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(Original Signature of Member)

110TH CONGRESS
1ST SESSION

H. R. _____

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.

IN THE HOUSE OF REPRESENTATIVES

Mr. DINGELL (for himself and [see ATTACHED LIST of cosponsors]) introduced the following bill; which was referred to the Committee on

A BILL

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”.

1 SEC. 2. TABLE OF CONTENTS.**2 The table of contents for this Act is as follows:**

- Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

- Sec. 101. Short title; references in title; finding.
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.
Sec. 107. Effective date.
Sec. 108. Savings clause.
Sec. 109. Technical amendment; conforming amendment.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

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

Subtitle A—Fees Related to Medical Devices

- Sec. 211. Definitions.
Sec. 212. Authority to assess and use device fees.
Sec. 213. Reauthorization; reporting requirements.
Sec. 214. Savings clause.
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.
Sec. 230. Report by the Food and Drug Administration regarding labeling information on the relationship between the use of indoor tanning devices and development of skin cancer or other skin damage.

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

3

- 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 surveillance.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

- Sec. 401. Short title.
- Sec. 402. Reauthorization of Pediatric Research Equity Act.
- Sec. 403. Establishment of internal committee.
- Sec. 404. 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.
- Sec. 503. Training of pediatric pharmacologists.

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. Expanded clinical trial registry data bank.

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

Subtitle A—Postmarket Studies and Surveillance

- 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. Active postmarket risk identification and analysis.
- Sec. 906. Statement for inclusion in direct-to-consumer advertisements of drugs.
- Sec. 907. No effect on veterinary medicine.
- Sec. 908. Authorization of appropriations.
- Sec. 909. Effective date and applicability.

Subtitle B—Other Provisions to Ensure Drug Safety and Surveillance

- Sec. 911. Clinical trial guidance for antibiotic drugs.
- Sec. 912. Prohibition against food to which drugs or biological products have been added.

4

- Sec. 913. Assuring pharmaceutical safety.
- Sec. 914. Citizen petitions and petitions for stay of agency action.
- Sec. 915. Postmarket drug safety information for patients and providers.
- Sec. 916. Action package for approval.
- Sec. 917. Risk communication.
- Sec. 918. Referral to advisory committee.
- Sec. 919. Response to the institute of medicine.
- Sec. 920. Database for authorized generic drugs.
- Sec. 921. Adverse drug reaction reports and postmarket safety.

TITLE X—FOOD SAFETY

- Sec. 1001. Findings.
- Sec. 1002. Ensuring the safety of pet food.
- Sec. 1003. Ensuring efficient and effective communications during a recall.
- Sec. 1004. State and Federal Cooperation.
- Sec. 1005. Reportable Food Registry.
- Sec. 1006. Enhanced aquaculture and seafood inspection.
- Sec. 1007. Consultation regarding genetically engineered seafood products.
- Sec. 1008. Sense of Congress.
- Sec. 1009. Annual report to Congress.
- Sec. 1010. Publication of annual reports.
- Sec. 1011. Rule of construction.

TITLE XI—OTHER PROVISIONS

Subtitle A—In General

- Sec. 1101. Policy on the review and clearance of scientific articles published by FDA employees.
- Sec. 1102. Priority review to encourage treatments for tropical diseases.
- Sec. 1103. Improving genetic test safety and quality.
- Sec. 1104. NIH Technical amendments.
- Sec. 1105. Severability clause.

Subtitle B—Antibiotic Access and Innovation

- Sec. 1111. Incentives for the development of, and access to, certain antibiotics.
- Sec. 1112. Identification of clinically susceptible concentrations of antimicrobials.
- Sec. 1113. Orphan antibiotic drugs.
- Sec. 1114. Exclusivity of certain drugs containing single enantiomers.
- Sec. 1115. Report.

- 1 **TITLE I—PRESCRIPTION DRUG**
- 2 **USER FEE AMENDMENTS OF 2007**
- 3 **SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.**
- 4 (a) SHORT TITLE.—This title may be cited as the
- 5 “Prescription Drug User Fee Amendments of 2007”.

1 (b) REFERENCES IN TITLE.—Except as otherwise
2 specified, amendments made by this title to a section or
3 other provision of law are amendments to such section or
4 other provision of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 301 et seq.).

6 (c) FINDING.—The Congress finds that the fees au-
7 thorized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-
10 cluding postmarket drug safety activities, as set forth in
11 the goals identified for purposes of part 2 of subchapter
12 C of chapter VII of the Federal Food, Drug, and Cosmetic
13 Act, in the letters from the Secretary of Health and
14 Human Services to the Chairman of the Committee on
15 Health, Education, Labor, and Pensions of the Senate and
16 the Chairman of the Committee on Energy and Commerce
17 of the House of Representatives, as set forth in the Con-
18 gressional Record.

19 **SEC. 102. DEFINITIONS.**

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

21 (1) in the matter before paragraph (1), by
22 striking “For purposes of this subchapter” and in-
23 serting “For purposes of this part”;

24 (2) in paragraph (1)—

1 (A) in subparagraph (A), by striking
2 “505(b)(1),” and inserting “505(b), or”;

3 (B) by striking subparagraph (B);

4 (C) by redesignating subparagraph (C) as
5 subparagraph (B); and

6 (D) in the matter following subparagraph
7 (B), as so redesignated, by striking “subpara-
8 graph (C)” and inserting “subparagraph (B)”;
9 (3) in paragraph (3)(C)—

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

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

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

19 (5) by amending paragraph (6)(F) to read as
20 follows:

21 “(F) Postmarket safety activities with re-
22 spect to drugs approved under human drug ap-
23 plications or supplements, including the fol-
24 lowing activities:

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

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

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

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

16 “(v) Carrying out section 505(k)(5)
17 (relating to adverse event reports and
18 postmarket safety activities).”;

19 (6) in paragraph (8)—

20 (A) by striking “April of the preceding fis-
21 cal year” and inserting “October of the pre-
22 ceding fiscal year”; and

23 (B) by striking “April 1997” and inserting
24 “October 1996”;

1 (7) by redesignating paragraph (9) as para-
2 graph (11); and

3 (8) by inserting after paragraph (8) the fol-
4 lowing paragraphs:

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

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

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

12 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
13 379h(a)) is amended—

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

16 (2) in paragraph (1)—

17 (A) in subparagraph (D)—

18 (i) in the heading, by inserting “OR
19 WITHDRAWN BEFORE FILING” after “RE-
20 FUSED FOR FILING”; and

21 (ii) by inserting before the period at
22 the end the following: “or withdrawn with-
23 out a waiver before filing”;

1 (B) by redesignating subparagraphs (E)
2 and (F) as subparagraphs (F) and (G), respec-
3 tively; and

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

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

16 (3) in paragraph (2)—

17 (A) in subparagraph (A), by striking “sub-
18 paragraph (B)” and inserting “subparagraphs
19 (B) and (C)”; and

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

21 “(C) SPECIAL RULES FOR POSITRON EMIS-
22 SION TOMOGRAPHY DRUGS.—

23 “(i) IN GENERAL.—Except as pro-
24 vided in clause (ii), each person who is
25 named as the applicant in an approved

1 human drug application for a positron
2 emission tomography drug shall be subject
3 under subparagraph (A) to one-sixth of an
4 annual establishment fee with respect to
5 each such establishment identified in the
6 application as producing positron emission
7 tomography drugs under the approved ap-
8 plication.

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

18 “(I) the person is a not-for-profit
19 medical center that has only 1 estab-
20 lishment for the production of
21 positron emission tomography drugs;
22 and

23 “(II) at least 95 percent of the
24 total number of doses of each positron
25 emission tomography drug produced

1 by such establishment during such fis-
2 cal year will be used within the med-
3 ical center.

4 “(iii) DEFINITION.—For purposes of
5 this subparagraph, the term ‘positron
6 emission tomography drug’ has the mean-
7 ing given to the term ‘compounded
8 positron emission tomography drug’ in sec-
9 tion 201(ii), except that paragraph (1)(B)
10 of such section shall not apply.”.

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

13 “(b) FEE REVENUE AMOUNTS.—

14 “(1) IN GENERAL.—For each of the fiscal years
15 2008 through 2012, fees under subsection (a) shall,
16 except as provided in subsections (c), (d), (f), and
17 (g), be established to generate a total revenue
18 amount under such subsection that is equal to the
19 sum of—

20 “(A) \$392,783,000; and

21 “(B) an amount equal to the modified
22 workload adjustment factor for fiscal year 2007
23 (as determined under paragraph (3)).

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

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

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

10 “(C) one-third shall be derived from fees
11 under subsection (a)(3) (relating to prescription
12 drug products).

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

1 tive during the most recent 12-month period for
2 which data on such submissions is available.

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

5 “(A) IN GENERAL.—For each of the fiscal
6 years 2008 through 2012, paragraph (1)(A)
7 shall be applied by substituting the amount de-
8 termined under subparagraph (B) for
9 ‘\$392,783,000’.

10 “(B) AMOUNT DETERMINED.—For each of
11 the fiscal years 2008 through 2012, the amount
12 determined under this subparagraph is the sum
13 of—

14 “(i) \$392,783,000; plus

15 “(ii)(I) for fiscal year 2008,
16 \$25,000,000;

17 “(II) for fiscal year 2009,
18 \$35,000,000;

19 “(III) for fiscal year 2010,
20 \$45,000,000;

21 “(IV) for fiscal year 2011,
22 \$55,000,000; and

23 “(V) for fiscal year 2012,
24 \$65,000,000.”.

25 (c) ADJUSTMENTS TO FEES.—

1 (1) INFLATION ADJUSTMENT.—Section
2 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

3 (A) in the matter preceding subparagraph
4 (A), by striking “The revenues established in
5 subsection (b)” and inserting “For fiscal year
6 2009 and subsequent fiscal years, the revenues
7 established in subsection (b)”;

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

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

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

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

20 (E) in the matter following subparagraph
21 (C) (as added by subparagraph (D)), by strik-
22 ing “fiscal year 2003” and inserting “fiscal
23 year 2008”.

24 (2) WORKLOAD ADJUSTMENT.—Section
25 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

1 (A) in the matter preceding subparagraph
2 (A), by striking “Beginning with fiscal year
3 2004,” and inserting “For fiscal year 2009 and
4 subsequent fiscal years,”;

5 (B) in subparagraph (A), in the first sen-
6 tence—

7 (i) by striking “human drug applica-
8 tions,” and inserting “human drug applica-
9 tions (adjusted for changes in review ac-
10 tivities, as described in the notice that the
11 Secretary is required to publish in the
12 Federal Register under this subpara-
13 graph),”;

14 (ii) by striking “commercial investiga-
15 tional new drug applications,”; and

16 (iii) by inserting before the period the
17 following: “, and the change in the total
18 number of active commercial investiga-
19 tional new drug applications (adjusted for
20 changes in review activities, as so de-
21 scribed) during the most recent 12-month
22 period for which data on such submissions
23 is available”;

24 (C) in subparagraph (B), by adding at the
25 end the following: “Any adjustment for changes

1 in review activities made in setting fees and rev-
2 enue amounts for fiscal year 2009 may not re-
3 sult in the total workload adjustment being
4 more than 2 percentage points higher than it
5 would have been in the absence of the adjust-
6 ment for changes in review activities.”; and

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

8 “(C) The Secretary shall contract with an
9 independent accounting firm to study the ad-
10 justment for changes in review activities applied
11 in setting fees and revenue amounts for fiscal
12 year 2009 and to make recommendations, if
13 warranted, for future changes in the method-
14 ology for calculating the adjustment. After re-
15 view of the recommendations, the Secretary
16 shall, if warranted, make appropriate changes
17 to the methodology, and the changes shall be ef-
18 fective for each of the fiscal years 2010 through
19 2012. The Secretary shall not make any adjust-
20 ment for changes in review activities for any
21 fiscal year after 2009 unless such study has
22 been completed.”.

23 (3) RENT AND RENT-RELATED COST ADJUST-
24 MENT.—Section 736(c) (21 U.S.C. 379h(c)) is
25 amended—

1 (A) by redesignating paragraphs (3), (4),
2 and (5) as paragraphs (4), (5), and (6), respec-
3 tively; and

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

6 “(3) RENT AND RENT-RELATED COST ADJUST-
7 MENT.—For fiscal year 2010 and each subsequent
8 fiscal year, the Secretary shall, before making ad-
9 justments under paragraphs (1) and (2), decrease
10 the fee revenue amount established in subsection (b)
11 if actual costs paid for rent and rent-related ex-
12 penses for the preceding fiscal year are less than es-
13 timates made for such year in fiscal year 2006. Any
14 reduction made under this paragraph shall not ex-
15 ceed the amount by which such costs fall below the
16 estimates made in fiscal year 2006 for such fiscal
17 year, and shall not exceed \$11,721,000 for any fiscal
18 year.”.

19 (4) FINAL YEAR ADJUSTMENT.—Paragraph (4)
20 of section 736(c) (21 U.S.C. 379h(c)), as redesign-
21 ated by paragraph (3)(A), is amended to read as
22 follows:

23 “(4) FINAL YEAR ADJUSTMENT.—

24 “(A) INCREASE IN FEES.—For fiscal year
25 2012, the Secretary may, in addition to adjust-

1 ments under this paragraph and paragraphs
2 (1), (2), and (3), further increase the fee reve-
3 nues and fees established in subsection (b) if
4 such an adjustment is necessary to provide for
5 not more than 3 months of operating reserves
6 of carryover user fees for the process for the re-
7 view of human drug applications for the first 3
8 months of fiscal year 2013. If such an adjust-
9 ment is necessary, the rationale for the amount
10 of the increase shall be contained in the annual
11 notice establishing fee revenues and fees for fis-
12 cal year 2012. If the Secretary has carryover
13 balances for such process in excess of 3 months
14 of such operating reserves, the adjustment
15 under this subparagraph shall not be made.

16 “(B) DECREASE IN FEES.—

17 “(i) IN GENERAL.—For fiscal year
18 2012, the Secretary may, in addition to
19 adjustments under this paragraph and
20 paragraphs (1), (2), and (3), decrease the
21 fee revenues and fees established in sub-
22 section (b) by the amount determined in
23 clause (ii), if, for fiscal year 2009 or
24 2010—

1 “(I) the amount of the total ap-
2 propriations for the Food and Drug
3 Administration for such fiscal year
4 (excluding the amount of fees appro-
5 priated for such fiscal year) exceeds
6 the amount of the total appropriations
7 for the Food and Drug Administra-
8 tion for fiscal year 2008 (excluding
9 the amount of fees appropriated for
10 such fiscal year), adjusted as provided
11 under paragraph (1); and

12 “(II) the amount of the total ap-
13 propriations expended for the process
14 for the review of human drug applica-
15 tions at the Food and Drug Adminis-
16 tration for such fiscal year (excluding
17 the amount of fees appropriated for
18 such fiscal year) exceeds the amount
19 of appropriations expended for the
20 process for the review of human drug
21 applications at the Food and Drug
22 Administration for fiscal year 2008
23 (excluding the amount of fees appro-
24 priated for such fiscal year), adjusted
25 as provided under paragraph (1).

1 “(ii) AMOUNT OF DECREASE.—The
2 amount determined in this clause is the
3 lesser of—

4 “(I) the amount equal to the sum
5 of the amounts that, for each of fiscal
6 years 2009 and 2010, is the lesser
7 of—

8 “(aa) the excess amount de-
9 scribed in clause (i)(II) for such
10 fiscal year; or

11 “(bb) the amount specified
12 in subsection (b)(4)(B)(ii) for
13 such fiscal year; or

14 “(II) \$65,000,000.

15 “(iii) LIMITATIONS.—

16 “(I) FISCAL YEAR CONDITION.—
17 In making the determination under
18 clause (ii), an amount described in
19 subclause (I) of such clause for fiscal
20 year 2009 or 2010 shall be taken into
21 account only if subclauses (I) and (II)
22 of clause (i) apply to such fiscal year.

23 “(II) RELATION TO SUBPARA-
24 GRAPH (A).—The Secretary shall limit
25 any decrease under this paragraph if

1 such a limitation is necessary to pro-
2 vide for the 3 months of operating re-
3 serves described in subparagraph
4 (A).”.

5 (5) LIMIT.—Paragraph (5) of section 736(c)
6 (21 U.S.C. 379h(c)), as redesignated by paragraph
7 (3)(A), is amended by striking “2002” and inserting
8 “2007”.

9 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
10 (21 U.S.C. 379h(d)) is amended—

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

13 (A) by inserting after “The Secretary shall
14 grant” the following: “to a person who is
15 named as the applicant in a human drug appli-
16 cation”; and

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

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

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

23 “(2) CONSIDERATIONS.—In determining wheth-
24 er to grant a waiver or reduction of a fee under
25 paragraph (1), the Secretary shall consider only the

1 circumstances and assets of the applicant involved
2 and any affiliate of the applicant.”; and

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

9 (e) CREDITING AND AVAILABILITY OF FEES.—

10 (1) AUTHORIZATION OF APPROPRIATIONS.—

11 Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amend-
12 ed to read as follows:

13 “(3) AUTHORIZATION OF APPROPRIATIONS.—

14 For each of the fiscal years 2008 through 2012,
15 there is authorized to be appropriated for fees under
16 this section an amount equal to the total revenue
17 amount determined under subsection (b) for the fis-
18 cal year, as adjusted or otherwise affected under
19 subsection (c) and paragraph (4) of this sub-
20 section.”.

21 (2) OFFSET.—Section 736(g)(4) (21 U.S.C.

22 379h(g)(4)) is amended to read as follows:

23 “(4) OFFSET.—If the sum of the cumulative

24 amount of fees collected under this section for the

25 fiscal years 2008 through 2010 and the amount of

1 fees estimated to be collected under this section for
2 fiscal year 2011 exceeds the cumulative amount ap-
3 propriated under paragraph (3) for the fiscal years
4 2008 through 2011, the excess shall be credited to
5 the appropriation account of the Food and Drug Ad-
6 ministration as provided in paragraph (1), and shall
7 be subtracted from the amount of fees that would
8 otherwise be authorized to be collected under this
9 section pursuant to appropriation Acts for fiscal
10 year 2012.”.

11 (f) EXEMPTION FOR ORPHAN DRUGS.—Section 736
12 (21 U.S.C. 379h) is further amended by adding at the
13 end the following:

14 “(k) ORPHAN DRUGS.—

15 “(1) EXEMPTION.—A drug designated under
16 section 526 for a rare disease or condition and ap-
17 proved under section 505 or under section 351 of
18 the Public Health Service Act shall be exempt from
19 product and establishment fees under this section, if
20 the drug meets all of the following conditions:

21 “(A) The drug meets the public health re-
22 quirements contained in this Act as such re-
23 quirements are applied to requests for waivers
24 for product and establishment fees.

1 “(B) The drug is owned or licensed and is
2 marketed by a company that had less than
3 \$50,000,000 in gross worldwide revenue during
4 the previous year.

5 “(2) EVIDENCE OF QUALIFICATION.—An ex-
6 emption under paragraph (1) applies with respect to
7 a drug only if the applicant involved submits a cer-
8 tification that its gross annual revenues did not ex-
9 ceed \$50,000,000 for the preceding 12 months be-
10 fore the exemption was requested.”.

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

15 (h) TECHNICAL AMENDMENT.—

16 (1) AMENDMENT.—Section 736(g)(1) (21
17 U.S.C. 379h(g)(1)) is amended by striking the first
18 sentence and inserting the following: “Fees author-
19 ized under subsection (a) shall be collected and
20 available for obligation only to the extent and in the
21 amount provided in advance in appropriations Acts.
22 Such fees are authorized to remain available until
23 expended.”.

24 (2) EFFECTIVE DATE.—Paragraph (1) shall
25 take effect as if included in section 504 of the Pre-

1 scription Drug User Fee Amendments of 2002
2 (Public Law 107-188; 116 Stat. 687).

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

5 Part 2 of subchapter C of chapter VII (21 U.S.C.
6 379g et seq.) is amended by adding after section 736 the
7 following:

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

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

14 “(1) ADVISORY REVIEW FEE.—

15 “(A) IN GENERAL.—With respect to a pro-
16 posed direct-to-consumer television advertise-
17 ment (referred to in this section as a ‘DTC ad-
18 vertisement’), each person that on or after Oc-
19 tober 1, 2007, submits such an advertisement
20 for advisory review by the Secretary prior to its
21 initial public dissemination shall, except as pro-
22 vided in subparagraph (B), be subject to a fee
23 established under subsection (c)(3).

24 “(B) EXCEPTION FOR REQUIRED SUBMIS-
25 SIONS.—A DTC advertisement that is required

1 to be submitted to the Secretary prior to initial
2 public dissemination is not subject to a fee
3 under subparagraph (A) unless the sponsor des-
4 ignates the submission as a submission for advi-
5 sory review.

6 “(C) NOTICE TO SECRETARY OF NUMBER
7 OF ADVERTISEMENTS.—Not later than June 1
8 of each fiscal year, the Secretary shall publish
9 a notice in the Federal Register requesting any
10 person to notify the Secretary within 30 days of
11 the number of DTC advertisements the person
12 intends to submit for advisory review in the
13 next fiscal year. Notwithstanding the preceding
14 sentence, for fiscal year 2008, the Secretary
15 shall publish such a notice in the Federal Reg-
16 ister not later than 30 days after the date of
17 the enactment of the Food and Drug Adminis-
18 tration Amendments Act of 2007.

19 “(D) PAYMENT.—

20 “(i) IN GENERAL.—The fee required
21 by subparagraph (A) (referred to in this
22 section as ‘an advisory review fee’) shall be
23 due not later than October 1 of the fiscal
24 year in which the DTC advertisement in-
25 volved is intended to be submitted for advi-

1 sory review, subject to subparagraph
2 (F)(i). Notwithstanding the preceding sen-
3 tence, the advisory review fee for any DTC
4 advertisement that is intended to be sub-
5 mitted for advisory review during fiscal
6 year 2008 shall be due not later than 120
7 days after the date of the enactment of the
8 Food and Drug Administration Amend-
9 ments of 2007 or an earlier date as speci-
10 fied by the Secretary.

11 “(ii) EFFECT OF SUBMISSION.—Noti-
12 fication of the Secretary under subpara-
13 graph (C) of the number of DTC adver-
14 tisements a person intends to submit for
15 advisory review is a legally binding com-
16 mitment by that person to pay the annual
17 advisory review fee for that number of sub-
18 missions on or before October 1 of the fis-
19 cal year in which the advertisement is in-
20 tended to be submitted. Notwithstanding
21 the preceding sentence, the commitment
22 shall be a legally binding commitment by
23 that person to pay the annual advisory re-
24 view fee for that number of submissions

1 for fiscal year 2008 by the date specified
2 in clause (i).

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

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

17 “(i) LATE PAYMENT.—If a person has
18 submitted a notification under subpara-
19 graph (C) with respect to a fiscal year and
20 has not paid all advisory review fees due
21 under subparagraph (D) not later than
22 November 1 of such fiscal year (or, in the
23 case of such a notification submitted with
24 respect to fiscal year 2008, not later than
25 150 days after the date of the enactment

1 of the Food and Drug Administration
2 Amendments Act of 2007 or an earlier
3 date specified by the Secretary), the fees
4 shall be regarded as late and an increase
5 in the amount of fees applies in accordance
6 with this clause, notwithstanding any other
7 provision of this section. For such person,
8 all advisory review fees for such fiscal year
9 shall be due and payable 20 days before
10 any direct-to-consumer advertisement is
11 submitted to the Secretary for advisory re-
12 view, and each such fee shall be equal to
13 150 percent of the fee that otherwise
14 would have applied pursuant to subsection
15 (c)(3).

16 “(ii) EXCEEDING IDENTIFIED NUM-
17 BER OF SUBMISSIONS.—If a person sub-
18 mits a number of DTC advertisements for
19 advisory review in a fiscal year that ex-
20 ceeds the number identified by the person
21 under subparagraph (C), an increase in the
22 amount of fees applies under this clause
23 for each submission in excess of such num-
24 ber, notwithstanding any other provision of
25 this section. For each such DTC advertise-

1 ment, the advisory review fee shall be due
2 and payable 20 days before the advertise-
3 ment is submitted to the Secretary, and
4 the fee shall be equal to 150 percent of the
5 fee that otherwise would have applied pur-
6 suant to subsection (c)(3).

7 “(F) LIMITS.—

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

23 “(ii) NO REFUNDS.—Except as pro-
24 vided by subsections (d)(4) and (f), fees

1 paid under this section shall not be re-
2 funded.

3 “(iii) NO WAIVERS, EXEMPTIONS, OR
4 REDUCTIONS.—The Secretary shall not
5 grant a waiver, exemption, or reduction of
6 any fees due or payable under this section.

7 “(iv) RIGHT TO ADVISORY REVIEW
8 NOT TRANSFERABLE.—The right to an ad-
9 visory review under this paragraph is not
10 transferable, except to a successor in inter-
11 est.

12 “(2) OPERATING RESERVE FEE.—

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

22 “(B) PAYMENT.—Except as provided in
23 subparagraph (C), the operating reserve fee
24 shall be due no later than—

1 “(i) October 1 of the first fiscal year
2 in which the person is required to pay an
3 advisory review fee under paragraph (1);
4 or

5 “(ii) for fiscal year 2008, 120 days
6 after the date of the enactment of the
7 Food and Drug Administration Amend-
8 ments Act of 2007 or an earlier date speci-
9 fied by the Secretary.

10 “(C) LATE NOTICE OF SUBMISSION.—If, in
11 the first fiscal year of a person’s participation
12 in the program under this section, that person
13 submits any DTC advertisements for advisory
14 review that are in excess of the number identi-
15 fied by that person in response to the Federal
16 Register notice described in subsection
17 (a)(1)(C), that person shall pay an operating
18 reserve fee for each of those advisory reviews
19 equal to the advisory review fee for each sub-
20 mission established under paragraph (1)(E)(ii).
21 Fees required by this subparagraph shall be in
22 addition to any fees required by subparagraph
23 (A). Fees under this subparagraph shall be due
24 20 days before any DTC advertisement is sub-

1 mitted by such person to the Secretary for advi-
2 sory review.

3 “(D) LATE PAYMENT.—

4 “(i) IN GENERAL.—Notwithstanding
5 subparagraph (B), and subject to clause
6 (ii), an operating reserve fee shall be re-
7 garded as late if the person required to
8 pay the fee has not paid the complete oper-
9 ating reserve fee by—

10 “(I) for fiscal year 2008, 150
11 days after the date of the enactment
12 of the Food and Drug Administration
13 Amendments Act of 2007 or an ear-
14 lier date specified by the Secretary; or

15 “(II) in any subsequent year, No-
16 vember 1.

17 “(ii) COMPLETE PAYMENT.—The
18 complete operating reserve fee shall be due
19 and payable 20 days before any DTC ad-
20 vertisement is submitted by such person to
21 the Secretary for advisory review.

22 “(iii) AMOUNT.—Notwithstanding any
23 other provision of this section, an oper-
24 ating reserve fee that is regarded as late
25 under this subparagraph shall be equal to

1 150 percent of the operating reserve fee
2 that otherwise would have applied pursu-
3 ant to subsection (d).

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

9 “(c) ADJUSTMENTS.—

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

15 “(A) the total percentage change that oc-
16 curred in the Consumer Price Index for all
17 urban consumers (all items; U.S. city average),
18 for the 12-month period ending June 30 pre-
19 ceding the fiscal year for which fees are being
20 established;

21 “(B) the total percentage change for the
22 previous fiscal year in basic pay under the Gen-
23 eral Schedule in accordance with section 5332
24 of title 5, United States Code, as adjusted by
25 any locality-based comparability payment pur-

1 suant to section 5304 of such title for Federal
2 employees stationed in the District of Columbia;
3 or

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

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

14 “(2) WORKLOAD ADJUSTMENT.—Beginning
15 with fiscal year 2009, after the fee revenues estab-
16 lished in subsection (b) are adjusted for a fiscal year
17 for inflation in accordance with paragraph (1), the
18 fee revenues shall be adjusted further for such fiscal
19 year to reflect changes in the workload of the Sec-
20 retary with respect to the submission of DTC adver-
21 tisements for advisory review prior to initial dissemi-
22 nation. With respect to such adjustment:

23 “(A) The adjustment shall be determined
24 by the Secretary based upon the number of
25 DTC advertisements identified pursuant to sub-

1 section (a)(1)(C) for the upcoming fiscal year,
2 excluding allowable previously paid carry over
3 submissions. The adjustment shall be deter-
4 mined by multiplying the number of such adver-
5 tisements projected for that fiscal year that ex-
6 ceeds 150 by \$27,600 (adjusted each year be-
7 ginning with fiscal year 2009 for inflation in
8 accordance with paragraph (1)). The Secretary
9 shall publish in the Federal Register the fee
10 revenues and fees resulting from the adjust-
11 ment and the supporting methodologies.

12 “(B) Under no circumstances shall the ad-
13 justment result in fee revenues for a fiscal year
14 that are less than the fee revenues established
15 for the prior fiscal year.

16 “(3) ANNUAL FEE SETTING FOR ADVISORY RE-
17 VIEW.—

18 “(A) IN GENERAL.—Not later than August
19 1 of each fiscal year (or, with respect to fiscal
20 year 2008, not later than 90 days after the date
21 of the enactment of the Food and Drug Admin-
22 istration Amendments Act of 2007), the Sec-
23 retary shall establish for the next fiscal year the
24 DTC advertisement advisory review fee under
25 subsection (a)(1), based on the revenue

1 amounts established under subsection (b), the
2 adjustments provided under paragraphs (1) and
3 (2), and the number of DTC advertisements
4 identified pursuant to subsection (a)(1)(C), ex-
5 cluding allowable previously-paid carry over
6 submissions. The annual advisory review fee
7 shall be established by dividing the fee revenue
8 for a fiscal year (as adjusted pursuant to this
9 subsection) by the number of DTC advertise-
10 ments so identified, excluding allowable pre-
11 viously-paid carry over submissions under sub-
12 section (a)(1)(F)(i).

13 “(B) FISCAL YEAR 2008 FEE LIMIT.—Not-
14 withstanding subsection (b) and the adjust-
15 ments pursuant to this subsection, the fee es-
16 tablished under subparagraph (A) for fiscal
17 year 2008 may not be more than \$83,000 per
18 submission for advisory review.

19 “(C) ANNUAL FEE LIMIT.—Notwith-
20 standing subsection (b) and the adjustments
21 pursuant to this subsection, the fee established
22 under subparagraph (A) for a fiscal year after
23 fiscal year 2008 may not be more than 50 per-
24 cent more than the fee established for the prior
25 fiscal year.

1 “(D) LIMIT.—The total amount of fees ob-
2 ligated for a fiscal year may not exceed the
3 total costs for such fiscal year for the resources
4 allocated for the process for the advisory review
5 of prescription drug advertising.

6 “(d) OPERATING RESERVES.—

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

17 “(2) FEE SETTING.—The Secretary shall estab-
18 lish the operating reserve fee under subsection
19 (a)(2)(A) for each person required to pay the fee by
20 multiplying the number of DTC advertisements iden-
21 tified by that person pursuant to subsection
22 (a)(1)(C) by the advisory review fee established pur-
23 suant to subsection (c)(3) for that fiscal year, except
24 that in no case shall the operating reserve fee as-
25 sessed be less than the operating reserve fee as-

1 sessed if the person had first participated in the pro-
2 gram under this section in fiscal year 2008.

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

13 “(4) REFUND OF OPERATING RESERVES.—
14 Within 120 days after the end of fiscal year 2012,
15 or if the program under this section ends early pur-
16 suant to subsection (f), the Secretary, after setting
17 aside sufficient operating reserve amounts to termi-
18 nate the program under this section, shall refund all
19 amounts remaining in the operating reserve on a pro
20 rata basis to each person that paid an operating re-
21 serve fee assessment. In no event shall the refund to
22 any person exceed the total amount of operating re-
23 serve fees paid by such person pursuant to sub-
24 section (a)(2).

1 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
2 standing any other requirement, a submission for advisory
3 review of a DTC advertisement submitted by a person sub-
4 ject to fees under subsection (a) shall be considered incom-
5 plete and shall not be accepted for review by the Secretary
6 until all fees owed by such person under this section have
7 been paid.

8 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
9 GRAM.—

10 “(1) INITIAL FUNDING.—If on November 1,
11 2007, or 120 days after the date of the enactment
12 of the Food and Drug Administration Amendments
13 Act of 2007, whichever is later, the Secretary has
14 not received at least \$11,250,000 in advisory review
15 fees and operating reserve fees combined, the pro-
16 gram under this section shall not commence and all
17 collected fees shall be refunded.

18 “(2) LATER FISCAL YEARS.—Beginning in fis-
19 cal year 2009, if, on November 1 of the fiscal year,
20 the combination of the operating reserves, annual fee
21 revenues from that fiscal year, and unobligated fee
22 revenues from prior fiscal years falls below
23 \$9,000,000, adjusted for inflation (as described in
24 subsection (c)(1)), the program under this section
25 shall terminate, and the Secretary shall notify all

1 participants, retain any money from the unused ad-
2 visory review fees and the operating reserves needed
3 to terminate the program, and refund the remainder
4 of the unused fees and operating reserves. To the ex-
5 tent required to terminate the program, the Sec-
6 retary shall first use unobligated advisory review fee
7 revenues from prior fiscal years, then the operating
8 reserves, and finally, unused advisory review fees
9 from the relevant fiscal year.

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

11 “(1) IN GENERAL.—Fees authorized under sub-
12 section (a) shall be collected and available for obliga-
13 tion only to the extent and in the amount provided
14 in advance in appropriations Acts. Such fees are au-
15 thorized to remain available until expended. Such
16 sums as may be necessary may be transferred from
17 the Food and Drug Administration salaries and ex-
18 penses appropriation account without fiscal year lim-
19 itation to such appropriation account for salaries
20 and expenses with such fiscal year limitation. The
21 sums transferred shall be available solely for the
22 process for the advisory review of prescription drug
23 advertising.

24 “(2) COLLECTIONS AND APPROPRIATION
25 ACTS.—

1 “(A) IN GENERAL.—The fees authorized
2 by this section—

3 “(i) shall be retained in each fiscal
4 year in an amount not to exceed the
5 amount specified in appropriation Acts, or
6 otherwise made available for obligation for
7 such fiscal year; and

8 “(ii) shall be available for obligation
9 only if the amounts appropriated as budget
10 authority for such fiscal year are sufficient
11 to support a number of full-time equivalent
12 review employees that is not fewer than the
13 number of such employees supported in fis-
14 cal year 2007.

15 “(B) REVIEW EMPLOYEES.—For purposes
16 of subparagraph (A)(ii), the term ‘full-time
17 equivalent review employees’ means the total
18 combined number of full-time equivalent em-
19 ployees in—

20 “(i) the Center for Drug Evaluation
21 and Research, Division of Drug Marketing,
22 Advertising, and Communications, Food
23 and Drug Administration; and

24 “(ii) the Center for Biologics Evalua-
25 tion and Research, Advertising and Pro-

1 motional Labeling Branch, Food and Drug
2 Administration.

3 “(3) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

21 “(1) The term ‘advisory review’ means review-
22 ing and providing advisory comments on DTC adver-
23 tisements regarding compliance of a proposed adver-
24 tisement with the requirements of this Act prior to
25 its initial public dissemination.

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

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

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

13 “(5) The term ‘DTC advertisement’ has the
14 meaning indicated for such term in subsection
15 (a)(1)(A).

16 “(6) The term ‘operating reserve fee’ has the
17 meaning indicated for such term in subsection
18 (a)(2)(A).

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

22 “(8) The term ‘process for the advisory review
23 of prescription drug advertising’ means the activities
24 necessary to review and provide advisory comments
25 on DTC advertisements prior to public dissemination

1 and, to the extent the Secretary has additional staff
2 resources available under the program under this
3 section that are not necessary for the advisory re-
4 view of DTC advertisements, the activities necessary
5 to review and provide advisory comments on other
6 proposed advertisements and promotional material
7 prior to public dissemination.

8 “(9) The term ‘resources allocated for the proc-
9 ess for the advisory review of prescription drug ad-
10 vertising’ means the expenses incurred in connection
11 with the process for the advisory review of prescrip-
12 tion drug advertising for—

13 “(A) officers and employees of the Food
14 and Drug Administration, contractors of the
15 Food and Drug Administration, advisory com-
16 mittees, and costs related to such officers, em-
17 ployees, and committees, and to contracts with
18 such contractors;

19 “(B) management of information, and the
20 acquisition, maintenance, and repair of com-
21 puter resources;

22 “(C) leasing, maintenance, renovation, and
23 repair of facilities and acquisition, maintenance,
24 and repair of fixtures, furniture, scientific

1 equipment, and other necessary materials and
2 supplies;

3 “(D) collection of fees under this section
4 and accounting for resources allocated for the
5 advisory review of prescription drug advertising;
6 and

7 “(E) terminating the program under this
8 section pursuant to subsection (f)(2) if that be-
9 comes necessary.

10 “(10) The term ‘resubmission’ means a subse-
11 quent submission for advisory review of a direct-to-
12 consumer television advertisement that has been re-
13 vised in response to the Secretary’s comments on an
14 original submission. A resubmission may not intro-
15 duce significant new concepts or creative themes into
16 the television advertisement.

17 “(11) The term ‘submission for advisory review’
18 means an original submission of a direct-to-con-
19 sumer television advertisement for which the sponsor
20 voluntarily requests advisory comments before the
21 advertisement is publicly disseminated.”.

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

23 Part 2 of subchapter C of chapter VII (21 U.S.C.
24 379g et seq.), as amended by section 104, is further
25 amended by inserting after section 736A the following:

1 **“SEC. 736B. REAUTHORIZATION; REPORTING REQUIRE-**
2 **MENTS.**

3 “(a) PERFORMANCE REPORT.—Beginning with fiscal
4 year 2008, not later than 120 days after the end of each
5 fiscal year for which fees are collected under this part,
6 the Secretary shall prepare and submit to the Committee
7 on Energy and Commerce of the House of Representatives
8 and the Committee on Health, Education, Labor, and
9 Pensions of the Senate a report concerning the progress
10 of the Food and Drug Administration in achieving the
11 goals identified in the letters described in section 101(c)
12 of the Food and Drug Administration Amendments Act
13 of 2007 during such fiscal year and the future plans of
14 the Food and Drug Administration for meeting the goals.
15 The report for a fiscal year shall include information on
16 all previous cohorts for which the Secretary has not given
17 a complete response on all human drug applications and
18 supplements in the cohort.

19 “(b) FISCAL REPORT.—Beginning with fiscal year
20 2008, not later than 120 days after the end of each fiscal
21 year for which fees are collected under this part, the Sec-
22 retary shall prepare and submit to the Committee on En-
23 ergy and Commerce of the House of Representatives and
24 the Committee on Health, Education, Labor, and Pen-
25 sions of the Senate a report on the implementation of the
26 authority for such fees during such fiscal year and the

1 use, by the Food and Drug Administration, of the fees
2 collected for such fiscal year.

3 “(c) PUBLIC AVAILABILITY.—The Secretary shall
4 make the reports required under subsections (a) and (b)
5 available to the public on the Internet Web site of the
6 Food and Drug Administration.

7 “(d) REAUTHORIZATION.—

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

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

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

19 “(C) scientific and academic experts;

20 “(D) health care professionals;

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

23 “(F) the regulated industry.

1 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
2 negotiations with the regulated industry on the reau-
3 thorization of this part, the Secretary shall—

4 “(A) publish a notice in the Federal Reg-
5 ister requesting public input on the reauthoriza-
6 tion;

7 “(B) hold a public meeting at which the
8 public may present its views on the reauthoriza-
9 tion, including specific suggestions for changes
10 to the goals referred to in subsection (a);

11 “(C) provide a period of 30 days after the
12 public meeting to obtain written comments from
13 the public suggesting changes to this part; and

14 “(D) publish the comments on the Food
15 and Drug Administration’s Internet Web site.

16 “(3) PERIODIC CONSULTATION.—Not less fre-
17 quently than once every month during negotiations
18 with the regulated industry, the Secretary shall hold
19 discussions with representatives of patient and con-
20 sumer advocacy groups to continue discussions of
21 their views on the reauthorization and their sugges-
22 tions for changes to this part as expressed under
23 paragraph (2).

1 “(4) PUBLIC REVIEW OF RECOMMENDA-
2 TIONS.—After negotiations with the regulated indus-
3 try, the Secretary shall—

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

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

9 “(C) provide for a period of 30 days for
10 the public to provide written comments on such
11 recommendations;

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

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

18 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
19 Not later than January 15, 2012, the Secretary
20 shall transmit to the Congress the revised rec-
21 ommendations under paragraph (4), a summary of
22 the views and comments received under such para-
23 graph, and any changes made to the recommenda-
24 tions in response to such views and comments.

25 “(6) MINUTES OF NEGOTIATION MEETINGS.—

1 “(A) PUBLIC AVAILABILITY.—Before pre-
2 senting the recommendations developed under
3 paragraphs (1) through (5) to the Congress, the
4 Secretary shall make publicly available, on the
5 public Web site of the Food and Drug Adminis-
6 tration, minutes of all negotiation meetings con-
7 ducted under this subsection between the Food
8 and Drug Administration and the regulated in-
9 dustry.

10 “(B) CONTENT.—The minutes described
11 under subparagraph (A) shall summarize any
12 substantive proposal made by any party to the
13 negotiations as well as significant controversies
14 or differences of opinion during the negotiations
15 and their resolution.”.

16 **SEC. 106. SUNSET DATES.**

17 (a) AUTHORIZATION.—The amendments made by
18 sections 102, 103, and 104 cease to be effective October
19 1, 2012.

20 (b) REPORTING REQUIREMENTS.—The amendment
21 made by section 105 ceases to be effective January 31,
22 2013.

23 **SEC. 107. EFFECTIVE DATE.**

24 The amendments made by this title shall take effect
25 on October 1, 2007, or the date of the enactment of this

1 Act, whichever is later, except that fees under part 2 of
2 subchapter C of chapter VII of the Federal Food, Drug,
3 and Cosmetic Act shall be assessed for all human drug
4 applications received on or after October 1, 2007, regard-
5 less of the date of the enactment of this Act.

6 **SEC. 108. SAVINGS CLAUSE.**

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

20 **SEC. 109. TECHNICAL AMENDMENT; CONFORMING AMEND-**
21 **MENT.**

22 (a) Section 739 (21 U.S.C. 379j–11) is amended in
23 the matter preceding paragraph (1) by striking “sub-
24 chapter” and inserting “part”.

1 (b) Paragraph (11) of section 739 (21 U.S.C. 379j–
2 11) is amended by striking “735(9)” and inserting
3 “735(11)”.

4 **TITLE II—MEDICAL DEVICE** 5 **USER FEE AMENDMENTS OF 2007**

6 **SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.**

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

9 (b) REFERENCES IN TITLE.—Except as otherwise
10 specified, amendments made by this title to a section or
11 other provision of law are amendments to such section or
12 other provision of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 301 et seq.).

14 (c) FINDING.—The Congress finds that the fees au-
15 thorized under the amendments made by this title will be
16 dedicated toward expediting the process for the review of
17 device applications and for assuring the safety and effec-
18 tiveness of devices, as set forth in the goals identified for
19 purposes of part 3 of subchapter C of chapter VII of the
20 Federal Food, Drug, and Cosmetic Act in the letters from
21 the Secretary of Health and Human Services to the Chair-
22 man of the Committee on Health, Education, Labor, and
23 Pensions of the Senate and the Chairman of the Com-
24 mittee on Energy and Commerce of the House of Rep-
25 resentatives, as set forth in the Congressional Record.

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

Section 737 is amended—

(1) in the matter preceding paragraph (1), by striking “For purposes of this subchapter” and inserting “For purposes of this part”;

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (8), (9), (10), and (12), respectively;

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

“(5) The term ‘30-day notice’ means a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

“(6) The term ‘request for classification information’ means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

“(7) The term ‘annual fee’, for periodic reporting concerning a class III device, means the annual

1 fee associated with periodic reports required by a
2 premarket application approval order.”;

3 (4) in paragraph (10), as so redesignated—

4 (A) by striking “April of the preceding fis-
5 cal year” and inserting “October of the pre-
6 ceding fiscal year”; and

7 (B) by striking “April 2002” and inserting
8 “October 2001”;

9 (5) by inserting after paragraph (10), as so
10 amended, the following:

11 “(11) The term ‘person’ includes an affiliate
12 thereof.”; and

13 (6) by inserting after paragraph (12), as so re-
14 designated, the following:

15 “(13) The term ‘establishment subject to a reg-
16 istration fee’ means an establishment that is re-
17 quired to register with the Secretary under section
18 510 and is one of the following types of establish-
19 ments:

20 “(A) MANUFACTURER.—An establishment
21 that makes by any means any article that is a
22 device, including an establishment that sterilizes
23 or otherwise makes such article for or on behalf
24 of a specification developer or any other person.

1 “(B) SINGLE-USE DEVICE REPROC-
2 ESSOR.—An establishment that, within the
3 meaning of section 201(l)(2)(A), performs ad-
4 ditional processing and manufacturing oper-
5 ations on a single-use device that has previously
6 been used on a patient.

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

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

17 (a) TYPES OF FEES.—

18 (1) IN GENERAL.—Section 738(a) (21 U.S.C.
19 379j(a)) is amended—

20 (A) in paragraph (1), by striking “Begin-
21 ning on the date of the enactment of the Med-
22 ical Device User Fee and Modernization Act of
23 2002” and inserting “Beginning in fiscal year
24 2008”; and

1 (B) by amending the designation and
2 heading of paragraph (2) to read as follows:

3 “(2) PREMARKET APPLICATION, PREMARKET
4 REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND
5 ANNUAL FEE FOR PERIODIC REPORTING CON-
6 CERNING A CLASS III DEVICE.—”.

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

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

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

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

16 (D) by redesignating clauses (vi) and (vii)
17 as clauses (vii) and (viii), respectively;

18 (E) by inserting after clause (v) the fol-
19 lowing:

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

23 (F) in clause (viii), as so redesignated—

24 (i) by striking “1.42 percent” and in-
25 serting “1.84 percent”; and

1 (ii) by striking “, subject to any ad-
2 justment under subsection (e)(2)(C)(ii)”;
3 and

4 (G) by inserting after such clause (viii) the
5 following:

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

9 “(x) For periodic reporting concerning
10 a class III device, an annual fee equal to
11 3.5 percent of the fee that applies under
12 clause (i).”.

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

15 “(C) PAYMENT.—The fee required by sub-
16 paragraph (A) shall be due upon submission of
17 the premarket application, premarket report,
18 supplement, premarket notification submission,
19 30-day notice, request for classification infor-
20 mation, or periodic reporting concerning a class
21 III device. Applicants submitting portions of
22 applications pursuant to section 515(c)(4) shall
23 pay such fees upon submission of the first por-
24 tion of such applications.”.

1 (4) REFUNDS.—Section 738(a)(2)(D) (21
2 U.S.C. 379j(a)(2)(D)) is amended—

3 (A) in clause (iii), by striking the last two
4 sentences; and

5 (B) by adding after clause (iii) the fol-
6 lowing:

7 “(iv) MODULAR APPLICATIONS WITH-
8 DRAWN BEFORE FIRST ACTION.—The Sec-
9 retary shall refund 75 percent of the appli-
10 cation fee paid for an application sub-
11 mitted under section 515(c)(4) that is
12 withdrawn before a second portion is sub-
13 mitted and before a first action on the first
14 portion.

15 “(v) LATER WITHDRAWN MODULAR
16 APPLICATIONS.—If an application sub-
17 mitted under section 515(c)(4) is with-
18 drawn after a second or subsequent portion
19 is submitted but before any first action,
20 the Secretary may return a portion of the
21 fee. The amount of refund, if any, shall be
22 based on the level of effort already ex-
23 pended on the review of the portions sub-
24 mitted.

1 “(vi) SOLE DISCRETION TO RE-
2 FUND.—The Secretary shall have sole dis-
3 cretion to refund a fee or portion of the fee
4 under clause (iii) or (v). A determination
5 by the Secretary concerning a refund
6 under clause (iii) or (v) shall not be review-
7 able.”.

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

11 “(3) ANNUAL ESTABLISHMENT REGISTRATION
12 FEE.—

13 “(A) IN GENERAL.—Except as provided in
14 subparagraph (B), each establishment subject
15 to a registration fee shall be subject to a fee for
16 each initial or annual registration under section
17 510 beginning with its registration for fiscal
18 year 2008.

19 “(B) EXCEPTION.—No fee shall be re-
20 quired under subparagraph (A) for an estab-
21 lishment operated by a State or Federal govern-
22 mental entity or an Indian tribe (as defined in
23 the Indian Self Determination and Educational
24 Assistance Act), unless a device manufactured

1 by the establishment is to be distributed com-
 2 mercially.

3 “(C) PAYMENT.—The fee required under
 4 subparagraph (A) shall be due once each fiscal
 5 year, upon the initial registration of the estab-
 6 lishment or upon the annual registration under
 7 section 510.”.

8 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.
 9 379j(b)) is amended to read as follows:

10 “(b) FEE AMOUNTS.—Except as provided in
 11 subsections (c), (d), (e), and (h) the fees under sub-
 12 section (a) shall be based on the following fee
 13 amounts:

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

14 (c) ANNUAL FEE SETTING.—

15 (1) IN GENERAL.—Section 738(c) (21 U.S.C.
 16 379j(c)(1)) is amended—

17 (A) in the subsection heading, by striking
 18 “Annual Fee Setting” and inserting “ANNUAL
 19 FEE SETTING”; and

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

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

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

8 (B) by inserting after paragraph (1) the
9 following:

10 “(2) ADJUSTMENT.—

11 “(A) IN GENERAL.—When setting fees for
12 fiscal year 2010, the Secretary may increase the
13 fee under subsection (a)(3)(A) (applicable to es-
14 tablishments subject to registration) only if the
15 Secretary estimates that the number of estab-
16 lishments submitting fees for fiscal year 2009 is
17 fewer than 12,250. The percentage increase
18 shall be the percentage by which the estimate of
19 establishments submitting fees in fiscal year
20 2009 is fewer than 12,750, but in no case may
21 the percentage increase be more than 8.5 per-
22 cent over that specified in subsection (b) for fis-
23 cal year 2010. If the Secretary makes any ad-
24 justment to the fee under subsection (a)(3)(A)
25 for fiscal year 2010, then such fee for fiscal

1 years 2011 and 2012 shall be adjusted so that
2 such fee for fiscal year 2011 is equal to the ad-
3 justed fee for fiscal year 2010 increased by 8.5
4 percent, and such fee for fiscal year 2012 is
5 equal to the adjusted fee for fiscal year 2011
6 increased by 8.5 percent.

7 “(B) PUBLICATION.—For any adjustment
8 made under subparagraph (A), the Secretary
9 shall publish in the Federal Register the Sec-
10 retary’s determination to make the adjustment
11 and the rationale for the determination.”; and

12 (C) in paragraph (4), as redesignated by
13 this paragraph, in subparagraph (A)—

14 (i) by striking “For fiscal years 2006
15 and 2007, the Secretary” and inserting
16 “The Secretary”; and

17 (ii) by striking “for the first month of
18 fiscal year 2008” and inserting “for the
19 first month of the next fiscal year”.

20 (d) SMALL BUSINESSES; FEE WAIVER AND FEE RE-
21 DUCTION REGARDING PREMARKET APPROVAL.—

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

24 (A) by striking “, partners, and parent
25 firms”; and

1 (B) by striking “clauses (i) through (vi) of
2 subsection (a)(2)(A)” and inserting “clauses (i)
3 through (v) and clauses (vii), (ix), and (x) of
4 subsection (a)(2)(A)”.

5 (2) RULES RELATING TO PREMARKET AP-
6 PROVAL FEES.—

7 (A) DEFINITION.—Section 738(d)(2)(A)
8 (21 U.S.C. 379j(d)(2)(A)) is amended by strik-
9 ing “, partners, and parent firms”.

10 (B) EVIDENCE OF QUALIFICATION.—Sec-
11 tion 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is
12 amended—

13 (i) by striking “(B) EVIDENCE OF
14 QUALIFICATION.—An applicant” and in-
15 serting the following:

16 “(B) EVIDENCE OF QUALIFICATION.—

17 “(i) IN GENERAL.—An applicant”;

18 (ii) by striking “The applicant shall
19 support its claim” and inserting the fol-
20 lowing:

21 “(ii) FIRMS SUBMITTING TAX RE-
22 TURNS TO THE UNITED STATES INTERNAL
23 REVENUE SERVICE.—The applicant shall
24 support its claim”;

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

3 (iv) by striking the last sentence and
4 inserting “If no tax forms are submitted
5 for any affiliate, the applicant shall certify
6 that the applicant has no affiliates.”; and

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

8 “(iii) FIRMS NOT SUBMITTING TAX
9 RETURNS TO THE UNITED STATES INTER-
10 NAL REVENUE SERVICE.—In the case of an
11 applicant that has not previously submitted
12 a Federal income tax return, the applicant
13 and each of its affiliates shall demonstrate
14 that it meets the definition under subpara-
15 graph (A) by submission of a signed cer-
16 tification, in such form as the Secretary
17 may direct through a notice published in
18 the Federal Register, that the applicant or
19 affiliate meets the criteria for a small busi-
20 ness and a certification, in English, from
21 the national taxing authority of the coun-
22 try in which the applicant or, if applicable,
23 affiliate is headquartered. The certification
24 from such taxing authority shall bear the
25 official seal of such taxing authority and

1 shall provide the applicant's or affiliate's
2 gross receipts or sales for the most recent
3 year in both the local currency of such
4 country and in United States dollars, the
5 exchange rate used in converting such local
6 currency to dollars, and the dates during
7 which these receipts or sales were collected.
8 The applicant shall also submit a state-
9 ment signed by the head of the applicant's
10 firm or by its chief financial officer that
11 the applicant has submitted certifications
12 for all of its affiliates, or that the applicant
13 has no affiliates.”.

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

16 “(C) REDUCED FEES.—Where the Sec-
17 retary finds that the applicant involved meets
18 the definition under subparagraph (A), the fees
19 established under subsection (c)(1) may be paid
20 at a reduced rate of—

21 “(i) 25 percent of the fee established
22 under such subsection for a premarket ap-
23 plication, a premarket report, a supple-
24 ment, or periodic reporting concerning a
25 class III device; and

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

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

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

9 (A) by striking “2004” and inserting
10 “2008”; and

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

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

15 (A) DEFINITION.—Section 738(e)(2)(A)
16 (21 U.S.C. 379j(e)(2)(A)) is amended by strik-
17 ing “, partners, and parent firms”.

18 (B) EVIDENCE OF QUALIFICATION.—Sec-
19 tion 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(B)) is
20 amended—

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

24 “(B) EVIDENCE OF QUALIFICATION.—

25 “(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 or 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 or sales were collected.
15 The applicant shall also submit a state-
16 ment signed by the head of the applicant's
17 firm or by its chief financial officer that
18 the applicant has submitted certifications
19 for all of its affiliates, or that the applicant
20 has no affiliates.”.

21 (3) REDUCED FEES.—Section 738(e)(2)(C) (21
22 U.S.C. 379j(e)(2)(C)) is amended to read as follows:
23 “(C) REDUCED FEES.—For fiscal year
24 2008 and each subsequent fiscal year, where
25 the Secretary finds that the applicant involved

1 meets the definition under subparagraph (A),
2 the fee for a premarket notification submission
3 may be paid at 50 percent of the fee that ap-
4 plies under subsection (a)(2)(A)(viii), and as es-
5 tablished under subsection (c)(1).”.

6 (f) EFFECT OF FAILURE TO PAY FEES.—Section
7 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

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

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

18 “(2) NO REGISTRATION.—Registration informa-
19 tion submitted under section 510 by an establish-
20 ment subject to a registration fee shall be considered
21 incomplete and shall not be accepted by the Sec-
22 retary until the registration fee under subsection
23 (a)(3) owed for the establishment has been paid.
24 Until the fee is paid and the registration is com-

1 plete, the establishment is deemed to have failed to
2 register in accordance with section 510.”.

3 (g) CONDITIONS.—Section 738(g) (21 U.S.C.
4 379j(g)) is amended—

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

7 “(1) PERFORMANCE GOALS; TERMINATION OF
8 PROGRAM.—With respect to the amount that, under
9 the salaries and expenses account of the Food and
10 Drug Administration, is appropriated for a fiscal
11 year for devices and radiological products, fees may
12 not be assessed under subsection (a) for the fiscal
13 year, and the Secretary is not expected to meet any
14 performance goals identified for the fiscal year, if—

15 “(A) the amount so appropriated for the
16 fiscal year, excluding the amount of fees appro-
17 priated for the fiscal year, is more than 1 per-
18 cent less than \$205,720,000 multiplied by the
19 adjustment factor applicable to such fiscal year;
20 or

21 “(B) fees were not assessed under sub-
22 section (a) for the previous fiscal year.”; and

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

1 “(2) AUTHORITY.—If the Secretary does not
2 assess fees under subsection (a) during any portion
3 of a fiscal year because of paragraph (1) and if at
4 a later date in such fiscal year the Secretary may as-
5 sess such fees, the Secretary may assess and collect
6 such fees, without any modification in the rate for
7 premarket applications, supplements, premarket re-
8 ports, premarket notification submissions, 30-day
9 notices, requests for classification information, peri-
10 odic reporting concerning a class III device, and es-
11 tablishment registrations at any time in such fiscal
12 year, notwithstanding the provisions of subsection
13 (a) relating to the date fees are to be paid.”.

14 (h) CREDITING AND AVAILABILITY OF FEES.—

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

18 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—

19 There are authorized to be appropriated for fees
20 under this section—

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

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

23 “(C) \$57,014,000 for fiscal year 2010;

24 “(D) \$61,860,000 for fiscal year 2011;

25 and

1 “(E) \$67,118,000 for fiscal year 2012.”.

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

4 “(4) OFFSET.—If the cumulative amount of
5 fees collected during fiscal years 2008, 2009, and
6 2010, added to the amount estimated to be collected
7 for fiscal year 2011, which estimate shall be based
8 upon the amount of fees received by the Secretary
9 through June 30, 2011, exceeds the amount of fees
10 specified in aggregate in paragraph (3) for these
11 four fiscal years, the aggregate amount in excess
12 shall be credited to the appropriation account of the
13 Food and Drug Administration as provided in para-
14 graph (1), and shall be subtracted from the amount
15 of fees that would otherwise be authorized to be col-
16 lected under this section pursuant to appropriation
17 Acts for fiscal year 2012.”.

18 **SEC. 213. REAUTHORIZATION; REPORTING REQUIREMENTS.**

19 Part 3 of subchapter C of chapter VII is amended
20 by inserting after section 738 the following:

21 **“SEC. 738A. REAUTHORIZATION; REPORTING REQUIRE-**
22 **MENTS.**

23 “(a) REPORTS.—

24 “(1) PERFORMANCE REPORT.—For fiscal years
25 2008 through 2012, not later than 120 days after

1 the end of each fiscal year during which fees are col-
2 lected under this part, the Secretary shall prepare
3 and submit to the Committee on Health, Education,
4 Labor, and Pensions of the Senate and the Com-
5 mittee on Energy and Commerce of the House of
6 Representatives, a report concerning the progress of
7 the Food and Drug Administration in achieving the
8 goals identified in the letters described in section
9 201(c) of the Food and Drug Administration
10 Amendments Act of 2007 during such fiscal year
11 and the future plans of the Food and Drug Adminis-
12 tration for meeting the goals. The report for a fiscal
13 year shall include information on all previous cohorts
14 for which the Secretary has not given a complete re-
15 sponse on all device premarket applications and re-
16 ports, supplements, and premarket notifications in
17 the cohort.

18 “(2) FISCAL REPORT.—For fiscal years 2008
19 through 2012, not later than 120 days after the end
20 of each fiscal year during which fees are collected
21 under this part, the Secretary shall prepare and sub-
22 mit to the Committee on Health, Education, Labor,
23 and Pensions of the Senate and the Committee on
24 Energy and Commerce of the House of Representa-
25 tives, a report on the implementation of the author-

1 ity for such fees during such fiscal year and the use,
2 by the Food and Drug Administration, of the fees
3 collected during such fiscal year for which the report
4 is made.

5 “(3) PUBLIC AVAILABILITY.—The Secretary
6 shall make the reports required under paragraphs
7 (1) and (2) available to the public on the Internet
8 Web site of the Food and Drug Administration.

9 “(b) REAUTHORIZATION.—

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

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

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

21 “(C) scientific and academic experts;

22 “(D) health care professionals;

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

25 “(F) the regulated industry.

1 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
2 negotiations with the regulated industry on the reau-
3 thorization of this part, the Secretary shall—

4 “(A) publish a notice in the Federal Reg-
5 ister requesting public input on the reauthoriza-
6 tion;

7 “(B) hold a public meeting at which the
8 public may present its views on the reauthoriza-
9 tion, including specific suggestions for changes
10 to the goals referred to in subsection (a)(1);

11 “(C) provide a period of 30 days after the
12 public meeting to obtain written comments from
13 the public suggesting changes to this part; and

14 “(D) publish the comments on the Food
15 and Drug Administration’s Internet Web site.

16 “(3) PERIODIC CONSULTATION.—Not less fre-
17 quently than once every month during negotiations
18 with the regulated industry, the Secretary shall hold
19 discussions with representatives of patient and con-
20 sumer advocacy groups to continue discussions of
21 their views on the reauthorization and their sugges-
22 tions for changes to this part as expressed under
23 paragraph (2).

1 “(4) PUBLIC REVIEW OF RECOMMENDA-
2 TIONS.—After negotiations with the regulated indus-
3 try, the Secretary shall—

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

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

9 “(C) provide for a period of 30 days for
10 the public to provide written comments on such
11 recommendations;

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

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

18 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
19 Not later than January 15, 2012, the Secretary
20 shall transmit to Congress the revised recommenda-
21 tions under paragraph (4), a summary of the views
22 and comments received under such paragraph, and
23 any changes made to the recommendations in re-
24 sponse to such views and comments.

25 “(6) MINUTES OF NEGOTIATION MEETINGS.—

1 “(A) PUBLIC AVAILABILITY.—Before pre-
2 senting the recommendations developed under
3 paragraphs (1) through (5) to the Congress, the
4 Secretary shall make publicly available, on the
5 public Web site of the Food and Drug Adminis-
6 tration, minutes of all negotiation meetings con-
7 ducted under this subsection between the Food
8 and Drug Administration and the regulated in-
9 dustry.

10 “(B) CONTENT.—The minutes described
11 under subparagraph (A) shall summarize any
12 substantive proposal made by any party to the
13 negotiations as well as significant controversies
14 or differences of opinion during the negotiations
15 and their resolution.”.

16 **SEC. 214. SAVINGS CLAUSE.**

17 Notwithstanding section 107 of the Medical Device
18 User Fee and Modernization Act of 2002 (Public Law
19 107–250), and notwithstanding the amendments made by
20 this subtitle, part 3 of subchapter C of chapter VII of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i
22 et seq.), as in effect on the day before the date of the
23 enactment of this subtitle, shall continue to be in effect
24 with respect to premarket applications, premarket reports,
25 premarket notification submissions, and supplements (as

1 defined in such part as of such day) that on or after Octo-
2 ber 1, 2002, but before October 1, 2007, were accepted
3 by the Food and Drug Administration for filing with re-
4 spect to assessing and collecting any fee required by such
5 part for a fiscal year prior to fiscal year 2008.

6 **SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIA-**
7 **TIONS FOR POSTMARKET SAFETY INFORMA-**
8 **TION.**

9 For the purpose of collecting, developing, reviewing,
10 and evaluating postmarket safety information on medical
11 devices, there are authorized to be appropriated to the
12 Food and Drug Administration, in addition to the
13 amounts authorized by other provisions of law for such
14 purpose—

- 15 (1) \$7,100,000 for fiscal year 2008;
16 (2) \$7,455,000 for fiscal year 2009;
17 (3) \$7,827,750 for fiscal year 2010;
18 (4) \$8,219,138 for fiscal year 2011; and
19 (5) \$8,630,094 for fiscal year 2012.

20 **SEC. 216. EFFECTIVE DATE.**

21 The amendments made by this subtitle shall take ef-
22 fect on October 1, 2007, or the date of the enactment of
23 this Act, whichever is later, except that fees under part
24 3 of subchapter C of chapter VII of the Federal Food,
25 Drug, and Cosmetic Act shall be assessed for all pre-

1 market applications, premarket reports, supplements, 30-
2 day notices, and premarket notification submissions re-
3 ceived on or after October 1, 2007, regardless of the date
4 of the enactment of this Act.

5 **SEC. 217. SUNSET CLAUSE.**

6 The amendments made by this subtitle cease to be
7 effective October 1, 2012, except that section 738A of the
8 Federal Food, Drug, and Cosmetic Act (regarding annual
9 performance and financial reports) ceases to be effective
10 January 31, 2013.

11 **Subtitle B—Amendments Regarding**
12 **Regulation of Medical De-**
13 **vices**

14 **SEC. 221. EXTENSION OF AUTHORITY FOR THIRD PARTY**
15 **REVIEW OF PREMARKET NOTIFICATION.**

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

18 **SEC. 222. REGISTRATION.**

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

- 22 (1) by striking “(b) On or before” and inserting
23 “(b)(1) On or before”;
24 (2) by striking “or a device or devices”; and
25 (3) by adding at the end the following:

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

8 (b) REGISTRATION OF FOREIGN ESTABLISH-
9 MENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is
10 amended by striking “On or before December 31” and all
11 that follows and inserting the following: “Any establish-
12 ment within any foreign country engaged in the manufac-
13 ture, preparation, propagation, compounding, or proc-
14 essing of a drug or device that is imported or offered for
15 import into the United States shall, through electronic
16 means in accordance with the criteria of the Secretary—

17 “(A) upon first engaging in any such activity,
18 immediately register with the Secretary the name
19 and place of business of the establishment, the name
20 of the United States agent for the establishment, the
21 name of each importer of such drug or device in the
22 United States that is known to the establishment,
23 and the name of each person who imports or offers
24 for import such drug or device to the United States
25 for purposes of importation; and

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

3 “(i) with respect to drugs, register with the
4 Secretary on or before December 31 of each
5 year; and

6 “(ii) with respect to devices, register with
7 the Secretary during the period beginning on
8 October 1 and ending on December 31 of each
9 year.”.

10 **SEC. 223. FILING OF LISTS OF DRUGS AND DEVICES MANU-**
11 **FACTURED, PREPARED, PROPAGATED, AND**
12 **COMPOUNDED BY REGISTRANTS; STATE-**
13 **MENTS; ACCOMPANYING DISCLOSURES.**

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

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

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

4 “(p) Registrations and listings under this section (in-
5 cluding the submission of updated information) shall be
6 submitted to the Secretary by electronic means unless the
7 Secretary grants a request for waiver of such requirement
8 because use of electronic means is not reasonable for the
9 person requesting such waiver.”.

10 **SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OF-**
11 **FICE.**

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

18 (b) CONSIDERATION.—In determining the effective-
19 ness of the premarket notification and classification au-
20 thority under section 510(k) and subsections (f) and (i)
21 of section 513 of the Federal Food, Drug, and Cosmetic
22 Act, the study under subsection (a) shall consider the Sec-
23 retary of Health and Human Services’s evaluation of the
24 respective intended uses and technologies of such devices,
25 including the effectiveness of such Secretary’s comparative

1 assessment of technological characteristics such as device
2 materials, principles of operations, and power sources.

3 (c) REPORT.—Not later than 1 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 **SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.**

8 (a) IN GENERAL.—Section 519 (21 U.S.C. 360i) is
9 amended—

10 (1) by redesignating subsection (f) as sub-
11 section (g); and

12 (2) by inserting after subsection (e) the fol-
13 lowing:

14 “Unique Device Identification System

15 “(f) The Secretary shall promulgate regulations es-
16 tablishing a unique device identification system for med-
17 ical devices requiring the label of devices to bear a unique
18 identifier, unless the Secretary requires an alternative
19 placement or provides an exception for a particular device
20 or type of device. The unique identifier shall adequately
21 identify the device through distribution and use, and may
22 include information on the lot or serial number.”.

23 (b) CONFORMING AMENDMENT.—Section 303 (21
24 U.S.C. 333) is amended—

1 (1) by redesignating the subsection that follows
2 subsection (e) as subsection (f); and

3 (2) in paragraph (1)(B)(ii) of subsection (f), as
4 so redesignated, by striking “519(f)” and inserting
5 “519(g)”.

6 **SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DE-**
7 **VICES.**

8 Subparagraph (B) of section 519(a)(1) (21 U.S.C.
9 360i(a)(1)) is amended by striking “were to recur;” and
10 inserting the following: “were to recur, which report under
11 this subparagraph—

12 “(i) shall be submitted in accordance
13 with part 803 of title 21, Code of Federal
14 Regulations (or successor regulations), un-
15 less the Secretary grants an exemption or
16 variance from, or an alternative to, a re-
17 quirement under such regulations pursuant
18 to section 803.19 of such part, if the de-
19 vice involved is—

20 “(I) a class III device;

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

24 “(III) a type of device which the
25 Secretary has, by notice published in

1 the Federal Register or letter to the
2 person who is the manufacturer or
3 importer of the device, indicated
4 should be subject to such part 803 in
5 order to protect the public health;

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; or

13 “(iii) shall, if the device is imported
14 into the United States and for which part
15 803 of title 21, Code of Federal Regula-
16 tions (or successor regulations) requires an
17 importer to submit a report to the manu-
18 facturer, be submitted by the importer to
19 the manufacturer in accordance with part
20 803 of title 21, Code of Federal Regula-
21 tions (or successor regulations)”.

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

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

24 (1) in paragraph (1), by striking “Not later
25 than one year after the date of the enactment of this

1 subsection, the Secretary” and inserting “The Sec-
2 retary”;

3 (2) in paragraph (2), by—

4 (A) striking “Not later than 180 days
5 after the date of enactment of this subsection,
6 the Secretary” and inserting “The Secretary”;
7 and

8 (B) striking the fifth sentence;

9 (3) in paragraph (3), by adding at the end the
10 following:

11 “(F) Such person shall notify the Secretary of
12 any withdrawal, suspension, restriction, or expiration
13 of certificate of conformance with the quality sys-
14 tems standard referred to in paragraph (7) for any
15 device establishment that such person inspects under
16 this subsection not later than 30 days after such
17 withdrawal, suspension, restriction, or expiration.

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

21 (4) by amending paragraph (6) to read as fol-
22 lows:

23 “(6)(A) Subject to subparagraphs (B) and (C), a de-
24 vice establishment is eligible for inspection by persons ac-

1 credited under paragraph (2) if the following conditions
2 are met:

3 “(i) The Secretary classified the results of the
4 most recent inspection of the establishment as ‘no
5 action indicated’ or ‘voluntary action indicated’.

6 “(ii) With respect to inspections of the estab-
7 lishment to be conducted by an accredited person,
8 the owner or operator of the establishment submits
9 to the Secretary a notice that—

10 “(I) provides the date of the last inspection
11 of the establishment by the Secretary and the
12 classification of that inspection;

13 “(II) states the intention of the owner or
14 operator to use an accredited person to conduct
15 inspections of the establishment;

16 “(III) identifies the particular accredited
17 person the owner or operator intends to select
18 to conduct such inspections; and

19 “(IV) includes a certification that, with re-
20 spect to the devices that are manufactured, pre-
21 pared, propagated, compounded, or processed in
22 the establishment—

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

1 “(bb) at least 1 of such devices is
2 marketed, or is intended to be marketed,
3 in 1 or more foreign countries, 1 of which
4 countries certifies, accredits, or otherwise
5 recognizes the person accredited under
6 paragraph (2) and identified under sub-
7 clause (III) as a person authorized to con-
8 duct inspections of device establishments.

9 “(B)(i) Except with respect to the requirement of
10 subparagraph (A)(i), a device establishment is deemed to
11 have clearance to participate in the program and to use
12 the accredited person identified in the notice under sub-
13 paragraph (A)(ii) for inspections of the establishment un-
14 less the Secretary, not later than 30 days after receiving
15 such notice, issues a response that—

16 “(I) denies clearance to participate as provided
17 under subparagraph (C); or

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

19 “(ii) The Secretary may request from the owner or
20 operator of a device establishment in response to the no-
21 tice under subparagraph (A)(ii) with respect to the estab-
22 lishment, or from the particular accredited person identi-
23 fied in such notice—

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

1 “(II) information concerning the relationship
2 between the owner or operator of the establishment
3 and the accredited person identified in such notice in
4 accordance with clause (iii)(II).

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

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

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

5 “(iv) A device establishment is deemed to have clear-
6 ance to participate in the program and to use the accred-
7 ited person identified in the notice under subparagraph
8 (A)(ii) for inspections of the establishment unless the Sec-
9 retary, not later than 60 days after receiving the informa-
10 tion requested under clause (ii), issues a response that de-
11 nies clearance to participate as provided under subpara-
12 graph (C).

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

18 “(ii) The Secretary may deny clearance to a device
19 establishment if the Secretary determines that the estab-
20 lishment has failed to demonstrate consistent compliance
21 for purposes of subparagraph (B)(iii)(I) and the Secretary
22 provides to the owner or operator of the establishment a
23 statement of the reasons for such determination.

24 “(iii)(I) The Secretary may reject the selection of the
25 accredited person identified in the notice under subpara-

1 graph (A)(ii) if the Secretary provides to the owner or op-
2 erator of the establishment a statement of the reasons for
3 such rejection. Reasons for the rejection may include that
4 the establishment or the accredited person, as the case
5 may be, has failed to fully respond to the request, or that
6 the Secretary has concerns regarding the relationship be-
7 tween the establishment and such accredited person.

8 “(II) If the Secretary rejects the selection of an ac-
9 credited person by the owner or operator of a device estab-
10 lishment, the owner or operator may make an additional
11 selection of an accredited person by submitting to the Sec-
12 retary a notice that identifies the additional selection.
13 Clauses (i) and (ii) of subparagraph (B), and subclause
14 (I) of this clause, apply to the selection of an accredited
15 person through a notice under the preceding sentence in
16 the same manner and to the same extent as such provi-
17 sions apply to a selection of an accredited person through
18 a notice under subparagraph (A)(ii).

19 “(iv) In the case of a device establishment that is de-
20 nied clearance under clause (i) or (ii) or with respect to
21 which the selection of the accredited person is rejected
22 under clause (iii), the Secretary shall designate a person
23 to review the statement of reasons, or statement summa-
24 rizing such evidence, as the case may be, of the Secretary
25 under such clause if, during the 30-day period beginning

1 on the date on which the owner or operator of the estab-
2 lishment receives such statement, the owner or operator
3 requests the review. The review shall commence not later
4 than 30 days after the owner or operator requests the re-
5 view, unless the Secretary and the owner or operator oth-
6 erwise agree.”;

7 (5) in paragraph (7)—

8 (A) in subparagraph (A), by striking “(A)
9 Persons” and all that follows through the end
10 and inserting the following: “(A) Persons ac-
11 credited under paragraph (2) to conduct inspec-
12 tions shall record in writing their inspection ob-
13 servations and shall present the observations to
14 the device establishment’s designated represent-
15 ative and describe each observation. Addition-
16 ally, such accredited person shall prepare an in-
17 spection report in a form and manner des-
18 ignated by the Secretary to conduct inspections,
19 taking into consideration the goals of inter-
20 national harmonization of quality systems
21 standards. Any official classification of the in-
22 spection shall be determined by the Secretary.”;
23 and

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

1 “(F) For the purpose of setting risk-based
2 inspectional priorities, the Secretary shall accept voluntary
3 submissions of reports of audits assessing conformance
4 with appropriate quality systems standards set by the
5 International Organization for Standardization (ISO) and
6 identified by the Secretary in public notice. If the owner
7 or operator of an establishment elects to submit audit re-
8 ports under this subparagraph, the owner or operator shall
9 submit all such audit reports with respect to the establish-
10 ment during the preceding 2-year periods.”; and

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

13 **SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING**
14 **TO MEDICAL DEVICES.**

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

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

19 (2) the causes of such nosocomial infections, in-
20 cluding the following:

21 (A) Reprocessed single-use devices.

22 (B) Handling of sterilized medical devices.

23 (C) In-hospital sterilization of medical de-
24 vices.

1 (D) Health care professionals' practices for
2 patient examination and treatment.

3 (E) Hospital-based policies and procedures
4 for infection control and prevention.

5 (F) Hospital-based practices for handling
6 of medical waste.

7 (G) Other causes.

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

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

17 **SEC. 230. REPORT BY THE FOOD AND DRUG ADMINISTRA-**
18 **TION REGARDING LABELING INFORMATION**
19 **ON THE RELATIONSHIP BETWEEN THE USE**
20 **OF INDOOR TANNING DEVICES AND DEVEL-**
21 **OPMENT OF SKIN CANCER OR OTHER SKIN**
22 **DAMAGE.**

23 (a) IN GENERAL.—The Secretary of Health and
24 Human Services (referred to in this section as the “Sec-

1 retary”), acting through the Commissioner of Food and
2 Drugs, shall determine—

3 (1) whether the labeling requirements for in-
4 door tanning devices, including the positioning re-
5 quirements, provide sufficient information to con-
6 sumers regarding the risks that the use of such de-
7 vices pose for the development of irreversible damage
8 to the eyes and skin, including skin cancer; and

9 (2)(A) whether modifying the warning label re-
10 quired on tanning beds to read, “Ultraviolet radi-
11 ation can cause skin cancer”, or any other additional
12 warning, would communicate the risks of indoor tan-
13 ning more effectively; or

14 (B) whether there is no warning that would be
15 capable of adequately communicating such risks.

16 (b) CONSUMER TESTING.—In making the determina-
17 tions under subsection (a), the Secretary shall conduct ap-
18 propriate consumer testing to determine consumer under-
19 standing of label warnings.

20 (c) REPORT.—Not later than 1 year after the date
21 of the enactment of this Act, the Secretary shall submit
22 to the Congress a report that provides the determinations
23 under subsection (a). In addition, the Secretary shall in-
24 clude in the report the measures being implemented by

1 the Secretary to significantly reduce the risks associated
2 with indoor tanning devices.

3 **TITLE III—PEDIATRIC MEDICAL**
4 **DEVICE SAFETY AND IM-**
5 **PROVEMENT ACT OF 2007**

6 **SEC. 301. SHORT TITLE.**

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

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

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

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

14 **“(a) NEW DEVICES.—**

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

21 **“(2) REQUIRED INFORMATION.—**The applica-
22 tion or protocol described in paragraph (1) shall in-
23 clude, with respect to the device for which approval
24 is sought and if readily available—

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

5 “(B) the number of affected pediatric pa-
6 tients.

7 “(3) ANNUAL REPORT.—Not later than 18
8 months after the date of the enactment of this sec-
9 tion, and annually thereafter, the Secretary shall
10 submit to the Committee on Health, Education,
11 Labor, and Pensions of the Senate and the Com-
12 mittee on Energy and Commerce of the House of
13 Representatives a report that includes—

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

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

24 “(C) the number of pediatric devices ap-
25 proved in the year preceding the year in which

1 the report is submitted, exempted from a fee
2 pursuant to section 738(a)(2)(B)(v); and

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

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

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

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

19 “(c) PEDIATRIC SUBPOPULATION.—For purposes of
20 this section, the term ‘pediatric subpopulation’ has the
21 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 the enactment of the Pedi-
14 atric 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, 2012.

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) The Secretary, acting through the Office of Pe-
6 diatric Therapeutics and the Center for Devices and Radi-
7 ological Health, shall provide for an annual review by the
8 Pediatric Advisory Committee of all devices described in
9 paragraph (6) to ensure that the exemption under para-
10 graph (2) remains appropriate for the pediatric popu-
11 lations 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 purchasing pediatric devices,
15 based on a representative sampling of children's hos-
16 pitals;

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

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

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

23 (7) an estimate of the extent of the use of the
24 pediatric devices by both adults and pediatric popu-

1 lations for a condition or disease other than the con-
2 dition or disease on the label of such devices;

3 (8) recommendations of the Comptroller Gen-
4 eral of the United States regarding the effectiveness
5 of such section 520(m)(6) (as amended by sub-
6 section (a)) and whether any modifications to such
7 section 520(m)(6) (as amended by subsection (a))
8 should be made;

9 (9) existing obstacles to pediatric device devel-
10 opment; and

11 (10) an evaluation of the demonstration grants
12 described in section 305, which shall include an eval-
13 uation of the number of pediatric medical devices—

14 (A) that have been or are being studied in
15 children; and

16 (B) that have been submitted to the Food
17 and Drug Administration for approval, clear-
18 ance, or review under such section 520(m) (as
19 amended by this Act) and any regulatory ac-
20 tions taken.

21 (c) GUIDANCE.—Not later than 180 days after the
22 date of the enactment of this Act, the Commissioner of
23 Food and Drugs shall issue guidance for institutional re-
24 view committees on how to evaluate requests for approval
25 for devices for which a humanitarian device exemption

1 under section 520(m)(2) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

3 **SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RE-**
4 **SEARCH.**

5 (a) CONTACT POINT FOR AVAILABLE FUNDING.—
6 Section 402(b) of the Public Health Service Act (42
7 U.S.C. 282(b)) is amended—

8 (1) in paragraph (21), by striking “and” after
9 the semicolon at the end;

10 (2) in paragraph (22), by striking the period at
11 the end and inserting “; and”; and

12 (3) by inserting after paragraph (22) the fol-
13 lowing:

14 “(23) shall designate a contact point or office
15 to help innovators and physicians identify sources of
16 funding available for pediatric medical device devel-
17 opment.”.

18 (b) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-
19 SEARCH.—

20 (1) IN GENERAL.—Not later than 180 days
21 after the date of the enactment of this Act, the Sec-
22 retary of Health and Human Services, acting
23 through the Commissioner of Food and Drugs, the
24 Director of the National Institutes of Health, and
25 the Director of the Agency for Healthcare Research

1 and Quality, shall submit to the Committee on
2 Health, Education, Labor, and Pensions of the Sen-
3 ate and the Committee on Energy and Commerce of
4 the House of Representatives a plan for expanding
5 pediatric medical device research and development.
6 In developing such plan, the Secretary of Health and
7 Human Services shall consult with individuals and
8 organizations with appropriate expertise in pediatric
9 medical devices.

10 (2) CONTENTS.—The plan under paragraph (1)
11 shall include—

12 (A) the current status of federally funded
13 pediatric medical device research;

14 (B) any gaps in such research, which may
15 include a survey of pediatric medical providers
16 regarding unmet pediatric medical device needs,
17 as needed; and

18 (C) a research agenda for improving pedi-
19 atric medical device development and Food and
20 Drug Administration clearance or approval of
21 pediatric medical devices, and for evaluating the
22 short- and long-term safety and effectiveness of
23 pediatric medical devices.

1 **SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
2 **ATRIC DEVICE AVAILABILITY.**

3 (a) IN GENERAL.—

4 (1) REQUEST FOR PROPOSALS.—Not later than
5 90 days after the date of the enactment of this Act,
6 the Secretary of Health and Human Services shall
7 issue a request for proposals for 1 or more grants
8 or contracts to nonprofit consortia for demonstration
9 projects to promote pediatric device development.

10 (2) DETERMINATION ON GRANTS OR CON-
11 TRACTS.—Not later than 180 days after the date the
12 Secretary of Health and Human Services issues a
13 request for proposals under paragraph (1), the Sec-
14 retary shall make a determination on the grants or
15 contracts under this section.

16 (b) APPLICATION.—A nonprofit consortium that de-
17 sires to receive a grant or contract under this section shall
18 submit an application to the Secretary of Health and
19 Human Services at such time, in such manner, and con-
20 taining such information as the Secretary may require.

21 (c) USE OF FUNDS.—A nonprofit consortium that re-
22 ceives a grant or contract under this section shall facilitate
23 the development, production, and distribution of pediatric
24 medical devices by—

1 (1) encouraging innovation and connecting
2 qualified individuals with pediatric device ideas with
3 potential manufacturers;

4 (2) mentoring and managing pediatric device
5 projects through the development process, including
6 product identification, prototype design, device devel-
7 opment, and marketing;

8 (3) connecting innovators and physicians to ex-
9 isting Federal and non-Federal resources, including
10 resources from the Food and Drug Administration,
11 the National Institutes of Health, the Small Busi-
12 ness Administration, the Department of Energy, the
13 Department of Education, the National Science
14 Foundation, the Department of Veterans Affairs,
15 the Agency for Healthcare Research and Quality,
16 and the National Institute of Standards and Tech-
17 nology;

18 (4) assessing the scientific and medical merit of
19 proposed pediatric device projects; and

20 (5) providing assistance and advice as needed
21 on business development, personnel training, proto-
22 type development, postmarket needs, and other ac-
23 tivities consistent with the purposes of this section.

24 (d) COORDINATION.—

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

4 (A) coordinate with the National Institutes
5 of Health’s pediatric device contact point or of-
6 fice, designated under section 402(b)(23) of the
7 Public Health Service Act, as added by section
8 304(a) of this Act; and

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

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

21 (3) EFFECTIVENESS AND OUTCOMES.—Each
22 consortium that receives a grant or contract under
23 this section shall annually report to the Secretary of
24 Health and Human Services on the status of pedi-

1 atric device development, production, and distribu-
2 tion that has been facilitated by the consortium.

3 (e) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section
5 \$6,000,000 for each of fiscal years 2008 through 2012.

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

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

14 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14
15 of the Best Pharmaceuticals for Children Act (42 U.S.C.
16 284m note) is amended—

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

20 (2) in subsection (b)—

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

24 (B) in paragraph (2)—

1 (i) in subparagraph (A), by striking
2 “and 505B” and inserting “505B, 510(k),
3 515, and 520(m)”;

4 (ii) by striking subparagraph (B) and
5 inserting the following:

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

12 (iii) in subparagraph (C), by inserting
13 “(including drugs and biological products)
14 and medical devices” after “therapeutics”.

15 **SEC. 307. POSTMARKET SURVEILLANCE.**

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

18 (1) by amending the section heading and des-
19 ignation to read as follows:

20 **“SEC. 522. POSTMARKET SURVEILLANCE.”;**

21 (2) by striking subsection (a) and inserting the
22 following:

23 “(a) POSTMARKET SURVEILLANCE.—

24 “(1) IN GENERAL.—

1 “(A) CONDUCT.—The Secretary may by
2 order require a manufacturer to conduct
3 postmarket surveillance for any device of the
4 manufacturer that is a class II or class III de-
5 vice—

6 “(i) the failure of which would be rea-
7 sonably likely to have serious adverse
8 health consequences;

9 “(ii) that is expected to have signifi-
10 cant use in pediatric populations; or

11 “(iii) that is intended to be—

12 “(I) implanted in the human
13 body for more than 1 year; or

14 “(II) a life-sustaining or life-sup-
15 porting device used outside a device
16 user facility.

17 “(B) CONDITION.—The Secretary may
18 order a postmarket surveillance under subpara-
19 graph (A) as a condition to approval or clear-
20 ance of a device described in subparagraph
21 (A)(ii).

22 “(2) RULE OF CONSTRUCTION.—The provisions
23 of paragraph (1) shall have no effect on authorities
24 otherwise provided under the Act or regulations
25 issued under this Act.”; and

1 (3) in subsection (b)—

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

4 “(b) SURVEILLANCE APPROVAL.—

5 “(1) IN GENERAL.—Each”;

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

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

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

13 “(2) LONGER SURVEILLANCE FOR PEDIATRIC
14 DEVICES.—The Secretary may by order require a
15 prospective surveillance period of more than 36
16 months with respect to a device that is expected to
17 have significant use in pediatric populations if such
18 period of more than 36 months is necessary in order
19 to assess the impact of the device on growth and de-
20 velopment, or the effects of growth, development, ac-
21 tivity level, or other factors on the safety or efficacy
22 of the device.

23 “(c) DISPUTE RESOLUTION.—A manufacturer may
24 request review under section 562 of any order or condition
25 requiring postmarket surveillance under this section. Dur-

1 ing the pendency of such review, the device subject to such
2 a postmarket surveillance order or condition shall not, be-
3 cause of noncompliance with such order or condition, be
4 deemed in violation of section 301(q)(1)(C), adulterated
5 under section 501(f)(1), misbranded under section
6 502(t)(3), or in violation of, as applicable, section 510(k)
7 or section 515, unless deemed necessary to protect the
8 public health.”.

9 **TITLE IV—PEDIATRIC**

10 **RESEARCH EQUITY ACT OF 2007**

11 **SEC. 401. SHORT TITLE.**

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

14 **SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQ-**

15 **UITY ACT.**

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

19 **“SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS**

20 **AND BIOLOGICAL PRODUCTS.**

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

22 “(1) IN GENERAL.—A person that submits, on
23 or after the date of the enactment of the Pediatric
24 Research Equity Act of 2007, an application (or
25 supplement to an application)—

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

5 “(B) under section 351 of the Public
6 Health Service Act (42 U.S.C. 262) for a new
7 active ingredient, new indication, new dosage
8 form, new dosing regimen, or new route of ad-
9 ministration,
10 shall submit with the application the assessments de-
11 scribed in paragraph (2).

12 “(2) ASSESSMENTS.—

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

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

22 “(ii) to support dosing and adminis-
23 tration for each pediatric subpopulation for
24 which the drug or the biological product is
25 safe and effective.

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

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

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

18 “(iii) INFORMATION ON EXTRAPO-
19 LATION.—A brief documentation of the sci-
20 entific data supporting the conclusion
21 under clauses (i) and (ii) shall be included
22 in any pertinent reviews for the application
23 under section 505 of this Act or section
24 351 of the Public Health Service Act (42
25 U.S.C. 262).

1 “(3) DEFERRAL.—

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

9 “(i) the Secretary finds that—

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

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

18 “(III) there is another appro-
19 priate reason for deferral; and

20 “(ii) the applicant submits to the Sec-
21 retary—

22 “(I) certification of the grounds
23 for deferring the assessments;

24 “(II) a description of the planned
25 or ongoing studies;

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

5 “(IV) a timeline for the comple-
6 tion of such studies.

7 “(B) ANNUAL REVIEW.—

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

13 “(I) Information detailing the
14 progress made in conducting pediatric
15 studies.

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

22 “(ii) PUBLIC AVAILABILITY.—The in-
23 formation submitted through the annual
24 review under clause (i) shall promptly be
25 made available to the public in an easily

1 accessible manner, including through the
2 Web site of the Food and Drug Adminis-
3 tration.

4 “(4) WAIVERS.—

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

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

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; or

20 “(iii) the drug or biological product—

21 “(I) does not represent a mean-
22 ingful therapeutic benefit over existing
23 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 Web
20 site 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.—After providing notice in
6 the form of a letter (that, for a drug approved under
7 section 505, references a declined written request
8 under section 505A for a labeled indication which
9 written request is not referred under section
10 505A(n)(1)(A) to the Foundation of the National
11 Institutes of Health for the pediatric studies), the
12 Secretary may (by order in the form of a letter) re-
13 quire the sponsor or holder of an approved applica-
14 tion for a drug under section 505 or the holder of
15 a license for a biological product under section 351
16 of the Public Health Service Act to submit by a
17 specified date the assessments described in sub-
18 section (a)(2), if the Secretary finds that—

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

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

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

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

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

6 “(2) WAIVERS.—

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

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

21 “(B) PARTIAL WAIVER.—At the request of
22 an applicant, the Secretary shall grant a partial
23 waiver, as appropriate, of the requirement to
24 submit assessments under this subsection with
25 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 Web
15 site 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 “(3) 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 “(c) MEANINGFUL THERAPEUTIC BENEFIT.—For
4 the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I)
5 of subsection (a) and paragraphs (1)(B) and
6 (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological
7 product shall be considered to represent a meaningful
8 therapeutic benefit over existing therapies if the Secretary
9 determines that—

10 “(1) if approved, the drug or biological product
11 could represent an improvement in the treatment,
12 diagnosis, or prevention of a disease, compared with
13 marketed products adequately labeled for that use in
14 the relevant pediatric population; or

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

18 “(d) SUBMISSION OF ASSESSMENTS.—If a person
19 fails to submit an assessment described in subsection
20 (a)(2), or a request for approval of a pediatric formulation
21 described in subsection (a) or (b), in accordance with ap-
22 plicable provisions of subsections (a) and (b)—

23 “(1) the drug or biological product that is the
24 subject of the assessment or request may be consid-
25 ered misbranded solely because of that failure and

1 subject to relevant enforcement action (except that
2 the drug or biological product shall not be subject to
3 action under section 303); but

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

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

8 “(B) to revoke the license for a biological
9 product under section 351 of the Public Health
10 Service Act.

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

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

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

19 “(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS,
20 DEFERRALS, AND WAIVERS.—

21 “(1) REVIEW.—Beginning not later than 30
22 days after the date of the enactment of the Pediatric
23 Research Equity Act of 2007, the Secretary shall
24 utilize the internal committee established under sec-
25 tion 505C to provide consultation to reviewing divi-

1 sions on all pediatric plans and assessments prior to
2 approval of an application or supplement for which
3 a pediatric assessment is required under this section
4 and all deferral and waiver requests granted pursu-
5 ant to this section.

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

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

16 “(4) REVIEW OF PEDIATRIC PLANS, ASSESS-
17 MENTS, DEFERRALS, AND WAIVERS.—Consultation
18 on pediatric plans and assessments by the committee
19 referred to in paragraph (1) pursuant to this section
20 shall occur prior to approval of an application or
21 supplement for which a pediatric assessment is re-
22 quired under this section. The committee shall re-
23 view all requests for deferrals and waivers from the
24 requirement to submit a pediatric assessment grant-
25 ed under this section and shall provide recommenda-

1 tions as needed to reviewing divisions, including with
2 respect to whether such a supplement, when sub-
3 mitted, shall be considered for priority review.

4 “(5) RETROSPECTIVE REVIEW OF PEDIATRIC
5 ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not
6 later than 1 year after the date of the enactment of
7 the Pediatric Research Equity Act of 2007, the com-
8 mittee referred to in paragraph (1) shall conduct a
9 retrospective review and analysis of a representative
10 sample of assessments submitted and deferrals and
11 waivers approved under this section since the enact-
12 ment of the Pediatric Research Equity Act of 2003.
13 Such review shall include an analysis of the quality
14 and consistency of pediatric information in pediatric
15 assessments and the appropriateness of waivers and
16 deferrals granted. Based on such review, the Sec-
17 retary shall issue recommendations to the review di-
18 visions for improvements and initiate guidance to in-
19 dustry related to the scope of pediatric studies re-
20 quired under this section.

21 “(6) TRACKING OF ASSESSMENTS AND LABEL-
22 ING CHANGES.—The Secretary, in consultation with
23 the committee referred to in paragraph (1), shall
24 track and make available to the public in an easily

1 accessible manner, including through posting on the
2 Web site of the Food and Drug Administration—

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);

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

8 “(J) the number of times the committee
9 referred to in paragraph (1) made a rec-
10 ommendation to the Secretary under paragraph
11 (4) regarding priority review, the number of
12 times the Secretary followed or did not follow
13 such a recommendation, and, if not followed,
14 the reasons why such a recommendation was
15 not followed.

16 “(g) LABELING CHANGES.—

17 “(1) DISPUTE RESOLUTION.—

18 “(A) REQUEST FOR LABELING CHANGE
19 AND FAILURE TO AGREE.—If, on or after the
20 date of the enactment of the Pediatric Research
21 Equity Act of 2007, the Commissioner deter-
22 mines that a sponsor and the Commissioner
23 have been unable to reach agreement on appro-
24 priate changes to the labeling for the drug that
25 is the subject of the application or supplement,

1 not later than 180 days after the date of the
2 submission of the application or supplement—

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

7 “(ii) if the sponsor does not agree
8 within 30 days after the Commissioner’s
9 request to make a labeling change re-
10 quested by the Commissioner, the Commis-
11 sioner shall refer the matter to the Pedi-
12 atric Advisory Committee.

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

17 “(i) review the pediatric study reports;
18 and

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

22 “(C) CONSIDERATION OF RECOMMENDA-
23 TIONS.—The Commissioner shall consider the
24 recommendations of the Pediatric Advisory
25 Committee and, if appropriate, not later than

1 30 days after receiving the recommendation,
2 make a request to the sponsor of the applica-
3 tion or supplement to make any labeling
4 changes that the Commissioner determines to
5 be appropriate.

6 “(D) MISBRANDING.—If the sponsor of the
7 application or supplement, within 30 days after
8 receiving a request under subparagraph (C),
9 does not agree to make a labeling change re-
10 quested by the Commissioner, the Commis-
11 sioner may deem the drug that is the subject of
12 the application or supplement to be misbranded.

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

22 “(2) OTHER LABELING CHANGES.—If, on or
23 after the date of the enactment of the Pediatric Re-
24 search Equity Act of 2007, the Secretary makes a
25 determination that a pediatric assessment conducted

1 under this section does or does not demonstrate that
2 the drug that is the subject of such assessment is
3 safe and effective in pediatric populations or sub-
4 populations, including whether such assessment re-
5 sults are inconclusive, the Secretary shall order the
6 label of such product to include information about
7 the results of the assessment and a statement of the
8 Secretary's determination.

9 “(h) DISSEMINATION OF PEDIATRIC INFORMA-
10 TION.—

11 “(1) IN GENERAL.—Not later than 210 days
12 after the date of submission of a pediatric assess-
13 ment under this section, the Secretary shall make
14 available to the public in an easily accessible manner
15 the medical, statistical, and clinical pharmacology re-
16 views of such pediatric assessments, and shall post
17 such assessments on the Web site of the Food and
18 Drug Administration.

19 “(2) DISSEMINATION OF INFORMATION RE-
20 GARDING LABELING CHANGES.—Beginning on the
21 date of the enactment of the Pediatric Research Eq-
22 uity Act of 2007, the Secretary shall require that
23 the sponsors of the assessments that result in label-
24 ing changes that are reflected in the annual sum-
25 mary developed pursuant to subsection (f)(6)(H) dis-

1 tribute such information to physicians and other
2 health care providers.

3 “(3) EFFECT OF SUBSECTION.—Nothing in this
4 subsection shall alter or amend section 301(j) of this
5 Act or section 552 of title 5 or section 1905 of title
6 18, United States Code.

7 “(i) ADVERSE EVENT REPORTING.—

8 “(1) REPORTING IN YEAR ONE.—Beginning on
9 the date of the enactment of the Pediatric Research
10 Equity Act of 2007, during the one-year period be-
11 ginning on the date a labeling change is made pur-
12 suant to subsection (g), the Secretary shall ensure
13 that all adverse event reports that have been re-
14 ceived for such drug (regardless of when such report
15 was received) are referred to the Office of Pediatric
16 Therapeutics. In considering such reports, the Direc-
17 tor of such Office shall provide for the review of
18 such reports by the Pediatric Advisory Committee,
19 including obtaining any recommendations of such
20 committee regarding whether the Secretary should
21 take action under this Act in response to such re-
22 ports.

23 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
24 lowing the one-year period described in paragraph
25 (1), the Secretary shall, as appropriate, refer to the

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

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

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

19 “(k) ORPHAN DRUGS.—Unless the Secretary re-
20 quires otherwise by regulation, this section does not apply
21 to any drug for an indication for which orphan designation
22 has been granted under section 526.

23 “(l) INSTITUTE OF MEDICINE STUDY.—

24 “(1) IN GENERAL.—Not later than three years
25 after the date of the enactment of the Pediatric Re-

1 search Equity Act of 2007, the Secretary shall con-
2 tract with the Institute of Medicine to conduct a
3 study and report to Congress regarding the pediatric
4 studies conducted pursuant to this section or pre-
5 cursor regulations since 1997 and labeling changes
6 made as a result of such studies.

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

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

20 “(m) INTEGRATION WITH OTHER PEDIATRIC STUD-
21 IES.—The authority under this section shall remain in ef-
22 fect so long as an application subject to this section may
23 be accepted for filing by the Secretary on or before the
24 date specified in section 505A(q).”.

25 (b) APPLICABILITY.—

1 (1) IN GENERAL.—Notwithstanding subsection
2 (h) of section 505B of the Federal Food, Drug and
3 Cosmetic Act, as in effect on the day before the date
4 of the enactment of this Act, a pending assessment,
5 including a deferred assessment, required under
6 such section 505B shall be deemed to have been re-
7 quired under section 505B of the Federal Food,
8 Drug and Cosmetic Act as in effect on or after the
9 date of the enactment of this Act.

10 (2) CERTAIN ASSESSMENTS AND WAIVER RE-
11 QUESTS.—An assessment pending on or after the
12 date that is 1 year prior to the date of the enact-
13 ment of this Act shall be subject to the tracking and
14 disclosure requirements established under such sec-
15 tion 505B, as in effect on or after such date of en-
16 actment, except that any such assessments sub-
17 mitted or waivers of such assessments requested be-
18 fore such date of enactment shall not be subject to
19 subsections (a)(4)(C), (b)(2)(C), (f)(6)(F), and (h)
20 of such section 505B.

21 **SEC. 403. ESTABLISHMENT OF INTERNAL COMMITTEE.**

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 505B the following:

1 **“SEC. 505C. INTERNAL COMMITTEE FOR REVIEW OF PEDI-**
2 **ATRIC PLANS, ASSESSMENTS, DEFERRALS,**
3 **AND WAIVERS.**

4 “The Secretary shall establish an internal committee
5 within the Food and Drug Administration to carry out the
6 activities as described in sections 505A(f) and 505B(f).
7 Such internal committee shall include employees of the
8 Food and Drug Administration, with expertise in pedi-
9 atrics (including representation from the Office of Pediatric
10 Therapeutics), biopharmacology, statistics, chemistry,
11 legal issues, pediatric ethics, and the appropriate expertise
12 pertaining to the pediatric product under review, such as
13 expertise in child and adolescent psychiatry, and other in-
14 dividuals designated by the Secretary.”.

15 **SEC. 404. GOVERNMENT ACCOUNTABILITY OFFICE RE-**
16 **PORT.**

17 Not later than January 1, 2011, the Comptroller
18 General of the United States, in consultation with the Sec-
19 retary of Health and Human Services, shall submit to the
20 Congress a report that addresses the effectiveness of sec-
21 tions 505A and 505B of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 355a, 355c) and section 409I of the
23 Public Health Service Act (42 U.S.C. 284m) in ensuring
24 that medicines used by children are tested and properly
25 labeled. Such report shall include—

1 (1) the number and importance of drugs and
2 biological products for children that are being tested
3 as a result of the amendments made by this title and
4 title V and the importance for children, health care
5 providers, parents, and others of labeling changes
6 made as a result of such testing;

7 (2) the number and importance of drugs and
8 biological products for children that are not being
9 tested for their use notwithstanding the provisions of
10 this title and title V and possible reasons for the
11 lack of testing;

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

21 (4) any recommendations for modifications to
22 the programs established under sections 505A and
23 505B of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 355a) and section 409I of the Public
25 Health Service Act (42 U.S.C. 284m) that the Sec-

1 retary determines to be appropriate, including a de-
2 tailed rationale for each recommendation; and

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

6 (B) the results of those efforts, including efforts
7 made to encourage the conduct of appropriate stud-
8 ies in neonates by companies with products that
9 have sufficient safety and other information to make
10 the conduct of the studies ethical and safe.

11 **TITLE V—BEST PHARMA-**
12 **CEUTICALS FOR CHILDREN**
13 **ACT OF 2007**

14 **SEC. 501. SHORT TITLE.**

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

17 **SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS**
18 **FOR CHILDREN ACT.**

19 (a) PEDIATRIC STUDIES OF DRUGS.—

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

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

24 “(a) DEFINITIONS.—As used in this section, the term
25 ‘pediatric studies’ or ‘studies’ means at least one clinical

1 investigation (that, at the Secretary's discretion, may in-
2 clude pharmacokinetic studies) in pediatric age groups (in-
3 cluding neonates in appropriate cases) in which a drug
4 is anticipated to be used, and, at the discretion of the Sec-
5 retary, may include preclinical studies.

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

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

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

1 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to
2 four years, to forty-eight months, and to seven
3 and one-half years are deemed to be **four and**
4 **one-half years, fifty-four months, and eight**
5 **years**, respectively; or

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

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

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

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

1 “(II) a listed patent for which a cer-
2 tification has been submitted under sub-
3 sections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)
4 of section 505,

5 the period during which an application may not
6 be approved under section 505(c)(3) or section
7 505(j)(5)(B) shall be extended by a period of
8 **【six months】** after the date the patent expires
9 (including any patent extensions); or

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

22 “(2) EXCEPTION.—The Secretary shall not ex-
23 tend the period referred to in paragraph (1)(A) or
24 (1)(B) if the determination made under subsection

1 (d)(3) is made later than 9 months prior to the expi-
2 ration of such period.

3 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-
4 KETED DRUGS.—

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

18 “(A)(i)(I) the period referred to in sub-
19 section (c)(3)(E)(ii) of section 505, and in sub-
20 section (j)(5)(F)(ii) of such section, is deemed
21 to be **【five years and six months】** rather than
22 five years, and the references in subsections
23 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to
24 four years, to forty-eight months, and to seven
25 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
7 **【three years and six months】** rather than three
8 years; 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
5 (including 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
17 (including 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 made under subsection
21 (d)(3) is made later than 9 months prior to the expi-
22 ration of such period.

23 “(d) CONDUCT OF PEDIATRIC STUDIES.—

24 “(1) REQUEST FOR STUDIES.—

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

17 “(B) SINGLE WRITTEN REQUEST.—A sin-
18 gle written request—

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

21 “(ii) may include uses that are both
22 approved and unapproved.

23 “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-
24 IES.—

25 “(A) REQUEST AND RESPONSE.—

1 “(i) IN GENERAL.—If the Secretary
2 makes a written request for pediatric stud-
3 ies (including neonates, as appropriate)
4 under subsection (b) or (c), the applicant
5 or holder, not later than 180 days after re-
6 ceiving the written request, shall respond
7 to the Secretary as to the intention of the
8 applicant or holder to act on the request
9 by—

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

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

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

1 reasons such pediatric formulation cannot
2 be developed.

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

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

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 “(e) NOTICE OF DETERMINATIONS ON STUDIES RE-
6 QUIREMENT.—

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

19 “(2) IDENTIFICATION OF CERTAIN DRUGS.—
20 The Secretary shall publish a notice identifying any
21 drug for which, on or after the date of the enact-
22 ment of the Best Pharmaceuticals for Children Act
23 of 2007, a pediatric formulation was developed,
24 studied, and found to be safe and effective in the pe-
25 diatric population (or specified subpopulation) if the

1 pediatric formulation for such drug is not introduced
2 onto the market within one year after the date that
3 the Secretary publishes the notice described in para-
4 graph (1). Such notice identifying such drug shall be
5 published not later than 30 days after the date of
6 the expiration of such one year period.

7 “(f) INTERNAL REVIEW OF WRITTEN REQUESTS
8 AND PEDIATRIC STUDIES.—

9 “(1) INTERNAL REVIEW.—The Secretary shall
10 utilize the internal review committee established
11 under section 505C to review all written requests
12 issued on or after the date of the enactment of the
13 Best Pharmaceuticals for Children Act of 2007, in
14 accordance with paragraph (2).

15 “(2) REVIEW OF WRITTEN REQUESTS.—The
16 committee referred to in paragraph (1) shall review
17 all written requests issued pursuant to this section
18 prior to being issued.

19 “(3) REVIEW OF PEDIATRIC STUDIES.—The
20 committee referred to in paragraph (1) may review
21 studies conducted pursuant to this section to make
22 a recommendation to the Secretary whether to ac-
23 cept or reject such reports under subsection (d)(3).

24 “(4) ACTIVITY BY COMMITTEE.—The committee
25 referred to in paragraph (1) may operate using ap-

1 appropriate members of such committee and need not
2 convene all members of the committee.

3 “(5) DOCUMENTATION OF COMMITTEE AC-
4 TION.—For each drug, the committee referred to in
5 paragraph (1) shall document, for each activity de-
6 scribed in paragraph (2) or (3), which members of
7 the committee participated in such activity.

8 “(6) TRACKING PEDIATRIC STUDIES AND LA-
9 BELING CHANGES.—The Secretary, in consultation
10 with the committee referred to in paragraph (1),
11 shall track and make available to the public, in an
12 easily accessible manner, including through posting
13 on the Web site of the Food and Drug Administra-
14 tion—

15 “(A) the number of studies conducted
16 under this section and under section 409I of
17 the Public Health Service Act;

18 “(B) the specific drugs and drug uses, in-
19 cluding labeled and off-labeled indications, stud-
20 ied under such sections;

21 “(C) the types of studies conducted under
22 such sections, including trial design, the num-
23 ber of pediatric patients studied, and the num-
24 ber of centers and countries involved;

1 “(D) the number of pediatric formulations
2 developed and the number of pediatric formula-
3 tions not developed and the reasons such for-
4 mulations were not developed;

5 “(E) the labeling changes made as a result
6 of studies conducted under such sections;

7 “(F) an annual summary of labeling
8 changes made as a result of studies conducted
9 under such sections for distribution pursuant to
10 subsection (k)(2); and

11 “(G) information regarding reports sub-
12 mitted on or after the date of the enactment of
13 the Best Pharmaceuticals for Children Act of
14 2007.

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

18 “(1) may receive an additional six-month period
19 under subsection (c)(1)(A)(i)(II) for a supplemental
20 application if all other requirements under this sec-
21 tion are satisfied, except that such drug may not re-
22 ceive any additional such period under subsection
23 (c)(1)(B); and

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

1 “(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-
2 QUIREMENTS.—Notwithstanding any other provision of
3 law, if any pediatric study is required by a provision of
4 law (including a regulation) other than this section and
5 such study meets the completeness, timeliness, and other
6 requirements of this section, such study shall be deemed
7 to satisfy the requirement for market exclusivity pursuant
8 to this section.

9 “(i) LABELING CHANGES.—

10 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-
11 CATIONS AND SUPPLEMENTS.—Any application or
12 supplement to an application under section 505 pro-
13 posing a labeling change as a result of any pediatric
14 study conducted pursuant to this section—

15 “(A) shall be considered to be a priority
16 application or supplement; and

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

20 “(2) DISPUTE RESOLUTION.—

21 “(A) REQUEST FOR LABELING CHANGE
22 AND FAILURE TO AGREE.—If, on or after the
23 date of the enactment of the Best Pharma-
24 ceuticals for Children Act of 2007, the Commis-
25 sioner determines that the sponsor and the

1 Commissioner have been unable to reach agree-
2 ment on appropriate changes to the labeling for
3 the drug that is the subject of the application,
4 not later than 180 days after the date of sub-
5 mission of the application—

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

10 “(ii) if the sponsor of the application
11 does not agree within 30 days after the
12 Commissioner’s request to make a labeling
13 change requested by the Commissioner, the
14 Commissioner shall refer the matter to the
15 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)(ii),
19 the Pediatric Advisory Committee shall—

20 “(i) review the pediatric study reports;
21 and

22 “(ii) make a recommendation to the
23 Commissioner concerning appropriate la-
24 beling changes, if any.

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

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

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

1 “(j) OTHER LABELING CHANGES.—If, on or after the
2 date of the enactment of the Best Pharmaceuticals for
3 Children Act of 2007, the Secretary determines that a pe-
4 diatric study conducted under this section does or does
5 not demonstrate that the drug that is the subject of the
6 study is safe and effective, including whether such study
7 results are inconclusive, in pediatric populations or sub-
8 populations, the Secretary shall order the labeling of such
9 product to include information about the results of the
10 study and a statement of the Secretary’s determination.

11 “(k) DISSEMINATION OF PEDIATRIC INFORMA-
12 TION.—

13 “(1) IN GENERAL.—Not later than 210 days
14 after the date of submission of a report on a pedi-
15 atric study under this section, the Secretary shall
16 make available to the public the medical, statistical,
17 and clinical pharmacology reviews of pediatric stud-
18 ies conducted under subsection (b) or (c).

19 “(2) DISSEMINATION OF INFORMATION RE-
20 GARDING LABELING CHANGES.—Beginning on the
21 date of the enactment of the Best Pharmaceuticals
22 for Children Act of 2007, the Secretary shall include
23 as a requirement of a written request that the spon-
24 sors of the studies that result in labeling changes
25 that are reflected in the annual summary developed

1 pursuant to subsection (f)(3)(F) distribute, at least
2 annually (or more frequently if the Secretary deter-
3 mines that it would be beneficial to the public
4 health), such information to physicians and other
5 health care providers.

6 “(3) EFFECT OF SUBSECTION.—Nothing in this
7 subsection alters or amends section 301(j) of this
8 Act or section 552 of title 5 or section 1905 of title
9 18, United States Code.

10 “(1) ADVERSE EVENT REPORTING.—

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

1 take action under this Act in response to such re-
2 ports.

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

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 “(m) CLARIFICATION OF INTERACTION OF MARKET
19 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-
20 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL
21 OF A DRUG UNDER SECTION 505(j).—If a 180-day period
22 under section 505(j)(5)(B)(iv) overlaps with a 6-month ex-
23 clusivity period under this section, so that the applicant
24 for approval of a drug under section 505(j) entitled to the
25 180-day period under that section loses a portion of the

1 180-day period to which the applicant is entitled for the
2 drug, the 180-day period shall be extended from—

3 “(1) the date on which the 180-day period
4 would have expired by the number of days of the
5 overlap, if the 180-day period would, but for the ap-
6 plication of this subsection, expire after the 6-month
7 exclusivity period; or

8 “(2) the date on which the 6-month exclusivity
9 period expires, by the number of days of the overlap
10 if the 180-day period would, but for the application
11 of this subsection, expire during the six-month exclu-
12 sivity period.

13 “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-
14 PLETED.—

15 “(1) IN GENERAL.—Beginning on the date of
16 the enactment of the Best Pharmaceuticals for Chil-
17 dren Act of 2007, if pediatric studies of a drug have
18 not been completed under subsection (d) and if the
19 Secretary, through the committee established under
20 section 505C, determines that there is a continuing
21 need for information relating to the use of the drug
22 in the pediatric population (including neonates, as
23 appropriate), the Secretary shall carry out the fol-
24 lowing:

1 “(A) For a drug for which a listed patent
2 has not expired, make a determination regard-
3 ing whether an assessment shall be required to
4 be submitted under section 505B. Prior to mak-
5 ing such a determination, the Secretary may
6 not take more than 30 days to certify whether
7 the Foundation for the National Institutes of
8 Health has sufficient funding at the time of
9 such certification to initiate and fund all of the
10 studies in the written request in their entirety
11 within the timeframes specified within the writ-
12 ten request. Only if the Secretary makes such
13 certification in the affirmative, the Secretary
14 shall refer all pediatric studies in the written
15 request to the Foundation for the National In-
16 stitutes of Health for the conduct of such stud-
17 ies, and such Foundation shall fund such stud-
18 ies. If no certification has been made at the end
19 of the 30-day period, or if the Secretary cer-
20 tifies that funds are not sufficient to initiate
21 and fund all the studies in their entirety, the
22 Secretary shall consider whether assessments
23 shall be required under section 505B for such
24 drug.

1 “(B) For a drug that has no listed patents
2 or has 1 or more listed patents that have ex-
3 pired, the Secretary shall refer the drug for in-
4 clusion on the list established under section
5 409I of the Public Health Service Act for the
6 conduct of studies.

7 “(2) PUBLIC NOTICE.—The Secretary shall give
8 the public notice of a decision under paragraph
9 (1)(A) not to require an assessment under section
10 505B and the basis for such decision.

11 “(3) EFFECT OF SUBSECTION.—Nothing in this
12 subsection alters or amends section 301(j) of this
13 Act or section 552 of title 5 or section 1905 of title
14 18, United States Code.

15 “(o) PROMPT APPROVAL OF DRUGS UNDER SECTION
16 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LA-
17 BELING.—

18 “(1) GENERAL RULE.—A drug for which an ap-
19 plication has been submitted or approved under sec-
20 tion 505(j) shall not be considered ineligible for ap-
21 proval under that section or misbranded under sec-
22 tion 502 on the basis that the labeling of the drug
23 omits a pediatric indication or any other aspect of
24 labeling pertaining to pediatric use when the omitted
25 indication or other aspect is protected by patent or

1 by exclusivity under clause (iii) or (iv) of section
2 505(j)(5)(F).

3 “(2) LABELING.—Notwithstanding clauses (iii)
4 and (iv) of section 505(j)(5)(F), the Secretary may
5 require that the labeling of a drug approved under
6 section 505(j) that omits a pediatric indication or
7 other aspect of labeling as described in paragraph
8 (1) include—

9 “(A) a statement that, because of mar-
10 keting exclusivity for a manufacturer—

11 “(i) the drug is not labeled for pedi-
12 atric use; or

13 “(ii) in the case of a drug for which
14 there is an additional pediatric use not re-
15 ferred to in paragraph (1), the drug is not
16 labeled for the pediatric use under para-
17 graph (1); and

18 “(B) a statement of any appropriate pedi-
19 atric contraindications, warnings, or pre-
20 cautions that the Secretary considers necessary.

21 “(3) PRESERVATION OF PEDIATRIC EXCLU-
22 SIVITY AND OTHER PROVISIONS.—This subsection
23 does not affect—

24 “(A) the availability or scope of exclusivity
25 under this section;

1 “(B) the availability or scope of exclusivity
2 under section 505 for pediatric formulations;

3 “(C) the question of the eligibility for ap-
4 proval of any application under section 505(j)
5 that omits any other conditions of approval en-
6 titled to exclusivity under clause (iii) or (iv) of
7 section 505(j)(5)(F); or

8 “(D) except as expressly provided in para-
9 graphs (1) and (2), the operation of section
10 505.

11 “(p) INSTITUTE OF MEDICINE STUDY.—Not later
12 than 3 years after the date of the enactment of the Best
13 Pharmaceuticals for Children Act of 2007, the Secretary
14 shall enter into a contract with the Institute of Medicine
15 to conduct a study and report to Congress regarding the
16 written requests made and the studies conducted pursuant
17 to this section. The Institute of Medicine may devise an
18 appropriate mechanism to review a representative sample
19 of requests made and studies conducted pursuant to this
20 section in order to conduct such study. Such study shall—

21 “(1) review such representative written requests
22 issued by the Secretary since 1997 under sub-
23 sections (b) and (c);

24 “(2) review and assess such representative pedi-
25 atric studies conducted under subsections (b) and (c)

1 since 1997 and labeling changes made as a result of
2 such studies;

3 “(3) review the use of extrapolation for pedi-
4 atric subpopulations, the use of alternative endpoints
5 for pediatric populations, neonatal assessment tools,
6 and ethical issues in pediatric clinical trials;

7 “(4) review and assess the pediatric studies of
8 biological products as required under subsections (a)
9 and (b) of section 505B; and

10 “(5) make recommendations regarding appro-
11 priate incentives for encouraging pediatric studies of
12 biologics.

13 “(q) SUNSET.—A drug may not receive any 6-month
14 period under subsection (b) or (c) unless—

15 “(1) on or before October 1, 2012, the Sec-
16 retary makes a written request for pediatric studies
17 of the drug;

18 “(2) on or before October 1, 2012, an applica-
19 tion for the drug is accepted for filing under section
20 505(b); and

21 “(3) all requirements of this section are met.”.

22 (2) APPLICABILITY.—

23 (A) IN GENERAL.—The amendment made
24 by this subsection shall apply to written re-
25 quests under section 505A of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355a)
2 issued on or after the date of the enactment of
3 this Act.

4 (B) CERTAIN WRITTEN REQUESTS.—A
5 written request issued under section 505A of
6 the Federal Food, Drug, and Cosmetic Act, as
7 in effect on the day before the date of the en-
8 actment of this Act, which has been accepted
9 and for which no determination under sub-
10 section (d)(2) of such section has been made
11 before such date of enactment, shall be subject
12 to such section 505A, except that such written
13 requests shall be subject to subsections
14 (d)(2)(A)(ii), (e)(1) and (2), (f), (i)(2)(A), (j),
15 (k)(1), (l)(1), and (n) of section 505A of the
16 Federal Food, Drug, and Cosmetic Act, as in
17 effect on or after the date of the enactment of
18 this Act.

19 (b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—
20 Section 409I of the Public Health Service Act (42 U.S.C.
21 284m) is amended to read as follows:

22 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

23 **“(a) LIST OF PRIORITY ISSUES IN PEDIATRIC**
24 **THERAPEUTICS.—**

1 “(1) IN GENERAL.—Not later than one year
2 after the date of the enactment of the Best Pharma-
3 ceuticals for Children Act of 2007, the Secretary,
4 acting through the Director of the National Insti-
5 tutes of Health and in consultation with the Com-
6 missioner of Food and Drugs and experts in pedi-
7 atric research, shall develop and publish a priority
8 list of needs in pediatric therapeutics, including
9 drugs or indications that require study. The list
10 shall be revised every three years.

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

14 “(A) therapeutic gaps in pediatrics that
15 may include developmental pharmacology,
16 pharmacogenetic determinants of drug re-
17 sponse, metabolism of drugs and biologics in
18 children, and pediatric clinical trials;

19 “(B) particular pediatric diseases, dis-
20 orders or conditions where more complete
21 knowledge and testing of therapeutics, including
22 drugs and biologics, may be beneficial in pedi-
23 atric populations; and

24 “(C) the adequacy of necessary infrastruc-
25 ture to conduct pediatric pharmacological re-

1 search, including research networks and trained
2 pediatric investigators.

3 “(b) PEDIATRIC STUDIES AND RESEARCH.—The
4 Secretary, acting through the National Institutes of
5 Health, shall award funds to entities that have the exper-
6 tise to conduct pediatric clinical trials or other research
7 (including qualified universities, hospitals, laboratories,
8 contract research organizations, practice groups, federally
9 funded programs such as pediatric pharmacology research
10 units, other public or private institutions, or individuals)
11 to enable the entities to conduct the drug studies or other
12 research on the issues described in subsection (a). The
13 Secretary may use contracts, grants, or other appropriate
14 funding mechanisms to award funds under this subsection.

15 “(c) PROCESS FOR PROPOSED PEDIATRIC STUDY
16 REQUESTS AND LABELING CHANGES.—

17 “(1) SUBMISSION OF PROPOSED PEDIATRIC
18 STUDY REQUEST.—The Director of the National In-
19 stitutes of Health shall, as appropriate, submit pro-
20 posed pediatric study requests for consideration by
21 the Commissioner of Food and Drugs for pediatric
22 studies of a specific pediatric indication identified
23 under subsection (a). Such a proposed pediatric
24 study request shall be made in a manner equivalent
25 to a written request made under subsection (b) or

1 (c) of section 505A of the Federal Food, Drug, and
2 Cosmetic Act, including with respect to the informa-
3 tion provided on the pediatric studies to be con-
4 ducted pursuant to the request. The Director of the
5 National Institutes of Health may submit a pro-
6 posed pediatric study request for a drug for which—

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

10 “(ii) there is a submitted application that
11 could be approved under the criteria of such
12 section; and

13 “(B) there is no patent protection or mar-
14 ket exclusivity protection for at least one form
15 of the drug under the Federal Food, Drug, and
16 Cosmetic Act; and

17 “(C) additional studies are needed to as-
18 sess the safety and effectiveness of the use of
19 the drug in the pediatric population.

20 “(2) WRITTEN REQUEST TO HOLDERS OF AP-
21 PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-
22 SIVITY.—The Commissioner of Food and Drugs, in
23 consultation with the Director of the National Insti-
24 tutes of Health, may issue a written request based
25 on the proposed pediatric study request for the indi-

1 cation or indications submitted pursuant to para-
2 graph (1) (which shall include a timeframe for nego-
3 tiations for an agreement) for pediatric studies con-
4 cerning a drug identified under subsection (a) to all
5 holders of an approved application for the drug
6 under section 505 of the Federal Food, Drug, and
7 Cosmetic Act. Such a written request shall be made
8 in a manner equivalent to the manner in which a
9 written request is made under subsection (b) or (c)
10 of section 505A of such Act, including with respect
11 to information provided on the pediatric studies to
12 be conducted pursuant to the request and using ap-
13 propriate formulations for each age group for which
14 the study is requested.

15 “(3) REQUESTS FOR PROPOSALS.—If the Com-
16 missioner of Food and Drugs does not receive a re-
17 sponse to a written request issued under paragraph
18 (2) not later than 30 days after the date on which
19 a request was issued, the Secretary, acting through
20 the Director of the National Institutes of Health and
21 in consultation with the Commissioner of Food and
22 Drugs, shall publish a request for proposals to con-
23 duct the pediatric studies described in the written
24 request in accordance with subsection (b).

1 “(4) DISQUALIFICATION.—A holder that re-
2 ceives a first right of refusal shall not be entitled to
3 respond to a request for proposals under paragraph
4 (3).

5 “(5) CONTRACTS, GRANTS, OR OTHER FUNDING
6 MECHANISMS.—A contract, grant, or other funding
7 may be awarded under this section only if a proposal
8 is submitted to the Secretary in such form and man-
9 ner, and containing such agreements, assurances,
10 and information as the Secretary determines to be
11 necessary to carry out this section.

12 “(6) REPORTING OF STUDIES.—

13 “(A) IN GENERAL.—On completion of a
14 pediatric study in accordance with an award
15 under this section, a report concerning the
16 study shall be submitted to the Director of the
17 National Institutes of Health and the Commis-
18 sioner of Food and Drugs. The report shall in-
19 clude all data generated in connection with the
20 study, including a written request if issued.

21 “(B) AVAILABILITY OF REPORTS.—Each
22 report submitted under subparagraph (A) shall
23 be considered to be in the public domain (sub-
24 ject to section 505A(d)(4) of the Federal Food,
25 Drug, and Cosmetic Act) and shall be assigned

1 a docket number by the Commissioner of Food
2 and Drugs. An interested person may submit
3 written comments concerning such pediatric
4 studies to the Commissioner of Food and
5 Drugs, and the written comments shall become
6 part of the docket file with respect to each of
7 the drugs.

8 “(C) ACTION BY COMMISSIONER.—The
9 Commissioner of Food and Drugs shall take ap-
10 propriate action in response to the reports sub-
11 mitted under subparagraph (A) in accordance
12 with paragraph (7).

13 “(7) REQUESTS FOR LABELING CHANGE.—Dur-
14 ing the 180-day period after the date on which a re-
15 port is submitted under paragraph (6)(A), the Com-
16 missioner of Food and Drugs shall—

17 “(A) review the report and such other data
18 as are available concerning the safe and effec-
19 tive use in the pediatric population of the drug
20 studied;

21 “(B) negotiate with the holders of ap-
22 proved applications for the drug studied for any
23 labeling changes that the Commissioner of Food
24 and Drugs determines to be appropriate and re-
25 quests the holders to make; and

1 “(C)(i) place in the public docket file a
2 copy of the report and of any requested labeling
3 changes; and

4 “(ii) publish in the Federal Register and
5 through a posting on the Web site of the Food
6 and Drug Administration a summary of the re-
7 port and a copy of any requested labeling
8 changes.

9 “(8) DISPUTE RESOLUTION.—

10 “(A) REFERRAL TO PEDIATRIC ADVISORY
11 COMMITTEE.—If, not later than the end of the
12 180-day period specified in paragraph (7), the
13 holder of an approved application for the drug
14 involved does not agree to any labeling change
15 requested by the Commissioner of Food and
16 Drugs under that paragraph, the Commissioner
17 of Food and Drugs shall refer the request to
18 the Pediatric Advisory Committee.

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

23 “(i) review the available information
24 on the safe and effective use of the drug

1 in the pediatric population, including study
2 reports submitted under this section; and

3 “(ii) make a recommendation to the
4 Commissioner of Food and Drugs as to ap-
5 propriate labeling changes, if any.

6 “(9) FDA DETERMINATION.—Not later than 30
7 days after receiving a recommendation from the Pe-
8 diatric Advisory Committee under paragraph
9 (8)(B)(ii) with respect to a drug, the Commissioner
10 of Food and Drugs shall consider the recommenda-
11 tion and, if appropriate, make a request to the hold-
12 ers of approved applications for the drug to make
13 any labeling change that the Commissioner of Food
14 and Drugs determines to be appropriate.

15 “(10) FAILURE TO AGREE.—If a holder of an
16 approved application for a drug, within 30 days
17 after receiving a request to make a labeling change
18 under paragraph (9), does not agree to make a re-
19 quested labeling change, the Commissioner of Food
20 and Drugs may deem the drug to be misbranded
21 under the Federal Food, Drug, and Cosmetic Act.

22 “(11) NO EFFECT ON AUTHORITY.—Nothing in
23 this subsection limits the authority of the United
24 States to bring an enforcement action under the
25 Federal Food, Drug, and Cosmetic Act when a drug

1 lacks appropriate pediatric labeling. Neither course
2 of action (the Pediatric Advisory Committee process
3 or an enforcement action referred to in the pre-
4 ceding sentence) shall preclude, delay, or serve as
5 the basis to stay the other course of action.

6 “(d) DISSEMINATION OF PEDIATRIC INFORMA-
7 TION.—Not later than one year after the date of the enact-
8 ment of the Best Pharmaceuticals for Children Act of
9 2007, the Secretary, acting through the Director of the
10 National Institutes of Health, shall study the feasibility
11 of establishing a compilation of information on pediatric
12 drug use and report the findings to Congress.

13 “(e) AUTHORIZATION OF APPROPRIATIONS.—

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

16 “(A) \$200,000,000 for fiscal year 2008;
17 and

18 “(B) such sums as are necessary for each
19 of the four succeeding fiscal years.

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

23 (c) FOUNDATION FOR THE NATIONAL INSTITUTES
24 OF HEALTH.—Section 499(c)(1)(C) of the Public Health
25 Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by

1 striking “and studies listed by the Secretary pursuant to
2 section 409I(a)(1)(A) of this Act and referred under sec-
3 tion 505A(d)(4)(C) of the Federal Food, Drug and Cos-
4 metic Act (21 U.S.C. 355(a)(d)(4)(C))” and inserting
5 “and studies for which the Secretary issues a certification
6 in the affirmative under section 505A(n)(1)(A) of the Fed-
7 eral Food, Drug, and Cosmetic Act”.

8 (d) CONTINUATION OF OPERATION OF COM-
9 MITTEE.—Section 14 of the Best Pharmaceuticals for
10 Children Act (42 U.S.C. 284m note) is amended by adding
11 at the end the following new subsection:

12 “(d) CONTINUATION OF OPERATION OF COM-
13 MITTEE.—Notwithstanding section 14 of the Federal Ad-
14 visory Committee Act, the advisory committee shall con-
15 tinue to operate during the five-year period beginning on
16 the date of the enactment of the Best Pharmaceuticals for
17 Children Act of 2007.”.

18 (e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
19 DRUGS ADVISORY COMMITTEE.—Section 15 of the Best
20 Pharmaceuticals for Children Act (42 U.S.C. 284m note)
21 is amended—

22 (1) in subsection (a)—

23 (A) in paragraph (1)—

24 (i) in subparagraph (B), by striking

25 “and” after the semicolon;

1 (ii) in subparagraph (C), by striking
2 the period at the end and inserting “;
3 and”; and

4 (iii) by adding at the end the fol-
5 lowing new subparagraph:

6 “(D) provide recommendations to the in-
7 ternal review committee created under section
8 505B(f) of the Federal Food, Drug, and Cos-
9 metic Act regarding the implementation of
10 amendments to sections 505A and 505B of the
11 Federal Food, Drug, and Cosmetic Act with re-
12 spect to the treatment of pediatric cancers.”;
13 and

14 (B) by adding at the end the following new
15 paragraph:

16 “(3) CONTINUATION OF OPERATION OF SUB-
17 COMMITTEE.—Notwithstanding section 14 of the
18 Federal Advisory Committee Act, the Subcommittee
19 shall continue to operate during the five-year period
20 beginning on the date of the enactment of the Best
21 Pharmaceuticals for Children Act of 2007.”; and

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

1 (f) EFFECTIVE DATE AND LIMITATION FOR RULE
2 RELATING TO TOLL-FREE NUMBER FOR ADVERSE
3 EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

4 (1) IN GENERAL.—Notwithstanding subchapter
5 II of chapter 5, and chapter 7, of title 5, United
6 States Code (commonly known as the “Administra-
7 tive Procedure Act”) and any other provision of law,
8 the proposed rule issued by the Commissioner of
9 Food and Drugs entitled “Toll-Free Number for Re-
10 porting Adverse Events on Labeling for Human
11 Drug Products,” 69 Fed. Reg. 21778, (April 22,
12 2004) shall take effect on January 1, 2008, unless
13 such Commissioner issues the final rule before such
14 date.

15 (2) LIMITATION.—The proposed rule that takes
16 effect under subsection (a), or the final rule de-
17 scribed under subsection (a), shall, notwithstanding
18 section 17(a) of the Best Pharmaceuticals for Chil-
19 dren Act (21 U.S.C. 355b(a)), not apply to a drug—

20 (A) for which an application is approved
21 under section 505 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 355);

23 (B) that is not described under section
24 503(b)(1) of such Act (21 U.S.C. 353(b)(1));
25 and

1 (C) the packaging of which includes a toll-
2 free number through which consumers can re-
3 port complaints to the manufacturer or dis-
4 tributor of the drug.

5 **SEC. 503. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

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

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

16 **TITLE VI—REAGAN-UDALL**
17 **FOUNDATION**

18 **SEC. 601. THE REAGAN-UDALL FOUNDATION FOR THE**
19 **FOOD AND DRUG ADMINISTRATION.**

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

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

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

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

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

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

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

1 devices, including diagnostics, biologics, and drugs,
2 and the safety of food, food ingredients, and cos-
3 metics, and including the incorporation of more sen-
4 sitive and predictive tools and devices to measure
5 safety;

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

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

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

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

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

14 “(7) ensure that—

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

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

22 “(C) executed licenses, memoranda of un-
23 derstanding, material transfer agreements, con-
24 tracts, and other such instruments, promote, to
25 the maximum extent practicable, the broadest

1 conversion to commercial and noncommercial
2 applications of licensed and patented inventions
3 of the Foundation to further the goals and pri-
4 orities established under paragraph (2);

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

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

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

16 “(d) BOARD OF DIRECTORS.—

17 “(1) ESTABLISHMENT.—

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

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

4 “(i) The Commissioner.

5 “(ii) The Director of the National In-
6 stitutes of Health.

7 “(iii) The Director of the Centers for
8 Disease Control and Prevention.

9 “(iv) The Director of the Agency for
10 Healthcare Research and Quality.

11 “(C) APPOINTED MEMBERS.—

12 “(i) IN GENERAL.—The ex officio
13 members of the Board under subparagraph
14 (B) shall, by majority vote, appoint to the
15 Board 14 individuals, of which 9 shall be
16 from a list of candidates to be provided by
17 the National Academy of Sciences and 5
18 shall be from lists of candidates provided
19 by patient and consumer advocacy groups,
20 professional scientific and medical soci-
21 eties, and industry trade organizations. Of
22 such appointed members—

23 “(I) 4 shall be representatives of
24 the general pharmaceutical, device,

1 food, cosmetic, and biotechnology in-
2 dustries;

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

5 “(III) 2 shall be representatives
6 of patient or consumer advocacy orga-
7 nizations;

8 “(IV) 1 shall be a representative
9 of health care providers; and

10 “(V) 4 shall be at-large members
11 with expertise or experience relevant
12 to the purpose of the Foundation.

13 “(ii) REQUIREMENTS.—

14 “(I) EXPERTISE.—The ex officio
15 members shall ensure the Board mem-
16 bership includes individuals with ex-
17 pertise in areas including the sciences
18 of developing, manufacturing, and
19 evaluating the safety and effectiveness
20 of devices, including diagnostics, bio-
21 logics, and drugs, and the safety of
22 food, food ingredients, and cosmetics.

23 “(II) FEDERAL EMPLOYEES.—
24 No employee of the Federal Govern-
25 ment shall be appointed as a member

1 of the Board under this subparagraph
2 or under paragraph (3)(B).

3 “(D) INITIAL MEETING.—

4 “(i) IN GENERAL.—Not later than 30
5 days after the date of the enactment of
6 this subchapter, the Secretary shall con-
7 vene a meeting of the ex officio members
8 of the Board to—

9 “(I) incorporate the Foundation;
10 and

11 “(II) appoint the members of the
12 Board in accordance with subpara-
13 graph (C).

14 “(ii) SERVICE OF EX OFFICIO MEM-
15 BERS.—Upon the appointment of the
16 members of the Board under clause
17 (i)(II)—

18 “(I) the terms of service of the
19 Director of the Centers for Disease
20 Control and Prevention and of the Di-
21 rector of the Agency for Healthcare
22 Research and Quality as ex officio
23 members of the Board shall termi-
24 nate; and

1 “(II) the Commissioner and the
2 Director of the National Institutes of
3 Health shall continue to serve as ex
4 officio members of the Board, but
5 shall be nonvoting members.

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

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

11 “(A) establish bylaws for the Foundation
12 that—

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

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

18 “(iii) establish policies, including eth-
19 ical standards, for the acceptance, solicita-
20 tion, and disposition of donations and
21 grants to the Foundation and for the dis-
22 position of the assets of the Foundation,
23 including appropriate limits on the ability
24 of donors to designate, by stipulation or re-

1 striction, the use or recipient of donated
2 funds;

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

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

18 “(vi) specify principles for the review
19 of proposals and awarding of grants and
20 contracts that include peer review and that
21 are consistent with those of the Founda-
22 tion for the National Institutes of Health,
23 to the extent determined practicable and
24 appropriate by the Board;

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

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

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

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

24 “(xi) establish specific duties of the
25 Executive Director;

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

3 “(C) evaluate the performance of the Exec-
4 utive Director; and

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

8 “(3) TERMS AND VACANCIES.—

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

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

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

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

23 “(C) PARTIAL TERM.—If a member of the
24 Board does not serve the full term applicable
25 under subparagraph (A), the individual ap-

1 pointed under subparagraph (B) to fill the re-
2 sulting vacancy shall be appointed for the re-
3 mainder of the term of the predecessor of the
4 individual.

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

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

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

18 “(f) NONPROFIT STATUS.—In carrying out sub-
19 section (b), the Board shall establish such policies and by-
20 laws under subsection (d), and the Executive Director
21 shall carry out such activities under subsection (g), as may
22 be necessary to ensure that the Foundation maintains sta-
23 tus as an organization that—

24 “(1) is described in subsection (c)(3) of section
25 501 of the Internal Revenue Code of 1986; and

1 “(2) is, under subsection (a) of such section, ex-
2 empt from taxation.

3 “(g) EXECUTIVE DIRECTOR.—

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

10 “(2) COMPENSATION.—The compensation of
11 the Executive Director shall be fixed by the Board
12 but shall not be greater than the compensation of
13 the Commissioner.

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

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

19 “(2) hire, promote, compensate, and discharge
20 1 or more officers, employees, and agents, as may be
21 necessary, and define their duties;

22 “(3) prescribe the manner in which—

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

1 “(B) general operations of the Foundation
2 are to be conducted; and

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

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

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

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

15 “(7) enter into such other contracts, leases, co-
16 operative agreements, and other transactions as the
17 Board considers appropriate to conduct the activities
18 of the Foundation;

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

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

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

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

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

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

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

23 “(k) DETAIL OF GOVERNMENT EMPLOYEES; FEL-
24 LOWSHIPS.—

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

11 “(2) VOLUNTARY SERVICE; ACCEPTANCE OF
12 FEDERAL EMPLOYEES.—

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

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

24 “(I) ANNUAL REPORTS.—

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

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

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

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

24 “(C) provides information on how the re-
25 sults of Foundation activities could be incor-

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

3 “(m) SEPARATION OF FUNDS.—The Executive Di-
4 rector shall ensure that the funds received from the Treas-
5 ury are held in separate accounts from funds received
6 from entities under subsection (i).

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

12 (b) OTHER FOUNDATION PROVISIONS.—Chapter VII
13 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 371 et seq.) (as amended by subsection (a)) is amended
15 by adding at the end the following:

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

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

19 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
20 **TRATION.**

21 “(a) IN GENERAL.—The Commissioner shall receive
22 and assess the report submitted to the Commissioner by
23 the Executive Director of the Foundation under section
24 770(l)(2).

1 “(b) REPORT TO CONGRESS.—Beginning with fiscal
2 year 2009, the Commissioner shall submit to Congress an
3 annual report summarizing the incorporation of the infor-
4 mation provided by the Foundation in the report described
5 under section 770(l)(2) and by other recipients of grants,
6 contracts, memoranda of understanding, or cooperative
7 agreements into regulatory and product review activities
8 of the Food and Drug Administration.

9 “(c) EXTRAMURAL GRANTS.—The provisions of this
10 subchapter and section 566 shall have no effect on any
11 grant, contract, memorandum of understanding, or coop-
12 erative agreement between the Food and Drug Adminis-
13 tration and any other entity entered into before, on, or
14 after the date of the enactment of this subchapter.”.

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

1 **SEC. 602. OFFICE OF THE CHIEF SCIENTIST.**

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

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

6 “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-
7 retary shall establish within the Office of the Commis-
8 sioner an office to be known as the Office of the Chief
9 Scientist. The Secretary shall appoint a Chief Scientist to
10 lead such Office.

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

13 “(1) oversee, coordinate, and ensure quality and
14 regulatory focus of the intramural research pro-
15 grams of the Food and Drug Administration;

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

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

25 “(4) develop a peer review process by which in-
26 tramural research can be evaluated;

1 “(5) identify and solicit intramural research
2 proposals from across the Food and Drug Adminis-
3 tration through an advisory board composed of em-
4 ployees of the Administration that shall include—

5 “(A) representatives of each of the centers
6 and the science-based offices within the Office
7 of the Commissioner; and

8 “(B) experts on trial design, epidemiology,
9 demographics, pharmacovigilance, basic science,
10 and public health; and

11 “(6) develop postmarket safety performance
12 measures that are as measurable and rigorous as the
13 ones already developed for premarket review.”.

14 **SEC. 603. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.**

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

18 **“SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNER-**
19 **SHIPS.**

20 “(a) ESTABLISHMENT.—The Secretary, acting
21 through the Commissioner of Food and Drugs, may enter
22 into collaborative agreements, to be known as Critical
23 Path Public-Private Partnerships, with one or more eligi-
24 ble entities to implement the Critical Path Initiative of the
25 Food and Drug Administration by developing innovative,

1 collaborative projects in research, education, and outreach
2 for the purpose of fostering medical product innovation,
3 enabling the acceleration of medical product development,
4 manufacturing, and translational therapeutics, and en-
5 hancing medical product safety.

6 “(b) ELIGIBLE ENTITY.—In this section, the term
7 ‘eligible entity’ means an entity that meets each of the
8 following:

9 “(1) The entity is—

10 “(A) an institution of higher education (as
11 such term is defined in section 101 of the High-
12 er Education Act of 1965) or a consortium of
13 such institutions; or

14 “(B) an organization described in section
15 501(c)(3) of the Internal Revenue Code of 1986
16 and exempt from tax under section 501(a) of
17 such Code.

18 “(2) The entity has experienced personnel and
19 clinical and other technical expertise in the bio-
20 medical sciences, which may include graduate train-
21 ing programs in areas relevant to priorities of the
22 Critical Path Initiative.

23 “(3) The entity demonstrates to the Secretary’s
24 satisfaction that the entity is capable of—

1 “(A) developing and critically evaluating
2 tools, methods, and processes—

3 “(i) to increase efficiency, predict-
4 ability, and productivity of medical product
5 development; and

6 “(ii) to more accurately identify the
7 benefits and risks of new and existing med-
8 ical products;

9 “(B) establishing partnerships, consortia,
10 and collaborations with health care practitioners
11 and other providers of health care goods or
12 services; pharmacists; pharmacy benefit man-
13 agers and purchasers; health maintenance orga-
14 nizations and other managed health care orga-
15 nizations; health care insurers; government
16 agencies; patients and consumers; manufactur-
17 ers of prescription drugs, biological products,
18 diagnostic technologies, and devices; and aca-
19 demic scientists; and

20 “(C) securing funding for the projects of a
21 Critical Path Public-Private Partnership from
22 Federal and nonfederal governmental sources,
23 foundations, and private individuals.

24 “(c) FUNDING.—The Secretary may not enter into
25 a collaborative agreement under subsection (a) unless the

1 eligible entity involved provides an assurance that the enti-
2 ty will not accept funding for a Critical Path Public-Pri-
3 vate Partnership project from any organization that man-
4 ufactures or distributes products regulated by the Food
5 and Drug Administration unless the entity provides assur-
6 ances in its agreement with the Food and Drug Adminis-
7 tration that the results of the Critical Path Public-Private
8 Partnership project will not be influenced by any source
9 of funding.

10 “(d) ANNUAL REPORT.—Not later than 18 months
11 after the date of the enactment of this section, and annu-
12 ally thereafter, the Secretary, in collaboration with the
13 parties to each Critical Path Public-Private Partnership,
14 shall submit a report to the Committee on Health, Edu-
15 cation, Labor, and Pensions of the Senate and the Com-
16 mittee on Energy and Commerce of the House of Rep-
17 resentatives—

18 “(1) reviewing the operations and activities of
19 the Partnerships in the previous year; and

20 “(2) addressing such other issues relating to
21 this section as the Secretary determines to be appro-
22 priate.

23 “(e) DEFINITION.—In this section, the term ‘medical
24 product’ includes a drug, a biological product as defined

1 in section 351 of the Public Health Service Act, a device,
2 and any combination of such products.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
4 carry out this section, there are authorized to be appro-
5 priated \$5,000,000 for fiscal year 2008 and such sums
6 as may be necessary for each of fiscal years 2009 through
7 2012.”.

8 **TITLE VII—CONFLICTS OF** 9 **INTEREST**

10 **SEC. 701. CONFLICTS OF INTEREST.**

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

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

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

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

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

24 “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

25 “(1) RECRUITMENT.—

1 “(A) IN GENERAL.—The Secretary shall—

2 “(i) develop and implement strategies
3 on effective outreach to potential members
4 of advisory committees at universities, col-
5 leges, other academic research centers,
6 professional and medical societies, and pa-
7 tient and consumer groups;

8 “(ii) seek input from professional
9 medical and scientific societies to deter-
10 mine the most effective informational and
11 recruitment activities; and

12 “(iii) take into account the advisory
13 committees with the greatest number of
14 vacancies.

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

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

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

1 point of contact regarding advisory com-
2 mittee nominations; and

3 “(iii) developing a method through
4 which an entity receiving funding from the
5 National Institutes of Health, the Agency
6 for Healthcare Research and Quality, the
7 Centers for Disease Control and Preven-
8 tion, or the Veterans Health Administra-
9 tion can identify a person who the Food
10 and Drug Administration can contact re-
11 garding the nomination of individuals to
12 serve on advisory committees.

13 “(2) EVALUATION AND CRITERIA.—When con-
14 sidering a term appointment to an advisory com-
15 mittee, the Secretary shall review the expertise of
16 the individual and the financial disclosure report
17 filed by the individual pursuant to the Ethics in
18 Government Act of 1978 for each individual under
19 consideration for the appointment, so as to reduce
20 the likelihood that an appointed individual will later
21 require a written determination as referred to in sec-
22 tion 208(b)(1) of title 18, United States Code, a
23 written certification as referred to in section
24 208(b)(3) of title 18, United States Code, or a waiv-
25 er as referred to in subsection (c)(2) of this section

1 for service on the committee at a meeting of the
2 committee.

3 “(c) DISCLOSURES; PROHIBITIONS ON PARTICIPA-
4 TION; WAIVERS.—

5 “(1) DISCLOSURE OF FINANCIAL INTEREST.—

6 Prior to a meeting of an advisory committee regard-
7 ing a ‘particular matter’ (as that term is used in
8 section 208 of title 18, United States Code), each
9 member of the committee who is a full-time Govern-
10 ment employee or special Government employee shall
11 disclose to the Secretary financial interests in ac-
12 cordance with subsection (b) of such section 208.

13 “(2) PROHIBITIONS AND WAIVERS ON PARTICI-
14 PATION.—

15 “(A) IN GENERAL.—Except as provided
16 under subparagraph (B), a member of an advi-
17 sory committee may not participate with respect
18 to a particular matter considered in an advisory
19 committee meeting if such member (or an im-
20 mediate family member of such member) has a
21 financial interest that could be affected by the
22 advice given to the Secretary with respect to
23 such matter, excluding interests exempted in
24 regulations issued by the Director of the Office
25 of Government Ethics as too remote or incon-

1 sequential to affect the integrity of the services
2 of the Government officers or employees to
3 which such regulations apply.

4 “(B) WAIVER.—If the Secretary deter-
5 mines it necessary to afford the advisory com-
6 mittee essential expertise, the Secretary may
7 grant a waiver of the prohibition in subpara-
8 graph (A) to permit a member described in
9 such subparagraph to—

10 “(i) participate as a non-voting mem-
11 ber with respect to a particular matter
12 considered in a committee meeting; or

13 “(ii) participate as a voting member
14 with respect to a particular matter consid-
15 ered in a committee meeting.

16 “(C) LIMITATION ON WAIVERS AND OTHER
17 EXCEPTIONS.—

18 “(i) DEFINITION.—For purposes of
19 this subparagraph, the term ‘exception’
20 means each of the following with respect to
21 members of advisory committees:

22 “(I) A waiver under section
23 505(n)(4) (as in effect on the day be-
24 fore the date of the enactment of the

1 Food and Drug Administration
2 Amendments Act of 2007).

3 “(II) A written determination
4 under section 208(b) of title 18,
5 United States Code.

6 “(III) A written certification
7 under section 208(b)(3) of such title.

8 “(ii) DETERMINATION OF TOTAL
9 NUMBER OF MEMBERS SLOTS AND MEM-
10 BER EXCEPTIONS DURING FISCAL YEAR
11 2007.—The Secretary shall determine—

12 “(I)(aa) for each meeting held by
13 any advisory committee during fiscal
14 year 2007, the number of members
15 who participated in the meeting; and
16 (bb) the sum of the respective num-
17 bers determined under item (aa) (re-
18 ferred to in this subparagraph as the
19 “total number of 2007 meeting
20 slots”); and

21 “(bb) for each meeting held by
22 any advisory committee during fiscal
23 year 2007, the number of members
24 who received an exception for the
25 meeting; and (bb) the sum of the re-

1 spective numbers determined under
2 item (aa) (referred to in this subpara-
3 graph as the “total number of 2007
4 meeting exceptions”).

5 “(iii) DETERMINATION OF PERCENT-
6 AGE REGARDING EXCEPTIONS DURING FIS-
7 CAL YEAR 2007.—The Secretary shall de-
8 termine the percentage constituted by—

9 “(I) the total number of 2007
10 meeting exceptions; divided by

11 “(II) the total number of 2007
12 meeting slots.

13 “(iv) LIMITATION FOR FISCAL YEARS
14 2008 THROUGH 2012.—The number of ex-
15 ceptions at the Food and Drug Adminis-
16 tration for members of advisory commit-
17 tees for a fiscal year may not exceed the
18 following:

19 “(I) For fiscal year 2008, 95 per-
20 cent of the percentage determined
21 under clause (iii) (referred to in this
22 clause as the “base percentage”).

23 “(II) For fiscal year 2009, 90
24 percent of the base percentage.

1 “(III) For fiscal year 2010, 85
2 percent of the base percentage.

3 “(IV) For fiscal year 2011, 80
4 percent of the base percentage.

5 “(V) For fiscal year 2012, 75
6 percent of the base percentage.

7 “(v) ALLOCATION OF EXCEPTIONS.—
8 The exceptions authorized under clause
9 (iii) for a fiscal year may be allocated with-
10 in the centers or other organizational units
11 of the Food and Drug Administration as
12 determined appropriate by the Secretary.

13 “(3) DISCLOSURE OF WAIVER.—Notwith-
14 standing section 107(a)(2) of the Ethics in Govern-
15 ment Act (5 U.S.C. App.), the following shall apply:

16 “(A) 15 OR MORE DAYS IN ADVANCE.—As
17 soon as practicable, but (except as provided in
18 subparagraph (B)) not later than 15 days prior
19 to a meeting of an advisory committee to which
20 a written determination as referred to in section
21 208(b)(1) of title 18, United States Code, a
22 written certification as referred to in section
23 208(b)(3) of title 18, United States Code, or a
24 waiver as referred to in paragraph (2)(B) ap-
25 plies, the Secretary shall disclose (other than

1 information exempted from disclosure under
2 section 552 of title 5, United States Code, and
3 section 552a of title 5, United States Code
4 (popularly known as the Freedom of Informa-
5 tion Act and the Privacy Act of 1974, respec-
6 tively)) on the Internet Web site of the Food
7 and Drug Administration—

8 “(i) the type, nature, and magnitude
9 of the financial interests of the advisory
10 committee member to which such deter-
11 mination, certification, or waiver applies;
12 and

13 “(ii) the reasons of the Secretary for
14 such determination, certification, or waiv-
15 er.

16 “(B) LESS THAN 30 DAYS IN ADVANCE.—
17 In the case of a financial interest that becomes
18 known to the Secretary less than 30 days prior
19 to a meeting of an advisory committee to which
20 a written determination as referred to in section
21 208(b)(1) of title 18, United States Code, a
22 written certification as referred to in section
23 208(b)(3) of title 18, United States Code, or a
24 waiver as referred to in paragraph (2)(B) ap-
25 plies, the Secretary shall disclose (other than

1 information exempted from disclosure under
2 section 552 of title 5, United States Code, and
3 section 552a of title 5, United States Code) on
4 the Internet Web site of the Food and Drug
5 Administration, the information described in
6 clauses (i) and (ii) of subparagraph (A) as soon
7 as practicable after the Secretary makes such
8 determination, certification, or waiver, but in no
9 case later than the date of such meeting.

10 “(d) PUBLIC RECORD.—The Secretary shall ensure
11 that the public record and transcript of each meeting of
12 an advisory committee includes the disclosure required
13 under subsection (c)(3) (other than information exempted
14 from disclosure under section 552 of title 5, United States
15 Code, and section 552a of title 5, United States Code).

16 “(e) ANNUAL REPORT.—Not later than February 1
17 of each year, the Secretary shall submit to the Committee
18 on Appropriations and the Committee on Health, Edu-
19 cation, Labor, and Pensions of the Senate, and the Com-
20 mittee on Appropriations and the Committee on Energy
21 and Commerce of the House of Representatives a report
22 that describes—

23 “(1) with respect to the fiscal year that ended
24 on September 30 of the previous year, the number
25 of vacancies on each advisory committee, the number

1 of nominees received for each committee, and the
2 number of such nominees willing to serve;

3 “(2) with respect to such year, the aggregate
4 number of disclosures required under subsection
5 (c)(3) for each meeting of each advisory committee
6 and the percentage of individuals to whom such dis-
7 closures did not apply who served on such committee
8 for each such meeting;

9 “(3) with respect to such year, the number of
10 times the disclosures required under subsection
11 (c)(3) occurred under subparagraph (B) of such sub-
12 section; and

13 “(4) how the Secretary plans to reduce the
14 number of vacancies reported under paragraph (1)
15 during the fiscal year following such year, and mech-
16 anisms to encourage the nomination of individuals
17 for service on an advisory committee, including those
18 who are classified by the Food and Drug Adminis-
19 tration as academicians or practitioners.

20 “(f) PERIODIC REVIEW OF GUIDANCE.—Not less
21 than once every 5 years, the Secretary shall review guid-
22 ance of the Food and Drug Administration regarding con-
23 flict of interest waiver determinations with respect to advi-
24 sory committees and update such guidance as necessary.”.

1 (b) CONFORMING AMENDMENTS.—Section 505(n) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(n)) is amended by—

4 (1) striking paragraph (4); and

5 (2) redesignating paragraphs (5), (6), (7), and
6 (8) as paragraphs (4), (5), (6), and (7), respectively.

7 (c) EFFECTIVE DATE.—The amendments made by
8 this section shall take effect on October 1, 2007.

9 **TITLE VIII—CLINICAL TRIAL**
10 **DATABASES**

11 **SEC. 801. EXPANDED CLINICAL TRIAL REGISTRY DATA**
12 **BANK.**

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

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

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

18 “(j) EXPANDED CLINICAL TRIAL REGISTRY DATA
19 BANK.—

20 “(1) DEFINITIONS; REQUIREMENT.—

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

22 “(i) APPLICABLE CLINICAL TRIAL.—

23 The term ‘applicable clinical trial’ means
24 an applicable device clinical trial or an ap-
25 plicable drug clinical trial.

1 “(ii) APPLICABLE DEVICE CLINICAL
2 TRIAL.—The term ‘applicable device clin-
3 ical trial’ means—

4 “(I) a prospective clinical study
5 of health outcomes comparing an
6 intervention with a device subject to
7 section 510(k), 515, or 520(m) of the
8 Federal Food, Drug, and Cosmetic
9 Act against a control in human sub-
10 jects (other than a small clinical trial
11 to determine the feasibility of a de-
12 vice, or a clinical trial to test proto-
13 type devices where the primary out-
14 come measure relates to feasibility
15 and not to health outcomes); and

16 “(II) a pediatric postmarket sur-
17 veillance as required under section
18 522 of the Federal Food, Drug, and
19 Cosmetic Act.

20 “(iii) APPLICABLE DRUG CLINICAL
21 TRIAL.—

22 “(I) IN GENERAL.—The term
23 ‘applicable drug clinical trial’ means a
24 controlled clinical investigation, other
25 than a phase I clinical investigation,

1 of a drug subject to section 505 of the
2 Federal Food, Drug, and Cosmetic
3 Act or to section 351 of this Act.

4 “(II) CLINICAL INVESTIGA-
5 TION.—For purposes of subclause (I),
6 the term ‘clinical investigation’ has
7 the meaning given that term in sec-
8 tion 312.3 of title 21, Code of Federal
9 Regulations (or any successor regula-
10 tion).

11 “(III) PHASE I.—For purposes
12 of subclause (I), the term ‘phase I’
13 has the meaning given that term in
14 section 312.21 of title 21, Code of
15 Federal Regulations (or any successor
16 regulation).

17 “(iv) CLINICAL TRIAL INFORMA-
18 TION.—The term ‘clinical trial information’
19 means, with respect to an applicable clin-
20 ical trial, those data elements that the re-
21 sponsible party is required to submit under
22 paragraph (2) or under paragraph (3).

23 “(v) COMPLETION DATE.—The term
24 ‘completion date’ means, with respect to an
25 applicable clinical trial, the date that the

1 final subject was examined or received an
2 intervention for the purposes of final col-
3 lection of data for the primary outcome,
4 whether the clinical trial concluded accord-
5 ing to the prespecified protocol or was ter-
6 minated.

7 “(vi) DEVICE.—The term ‘device’
8 means a device as defined in section
9 201(h) of the Federal Food, Drug, and
10 Cosmetic Act.

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

16 “(viii) ONGOING.—The term ‘ongoing’
17 means, with respect to a clinical trial of a
18 drug or a device and to a date, that—

19 “(I) 1 or more patients is en-
20 rolled in the clinical trial; and

21 “(II) the date is before the com-
22 pletion date of the clinical trial.

23 “(ix) RESPONSIBLE PARTY.—The
24 term ‘responsible party’, with respect to a
25 clinical trial of a drug or device, means—

1 “(I) the sponsor of the clinical
2 trial (as defined in section 50.3 of
3 title 21, Code of Federal Regulations
4 (or any successor regulation)); or

5 “(II) the principal investigator of
6 such clinical trial if so designated by
7 a sponsor, grantee, contractor, or
8 awardee, so long as the principal in-
9 vestigator is responsible for con-
10 ducting the trial, has access to and
11 control over the data from the clinical
12 trial, has the right to publish the re-
13 sults of the trial, and has the ability
14 to meet all of the requirements under
15 this subsection for the submission of
16 clinical trial information.

17 “(B) REQUIREMENT.—The Secretary shall
18 develop a mechanism by which the responsible
19 party for each applicable clinical trial shall sub-
20 mit the identity and contact information of such
21 responsible party to the Secretary at the time
22 of submission of clinical trial information under
23 paragraph (2).

1 “(2) EXPANSION OF CLINICAL TRIAL REGISTRY
2 DATA BANK WITH RESPECT TO CLINICAL TRIAL IN-
3 FORMATION.—

4 “(A) IN GENERAL.—

5 “(i) EXPANSION OF DATA BANK.—To
6 enhance patient enrollment and provide a
7 mechanism to track subsequent progress of
8 clinical trials, the Secretary, acting
9 through the Director of NIH, shall expand,
10 in accordance with this subsection, the
11 clinical trials registry of the data bank de-
12 scribed under subsection (i)(1) (referred to
13 in this subsection as the ‘registry data
14 bank’). The Director of NIH shall ensure
15 that the registry data bank is made pub-
16 licly available through the Internet.

17 “(ii) CONTENT.—The clinical trial in-
18 formation required to be submitted under
19 this paragraph for an applicable clinical
20 trial shall include—

21 “(I) descriptive information, in-
22 cluding—

23 “(aa) a brief title, intended
24 for the lay public;

1 “(bb) a brief summary, in-
2 tended for the lay public;
3 “(cc) the primary purpose;
4 “(dd) the study design;
5 “(ee) for an applicable drug
6 clinical trial, the study phase;
7 “(ff) study type;
8 “(gg) the primary disease or
9 condition being studied, or the
10 focus of the study;
11 “(hh) the intervention name
12 and intervention type;
13 “(ii) the study start date;
14 “(jj) the expected completion
15 date;
16 “(kk) the target number of
17 subjects; and
18 “(ll) outcomes, including pri-
19 mary and secondary outcome
20 measures;
21 “(II) recruitment information, in-
22 cluding—
23 “(aa) eligibility criteria;
24 “(bb) gender;
25 “(cc) age limits;

225

1 “(dd) whether the trial ac-
2 cepts healthy volunteers;

3 “(ee) overall recruitment
4 status;

5 “(ff) individual site status;
6 and

7 “(gg) in the case of an ap-
8 plicable drug clinical trial, if the
9 drug is not approved under sec-
10 tion 505 of the Federal Food,
11 Drug, and Cosmetic Act or li-
12 censed under section 351 of this
13 Act, specify whether or not there
14 is expanded access to the drug
15 under section 561 of the Federal
16 Food, Drug, and Cosmetic Act
17 for those who do not qualify for
18 enrollment in the clinical trial
19 and how to obtain information
20 about such access;

21 “(III) location and contact infor-
22 mation, including—

23 “(aa) the name of the spon-
24 sor;

1 “(bb) the responsible party,
2 by official title; and

3 “(cc) the facility name and
4 facility contact information (in-
5 cluding the city, State, and zip
6 code for each clinical trial loca-
7 tion, or a toll-free number
8 through which such location in-
9 formation may be accessed); and

10 “(IV) administrative data (which
11 the Secretary may make publicly
12 available as necessary), including—

13 “(aa) the unique protocol
14 identification number;

15 “(bb) other protocol identi-
16 fication numbers, if any; and

17 “(cc) the Food and Drug
18 Administration IND/IDE pro-
19 tocol number and the record
20 verification date.

21 “(iii) MODIFICATIONS.—The Sec-
22 retary may by regulation modify the re-
23 quirements for clinical trial information
24 under this paragraph, if the Secretary pro-
25 vides a rationale for why such a modifica-

1 tion improves and does not reduce such
2 clinical trial information.

3 “(B) FORMAT AND STRUCTURE.—

4 “(i) SEARCHABLE CATEGORIES.—The
5 Director of NIH shall ensure that the pub-
6 lic may, in addition to keyword searching,
7 search the entries in the registry data bank
8 by 1 or more of the following criteria:

9 “(I) The disease or condition
10 being studied in the clinical trial,
11 using Medical Subject Headers
12 (MeSH) descriptors.

13 “(II) The name of the interven-
14 tion, including any drug or device
15 being studied in the clinical trial.

16 “(III) The location of the clinical
17 trial.

18 “(IV) The age group studied in
19 the clinical trial, including pediatric
20 subpopulations.

21 “(V) The study phase of the clin-
22 ical trial.

23 “(VI) The sponsor of the clinical
24 trial, which may be the National Insti-
25 tutes of Health or another Federal

1 agency, a private industry source, or a
2 university or other organization.

3 “(VII) The recruitment status of
4 the clinical trial.

5 “(VIII) The National Clinical
6 Trial number or other study identi-
7 fication for the clinical trial.

8 “(ii) ADDITIONAL SEARCHABLE CAT-
9 EGORY.—Not later than 18 months after
10 the date of the enactment of the Food and
11 Drug Administration Amendments Act of
12 2007, the Director of NIH shall ensure
13 that the public may search the entries of
14 the registry data bank by the safety issue,
15 if any, being studied in the clinical trial as
16 a primary or secondary outcome.

17 “(iii) OTHER ELEMENTS.—The Direc-
18 tor of NIH shall also ensure that the pub-
19 lic may search the entries of the registry
20 data bank by such other elements as the
21 Director deems necessary on an ongoing
22 basis.

23 “(iv) FORMAT.—The Director of the
24 NIH shall ensure that the registry data

1 bank is easily used by the public, and that
2 entries are easily compared.

3 “(C) DATA SUBMISSION.—The responsible
4 party for an applicable clinical trial, including
5 an applicable drug clinical trial for a serious or
6 life-threatening disease or condition, that is ini-
7 tiated after, or is ongoing on the date that is
8 90 days after, the date of the enactment of the
9 Food and Drug Administration Amendments
10 Act of 2007, shall submit to the Director of
11 NIH for inclusion in the registry data bank the
12 clinical trial information described in of sub-
13 paragraph (A)(ii) not later than the later of—

14 “(i) 90 days after such date of enact-
15 ment;

16 “(ii) 21 days after the first patient is
17 enrolled in such clinical trial; or

18 “(iii) in the case of a clinical trial that
19 is not for a serious or life-threatening dis-
20 ease or condition and that is ongoing on
21 such date of enactment, 1 year after such
22 date of enactment.

23 “(D) POSTING OF DATA.—

24 “(i) APPLICABLE DRUG CLINICAL
25 TRIAL.—The Director of NIH shall ensure

1 that clinical trial information for an appli-
2 cable drug clinical trial submitted in ac-
3 cordance with this paragraph is posted in
4 the registry data bank not later than 30
5 days after such submission.

6 “(ii) APPLICABLE DEVICE CLINICAL
7 TRIAL.—The Director of NIH shall ensure
8 that clinical trial information for an appli-
9 cable device clinical trial submitted in ac-
10 cordance with this paragraph is posted
11 publicly in the registry data bank—

12 “(I) not earlier than the date of
13 clearance under section 510(k) of the
14 Federal Food, Drug, and Cosmetic
15 Act, or approval under section 515 or
16 520(m) of such Act, as applicable, for
17 a device that was not previously
18 cleared or approved, and not later
19 than 30 days after such date; or

20 “(II) for a device that was pre-
21 viously cleared or approved, not later
22 than 30 days after the clinical trial in-
23 formation under paragraph (3)(C) is
24 required to be posted by the Sec-
25 retary.

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

3 “(A) LINKING REGISTRY DATA BANK TO
4 EXISTING RESULTS.—

5 “(i) IN GENERAL.—Beginning not
6 later than 90 days after the date of the en-
7 actment of the Food and Drug Administra-
8 tion Amendments Act of 2007, for those
9 clinical trials that form the primary basis
10 of an efficacy claim or are conducted after
11 the drug involved is approved or after the
12 device involved is cleared or approved, the
13 Secretary shall ensure that the registry
14 data bank includes links to results infor-
15 mation as described in clause (ii) for such
16 clinical trial—

17 “(I) not earlier than 30 days
18 after the date of the approval of the
19 drug involved or clearance or approval
20 of the device involved; or

21 “(II) not later than 30 days after
22 the results information described in
23 clause (ii) becomes publicly available.

24 “(ii) REQUIRED INFORMATION.—

1 “(I) FDA INFORMATION.—The
2 Secretary shall ensure that the reg-
3 istry data bank includes links to the
4 following information:

5 “(aa) If an advisory com-
6 mittee considered at a meeting
7 an applicable clinical trial, any
8 posted Food and Drug Adminis-
9 tration summary document re-
10 garding such applicable clinical
11 trial.

12 “(bb) If an applicable drug
13 clinical trial was conducted under
14 section 505A or 505B of the
15 Federal Food, Drug, and Cos-
16 metic Act, a link to the posted
17 Food and Drug Administration
18 assessment of the results of such
19 trial.

20 “(cc) Food and Drug Ad-
21 ministration public health
22 advisories regarding the drug or
23 device that is the subject of the
24 applicable clinical trial, if any.

1 “(dd) For an applicable
2 drug clinical trial, the Food and
3 Drug Administration action
4 package for approval document
5 required under section 505(l)(2)
6 of the Federal Food, Drug, and
7 Cosmetic Act.

8 “(ee) For an applicable de-
9 vice clinical trial, in the case of a
10 premarket application under sec-
11 tion 515 of the Federal Food,
12 Drug, and Cosmetic Act, the de-
13 tailed summary of information
14 respecting the safety and effec-
15 tiveness of the device required
16 under section 520(h)(1) of such
17 Act, or, in the case of a report
18 under section 510(k) of such Act,
19 the section 510(k) summary of
20 the safety and effectiveness data
21 required under section 807.95(d)
22 of title 21, Code of Federal Reg-
23 ulations (or any successor regula-
24 tion).

1 “(II) NIH INFORMATION.—The
2 Secretary shall ensure that the reg-
3 istry data bank includes links to the
4 following information:

5 “(aa) Medline citations to
6 any publications focused on the
7 results of an applicable clinical
8 trial.

9 “(bb) The entry for the drug
10 that is the subject of an applica-
11 ble drug clinical trial in the Na-
12 tional Library of Medicine data-
13 base of structured product labels,
14 if available.

15 “(iii) RESULTS FOR EXISTING DATA
16 BANK ENTRIES.—The Secretary may in-
17 clude the links described in clause (ii) for
18 data bank entries for clinical trials sub-
19 mitted to the data bank prior to enactment
20 of the Food and Drug Administration
21 Amendments Act of 2007, as available.

22 “(B) INCLUSION OF RESULTS.—The Sec-
23 retary, acting through the Director of NIH,
24 shall—

1 “(i) expand the registry data bank to
2 include the results of applicable clinical
3 trials (referred to in this subsection as the
4 ‘registry and results data bank’);

5 “(ii) ensure that such results are
6 made publicly available through the Inter-
7 net;

8 “(iii) post publicly a glossary for the
9 lay public explaining technical terms re-
10 lated to the results of clinical trials; and

11 “(iv) in consultation with experts on
12 risk communication, provide information
13 with the information included under sub-
14 paragraph (C) in the registry and results
15 data bank to help ensure that such infor-
16 mation does not mislead the patients or
17 the public.

18 “(C) BASIC RESULTS.—Not later than 1
19 year after the date of the enactment of the
20 Food and Drug Administration Amendments
21 Act of 2007, the Secretary shall include in the
22 registry and results data bank the following ele-
23 ments for drugs that are approved under sec-
24 tion 505 of the Federal Food, Drug, and Cos-
25 metic Act or licensed under section 351 of this

1 Act and devices that are cleared under section
2 510(k) of the Federal Food, Drug, and Cos-
3 metic Act or approved under section 515 or
4 520(m) of such Act:

5 “(i) DEMOGRAPHIC AND BASELINE
6 CHARACTERISTICS OF PATIENT SAMPLE.—

7 A table of the demographic and baseline
8 data collected overall and for each arm of
9 the clinical trial to describe the patients
10 who participated in the clinical trial, in-
11 cluding the number of patients who
12 dropped out of the clinical trial and the
13 number of patients excluded from the anal-
14 ysis, if any.

15 “(ii) PRIMARY AND SECONDARY OUT-
16 COMES.—The primary and secondary out-
17 come measures as submitted under para-
18 graph (2)(A)(ii)(I)(II), and a table of val-
19 ues for each of the primary and secondary
20 outcome measures for each arm of the clin-
21 ical trial, including the results of scientif-
22 ically appropriate tests of the statistical
23 significance of such outcome measures.

1 “(iii) POINT OF CONTACT.—A point of
2 contact for scientific information about the
3 clinical trial results.

4 “(iv) CERTAIN AGREEMENTS.—
5 Whether there exists an agreement (other
6 than an agreement solely to comply with
7 applicable provisions of law protecting the
8 privacy of participants) between the spon-
9 sor or its agent and the principal investi-
10 gator (unless the sponsor is an employer of
11 the principal investigator) that restricts in
12 any manner the ability of the principal in-
13 vestigator, after the completion date of the
14 trial, to discuss the results of the trial at
15 a scientific meeting or any other public or
16 private forum, or to publish in a scientific
17 or academic journal information con-
18 cerning the results of the trial.

19 “(D) EXPANDED REGISTRY AND RESULTS
20 DATA BANK.—

21 “(i) EXPANSION BY RULEMAKING.—
22 To provide more complete results informa-
23 tion and to enhance patient access to and
24 understanding of the results of clinical
25 trials, not later than 3 years after the date

1 of the enactment of the Food and Drug
2 Administration Amendments Act of 2007,
3 the Secretary shall by regulation expand
4 the registry and results data bank as pro-
5 vided under this subparagraph.

6 “(ii) CLINICAL TRIALS.—

7 “(I) APPROVED PRODUCTS.—The
8 regulations under this subparagraph
9 shall require the inclusion of the re-
10 sults information described in clause
11 (iii) for—

12 “(aa) each applicable drug
13 clinical trial for a drug that is
14 approved under section 505 of
15 the Federal Food, Drug, and
16 Cosmetic Act or licensed under
17 section 351 of this Act; and

18 “(bb) each applicable device
19 clinical trial for a device that is
20 cleared under section 510(k) of
21 the Federal Food, Drug, and
22 Cosmetic Act or approved under
23 section 515 or 520(m) of such
24 Act.

1 “(II) UNAPPROVED PRODUCTS.—

2 The regulations under this subpara-
3 graph shall establish whether or not
4 the results information described in
5 clause (iii) shall be required for—

6 “(aa) an applicable drug
7 clinical trial for a drug that is
8 not approved under section 505
9 of the Federal Food, Drug, and
10 Cosmetic Act and not licensed
11 under section 351 of this Act
12 (whether approval or licensure
13 was sought or not); and

14 “(bb) an applicable device
15 clinical trial for a device that is
16 not cleared under section 510(k)
17 of the Federal Food, Drug, and
18 Cosmetic Act and not approved
19 under section 515 or section
20 520(m) of such Act (whether
21 clearance or approval was sought
22 or not).

23 “(iii) REQUIRED ELEMENTS.—The
24 regulations under this subparagraph shall
25 require, in addition to the elements de-

1 scribed in subparagraph (C), information
2 within each of the following categories:

3 “(I) A summary of the clinical
4 trial and its results that is written in
5 non-technical, understandable lan-
6 guage for patients, if the Secretary
7 determines that such types of sum-
8 mary can be included without being
9 misleading or promotional.

10 “(II) A summary of the clinical
11 trial and its results that is technical
12 in nature, if the Secretary determines
13 that such types of summary can be in-
14 cluded without being misleading or
15 promotional.

16 “(III) The full protocol or such
17 information on the protocol for the
18 trial as may be necessary to help to
19 evaluate the results of the trial.

20 “(IV) Such other categories as
21 the Secretary determines appropriate.

22 “(iv) RESULTS SUBMISSION.—The re-
23 sults information described in clause (iii)
24 shall be submitted to the Director of NIH
25 for inclusion in the registry and results

1 data bank as provided by subparagraph
2 (E), except that the Secretary shall by reg-
3 ulation determine—

4 “(I) whether the 1-year period
5 for submission of clinical trial infor-
6 mation described in subparagraph
7 (E)(i) should be increased from 1 year
8 to a period not to exceed 18 months;

9 “(II) whether the clinical trial in-
10 formation described in clause (iii)
11 should be required to be submitted for
12 an applicable clinical trial for which
13 the clinical trial information described
14 in subparagraph (C) is submitted to
15 the registry and results data bank be-
16 fore the effective date of the regula-
17 tions issued under this subparagraph;
18 and

19 “(III) in the case when the clin-
20 ical trial information described in
21 clause (iii) is required to be submitted
22 for the applicable clinical trials de-
23 scribed in clause (ii)(II), the date by
24 which such clinical trial information

1 shall be required to be submitted, tak-
2 ing into account—

3 “(aa) the certification proc-
4 ess under subparagraph (E)(iii)
5 when approval, licensure, or
6 clearance is sought; and

7 “(bb) whether there should
8 be a delay of submission when
9 approval, licensure, or clearance
10 will not be sought.

11 “(v) ADDITIONAL PROVISIONS.—The
12 regulations under this subparagraph shall
13 also establish—

14 “(I) a standard format for the
15 submission of clinical trial information
16 under this paragraph to the registry
17 and results data bank;

18 “(II) additional information on
19 clinical trials and results that is writ-
20 ten in nontechnical, understandable
21 language for patients;

22 “(III) considering the experience
23 under the pilot quality control project
24 described in paragraph (5)(C), proce-
25 dures for quality control, including

1 using representative samples, with re-
2 spect to completeness and content of
3 clinical trial information under this
4 subsection, to help ensure that data
5 elements are not false or misleading
6 and are non-promotional;

7 “(IV) the appropriate timing and
8 requirements for updates of clinical
9 trial information, and whether and, if
10 so, how such updates should be
11 tracked;

12 “(V) a statement to accompany
13 the entry for an applicable clinical
14 trial when the primary and secondary
15 outcome measures for such clinical
16 trial are submitted under paragraph
17 (4)(A) after the date specified for the
18 submission of such information in
19 paragraph (2)(C); and

20 “(VI) additions or modifications
21 to the manner of reporting of the data
22 elements established under subpara-
23 graph (C).

24 “(vi) CONSIDERATION OF WORLD
25 HEALTH ORGANIZATION DATA SET.—The

1 Secretary shall consider the status of the
2 consensus data elements set for reporting
3 clinical trial results of the World Health
4 Organization when issuing the regulations
5 under this subparagraph.

6 “(vii) PUBLIC MEETING.—The Sec-
7 retary shall hold a public meeting no later
8 than 18 months after the date of the en-
9 actment of the Food and Drug Administra-
10 tion Amendments Act of 2007 to provide
11 an opportunity for input from interested
12 parties with regard to the regulations to be
13 issued under this subparagraph.

14 “(E) SUBMISSION OF RESULTS INFORMA-
15 TION.—

16 “(i) IN GENERAL.—Except as pro-
17 vided in clause (iii), (iv), (v), and (vi) the
18 responsible party for an applicable clinical
19 trial that is described in clause (ii) shall
20 submit to the Director of NIH for inclu-
21 sion in the registry and results data bank
22 the clinical trial information described in
23 subparagraph (C) not later than 1 year, or
24 such other period as may be provided by

1 regulation under subparagraph (D), after
2 the earlier of—

3 “(I) the estimated completion
4 date of the trial as described in para-
5 graph (2)(A)(ii)(I)(jj)); or

6 “(II) the actual date of comple-
7 tion.

8 “(ii) CLINICAL TRIALS DESCRIBED.—
9 An applicable clinical trial described in this
10 clause is an applicable clinical trial subject
11 to—

12 “(I) paragraph (2)(C); and

13 “(II)(aa) subparagraph (C); or

14 “(bb) the regulations issued
15 under subparagraph (D).

16 “(iii) DELAYED SUBMISSION OF RE-
17 SULTS WITH CERTIFICATION.—If the re-
18 sponsible party for an applicable clinical
19 trial submits a certification that clause (iv)
20 or (v) applies to such clinical trial, the re-
21 sponsible party shall submit to the Direc-
22 tor of NIH for inclusion in the registry
23 and results data bank the clinical trial in-
24 formation described in subparagraphs (C)

1 and (D) as required under the applicable
2 clause.

3 “(iv) SEEKING INITIAL APPROVAL OF
4 A DRUG OR DEVICE.—With respect to an
5 applicable clinical trial that is completed
6 before the drug is initially approved under
7 section 505 of the Federal Food, Drug,
8 and Cosmetic Act or initially licensed
9 under section 351 of this Act, or the device
10 is initially cleared under section 510(k) or
11 initially approved under section 515 or
12 520(m) of the Federal Food, Drug, and
13 Cosmetic Act, the responsible party shall
14 submit to the Director of NIH for inclu-
15 sion in the registry and results data bank
16 the clinical trial information described in
17 subparagraphs (C) and (D) not later than
18 30 days after the drug or device is ap-
19 proved under such section 505, licensed
20 under such section 351, cleared under such
21 section 510(k), or approved under such
22 section 515 or 520(m), as applicable.

23 “(v) SEEKING APPROVAL OF A NEW
24 USE FOR THE DRUG OR DEVICE.—

1 “(I) IN GENERAL.—With respect
2 to an applicable clinical trial where
3 the manufacturer of the drug or de-
4 vice is the sponsor of an applicable
5 clinical trial, and such manufacturer
6 has filed, or will file within 1 year, an
7 application seeking approval under
8 section 505 of the Federal Food,
9 Drug, and Cosmetic Act, licensing
10 under section 351 of this Act, or
11 clearance under section 510(k), or ap-
12 proval under section 515 or 520(m),
13 of the Federal Food, Drug, and Cos-
14 metic Act for the use studied in such
15 clinical trial (which use is not included
16 in the labeling of the approved drug
17 or device), then the responsible party
18 shall submit to the Director of NIH
19 for inclusion in the registry and re-
20 sults data bank the clinical trial infor-
21 mation described in subparagraphs
22 (C) and (D) on the earlier of the date
23 that is 30 days after the date—
24 “(aa) the new use of the
25 drug or device is approved under

248

1 such section 505, licensed under
2 such section 351, cleared under
3 such section 510(k), or approved
4 under such section 515 or
5 520(m);

6 “(bb) the Secretary issues a
7 letter, such as a complete re-
8 sponse letter, not approving the
9 submission or not clearing the
10 submission, a not approvable let-
11 ter, or a not substantially equiva-
12 lent letter for the new use of the
13 drug or device under such section
14 505, 351, 510(k), 515, or
15 520(m); or

16 “(cc) except as provided in
17 subclause (III), the application or
18 premarket notification under
19 such section 505, 351, 510(k),
20 515, or 520(m) is withdrawn
21 without resubmission for no less
22 than 210 days.

23 “(II) REQUIREMENT THAT EACH
24 CLINICAL TRIAL IN APPLICATION BE
25 TREATED THE SAME.—If a manufac-

1 turer makes a certification under
2 clause (iii) that this clause applies
3 with respect to a clinical trial, the
4 manufacturer shall make such a cer-
5 tification with respect to each applica-
6 ble clinical trial that is required to be
7 submitted in an application or report
8 for licensure, approval, or clearance
9 (under section 351 of this Act or sec-
10 tion 505, 510(k), 515, or 520(m) of
11 the Federal Food, Drug, and Cos-
12 metic Act, as applicable) of the use
13 studied in the clinical trial.

14 “(III) TWO-YEAR LIMITATION.—
15 The responsible party shall submit to
16 the Director of NIH for inclusion in
17 the registry and results data bank the
18 clinical trial information subject to
19 subclause (I) on the date that is 2
20 years after the date a certification
21 under clause (iii) was made to the Di-
22 rector of NIH, if an action referred to
23 in item (aa), (bb), or (cc) of subclause
24 (I) has not occurred by such date.

1 “(vi) EXTENSIONS.—The Director of
2 NIH may provide an extension of the
3 deadline for submission of clinical trial in-
4 formation under clause (i) if the respon-
5 sible party for the trial submits to the Di-
6 rector a written request that demonstrates
7 good cause for the extension and provides
8 an estimate of the date on which the infor-
9 mation will be submitted. The Director of
10 NIH may grant more than one such exten-
11 sion for a clinical trial.

12 “(F) NOTICE TO DIRECTOR OF NIH.—The
13 Commissioner of Food and Drugs shall notify
14 the Director of NIH when there is an action de-
15 scribed in subparagraph (E)(iv) or item (aa),
16 (bb), or (cc) of subparagraph (E)(v)(I) with re-
17 spect to an application or a report that includes
18 a certification required under paragraph (5)(B)
19 of such action not later than 30 days after such
20 action.

21 “(G) POSTING OF DATA.—The Director of
22 NIH shall ensure that the clinical trial informa-
23 tion described in subparagraphs (C) and (D)
24 for an applicable clinical trial submitted in ac-
25 cordance with this paragraph is posted publicly

1 in the registry and results database not later
2 than 30 days after such submission.

3 “(H) WAIVERS REGARDING CERTAIN CLIN-
4 ICAL TRIAL RESULTS.—The Secretary may
5 waive any applicable requirements of this para-
6 graph for an applicable clinical trial, upon a
7 written request from the responsible party, if
8 the Secretary determines that extraordinary cir-
9 cumstances justify the waiver and that pro-
10 viding the waiver is consistent with the protec-
11 tion of public health, or in the interest of na-
12 tional security. Not later than 30 days after
13 any part of a waiver is granted, the Secretary
14 shall notify, in writing, the appropriate commit-
15 tees of Congress of the waiver and provide an
16 explanation for why the waiver was granted.

17 “(I) ADVERSE EVENTS.—

18 “(i) REGULATIONS.—Not later than
19 18 months after the date of the enactment
20 of the Food and Drug Administration
21 Amendments Act of 2007, the Secretary
22 shall by regulation determine the best
23 method for including in the registry and
24 results data bank appropriate results infor-
25 mation on serious adverse and frequent ad-

1 verse events for drugs described in sub-
2 paragraph (C) in a manner and form that
3 is useful and not misleading to patients,
4 physicians, and scientists.

5 “(ii) DEFAULT.—If the Secretary fails
6 to issue the regulation required by clause
7 (i) by the date that is 24 months after the
8 date of the enactment of the Food and
9 Drug Administration Amendments Act of
10 2007, clause (iii) shall take effect.

11 “(iii) ADDITIONAL ELEMENTS.—Upon
12 the application of clause (ii), the Secretary
13 shall include in the registry and results
14 data bank for drugs described in subpara-
15 graph (C), in addition to the clinical trial
16 information described in subparagraph (C),
17 the following elements:

18 “(I) SERIOUS ADVERSE
19 EVENTS.—A table of anticipated and
20 unanticipated serious adverse events
21 grouped by organ system, with num-
22 ber and frequency of such event in
23 each arm of the clinical trial.

24 “(II) FREQUENT ADVERSE
25 EVENTS.—A table of anticipated and

1 unanticipated adverse events that are
2 not included in the table described in
3 subclause (I) that exceed a frequency
4 of 5 percent within any arm of the
5 clinical trial, grouped by organ sys-
6 tem, with number and frequency of
7 such event in each arm of the clinical
8 trial.

9 “(iv) POSTING OF OTHER INFORMA-
10 TION.—In carrying out clause (iii), the
11 Secretary shall, in consultation with ex-
12 perts in risk communication, post with the
13 tables information to enhance patient un-
14 derstanding and to ensure such tables do
15 not mislead patients or the lay public.

16 “(v) RELATION TO SUBPARAGRAPH
17 (C).—Clinical trial information included in
18 the registry and results data bank pursu-
19 ant to this subparagraph is deemed to be
20 clinical trial information included in such
21 data bank pursuant to subparagraph (C).

22 “(4) ADDITIONAL SUBMISSIONS OF CLINICAL
23 TRIAL INFORMATION.—

24 “(A) VOLUNTARY SUBMISSIONS.—A re-
25 sponsible party for a clinical trial that is not an

1 applicable clinical trial, or that is an applicable
2 clinical trial that is not subject to paragraph
3 (2)(C), may submit complete clinical trial infor-
4 mation described in paragraph (2) or paragraph
5 (3) provided the responsible party submits clin-
6 ical trial information for each applicable clinical
7 trial that is required to be submitted under sec-
8 tion 351 or under section 505, 510(k), 515, or
9 520(m) of the Federal Food, Drug, and Cos-
10 metic Act in an application or report for licen-
11 sure, approval, or clearance of the drug or de-
12 vice for the use studied in the clinical trial.

13 “(B) REQUIRED SUBMISSIONS.—

14 “(i) IN GENERAL.—Notwithstanding
15 paragraphs (2) and (3) and subparagraph
16 (A), in any case in which the Secretary de-
17 termines for a specific clinical trial de-
18 scribed in clause (ii) that posting in the
19 registry and results data bank of clinical
20 trial information for such clinical trial is
21 necessary to protect the public health—

22 “(I) the Secretary may require
23 by notification that such information
24 be submitted to the Secretary in ac-
25 cordance with paragraphs (2) and (3)

1 except with regard to timing of sub-
2 mission;

3 “(II) unless the responsible party
4 submits a certification under para-
5 graph (3)(E)(iii), such information
6 shall be submitted not later than 30
7 days after the date specified by the
8 Secretary in the notification; and

9 “(III) failure to comply with the
10 requirements under subclauses (I) and
11 (II) shall be treated as a violation of
12 the corresponding requirement of such
13 paragraphs.

14 “(ii) CLINICAL TRIALS DESCRIBED.—
15 A clinical trial described in this clause is—

16 “(I) an applicable clinical trial
17 for a drug that is approved under sec-
18 tion 505 of the Federal Food, Drug,
19 and Cosmetic Act or licensed under
20 section 351 of this Act or for a device
21 that is cleared under section 510(k) of
22 the Federal Food, Drug, and Cos-
23 metic Act or approved under section
24 515 or section 520(m) of such Act,
25 whose completion date is on or after

1 the date 10 years before the date of
2 the enactment of the Food and Drug
3 Administration Amendments Act of
4 2007; or

5 “(II) an applicable clinical trial
6 that is described by both by para-
7 graph (2)(C) and paragraph
8 (3)(D)(ii)(II)).

9 “(C) UPDATES TO CLINICAL TRIAL DATA
10 BANK.—

11 “(i) SUBMISSION OF UPDATES.—The
12 responsible party for an applicable clinical
13 trial shall submit to the Director of NIH
14 for inclusion in the registry and results
15 data bank updates to reflect changes to the
16 clinical trial information submitted under
17 paragraph (2). Such updates—

18 “(I) shall be provided not less
19 than once every 12 months, unless
20 there were no changes to the clinical
21 trial information during the preceding
22 12-month period;

23 “(II) shall include identification
24 of the dates of any such changes;

1 “(III) not later than 30 days
2 after the recruitment status of such
3 clinical trial changes, shall include an
4 update of the recruitment status; and

5 “(IV) not later than 30 days
6 after the completion date of the clin-
7 ical trial, shall include notification to
8 the Director that such clinical trial is
9 complete.

10 “(ii) PUBLIC AVAILABILITY OF UP-
11 DATES.—The Director of NIH shall make
12 updates submitted under clause (i) publicly
13 available in the registry data bank. Except
14 with regard to overall recruitment status,
15 individual site status, location, and contact
16 information, the Director of NIH shall en-
17 sure that updates to elements required
18 under subclauses (I) to (V) of paragraph
19 (2)(A)(ii) do not result in the removal of
20 any information from the original submis-
21 sions or any preceding updates, and infor-
22 mation in such databases is presented in a
23 manner that enables users to readily access
24 each original element submission and to
25 track the changes made by the updates.

1 The Director of NIH shall provide a link
2 from the table of primary and secondary
3 outcomes required under paragraph
4 (3)(C)(ii) to the tracked history required
5 under this clause of the primary and sec-
6 ondary outcome measures submitted under
7 paragraph (2)(A)(ii)(I)(II).

8 “(5) COORDINATION AND COMPLIANCE.—

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

11 “(i) GRANTS FROM CERTAIN FEDERAL
12 AGENCIES.—If an applicable clinical trial is
13 funded in whole or in part by a grant from
14 any agency of the Department of Health
15 and Human Services, including the Food
16 and Drug Administration, the National In-
17 stitutes of Health, or the Agency for
18 Healthcare Research and Quality, any
19 grant or progress report forms required
20 under such grant shall include a certifi-
21 cation that the responsible party has made
22 all required submissions to the Director of
23 NIH under paragraph (2) and (3).

24 “(ii) VERIFICATION BY FEDERAL
25 AGENCIES.—The heads of the agencies re-

1 ferred to in clause (i), as applicable, shall
2 verify that the clinical trial information for
3 each applicable clinical trial for which a
4 grantee is the responsible party has been
5 submitted under paragraph (2) and (3) be-
6 fore releasing any remaining funding for a
7 grant or funding for a future grant to such
8 grantee.

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

19 “(iv) CONSULTATION WITH OTHER
20 FEDERAL AGENCIES.—The Secretary
21 shall—

22 “(I) consult with other agencies
23 that conduct research involving
24 human subjects in accordance with
25 any section of part 46 of title 45,

1 Code of Federal Regulations (or any
2 successor regulations), to determine if
3 any such research is an applicable
4 clinical trial; and

5 “(II) develop with such agencies
6 procedures comparable to those de-
7 scribed in clauses (i), (ii), and (iii) to
8 ensure that clinical trial information
9 for such applicable clinical trial is
10 submitted under paragraph (2) and
11 (3).

12 “(B) CERTIFICATION TO ACCOMPANY
13 DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUB-
14 MISSIONS.—At the time of submission of an ap-
15 plication under section 505 of the Federal
16 Food, Drug, and Cosmetic Act, section 515 of
17 such Act, section 520(m) of such Act, or section
18 351 of this Act, or submission of a report under
19 section 510(k) of such Act, such application or
20 submission shall be accompanied by a certifi-
21 cation that all applicable requirements of this
22 subsection have been met. Where available, such
23 certification shall include the appropriate Na-
24 tional Clinical Trial control numbers.

25 “(C) QUALITY CONTROL.—

1 “(i) PILOT QUALITY CONTROL
2 PROJECT.—Until the effective date of the
3 regulations issued under paragraph (3)(D),
4 the Secretary, acting through the Director
5 of NIH and the Commissioner of Food and
6 Drugs, shall conduct a pilot project to de-
7 termine the optimal method of verification
8 to help to ensure that the clinical trial in-
9 formation submitted under paragraph
10 (3)(C) is non-promotional and is not false
11 or misleading in any particular under sub-
12 paragraph (D). The Secretary shall use the
13 publicly available information described in
14 paragraph (3)(A) and any other informa-
15 tion available to the Secretary about appli-
16 cable clinical trials to verify the accuracy
17 of the clinical trial information submitted
18 under paragraph (3)(C).

19 “(ii) NOTICE OF COMPLIANCE.—If the
20 Secretary determines that any clinical trial
21 information was not submitted as required
22 under this subsection, or was submitted
23 but is false or misleading in any particular,
24 the Secretary shall notify the responsible
25 party and give such party an opportunity

1 to remedy such noncompliance by submit-
2 ting the required revised clinical trial infor-
3 mation not later than 30 days after such
4 notification.

5 “(D) TRUTHFUL CLINICAL TRIAL INFOR-
6 MATION.—

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

11 “(ii) EFFECT.—Clause (i) shall not
12 have the effect of—

13 “(I) requiring clinical trial infor-
14 mation with respect to an applicable
15 clinical trial to include information
16 from any source other than such clin-
17 ical trial involved; or

18 “(II) requiring clinical trial infor-
19 mation described in paragraph (3)(D)
20 to be submitted for purposes of para-
21 graph (3)(C).

22 “(E) PUBLIC NOTICES.—

23 “(i) NOTICE OF VIOLATIONS.—If the
24 responsible party for an applicable clinical
25 trial fails to submit clinical trial informa-

1 tion for such clinical trial as required
2 under paragraphs (2) or (3), the Director
3 of NIH shall include in the registry and re-
4 sults data bank entry for such clinical trial
5 a notice—

6 “(I) that the responsible party is
7 not in compliance with this Act by—

8 “(aa) failing to submit re-
9 quired clinical trial information;
10 or

11 “(bb) submitting false or
12 misleading clinical trial informa-
13 tion;

14 “(II) of the penalties imposed for
15 the violation, if any; and

16 “(III) whether the responsible
17 party has corrected the clinical trial
18 information in the registry and results
19 data bank.

20 “(ii) NOTICE OF FAILURE TO SUBMIT
21 PRIMARY AND SECONDARY OUTCOMES.—If
22 the responsible party for an applicable clin-
23 ical trial fails to submit the primary and
24 secondary outcomes as required under sec-
25 tion 2(A)(ii)(I)(ll), the Director of NIH

1 shall include in the registry and results
2 data bank entry for such clinical trial a no-
3 tice that the responsible party is not in
4 compliance by failing to register the pri-
5 mary and secondary outcomes in accord-
6 ance with this act, and that the primary
7 and secondary outcomes were not publicly
8 disclosed in the database before conducting
9 the clinical trial.

10 “(iii) FAILURE TO SUBMIT STATE-
11 MENT.—The notice under clause (i) for a
12 violation described in clause (i)(I)(aa) shall
13 include the following statement: ‘The entry
14 for this clinical trial was not complete at
15 the time of submission, as required by law.
16 This may or may not have any bearing on
17 the accuracy of the information in the
18 entry.’.

19 “(iv) SUBMISSION OF FALSE INFOR-
20 MATION STATEMENT.—The notice under
21 clause (i) for a violation described in clause
22 (i)(I)(bb) shall include the following state-
23 ment: ‘The entry for this clinical trial was
24 found to be false or misleading and there-
25 fore not in compliance with the law.’.

1 “(v) NON-SUBMISSION OF STATE-
2 MENT.—The notice under clause (ii) for a
3 violation described in clause (ii) shall in-
4 clude the following statement: ‘The entry
5 for this clinical trial did not contain infor-
6 mation on the primary and secondary out-
7 comes at the time of submission, as re-
8 quired by law. This may or may not have
9 any bearing on the accuracy of the infor-
10 mation in the entry.’

11 “(vi) COMPLIANCE SEARCHES.—The
12 Director of NIH shall provide that the
13 public may easily search the registry and
14 results data bank for entries that include
15 notices required under this subparagraph.

16 “(6) LIMITATION ON DISCLOSURE OF CLINICAL
17 TRIAL INFORMATION.—

18 “(A) IN GENERAL.—Nothing in this sub-
19 section (or under section 552 of title 5, United
20 States Code) shall require the Secretary to pub-
21 licly disclose, by any means other than the reg-
22 istry and results data bank, information de-
23 scribed in subparagraph (B).

24 “(B) INFORMATION DESCRIBED.—Infor-
25 mation described in this subparagraph is—

1 “(i) information submitted to the Di-
2 rector of NIH under this subsection, or in-
3 formation of the same general nature as
4 (or integrally associated with) the informa-
5 tion so submitted; and

6 “(ii) information not otherwise pub-
7 licly available, including because it is pro-
8 tected from disclosure under section 552 of
9 title 5, United States Code.

10 “(7) AUTHORIZATION OF APPROPRIATIONS.—

11 There are authorized to be appropriated to carry out
12 this subsection \$10,000,000 for each fiscal year.”.

13 (b) CONFORMING AMENDMENTS.—

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

17 “(jj)(1) The failure to submit the certification re-
18 quired by section 402(j)(5)(B) of the Public Health Serv-
19 ice Act, or knowingly submitting a false certification under
20 such section.

21 “(2) The failure to submit clinical trial information
22 required under subsection (j) of section 402 of the Public
23 Health Service Act.

24 “(3) The submission of clinical trial information
25 under subsection (j) of section 402 of the Public Health

1 Service Act that is false or misleading in any particular
2 under paragraph (5)(D) of such subsection (j).”.

3 (2) CIVIL MONEY PENALTIES.—Subsection (f)
4 of section 303 of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 333), as redesignated by sec-
6 tion 226, is amended—

7 (A) by redesignating paragraphs (3), (4),
8 and (5) as paragraphs (5), (6), and (7), respec-
9 tively;

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

12 “(3)(A) Any person who violates section 301(jj) shall
13 be subject to a civil monetary penalty of not more than
14 \$10,000 for all violations adjudicated in a single pro-
15 ceeding.

16 “(B) If a violation of section 301(jj) is not corrected
17 within the 30-day period following notification under sec-
18 tion 402(j)(5)(C)(ii), the person shall, in addition to any
19 penalty under subparagraph (A), be subject to a civil mon-
20 etary penalty of not more than \$10,000 for each day of
21 the violation after such period until the violation is cor-
22 rected.”;

23 (C) in paragraph (2)(C), by striking
24 “paragraph (3)(A)” and inserting “paragraph
25 (5)(A)”;

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

5 (E) in paragraph (6), as so redesignated,
6 by striking “paragraph (3)(A)” and inserting
7 “paragraph (5)(A)”;

8 (F) in paragraph (7), as so redesignated,
9 by striking “paragraph (4)” each place it ap-
10 pears and inserting “paragraph (6)”.

11 (3) NEW DRUGS AND DEVICES.—

12 (A) INVESTIGATIONAL NEW DRUGS.—Sec-
13 tion 505(i) of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 355(i)) is amended in
15 paragraph (4), by adding at the end the fol-
16 lowing: “The Secretary shall update such regu-
17 lations to require inclusion in the informed con-
18 sent documents and process a statement that
19 clinical trial information for such clinical inves-
20 tigation has been or will be submitted for inclu-
21 sion in the registry data bank pursuant to sub-
22 section (j) of section 402 of the Public Health
23 Service Act.”.

24 (B) NEW DRUG APPLICATIONS.—Section
25 505(b) of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 355(b)) is amended by
2 adding at the end the following:

3 “(6) An application submitted under this sub-
4 section shall be accompanied by the certification re-
5 quired under section 402(j)(5)(B) of the Public
6 Health Service Act. Such certification shall not be
7 considered an element of such application.”.

8 (C) DEVICE REPORTS UNDER SECTION
9 510(k).—Section 510(k) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 360(k)) is
11 amended by adding at the end the following:

12 “A notification submitted under this subsection that con-
13 tains clinical trial data for an applicable device clinical
14 trial (as defined in section 402(j)(1) of the Public Health
15 Service Act) shall be accompanied by the certification re-
16 quired under section 402(j)(5)(B) of such Act. Such cer-
17 tification shall not be considered an element of such notifi-
18 cation.”.

19 (D) DEVICE PREMARKET APPROVAL APPLI-
20 CATION.—Section 515(c)(1) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C.
22 360e(c)(1)) is amended—

23 (i) in subparagraph (F), by striking “;
24 and” and inserting a semicolon;

1 (ii) by redesignating subparagraph
2 (G) as subparagraph (H); and

3 (iii) by inserting after subparagraph
4 (F) the following:

5 “(G) the certification required under sec-
6 tion 402(j)(5)(B) of the Public Health Service
7 Act (which shall not be considered an element
8 of such application); and”.

9 (E) HUMANITARIAN DEVICE EXEMP-
10 TION.—Section 520(m)(2) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is
12 amended in the first sentence in the matter fol-
13 lowing subparagraph (C), by inserting at the
14 end before the period “and such application
15 shall include the certification required under
16 section 402(j)(5)(B) of the Public Health Serv-
17 ice Act (which shall not be considered an ele-
18 ment of such application)”.

19 (c) SURVEILLANCES.—Not later than 12 months
20 after the date of the enactment of this Act, the Secretary
21 of Health and Human Services shall issue guidance on
22 how the requirements of section 402(j) of the Public
23 Health Service Act, as added by this section, apply to a
24 pediatric postmarket surveillance described in paragraph

1 (1)(A)(ii)(II) of such section 402(j) that is not a clinical
2 trial.

3 (d) PREEMPTION.—

4 (1) IN GENERAL.—Upon the expansion of the
5 registry and results data bank under section
6 402(j)(3)(D) of the Public Health Service Act, as
7 added by this section, no State or political subdivi-
8 sion of a State may establish or continue in effect
9 any requirement for the registration of clinical trials
10 or for the inclusion of information relating to the re-
11 sults of clinical trials in a database.

12 (2) RULE OF CONSTRUCTION.—The fact of sub-
13 mission of clinical trial information, if submitted in
14 compliance with subsection (j) of section 402 of the
15 Public Health Service Act (as amended by this sec-
16 tion), that relates to a use of a drug or device not
17 included in the official labeling of the approved drug
18 or device shall not be construed by the Secretary of
19 Health and Human Services or in any administra-
20 tive or judicial proceeding, as evidence of a new in-
21 tended use of the drug or device that is different
22 from the intended use of the drug or device set forth
23 in the official labeling of the drug or device. The
24 availability of clinical trial information through the
25 registry and results data bank under such subsection

1 (j), if submitted in compliance with such subsection,
2 shall not be considered as labeling, adulteration, or
3 misbranding of the drug or device under the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
5 seq.).

6 **TITLE IX—ENHANCED AUTHORI-**
7 **TIES REGARDING**
8 **POSTMARKET SAFETY OF**
9 **DRUGS**

10 **Subtitle A—Postmarket Studies**
11 **and Surveillance**

12 **SEC. 901. POSTMARKET STUDIES AND CLINICAL TRIALS RE-**
13 **GARDING HUMAN DRUGS; RISK EVALUATION**
14 **AND MITIGATION STRATEGIES.**

15 (a) IN GENERAL.—Section 505 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by
17 adding at the end the following subsections:

18 “(o) POSTMARKET STUDIES AND CLINICAL TRIALS;
19 LABELING.—

20 “(1) IN GENERAL.—A responsible person may
21 not introduce or deliver for introduction into inter-
22 state commerce the new drug involved if the person
23 is in violation of a requirement established under
24 paragraph (3) or (4) with respect to the drug.

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

3 “(A) RESPONSIBLE PERSON.—The term
4 ‘responsible person’ means a person who—

5 “(i) has submitted to the Secretary a
6 covered application that is pending; or

7 “(ii) is the holder of an approved cov-
8 ered application.

9 “(B) COVERED APPLICATION.—The term
10 ‘covered application’ means—

11 “(i) an application under subsection
12 (b) for a drug that is subject to section
13 503(b); and

14 “(ii) an application under section 351
15 of the Public Health Service Act.

16 “(C) NEW SAFETY INFORMATION; SERIOUS
17 RISK.—The terms ‘new safety information’, ‘se-
18 rious risk’, and ‘signal of a serious risk’ have
19 the meanings given such terms in section 505–
20 1(b).

21 “(3) STUDIES AND CLINICAL TRIALS.—

22 “(A) IN GENERAL.—For any or all of the
23 purposes specified in subparagraph (B), the
24 Secretary may, subject to subparagraph (D),
25 require a responsible person for a drug to con-

1 duct a postapproval study or studies of the
2 drug, or a postapproval clinical trial or trials of
3 the drug, on the basis of scientific data deemed
4 appropriate by the Secretary, including infor-
5 mation regarding chemically-related or pharma-
6 cologically-related drugs.

7 “(B) PURPOSES OF STUDY OR CLINICAL
8 TRIAL.—The purposes referred to in this sub-
9 paragraph with respect to a postapproval study
10 or postapproval clinical trial are the following:

11 “(i) To assess a known serious risk
12 related to the use of the drug involved.

13 “(ii) To assess signals of serious risk
14 related to the use of the drug.

15 “(iii) To identify an unexpected seri-
16 ous risk when available data indicates the
17 potential for a serious risk.

18 “(C) ESTABLISHMENT OF REQUIREMENT
19 AFTER APPROVAL OF COVERED APPLICATION.—
20 The Secretary may require a postapproval study
21 or studies or postapproval clinical trial or trials
22 for a drug for which an approved covered appli-
23 cation is in effect as of the date on which the
24 Secretary seeks to establish such requirement

1 only if the Secretary becomes aware of new
2 safety information.

3 “(D) DETERMINATION BY SECRETARY.—

4 “(i) POSTAPPROVAL STUDIES.—The
5 Secretary may not require the responsible
6 person to conduct a study under this para-
7 graph, unless the Secretary makes a deter-
8 mination that the reports under subsection
9 (k)(1) and the active postmarket risk iden-
10 tification and analysis system as available
11 under subsection (k)(3) will not be suffi-
12 cient to meet the purposes set forth in sub-
13 paragraph (B).

14 “(ii) POSTAPPROVAL CLINICAL
15 TRIALS.—The Secretary may not require
16 the responsible person to conduct a clinical
17 trial under this paragraph, unless the Sec-
18 retary makes a determination that a post-
19 approval study or studies will not be suffi-
20 cient to meet the purposes set forth in sub-
21 paragraph (B).

22 “(E) NOTIFICATION; TIMETABLES; PERI-
23 ODIC REPORTS.—

24 “(i) NOTIFICATION.—The Secretary
25 shall notify the responsible person regard-

1 ing a requirement under this paragraph to
2 conduct a postapproval study or clinical
3 trial by the target dates for communication
4 of feedback from the review team to the re-
5 sponsible person regarding proposed label-
6 ing and postmarketing study commitments
7 as set forth in the letters described in sec-
8 tion 101(c) of the Food and Drug Admin-
9 istration Amendments Act of 2007.

10 “(ii) TIMETABLE; PERIODIC RE-
11 PORTS.—For each study or clinical trial re-
12 quired to be conducted under this para-
13 graph, the Secretary shall require that the
14 responsible person submit a timetable for
15 completion of the study or clinical trial.
16 With respect to each study required to be
17 conducted under this paragraph or other-
18 wise undertaken by the responsible person
19 to investigate a safety issue, the Secretary
20 shall require the responsible person to peri-
21 odically report to the Secretary on the sta-
22 tus of such study including whether any
23 difficulties in completing the study have
24 been encountered. With respect to each
25 clinical trial required to be conducted

1 under this paragraph or otherwise under-
2 taken by the responsible person to inves-
3 tigate a safety issue, the Secretary shall
4 require the responsible person to periodi-
5 cally report to the Secretary on the status
6 of such clinical trial including whether en-
7 rollment has begun, the number of partici-
8 pants enrolled, the expected completion
9 date, whether any difficulties completing
10 the clinical trial have been encountered,
11 and registration information with respect
12 to the requirements under section 402(j) of
13 the Public Health Service Act. If the re-
14 sponsible person fails to comply with such
15 timetable or violates any other requirement
16 of this subparagraph, the responsible per-
17 son shall be considered in violation of this
18 subsection, unless the responsible person
19 demonstrates good cause for such non-
20 compliance or such other violation. The
21 Secretary shall determine what constitutes
22 good cause under the preceding sentence.

23 “(F) DISPUTE RESOLUTION.—The respon-
24 sible person may appeal a requirement to con-
25 duct a study or clinical trial under this para-

1 graph using dispute resolution procedures es-
2 tablished by the Secretary in regulation and
3 guidance.

4 “(4) SAFETY LABELING CHANGES REQUESTED
5 BY SECRETARY.—

6 “(A) NEW SAFETY INFORMATION.—If the
7 Secretary becomes aware of new safety informa-
8 tion that the Secretary believes should be in-
9 cluded in the labeling of the drug, the Secretary
10 shall promptly notify the responsible person or,
11 if the same drug approved under section 505(b)
12 is not currently marketed, the holder of an ap-
13 proved application under 505(j).

14 “(B) RESPONSE TO NOTIFICATION.—Fol-
15 lowing notification pursuant to subparagraph
16 (A), the responsible person or the holder of the
17 approved application under section 505(j) shall
18 within 30 days—

19 “(i) submit a supplement proposing
20 changes to the approved labeling to reflect
21 the new safety information, including
22 changes to boxed warnings, contraindica-
23 tions, warnings, precautions, or adverse re-
24 actions; or

1 “(ii) notify the Secretary that the re-
2 sponsible person or the holder of the ap-
3 proved application under section 505(j)
4 does not believe a labeling change is war-
5 ranted and submit a statement detailing
6 the reasons why such a change is not war-
7 ranted.

8 “(C) REVIEW.—Upon receipt of such sup-
9 plement, the Secretary shall promptly review
10 and act upon such supplement. If the Secretary
11 disagrees with the proposed changes in the sup-
12 plement or with the statement setting forth the
13 reasons why no labeling change is necessary,
14 the Secretary shall initiate discussions to reach
15 agreement on whether the labeling for the drug
16 should be modified to reflect the new safety in-
17 formation, and if so, the contents of such label-
18 ing changes.

19 “(D) DISCUSSIONS.—Such discussions
20 shall not extend for more than 30 days after
21 the response to the notification under subpara-
22 graph (B), unless the Secretary determines an
23 extension of such discussion period is war-
24 ranted.

1 “(E) ORDER.—Within 15 days of the con-
2 clusion of the discussions under subparagraph
3 (D), the Secretary may issue an order directing
4 the responsible person or the holder of the ap-
5 proved application under section 505(j) to make
6 such a labeling change as the Secretary deems
7 appropriate to address the new safety informa-
8 tion. Within 15 days of such an order, the re-
9 sponsible person or the holder of the approved
10 application under section 505(j) shall submit a
11 supplement containing the labeling change.

12 “(F) DISPUTE RESOLUTION.—Within 5
13 days of receiving an order under subparagraph
14 (E), the responsible person or the holder of the
15 approved application under section 505(j) may
16 appeal using dispute resolution procedures es-
17 tablished by the Secretary in regulation and
18 guidance.

19 “(G) VIOLATION.—If the responsible per-
20 son or the holder of the approved application
21 under section 505(j) has not submitted a sup-
22 plement within 15 days of the date of such
23 order under subparagraph (E), and there is no
24 appeal or dispute resolution proceeding pend-
25 ing, the responsible person or holder shall be

1 considered to be in violation of this subsection.
2 If at the conclusion of any dispute resolution
3 procedures the Secretary determines that a sup-
4 plement must be submitted and such a supple-
5 ment is not submitted within 15 days of the
6 date of that determination, the responsible per-
7 son or holder shall be in violation of this sub-
8 section.

9 “(H) PUBLIC HEALTH THREAT.—Notwith-
10 standing subparagraphs (A) through (F), if the
11 Secretary concludes that such a labeling change
12 is necessary to protect the public health, the
13 Secretary may accelerate the timelines in such
14 subparagraphs.

15 “(I) RULE OF CONSTRUCTION.—This para-
16 graph shall not be construed to affect the re-
17 sponsibility of the responsible person or the
18 holder of the approved application under section
19 505(j) to maintain its label in accordance with
20 existing requirements, including subpart B of
21 part 201 and sections 314.70 and 601.12 of
22 title 21, Code of Federal Regulations (or any
23 successor regulations).

24 “(5) NON-DELEGATION.—Determinations by
25 the Secretary under this subsection for a drug shall

1 be made by individuals at or above the level of indi-
2 viduals empowered to approve a drug (such as divi-
3 sion directors within the Center for Drug Evaluation
4 and Research).

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

7 “(1) IN GENERAL.—A person may not intro-
8 duce or deliver for introduction into interstate com-
9 merce a new drug if—

10 “(A)(i) the application for such drug is ap-
11 proved under subsection (b) or (j) and is sub-
12 ject to section 503(b); or

13 “(ii) the application for such drug is ap-
14 proved under section 351 of the Public Health
15 Service Act; and

16 “(B) a risk evaluation and mitigation
17 strategy is required under section 505–1 with
18 respect to the drug and the person fails to
19 maintain compliance with the requirements of
20 the approved strategy or with other require-
21 ments under section 505–1, including require-
22 ments regarding assessments of approved strat-
23 egies.

24 “(2) CERTAIN POSTMARKET STUDIES.—The
25 failure to conduct a postmarket study under section

1 506, subpart H of part 314, or subpart E of part
2 601 of title 21, Code of Federal Regulations (or any
3 successor regulations), is deemed to be a violation of
4 paragraph (1).”.

5 (b) REQUIREMENTS REGARDING STRATEGIES.—
6 Chapter V of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
8 tion 505 the following section:

9 **“SEC. 505–1. RISK EVALUATION AND MITIGATION STRATE-**
10 **GIES.**

11 “(a) SUBMISSION OF PROPOSED STRATEGY.—

12 “(1) INITIAL APPROVAL.—If the Secretary, in
13 consultation with the office responsible for reviewing
14 the drug and the office responsible for postapproval
15 safety with respect to the drug, determines that a
16 risk evaluation and mitigation strategy is necessary
17 to ensure that the benefits of the drug outweigh the
18 risks of the drug, and informs the person who sub-
19 mits such application of such determination, then
20 such person shall submit to the Secretary as part of
21 such application a proposed risk evaluation and miti-
22 gation strategy. In making such a determination, the
23 Secretary shall consider the following factors:

24 “(A) The estimated size of the population
25 likely to use the drug involved.

1 “(B) The seriousness of the disease or con-
2 dition that is to be treated with the drug.

3 “(C) The expected benefit of the drug with
4 respect to such disease or condition.

5 “(D) The expected or actual duration of
6 treatment with the drug.

7 “(E) The seriousness of any known or po-
8 tential adverse events that may be related to
9 the drug and the background incidence of such
10 events in the population likely to use the drug.

11 “(F) Whether the drug is a new molecular
12 entity.

13 “(2) POSTAPPROVAL REQUIREMENT.—

14 “(A) IN GENERAL.—If the Secretary has
15 approved a covered application (including an
16 application approved before the effective date of
17 this section) and did not when approving the
18 application require a risk evaluation and mitiga-
19 tion strategy under paragraph (1), the Sec-
20 retary, in consultation with the offices described
21 in paragraph (1), may subsequently require
22 such a strategy for the drug involved (including
23 when acting on a supplemental application seek-
24 ing approval of a new indication for use of the
25 drug) if the Secretary becomes aware of new

1 safety information and makes a determination
2 that such a strategy is necessary to ensure that
3 the benefits of the drug outweigh the risks of
4 the drug.

5 “(B) SUBMISSION OF PROPOSED STRAT-
6 EGY.—Not later than 120 days after the Sec-
7 retary notifies the holder of an approved cov-
8 ered application that the Secretary has made a
9 determination under subparagraph (A) with re-
10 spect to the drug involved, or within such other
11 reasonable time as the Secretary requires to
12 protect the public health, the holder shall sub-
13 mit to the Secretary a proposed risk evaluation
14 and mitigation strategy.

15 “(3) ABBREVIATED NEW DRUG APPLICA-
16 TIONS.—The applicability of this section to an appli-
17 cation under section 505(j) is subject to subsection
18 (i).

19 “(4) NON-DELEGATION.—Determinations by
20 the Secretary under this subsection for a drug shall
21 be made by individuals at or above the level of indi-
22 viduals empowered to approve a drug (such as divi-
23 sion directors within the Center for Drug Evaluation
24 and Research).

25 “(b) DEFINITIONS.—For purposes of this section:

1 “(1) ADVERSE DRUG EXPERIENCE.—The term
2 ‘adverse drug experience’ means any adverse event
3 associated with the use of a drug in humans, wheth-
4 er or not considered drug related, including—

5 “(A) an adverse event occurring in the
6 course of the use of the drug in professional
7 practice;

8 “(B) an adverse event occurring from an
9 overdose of the drug, whether accidental or in-
10 tentional;

11 “(C) an adverse event occurring from
12 abuse of the drug;

13 “(D) an adverse event occurring from
14 withdrawal of the drug; and

15 “(E) any failure of expected pharma-
16 cological action of the drug.

17 “(2) COVERED APPLICATION.—The term ‘cov-
18 ered application’ means an application referred to in
19 section 505(p)(1)(A).

20 “(3) NEW SAFETY INFORMATION.—The term
21 ‘new safety information’, with respect to a drug,
22 means information derived from a clinical trial, an
23 adverse event report, a postapproval study (including
24 a study under section 505(o)(3)), or peer-reviewed
25 biomedical literature; data derived from the

1 postmarket risk identification and analysis system
2 under section 505(k); or other scientific data deemed
3 appropriate by the Secretary about—

4 “(A) a serious risk or an unexpected seri-
5 ous risk associated with use of the drug that
6 the Secretary has become aware of (that may
7 be based on a new analysis of existing informa-
8 tion) since the drug was approved, since the
9 risk evaluation and mitigation strategy was re-
10 quired, or since the last assessment of the ap-
11 proved risk evaluation and mitigation strategy
12 for the drug; or

13 “(B) the effectiveness of the approved risk
14 evaluation and mitigation strategy for the drug
15 obtained since the last assessment of such
16 strategy.

17 “(4) SERIOUS ADVERSE DRUG EXPERIENCE.—
18 The term ‘serious adverse drug experience’ is an ad-
19 verse drug experience that—

20 “(A) results in—

21 “(i) death;

22 “(ii) an adverse drug experience that
23 places the patient at immediate risk of
24 death from the adverse drug experience as
25 it occurred (not including an adverse drug

1 experience that might have caused death
2 had it occurred in a more severe form);

3 “(iii) inpatient hospitalization or pro-
4 longation of existing hospitalization;

5 “(iv) a persistent or significant inca-
6 pacity or substantial disruption of the abil-
7 ity to conduct normal life functions; or

8 “(v) a congenital anomaly or birth de-
9 fect; or

10 “(B) based on appropriate medical judg-
11 ment, may jeopardize the patient and may re-
12 quire a medical or surgical intervention to pre-
13 vent an outcome described under subparagraph
14 (A).

15 “(5) SERIOUS RISK.—The term ‘serious risk’
16 means a risk of a serious adverse drug experience.

17 “(6) SIGNAL OF A SERIOUS RISK.—The term
18 ‘signal of a serious risk’ means information related
19 to a serious adverse drug experience associated with
20 use of a drug and derived from—

21 “(A) a clinical trial;

22 “(B) adverse event reports;

23 “(C) a postapproval study, including a
24 study under section 505(o)(3);

25 “(D) peer-reviewed biomedical literature;

1 “(E) data derived from the postmarket
2 risk identification and analysis system under
3 section 505(k)(4); or

4 “(F) other scientific data deemed appro-
5 priate by the Secretary.

6 “(7) RESPONSIBLE PERSON.—The term ‘re-
7 sponsible person’ means the person submitting a
8 covered application or the holder of the approved
9 such application.

10 “(8) UNEXPECTED SERIOUS RISK.—The term
11 ‘unexpected serious risk’ means a serious adverse
12 drug experience that is not listed in the labeling of
13 a drug, or that may be symptomatically and
14 pathophysiologically related to an adverse drug expe-
15 rience identified in the labeling, but differs from
16 such adverse drug experience because of greater se-
17 verity, specificity, or prevalence.

18 “(c) CONTENTS.—A proposed risk evaluation and
19 mitigation strategy under subsection (a) shall—

20 “(1) include the timetable required under sub-
21 section (d); and

22 “(2) to the extent required by the Secretary, in
23 consultation with the office responsible for reviewing
24 the drug and the office responsible for postapproval

1 safety with respect to the drug, include additional
2 elements described in subsections (e) and (f).

3 “(d) MINIMAL STRATEGY.—For purposes of sub-
4 section (c)(1), the risk evaluation and mitigation strategy
5 for a drug shall require a timetable for submission of as-
6 sessments of the strategy that—

7 “(1) includes an assessment, by the date that is
8 18 months after the strategy is initially approved;

9 “(2) includes an assessment by the date that is
10 3 years after the strategy is initially approved;

11 “(3) includes an assessment in the seventh year
12 after the strategy is so approved; and

13 “(4) subject to paragraphs (1), (2), and (3)—

14 “(A) is at a frequency specified in the
15 strategy;

16 “(B) is increased or reduced in frequency
17 as necessary as provided for in subsection
18 (g)(4)(A); and

19 “(C) is eliminated after the 3-year period
20 described in paragraph (1) if the Secretary de-
21 termines that serious risks of the drug have
22 been adequately identified and assessed and are
23 being adequately managed.

24 “(e) ADDITIONAL POTENTIAL ELEMENTS OF STRAT-
25 EGY.—

1 “(1) IN GENERAL.—The Secretary, in consulta-
2 tion with the offices described in subsection (c)(2),
3 may under such subsection require that the risk
4 evaluation and mitigation strategy for a drug include
5 1 or more of the additional elements described in
6 this subsection if the Secretary makes the deter-
7 mination required with respect to each element in-
8 volved.

9 “(2) MEDICATION GUIDE; PATIENT PACKAGE
10 INSERT.—The risk evaluation and mitigation strat-
11 egy for a drug may require that, as applicable, the
12 responsible person develop for distribution to each
13 patient when the drug is dispensed—

14 “(A) a Medication Guide, as provided for
15 under part 208 of title 21, Code of Federal
16 Regulations (or any successor regulations); and

17 “(B) a patient package insert, if the Sec-
18 retary determines that such insert may help
19 mitigate a serious risk of the drug.

20 “(3) COMMUNICATION PLAN.—The risk evalua-
21 tion and mitigation strategy for a drug may require
22 that the responsible person conduct a communica-
23 tion plan to health care providers, if, with respect to
24 such drug, the Secretary determines that such plan
25 may support implementation of an element of the

1 strategy (including under this paragraph). Such plan
2 may include—

3 “(A) sending letters to health care pro-
4 viders;

5 “(B) disseminating information about the
6 elements of the risk evaluation and mitigation
7 strategy to encourage implementation by health
8 care providers of components that apply to such
9 health care providers, or to explain certain safe-
10 ty protocols (such as medical monitoring by
11 periodic laboratory tests); or

12 “(C) disseminating information to health
13 care providers through professional societies
14 about any serious risks of the drug and any
15 protocol to assure safe use.

16 “(f) PROVIDING SAFE ACCESS FOR PATIENTS TO
17 DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD
18 OTHERWISE BE UNAVAILABLE.—

19 “(1) ALLOWING SAFE ACCESS TO DRUGS WITH
20 KNOWN SERIOUS RISKS.—The Secretary, in con-
21 sultation with the offices described in subsection
22 (c)(2), may require that the risk evaluation and
23 mitigation strategy for a drug include such elements
24 as are necessary to assure safe use of the drug, be-

1 cause of its inherent toxicity or potential harmful-
2 ness, if the Secretary determines that—

3 “(A) the drug, which has been shown to be
4 effective, but is associated with a serious ad-
5 verse drug experience, can be approved only if,
6 or would be withdrawn unless, such elements
7 are required as part of such strategy to miti-
8 gate a specific serious risk listed in the labeling
9 of the drug; and

10 “(B) for a drug initially approved without
11 elements to assure safe use, other elements
12 under subsections (c), (d), and (e) are not suffi-
13 cient to mitigate such serious risk.

14 “(2) ASSURING ACCESS AND MINIMIZING BUR-
15 DEN.—Such elements to assure safe use under para-
16 graph (1) shall—

17 “(A) be commensurate with the specific se-
18 rious risk listed in the labeling of the drug;

19 “(B) within 30 days of the date on which
20 any element under paragraph (1) is imposed, be
21 posted publicly by the Secretary with an expla-
22 nation of how such elements will mitigate the
23 observed safety risk;

1 “(C) considering such risk, not be unduly
2 burdensome on patient access to the drug, con-
3 sidering in particular—

4 “(i) patients with serious or life-
5 threatening diseases or conditions; and

6 “(ii) patients who have difficulty ac-
7 cessing health care (such as patients in
8 rural or medically underserved areas); and

9 “(D) to the extent practicable, so as to
10 minimize the burden on the health care delivery
11 system—

12 “(i) conform with elements to assure
13 safe use for other drugs with similar, seri-
14 ous risks; and

15 “(ii) be designed to be compatible
16 with established distribution, procurement,
17 and dispensing systems for drugs.

18 “(3) ELEMENTS TO ASSURE SAFE USE.—The
19 elements to assure safe use under paragraph (1)
20 shall include 1 or more goals to mitigate a specific
21 serious risk listed in the labeling of the drug and,
22 to mitigate such risk, may require that—

23 “(A) health care providers who prescribe
24 the drug have particular training or experience,
25 or are specially certified (the opportunity to ob-

1 tain such training or certification with respect
2 to the drug shall be available to any willing pro-
3 vider from a frontier area in a widely available
4 training or certification method (including an
5 on-line course or via mail) as approved by the
6 Secretary at reasonable cost to the provider);

7 “(B) pharmacies, practitioners, or health
8 care settings that dispense the drug are spe-
9 cially certified (the opportunity to obtain such
10 certification shall be available to any willing
11 provider from a frontier area);

12 “(C) the drug be dispensed to patients only
13 in certain health care settings, such as hos-
14 pitals;

15 “(D) the drug be dispensed to patients
16 with evidence or other documentation of safe-
17 use conditions, such as laboratory test results;

18 “(E) each patient using the drug be sub-
19 ject to certain monitoring; or

20 “(F) each patient using the drug be en-
21 rolled in a registry.

22 “(4) IMPLEMENTATION SYSTEM.—The elements
23 to assure safe use under paragraph (1) that are de-
24 scribed in subparagraphs (B), (C), and (D) of para-

1 graph (3) may include a system through which the
2 applicant is able to take reasonable steps to—

3 “(A) monitor and evaluate implementation
4 of such elements by health care providers, phar-
5 macists, and other parties in the health care
6 system who are responsible for implementing
7 such elements; and

8 “(B) work to improve implementation of
9 such elements by such persons.

10 “(5) EVALUATION OF ELEMENTS TO ASSURE
11 SAFE USE.—The Secretary, through the Drug Safety
12 and Risk Management Advisory Committee (or suc-
13 cessor committee) of the Food and Drug Adminis-
14 tration, shall—

15 “(A) seek input from patients, physicians,
16 pharmacists, and other health care providers
17 about how elements to assure safe use under
18 this subsection for 1 or more drugs may be
19 standardized so as not to be—

20 “(i) unduly burdensome on patient ac-
21 cess to the drug; and

22 “(ii) to the extent practicable, mini-
23 mize the burden on the health care delivery
24 system;

1 “(B) at least annually, evaluate, for 1 or
2 more drugs, the elements to assure safe use of
3 such drug to assess whether the elements—

4 “(i) assure safe use of the drug;

5 “(ii) are not unduly burdensome on
6 patient access to the drug; and

7 “(iii) to the extent practicable, mini-
8 mize the burden on the health care delivery
9 system; and

10 “(C) considering such input and evalua-
11 tions—

12 “(i) issue or modify agency guidance
13 about how to implement the requirements
14 of this subsection; and

15 “(ii) modify elements under this sub-
16 section for 1 or more drugs as appropriate.

17 “(6) ADDITIONAL MECHANISMS TO ASSURE AC-
18 CESS.—The mechanisms under section 561 to pro-
19 vide for expanded access for patients with serious or
20 life-threatening diseases or conditions may be used
21 to provide access for patients with a serious or life-
22 threatening disease or condition, the treatment of
23 which is not an approved use for the drug, to a drug
24 that is subject to elements to assure safe use under
25 this subsection. The Secretary shall promulgate reg-

1 ulations for how a physician may provide the drug
2 under the mechanisms of section 561.

3 “(7) WAIVER IN PUBLIC HEALTH EMER-
4 GENCIES.—The Secretary may waive any require-
5 ment of this subsection during the period described
6 in section 319(a) of the Public Health Service Act
7 with respect to a qualified countermeasure described
8 under section 319F–1(a)(2) of such Act, to which a
9 requirement under this subsection has been applied,
10 if the Secretary has—

11 “(A) declared a public health emergency
12 under such section 319; and

13 “(B) determined that such waiver is re-
14 quired to mitigate the effects of, or reduce the
15 severity of, such public health emergency.

16 “(8) LIMITATION.—No holder of an approved
17 covered application shall use any element to assure
18 safe use required by the Secretary under this sub-
19 section to block or delay approval of an application
20 under section 505(b)(2) or (j) or to prevent applica-
21 tion of such element under subsection (i)(1)(B) to a
22 drug that is the subject of an abbreviated new drug
23 application.

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, in consulta-
25 tion with the offices described in subsection

1 (c)(2), determines that new safety or effective-
2 ness information indicates 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, in consultation with the offices de-
11 scribed in subsection (c)(2), if the Secretary de-
12 termines that there may be a cause for action
13 by the Secretary under section 505(e).

14 “(3) REQUIREMENTS FOR ASSESSMENTS.—An
15 assessment under paragraph (1) or (2) of an ap-
16 proved risk evaluation and mitigation strategy for a
17 drug shall include—

18 “(A) with respect to any goal under sub-
19 section (f), an assessment of the extent to
20 which the elements to assure safe use are meet-
21 ing the goal or whether the goal or such ele-
22 ments should be modified;

23 “(B) with respect to any postapproval
24 study required under section 505(o) or other-
25 wise undertaken by the responsible person to

1 investigate a safety issue, the status of such
2 study, including whether any difficulties com-
3 pleting the study have been encountered; and

4 “(C) with respect to any postapproval clin-
5 ical trial required under section 505(o) or oth-
6 erwise undertaken by the responsible party to
7 investigate a safety issue, the status of such
8 clinical trial, including whether enrollment has
9 begun, the number of participants enrolled, the
10 expected completion date, whether any difficul-
11 ties completing the clinical trial have been en-
12 countered, and registration information with re-
13 spect to requirements under subsections (i) and
14 (j) of section 402 of the Public Health Service
15 Act.

16 “(4) MODIFICATION.—A modification (whether
17 an enhancement or a reduction) to the approved risk
18 evaluation and mitigation strategy for a drug may
19 include the addition or modification of any element
20 under subsection (d) or the addition, modification,
21 or removal of any element under subsection (e) or
22 (f), such as—

23 “(A) modifying the timetable for assess-
24 ments of the strategy as provided in subsection
25 (d)(3), including to eliminate assessments; or

1 “(B) adding, modifying, or removing an
2 element to assure safe use under subsection (f).

3 “(h) REVIEW OF PROPOSED STRATEGIES; REVIEW
4 OF ASSESSMENTS OF APPROVED STRATEGIES.—

5 “(1) IN GENERAL.—The Secretary, in consulta-
6 tion with the offices described in subsection (c)(2),
7 shall promptly review each proposed risk evaluation
8 and mitigation strategy for a drug submitted under
9 subsection (a) and each assessment of an approved
10 risk evaluation and mitigation strategy for a drug
11 submitted under subsection (g).

12 “(2) DISCUSSION.—The Secretary, in consulta-
13 tion with the offices described in subsection (c)(2),
14 shall initiate discussions with the responsible person
15 for purposes of this subsection to determine a strat-
16 egy not later than 60 days after any such assess-
17 ment is submitted or, in the case of an assessment
18 submitted under subsection (g)(2)(D), not later than
19 30 days after such assessment is submitted.

20 “(3) ACTION.—

21 “(A) IN GENERAL.—Unless the dispute
22 resolution process described under paragraph
23 (4) or (5) applies, the Secretary, in consultation
24 with the offices described in subsection (c)(2),
25 shall describe any required risk evaluation and

1 mitigation strategy for a drug, or any modifica-
2 tion to any required strategy—

3 “(i) as part of the action letter on the
4 application, when a proposed strategy is
5 submitted under subsection (a) or a modi-
6 fication to the strategy is proposed as part
7 of an assessment of the strategy submitted
8 under subsection (g)(1); or

9 “(ii) in an order issued not later than
10 90 days after the date discussions of such
11 modification begin under paragraph (2),
12 when a modification to the strategy is pro-
13 posed as part of an assessment of the
14 strategy submitted under subsection (g)(1)
15 or under any of subparagraphs (B)
16 through (D) of subsection (g)(2).

17 “(B) INACTION.—An approved risk evalua-
18 tion and mitigation strategy shall remain in ef-
19 fect until the Secretary acts, if the Secretary
20 fails to act as provided under subparagraph
21 (A).

22 “(C) PUBLIC AVAILABILITY.—Any action
23 letter described in subparagraph (A)(i) or order
24 described in subparagraph (A)(ii) shall be made
25 publicly available.

1 “(4) DISPUTE RESOLUTION AT INITIAL AP-
2 PROVAL.—If a proposed risk evaluation and mitiga-
3 tion strategy is submitted under subsection (a)(1) in
4 an application for initial approval of a drug and
5 there is a dispute about the strategy, the responsible
6 person shall use the major dispute resolution proce-
7 dures as set forth in the letters described in section
8 101(c) of the Food and Drug Administration
9 Amendments Act of 2007.

10 “(5) DISPUTE RESOLUTION IN ALL OTHER
11 CASES.—

12 “(A) REQUEST FOR REVIEW.—

13 “(i) IN GENERAL.—Not earlier than
14 15 days, and not later than 35 days, after
15 discussions under paragraph (2) have
16 begun, the responsible person may request
17 in writing that a dispute about the strat-
18 egy be reviewed by the Drug Safety Over-
19 sight Board under subsection (j), except
20 that the determination of the Secretary to
21 require a risk evaluation and mitigation
22 strategy is not subject to review under this
23 paragraph. The preceding sentence does
24 not prohibit review under this paragraph of
25 the particular elements of such a strategy.

1 “(ii) SCHEDULING.—Upon receipt of
2 a request under clause (i), the Secretary
3 shall schedule the dispute involved for re-
4 view under subparagraph (B) and, not
5 later than 5 business days of scheduling
6 the dispute for review, shall publish by
7 posting on the Internet or otherwise a no-
8 tice that the dispute will be reviewed by
9 the Drug Safety Oversight Board.

10 “(B) SCHEDULING REVIEW.—If a respon-
11 sible person requests review under subpara-
12 graph (A), the Secretary—

13 “(i) shall schedule the dispute for re-
14 view at 1 of the next 2 regular meetings of
15 the Drug Safety Oversight Board, which-
16 ever meeting date is more practicable; or

17 “(ii) may convene a special meeting of
18 the Drug Safety Oversight Board to review
19 the matter more promptly, including to
20 meet an action deadline on an application
21 (including a supplemental application).

22 “(C) AGREEMENT AFTER DISCUSSION OR
23 ADMINISTRATIVE APPEALS.—

24 “(i) FURTHER DISCUSSION OR ADMIN-
25 ISTRATIVE APPEALS.—A request for review

1 under subparagraph (A) shall not preclude
2 further discussions to reach agreement on
3 the risk evaluation and mitigation strategy,
4 and such a request shall not preclude the
5 use of administrative appeals within the
6 Food and Drug Administration to reach
7 agreement on the strategy, including ap-
8 peals as described in the letters described
9 in section 101(c) of the Food and Drug
10 Administration Amendments Act of 2007
11 for procedural or scientific matters involv-
12 ing the review of human drug applications
13 and supplemental applications that cannot
14 be resolved at the divisional level. At the
15 time a review has been scheduled under
16 subparagraph (B) and notice of such re-
17 view has been posted, the responsible per-
18 son shall either withdraw the request
19 under subparagraph (A) or terminate the
20 use of such administrative appeals.

21 “(ii) AGREEMENT TERMINATES DIS-
22 PUTE RESOLUTION.—At any time before a
23 decision and order is issued under sub-
24 paragraph (G) , the Secretary (in consulta-
25 tion with the offices described in sub-

1 section (c)(2)) and the responsible person
2 may reach an agreement on the risk eval-
3 uation and mitigation strategy through
4 further discussion or administrative ap-
5 peals, terminating the dispute resolution
6 process, and the Secretary shall issue an
7 action letter or order, as appropriate, that
8 describes the strategy.

9 “(D) MEETING OF THE BOARD.—At a
10 meeting of the Drug Safety Oversight Board
11 described in subparagraph (B), the Board
12 shall—

13 “(i) hear from both parties via written
14 or oral presentation; and

15 “(ii) review the dispute.

16 “(E) RECORD OF PROCEEDINGS.—The
17 Secretary shall ensure that the proceedings of
18 any such meeting are recorded, transcribed, and
19 made public within 90 days of the meeting. The
20 Secretary shall redact the transcript to protect
21 any trade secrets and other information that is
22 exempted from disclosure under section 552 of
23 title 5, United States Code, or section 552a of
24 title 5, United States Code.

1 “(F) RECOMMENDATION OF THE
2 BOARD.—Not later than 5 days after any such
3 meeting, the Drug Safety Oversight Board shall
4 provide a written recommendation on resolving
5 the dispute to the Secretary. Not later than 5
6 days after the Board provides such written rec-
7 ommendation to the Secretary, the Secretary
8 shall make the recommendation available to the
9 public.

10 “(G) ACTION BY THE SECRETARY.—

11 “(i) ACTION LETTER.—With respect
12 to a proposal or assessment referred to in
13 paragraph (1), the Secretary shall issue an
14 action letter that resolves the dispute not
15 later than the later of—

16 “(I) the action deadline for the
17 action letter on the application; or

18 “(II) 7 days after receiving the
19 recommendation of the Drug Safety
20 Oversight Board.

21 “(ii) ORDER.—With respect to an as-
22 sessment of an approved risk evaluation
23 and mitigation strategy under subsection
24 (g)(1) or under any of subparagraphs (B)
25 through (D) of subsection (g)(2), the Sec-

1 retary shall issue an order, which shall be
2 made public, that resolves the dispute not
3 later than 7 days after receiving the rec-
4 ommendation of the Drug Safety Oversight
5 Board.

6 “(H) 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 for under subparagraph
10 (G).

11 “(I) EFFECT ON ACTION DEADLINE.—
12 With respect to a proposal or assessment re-
13 ferred to in paragraph (1), the Secretary shall
14 be considered to have met the action deadline
15 for the action letter on the application if the re-
16 sponsible person requests the dispute resolution
17 process described in this paragraph and if the
18 Secretary—

19 “(i) has initiated the discussions de-
20 scribed under paragraph (2) not less than
21 60 days before such action deadline; and

22 “(ii) has complied with the timing re-
23 quirements of scheduling review by the
24 Drug Safety Oversight Board, providing a
25 written recommendation, and issuing an

1 action letter under subparagraphs (B),
2 (F), and (G), respectively.

3 “(J) DISQUALIFICATION.—No individual
4 who is an employee of the Food and Drug Ad-
5 ministration and who reviews a drug or who
6 participated in an administrative appeal under
7 subparagraph (C)(i) with respect to such drug
8 may serve on the Drug Safety Oversight Board
9 at a meeting under subparagraph (D) to review
10 a dispute about the risk evaluation and mitiga-
11 tion strategy for such drug.

12 “(K) ADDITIONAL EXPERTISE.—The Drug
13 Safety Oversight Board may add members with
14 relevant expertise from the Food and Drug Ad-
15 ministration, including the Office of Pediatrics,
16 the Office of Women’s Health, or the Office of
17 Rare Diseases, or from other Federal public
18 health or health care agencies, for a meeting
19 under subparagraph (D) of the Drug Safety
20 Oversight Board.

21 “(6) USE OF ADVISORY COMMITTEES.—The
22 Secretary may convene a meeting of 1 or more advi-
23 sory committees of the Food and Drug Administra-
24 tion to—

1 “(A) review a concern about the safety of
2 a drug or class of drugs, including before an as-
3 sessment of the risk evaluation and mitigation
4 strategy or strategies of such drug or drugs is
5 required to be submitted under any of subpara-
6 graphs (B) through (D) of subsection (g)(2);

7 “(B) review the risk evaluation and mitiga-
8 tion strategy or strategies of a drug or group
9 of drugs; or

10 “(C) review a dispute under paragraph (4)
11 or (5).

12 “(7) PROCESS FOR ADDRESSING DRUG CLASS
13 EFFECTS.—

14 “(A) IN GENERAL.—When a concern about
15 a serious risk of a drug may be related to the
16 pharmacological class of the drug, the Sec-
17 retary, in consultation with the offices described
18 in subsection (c)(2), may defer assessments of
19 the approved risk evaluation and mitigation
20 strategies for such drugs until the Secretary
21 has convened 1 or more public meetings to con-
22 sider possible responses to such concern.

23 “(B) NOTICE.—If the Secretary defers an
24 assessment under subparagraph (A), the Sec-
25 retary shall—

1 “(i) give notice of the deferral to the
2 holder of the approved covered application
3 not later than 5 days after the deferral;

4 “(ii) publish the deferral in the Fed-
5 eral Register; and

6 “(iii) give notice to the public of any
7 public meetings to be convened under sub-
8 paragraph (A), including a description of
9 the deferral.

10 “(C) PUBLIC MEETINGS.—Such public
11 meetings may include—

12 “(i) 1 or more meetings of the respon-
13 sible person for such drugs;

14 “(ii) 1 or more meetings of 1 or more
15 advisory committees of the Food and Drug
16 Administration, as provided for under
17 paragraph (6); or

18 “(iii) 1 or more workshops of sci-
19 entific experts and other stakeholders.

20 “(D) ACTION.—After considering the dis-
21 cussions from any meetings under subpara-
22 graph (A), the Secretary may—

23 “(i) announce in the Federal Register
24 a planned regulatory action, including a
25 modification to each risk evaluation and

1 mitigation strategy, for drugs in the phar-
2 macological class;

3 “(ii) seek public comment about such
4 action; and

5 “(iii) after seeking such comment,
6 issue an order addressing such regulatory
7 action.

8 “(8) INTERNATIONAL COORDINATION.—The
9 Secretary, in consultation with the offices described
10 in subsection (c)(2), may coordinate the timetable
11 for submission of assessments under subsection (d),
12 or a study or clinical trial under section 505(o)(3),
13 with efforts to identify and assess the serious risks
14 of such drug by the marketing authorities of other
15 countries whose drug approval and risk management
16 processes the Secretary deems comparable to the
17 drug approval and risk management processes of the
18 United States. If the Secretary takes action to co-
19 ordinate such timetable, the Secretary shall give no-
20 tice to the responsible person.

21 “(9) EFFECT.—Use of the processes described
22 in paragraphs (7) and (8) shall not be the sole
23 source of delay of action on an application or a sup-
24 plement to an application for a drug.

25 “(i) ABBREVIATED NEW DRUG APPLICATIONS.—

1 “(1) IN GENERAL.—A drug that is the subject
2 of an abbreviated new drug application under section
3 505(j) is subject to only the following elements of
4 the risk evaluation and mitigation strategy required
5 under subsection (a) for the applicable listed drug:

6 “(A) A Medication Guide or patient pack-
7 age insert, if required under subsection (e) for
8 the applicable listed drug.

9 “(B) Elements to assure safe use, if re-
10 quired under subsection (f) for the listed drug.
11 A drug that is the subject of an abbreviated
12 new drug application and the listed drug shall
13 use a single, shared system under subsection
14 (f). The Secretary may waive the requirement
15 under the preceding sentence for a drug that is
16 the subject of an abbreviated new drug applica-
17 tion, and permit the applicant to use a dif-
18 ferent, comparable aspect of the elements to as-
19 sure safe use, if the Secretary determines
20 that—

21 “(i) the burden of creating a single,
22 shared system outweighs the benefit of a
23 single, system, taking into consideration
24 the impact on health care providers, pa-
25 tients, the applicant for the abbreviated

1 new drug application, and the holder of the
2 reference drug product; or

3 “(ii) an aspect of the elements to as-
4 sure safe use for the applicable listed drug
5 is claimed by a patent that has not expired
6 or is a method or process that, as a trade
7 secret, is entitled to protection, and the ap-
8 plicant for the abbreviated new drug appli-
9 cation certifies that it has sought a license
10 for use of an aspect of the elements to as-
11 sure safe use for the applicable listed drug
12 and that it was unable to obtain a license.

13 A certification under clause (ii) shall include a
14 description of the efforts made by the applicant
15 for the abbreviated new drug application to ob-
16 tain a license. In a case described in clause (ii),
17 the Secretary may seek to negotiate a voluntary
18 agreement with the owner of the patent, meth-
19 od, or process for a license under which the ap-
20 plicant for such abbreviated new drug applica-
21 tion may use an aspect of the elements to as-
22 sure safe use, if required under subsection (f)
23 for the applicable listed drug, that is claimed by
24 a patent that has not expired or is a method or

1 process that as a trade secret is entitled to pro-
2 tection.

3 “(2) ACTION BY SECRETARY.—For an applica-
4 ble listed drug for which a drug is approved under
5 section 505(j), the Secretary—

6 “(A) shall undertake any communication
7 plan to health care providers required under
8 subsection (e)(3) for the applicable listed drug;
9 and

10 “(B) shall inform the responsible person
11 for the drug that is so approved if the risk eval-
12 uation and mitigation strategy for the applica-
13 ble listed drug is modified.

14 “(j) DRUG SAFETY OVERSIGHT BOARD.—

15 “(1) IN GENERAL.—There is established a
16 Drug Safety Oversight Board.

17 “(2) COMPOSITION; MEETINGS.—The Drug
18 Safety Oversight Board shall—

19 “(A) be composed of scientists and health
20 care practitioners appointed by the Secretary,
21 each of whom is an employee of the Federal
22 Government;

23 “(B) include representatives from offices
24 throughout the Food and Drug Administration,

1 including the offices responsible for post-
2 approval safety of drugs;

3 “(C) include at least 1 representative each
4 from the National Institutes of Health and the
5 Department of Health and Human Services
6 (other than the Food and Drug Administra-
7 tion);

8 “(D) include such representatives as the
9 Secretary shall designate from other appro-
10 priate agencies that wish to provide representa-
11 tives; and

12 “(E) meet at least monthly to provide
13 oversight and advice to the Secretary on the
14 management of important drug safety issues.”.

15 (c) REGULATION OF BIOLOGICAL PRODUCTS.—Sec-
16 tion 351 of the Public Health Service Act (42 U.S.C. 262)
17 is amended—

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

20 “(D) POSTMARKET STUDIES AND CLINICAL TRIALS;
21 LABELING; RISK EVALUATION AND MITIGATION STRAT-
22 EGY.—A person that submits an application for a license
23 under this paragraph is subject to sections 505(o), 505(p),
24 and 505–1 of the Federal Food, Drug, and Cosmetic
25 Act.”; and

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

4 (d) ADVERTISEMENTS OF DRUGS.—The Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),
6 as amended by section 801(b), is amended—

7 (1) in section 301 (21 U.S.C. 331), by adding
8 at the end the following:

9 “(kk) The dissemination of a television advertisement
10 without complying with section 503B.”; and

11 (2) by inserting after section 503A the fol-
12 lowing:

13 **“SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.**

14 “(a) IN GENERAL.—The Secretary may require the
15 submission of any television advertisement for a drug (in-
16 cluding any script, story board, rough, or a completed
17 video production of the television advertisement) to the
18 Secretary for review under this section not later than 45
19 days before dissemination of the television advertisement.

20 “(b) REVIEW.—In conducting a review of a television
21 advertisement under this section, the Secretary may make
22 recommendations—

23 “(1) on changes that are—

24 “(A) necessary to protect the consumer
25 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.—Ex-
10 cept as provided by subsection (e), this section does not
11 authorize the Secretary to make or direct changes in any
12 material submitted pursuant to subsection (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 “(d) 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 or section 351 of the Public Health Service Act, a
9 specific disclosure of such date of approval if the
10 Secretary determines that the advertisement would
11 otherwise be false or misleading.

12 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion may be construed as having any effect on require-
14 ments under section 502(n) or on the authority of the Sec-
15 retary under section 314.550, 314.640, 601.45, or 601.94
16 of title 21, Code of Federal Regulations (or successor reg-
17 ulations).”.

18 (3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

19 (A) IN GENERAL.—Section 502(n) of the
20 Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 352(n)) is amended by adding at the
22 end the following: “In the case of an advertise-
23 ment for a drug subject to section 503(b)(1)
24 presented directly to consumers in television or
25 radio format and stating the name of the drug

1 and its conditions of use, the major statement
2 relating to side effects and contraindications
3 shall be presented in a clear, conspicuous, and
4 neutral manner.”.

5 (B) REGULATIONS TO DETERMINE CLEAR,
6 CONSPICUOUS, AND NEUTRAL MANNER.—Not
7 later than 30 months after the date of the en-
8 actment of the Food and Drug Administration
9 Amendments Act of 2007, the Secretary of
10 Health and Human Services shall by regulation
11 establish standards for determining whether a
12 major statement relating to side effects and
13 contraindications of a drug, described in section
14 502(n) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 352(n)) (as amended by
16 subparagraph (A)) is presented in the manner
17 required under such section.

18 (4) CIVIL PENALTIES.—Section 303 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333),
20 as amended by section 801(b), is amended by adding
21 at the end the following:

22 “(g)(1) With respect to a person who is a holder of
23 an approved application under section 505 for a drug sub-
24 ject to section 503(b) or under section 351 of the Public
25 Health Service Act, any such person who disseminates or

1 causes another party to disseminate a direct-to-consumer
2 advertisement that is false or misleading shall be liable
3 to the United States for a civil penalty in an amount not
4 to exceed \$250,000 for the first such violation in any 3-
5 year period, and not to exceed \$500,000 for each subse-
6 quent violation in any 3-year period. No other civil mone-
7 tary penalties in this Act (including the civil penalty in
8 section 303(f)(4)) shall apply to a violation regarding di-
9 rect-to-consumer advertising. For purposes of this para-
10 graph: (A) Repeated dissemination of the same or similar
11 advertisement prior to the receipt of the written notice re-
12 ferred to in paragraph (2) for such advertisements shall
13 be considered one violation. (B) On and after the date of
14 the receipt of such a notice, all violations under this para-
15 graph occurring in a single day shall be considered one
16 violation. With respect to advertisements that appear in
17 magazines or other publications that are published less
18 frequently than daily, each issue date (whether weekly or
19 monthly) shall be treated as a single day for the purpose
20 of calculating the number of violations under this para-
21 graph.

22 “(2) A civil penalty under paragraph (1) shall be as-
23 sessed by the Secretary by an order made on the record
24 after providing written notice to the person to be assessed
25 a civil penalty and an opportunity for a hearing in accord-

1 ance with this paragraph and section 554 of title 5, United
2 States Code. If upon receipt of the written notice, the per-
3 son to be assessed a civil penalty objects and requests a
4 hearing, then in the course of any investigation related
5 to such hearing, the Secretary may issue subpoenas re-
6 quiring the attendance and testimony of witnesses and the
7 production of evidence that relates to the matter under
8 investigation, including information pertaining to the fac-
9 tors described in paragraph (3).

10 “(3) The Secretary, in determining the amount of the
11 civil penalty under paragraph (1), shall take into account
12 the nature, circumstances, extent, and gravity of the viola-
13 tion or violations, including the following factors:

14 “(A) Whether the person submitted the adver-
15 tisement or a similar advertisement for review under
16 section 736A.

17 “(B) Whether the person submitted the adver-
18 tisement for review if required under section 503B.

19 “(C) Whether, after submission of the adver-
20 tisement as described in subparagraph (A) or (B),
21 the person disseminated or caused another party to
22 disseminate the advertisement before the end of the
23 45-day comment period.

24 “(D) Whether the person incorporated any com-
25 ments made by the Secretary with regard to the ad-

1 vertisement into the advertisement prior to its dis-
2 semination.

3 “(E) Whether the person ceased distribution of
4 the advertisement upon receipt of the written notice
5 referred to in paragraph (2) for such advertisement.

6 “(F) Whether the person had the advertisement
7 reviewed by qualified medical, regulatory, and legal
8 reviewers prior to its dissemination.

9 “(G) Whether the violations were material.

10 “(H) Whether the person who created the ad-
11 vertisement or caused the advertisement to be cre-
12 ated acted in good faith.

13 “(I) Whether the person who created the adver-
14 tisement or caused the advertisement to be created
15 has been assessed a civil penalty under this provision
16 within the previous 1-year period.

17 “(J) The scope and extent of any voluntary,
18 subsequent remedial action by the person.

19 “(K) Such other matters, as justice may re-
20 quire.

21 “(4)(A) Subject to subparagraph (B), no person shall
22 be required to pay a civil penalty under paragraph (1) if
23 the person submitted the advertisement to the Secretary
24 and disseminated or caused another party to disseminate

1 such advertisement after incorporating each comment re-
2 ceived from the Secretary.

3 “(B) The Secretary may retract or modify any prior
4 comments the Secretary has provided to an advertisement
5 submitted to the Secretary based on new information or
6 changed circumstances, so long as the Secretary provides
7 written notice to the person of the new views of the Sec-
8 retary on the advertisement and provides a reasonable
9 time for modification or correction of the advertisement
10 prior to seeking any civil penalty under paragraph (1).

11 “(5) The Secretary may compromise, modify, or
12 remit, with or without conditions, any civil penalty which
13 may be assessed under paragraph (1). The amount of such
14 penalty, when finally determined, or the amount charged
15 upon in compromise, may be deducted from any sums
16 owed by the United States to the person charged.

17 “(6) Any person who requested, in accordance with
18 paragraph (2), a hearing with respect to the assessment
19 of a civil penalty and who is aggrieved by an order assess-
20 ing a civil penalty, may file a petition for de novo judicial
21 review of such order with the United States Court of Ap-
22 peals for the District of Columbia Circuit or for any other
23 circuit in which such person resides or transacts business.
24 Such a petition may only be filed within the 60-day period

1 beginning on the date the order making such assessments
2 was issued.

3 “(7) If any person fails to pay an assessment of a
4 civil penalty under paragraph (1)—

5 “(A) after the order making the assessment be-
6 comes final, and if such person does not file a peti-
7 tion for judicial review of the order in accordance
8 with paragraph (6), or

9 “(B) after a court in an action brought under
10 paragraph (6) has entered a final judgment in favor
11 of the Secretary,

12 the Attorney General of the United States shall recover
13 the amount assessed (plus interest at currently prevailing
14 rates from the date of the expiration of the 60-day period
15 referred to in paragraph (6) or the date of such final judg-
16 ment, as the case may be) in an action brought in any
17 appropriate district court of the United States. In such
18 an action, the validity, amount, and appropriateness of
19 such penalty shall not be subject to review.”.

20 (5) REPORT ON DIRECT-TO-CONSUMER ADVER-
21 TISING.—Not later than 24 months after the date of
22 the enactment of this Act, the Secretary of Health
23 and Human Services shall report to the Congress on
24 direct-to-consumer advertising and its ability to com-
25 municate to subsets of the general population, in-

1 cluding elderly populations, children, and racial and
2 ethnic minority communities. The Secretary shall
3 utilize the Advisory Committee on Risk Communica-
4 tion established under this Act to advise the Sec-
5 retary with respect to such report. The Advisory
6 Committee shall study direct-to-consumer adver-
7 tising as it relates to increased access to health in-
8 formation and decreased health disparities for these
9 populations. The report required by this paragraph
10 shall recommend effective ways to present and dis-
11 seminate information to these populations. Such re-
12 port shall also make recommendations regarding im-
13 pediments to the participation of elderly populations,
14 children, racially and ethnically diverse communities,
15 and medically underserved populations in clinical
16 drug trials and shall recommend best practice ap-
17 proaches for increasing the inclusion of such subsets
18 of the general population. The Secretary of Health
19 and Human Services shall submit the report under
20 this paragraph to the Committee on Health, Edu-
21 cation, Labor, and Pensions of the Senate and the
22 Committee on Energy and Commerce of the House
23 of Representatives.

24 (6) RULEMAKING.—Section 502(n) of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 352(n)) is amended by striking “the procedure spec-
2 ified in section 701(e) of this Act” and inserting
3 “section 701(a)”.

4 (e) **RULE OF CONSTRUCTION REGARDING PEDIATRIC**
5 **STUDIES.**—This title and the amendments made by this
6 title may not be construed as affecting the authority of
7 the Secretary of Health and Human Services to request
8 pediatric studies under section 505A of the Federal Food,
9 Drug, and Cosmetic Act or to require such studies under
10 section 505B of such Act.

11 **SEC. 902. ENFORCEMENT.**

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

15 “(y) If it is a drug subject to an approved risk evalua-
16 tion and mitigation strategy pursuant to section 505(p)
17 and the responsible person (as such term is used in section
18 505–1) fails to comply with a requirement of such strategy
19 provided for under subsection (d), (e), or (f) of section
20 505–1.

21 “(z) If it is a drug, and the responsible person (as
22 such term is used in section 505(o)) is in violation of a
23 requirement established under paragraph (3) (relating to
24 postmarket studies and clinical trials) or paragraph (4)

1 (relating to labeling) of section 505(o) with respect to such
2 drug.”.

3 (b) CIVIL PENALTIES.—Section 303(f) of the Federal
4 Food, Drug, and Cosmetic Act, as amended by section
5 801(b), is amended—

6 (1) by inserting after paragraph (3), as added
7 by section 801(b)(2), the following:

8 “(4)(A) Any responsible person (as such term is used
9 in section 505-1) that violates a requirement of section
10 505(o), 505(p), or 505-1 shall be subject to a civil mone-
11 tary penalty of—

12 “(i) not more than \$250,000 per violation, and
13 not to exceed \$1,000,000 for all such violations ad-
14 judicated in a single proceeding; or

15 “(ii) in the case of a violation that continues
16 after the Secretary provides written notice to the re-
17 sponsible person, the responsible person shall be sub-
18 ject to a civil monetary penalty of \$250,000 for the
19 first 30-day period (or any portion thereof) that the
20 responsible person continues to be in violation, and
21 such amount shall double for every 30-day period
22 thereafter that the violation continues, not to exceed
23 **【\$1,000,000】** for any 30-day period, and not to ex-
24 ceed **【\$10,000,000】** for all such violations adju-
25 dicated in a single proceeding.

1 “(B) In determining the amount of a civil penalty
2 under subparagraph (A)(ii), the Secretary shall take into
3 consideration whether the responsible person is making
4 **【substantial progress】** toward correcting the violation of
5 the requirement of section 505(o), 505(p), or 505-1 for
6 which the responsible person is subject to such civil pen-
7 alty.”; and

8 (2) in paragraph (5), as redesignated by section
9 801(b)(2)(A), by striking “paragraph (1), (2), or
10 (3)” each place it appears and inserting “paragraph
11 (1), (2), (3), or (4)”.

12 **SEC. 903. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**
13 **APPROVAL.**

14 Section 505(e) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 355(e)) is amended by adding at
16 the end the following: “The Secretary may withdraw the
17 approval of an application submitted under this section,
18 or suspend the approval of such an application, as pro-
19 vided under this subsection, without first ordering the ap-
20 plicant to submit an assessment of the approved risk eval-
21 uation and mitigation strategy for the drug under section
22 505–1(g)(2)(D).”.

23 **SEC. 904. BENEFIT-RISK ASSESSMENTS.**

24 Not later than 1 year after the date of the enactment
25 of this Act, the Commissioner of Food and Drugs shall

1 submit to the Congress a report on how best to commu-
2 nicate to the public the risks and benefits of new drugs
3 and the role of the risk evaluation and mitigation strategy
4 in assessing such risks and benefits. As part of such study,
5 the Commissioner may consider the possibility of including
6 in the labeling and any direct-to-consumer advertisements
7 of a newly approved drug or indication a unique symbol
8 indicating the newly approved status of the drug or indica-
9 tion for a period after approval.

10 **SEC. 905. ACTIVE POSTMARKET RISK IDENTIFICATION AND**
11 **ANALYSIS.**

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

15 “(3) ACTIVE POSTMARKET RISK IDENTIFICA-
16 TION.—

17 “(A) DEFINITION.—In this paragraph, the
18 term ‘data’ refers to information with respect to
19 a drug approved under this section or under
20 section 351 of the Public Health Service Act,
21 including claims data, patient survey data,
22 standardized analytic files that allow for the
23 pooling and analysis of data from disparate
24 data environments, and any other data deemed
25 appropriate by the Secretary.

1 “(B) DEVELOPMENT OF POSTMARKET
2 RISK IDENTIFICATION AND ANALYSIS METH-
3 ODS.—The Secretary shall, not later than 2
4 years after the date of the enactment of the
5 Food and Drug Administration Amendments
6 Act of 2007, in collaboration with public, aca-
7 demic, and private entities—

8 “(i) develop methods to obtain access
9 to disparate data sources including the
10 data sources specified in subparagraph
11 (C);

12 “(ii) develop validated methods for the
13 establishment of a postmarket risk identi-
14 fication and analysis system to link and
15 analyze safety data from multiple sources,
16 with the goals of including, in aggregate—

17 “(I) at least 25,000,000 patients
18 by July 1, 2010; and

19 “(II) at least 100,000,000 pa-
20 tients by July 1, 2012; and

21 “(iii) convene a committee of experts,
22 including individuals who are recognized in
23 the field of protecting data privacy and se-
24 curity, to make recommendations to the
25 Secretary on the development of tools and

1 methods for the ethical and scientific uses
2 for, and communication of, postmarketing
3 data specified under subparagraph (C), in-
4 cluding recommendations on the develop-
5 ment of effective research methods for the
6 study of drug safety questions.

7 “(C) ESTABLISHMENT OF THE
8 POSTMARKET RISK IDENTIFICATION AND ANAL-
9 YSIS SYSTEM.—

10 “(i) IN GENERAL.—The Secretary
11 shall, not later than 1 year after the devel-
12 opment of the risk identification and anal-
13 ysis methods under subparagraph (B), es-
14 tablish and maintain procedures—

15 “(I) for risk identification and
16 analysis based on electronic health
17 data, in compliance with the regula-
18 tions promulgated under section
19 264(c) of the Health Insurance Port-
20 ability and Accountability Act of
21 1996, and in a manner that does not
22 disclose individually identifiable health
23 information in violation of paragraph
24 (4)(B);

1 “(II) for the reporting (in a
2 standardized form) of data on all seri-
3 ous adverse drug experiences (as de-
4 fined in section 505–1(b)) submitted
5 to the Secretary under paragraph (1),
6 and those adverse events submitted by
7 patients, providers, and drug spon-
8 sors, when appropriate;

9 “(III) to provide for active ad-
10 verse event surveillance using the fol-
11 lowing data sources, as available:

12 “(aa) Federal health-related
13 electronic data (such as data
14 from the Medicare program and
15 the health systems of the Depart-
16 ment of Veterans Affairs);

17 “(bb) private sector health-
18 related electronic data (such as
19 pharmaceutical purchase data
20 and health insurance claims
21 data); and

22 “(cc) other data as the Sec-
23 retary deems necessary to create
24 a robust system to identify ad-

1 verse events and potential drug
2 safety signals;

3 “(IV) to identify certain trends
4 and patterns with respect to data
5 accessed by the system;

6 “(V) to provide regular reports to
7 the Secretary concerning adverse
8 event trends, adverse event patterns,
9 incidence and prevalence of adverse
10 events, and other information the Sec-
11 retary determines appropriate, which
12 may include data on comparative na-
13 tional adverse event trends; and

14 “(VI) to enable the program to
15 export data in a form appropriate for
16 further aggregation, statistical anal-
17 ysis, and reporting.

18 “(ii) TIMELINESS OF REPORTING.—

19 The procedures established under clause (i)
20 shall ensure that such data are accessed,
21 analyzed, and reported in a timely, routine,
22 and systematic manner, taking into consid-
23 eration the need for data completeness,
24 coding, cleansing, and standardized anal-
25 ysis and transmission.

1 “(iii) PRIVATE SECTOR RESOURCES.—

2 To ensure the establishment of the active
3 postmarket risk identification and analysis
4 system under this subsection not later than
5 1 year after the development of the risk
6 identification and analysis methods under
7 subparagraph (B), as required under
8 clause (i), the Secretary may, on a tem-
9 porary or permanent basis, implement sys-
10 tems or products developed by private enti-
11 ties.

12 “(iv) COMPLEMENTARY AP-
13 PROACHES.—To the extent the active
14 postmarket risk identification and analysis
15 system under this subsection is not suffi-
16 cient to gather data and information rel-
17 evant to a priority drug safety question,
18 the Secretary shall develop, support, and
19 participate in complementary approaches
20 to gather and analyze such data and infor-
21 mation, including—

22 “(I) approaches that are com-
23 plementary with respect to assessing
24 the safety of use of a drug in domestic
25 populations not included, or underrep-

1 resented, in the trials used to approve
2 the drug (such as older people, people
3 with comorbidities, pregnant women,
4 or children); and

5 “(II) existing approaches such as
6 the Vaccine Adverse Event Reporting
7 System and the Vaccine Safety
8 Datalink or successor databases.

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

13 “(4) ADVANCED ANALYSIS OF DRUG SAFETY
14 DATA.—

15 “(A) PURPOSE.—The Secretary shall es-
16 tablish collaborations with public, academic,
17 and private entities, which may include the
18 Centers for Education and Research on Thera-
19 peutics under section 912 of the Public Health
20 Service Act, to provide for advanced analysis of
21 drug safety data described in paragraph (3)(C)
22 and other information that is publicly available
23 or is provided by the Secretary, in order to—

1 “(i) improve the quality and efficiency
2 of postmarket drug safety risk-benefit
3 analysis;

4 “(ii) provide the Secretary with rou-
5 tine access to outside expertise to study
6 advanced drug safety questions; and

7 “(iii) enhance the ability of the Sec-
8 retary to make timely assessments based
9 on drug safety data.

10 “(B) PRIVACY.—Such analysis shall not
11 disclose individually identifiable health informa-
12 tion when presenting such drug safety signals
13 and trends or when responding to inquiries re-
14 garding such drug safety signals and trends.

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

22 “(i) priority drug safety questions;
23 and

24 “(ii) mechanisms for answering such
25 questions, including through—

1 “(I) active risk identification
2 under paragraph (3); and

3 “(II) when such risk identifica-
4 tion is not sufficient, postapproval
5 studies and clinical trials under sub-
6 section (o)(3).

7 “(D) PROCEDURES FOR THE DEVELOP-
8 MENT OF DRUG SAFETY COLLABORATIONS.—

9 “(i) IN GENERAL.—Not later than
10 180 days after the date of the establish-
11 ment of the active postmarket risk identi-
12 fication and analysis system under this
13 subsection, the Secretary shall establish
14 and implement procedures under which the
15 Secretary may routinely contract with one
16 or more qualified entities to—

17 “(I) classify, analyze, or aggre-
18 gate data described in paragraph
19 (3)(C) and information that is pub-
20 licly available or is provided by the
21 Secretary;

22 “(II) allow for prompt investiga-
23 tion of priority drug safety questions,
24 including—

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

4 “(bb) for a newly-approved
5 drugs, safety signals from clinical
6 trials used to approve the drug
7 and other preapproval trials;
8 rare, serious drug side effects;
9 and the safety of use in domestic
10 populations not included, or
11 underrepresented, in the trials
12 used to approve the drug (such
13 as older people, people with
14 comorbidities, pregnant women,
15 or children);

16 “(III) perform advanced research
17 and analysis on identified drug safety
18 risks;

19 “(IV) focus postapproval studies
20 and clinical trials under subsection
21 (o)(3) more effectively on cases for
22 which reports under paragraph (1)
23 and other safety signal detection is
24 not sufficient to resolve whether there
25 is an elevated risk of a serious adverse

1 event associated with the use of a
2 drug; and

3 “(V) carry out other activities as
4 the Secretary deems necessary to
5 carry out the purposes of this para-
6 graph.

7 “(ii) REQUEST FOR SPECIFIC METH-
8 ODOLOGY.—The procedures described in
9 clause (i) shall permit the Secretary to re-
10 quest that a specific methodology be used
11 by the qualified entity. The qualified entity
12 shall work with the Secretary to finalize
13 the methodology to be used.

14 “(E) USE OF ANALYSES.—The Secretary
15 shall provide the analyses described in this
16 paragraph, including the methods and results of
17 such analyses, about a drug to the sponsor or
18 sponsors of such drug.

19 “(F) QUALIFIED ENTITIES.—

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

1 “(ii) QUALIFICATION.—The Secretary
2 shall enter into a contract with an entity
3 under clause (i) only if the Secretary deter-
4 mines that the entity has a significant
5 presence in the United States and has one
6 or more of the following qualifications:

7 “(I) The research, statistical, epi-
8 demiologic, or clinical capability and
9 expertise to conduct and complete the
10 activities under this paragraph, in-
11 cluding the capability and expertise to
12 provide the Secretary de-identified
13 data consistent with the requirements
14 of this subsection.

15 “(II) An information technology
16 infrastructure in place to support elec-
17 tronic data and operational standards
18 to provide security for such data.

19 “(III) Experience with, and ex-
20 pertise on, the development of drug
21 safety and effectiveness research using
22 electronic population data.

23 “(IV) An understanding of drug
24 development or risk/benefit balancing
25 in a clinical setting.

1 “(V) Other expertise which the
2 Secretary deems necessary to fulfill
3 the activities under this paragraph.

4 “(G) CONTRACT REQUIREMENTS.—Each
5 contract with a qualified entity under subpara-
6 graph (F)(i) shall contain the following require-
7 ments:

8 “(i) ENSURING PRIVACY.—The quali-
9 fied entity shall ensure that the entity will
10 not use data under this subsection in a
11 manner that—

12 “(I) violates the regulations pro-
13 mulgated under section 264(c) of the
14 Health Insurance Portability and Ac-
15 countability Act of 1996;

16 “(II) violates sections 552 or
17 552a of title 5, United States Code,
18 with regard to the privacy of individ-
19 ually-identifiable beneficiary health in-
20 formation; or

21 “(III) discloses individually iden-
22 tifiable health information when pre-
23 senting drug safety signals and trends
24 or when responding to inquiries re-

1 garding drug safety signals and
2 trends.

3 Nothing in this clause prohibits lawful dis-
4 closure for other purposes.

5 “(ii) COMPONENT OF ANOTHER ORGA-
6 NIZATION.—If a qualified entity is a com-
7 ponent of another organization—

8 “(I) the qualified entity shall es-
9 tablish appropriate security measures
10 to maintain the confidentiality and
11 privacy of such data; and

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

17 “(iii) TERMINATION OR NON-
18 RENEWAL.—If a contract with a qualified
19 entity under this subparagraph is termi-
20 nated or not renewed, the following re-
21 quirements shall apply:

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

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

3 “(II) DISPOSITION OF DATA.—

4 The entity shall return any data dis-
5 closed to such entity under this sub-
6 section to which it would not other-
7 wise have access or, if returning the
8 data is not practicable, destroy the
9 data.

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

15 “(I) REVIEW OF CONTRACT IN THE EVENT
16 OF A MERGER OR ACQUISITION.—The Secretary
17 shall review the contract with a qualified entity
18 under this paragraph in the event of a merger
19 or acquisition of the entity in order to ensure
20 that the requirements under this paragraph will
21 continue to be met.

22 “(J) COORDINATION.—In carrying out this
23 paragraph, the Secretary shall provide for ap-
24 propriate communications to the public, sci-
25 entific, public health, and medical communities,

1 and other key stakeholders, and to the extent
2 practicable shall coordinate with the activities
3 of private entities, professional associations, or
4 other entities that may have sources of drug
5 safety data.”.

6 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
7 tion or the amendment made by this section shall be con-
8 strued to prohibit the lawful disclosure or use of data or
9 information by an entity other than as described in para-
10 graph (4)(B) or (4)(G) of section 505(k) of the Federal
11 Food, Drug, and Cosmetic Act, as added by subsection
12 (a).

13 (c) REPORT TO CONGRESS.—Not later than 4 years
14 after the date of the enactment of this Act, the Secretary
15 shall report to the Congress on the ways in which the Sec-
16 retary has used the active postmarket risk identification
17 and analysis system described in paragraphs (3) and (4)
18 of section 505(k) of the Federal Food, Drug, and Cos-
19 metic Act, as added by subsection (a), to identify specific
20 drug safety signals and to better understand the outcomes
21 associated with drugs marketed in the United States.

22 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
23 out activities under the amendment made by this section
24 for which funds are made available under section 736 of
25 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 379h), there are authorized to be appropriated to carry
2 out the amendment made by this section, in addition to
3 such funds, \$25,000,000 for each of fiscal years 2008
4 through 2012.

5 (e) GAO REPORT.—Not later than 18 months after
6 the date of the enactment of this Act, the Comptroller
7 General of the United States shall evaluate data privacy,
8 confidentiality, and security issues relating to accessing,
9 transmitting, and maintaining data for the active
10 postmarket risk identification and analysis system de-
11 scribed in paragraphs (3) and (4) of section 505(k) of the
12 Federal Food, Drug, and Cosmetic Act, as added by sub-
13 section (a), and make recommendations to the Committee
14 on Energy and Commerce of the House of Representatives
15 and the Committee on Health, Education, Labor and Pen-
16 sions of the Senate, and any other congressional commit-
17 tees of relevant jurisdiction, regarding the need for any
18 additional legislative or regulatory actions to ensure pri-
19 vacy, confidentiality, and security of this data or otherwise
20 address privacy, confidentiality, and security issues to en-
21 sure the effective operation of such active postmarket
22 identification and analysis system.

1 **SEC. 906. STATEMENT FOR INCLUSION IN DIRECT-TO-CON-**
2 **SUMER ADVERTISEMENTS OF DRUGS.**

3 (a) PUBLISHED DIRECT-TO-CONSUMER ADVERTISE-
4 MENTS.—Section 502(n) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 352), as amended by section
6 901(d)(6), is further amended by inserting “and in the
7 case of published direct-to-consumer advertisements the
8 following statement printed in conspicuous text: ‘You are
9 encouraged to report negative side effects of prescription
10 drugs to the FDA. Visit www.fda.gov/medwatch, or call
11 1-800-FDA-1088.’,” after “section 701(a),”.

12 (b) STUDY.—

13 (1) IN GENERAL.—In the case of direct-to-con-
14 sumer television advertisements, the Secretary of
15 Health and Human Services, in consultation with
16 the Advisory Committee on Risk Communication
17 under section 567 of the Federal Food, Drug, and
18 Cosmetic Act (as added by section 917), shall, not
19 later than 6 months after the date of the enactment
20 of this Act, conduct a study to determine if the
21 statement in section 502(n) of such Act (as added
22 by subsection (a)) required with respect to published
23 direct-to-consumer advertisements is appropriate for
24 inclusion in such television advertisements.

25 (2) CONTENT.—As part of the study under
26 paragraph (1), such Secretary shall consider whether

1 the information in the statement described in para-
2 graph (1) would detract from the presentation of
3 risk information in a direct-to-consumer television
4 advertisement. If such Secretary determines the in-
5 clusion of such statement is appropriate in direct-to-
6 consumer television advertisements, such Secretary
7 shall issue regulations requiring the implementation
8 of such statement in direct-to-consumer television
9 advertisements, including determining a reasonable
10 length of time for displaying the statement in such
11 advertisements. The Secretary shall report to the ap-
12 propriate committees of Congress the findings of
13 such study and any plans to issue regulations under
14 this paragraph.

15 **SEC. 907. NO EFFECT ON VETERINARY MEDICINE.**

16 This subtitle, and the amendments made by this sub-
17 title, shall have no effect on the use of drugs approved
18 under section 505 of the Federal Food, Drug, and Cos-
19 metic Act by, or on the lawful written or oral order of,
20 a licensed veterinarian within the context of a veteri-
21 narian-client-patient relationship, as provided for under
22 section 512(a)(5) of such Act.

23 **SEC. 908. AUTHORIZATION OF APPROPRIATIONS.**

24 (a) IN GENERAL.—For carrying out this subtitle and
25 the amendments made by this subtitle, there is authorized

1 to be appropriated \$25,000,000 for each of fiscal years
2 2008 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 subtitle
6 and the amendments made by this subtitle.

7 **SEC. 909. EFFECTIVE DATE AND APPLICABILITY.**

8 (a) EFFECTIVE DATE.—This subtitle takes effect
9 180 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) (referred to in
18 this section as the “Act”) if there are in effect on
19 the effective date of this Act elements to assure safe
20 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 timetable
5 required under section 505-1(d) and any addi-
6 tional elements under subsections (e) and (f) of
7 such section in effect for such drug on the ef-
8 fective date of this Act; and

9 (B) is subject to enforcement by the Sec-
10 retary to the same extent as any other risk
11 evaluation and mitigation strategy under sec-
12 tion 505–1 of the Act, except that sections
13 303(f)(4) and 502(y) and (z) of the Act (as
14 added by section 902) shall not apply to such
15 strategy before the Secretary has completed re-
16 view of, and acted on, the first assessment of
17 such strategy under such section 505-1.

18 (3) SUBMISSION.—Not later than 180 days
19 after the effective date of this Act, the holder of an
20 approved application for which a risk evaluation and
21 mitigation strategy is deemed to be in effect under
22 paragraph (1) shall submit to the Secretary a pro-
23 posed risk evaluation and mitigation strategy. Such
24 proposed strategy is subject to section 505–1 of the

1 Act as if included in such application at the time of
2 submission of the application to the Secretary.

3 **Subtitle B—Other Provisions to En-**
4 **sure Drug Safety and Surveil-**
5 **lance**

6 **SEC. 911. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC**
7 **DRUGS.**

8 Chapter V of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 351 et seq.) is amended by inserting after
10 section 510 the following:

11 **“SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC**
12 **DRUGS.**

13 “(a) IN GENERAL.—Not later than 1 year after the
14 date of the enactment of this section, the Secretary shall
15 issue guidance for the conduct of clinical trials with re-
16 spect to antibiotic drugs, including antimicrobials to treat
17 acute bacterial sinusitis, acute bacterial otitis media, and
18 acute bacterial exacerbation of chronic bronchitis. Such
19 guidance shall indicate the appropriate models and valid
20 surrogate markers.

21 “(b) REVIEW.—Not later than 5 years after the date
22 of the enactment of this section, the Secretary shall review
23 and update the guidance described under subsection (a)
24 to reflect developments in scientific and medical informa-
25 tion and technology.”.

1 **SEC. 912. PROHIBITION AGAINST FOOD TO WHICH DRUGS**
2 **OR BIOLOGICAL PRODUCTS HAVE BEEN**
3 **ADDED.**

4 (a) PROHIBITION.—Section 301 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 331), as amended by
6 section 901(d), is amended by adding at the end the fol-
7 lowing:

8 “(1) The introduction or delivery for introduction
9 into interstate commerce of any food to which has been
10 added a drug approved under section 505, a biological
11 product licensed under section 351 of the Public Health
12 Service Act, or a drug or a biological product for which
13 substantial clinical investigations have been instituted and
14 for which the existence of such investigations has been
15 made public, unless—

16 “(1) such drug or such biological product was
17 marketed in food before any approval of the drug
18 under section 505, before licensure of the biological
19 product under such section 351, and before any sub-
20 stantial clinical investigations involving the drug or
21 the biological product have been instituted;

22 “(2) the Secretary, in the Secretary’s discre-
23 tion, has issued a regulation, after notice and com-
24 ment, approving the use of such drug or such bio-
25 logical product in the food;

1 “(3) the use of the drug or the biological prod-
2 uct in the food is to enhance the safety of the food
3 to which the drug or the biological product is added
4 or applied and not to have independent biological or
5 therapeutic effects on humans, and the use is in con-
6 formity with—

7 “(A) a regulation issued under section 409
8 prescribing conditions of safe use in food;

9 “(B) a regulation listing or affirming con-
10 ditions under which the use of the drug or the
11 biological product in food is generally recog-
12 nized as safe;

13 “(C) the conditions of use identified in a
14 notification to the Secretary of a claim of ex-
15 emption from the premarket approval require-
16 ments for food additives based on the notifier’s
17 determination that the use of the drug or the
18 biological product in food is generally recog-
19 nized as safe, provided that the Secretary has
20 not questioned the general recognition of safety
21 determination in a letter to the notifier;

22 “(D) a food contact substance notification
23 that is effective under section 409(h); or

24 “(E) such drug or biological product had
25 been marketed for smoking cessation prior to

1 the date of the enactment of the Food and
2 Drug Administration Amendments Act of 2007;
3 or
4 “(4) the drug is a new animal drug whose use
5 is not unsafe under section 512.”.

6 (b) CONFORMING CHANGES.—The Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amend-
8 ed—

9 (1) in section 304(a)(1), by striking “section
10 404 or 505” and inserting “section 301(ll), 404, or
11 505”; and

12 (2) in section 801(a), by striking “is adulter-
13 ated, misbranded, or in violation of section 505,”
14 and inserting “is adulterated, misbranded, or in vio-
15 lation of section 505, or prohibited from introduction
16 or delivery for introduction into interstate commerce
17 under section 301(ll),”.

18 **SEC. 913. ASSURING PHARMACEUTICAL SAFETY.**

19 Chapter V of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 351 et seq.), as amended in section 403,
21 is amended by inserting after section 505C the following:

22 **“SEC. 505D. PHARMACEUTICAL SECURITY.**

23 “(a) IN GENERAL.—The Secretary shall develop
24 standards and identify and validate effective technologies
25 for the purpose of securing the drug supply chain against

1 counterfeit, diverted, subpotent, substandard, adulterated,
2 misbranded, or expired drugs.

3 “(b) STANDARDS DEVELOPMENT.—

4 “(1) IN GENERAL.—The Secretary shall, in con-
5 sultation with the agencies specified in paragraph
6 (4), manufacturers, distributors, pharmacies, and
7 other supply chain stakeholders, prioritize and de-
8 velop standards for the identification, validation, au-
9 thentication, and tracking and tracing of prescrip-
10 tion drugs.

11 “(2) STANDARDIZED NUMERAL IDENTIFIER.—

12 Not later than 30 months after the date of the en-
13 actment of the Food and Drug Administration
14 Amendments Act of 2007, the Secretary shall de-
15 velop a standardized numerical identifier (which, to
16 the extent practicable, shall be harmonized with
17 international consensus standards for such an identi-
18 fier) to be applied to a prescription drug at the point
19 of manufacturing and repackaging (in which case
20 the numerical identifier shall be linked to the numer-
21 ical identifier applied at the point of manufacturing)
22 at the package or pallet level, sufficient to facilitate
23 the identification, validation, authentication, and
24 tracking and tracing of the prescription drug.

1 “(3) PROMISING TECHNOLOGIES.—The stand-
2 ards developed under this subsection shall address
3 promising technologies, which may include—

4 “(A) radio frequency identification tech-
5 nology;

6 “(B) nanotechnology;

7 “(C) encryption technologies; and

8 “(D) other track-and-trace or authentica-
9 tion technologies.

10 “(4) INTERAGENCY COLLABORATION.—In car-
11 rying out this subsection, the Secretary shall consult
12 with Federal health and security agencies, includ-
13 ing—

14 “(A) the Department of Justice;

15 “(B) the Department of Homeland Secu-
16 rity;

17 “(C) the Department of Commerce; and

18 “(D) other appropriate Federal and State
19 agencies.

20 “(c) INSPECTION AND ENFORCEMENT.—

21 “(1) IN GENERAL.—The Secretary shall expand
22 and enhance the resources and facilities of agency
23 components of the Food and Drug Administration
24 involved with regulatory and criminal enforcement of
25 this Act to secure the drug supply chain against

1 counterfeit, diverted, subpotent, substandard, adul-
2 terated, misbranded, or expired drugs including bio-
3 logical products and active pharmaceutical ingredi-
4 ents from domestic and foreign sources.

5 “(2) ACTIVITIES.—The Secretary shall under-
6 take enhanced and joint enforcement activities with
7 other Federal and State agencies, and establish re-
8 gional capacities for the validation of prescription
9 drugs and the inspection of the prescription drug
10 supply chain.

11 “(d) DEFINITION.—In this section, the term ‘pre-
12 scription drug’ means a drug subject to section
13 503(b)(1).”.

14 **SEC. 914. CITIZEN PETITIONS AND PETITIONS FOR STAY OF**
15 **AGENCY ACTION.**

16 (a) IN GENERAL.—Section 505 of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
18 section 901(a), is amended by adding at the end the fol-
19 lowing:

20 “(q) PETITIONS AND CIVIL ACTIONS REGARDING AP-
21 PROVAL OF CERTAIN APPLICATIONS.—

22 “(1) IN GENERAL.—

23 “(A) DETERMINATION.—The Secretary
24 shall not delay approval of a pending applica-
25 tion submitted under subsection (b)(2) or (j)

1 because of any request to take any form of ac-
2 tion relating to the application, either before or
3 during consideration of the request, unless—

4 “(i) the request is in writing and is a
5 petition submitted to the Secretary pursu-
6 ant to section 10.30 or 10.35 of title 21,
7 Code of Federal Regulations (or any suc-
8 cessor regulations); and

9 “(ii) the Secretary determines, upon
10 reviewing the petition, that a delay is nec-
11 essary to protect the public health.

12 “(B) NOTIFICATION.—If the Secretary de-
13 termines under subparagraph (A) that a delay
14 is necessary with respect to an application, the
15 Secretary shall provide to the applicant, not
16 later than 30 days after making such deter-
17 mination, the following information:

18 “(i) Notification of the fact that a de-
19 termination under subparagraph (A) has
20 been made.

21 “(ii) If applicable, any clarification or
22 additional data that the applicant should
23 submit to the docket on the petition to
24 allow the Secretary to review the petition
25 promptly.

1 “(iii) A brief summary of the specific
2 substantive issues raised in the petition
3 which form the basis of the determination.

4 “(C) FORMAT.—The information described
5 in subparagraph (B) shall be conveyed via ei-
6 ther, at the discretion of the Secretary—

7 “(i) a document; or

8 “(ii) a meeting with the applicant in-
9 volved.

10 “(D) PUBLIC DISCLOSURE.—Any informa-
11 tion conveyed by the Secretary under subpara-
12 graph (C) shall be considered part of the appli-
13 cation and shall be subject to the disclosure re-
14 quirements applicable to information in such
15 application.

16 “(E) DENIAL BASED ON INTENT TO
17 DELAY.—If the Secretary determines that a pe-
18 tition or a supplement to the petition was sub-
19 mitted with the primary purpose of delaying the
20 approval of an application and the petition does
21 not on its face raise valid scientific or regu-
22 latory issues, the Secretary may deny the peti-
23 tion at any point based on such determination.
24 The Secretary may issue guidance to describe
25 the factors that will be used to determine under

1 this subparagraph whether a petition is sub-
2 mitted with the primary purpose of delaying the
3 approval of an application.

4 “(F) FINAL AGENCY ACTION.—The Sec-
5 retary shall take final agency action on a peti-
6 tion not later than 180 days after the date on
7 which the petition is submitted. The Secretary
8 shall not extend such period for any reason, in-
9 cluding—

10 “(i) any determination made under
11 subparagraph (A);

12 “(ii) the submission of comments re-
13 lating to the petition or supplemental in-
14 formation supplied by the petitioner; or

15 “(iii) the consent of the petitioner.

16 “(G) EXTENSION OF 30-MONTH PERIOD.—
17 If the filing of an application resulted in first-
18 applicant status under subsection
19 (j)(5)(D)(i)(IV) and approval of the application
20 was delayed because of a petition, the 30-month
21 period under such subsection is deemed to be
22 extended by a period of time equal to the period
23 beginning on the date on which the Secretary
24 received the petition and ending on the date of
25 final agency action on the petition (inclusive of

1 such beginning and ending dates), without re-
2 gard to whether the Secretary grants, in whole
3 or in part, or denies, in whole or in part, the
4 petition.

5 “(H) CERTIFICATION.—The Secretary
6 shall not consider a petition for review unless
7 the party submitting such petition does so in
8 written form and the subject document is
9 signed and contains the following certification:
10 ‘I certify that, to my best knowledge and belief:
11 (a) this petition includes all information and
12 views upon which the petition relies; (b) this pe-
13 tition includes representative data and/or infor-
14 mation known to the petitioner which are unfa-
15 vorable to the petition; and (c) I have taken
16 reasonable steps to ensure that any representa-
17 tive data and/or information which are unfavor-
18 able to the petition were disclosed to me. I fur-
19 ther certify that the information upon which I
20 have based the action requested herein first be-
21 came known to the party on whose behalf this
22 petition is submitted on or about the following
23 date: _____. If I received or
24 expect to receive payments, including cash and
25 other forms of consideration, to file this infor-

1 mation or its contents, I received or expect to
2 receive those payments from the following per-
3 sons or organizations:
4 _____. I verify under
5 penalty of perjury that the foregoing is true
6 and correct as of the date of the submission of
7 this petition.’, with the date on which such in-
8 formation first became known to such party
9 and the names of such persons or organizations
10 inserted in the first and second blank space, re-
11 spectively.

12 “(I) VERIFICATION.—The Secretary shall
13 not accept for review any supplemental informa-
14 tion or comments on a petition unless the party
15 submitting such information or comments does
16 so in written form and the subject document is
17 signed and contains the following verification: ‘I
18 certify that, to my best knowledge and belief:
19 (a) I have not intentionally delayed submission
20 of this document or its contents; and (b) the in-
21 formation upon which I have based the action
22 requested herein first became known to me on
23 or about _____. If I received
24 or expect to receive payments, including cash
25 and other forms of consideration, to file this in-

1 formation or its contents, I received or expect
2 to receive those payments from the following
3 persons or organizations: _____. I verify
4 under penalty of perjury that the foregoing is
5 true and correct as of the date of the submis-
6 sion of this petition.’, with the date on which
7 such information first became known to the
8 party and the names of such persons or organi-
9 zations inserted in the first and second blank
10 space, respectively.

11 “(2) EXHAUSTION OF ADMINISTRATIVE REM-
12 EDIES.—

13 “(A) FINAL AGENCY ACTION WITHIN 180
14 DAYS.—The Secretary shall be considered to
15 have taken final agency action on a petition
16 if—

17 “(i) during the 180-day period re-
18 ferred to in paragraph (1)(F), the Sec-
19 retary makes a final decision within the
20 meaning of section 10.45(d) of title 21,
21 Code of Federal Regulations (or any suc-
22 cessor regulation); or

23 “(ii) such period expires without the
24 Secretary having made such a final deci-
25 sion.

1 “(B) DISMISSAL OF CERTAIN CIVIL AC-
2 TIONS.—If a civil action is filed against the
3 Secretary with respect to any issue raised in the
4 petition before the Secretary has taken final
5 agency action on the petition within the mean-
6 ing of subparagraph (A), the court shall dismiss
7 without prejudice the action for failure to ex-
8 haust administrative remedies.

9 “(C) ADMINISTRATIVE RECORD.—For pur-
10 poses of judicial review related to the approval
11 of an application for which a petition under
12 paragraph (1) was submitted, the administra-
13 tive record regarding any issue raised by the
14 petition shall include—

15 “(i) the petition filed under paragraph
16 (1) and any supplements and comments
17 thereto;

18 “(ii) the Secretary’s response to such
19 petition, if issued; and

20 “(iii) other information, as designated
21 by the Secretary, related to the Secretary’s
22 determinations regarding the issues raised
23 in such petition, as long as the information
24 was considered by the agency no later than
25 the date of final agency action as defined

1 under subparagraph (2)(A), and regardless
2 of whether the Secretary responded to the
3 petition at or before the approval of the
4 application at issue in the petition.

5 “(3) ANNUAL REPORT ON DELAYS IN APPROV-
6 ALS PER PETITIONS.—The Secretary shall annually
7 submit to the Congress a report that specifies—

8 “(A) the number of applications that were
9 approved during the preceding 12-month pe-
10 riod;

11 “(B) the number of such applications
12 whose effective dates were delayed by petitions
13 referred to in paragraph (1) during such period;

14 “(C) the number of days by which such ap-
15 plications were so delayed; and

16 “(D) the number of such petitions that
17 were submitted during such period.

18 “(4) EXCEPTIONS.—This subsection does not
19 apply to—

20 “(A) a petition that relates solely to the
21 timing of the approval of an application pursu-
22 ant to subsection (j)(5)(B)(iv); or

23 “(B) a petition that is made by the spon-
24 sor of an application and that seeks only to
25 have the Secretary take or refrain from taking

1 any form of action with respect to that applica-
2 tion.

3 “(5) DEFINITIONS.—

4 “(A) APPLICATION.—For purposes of this
5 subsection, the term ‘application’ means an ap-
6 plication submitted under subsection (b)(2) or
7 (j).

8 “(B) PETITION.—For purposes of this
9 subsection, other than paragraph (1)(A)(i), the
10 term ‘petition’ means a request described in
11 paragraph (1)(A)(i).”.

12 (b) REPORT.—Not later than 1 year after the date
13 of the enactment of this Act, the Secretary of Health and
14 Human Services shall submit a report to the Congress on
15 ways to encourage the early submission of petitions under
16 section 505(q), as added by subsection (a).

17 **SEC. 915. POSTMARKET DRUG SAFETY INFORMATION FOR**
18 **PATIENTS AND PROVIDERS.**

19 Section 505 of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 355), as amended by section 914(a), is
21 amended by adding at the end the following:

22 “(r) POSTMARKET DRUG SAFETY INFORMATION FOR
23 PATIENTS AND PROVIDERS.—

24 “(1) ESTABLISHMENT.—Not later than 1 year
25 after the date of the enactment of the Food and

1 Drug Administration Amendments Act of 2007, the
2 Secretary shall improve the transparency of informa-
3 tion about drugs and allow patients and health care
4 providers better access to information about drugs
5 by developing and maintaining an Internet Web site
6 that—

7 “(A) provides links to drug safety informa-
8 tion listed in paragraph (2) for prescription
9 drugs that are approved under this section or li-
10 censed under section 351 of the Public Health
11 Service Act; and

12 “(B) improves communication of drug
13 safety information to patients and providers.

14 “(2) INTERNET WEB SITE.—The Secretary
15 shall carry out paragraph (1) by—

16 “(A) developing and maintaining an acces-
17 sible, consolidated Internet Web site with easily
18 searchable drug safety information, including
19 the information found on United States Govern-
20 ment Internet Web sites, such as the United
21 States National Library of Medicine’s Daily
22 Med and Medline Plus Web sites, in addition to
23 other such Web sites maintained by the Sec-
24 retary;

1 “(B) ensuring that the information pro-
2 vided on the Internet Web site is comprehensive
3 and includes, when available and appropriate—

4 “(i) patient labeling and patient pack-
5 aging inserts;

6 “(ii) a link to a list of each drug,
7 whether approved under this section or li-
8 censed under such section 351, for which
9 a Medication Guide, as provided for under
10 part 208 of title 21, Code of Federal Regu-
11 lations (or any successor regulations), is
12 required;

13 “(iii) a link to the registry and results
14 data bank provided for under subsections
15 (i) and (j) of section 402 of the Public
16 Health Service Act;

17 “(iv) the most recent safety informa-
18 tion and alerts issued by the Food and
19 Drug Administration for drugs approved
20 by the Secretary under this section, such
21 as product recalls, warning letters, and im-
22 port alerts;

23 “(v) publicly available information
24 about implemented RiskMAPs and risk

1 evaluation and mitigation strategies under
2 subsection (o);

3 “(vi) guidance documents and regula-
4 tions related to drug safety; and

5 “(vii) other material determined ap-
6 propriate by the Secretary;

7 “(C) providing access to summaries of the
8 assessed and aggregated data collected from the
9 active surveillance infrastructure under sub-
10 section (k)(3) to provide information of known
11 and serious side-effects for drugs approved
12 under this section or licensed under such sec-
13 tion 351;

14 “(D) preparing, by 18 months after ap-
15 proval of a drug or after use of the drug by
16 10,000 individuals, whichever is later, a sum-
17 mary analysis of the adverse drug reaction re-
18 ports received for the drug, including identifica-
19 tion of any new risks not previously identified,
20 potential new risks, or known risks reported in
21 unusual number;

22 “(E) enabling patients, providers, and
23 drug sponsors to submit adverse event reports
24 through the Internet Web site;

1 “(F) providing educational materials for
2 patients and providers about the appropriate
3 means of disposing of expired, damaged, or un-
4 usable medications; and

5 “(G) supporting initiatives that the Sec-
6 retary determines to be useful to fulfill the pur-
7 poses of the Internet Web site.

8 “(3) POSTING OF DRUG LABELING.—The Sec-
9 retary shall post on the Internet Web site estab-
10 lished under paragraph (1) the approved profes-
11 sional labeling and any required patient labeling of
12 a drug approved under this section or licensed under
13 such section 351 not later than 21 days after the
14 date the drug is approved or licensed, including in
15 a supplemental application with respect to a labeling
16 change.

17 “(4) PRIVATE SECTOR RESOURCES.—To ensure
18 development of the Internet Web site by the date de-
19 scribed in paragraph (1), the Secretary may, on a
20 temporary or permanent basis, implement systems
21 or products developed by private entities.

22 “(5) AUTHORITY FOR CONTRACTS.—The Sec-
23 retary may enter into contracts with public and pri-
24 vate entities to fulfill the requirements of this sub-
25 section.

1 “(6) REVIEW.—The Advisory Committee on
2 Risk Communication under section 567 shall, on a
3 regular basis, perform a comprehensive review and
4 evaluation of the types of risk communication infor-
5 mation provided on the Internet Web site established
6 under paragraph (1) and, through other means,
7 shall identify, clarify, and define the purposes and
8 types of information available to facilitate the effi-
9 cient flow of information to patients and providers,
10 and shall recommend ways for the Food and Drug
11 Administration to work with outside entities to help
12 facilitate the dispensing of risk communication infor-
13 mation to patients and providers.”.

14 **SEC. 916. ACTION PACKAGE FOR APPROVAL.**

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

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

20 (2) striking “(l) Safety and” and inserting
21 “(l)(1) Safety and”; and

22 (3) adding at the end the following:

23 “(2) ACTION PACKAGE FOR APPROVAL.—

24 “(A) ACTION PACKAGE.—The Secretary shall
25 publish the action package for approval of an appli-

1 cation under subsection (b) or section 351 of the
2 Public Health Service Act on the Internet Web site
3 of the Food and Drug Administration—

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

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

15 “(B) IMMEDIATE PUBLICATION OF SUMMARY
16 REVIEW.—Notwithstanding subparagraph (A), the
17 Secretary shall publish, on the Internet Web site of
18 the Food and Drug Administration, the materials
19 described in subparagraph (C)(iv) not later than 48
20 hours after the date of approval of the drug, except
21 where such materials require redaction by the Sec-
22 retary.

23 “(C) CONTENTS.—An action package for ap-
24 proval of an application under subparagraph (A)
25 shall be dated and shall include the following:

1 “(i) Documents generated by the Food and
2 Drug Administration related to review of the
3 application.

4 “(ii) Documents pertaining to the format
5 and content of the application generated during
6 drug development.

7 “(iii) Labeling submitted by the applicant.

8 “(iv) A summary review that documents
9 conclusions from all reviewing disciplines about
10 the drug, noting any critical issues and dis-
11 agreements with the applicant and within the
12 review team and how they were resolved, rec-
13 ommendations for action, and an explanation of
14 any nonconcurrence with review conclusions.

15 “(v) The Division Document and Office
16 Director’s decision document which includes—

17 “(I) a brief statement of concurrence
18 with the summary review;

19 “(II) a separate review or addendum
20 to the review if disagreeing with the sum-
21 mary review; and

22 “(III) a separate review or addendum
23 to the review to add further analysis.

1 “(vi) Identification by name of each officer
2 or employee of the Food and Drug Administra-
3 tion who—

4 “(I) participated in the decision to ap-
5 prove the application; and

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

8 “(D) REVIEW.—A scientific review of an appli-
9 cation is considered the work of the reviewer and
10 shall not be altered by management or the reviewer
11 once final.

12 “(E) CONFIDENTIAL INFORMATION.—This
13 paragraph does not authorize the disclosure of any
14 trade secret, confidential commercial or financial in-
15 formation, or other matter listed in section 552(b)
16 of title 5, United States Code.”.

17 **SEC. 917. RISK COMMUNICATION.**

18 Subchapter E of chapter V of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as
20 amended by section 603, is amended by adding at the end
21 the following:

22 **“SEC. 567. RISK COMMUNICATION.**

23 “(a) ADVISORY COMMITTEE ON RISK COMMUNICA-
24 TION.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish an advisory committee to be known as the ‘Advi-
3 sory Committee on Risk Communication’ (referred
4 to in this section as the ‘Committee’).

5 “(2) DUTIES OF COMMITTEE.—The Committee
6 shall advise the Commissioner on methods to effec-
7 tively communicate risks associated with the prod-
8 ucts regulated by the Food and Drug Administra-
9 tion.

10 “(3) MEMBERS.—The Secretary shall ensure
11 that the Committee is composed of experts on risk
12 communication, experts on the risks described in
13 subsection (b), and representatives of patient, con-
14 sumer, and health professional organizations.

15 “(4) PERMANENCE OF COMMITTEE.—Section
16 14 of the Federal Advisory Committee Act shall not
17 apply to the Committee established under this sub-
18 section.

19 “(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

20 “(1) IN GENERAL.—The Secretary shall partner
21 with professional medical societies, medical schools,
22 academic medical centers, and other stakeholders to
23 develop robust and multi-faceted systems for com-
24 munication to health care providers about emerging
25 postmarket drug risks.

1 “(2) PARTNERSHIPS.—The systems developed
2 under paragraph (1) shall—

3 “(A) account for the diversity among phy-
4 sicians in terms of practice, willingness to adopt
5 technology, and medical specialty; and

6 “(B) include the use of existing commu-
7 nication channels, including electronic commu-
8 nications, in place at the Food and Drug Ad-
9 ministration.”.

10 **SEC. 918. REFERRAL TO ADVISORY COMMITTEE.**

11 Section 505 of the Federal Food, Drug, and Cosmetic
12 Act, as amended by section 915, is further amended by
13 adding at the end the following:

14 “(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to
15 the approval of a drug no active ingredient (including any
16 ester or salt of the active ingredient) of which has been
17 approved in any other application under this section or
18 section 351 of the Public Health Service Act, the Sec-
19 retary shall—

20 “(1) refer such drug to a Food and Drug Ad-
21 ministration advisory committee for review at a
22 meeting of such advisory committee; or

23 “(2) if the Secretary does not refer such a drug
24 to a Food and Drug Administration advisory com-
25 mittee prior to the approval of the drug, provide in

1 the action letter on the application for the drug a
2 summary of the reasons why the Secretary did not
3 refer the drug to an advisory committee prior to ap-
4 proval.”.

5 **SEC. 919. RESPONSE TO THE INSTITUTE OF MEDICINE.**

6 (a) IN GENERAL.—Not later than 1 year after the
7 date of the enactment of this title, the Secretary shall
8 issue a report responding to the 2006 report of the Insti-
9 tute of Medicine entitled “The Future of Drug Safety—
10 Promoting and Protecting the Health of the Public”.

11 (b) CONTENT OF REPORT.—The report issued by the
12 Secretary under subsection (a) shall include—

13 (1) an update on the implementation by the
14 Food and Drug Administration of its plan to re-
15 spond to the Institute of Medicine report described
16 under such subsection; and

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

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

21 (B) the requirement under section 505–
22 1(c)(2) of the Federal Food, Drug, and Cos-
23 metic Act (as added by this title), that the ap-
24 propriate office responsible for reviewing a drug
25 and the office responsible for postapproval safe-

1 ty with respect to the drug work together to as-
2 sess, implement, and ensure compliance with
3 the requirements of such section 505–1.

4 **SEC. 920. DATABASE FOR AUTHORIZED GENERIC DRUGS.**

5 Section 505 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355), as amended by section 918, is fur-
7 ther amended by adding at the end the following:

8 “(t) DATABASE FOR AUTHORIZED GENERIC
9 DRUGS.—

10 “(1) IN GENERAL.—

11 “(A) PUBLICATION.—The Commissioner
12 shall—

13 “(i) not later than 9 months after the
14 date of the enactment of the Food and
15 Drug Administration Amendments Act of
16 2007, publish a complete list on the Inter-
17 net Web site of the Food and Drug Admin-
18 istration of all authorized generic drugs
19 (including drug trade name, brand com-
20 pany manufacturer, and the date the au-
21 thorized generic drug entered the market);
22 and

23 “(ii) update the list quarterly to in-
24 clude each authorized generic drug in-
25 cluded in an annual report submitted to

1 the Secretary by the sponsor of a listed
2 drug during the preceding 3-month period.

3 “(B) NOTIFICATION.—The Commissioner
4 shall notify relevant Federal agencies, including
5 the Centers for Medicare & Medicaid Services
6 and the Federal Trade Commission, when the
7 Commissioner first publishes the information
8 described in subparagraph (A) that the infor-
9 mation has been published and that the infor-
10 mation will be updated quarterly.

11 “(2) INCLUSION.—The Commissioner shall in-
12 clude in the list described in paragraph (1) each au-
13 thorized generic drug included in an annual report
14 submitted to the Secretary by the sponsor of a listed
15 drug after January 1, 1999.

16 “(3) AUTHORIZED GENERIC DRUG.—In this
17 section, the term ‘authorized generic drug’ means a
18 listed drug (as that term is used in subsection (j))
19 that—

20 “(A) has been approved under subsection
21 (c); and

22 “(B) is marketed, sold, or distributed di-
23 rectly or indirectly to retail class of trade under
24 a different labeling, packaging (other than re-
25 packaging as the listed drug in blister packs,

1 unit doses, or similar packaging for use in insti-
2 tutions), product code, labeler code, trade name,
3 or trade mark than the listed drug.”.

4 **SEC. 921. ADVERSE DRUG REACTION REPORTS AND**
5 **POSTMARKET SAFETY.**

6 Subsection (k) of section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
8 section 905, is amended by adding at the end the fol-
9 lowing:

10 “(5) The Secretary shall—

11 “(A) conduct regular, bi-weekly screening
12 of the Adverse Event Reporting System data-
13 base and post a quarterly report on the Adverse
14 Event Reporting System Web site of any new
15 safety information or potential signal of a seri-
16 ous risk identified by Adverse Event Reporting
17 System within the last quarter;

18 “(B) report to Congress not later than 2
19 year after the date of the enactment of the
20 Food and Drug Administration Amendments
21 Act of 2007 on procedures and processes of the
22 Food and Drug Administration for addressing
23 ongoing post market safety issues identified by
24 the Office of Surveillance and Epidemiology and
25 how recommendations of the Office of Surveil-

1 lance and Epidemiology are handled within the
2 agency; and

3 “(C) on an annual basis, review the entire
4 backlog of postmarket safety commitments to
5 determine which commitments require revision
6 or should be eliminated, report to the Congress
7 on these determinations, and assign start dates
8 and estimated completion dates for such com-
9 mitments.”.

10 **TITLE X—FOOD SAFETY**

11 **SEC. 1001. FINDINGS.**

12 Congress finds that—

13 (1) the safety and integrity of the United
14 States food supply are vital to public health, to pub-
15 lic confidence in the food supply, and to the success
16 of the food sector of the Nation’s economy;

17 (2) illnesses and deaths of individuals and com-
18 panion animals caused by contaminated food—

19 (A) have contributed to a loss of public
20 confidence in food safety; and

21 (B) have caused significant economic losses
22 to manufacturers and producers not responsible
23 for contaminated food items;

1 (3) the task of preserving the safety of the food
2 supply of the United States faces tremendous pres-
3 sures with regard to—

4 (A) emerging pathogens and other con-
5 taminants and the ability to detect all forms of
6 contamination;

7 (B) an increasing volume of imported food
8 from a wide variety of countries; and

9 (C) a shortage of adequate resources for
10 monitoring and inspection;

11 (4) according to the Economic Research Service
12 of the Department of Agriculture, the United States
13 is increasing the amount of food that it imports such
14 that—

15 (A) from 2003 to 2007, the value of food
16 imports has increased from \$45,600,000,000 to
17 \$64,000,000,000; and

18 (B) imported food accounts for 13 percent
19 of the average American diet including 31 per-
20 cent of fruits, juices, and nuts, 9.5 percent of
21 red meat, and 78.6 percent of fish and shellfish;
22 and

23 (5) the number of full-time equivalent Food and
24 Drug Administration employees conducting inspec-
25 tions has decreased from 2003 to 2007.

1 **SEC. 1002. ENSURING THE SAFETY OF PET FOOD.**

2 (a) PROCESSING AND INGREDIENT STANDARDS.—

3 Not later than 2 years after the date of the enactment
4 of this Act, the Secretary of Health and Human Services
5 (referred to in this title as the “Secretary”), in consulta-
6 tion with the Association of American Feed Control Offi-
7 cials and other relevant stakeholder groups, including vet-
8 erinary medical associations, animal health organizations,
9 and pet food manufacturers, shall by regulation estab-
10 lish—

11 (1) ingredient standards and definitions with
12 respect to pet food;

13 (2) processing standards for pet food; and

14 (3) updated standards for the labeling of pet
15 food that include nutritional and ingredient informa-
16 tion.

17 (b) EARLY WARNING SURVEILLANCE SYSTEMS AND

18 NOTIFICATION DURING PET FOOD RECALLS.—Not later

19 than 1 year after the date of the enactment of this Act,
20 the Secretary shall establish an early warning and surveil-
21 lance system to identify adulteration of the pet food supply
22 and outbreaks of illness associated with pet food. In estab-
23 lishing such system, the Secretary shall—

24 (1) consider using surveillance and monitoring
25 mechanisms similar to, or in coordination with, those
26 used to monitor human or animal health, such as

1 the Foodborne Diseases Active Surveillance Network
2 (FoodNet) and PulseNet of the Centers for Disease
3 Control and Prevention, the Food Emergency Re-
4 sponse Network of the Food and Drug Administra-
5 tion and the Department of Agriculture, and the
6 National Animal Health Laboratory Network of the
7 Department of Agriculture;

8 (2) consult with relevant professional associa-
9 tions and private sector veterinary hospitals;

10 (3) work with the National Companion Animal
11 Surveillance Program, the Health Alert Network, or
12 other notification networks as appropriate to inform
13 veterinarians and relevant stakeholders during any
14 recall of pet food; and

15 (4) use such information and conduct such
16 other activities as the Secretary deems appropriate.

17 **SEC. 1003. ENSURING EFFICIENT AND EFFECTIVE COMMU-**
18 **NICATIONS DURING A RECALL.**

19 The Secretary shall, during an ongoing recall of
20 human or pet food regulated by the Secretary—

21 (1) work with companies, relevant professional
22 associations, and other organizations to collect and
23 aggregate information pertaining to the recall;

24 (2) use existing networks of communication, in-
25 cluding electronic forms of information dissemina-

1 tion, to enhance the quality and speed of commu-
2 nication with the public; and

3 (3) post information regarding recalled human
4 and pet foods on the Internet Web site of the Food
5 and Drug Administration in a single location, which
6 shall include a searchable database of recalled
7 human foods and a searchable database of recalled
8 pet foods, that is easily accessed and understood by
9 the public.

10 **SEC. 1004. STATE AND FEDERAL COOPERATION.**

11 (a) IN GENERAL.—The Secretary shall work with the
12 States in undertaking activities and programs that assist
13 in improving the safety of food, including fresh and proc-
14 essed produce, so that State food safety programs and ac-
15 tivities conducted by the Secretary function in a coordi-
16 nated and cost-effective manner. With the assistance pro-
17 vided under subsection (b), the Secretary shall encourage
18 States to—

19 (1) establish, continue, or strengthen State food
20 safety programs, especially with respect to the regu-
21 lation of retail commercial food establishments; and

22 (2) establish procedures and requirements for
23 ensuring that processed produce under the jurisdic-
24 tion of State food safety programs is not unsafe for
25 human consumption.

1 (b) ASSISTANCE.—The Secretary may provide to a
2 State, for planning, developing, and implementing such a
3 food safety program—

4 (1) advisory assistance;

5 (2) technical assistance, training, and labora-
6 tory assistance (including necessary materials and
7 equipment); and

8 (3) financial and other assistance.

9 (c) SERVICE AGREEMENTS.—The Secretary may,
10 under an agreement entered into with a Federal, State,
11 or local agency, use, on a reimbursable basis or otherwise,
12 the personnel, services, and facilities of the agency to carry
13 out the responsibilities of the agency under this section.
14 An agreement entered into with a State agency under this
15 subsection may provide for training of State employees.

16 **SEC. 1005. REPORTABLE FOOD REGISTRY.**

17 (a) FINDINGS.—Congress makes the following find-
18 ings:

19 (1) In 1994, Congress passed the Dietary Sup-
20 plement Health and Education Act of 1994 (Public
21 Law 103-417) to provide the Food and Drug Ad-
22 ministration the legal framework which is intended
23 to ensure that dietary supplements are safe and
24 properly labeled foods.

1 (2) In 2006, Congress passed the Dietary Sup-
2 plement and Nonprescription Drug Consumer Pro-
3 tection Act (Public Law 109-462) to establish a
4 mandatory reporting system of serious adverse
5 events for nonprescription drugs and dietary supple-
6 ments sold and consumed in the United States.

7 (3) The adverse event reporting system created
8 under the Dietary Supplement and Nonprescription
9 Drug Consumer Protection Act is intended to serve
10 as an early warning system for potential public
11 health issues associated with the use of these prod-
12 ucts.

13 (4) A reliable mechanism to track patterns of
14 adulteration in food would support efforts by the
15 Food and Drug Administration to target limited in-
16 spection resources to protect the public health.

17 (b) IN GENERAL.—Chapter IV of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
19 ed by adding at the end the following:

20 **“SEC. 417. REPORTABLE FOOD REGISTRY.**

21 “(a) DEFINITIONS.—In this section:

22 “(1) RESPONSIBLE PARTY.—The term ‘respon-
23 sible party’, with respect to an article of food, means
24 a person that submits the registration under section
25 415(a) for a food facility that is required to register

1 under section 415(a), at which such article of food
2 is manufactured, processed, packed, or held.

3 “(2) REPORTABLE FOOD.—The term ‘report-
4 able food’ means an article of food (other than in-
5 fant formula) for which there is a reasonable prob-
6 ability that the use of, or exposure to, such article
7 of food will cause serious adverse health con-
8 sequences or death to humans or animals.

9 “(b) ESTABLISHMENT.—

10 “(1) IN GENERAL.—Not later than 1 year after
11 the date of the enactment of this section, the Sec-
12 retary shall establish within the Food and Drug Ad-
13 ministration a Reportable Food Registry to which
14 instances of reportable food may be submitted by the
15 Food and Drug Administration after receipt of re-
16 ports under subsection (d), via an electronic portal,
17 from—

18 “(A) Federal, State, and local public
19 health officials; or

20 “(B) responsible parties.

21 “(2) REVIEW BY SECRETARY.—The Secretary
22 shall promptly review and assess the information
23 submitted under paragraph (1) for the purposes of
24 identifying reportable food, submitting entries to the
25 Reportable Food Registry, acting under subsection

1 (c), and exercising other existing food safety authori-
2 ties under this Act to protect the public health.

3 “(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

4 “(1) IN GENERAL.—The Secretary shall issue,
5 or cause to be issued, an alert or a notification with
6 respect to a reportable food using information from
7 the Reportable Food Registry as the Secretary
8 deems necessary to protect the public health.

9 “(2) EFFECT.—Paragraph (1) shall not affect
10 the authority of the Secretary to issue an alert or
11 a notification under any other provision of this Act.

12 “(d) REPORTING AND NOTIFICATION.—

13 “(1) IN GENERAL.—Except as provided in para-
14 graph (2), as soon as practicable, but in no case
15 later than 24 hours after a responsible party deter-
16 mines that an article of food is a reportable food,
17 the responsible party shall—

18 “(A) submit a report to the Food and
19 Drug Administration through the electronic
20 portal established under subsection (b) that in-
21 cludes the data elements described in subsection
22 (e) (except the elements described in para-
23 graphs (8), (9), and (10) of such subsection);
24 and

1 “(B) investigate the cause of the adultera-
2 tion if the adulteration of the article of food
3 may have originated with the responsible party.

4 “(2) NO REPORT REQUIRED.—A responsible
5 party is not required to submit a report under para-
6 graph (1) if—

7 “(A) the adulteration originated with the
8 responsible party;

9 “(B) the responsible party detected the
10 adulteration prior to any transfer to another
11 person of such article of food; and

12 “(C) the responsible party—

13 “(i) corrected such adulteration; or

14 “(ii) destroyed or caused the destruc-
15 tion of such article of food.

16 “(3) REPORTS BY PUBLIC HEALTH OFFI-
17 CIALS.—A Federal, State, or local public health offi-
18 cial may submit a report about a reportable food to
19 the Food and Drug Administration through the elec-
20 tronic portal established under subsection (b) that
21 includes the data elements described in subsection
22 (e) that the official is able to provide.

23 “(4) REPORT NUMBER.—The Secretary shall
24 ensure that, upon submission of a report under
25 paragraph (1) or (3), a unique number is issued

1 through the electronic portal established under sub-
2 section (b) to the person submitting such report, by
3 which the Secretary is able to link reports about the
4 reportable food submitted and amended under this
5 subsection and identify the supply chain for such re-
6 reportable food.

7 “(5) REVIEW.—The Secretary shall promptly
8 review a report submitted under paragraph (1) or
9 (3).

10 “(6) RESPONSE TO REPORT SUBMITTED BY A
11 RESPONSIBLE PARTY.—After consultation with the
12 responsible party that submitted a report under
13 paragraph (1), the Secretary may require such re-
14 sponsible party to perform, as soon as practicable,
15 but in no case later than a time specified by the Sec-
16 retary, 1 or more of the following:

17 “(A) Amend the report submitted by the
18 responsible party under paragraph (1) to in-
19 clude the data element described in subsection
20 (e)(9).

21 “(B) Provide a notification—

22 “(i) to the immediate previous source
23 of the article of food, if the Secretary
24 deems necessary;

1 “(ii) to the immediate subsequent re-
2 cipient of the article of food, if the Sec-
3 retary deems necessary; and

4 “(iii) that includes—

5 “(I) the data elements described
6 in subsection (e) that the Secretary
7 deems necessary;

8 “(II) the actions described under
9 paragraph (7) that the recipient of
10 the notification shall perform, as re-
11 quired by the Secretary; and

12 “(III) any other information that
13 the Secretary may require.

14 “(7) SUBSEQUENT REPORTS AND NOTIFICA-
15 TIONS.—Except as provided in paragraph (8), the
16 Secretary may require a responsible party to per-
17 form, as soon as practicable, but in no case later
18 than a time specified by the Secretary, after the re-
19 sponsible party receives a notification under sub-
20 paragraph (C) or paragraph (6)(B), 1 or more of
21 the following:

22 “(A) Submit a report to the Food and
23 Drug Administration through the electronic
24 portal established under subsection (b) that in-
25 cludes those data elements described in sub-

1 section (e) and other information that the Sec-
2 retary deems necessary.

3 “(B) Investigate the cause of the adultera-
4 tion if the adulteration of the article of food
5 may have originated with the responsible party.

6 “(C) Provide a notification—

7 “(i) to the immediate previous source
8 of the article of food, if the Secretary
9 deems necessary;

10 “(ii) to the immediate subsequent re-
11 cipient of the article of food, if the Sec-
12 retary deems necessary; and

13 “(iii) that includes—

14 “(I) the data elements described
15 in subsection (e) that the Secretary
16 deems necessary;

17 “(II) the actions described under
18 this paragraph that the recipient of
19 the notification shall perform, as re-
20 quired by the Secretary; and

21 “(III) any other information that
22 the Secretary may require.

23 “(8) AMENDED REPORT.—If a responsible
24 party receives a notification under paragraph (6)(B)
25 or paragraph (7)(C) with respect to an article of

1 food after the responsible party has submitted a re-
2 port to the Food and Drug Administration under
3 paragraph (1) with respect to such article of food—

4 “(A) the responsible party is not required
5 to submit an additional report or make a notifi-
6 cation under paragraph (7); and

7 “(B) the responsible party shall amend the
8 report submitted by the responsible party under
9 paragraph (1) to include the data elements de-
10 scribed in paragraph (9), and, with respect to
11 both such notification and such report, para-
12 graph (11) of subsection (e).

13 “(e) DATA ELEMENTS.—The data elements described
14 in this subsection are the following:

15 “(1) The registration numbers of the respon-
16 sible party under section 415(a)(3).

17 “(2) The date on which an article of food was
18 determined to be a reportable food.

19 “(3) A description of the article of food includ-
20 ing the quantity or amount.

21 “(4) The extent and nature of the adulteration.

22 “(5) If the adulteration of the article of food
23 may have originated with the responsible party, the
24 results of the investigation required under paragraph

1 (1)(B) or (7)(B) of subsection (d), as applicable and
2 when known.

3 “(6) The disposition of the article of food, when
4 known.

5 “(7) Product information typically found on
6 packaging including product codes, use-by dates, and
7 names of manufacturers, packers, or distributors
8 sufficient to identify the article of food.

9 “(8) Contact information for the responsible
10 party.

11 “(9) The contact information for parties di-
12 rectly linked in the supply chain and notified under
13 paragraph (6)(B) or (7)(C) of subsection (d), as ap-
14 plicable.

15 “(10) The information required by the Sec-
16 retary to be included in a notification provided by
17 the responsible party involved under paragraph
18 (6)(B) or (7)(C) of subsection (d) or required in a
19 report under subsection (d)(7)(A).

20 “(11) The unique number described in sub-
21 section (d)(4).

22 “(f) COORDINATION OF FEDERAL, STATE, AND
23 LOCAL EFFORTS.—

24 “(1) DEPARTMENT OF AGRICULTURE.—In im-
25 plementing this section, the Secretary shall—

1 “(A) share information and coordinate reg-
2 ulatory efforts with the Department of Agri-
3 culture; and

4 “(B) if the Secretary receives a report sub-
5 mitted about a food within the jurisdiction of
6 the Department of Agriculture, promptly pro-
7 vide such report to the Department of Agri-
8 culture.

9 “(2) STATES AND LOCALITIES.—In imple-
10 menting this section, the Secretary shall work with
11 the State and local public health officials to share
12 information and coordinate regulatory efforts, in
13 order to—

14 “(A) help to ensure coverage of the safety
15 of the food supply chain, including those food
16 establishments regulated by the States and lo-
17 calities that are not required to register under
18 section 415; and

19 “(B) reduce duplicative regulatory efforts.

20 “(g) MAINTENANCE AND INSPECTION OF
21 RECORDS.—The responsible party shall maintain records
22 related to each report received, notification made, and re-
23 port submitted to the Food and Drug Administration
24 under this section for 2 years. A responsible party shall,

1 at the request of the Secretary, permit inspection of such
2 records as provided for section 414.

3 “(h) REQUEST FOR INFORMATION.—Except as pro-
4 vided by section 415(a)(4), section 552 of title 5, United
5 States Code, shall apply to any request for information
6 regarding a record in the Reportable Food Registry.

7 “(i) SAFETY REPORT.—A report or notification
8 under subsection (d) shall be considered to be a safety re-
9 port under section 756 and may be accompanied by a
10 statement, which shall be part of any report released for
11 public disclosure, that denies that the report or the notifi-
12 cation constitutes an admission that the product involved
13 caused or contributed to a death, serious injury, or serious
14 illness.

15 “(j) ADMISSION.—A report or notification under this
16 section shall not be considered an admission that the arti-
17 cle of food involved is adulterated or caused or contributed
18 to a death, serious injury, or serious illness.

19 “(k) HOMELAND SECURITY NOTIFICATION.—If,
20 after receiving a report under subsection (d), the Sec-
21 retary believes such food may have been deliberately adul-
22 terated, the Secretary shall immediately notify the Sec-
23 retary of Homeland Security. The Secretary shall make
24 relevant information from the Reportable Food Registry
25 available to the Secretary of Homeland Security.”.

1 (c) DEFINITION.—Section 201(ff) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is
3 amended by striking “section 201(g)” and inserting “sec-
4 tions 201(g) and 417”.

5 (d) PROHIBITED ACTS.—Section 301 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
7 amended by section 912, is further amended—

8 (1) in subsection (e), by—

9 (A) striking “414,” and inserting “414,
10 417(g),”; and

11 (B) striking “414(b)” and inserting
12 “414(b), 417”; and

13 (2) by adding at the end the following:

14 “(mm) The failure to submit a report or provide a
15 notification required under section 417(d).

16 “(nn) The falsification of a report or notification re-
17 quired under section 417(d).”.

18 (e) EFFECTIVE DATE.—The requirements of section
19 417(d) of the Federal Food, Drug, and Cosmetic Act, as
20 added by subsection (a), shall become effective 1 year after
21 the date of the enactment of this Act.

22 (f) GUIDANCE.—Not later than 9 months after the
23 date of the enactment of this Act, the Secretary shall issue
24 a guidance to industry about submitting reports to the
25 electronic portal established under section 417 of the Fed-

1 eral Food, Drug, and Cosmetic Act (as added by this sec-
2 tion) and providing notifications to other persons in the
3 supply chain of an article of food under such section 417.

4 (g) EFFECT.—Nothing in this title, or an amendment
5 made by this title, shall be construed to alter the jurisdic-
6 tion between the Secretaries of Agriculture and of Health
7 and Human Services, under applicable statutes and regu-
8 lations.

9 **SEC. 1006. ENHANCED AQUACULTURE AND SEAFOOD IN-**
10 **SPECTION.**

11 (a) FINDINGS.—Congress finds the following:

12 (1) In 2007, there has been an overwhelming
13 increase in the volume of aquaculture and seafood
14 that has been found to contain substances that are
15 not approved for use in food in the United States.

16 (2) As of May 2007, inspection programs are
17 not able to satisfactorily accomplish the goals of en-
18 suring the food safety of the United States.

19 (3) To protect the health and safety of con-
20 sumers in the United States, the ability of the Sec-
21 retary to perform inspection functions must be en-
22 hanced.

23 (b) HEIGHTENED INSPECTIONS.—The Secretary is
24 authorized to enhance, as necessary, the inspection regime
25 of the Food and Drug Administration for aquaculture and

1 seafood, consistent with obligations of the United States
2 under international agreements and United States law.

3 (c) REPORT TO CONGRESS.—Not later than 180 days
4 after the date of the enactment of this Act, the Secretary
5 shall submit to Congress a report that—

6 (1) describes the specifics of the aquaculture
7 and seafood inspection program;

8 (2) describes the feasibility of developing a
9 traceability system for all catfish and seafood prod-
10 ucts, both domestic and imported, for the purpose of
11 identifying the processing plant of origin of such
12 products; and

13 (3) provides for an assessment of the risks as-
14 sociated with particular contaminants and banned
15 substances.

16 (d) PARTNERSHIPS WITH STATES.—Upon the re-
17 quest by any State, the Secretary may enter into partner-
18 ship agreements, as soon as practicable after the request
19 is made, to implement inspection programs to Federal
20 standards regarding the importation of aquaculture and
21 seafood.

22 **SEC. 1007. CONSULTATION REGARDING GENETICALLY EN-**
23 **GINEERED SEAFOOD PRODUCTS.**

24 The Commissioner of Food and Drugs shall consult
25 with the Assistant Administrator of the National Marine

1 Fisheries Service of the National Oceanic and Atmos-
2 pheric Administration to produce a report on any environ-
3 mental risks associated with genetically engineered sea-
4 food products, including the impact on wild fish stocks.

5 **SEC. 1008. SENSE OF CONGRESS.**

6 It is the sense of Congress that—

7 (1) it is vital for Congress to provide the Food
8 and Drug Administration with additional resources,
9 authorities, and direction with respect to ensuring
10 the safety of the food supply of the United States;

11 (2) additional inspectors are required to im-
12 prove the Food and Drug Administration's ability to
13 safeguard the food supply of the United States;

14 (3) because of the increasing volume of inter-
15 national trade in food products the Secretary should
16 make it a priority to enter into agreements with the
17 trading partners of the United States with respect to
18 food safety; and

19 (4) Congress should work to develop a com-
20 prehensive response to the issue of food safety.

21 **SEC. 1009. ANNUAL REPORT TO CONGRESS.**

22 The Secretary shall, on an annual basis, submit to
23 the Committee on Health, Education, Labor, and Pen-
24 sions and the Committee on Appropriations of the Senate
25 and the Committee on Energy and Commerce and the

1 Committee on Appropriations of the House of Representa-
2 tives a report that includes, with respect to the preceding
3 1-year period—

4 (1) the number and amount of food products
5 regulated by the Food and Drug Administration im-
6 ported into the United States, aggregated by country
7 and type of food;

8 (2) a listing of the number of Food and Drug
9 Administration inspectors of imported food products
10 referenced in paragraph (1) and the number of Food
11 and Drug Administration inspections performed on
12 such products; and

13 (3) aggregated data on the findings of such in-
14 spections, including data related to violations of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 201 et seq.), and enforcement actions used to follow-
17 up on such findings and violations.

18 **SEC. 1010. PUBLICATION OF ANNUAL REPORTS.**

19 (a) IN GENERAL.—The Commissioner of Food and
20 Drugs shall annually submit to Congress and publish on
21 the Internet Web site of the Food and Drug Administra-
22 tion, a report concerning the results of the Administra-
23 tion's pesticide residue monitoring program, that in-
24 cludes—

1 (1) information and analysis similar to that
2 contained in the report entitled “Food and Drug Ad-
3 ministration Pesticide Program Residue Monitoring
4 2003” as released in June of 2005;

5 (2) based on an analysis of previous samples,
6 an identification of products or countries (for im-
7 ports) that require special attention and additional
8 study based on a comparison with equivalent prod-
9 ucts manufactured, distributed, or sold in the United
10 States (including details on the plans for such addi-
11 tional studies), including in the initial report (and
12 subsequent reports as determined necessary) the re-
13 sults and analysis of the Ginseng Dietary Supple-
14 ments Special Survey as described on page 13 of the
15 report entitled “Food and Drug Administration Pes-
16 ticide Program Residue Monitoring 2003”;

17 (3) information on the relative number of inter-
18 state and imported shipments of each tested com-
19 modity that were sampled, including recommenda-
20 tions on whether sampling is statistically significant,
21 provides confidence intervals or other related statis-
22 tical information, and whether the number of sam-
23 ples should be increased and the details of any plans
24 to provide for such increase; and

1 (4) a description of whether certain commod-
2 ities are being improperly imported as another com-
3 modity, including a description of additional steps
4 that are being planned to prevent such smuggling.

5 (b) INITIAL REPORTS.—Annual reports under sub-
6 section (a) for fiscal years 2004 through 2006 may be
7 combined into a single report, by not later than June 1,
8 2008, for purposes of publication under subsection (a).
9 Thereafter such reports shall be completed by June 1 of
10 each year for the data collected for the year that was 2-
11 years prior to the year in which the report is published.

12 (c) MEMORANDUM OF UNDERSTANDING.—The Com-
13 missioner of Food and Drugs, the Administrator of the
14 Food Safety and Inspection Service, the Department of
15 Commerce, and the head of the Agricultural Marketing
16 Service shall enter into a memorandum of understanding
17 to permit inclusion of data in the reports under subsection
18 (a) relating to testing carried out by the Food Safety and
19 Inspection Service and the Agricultural Marketing Service
20 on meat, poultry, eggs, and certain raw agricultural prod-
21 ucts, respectively.

22 **SEC. 1011. RULE OF CONSTRUCTION.**

23 Nothing in this title (or an amendment made by this
24 title) shall be construed to affect—

1 (1) the regulation of dietary supplements under
2 the Dietary Supplement Health and Education Act
3 of 1994 (Public Law 103–417); or

4 (2) the adverse event reporting system for die-
5 tary supplements created under the Dietary Supple-
6 ment and Nonprescription Drug Consumer Protec-
7 tion Act (Public Law 109–462).

8 **TITLE XI—OTHER PROVISIONS**

9 **Subtitle A—In General**

10 **SEC. 1101. POLICY ON THE REVIEW AND CLEARANCE OF** 11 **SCIENTIFIC ARTICLES PUBLISHED BY FDA** 12 **EMPLOYEES.**

13 Subchapter A of chapter VII of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as
15 amended by section 701, is further amended by adding
16 at the end the following:

17 **“SEC. 713. POLICY ON THE REVIEW AND CLEARANCE OF** 18 **SCIENTIFIC ARTICLES PUBLISHED BY FDA** 19 **EMPLOYEES.**

20 “(a) DEFINITION.—In this section, the term ‘article’
21 means a paper, poster, abstract, book, book chapter, or
22 other published writing.

23 “(b) POLICIES.—The Secretary, through the Com-
24 missioner of Food and Drugs, shall establish and make
25 publicly available clear written policies to implement this

1 section and govern the timely submission, review, clear-
2 ance, and disclaimer requirements for articles.

3 “(c) TIMING OF SUBMISSION FOR REVIEW.—If an of-
4 ficer or employee, including a Staff Fellow and a con-
5 tractor who performs staff work, of the Food and Drug
6 Administration is directed by the policies established
7 under subsection (b) to submit an article to the supervisor
8 of such officer or employee, or to some other official of
9 the Food and Drug Administration, for review and clear-
10 ance before such officer or employee may seek to publish
11 or present such an article at a conference, such officer
12 or employee shall submit such article for such review and
13 clearance not less than 30 days before submitting the arti-
14 cle for publication or presentation.

15 “(d) TIMING FOR REVIEW AND CLEARANCE.—The
16 supervisor or other reviewing official shall review such ar-
17 ticle and provide written clearance, or written clearance
18 on the condition of specified changes being made, to such
19 officer or employee not later than 30 days after such offi-
20 cer or employee submitted such article for review.

21 “(e) NON-TIMELY REVIEW.—If, 31 days after such
22 submission under subsection (c), the supervisor or other
23 reviewing official has not cleared or has not reviewed such
24 article and provided written clearance, such officer or em-
25 ployee may consider such article not to have been cleared

1 and may submit the article for publication or presentation
2 with an appropriate disclaimer as specified in the policies
3 established under subsection (b).

4 “(f) EFFECT.—Nothing in this section shall be con-
5 strued as affecting any restrictions on such publication or
6 presentation provided by other provisions of law.”.

7 **SEC. 1102. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
8 **FOR TROPICAL DISEASES.**

9 Subchapter A of chapter V of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
11 ed by adding at the end the following:

12 **“SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
13 **FOR TROPICAL DISEASES.**

14 “(a) DEFINITIONS.—In this section:

15 “(1) PRIORITY REVIEW.—The term ‘priority re-
16 view’, with respect to a human drug application as
17 defined in section 735(1), means review and action
18 by the Secretary on such application not later than
19 6 months after receipt by the Secretary of such ap-
20 plication, as described in the Manual of Policies and
21 Procedures of the Food and Drug Administration
22 and goals identified in the letters described in sec-
23 tion 101(c) of the Food and Drug Administration
24 Amendments Act of 2007.

1 “(2) PRIORITY REVIEW VOUCHER.—The term
2 ‘priority review voucher’ means a voucher issued by
3 the Secretary to the sponsor of a tropical disease
4 product application that entitles the holder of such
5 voucher to priority review of a single human drug
6 application submitted under section 505(b)(1) or
7 section 351 of the Public Health Service Act after
8 the date of approval of the tropical disease product
9 application.

10 “(3) TROPICAL DISEASE.—The term ‘tropical
11 disease’ means any of the following:

12 “(A) Tuberculosis.

13 “(B) Malaria.

14 “(C) Blinding trachoma.

15 “(D) Buruli Ulcer.

16 “(E) Cholera.

17 “(F) Dengue/dengue haemorrhagic fever.

18 “(G) Dracunculiasis (guinea-worm dis-
19 ease).

20 “(H) Fascioliasis.

21 “(I) Human African trypanosomiasis.

22 “(J) Leishmaniasis.

23 “(K) Leprosy.

24 “(L) Lymphatic filariasis.

25 “(M) Onchocerciasis.

1 “(N) Schistosomiasis.

2 “(O) Soil transmitted helminthiasis.

3 “(P) Yaws.

4 “(Q) Any other infectious disease for
5 which there is no significant market in devel-
6 oped nations and that disproportionately affects
7 poor and marginalized populations, designated
8 by regulation by the Secretary.

9 “(4) TROPICAL DISEASE PRODUCT APPLICA-
10 TION.—The term ‘tropical disease product applica-
11 tion’ means an application that—

12 “(A) is a human drug application as de-
13 fined in section 735(1)—

14 “(i) for prevention or treatment of a
15 tropical disease; and

16 “(ii) the Secretary deems eligible for
17 priority review;

18 “(B) is approved after the date of the en-
19 actment of the Food and Drug Administration
20 Amendments Act of 2007, by the Secretary for
21 use in the prevention, detection, or treatment of
22 a tropical disease; and

23 “(C) is for a human drug, no active ingre-
24 dient (including any ester or salt of the active
25 ingredient) of which has been approved in any

1 other application under section 505(b)(1) or
2 section 351 of the Public Health Service Act.

3 “(b) PRIORITY REVIEW VOUCHER.—

4 “(1) IN GENERAL.—The Secretary shall award
5 a priority review voucher to the sponsor of a tropical
6 disease product application upon approval by the
7 Secretary of such tropical disease product applica-
8 tion.

9 “(2) TRANSFERABILITY.—The sponsor of a
10 tropical disease product that receives a priority re-
11 view voucher under this section may transfer (in-
12 cluding by sale) the entitlement to such voucher to
13 a sponsor of a human drug for which an application
14 under section 505(b)(1) or section 351 of the Public
15 Health Service Act will be submitted after the date
16 of the approval of the tropical disease product appli-
17 cation.

18 “(3) LIMITATION.—

19 “(A) NO AWARD FOR PRIOR APPROVED AP-
20 PLICATION.—A sponsor of a tropical disease
21 product may not receive a priority review
22 voucher under this section if the tropical dis-
23 ease product application was submitted to the
24 Secretary prior to the date of the enactment of
25 this section.

1 “(B) ONE-YEAR WAITING PERIOD.—The
2 Secretary shall issue a priority review voucher
3 to the sponsor of a tropical disease product no
4 earlier than the date that is 1 year after the
5 date of the enactment of the Food and Drug
6 Administration Amendments Act of 2007.

7 “(4) NOTIFICATION.—The sponsor of a human
8 drug application shall notify the Secretary not later
9 than 365 days prior to submission of the human
10 drug application that is the subject of a priority re-
11 view voucher of an intent to submit the human drug
12 application, including the date on which the sponsor
13 intends to submit the application. Such notification
14 shall be a legally binding commitment to pay for the
15 user fee to be assessed in accordance with this sec-
16 tion.

17 “(c) PRIORITY REVIEW USER FEE.—

18 “(1) IN GENERAL.—The Secretary shall estab-
19 lish a user fee program under which a sponsor of a
20 human drug application that is the subject of a pri-
21 ority review voucher shall pay to the Secretary a fee
22 determined under paragraph (2). Such fee shall be
23 in addition to any fee required to be submitted by
24 the sponsor under chapter VII.

1 “(2) FEE AMOUNT.—The amount of the pri-
2 ority review user fee shall be determined each fiscal
3 year by the Secretary and based on the average cost
4 incurred by the agency in the review of a human
5 drug application subject to priority review in the
6 previous fiscal year.

7 “(3) ANNUAL FEE SETTING.—The Secretary
8 shall establish, before the beginning of each fiscal
9 year beginning after September 30, 2007, for that
10 fiscal year, the amount of the priority review user
11 fee.

12 “(4) PAYMENT.—

13 “(A) IN GENERAL.—The priority review
14 user fee required by this subsection shall be due
15 upon the submission of a human drug applica-
16 tion under section 505(b)(1) or section 351 of
17 the Public Health Services Act for which the
18 priority review voucher is used.

19 “(B) COMPLETE APPLICATION.—An appli-
20 cation described under subparagraph (A) for
21 which the sponsor requests the use of a priority
22 review voucher shall be considered incomplete if
23 the fee required by this subsection and all other
24 applicable user fees are not paid in accordance

1 with the Secretary's procedures for paying such
2 fees.

3 “(C) NO WAIVERS, EXEMPTIONS, REDUC-
4 TIONS, OR REFUNDS.—The Secretary may not
5 grant a waiver, exemption, reduction, or refund
6 of any fees due and payable under this section.

7 “(5) OFFSETTING COLLECTIONS.—Fees col-
8 lected pursuant to this subsection for any fiscal
9 year—

10 “(A) shall be deposited and credited as off-
11 setting collections to the account providing ap-
12 propriations to the Food and Drug Administra-
13 tion; and

14 “(B) shall not be collected for any fiscal
15 year except to the extent provided in advance in
16 appropriation Acts.”.

17 **SEC. 1103. IMPROVING GENETIC TEST SAFETY AND QUAL-**
18 **ITY.**

19 (a) REPORT.—If the Secretary's Advisory Committee
20 on Genetics, Health, and Society does not complete and
21 submit the Regulatory Oversight of Genetic/Genomic Test-
22 ing Report & Action Recommendations to the Secretary
23 of Health and Human Services (referred to in this section
24 as the “Secretary”) by July of 2008, the Secretary shall
25 enter into a contract with the Institute of Medicine to con-

1 duct a study to assess the overall safety and quality of
2 genetic tests and prepare a report that includes rec-
3 ommendations to improve Federal oversight and regula-
4 tion of genetic tests. Such study shall take into consider-
5 ation relevant reports by the Secretary's Advisory Com-
6 mittee on Genetics, Health, and Society and other groups
7 and shall be completed not later than 1 year after the date
8 on which the Secretary entered into such contract.

9 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
10 tion shall be construed as requiring Federal efforts with
11 respect to regulatory oversight of genetic tests to cease
12 or be limited or delayed pending completion of the report
13 by the Secretary's Advisory Committee on Genetics,
14 Health, and Society or the Institute of Medicine.

15 **SEC. 1104. NIH TECHNICAL AMENDMENTS.**

16 The Public Health Service Act (42 U.S.C. 201 et
17 seq.) is amended—

18 (1) in section 319C–2(j)(3)(B), by striking
19 “section 319C–1(h)” and inserting “section 319C–
20 1(i)”;

21 (2) in section 402(b)(4), by inserting “minority
22 and other” after “reducing”;

23 (3) in section 403(a)(4)(C)(iv)(III), by inserting
24 “and postdoctoral training funded through research
25 grants” before the semicolon;

1 (4) by designating the second section 403C (re-
2 lating to the drug diethylstilbestrol) as section
3 403D; and

4 (5) in section 403C(a)—

5 (A) in the matter preceding paragraph
6 (1)—

7 (i) by inserting “graduate students
8 supported by the National Institutes of
9 Health” after “with respect to”; and

10 (ii) by deleting “each degree-granting
11 program”;

12 (B) in paragraph (1), by inserting “such”
13 after “percentage of”; and

14 (C) in paragraph (2), by inserting “(not
15 including any leaves of absence)” after “average
16 time”.

17 **SEC. 1105. SEVERABILITY CLAUSE.**

18 If any provision of this Act, an amendment made this
19 Act, or the application of such provision or amendment
20 to any person or circumstance is held to be unconstitu-
21 tional, the remainder of this Act, the amendments made
22 by this Act, and the application of the provisions of such
23 to any person or circumstances shall not be affected there-
24 by.

1 **Subtitle B—Antibiotic Access and**
2 **Innovation**

3 **SEC. 1111. INCENTIVES FOR THE DEVELOPMENT OF, AND**
4 **ACCESS TO, CERTAIN ANTIBIOTICS.**

5 (a) IN GENERAL.—Section 505 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
7 section 920, is further amended by adding at the end the
8 following:

9 “(u) ANTIBIOTIC DRUGS SUBMITTED BEFORE NO-
10 VEMBER 21, 1997.—

11 “(1) ANTIBIOTIC DRUGS APPROVED BEFORE
12 NOVEMBER 21, 1997.—

13 “(A) IN GENERAL.—Notwithstanding any
14 provision of the Food and Drug Administration
15 Modernization Act of 1997 or any other provi-
16 sion of law, a sponsor of a drug that is the sub-
17 ject of an application described in subparagraph
18 (B)(i) shall be eligible for, with respect to the
19 drug, the 3-year exclusivity period referred to
20 under clauses (iii) and (iv) of subsection
21 (c)(3)(E) and under clauses (iii) and (iv) of
22 subsection (j)(5)(F), subject to the require-
23 ments of such clauses, as applicable.

24 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
25 SCRIBED.—

1 “(i) APPLICATION.—An application
2 described in this clause is an application
3 for marketing submitted under this section
4 after the date of the enactment of this sub-
5 section in which the drug that is the sub-
6 ject of the application contains an anti-
7 biotic drug described in clause (ii).

8 “(ii) ANTIBIOTIC DRUG.—An anti-
9 biotic drug described in this clause is an
10 antibiotic drug that was the subject of an
11 application approved by the Secretary
12 under section 507 of this Act (as in effect
13 before November 21, 1997).

14 “(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE
15 NOVEMBER 21, 1997, BUT NOT APPROVED.—

16 “(A) IN GENERAL.—Notwithstanding any
17 provision of the Food and Drug Administration
18 Modernization Act of 1997 or any other provi-
19 sion of law, a sponsor of a drug that is the sub-
20 ject of an application described in subparagraph
21 (B)(i) may elect to be eligible for, with respect
22 to the drug—

23 “(i)(I) the 3-year exclusivity period re-
24 ferred to under clauses (iii) and (iv) of
25 subsection (c)(3)(E) and under clauses (iii)

1 and (iv) of subsection (j)(5)(F), subject to
2 the requirements of such clauses, as appli-
3 cable; and

4 “(II) the 5-year exclusivity period re-
5 ferred to under clause (ii) of subsection
6 (c)(3)(E) and under clause (ii) of sub-
7 section (j)(5)(F), subject to the require-
8 ments of such clauses, as applicable; or

9 “(ii) a patent term extension under
10 section 156 of title 35, United States
11 Code, subject to the requirements of such
12 section.

13 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
14 SCRIBED.—

15 “(i) APPLICATION.—An application
16 described in this clause is an application
17 for marketing submitted under this section
18 after the date of the enactment of this sub-
19 section in which the drug that is the sub-
20 ject of the application contains an anti-
21 biotic drug described in clause (ii).

22 “(ii) ANTIBIOTIC DRUG.—An anti-
23 biotic drug described in this clause is an
24 antibiotic drug that was the subject of 1 or
25 more applications received by the Secretary

1 under section 507 of this Act (as in effect
2 before November 21, 1997), none of which
3 was approved by the Secretary under such
4 section.

5 “(3) LIMITATIONS.—

6 “(A) EXCLUSIVITIES AND EXTENSIONS.—

7 Paragraphs (1)(A) and (2)(A) shall not be con-
8 strued to entitle a drug that is the subject of
9 an approved application described in subpara-
10 graphs (1)(B)(i) or (2)(B)(i), as applicable, to
11 any market exclusivities or patent extensions
12 other than those exclusivities or extensions de-
13 scribed in paragraph (1)(A) or (2)(A).

14 “(B) CONDITIONS OF USE.—Paragraphs
15 (1)(A) and (2)(A)(i) shall not apply to any con-
16 dition of use for which the drug referred to in
17 subparagraph (1)(B)(i) or (2)(B)(i), as applica-
18 ble, was approved before the date of the enact-
19 ment of this subsection.

20 “(4) APPLICATION OF CERTAIN PROVISIONS.—

21 Notwithstanding section 125, or any other provision,
22 of the Food and Drug Administration Modernization
23 Act of 1997, or any other provision of law, and sub-
24 ject to the limitations in paragraphs (1), (2), and
25 (3), the provisions of the Drug Price Competition

1 and Patent Term Restoration Act of 1984 shall
2 apply to any drug subject to paragraph (1) or any
3 drug with respect to which an election is made under
4 paragraph (2)(A).”.

5 (b) TRANSITIONAL RULES.—

6 (1) With respect to a patent issued on or before
7 the date of the enactment of this Act, any patent in-
8 formation required to be filed with the Secretary of
9 Health and Human Services under subsection (b)(1)
10 or (c)(2) of section 505 of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 355) to be listed on a
12 drug to which subsection (u)(1) of such section 505
13 (as added by this section) applies shall be filed with
14 the Secretary not later than 60 days after the date
15 of the enactment of this Act.

16 (2) With respect to any patent information re-
17 ferred to in paragraph (1) of this subsection that is
18 filed with the Secretary within the 60-day period
19 after the date of the enactment of this Act, the Sec-
20 retary shall publish such information in the elec-
21 tronic version of the list referred to at section
22 505(j)(7) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 355(j)(7)) as soon as it is received,
24 but in no event later than the date that is 90 days
25 after the enactment of this Act.

1 (3) With respect to any patent information re-
2 ferred to in paragraph (1) that is filed with the Sec-
3 retary within the 60-day period after the date of en-
4 actment of this Act, each applicant that, not later
5 than 120 days after the date of the enactment of
6 this Act, amends an application that is, on or before
7 the date of the enactment of this Act, a substantially
8 complete application (as defined in paragraph
9 (5)(B)(iv) of section 505(j) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355(j))) to con-
11 tain a certification described in paragraph
12 (2)(A)(vii)(IV) of such section 505(j) with respect to
13 that patent shall be deemed to be a first applicant
14 (as defined in paragraph (5)(B)(iv) of such section
15 505(j)).

16 **SEC. 1112. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE**
17 **CONCENTRATIONS OF ANTIMICROBIALS.**

18 (a) DEFINITION.—In this section, the term “clinically
19 susceptible concentrations” means specific values which
20 characterize bacteria as clinically susceptible, inter-
21 mediate, or resistant to the drug (or drugs) tested.

22 (b) IDENTIFICATION.—The Secretary of Health and
23 Human Services (referred to in this section as the “Sec-
24 retary”), through the Commissioner of Food and Drugs,
25 shall identify (where such information is reasonably avail-

1 able) and periodically update clinically susceptible con-
2 centrations.

3 (c) PUBLIC AVAILABILITY.—The Secretary, through
4 the Commissioner of Food and Drugs, shall make such
5 clinically susceptible concentrations publicly available,
6 such as by posting on the Internet, not later than 30 days
7 after the date of identification and any update under this
8 section.

9 (d) EFFECT.—Nothing in this section shall be con-
10 strued to restrict, in any manner, the prescribing of anti-
11 biotics by physicians, or to limit the practice of medicine,
12 including for diseases such as Lyme and tick-borne dis-
13 eases.

14 **SEC. 1113. ORPHAN ANTIBIOTIC DRUGS.**

15 (a) PUBLIC MEETING.—The Commissioner of Food
16 and Drugs shall convene a public meeting regarding which
17 serious and life threatening infectious diseases, such as
18 diseases due to gram-negative bacteria and other diseases
19 due to antibiotic-resistant bacteria, potentially qualify for
20 available grants and contracts under section 5(a) of the
21 Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives
22 for development.

23 (b) GRANTS AND CONTRACTS FOR THE DEVELOP-
24 MENT OF ORPHAN DRUGS.—Section 5(c) of the Orphan

1 Drug Act (21 U.S.C. 360ee(c)) is amended to read as fol-
2 lows:

3 “(c) For grants and contracts under subsection (a),
4 there is authorized to be appropriated \$30,000,000 for
5 each of fiscal years 2008 through 2012.”.

6 **SEC. 1114. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING**
7 **SINGLE ENANTIOMERS.**

8 Section 505 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 355), as amended by section 1111, is fur-
10 ther amended by adding at the end the following:

11 “(v) CERTAIN DRUGS CONTAINING SINGLE
12 ENANTIOMERS.—

13 “(1) IN GENERAL.—For purposes of sub-
14 sections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an applica-
15 tion is submitted under subsection (b) for a non-ra-
16 cemic drug containing as an active ingredient (in-
17 cluding any ester or salt of the active ingredient) a
18 single enantiomer that is contained in a racemic
19 drug approved in another application under sub-
20 section (b), the applicant may, in the application for
21 such non-racemic drug, elect to have the single
22 enantiomer not be considered the same active ingre-
23 dient as that contained in the approved racemic
24 drug, if—

1 “(A)(i) the single enantiomer has not been
2 previously approved except in the approved ra-
3 cemic drug; and

4 “(ii) the application submitted under sub-
5 section (b) for such non-racemic drug—

6 “(I) includes full reports of new clin-
7 ical investigations (other than bio-
8 availability studies)—

9 “(aa) necessary for the approval
10 of the application under subsections
11 (c) and (d); and

12 “(bb) conducted or sponsored by
13 the applicant; and

14 “(II) does not rely on any investiga-
15 tions that are part of an application sub-
16 mitted under subsection (b) for approval of
17 the approved racemic drug; and

18 “(B) the application submitted under sub-
19 section (b) for such non-racemic drug is not
20 submitted for approval of a condition of use—

21 “(i) in a therapeutic category in which
22 the approved racemic drug has been ap-
23 proved; or

24 “(ii) for which any other enantiomer
25 of the racemic drug has been approved.

1 “(2) LIMITATION.—

2 “(A) NO APPROVAL IN CERTAIN THERA-
3 PEUTIC CATEGORIES.—Until the date that is 10
4 years after the date of approval of a non-race-
5 mic drug described in paragraph (1) and with
6 respect to which the applicant has made the
7 election provided for by such paragraph, the
8 Secretary shall not approve such non-racemic
9 drug for any condition of use in the therapeutic
10 category in which the racemic drug has been
11 approved.

12 “(B) LABELING.—If applicable, the label-
13 ing of a non-racemic drug described in para-
14 graph (1) and with respect to which the appli-
15 cant has made the election provided for by such
16 paragraph shall include a statement that the
17 non-racemic drug is not approved, and has not
18 been shown to be safe and effective, for any
19 condition of use of the racemic drug.

20 “(3) DEFINITION.—

21 “(A) IN GENERAL.—For purposes of this
22 subsection, the term ‘therapeutic category’
23 means a therapeutic category identified in the
24 list developed by the United States Pharma-
25 copeia pursuant to section 1860D—

1 4(b)(3)(C)(ii) of the Social Security Act and as
2 in effect on the date of the enactment of this
3 subsection.

4 “(B) PUBLICATION BY SECRETARY.—The
5 Secretary shall publish the list described in sub-
6 paragraph (A) and may amend such list by reg-
7 ulation.

8 “(4) AVAILABILITY.—The election referred to
9 in paragraph (1) may be made only in an application
10 that is submitted to the Secretary after the date of
11 the enactment of this subsection and before October
12 1, 2012.”.

13 **SEC. 1115. REPORT.**

14 Not later than January 1, 2012, the Comptroller
15 General of the United States shall submit a report to the
16 Committee on Health, Education, Labor, and Pensions of
17 the Senate and the Committee on Energy and Commerce
18 of the House of Representatives that examines whether
19 and how this subtitle has—

20 (1) encouraged the development of new anti-
21 biotics and other drugs; and

22 (2) prevented or delayed timely generic drug
23 entry into the market.