 a postapproval clinical trial or trials of the

1 drug, on the basis of scientific information, in-
2 cluding information regarding chemically-re-
3 lated or pharmacologically-related drugs.

4 “(B) PURPOSES OF STUDY OR TRIAL.—

5 The purposes referred to in this subparagraph
6 with respect to a postapproval study or post-
7 approval clinical trial are the following:

8 “(i) To assess a known serious risk
9 related to the use of the drug involved.

10 “(ii) To assess signals of serious risk
11 related to the use of the drug.

12 “(iii) To identify a serious risk.

13 “(C) ESTABLISHMENT OF REQUIREMENT

14 AFTER APPROVAL OF COVERED APPLICATION.—

15 The Secretary may require a postapproval study
16 or studies or postapproval trial or trials for a
17 drug for which an approved covered application
18 is in effect as of the date on which the Sec-
19 retary seeks to establish such requirement only
20 if the Secretary becomes aware of new safety
21 information. For each study required to be con-
22 ducted under this subparagraph, the Secretary
23 shall require that the applicant submit a time-
24 table for completion of the study and shall re-
25 quire the applicant to periodically report to the

1 Secretary on the status of the study. Unless the
2 applicant demonstrates good cause for failure to
3 comply with such timeline, the applicant shall
4 be in violation of this subsection. The Secretary
5 shall determine what constitutes good cause
6 under the preceding sentence.

7 “(4) SAFETY LABELING CHANGES REQUESTED
8 BY SECRETARY.—

9 “(A) NEW SAFETY INFORMATION.—The
10 Secretary shall promptly notify the responsible
11 person if the Secretary becomes aware of new
12 safety information that the Secretary believes
13 should be included in the labeling of the drug.

14 “(B) RESPONSE TO NOTIFICATION.—Fol-
15 lowing notification pursuant to subparagraph
16 (A), the responsible person shall within 30
17 days—

18 “(i) submit a supplement proposing
19 changes to the approved labeling to reflect
20 the new safety information, including
21 changes to boxed warnings, contraindica-
22 tions, warnings, precautions, or adverse re-
23 actions; or

24 “(ii) notify the Secretary that the re-
25 sponsible person does not believe a labeling

1 change is warranted and submit a state-
2 ment detailing the reasons why such a
3 change is not warranted.

4 “(C) REVIEW.—Upon receipt of such sup-
5 plement, the Secretary shall promptly review
6 and act upon such supplement. If the Secretary
7 disagrees with the proposed changes in the sup-
8 plement or with the statement setting forth the
9 responsible person’s reasons why no labeling
10 change is necessary, the Secretary shall initiate
11 discussions with the responsible person to reach
12 agreement on whether the labeling for the drug
13 should be modified to reflect the new safety in-
14 formation, and if so, the contents of such label-
15 ing changes.

16 “(D) DISCUSSIONS.—Such discussions
17 shall not extend for more than 30 days after
18 the response to the notification under subpara-
19 graph (B), unless the Secretary determines an
20 extension of such discussion period is war-
21 ranted.

22 “(E) ORDER.—Within 15 days of the con-
23 clusion of the discussions under subparagraph
24 (D), the Secretary may issue an order directing
25 the responsible person to make such a labeling

1 change as the Secretary deems appropriate to
2 address the new safety information. Within 15
3 days of such an order, the responsible person
4 shall submit a supplement containing the label-
5 ing change.

6 “(F) DISPUTE RESOLUTION.—Within 5
7 days of receiving an order under subparagraph
8 (E), the responsible person may appeal using
9 the Food and Drug Administration’s normal
10 dispute resolution procedures established by the
11 Secretary in regulation and guidance.

12 “(G) VIOLATION.—If the change required
13 by an order under subparagraph (E) is not
14 made by the date so specified, the responsible
15 person shall be considered to be in violation of
16 this section.

17 “(H) SERIOUS PUBLIC HEALTH THREAT.—
18 Notwithstanding subparagraphs (A) through
19 (F), if the Secretary concludes that failure to
20 make such a labeling change is necessary to
21 protect against a serious public health threat,
22 the Secretary may accelerate the timelines in
23 such subparagraphs.

24 “(I) RULE OF CONSTRUCTION.—This para-
25 graph shall not be construed to affect the re-

1 sponsibility of the responsible person to main-
2 tain its label in accordance with existing re-
3 quirements, including subpart B and section
4 314.70 of title 21, Code of Federal Regulations
5 (or any successor regulations).

6 “(p) RISK EVALUATION AND MITIGATION STRAT-
7 EGY.—

8 “(1) IN GENERAL.—A person may not intro-
9 duce or deliver for introduction into interstate com-
10 merce a new drug if—

11 “(A)(i) the application for such drug is ap-
12 proved under subsection (b) or (j) and is sub-
13 ject to section 503(b); or

14 “(ii) the application for such drug is ap-
15 proved under section 351 of the Public Health
16 Service Act; and

17 “(B) a risk evaluation and mitigation
18 strategy is required under section 505–1 with
19 respect to the drug and—

20 “(i) the person fails to maintain com-
21 pliance with the requirements of the ap-
22 proved strategy or with other requirements
23 under section 505–1, including require-
24 ments regarding assessments of approved
25 strategies; or

1 “(ii) in the case of a requirement for
2 such a strategy that is first established
3 after the applicable application referred to
4 in subparagraph (A) was approved with re-
5 spect to the drug, the Secretary, after no-
6 tice and opportunity for a hearing, pub-
7 lishes in the Federal Register a statement
8 that the person is not cooperating with the
9 Secretary in developing such a strategy for
10 the drug.

11 “(2) REQUIRED STATEMENT DURING APPROVAL
12 PROCESS.—In the case of an application approved
13 under subsection (b) or (j) for a new drug that is
14 subject to section 503(b), or an application approved
15 under section 351 of the Public Health Service Act,
16 or a supplement to such an application that requires
17 substantive data, the Secretary may not approve the
18 application or supplement unless the person involved
19 has complied with the following:

20 “(A) The person has submitted to the Sec-
21 retary a statement that provides the following
22 information:

23 “(i) Whether the person believes that
24 a risk evaluation and mitigation strategy
25 should be required under section 505–1.

1 “(ii) Whether a postmarket study or
2 clinical trial should be required under sub-
3 section (o)(3).

4 “(B) In making the statement under sub-
5 paragraph (A), the person took into account
6 each of the following factors:

7 “(i) The estimated size of the popu-
8 lation likely to use the drug involved.

9 “(ii) The seriousness of the disease or
10 condition that is to be treated with the
11 drug.

12 “(iii) The expected benefit of the drug
13 with respect to such disease or condition.

14 “(iv) The expected or actual duration
15 of treatment with the drug.

16 “(v) The seriousness of any known or
17 potential adverse events that may be re-
18 lated to the drug and the background inci-
19 dence of such events in the population like-
20 ly to use the drug.

21 “(3) CERTAIN POSTMARKET STUDIES.—The
22 failure to conduct a postmarket study under subpart
23 H of part 314 of title 21, Code of Federal Regula-
24 tions (or any successor regulation), is deemed to be
25 a violation of paragraph (1).”.

1 (b) REQUIREMENTS REGARDING STRATEGIES.—
2 Chapter V of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
4 tion 505 the following section:

5 **“SEC. 505–1. RISK EVALUATION AND MITIGATION STRATE-**
6 **GIES.**

7 “(a) SUBMISSION OF PROPOSED STRATEGY.—

8 “(1) INITIAL APPROVAL.—A person who sub-
9 mits an application referred to in section
10 505(p)(1)(A) (referred to in this section as a ‘cov-
11 ered application’) shall submit to the Secretary as
12 part of the application a proposed risk evaluation
13 and mitigation strategy if the Secretary determines
14 such a strategy is necessary to ensure that the bene-
15 fits of the drug involved outweigh the risks of the
16 drug. In making such a determination, the Secretary
17 shall consider the statement submitted by the person
18 under section 505(p)(2) with respect to the drug and
19 shall consider the following factors:

20 “(A) The estimated size of the population
21 likely to use the drug involved.

22 “(B) The seriousness of the disease or con-
23 dition that is to be treated with the drug.

24 “(C) The expected benefit of the drug with
25 respect to such disease or condition.

1 “(D) The expected or actual duration of
2 treatment with the drug.

3 “(E) The seriousness of any known or po-
4 tential adverse events that may be related to
5 the drug and the background incidence of such
6 events in the population likely to use the drug.

7 “(F) The availability and safety of a drug
8 or other treatment, if any, for such disease or
9 condition to which the safety of the drug may
10 be compared.

11 “(G) Whether the drug is a new molecular
12 entity.

13 “(2) POSTAPPROVAL REQUIREMENT.—

14 “(A) IN GENERAL.—If the Secretary ap-
15 proves a covered application and does not when
16 approving the application require a risk evalua-
17 tion and mitigation strategy under paragraph
18 (1), the Secretary may subsequently require
19 such a strategy for the drug involved if the Sec-
20 retary becomes aware of new safety information
21 and makes a determination that such a strategy
22 is necessary to ensure that the benefits of the
23 drug outweigh the risks of the drug.

24 “(B) SUBMISSION OF PROPOSED STRAT-
25 EGY.—Not later than 120 days after the Sec-

1 retary notifies the holder of an approved cov-
2 ered application that the Secretary has made a
3 determination under subparagraph (A) with re-
4 spect to the drug involved, or within such other
5 time as the Secretary requires to protect the
6 public health, the holder shall submit to the
7 Secretary a proposed risk evaluation and miti-
8 gation strategy.

9 “(3) APPROVAL OF NEW INDICATION FOR
10 USE.—The applicability of paragraph (2) includes
11 applicability to a drug for which an approved cov-
12 ered application was in effect on the day before the
13 effective date of this section and for which, on or
14 after such effective date, the holder of the approved
15 application submits to the Secretary a supplemental
16 application seeking approval of a new indication for
17 use of the drug.

18 “(4) ABBREVIATED NEW DRUG APPLICA-
19 TIONS.—The applicability of this section to an appli-
20 cation under section 505(j) is subject to subsection
21 (i).

22 “(b) DEFINITIONS.—For purposes of this section:

23 “(1) ADVERSE DRUG EXPERIENCE.—The term
24 ‘adverse drug experience’ means any adverse event

1 associated with the use of a drug in humans, wheth-
2 er or not considered drug related, including—

3 “(A) an adverse event occurring in the
4 course of the use of the drug in professional
5 practice;

6 “(B) an adverse event occurring from an
7 overdose of the drug, whether accidental or in-
8 tentional;

9 “(C) an adverse event occurring from
10 abuse of the drug;

11 “(D) an adverse event occurring from
12 withdrawal of the drug; and

13 “(E) any failure of expected pharma-
14 cological action of the drug.

15 “(2) COVERED APPLICATION.—The term ‘cov-
16 ered application’ has the meaning indicated for such
17 term in subsection (a)(1).

18 “(3) NEW SAFETY INFORMATION.—The term
19 ‘new safety information’ with respect to a drug
20 means information about—

21 “(A) a serious risk or an unexpected seri-
22 ous risk associated with use of the drug that
23 the Secretary has become aware of since the
24 drug was approved, since the risk evaluation
25 and mitigation strategy was required, or since

1 the last assessment of the approved risk evalua-
2 tion and mitigation strategy for the drug; or

3 “(B) the effectiveness of the approved risk
4 evaluation and mitigation strategy for the drug
5 obtained since the last assessment of such
6 strategy.

7 “(4) SERIOUS ADVERSE DRUG EXPERIENCE.—
8 The term ‘serious adverse drug experience’ is an ad-
9 verse event that—

10 “(A) results in—

11 “(i) death;

12 “(ii) an adverse drug experience that
13 places the patient at immediate risk of
14 death from the adverse drug experience as
15 it occurred (not including an adverse drug
16 experience that might have caused death
17 had it occurred in a more severe form);

18 “(iii) inpatient hospitalization or pro-
19 longation of existing hospitalization;

20 “(iv) a persistent or significant inca-
21 pacity or substantial disruption of the abil-
22 ity to conduct normal life functions; or

23 “(v) a congenital anomaly or birth de-
24 fect; or

1 “(B) based on appropriate medical judg-
2 ment, may jeopardize the patient and may re-
3 quire a medical or surgical intervention to pre-
4 vent an outcome described under subparagraph
5 (A).

6 “(5) SERIOUS RISK.—The term ‘serious risk’
7 means a risk of a serious adverse drug experience.

8 “(6) SIGNAL OF A SERIOUS RISK.—The term
9 ‘signal of a serious risk’ means information related
10 to a serious adverse drug experience associated with
11 use of a drug and derived from—

12 “(A) a clinical trial;

13 “(B) adverse event reports;

14 “(C) a postapproval study, including a
15 study under section 505(o)(3);

16 “(D) peer-reviewed biomedical literature;
17 or

18 “(E) data derived from a postmarket risk
19 identification and analysis system under section
20 505(k)(3).

21 “(7) RESPONSIBLE PERSON.—The term ‘re-
22 sponsible person’ has the meaning indicated for such
23 term in subsection (e)(2).

24 “(8) UNEXPECTED SERIOUS RISK.—The term
25 ‘unexpected serious risk’ means a serious adverse

1 drug experience that is not listed in the labeling of
2 a drug, or that may be symptomatically and
3 pathophysiologically related to an adverse drug expe-
4 rience identified in the labeling, but differs from
5 such adverse drug experience because of greater se-
6 verity, specificity, or prevalence.

7 “(c) CONTENTS.—A proposed risk evaluation and
8 mitigation strategy under subsection (a) shall—

9 “(1) include the timetable required under sub-
10 section (d); and

11 “(2) to the extent required by the Secretary, in-
12 clude additional elements described in subsections
13 (e) and (f).

14 “(d) MINIMAL STRATEGY.—For purposes of sub-
15 section (c)(1), the risk evaluation and mitigation strategy
16 for a drug shall require a timetable for submission of as-
17 sessments of the strategy that—

18 “(1) is not less frequent than once annually for
19 the first 3 years after the strategy is initially ap-
20 proved;

21 “(2) includes an assessment in the seventh year
22 after the strategy is so approved; and

23 “(3) subject to paragraph (2), for subsequent
24 years—

1 “(A) is at a frequency specified in the
2 strategy;

3 “(B) is increased or reduced in frequency
4 as necessary as provided for in subsection
5 (g)(4)(A); and

6 “(C) is eliminated after the 3-year period
7 described in paragraph (1) if the Secretary de-
8 termines that serious risks of the drug have
9 been adequately identified and assessed and are
10 being adequately managed.

11 “(e) ADDITIONAL POTENTIAL ELEMENTS OF STRAT-
12 EGY.—

13 “(1) IN GENERAL.—The Secretary may under
14 subsection (c)(2) require that the risk evaluation
15 and mitigation strategy for a drug include 1 or more
16 of the additional elements described in this sub-
17 section if the Secretary makes the determination re-
18 quired with respect to the element involved.

19 “(2) MEDGUIDE; PATIENT PACKAGE INSERT.—
20 The risk evaluation and mitigation strategy for a
21 drug may require that, as applicable, the person sub-
22 mitting the covered application or the holder of the
23 approved such application (referred to in this section
24 as the ‘responsible person’) develop for distribution
25 to each patient when the drug is dispensed—

1 “(A) a Medication Guide, as provided for
2 under part 208 of title 21, Code of Federal
3 Regulations (or any successor regulations); and

4 “(B) a patient package insert, if the Sec-
5 retary determines that such insert may help
6 mitigate a serious risk of the drug.

7 “(3) COMMUNICATION PLAN.—The risk evalua-
8 tion and mitigation strategy for a drug may require
9 that the responsible person conduct a communica-
10 tion plan to health care providers, if, with respect to
11 such drug, the Secretary determines that such plan
12 may support implementation of an element of the
13 strategy. Such plan may include—

14 “(A) sending letters to health care pro-
15 viders;

16 “(B) disseminating information about the
17 elements of the risk evaluation and mitigation
18 strategy to encourage implementation by health
19 care providers of components that apply to such
20 health care providers, or to explain certain safe-
21 ty protocols (such as medical monitoring by
22 periodic laboratory tests); or

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

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

3 “(f) RESTRICTIONS ON DISTRIBUTION OR USE.—

4 “(1) IN GENERAL.—If the Secretary determines
5 that a drug shown to be effective can be safely used
6 only if distribution or use of such drug is restricted,
7 the Secretary may under subsection (c)(2) require as
8 elements of the risk evaluation and mitigation strat-
9 egy such restrictions on distribution or use as are
10 needed to ensure safe use of the drug.

11 “(2) ASSURING ACCESS AND MINIMIZING BUR-
12 DEN.—Elements of a risk evaluation and mitigation
13 strategy included under paragraph (1) shall—

14 “(A) be commensurate with a specific seri-
15 ous risk listed in the labeling of the drug;

16 “(B) be posted publicly by the Secretary
17 with an explanation of how such elements will
18 mitigate the observed safety risk, which posting
19 shall be made within 30 days after the date on
20 which the Secretary requires the element in-
21 volved;

22 “(C) considering the risk referred to in
23 subparagraph (A), not be unduly burdensome
24 on patient access to the drug, considering in
25 particular—

1 “(i) patients with serious or life-
2 threatening diseases or conditions; and

3 “(ii) patients who have difficulty ac-
4 cessing health care (such as patients in
5 rural or medically underserved areas); and

6 “(D) to the extent practicable, so as to
7 minimize the burden on the health care delivery
8 system—

9 “(i) conform with elements to assure
10 safe use for other drugs with similar, seri-
11 ous risks; and

12 “(ii) be designed to be compatible
13 with established distribution, procurement,
14 and dispensing systems for drugs.

15 “(3) ELEMENTS.—The restrictions on distribu-
16 tion or use described in paragraph (1) shall include
17 1 or more goals to evaluate or mitigate a serious
18 risk listed in the labeling of the drug, and may re-
19 quire that—

20 “(A) health care providers that prescribe
21 the drug have special training or experience, or
22 are specially certified, which training or certifi-
23 cation with respect to the drug is available to
24 any willing provider from a frontier area;

1 “(B) pharmacies, practitioners, or health
2 care settings that dispense the drug are spe-
3 cially certified, which training or certification
4 with respect to the drug is available to any will-
5 ing provider from a frontier area;

6 “(C) the drug be dispensed to patients only
7 in certain health care settings, such as hos-
8 pitals;

9 “(D) the drug be dispensed to patients
10 with evidence or other documentation of safe-
11 use conditions, such as laboratory test results;

12 “(E) each patient using the drug be sub-
13 ject to certain monitoring; or

14 “(F) each patient using the drug be en-
15 rolled in a registry.

16 “(4) IMPLEMENTATION SYSTEM.—The restric-
17 tions on distribution or use described in paragraph
18 (1) may require a system through which the respon-
19 sible person is able to—

20 “(A) monitor and evaluate implementation
21 of the restrictions by health care providers,
22 pharmacists, patients, and other parties in the
23 health care system who are responsible for im-
24 plementing the restrictions;

1 “(B) work to improve implementation of
2 the restrictions by health care providers, phar-
3 macists, patients, and other parties in the
4 health care system who are responsible for im-
5 plementing the restrictions; and

6 “(C) notify wholesalers of the drug of
7 those health care providers—

8 “(i) who are responsible for imple-
9 menting the restrictions; and

10 “(ii) whom the responsible person
11 knows have failed to meet their responsibil-
12 ities for implementing the restrictions,
13 after the responsible person has informed
14 such party of such failure and such party
15 has not remedied such failure.

16 “(5) LIMITATION.—No holder of an approved
17 application shall use any restriction on distribution
18 required by the Secretary as necessary to assure safe
19 use of the drug to block or delay approval of an ap-
20 plication under section 505(b)(2) or (j) or to prevent
21 application of such restriction under subsection
22 (i)(1)(B) to a drug that is the subject of an abbrevi-
23 ated new drug application.

24 “(6) BIOEQUIVALENCE TESTING.—Notwith-
25 standing any other provisions in this subsection, the

1 holder of an approved application that is subject to
2 distribution restrictions required under this sub-
3 section that limit the ability of a sponsor seeking ap-
4 proval of an application under subsection 505(b)(2)
5 or (j) to purchase on the open market a sufficient
6 quantity of drug to conduct bioequivalence testing
7 shall provide to such a sponsor a sufficient amount
8 of drug to conduct bioequivalence testing if the spon-
9 sor seeking approval under section 505(b)(2) or
10 (j)—

11 “(A) agrees to such restrictions on dis-
12 tribution as the Secretary finds necessary to as-
13 sure safe use of the drug during bioequivalence
14 testing; and

15 “(B) pays the holder of the approved appli-
16 cation the fair market value of the drug pur-
17 chased for bioequivalence testing.

18 “(7) LETTER BY SECRETARY.—Upon a showing
19 by the sponsor seeking approval under section
20 505(b)(2) or (j) that the sponsor has agreed to such
21 restrictions necessary to assure safe use of the drug
22 during bioequivalence testing, the Secretary shall
23 issue to the sponsor seeking to conduct bioequiva-
24 lence testing a letter that describes the Secretary’s
25 finding which shall serve as proof that the sponsor

1 has satisfied the requirements of subparagraph
2 (6)(A).

3 “(8) EVALUATION OF ELEMENTS TO ASSURE
4 SAFE USE.—The Secretary, acting through the Drug
5 Safety and Risk Management Advisory Committee
6 (or any successor committee) of the Food and Drug
7 Administration, shall—

8 “(A) seek input from patients, physicians,
9 pharmacists, and other health care providers
10 about how elements to assure safe use under
11 this subsection for 1 or more drugs may be
12 standardized so as not to be—

13 “(i) unduly burdensome on patient ac-
14 cess to the drug; and

15 “(ii) to the extent practicable, mini-
16 mize the burden on the health care delivery
17 system;

18 “(B) at least annually, evaluate, for 1 or
19 more drugs, the elements to assure safe use of
20 such drug to assess whether the elements—

21 “(i) assure safe use of the drug;

22 “(ii) are not unduly burdensome on
23 patient access to the drug; and

1 “(iii) to the extent practicable, mini-
2 mize the burden on the health care delivery
3 system; and

4 “(C) considering such input and evalua-
5 tions—

6 “(i) issue or modify agency guidance
7 about how to implement the requirements
8 of this subsection; and

9 “(ii) modify elements under this sub-
10 section for 1 or more drugs as appropriate.

11 “(9) WAIVER IN PUBLIC HEALTH EMER-
12 GENCIES.—The Secretary may waive any restriction
13 on distribution or use under this subsection during
14 the period described in section 319(a) of the Public
15 Health Service Act with respect to a qualified coun-
16 termeasure described under section 319F–1(a)(2) of
17 such Act, to which a restriction or use under this
18 subsection has been applied, if the Secretary has—

19 “(A) declared a public health emergency
20 under such section 319; and

21 “(B) determined that such waiver is re-
22 quired to mitigate the effects of, or reduce the
23 severity of, such public health emergency.

24 “(g) ASSESSMENT AND MODIFICATION OF APPROVED
25 STRATEGY.—

1 “(1) VOLUNTARY ASSESSMENTS.—After the ap-
2 proval of a risk evaluation and mitigation strategy
3 under subsection (a), the responsible person involved
4 may, subject to paragraph (2), submit to the Sec-
5 retary an assessment of, and propose a modification
6 to, the approved strategy for the drug involved at
7 any time.

8 “(2) REQUIRED ASSESSMENTS.—A responsible
9 person shall, subject to paragraph (5), submit an as-
10 sessment of, and may propose a modification to, the
11 approved risk evaluation and mitigation strategy for
12 a drug—

13 “(A) when submitting a supplemental ap-
14 plication for a new indication for use under sec-
15 tion 505(b) or under section 351 of the Public
16 Health Service Act, unless the drug is not sub-
17 ject to section 503(b) and the risk evaluation
18 and mitigation strategy for the drug includes
19 only the timetable under subsection (d);

20 “(B) when required by the strategy, as
21 provided for in such timetable under subsection
22 (d);

23 “(C) within a time period to be determined
24 by the Secretary, if the Secretary determines

1 that new safety or effectiveness information in-
2 dicates that—

3 “(i) an element under subsection (d)
4 or (e) should be modified or included in
5 the strategy; or

6 “(ii) an element under subsection (f)
7 should be modified or included in the strat-
8 egy; or

9 “(D) within 15 days when ordered by the
10 Secretary, if the Secretary determines that
11 there may be a cause for action by the Sec-
12 retary under section 505(e).

13 “(3) REQUIREMENTS FOR ASSESSMENTS.—An
14 assessment under paragraph (1) or (2) of an ap-
15 proved risk evaluation and mitigation strategy for a
16 drug shall include—

17 “(A) with respect to any goal under sub-
18 section (f), an assessment of the extent to
19 which the restrictions on distribution or use are
20 meeting the goal or whether the goal or such
21 restrictions should be modified;

22 “(B) with respect to any postapproval
23 study required under section 505(o)(3), the sta-
24 tus of such study, including whether any dif-

1 difficulties completing the study have been en-
2 countered; and

3 “(C) with respect to any postapproval clin-
4 ical trial required under section 505(o), the sta-
5 tus of such clinical trial, including whether en-
6 rollment has begun, the number of participants
7 enrolled, the expected completion date, whether
8 any difficulties completing the clinical trial have
9 been encountered, and registration information
10 with respect to requirements under section
11 492C of the Public Health Service Act.

12 “(4) MODIFICATION.—A modification (whether
13 an enhancement or a reduction) to the approved risk
14 evaluation and mitigation strategy for a drug may
15 include the addition or modification of any element
16 under subsection (d) or the addition, modification,
17 or removal of any element under subsection (e) or
18 (f), such as—

19 “(A) modifying the timetable for assess-
20 ments of the strategy under subsection (d), in-
21 cluding to eliminate assessments; or

22 “(B) adding, modifying, or removing a re-
23 striction on distribution or use under subsection
24 (f).

1 “(5) NO EFFECT ON LABELING CHANGES THAT
2 DO NOT REQUIRE PREAPPROVAL.—In the case of a
3 labeling change to which section 314.70 of title 21,
4 Code of Federal Regulations (or any successor regu-
5 lation), applies for which the submission of a supple-
6 mental application is not required or for which dis-
7 tribution of the drug involved may commence upon
8 the receipt by the Secretary of a supplemental appli-
9 cation for the change, the submission of an assess-
10 ment of the approved risk evaluation and mitigation
11 strategy for the drug under paragraph (2) is not re-
12 quired.

13 “(h) REVIEW OF PROPOSED STRATEGIES; REVIEW
14 OF ASSESSMENTS OF APPROVED STRATEGIES.—

15 “(1) IN GENERAL.—The Secretary shall
16 promptly review each proposed risk evaluation and
17 mitigation strategy for a drug submitted under sub-
18 section (a) and each assessment of an approved risk
19 evaluation and mitigation strategy for a drug sub-
20 mitted under subsection (g).

21 “(2) MARKETING PLAN.—

22 “(A) IN GENERAL.—As part of a review
23 conducted under this subsection, the Secretary
24 may require the applicant to submit informa-
25 tion regarding its marketing plan and practices

1 for the drug, so as to allow the Secretary to de-
2 termine whether any of the proposed or ongoing
3 marketing activities undermine any of the re-
4 quirements of the risk evaluation and mitiga-
5 tion strategy.

6 “(B) RULE OF CONSTRUCTION.—Subpara-
7 graph (A) may not be construed as authorizing
8 the Secretary to make or direct any change in
9 the marketing plan or practices involved. The
10 preceding sentence does not affect any author-
11 ity of the Secretary under this Act, other than
12 the authority of the Secretary under subpara-
13 graph (A).

14 “(3) DISCUSSION.—The Secretary shall initiate
15 discussions with a responsible person for purposes of
16 this subsection to determine a strategy—

17 “(A) if the proposed strategy is submitted
18 as part of an application or supplemental appli-
19 cation under subsection (a) or subsection
20 (g)(2)(A), not less than 60 days before the ac-
21 tion deadline for the application that has been
22 agreed to by the Secretary and that has been
23 set forth in goals identified in letters of the
24 Secretary (relating to the use of fees collected
25 under section 736 to expedite the drug develop-

1 ment process and the process for the review of
2 human drug applications);

3 “(B) if the assessment is submitted under
4 subparagraph (B) or (C) or subsection (g)(2),
5 not later than 20 days after such submission;

6 “(C) if the assessment is submitted under
7 subsection (g)(1) or subsection (g)(2)(D) , not
8 later than 30 days after such submission; or

9 “(D) if the assessment is submitted under
10 subsection (g)(2)(D), not later than 10 days
11 after such submission.

12 “(4) ACTION.—

13 “(A) IN GENERAL.—Unless the responsible
14 person requests the dispute resolution process
15 described under paragraph (5), the Secretary
16 shall approve and describe the risk evaluation
17 and mitigation strategy for a drug, or any
18 modification to the strategy—

19 “(i) as part of the action letter on the
20 application, when a proposed strategy is
21 submitted under subsection (a) or an as-
22 sessment of the strategy is submitted
23 under subsection (g)(1); or

24 “(ii) in an order issued not later than
25 50 days after the date discussions of such

1 modification begin under paragraph (3),
2 when an assessment of the strategy is sub-
3 mitted under subsection (g)(1) or under
4 any of subparagraphs (B) through (D) of
5 subsection (g)(2).

6 “(B) INACTION.—An approved risk evalua-
7 tion and mitigation strategy shall remain in ef-
8 fect until the Secretary acts, if the Secretary
9 fails to act as provided under subparagraph
10 (A).

11 “(C) PUBLIC AVAILABILITY.—Any action
12 letter described in subparagraph (A)(i) or order
13 described in subparagraph (A)(ii) shall be made
14 publicly available.

15 “(5) DISPUTE RESOLUTION.—

16 “(A) REQUEST FOR REVIEW.—

17 “(i) IN GENERAL.—Not earlier than
18 15 days, and not later than 35 days, after
19 discussions under paragraph (3) have
20 begun, the responsible person may request
21 in writing that a dispute about the strat-
22 egy be reviewed by the Drug Safety Over-
23 sight Board under subsection (j), except
24 that the determination of the Secretary to
25 require a risk evaluation and mitigation

1 strategy is not subject to review under this
2 paragraph. The preceding sentence does
3 not prohibit review under this paragraph of
4 the particular elements of such a strategy.

5 “(ii) SCHEDULING.—Upon receipt of
6 a request under clause (i), the Secretary
7 shall schedule the dispute involved for re-
8 view under subparagraph (B) and, not
9 later than 5 business days of scheduling
10 the dispute for review, shall publish by
11 posting on the Internet or otherwise a no-
12 tice that the dispute will be reviewed by
13 the Drug Safety Oversight Board.

14 “(B) SCHEDULING REVIEW.—If a respon-
15 sible person requests review under subpara-
16 graph (A), the Secretary—

17 “(i) shall schedule the dispute for re-
18 view at 1 of the next 2 regular meetings of
19 the Drug Safety Oversight Board, which-
20 ever meeting date is more practicable; or

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

1 “(C) AGREEMENT AFTER DISCUSSION OR
2 ADMINISTRATIVE APPEALS.—

3 “(i) FURTHER DISCUSSION OR ADMIN-
4 ISTRATIVE APPEALS.—A request for review
5 under subparagraph (A) shall not preclude
6 further discussions to reach agreement on
7 the risk evaluation and mitigation strategy,
8 and such a request shall not preclude the
9 use of administrative appeals within the
10 Food and Drug Administration to reach
11 agreement on the strategy, including ap-
12 peals as described in letters of the Sec-
13 retary (relating to the use of fees collected
14 under section 736 to expedite the drug de-
15 velopment process and the process for the
16 review of human drug applications) for
17 procedural or scientific matters involving
18 the review of human drug applications and
19 supplemental applications that cannot be
20 resolved at the divisional level.

21 “(ii) AGREEMENT TERMINATES DIS-
22 PUTATE RESOLUTION.—At any time before a
23 decision and order is issued under sub-
24 paragraph (G) , the Secretary and the re-
25 sponsible person may reach an agreement

1 on the risk evaluation and mitigation strat-
2 egy through further discussion or adminis-
3 trative appeals, terminating the dispute
4 resolution process, and the Secretary shall
5 issue an action letter or order, as appro-
6 priate, that describes the strategy.

7 “(D) MEETING OF THE BOARD.—At a
8 meeting of the Drug Safety Oversight Board
9 described in subparagraph (B), the Board
10 shall—

11 “(i) hear from both parties; and

12 “(ii) review the dispute.

13 “(E) RECORD OF PROCEEDINGS.—The
14 Secretary shall ensure that the proceedings of
15 any such meeting are recorded, transcribed, and
16 made public within 30 days of the meeting. The
17 Secretary shall redact the transcript to protect
18 any trade secrets or other confidential informa-
19 tion described in section 552(b)(4) of title 5,
20 United States Code.

21 “(F) RECOMMENDATION OF THE
22 BOARD.—Not later than 5 days after any such
23 meeting, the Drug Safety Oversight Board shall
24 provide a written recommendation on resolving
25 the dispute to the Secretary. Not later than 5

1 days after the Board provides such written rec-
2 ommendation to the Secretary, the Secretary
3 shall make the recommendation available to the
4 public.

5 “(G) ACTION BY THE SECRETARY.—

6 “(i) ACTION LETTER.—With respect
7 to a proposal or assessment referred to in
8 paragraph (1), the Secretary shall issue an
9 action letter that resolves the dispute not
10 later than the later of—

11 “(I) the action deadline referred
12 to in paragraph (3)(A); or

13 “(II) 7 days after receiving the
14 recommendation of the Drug Safety
15 Oversight Board.

16 “(ii) ORDER.—With respect to an as-
17 sessment of an approved risk evaluation
18 and mitigation strategy under subsection
19 (g)(1) or under any of subparagraphs (B)
20 through (D) of subsection (g)(2), the Sec-
21 retary shall issue an order, which shall be
22 made public, that resolves the dispute not
23 later than 7 days after receiving the rec-
24 ommendation of the Drug Safety Oversight
25 Board.

1 “(H) INACTION.—An approved risk evalua-
2 tion and mitigation strategy shall remain in ef-
3 fect until the Secretary acts, if the Secretary
4 fails to act as provided for under subparagraph
5 (G).

6 “(I) EFFECT ON ACTION DEADLINE.—
7 With respect to a proposal or assessment re-
8 ferred to in paragraph (1), the Secretary shall
9 be considered to have met the action deadline
10 referred to in paragraph (3)(A) with respect to
11 the application involved if the responsible per-
12 son requests the dispute resolution process de-
13 scribed in this paragraph and if the Secretary—

14 “(i) has initiated the discussions de-
15 scribed under paragraph (3) not less than
16 60 days before such action deadline; and

17 “(ii) has complied with the timing re-
18 quirements of scheduling review by the
19 Drug Safety Oversight Board, providing a
20 written recommendation, and issuing an
21 action letter under subparagraphs (B),
22 (F), and (G), respectively.

23 “(J) DISQUALIFICATION.—No individual
24 who is an employee of the Food and Drug Ad-
25 ministration and who reviews a drug or who

1 participated in an administrative appeal under
2 subparagraph (C)(i) with respect to such drug
3 may serve on the Drug Safety Oversight Board
4 at a meeting under subparagraph (D) to review
5 a dispute about the risk evaluation and mitiga-
6 tion strategy for such drug.

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

16 “(6) USE OF ADVISORY COMMITTEES.—The
17 Secretary may convene a meeting of 1 or more advi-
18 sory committees of the Food and Drug Administra-
19 tion to—

20 “(A) review a concern about the safety of
21 a drug or class of drugs, including before an as-
22 sessment of the risk evaluation and mitigation
23 strategy or strategies of such drug or drugs is
24 required to be submitted under any of subpara-
25 graphs (B) through (D) of subsection (g)(2);

1 “(B) review the risk evaluation and mitiga-
2 tion strategy or strategies of a drug or group
3 of drugs; or

4 “(C) review a dispute under paragraph (5).

5 “(7) PROCESS FOR ADDRESSING DRUG CLASS
6 EFFECTS.—

7 “(A) IN GENERAL.—When a concern about
8 a serious risk of a drug may be related to the
9 pharmacological class of the drug, the Secretary
10 may defer assessments of the approved risk
11 evaluation and mitigation strategies for such
12 drugs until the Secretary has convened 1 or
13 more public meetings to consider possible re-
14 sponses to such concern. If the Secretary defers
15 an assessment under this subparagraph, the
16 Secretary shall give notice to the public of the
17 deferral not later than 5 days of the deferral.

18 “(B) PUBLIC MEETINGS.—Such public
19 meetings may include—

20 “(i) 1 or more meetings of the re-
21 viewed entities for such drugs;

22 “(ii) 1 or more meetings of 1 or more
23 advisory committees of the Food and Drug
24 Administration, as provided for under
25 paragraph (6); or

1 “(iii) 1 or more workshops of sci-
2 entific experts and other stakeholders.

3 “(C) ACTION.—After considering the dis-
4 cussions from any meetings under subpara-
5 graph (B), the Secretary may—

6 “(i) announce in the Federal Register
7 a planned regulatory action, including a
8 modification to each risk evaluation and
9 mitigation strategy, for drugs in the phar-
10 macological class;

11 “(ii) seek public comment about such
12 action; and

13 “(iii) after seeking such comment,
14 issue an order addressing such regulatory
15 action.

16 “(8) INTERNATIONAL COORDINATION.—The
17 Secretary may coordinate the timetable for submis-
18 sion of assessments under subsection (d), or a study
19 or clinical trial under section 505(o)(3), with efforts
20 to identify and assess the serious risks of such drug
21 by the marketing authorities of other countries
22 whose drug approval and risk management processes
23 the Secretary deems comparable to the drug ap-
24 proval and risk management processes of the United
25 States. If the Secretary takes action to coordinate

1 such timetable, the Secretary shall give notice to the
2 public of the action not later than 5 days after the
3 action.

4 “(9) EFFECT.—Use of the processes described
5 in paragraphs (7) and (8) shall not delay action on
6 an application or a supplement to an application for
7 a drug.

8 “(i) ABBREVIATED NEW DRUG APPLICATIONS.—

9 “(1) IN GENERAL.—A drug that is the subject
10 of an abbreviated new drug application under section
11 505(j) is subject to only the following elements of
12 the risk evaluation and mitigation strategy required
13 under subsection (a) for the applicable listed drug:

14 “(A) A Medication Guide or patient pack-
15 age insert, if required under subsection (e) for
16 the applicable listed drug.

17 “(B) Restrictions on distribution or use, if
18 required under subsection (f) for the listed
19 drug. A drug that is the subject of an abbrev-
20 iated new drug application and the listed drug
21 shall use a single, shared system under sub-
22 section (f)(4). The Secretary may waive the re-
23 quirement under the preceding sentence for a
24 drug that is the subject of an abbreviated new

1 drug application if the Secretary determines
2 that—

3 “(i) it is not practical for the drug to
4 use such single, shared system; or

5 “(ii) the burden of using the single,
6 shared system outweighs the benefit of
7 using the single system.

8 “(2) ACTION BY SECRETARY.—For an applica-
9 ble listed drug for which a drug is approved under
10 section 505(j), the Secretary—

11 “(A) shall undertake any communication
12 plan to health care providers required under
13 subsection (e)(3) for the applicable listed drug;
14 and

15 “(B) shall inform the responsible person
16 for the drug that is so approved if the risk eval-
17 uation and mitigation strategy for the applica-
18 ble listed drug is modified.

19 “(j) DRUG SAFETY OVERSIGHT BOARD.—

20 “(1) IN GENERAL.—There is established a
21 Drug Safety Oversight Board.

22 “(2) COMPOSITION; MEETINGS.—The Drug
23 Safety Oversight Board shall—

24 “(A) be composed of scientists and health
25 care practitioners appointed by the Secretary,

1 each of whom is an employee of the Federal
2 Government;

3 “(B) include representatives from offices
4 throughout the Food and Drug Administration;

5 “(C) include at least 1 representative from
6 each of the National Institutes of Health and
7 the Department of Health and Human Services
8 (other than the Food and Drug Administra-
9 tion);

10 “(D) include such representatives as the
11 Secretary shall designate from other appro-
12 priate agencies that wish to provide representa-
13 tives; and

14 “(E) meet at least monthly to provide
15 oversight and advice to the Secretary on the
16 management of important drug safety issues.”.

17 (c) REGULATION OF BIOLOGICAL PRODUCTS.—Sec-
18 tion 351 of the Public Health Service Act (42 U.S.C. 262)
19 is amended—

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

22 “(D) RISK EVALUATION AND MITIGATION STRAT-
23 EGY.—A person that submits an application for a license
24 under this paragraph is subject to section 505(p) of the
25 Federal Food, Drug, and Cosmetic Act.”; and

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

(d) PREREVIEW OF ADVERTISEMENTS.—

(1) SENSE OF CONGRESS.—It is the sense of the Congress that—

(A) “Guidance for Industry Consumer-Directed Broadcast Advertisements” issued by the Food and Drug Administration in August, 1999, represents generally good guidance for direct-to-consumer (DTC) advertising of prescription medicines and other treatments;

(B) direct-to-consumer advertising as an accurate source of health information for all populations, specifically including the elderly populations, children, chronically ill and racial and ethnic minority populations, should be made more reliable by ensuring the truth and credibility of information provided through such advertising; and

(C) the Congress will work with the Food and Drug Administration to ensure that information provided through direct-to-consumer advertising of prescription medicines and other treatments is not false or misleading and com-

1 communicates clearly and sensitively to all commu-
2 nities.

3 (2) PREREVIEW.—The Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 301 et seq.) is amend-
5 ed—

6 (A) in section 301 (21 U.S.C. 331), by
7 adding at the end the following:

8 “(jj) The dissemination of a television advertisement
9 without complying with section 503B.”; and

10 (B) by inserting after section 503A the fol-
11 lowing:

12 **“SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.**

13 “(a) IN GENERAL.—The Secretary may require the
14 submission of any television advertisement for a drug (in-
15 cluding any script, story board, rough, or a completed
16 video production of the television advertisement) to the
17 Secretary for review under this section not later than 45
18 days before dissemination of the television advertisement.

19 “(b) REVIEW.—In conducting a review of a television
20 advertisement under this section, the Secretary may make
21 recommendations—

22 “(1) on changes that are—

23 “(A) necessary to protect the consumer
24 good and well-being; or

1 “(B) consistent with prescribing informa-
2 tion for the product under review; and

3 “(2) if appropriate and if information exists, on
4 statements for inclusion in the advertisement to ad-
5 dress the specific efficacy of the drug as it relates
6 to a specific population group, including elderly pop-
7 ulations, children, and racially and ethnically diverse
8 populations.

9 “(c) NO AUTHORITY TO REQUIRE CHANGES.—This
10 section does not authorize the Secretary to make or direct
11 changes in any material submitted pursuant to subsection
12 (a).

13 “(d) ELDERLY POPULATIONS, CHILDREN, RACIALLY
14 AND ETHNICALLY DIVERSE COMMUNITIES.—In formu-
15 lating recommendations under subsection (b), the Sec-
16 retary shall take into consideration the impact of the ad-
17 vertised drug on elderly populations, children, and racially
18 and ethnically diverse communities.

19 “(e) SPECIFIC DISCLOSURES.—

20 “(1) SERIOUS RISK; SAFETY PROTOCOL.—In
21 conducting a review of a television advertisement
22 under this section, if the Secretary determines that
23 the advertisement would be false or misleading with-
24 out a specific disclosure about a serious risk listed
25 in the labeling of the drug involved, the Secretary

1 may require inclusion of such disclosure in the ad-
2 vertisement.

3 “(2) DATE OF APPROVAL.—In conducting a re-
4 view of a television advertisement under this section,
5 the Secretary may require the advertisement to in-
6 clude, for a period not to exceed 2 years from the
7 date of the approval of the drug under section 505,
8 a specific disclosure of such date of approval if the
9 Secretary determines that the advertisement would
10 otherwise be false or misleading.

11 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
12 tion may be construed as having any effect on the author-
13 ity of the Secretary under section 314.550, 314.640,
14 601.45, or 601.94 of title 21, Code of Federal Regulations
15 (or successor regulations).”.

16 (3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

17 (A) IN GENERAL.—Section 502(n) of the
18 Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 352(n)) is amended by adding at the
20 end the following: “In the case of an advertise-
21 ment for a drug subject to section 503(b)(1)
22 presented directly to consumers in television or
23 radio format and stating the name of the drug
24 and its conditions of use, the major statement
25 relating to side effects and contraindications

1 shall be presented in a clear and conspicuous
2 manner.”.

3 (B) REGULATIONS TO DETERMINE CLEAR
4 AND CONSPICUOUS MANNER.—The Secretary of
5 Health and Human Services shall by regulation
6 establish standards for determining whether a
7 major statement relating to side effects and
8 contraindications of a drug, described in section
9 502(n) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 352(n)) (as amended by
11 subparagraph (A)) is presented in the manner
12 required under such section.

13 (4) CIVIL PENALTIES.—Section 303 of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333)
15 is amended—

16 (A) by redesignating subsection (g) (relat-
17 ing to civil penalties) as subsection (f); and

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

19 “(g)(1) With respect to a person who is a holder of
20 an approved application under section 505 for a drug sub-
21 ject to section 503(b) or under section 351 of the Public
22 Health Service Act, any such person who disseminates a
23 direct-to-consumer advertisement that is false or mis-
24 leading shall be liable to the United States for a civil pen-
25 alty in an amount not to exceed \$250,000 for the first

1 such violation in any 3-year period, and not to exceed
2 \$500,000 for each subsequent violation in any 3-year pe-
3 riod. No other civil monetary penalties in this Act (includ-
4 ing the civil penalty in section 303(f)(3)) shall apply to
5 a violation regarding direct-to-consumer advertising. For
6 purposes of this paragraph: (A) Repeated dissemination
7 of the same or similar advertisement prior to the receipt
8 of the written notice referred to in paragraph (2) for such
9 advertisements shall be considered one violation. (B) On
10 and after the date of the receipt of such a notice, all viola-
11 tions under this paragraph occurring in a single day shall
12 be considered one violation

13 “(2) A civil penalty under paragraph (1) shall be as-
14 sessed by the Secretary by an order made on the record
15 after providing written notice to the person to be assessed
16 a civil penalty and an opportunity for a hearing in accord-
17 ance with this paragraph and section 554 of title 5, United
18 States Code. If upon receipt of the written notice, the per-
19 son to be assessed a civil penalty objects and requests a
20 hearing, then in the course of any investigation related
21 to such hearing, the Secretary may issue subpoenas re-
22 quiring the attendance and testimony of witnesses and the
23 production of evidence that relates to the matter under
24 investigation, including information pertaining to the fac-
25 tors described in paragraph (3).

1 “(3) Upon the request of the person to be assessed
2 a civil penalty under paragraph (1), the Secretary, in de-
3 termining the amount of the civil penalty, shall take into
4 account the nature, circumstances, extent, and gravity of
5 the violation or violations, including the following factors:

6 “(A) Whether the person submitted the adver-
7 tisement or a similar advertisement for review under
8 section 736A.

9 “(B) Whether the person submitted the adver-
10 tisement for review if required under section 503B.

11 “(C) Whether, after submission of the adver-
12 tisement as described in subparagraph (A) or (B),
13 the person disseminated the advertisement before
14 the end of the 45-day comment period.

15 “(D) Whether the person incorporated any com-
16 ments made by the Secretary with regard to the ad-
17 vertisement into the advertisement prior to its dis-
18 semination.

19 “(E) Whether the person ceased distribution of
20 the advertisement upon receipt of the written notice
21 referred to in paragraph (2) for such advertisement.

22 “(F) Whether the person had the advertisement
23 reviewed by qualified medical, regulatory, and legal
24 reviewers prior to its dissemination.

25 “(G) Whether the violations were material.

1 “(H) Whether the person who created the ad-
2 vertisement acted in good faith.

3 “(I) Whether the person who created the adver-
4 tisement has been assessed a civil penalty under this
5 provision within the previous 1-year period.

6 “(J) The scope and extent of any voluntary,
7 subsequent remedial action by the person.

8 “(K) Such other matters, as justice may re-
9 quire.

10 “(4)(A) Subject to subparagraph (B), no person shall
11 be required to pay a civil penalty under paragraph (1) if
12 the person submitted the advertisement to the Secretary
13 and disseminated such advertisement after incorporating
14 any comment received from the Secretary other than a
15 recommendation subject to subsection 503B(c).

16 “(B) The Secretary may retract or modify any prior
17 comments the Secretary has provided to an advertisement
18 submitted to the Secretary based on new information or
19 changed circumstances, so long as the Secretary provides
20 written notice to the person of the new views of the Sec-
21 retary on the advertisement and provides a reasonable
22 time for modification or correction of the advertisement
23 prior to seeking any civil penalty under paragraph (1).

24 “(5) The Secretary may compromise, modify, or
25 remit, with or without conditions, any civil penalty which

1 may be assessed under paragraph (1). The amount of such
2 penalty, when finally determined, or the amount charged
3 upon in compromise, may be deducted from any sums
4 owed by the United States to the person charged.

5 “(6) Any person who requested, in accordance with
6 paragraph (2), a hearing with respect to the assessment
7 of a civil penalty and who is aggrieved by an order assess-
8 ing a civil penalty, may file a petition for de novo judicial
9 review of such order with the United States Court of Ap-
10 peals for the District of Columbia Circuit or for any other
11 circuit in which such person resides or transacts business.
12 Such a petition may only be filed within the 60-day period
13 beginning on the date the order making such assessments
14 was issued.

15 “(7) On an annual basis, the Secretary shall report
16 to the Congress on direct-to-consumer advertising and its
17 ability to communicate to subsets of the general popu-
18 lation, including elderly populations, children, and racial
19 and ethnic minority communities. The Secretary shall es-
20 tablish a permanent advisory committee to advise the Sec-
21 retary with respect to such report. The membership of the
22 advisory committee shall consist of nationally recognized
23 medical, advertising, and communications experts, includ-
24 ing experts representing subsets of the general population.
25 The members of the advisory committee shall serve with-

1 out pay, but may receive travel expenses, including per
2 diem in lieu of subsistence in accordance with applicable
3 provisions under subchapter I of chapter 57 of title 5,
4 United States Code. The advisory committee shall study
5 direct-to-consumer advertising as it relates to increased
6 access to health information and decreased health dispari-
7 ties for these populations. The annual report required by
8 this paragraph shall recommend effective ways to present
9 and disseminate information to these populations. Such
10 report shall also make recommendations regarding impedi-
11 ments to the participation of elderly populations, children,
12 racially and ethnically diverse communities, and medically
13 underserved populations in clinical drug trials and shall
14 recommend best practice approaches for increasing the in-
15 clusion of such subsets of the general population. The Sec-
16 retary shall submit the first annual report under this para-
17 graph to the Committee on Health, Education, Labor, and
18 Pensions of the Senate and the Committee on Energy and
19 Commerce of the House of Representatives not later than
20 18 months after the advisory committee has been con-
21 vened by the Secretary.

22 “(8) If any person fails to pay an assessment of a
23 civil penalty under paragraph (1)—

24 “(A) after the order making the assessment be-
25 comes final, and if such person does not file a peti-

1 tion for judicial review of the order in accordance
2 with paragraph (6), or

3 “(B) after a court in an action brought under
4 paragraph (6) has entered a final judgment in favor
5 of the Secretary,

6 the Attorney General of the United States shall recover
7 the amount assessed (plus interest at currently prevailing
8 rates from the date of the expiration of the 60-day period
9 referred to in paragraph (6) or the date of such final judg-
10 ment, as the case may be) in an action brought in any
11 appropriate district court of the United States. In such
12 an action, the validity, amount, and appropriateness of
13 such penalty shall not be subject to review.”.

14 (e) **RULE OF CONSTRUCTION REGARDING PEDIATRIC**
15 **STUDIES.**—This title and the amendments made by this
16 title may not be construed as affecting the authority of
17 the Secretary of Health and Human Services to request
18 pediatric studies under section 505A of the Federal Food,
19 Drug, and Cosmetic Act or to require such studies under
20 section 505B of such Act.

21 **SEC. 902. ENFORCEMENT.**

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

1 “(y) If it is a drug subject to an approved risk evalua-
2 tion and mitigation strategy pursuant to section 505(p)
3 and the person responsible for complying with the strategy
4 fails to comply with a requirement of such strategy pro-
5 vided for under subsection (d), (e), or (f) of section 505–
6 1.

7 “(z) If it is a drug, and the responsible person (as
8 such term is used in section 505(o)) is in violation of a
9 requirement established under paragraph (3) (relating to
10 postmarket studies and clinical trials) or paragraph (4)
11 (relating to labeling) of section 505(o) with respect to such
12 drug.”.

13 (b) CIVIL PENALTIES.—Section 303(f) of the Federal
14 Food, Drug, and Cosmetic Act, as redesignated by section
15 901(d)(4), is amended—

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

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

20 “(3) Any applicant (as such term is used in section
21 505–1) who violates a requirement of section 505(o), sec-
22 tion 505(p), or section 505–1 shall be subject to a civil
23 monetary penalty of—

1 “(A) not more than \$250,000 per violation, and
2 not to exceed \$1,000,000 for all such violations ad-
3 judicated in a single proceeding; or

4 “(B) in the case of a violation that continues
5 after the Secretary provides notice of such violation
6 to the applicant, not more than \$10,000,000 per vio-
7 lation, and not to exceed \$50,000,000 for all such
8 violations adjudicated in a single proceeding.

9 If a violation referred to in subparagraph (A) or (B) is
10 continuing in nature and poses a substantial threat to the
11 public health, the Secretary may impose a civil penalty not
12 to exceed \$1,000,000 per day during such time period
13 such person is in violation.”;

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

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

20 (5) in paragraph (6), as so redesignated, by
21 striking “paragraph (4)” each place it appears and
22 inserting “paragraph (5)”.

1 **SEC. 903. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**
2 **APPROVAL.**

3 Section 505(e) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355(e)) is amended by adding at
5 the end the following: “The Secretary may withdraw the
6 approval of an application submitted under this section,
7 or suspend the approval of such an application, as pro-
8 vided under this subsection, without first ordering the ap-
9 plicant to submit an assessment of the approved risk eval-
10 uation and mitigation strategy for the drug under section
11 505–1(g)(2)(D).”.

12 **SEC. 904. BENEFIT-RISK ASSESSMENTS.**

13 Not later than 1 year after the date of the enactment
14 of this Act, the Commissioner of Food and Drugs shall
15 submit to the Congress a report on how best to commu-
16 nicate to the public the risks and benefits of new drugs
17 and the role of the risk evaluation and mitigation strategy
18 in assessing such risks and benefits. As part of such study,
19 the Commissioner shall consider the possibility of includ-
20 ing in the labeling and any direct-to-consumer advertise-
21 ments of a newly approved drug or indication a unique
22 symbol indicating the newly approved status of the drug
23 or indication for a period after approval.

1 **SEC. 905. POSTMARKET RISK IDENTIFICATION AND ANAL-**
2 **YSIS SYSTEM FOR ACTIVE SURVEILLANCE**
3 **AND ASSESSMENT.**

4 (a) FINDINGS.—Congress finds the following:

5 (1) It is in the best interests of healthcare pro-
6 viders and patients that a postmarketing surveil-
7 lance system be developed that will enable active sur-
8 veillance of disparate sources of data to identify sig-
9 nals of unexpected adverse events and trends in the
10 frequency of known adverse events, to provide data
11 on the outcomes of off label uses, and to enable
12 identification of safety issues earlier than can be
13 done today.

14 (2) Such a system can best be developed
15 through public private partnerships to develop meth-
16 ods and tools for conducting surveillance using elec-
17 tronic databases that currently contain data on mil-
18 lions of patient encounters and are expected to grow
19 significantly in the next decade, as well as electronic
20 databases that contain millions of medical product
21 purchases, health care claims, and similar informa-
22 tion relevant to product use, efficacy, and safety.

23 (3) Therefore, this section directs the Secretary
24 of Health and Human Services to enter into such
25 public private partnerships as are necessary to de-
26 velop such a surveillance system and the tools and

1 methods necessary to conduct active surveillance
2 using the system.

3 (b) DEVELOPMENT OF THE POSTMARKET RISK
4 IDENTIFICATION AND ANALYSIS SYSTEM.—Subsection (k)
5 of section 505 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355) is amended by adding at the end the
7 following:

8 “(3) The Secretary shall establish public private part-
9 nerships to develop tools and methods to enable the Sec-
10 retary and others to use available electronic databases to
11 create a robust surveillance system that will support active
12 surveillance on important drug safety questions including
13 detecting and assessing drug safety signals; monitoring
14 the frequency of known adverse events; and evaluating the
15 outcomes of off label uses. Such surveillance shall provide
16 for adverse event surveillance using the following data
17 sources:

18 “(A) Federal health-related electronic data
19 (such as data from the Medicare program and the
20 health systems of the Department of Veterans Af-
21 fairs).

22 “(B) Private sector health-related electronic
23 data (such as pharmaceutical purchase data and
24 health insurance claims data).

1 “(C) Other information as the Secretary deems
2 useful to create a robust system to identify and as-
3 sess adverse events and potential drug safety signals
4 and to evaluate the extent and outcomes of off label
5 uses of drugs.

6 “(4) Not later than 1 year after the date of the enact-
7 ment of this paragraph, the Secretary, in consultation
8 with experts including individuals who are recognized in
9 the field of data privacy and security, shall develop meth-
10 ods for integrating and analyzing safety data from mul-
11 tiple sources and mechanisms for obtaining access to such
12 data. Such methods and mechanisms shall not compromise
13 the protection of individually identifiable health informa-
14 tion.

15 “(5) Not later than 2 years after the date of the en-
16 actment of this paragraph, the Secretary shall have en-
17 tered into partnerships that will allow the analysis of avail-
18 able data from the various data sources using the stand-
19 ards and methods to identify drug safety signals and
20 trends. Such analysis shall not disclose individually identi-
21 fiable health information when presenting such drug safe-
22 ty signals and trends or when responding to inquiries re-
23 garding such drug safety signals and trends.

24 “(6) Not later than 4 years after the date of the en-
25 actment of this paragraph, the Secretary shall report to

1 the Congress on the ways in which the Secretary has used
2 the surveillance system described in this subsection to
3 identify specific drug safety signals and to better under-
4 stand the outcomes associated with drugs marketed in the
5 United States.

6 “(7) Disclosure of individually identifiable informa-
7 tion is prohibited in the surveillance system described in
8 this subsection. Nothing in this subsection prohibits lawful
9 disclosure of such information for other purposes.

10 “(8) Nothing in this subsection shall be construed as
11 limiting public health activities authorized under law.”.

12 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
13 out activities under the amendment made by subsection
14 (b) for which funds are made available under section 736
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379h), there are authorized to be appropriated, in addition
17 to such funds, \$25,000,000 for each of fiscal years 2008
18 through 2012.

19 (d) GAO REPORT.—Not later than 18 months after
20 the date of the enactment of this Act, the Comptroller
21 General of the United States shall evaluate data confiden-
22 tiality and security issues relating to collection, trans-
23 mission, and maintenance of data for the surveillance sys-
24 tem developed pursuant to this section, and make rec-
25 ommendations to the Committee on Energy and Com-

1 merce of the House of Representatives and the Committee
2 on Health, Education, Labor and Pensions of the Senate,
3 and any other congressional committees of relevant juris-
4 diction, regarding the need for any additional legislative
5 or regulatory actions to ensure confidentiality and security
6 of this data or otherwise address confidentiality and secu-
7 rity issues to ensure the effective operation of the surveil-
8 lance system.

9 **SEC. 907. STATEMENT FOR INCLUSION IN DIRECT-TO-CON-**
10 **SUMER ADVERTISEMENTS OF DRUGS.**

11 Section 502(n) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 352), as amended by section
13 901(d)(3), is further amended by striking “of this Act,
14 except that” and inserting “of this Act, and in the case
15 of any direct-to-consumer advertisement the following
16 statement: ‘You are encouraged to report adverse effects
17 of prescription drug medication to the FDA. Log onto
18 www.fda.gov/medwatch or call 1–800-FDA-1088.’, except
19 that”.

20 **SEC. 908. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC**
21 **DRUGS.**

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 510 the following:

1 **“SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC**
2 **DRUGS.**

3 “(a) IN GENERAL.—Not later than 1 year after the
4 date of enactment of this section, the Secretary, acting
5 through the Commissioner of Food and Drugs, shall issue
6 guidance for the conduct of clinical trials with respect to
7 antibiotic drugs, including antimicrobials to treat acute
8 bacterial sinusitis, acute bacterial otitis media, and acute
9 bacterial exacerbation of chronic bronchitis. Such guide-
10 lines shall indicate the appropriate animal models of infec-
11 tion, in vitro techniques, and valid microbiologic surrogate
12 markers.

13 “(b) REVIEW.—Not later than 5 years after the date
14 of enactment of this section, the Secretary, acting through
15 the Commissioner of Food and Drugs, shall review and
16 update the guidance described under subsection (a) to re-
17 flect developments in scientific and medical information
18 and technology.”.

19 **SEC. 909. PROHIBITION AGAINST FOOD TO WHICH DRUGS**
20 **OR BIOLOGICAL PRODUCTS HAVE BEEN**
21 **ADDED.**

22 Section 301 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 331), as amended by section 901(d)(2)(A),
24 is amended by adding at the end the following:

1 “(kk) The introduction or delivery for introduction
2 into interstate commerce of any food to which has been
3 added—

4 “(1) a drug approved under section 505,

5 “(2) a biological product licensed under section
6 351 of the Public Health Service Act, or

7 “(3) a drug or biological product for which sub-
8 stantial clinical investigations have been instituted
9 and for which the existence of such investigations
10 has been made public,

11 unless such drug or biological product was marketed in
12 food before any approval of the drug under section 505
13 of this Act, before licensure of the biological product under
14 section 351 of the Public Health Service Act, and before
15 any substantial clinical investigations involving the drug
16 or biological product have been instituted, or unless the
17 Secretary, in the Secretary’s discretion, has issued a regu-
18 lation, after notice and comment, approving the addition
19 of such drug or biological product to the food.”.

20 **SEC. 910. ASSURING PHARMACEUTICAL SAFETY.**

21 Chapter V of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 351 et seq.) is amended by inserting after
23 section 505B the following:

1 **“SEC. 505C. PHARMACEUTICAL SECURITY.**

2 “(a) IN GENERAL.—The Secretary shall develop
3 standards and identify and validate effective technologies
4 for the purpose of securing the prescription drug distribu-
5 tion system against counterfeit, diverted, subpotent, sub-
6 standard, adulterated, misbranded, or expired drugs.

7 “(b) STANDARDS DEVELOPMENT.—

8 “(1) IN GENERAL.—The Secretary shall, in con-
9 sultation with the agencies specified in paragraph
10 (3), prioritize and develop standards for the identi-
11 fication, validation, authentication, and tracking of
12 prescription drugs.

13 “(2) PROMISING TECHNOLOGIES.—The stand-
14 ards developed under this subsection shall address
15 promising technologies, including—

16 “(A) radio frequency identification tech-
17 nology;

18 “(B) nanotechnology;

19 “(C) encryption technologies; and

20 “(D) other track-and-trace technologies.

21 “(3) INTERAGENCY COLLABORATION.—In car-
22 rying out this subsection, the Secretary shall consult
23 with Federal health and security agencies, includ-
24 ing—

25 “(A) the Administrator of the Drug En-
26 forcement Administration;

1 “(B) the Secretary of the Department of
2 Homeland Security;

3 “(C) the Secretary of Commerce; and

4 “(D) other appropriate Federal and State
5 agencies.

6 “(c) INSPECTION AND ENFORCEMENT.—

7 “(1) IN GENERAL.—The Secretary shall expand
8 and enhance the resources and facilities of the Office
9 of Regulatory Affairs of the Food and Drug Admin-
10 istration to protect the prescription drug distribution
11 system against counterfeit, diverted, subpotent, sub-
12 standard, adulterated, misbranded, or expired drugs.

13 “(2) ACTIVITIES.—The Secretary shall under-
14 take enhanced and joint enforcement activities with
15 other Federal agencies and State officials, and es-
16 tablish regional capacities for the validation of pre-
17 scription drugs and the inspection of the prescrip-
18 tion drug distribution system.

19 “(d) DEFINITION.—In this section, the term ‘pre-
20 scription drug’ means a drug subject to section
21 503(b)(1).”.

22 **SEC. 911. ORPHAN ANTIBIOTIC DRUGS.**

23 (a) PUBLIC MEETING.—The Commissioner of Food
24 and Drugs shall convene a public meeting regarding which
25 serious and life threatening infectious diseases, such as

1 diseases due to gram-negative bacteria and other diseases
 2 due to antibiotic-resistant bacteria, potentially qualify for
 3 available grants and contracts under section 5(a) of the
 4 Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives
 5 for development.

6 (b) GRANTS AND CONTRACTS FOR THE DEVELOP-
 7 MENT OF ORPHAN DRUGS.—Section 5(c) of the Orphan
 8 Drug Act (21 U.S.C. 360ee(c)) is amended to read as fol-
 9 lows:

10 “(c) For grants and contracts under subsection (a),
 11 there is authorized to be appropriated \$30,000,000 for
 12 each of fiscal years 2008 through 2012.”.

13 **SEC. 912. CITIZEN PETITIONS AND PETITIONS FOR STAY OF**
 14 **AGENCY ACTION.**

15 (a) IN GENERAL.—Section 505 of the Federal Food,
 16 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
 17 section 901(a), is amended by adding at the end the fol-
 18 lowing:

19 “(q) PETITIONS AND CIVIL ACTIONS REGARDING AP-
 20 PROVAL OF CERTAIN APPLICATIONS.—

21 “(1) IN GENERAL.—With respect to a pending
 22 application under subsection (b)(2) or (j), if a peti-
 23 tion is submitted to the Secretary that seeks to have
 24 the Secretary take, or refrain from taking, any form
 25 of action relating to the approval of the application,

1 including a delay in the effective date of the applica-
2 tion, the following applies, subject to paragraph (5):

3 “(A) The Secretary may not, on the basis
4 of the petition, delay approval of the application
5 unless the Secretary determines that a delay is
6 necessary to protect the public health and pro-
7 vides the applicant with a written explanation
8 of the reasons for the delay. Consideration of a
9 petition shall be separate and apart from the
10 review and approval of the application.

11 “(B) The Secretary shall take final agency
12 action on the petition not later than 180 days
13 after the date on which the petition is sub-
14 mitted. The Secretary shall not extend such pe-
15 riod, even with the consent of the petitioner, for
16 any reason, including based upon the submis-
17 sion of comments relating to the petition or
18 supplemental information supplied by the peti-
19 tioner.

20 “(C) If the Secretary determines that the
21 petition was submitted with the primary pur-
22 pose of delaying approval of a drug under sub-
23 section (b)(2) or (j), the Secretary may deny
24 the petition at any point.

1 “(D) If the filing of the application re-
2 sulted in first-applicant status under subsection
3 (j)(5)(D)(i)(IV), the 30-month period under
4 such subsection is deemed to be extended by a
5 period of time equal to the period beginning on
6 the date on which the Secretary received the pe-
7 tition and ending on the date of final agency
8 action on the petition (inclusive of such begin-
9 ning and ending dates), without regard to
10 whether the Secretary grants, in whole or in
11 part, or denies, in whole or in part, the petition.

12 “(E) The Secretary may not consider the
13 petition for review unless it is signed and con-
14 tains the following certification: ‘I certify that,
15 to my best knowledge and belief: (a) this peti-
16 tion includes all information and views upon
17 which the petition relies; (b) this petition in-
18 cludes representative data and/or information
19 known to the petitioner which are unfavorable
20 to the petition; and (c) I have taken reasonable
21 steps to ensure that any representative data
22 and/or information which are unfavorable to the
23 petition were disclosed to me. I further certify
24 that the information upon which I have based
25 the action requested herein first became known

1 to the party on whose behalf this petition is
2 submitted on or about the following date:

3 _____ . I received or expect to
4 receive payments, including cash and other
5 forms of consideration, from the following per-
6 sons or organizations to file this petition:

7 _____ . I verify under
8 penalty of perjury that the foregoing is true
9 and correct.’.

10 “(2) EXHAUSTION OF ADMINISTRATIVE REM-
11 EDIES.—

12 “(A) FINAL AGENCY ACTION WITHIN 180
13 DAYS.—The Secretary shall be considered to
14 have taken final agency action on a petition re-
15 ferred to in paragraph (1) if—

16 “(i) during the 180-day period re-
17 ferred to in subparagraph (B) of such
18 paragraph, the Secretary makes a final de-
19 cision within the meaning of section
20 10.45(d) of title 21, Code of Federal Regu-
21 lations (or any successor regulation); or

22 “(ii) such period expires without the
23 Secretary having made such a final deci-
24 sion.

1 “(B) DISMISSAL OF CERTAIN CIVIL AC-
2 TIONS.—If a civil action is filed with respect to
3 any issue raised in a petition under paragraph
4 (1) before the Secretary has taken final agency
5 action on the petition within the meaning of
6 subparagraph (A), the court shall dismiss the
7 action for failure to exhaust administrative rem-
8 edies.

9 “(3) APPLICABILITY OF CERTAIN REGULA-
10 TIONS.—The provisions of this section are in addi-
11 tion to the requirements for the submission of a pe-
12 tition to the Secretary that apply under section
13 10.30 or 10.35 of title 21, Code of Federal Regula-
14 tions (or any successor regulations).

15 “(4) ANNUAL REPORT ON DELAYS IN APPROV-
16 ALS PER PETITIONS.—The Secretary shall annually
17 submit to the Congress a report that specifies—

18 “(A) the number of applications under
19 subsections (b)(2) and (j) that were approved
20 during the preceding 12-month period;

21 “(B) the number of such applications
22 whose effective dates were delayed by petitions
23 referred to in paragraph (1) during such period;
24 and

1 “(C) the number of days by which the ap-
2 plications were so delayed.

3 “(5) EXCEPTIONS.—This subsection does not
4 apply to—

5 “(A) a petition that relates solely to the
6 timing of the approval of an application pursu-
7 ant to subsection (j)(5)(B)(iv); or

8 “(B) a petition that is made by the spon-
9 sor of an application under subsection (b)(2) or
10 (j) and that seeks only to have the Secretary
11 take or refrain from taking any form of action
12 with respect to that application.

13 “(6) DEFINITION.—For purposes of this sub-
14 section, the term ‘petition’ includes any request to
15 the Secretary for an action described in paragraph
16 (1), without regard to whether the request is charac-
17 terized as a petition.”.

18 (b) REPORT.—Not later than 1 year after the date
19 of the enactment of this Act, the Secretary of Health and
20 Human Services shall submit a report to the Congress on
21 ways to encourage the early submission of petitions under
22 section 505(q), as added by subsection (a).

23 **SEC. 913. AUTHORIZATION OF APPROPRIATIONS.**

24 (a) IN GENERAL.—For carrying out this title and the
25 amendments made by this title, there is authorized to be

1 appropriated \$25,000,000 for each of fiscal years 2008
2 through 2012.

3 (b) RELATION TO OTHER FUNDING.—The authoriza-
4 tion of appropriations under subsection (a) is in addition
5 to any other funds available for carrying out this title and
6 the amendments made by this title.

7 **SEC. 914. EFFECTIVE DATE AND APPLICABILITY.**

8 (a) EFFECTIVE DATE.—This title takes effect 180
9 days after the date of the enactment of this Act.

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

12 (1) IN GENERAL.—A drug that was approved
13 before the effective date of this Act is, in accordance
14 with paragraph (2), deemed to have in effect an ap-
15 proved risk evaluation and mitigation strategy under
16 section 505–1 of the Federal Food, Drug, and Cos-
17 metic Act (as added by section 901 of this title) (re-
18 ferred to in this section as the “Act”) if there are
19 in effect on the effective date of this Act restrictions
20 on distribution or use—

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

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

1 (2) ELEMENTS OF STRATEGY; ENFORCE-
2 MENT.—The approved risk evaluation and mitigation
3 strategy in effect for a drug under paragraph (1)—

4 (A) is deemed to consist of the elements
5 described in paragraphs (1) and (2) of section
6 505–1(d) of the Act and any additional ele-
7 ments under subsections (d) and (e) of such
8 section in effect for such drug on the effective
9 date of this Act; and

10 (B) is subject to enforcement by the Sec-
11 retary to the same extent as any other risk
12 evaluation and mitigation strategy under sec-
13 tion 505–1 of the Act.

14 (3) SUBMISSION.—Not later than 180 days
15 after the effective date of this Act, the holder of an
16 approved application for which a risk evaluation and
17 mitigation strategy is deemed to be in effect under
18 paragraph (1) shall submit to the Secretary a pro-
19 posed risk evaluation and mitigation strategy. Such
20 proposed strategy is subject to section 505–1 of the
21 Act as if included in such application at the time of
22 submission of the application to the Secretary.

23 (c) OTHER DRUGS APPROVED BEFORE THE EFEC-
24 TIVE DATE.—The Secretary, on a case-by-case basis, may
25 require the holder of an application approved before the

1 effective date of this Act to which subsection (b) does not
2 apply to submit a proposed risk evaluation and mitigation
3 strategy in accordance with the timeframes provided for
4 in subparagraphs (C) through (D) of section 505–1(g)(2)
5 of the Act if the Secretary determines (with respect to
6 such drug or with respect to the group of drugs to which
7 such drug belongs) that—

8 (1) an element described under section 505–
9 1(d)(1) of the Act may require modification; or

10 (2) a standard for adding an element described
11 in subsection (e) or (d) of section 505–1 of the Act
12 that is not in effect with respect to such drug or
13 class of drugs may apply.

14 (d) USE OF ADVISORY COMMITTEES; PROCESS FOR
15 ADDRESSING DRUG CLASS EFFECTS.—In imposing a re-
16 quirement under subsection (c), the Secretary—

17 (1) may convene a meeting of 1 or more advi-
18 sory committees of the Food and Drug Administra-
19 tion in accordance with paragraph (6) of section
20 505–1(h) of the Act; and

21 (2) may use the process described in paragraph
22 (7) of such section 505–1(h) (relating to addressing
23 drug class effects).

Passed the House of Representatives July 11, 2007.

Attest:

LORRAINE C. MILLER,

Clerk.

Calendar No. 270

110TH CONGRESS
1ST Session

H. R. 2900

AN ACT

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

JULY 16, 2007

Received; read twice and placed on the calendar