

# Union Calendar No. 140

110TH CONGRESS  
1ST SESSION

# H. R. 2900

[Report No. 110-225]

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.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2007

Mr. DINGELL (for himself, Mr. BARTON of Texas, Mr. PALLONE, Mr. DEAL of Georgia, Mr. WAXMAN, Mr. BARROW, Mr. BUTTERFIELD, Mr. GONZALEZ, Mr. GENE GREEN of Texas, Mr. GORDON of Tennessee, Ms. SOLIS, Mr. MATHESON, Mr. INSLEE, Ms. ESHOO, Ms. HOOLEY, Ms. BALDWIN, Mr. FERGUSON, Mr. ENGEL, Mr. ROSS, Mr. TOWNS, Mr. ROGERS of Michigan, Mr. MARKEY, Ms. DEGETTE, Ms. SCHAKOWSKY, Mr. ALLEN, Mr. BURGESS, Mr. TERRY, Mrs. BONO, Mrs. MYRICK, Mrs. CAPPS, Mr. UPTON, Mr. MELANCON, and Mr. RUSH) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 11, 2007

Additional sponsors: Mr. WYNN and Mr. HILL

JULY 11, 2007

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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## 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”.

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

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

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

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

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

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

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

Subtitle A—Fees Related to Medical Devices

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

Subtitle B—Amendments Regarding Regulation of Medical Devices

- Sec. 221. Extension of authority for third party review of premarket notification.
- Sec. 222. Registration.
- Sec. 223. Filing of lists of drugs and devices manufactured, prepared, propagated, and compounded by registrants; statements; accompanying disclosures.

- Sec. 224. Electronic registration and listing.
- Sec. 225. Report by Government Accountability Office.
- Sec. 226. Unique device identification system.
- Sec. 227. Frequency of reporting for certain devices.
- Sec. 228. Inspections by accredited persons.
- Sec. 229. Study of nosocomial infections relating to medical devices.

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

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

#### TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

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

#### TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

- Sec. 501. Short title.
- Sec. 502. Reauthorization of Best Pharmaceuticals for Children Act.

#### TITLE VI—REAGAN-UDALL FOUNDATION

- Sec. 601. The Reagan-Udall Foundation for the Food and Drug Administration.
- Sec. 602. Office of the Chief Scientist.
- Sec. 603. Critical path public-private partnerships.

#### TITLE VII—CONFLICTS OF INTEREST

- Sec. 701. Conflicts of interest.

#### TITLE VIII—CLINICAL TRIAL DATABASES

- Sec. 801. Clinical trial registry database and clinical trial results database.
- Sec. 802. Study by Government Accountability Office.

#### TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

- Sec. 901. Postmarket studies and clinical trials regarding human drugs; risk evaluation and mitigation strategies.
- Sec. 902. Enforcement.
- Sec. 903. No effect on withdrawal or suspension of approval.
- Sec. 904. Benefit-risk assessments.
- Sec. 905. Postmarket risk identification and analysis system for active surveillance and assessment.
- Sec. 907. Statement for inclusion in direct-to-consumer advertisements of drugs.

Sec. 908. Clinical trial guidance for antibiotic drugs.

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

Sec. 910. Assuring pharmaceutical safety.

Sec. 911. Orphan antibiotic drugs.

Sec. 912. Authorization of appropriations.

Sec. 913. Effective date and applicability.

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

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

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

6 (b) **REFERENCES IN ACT.**—Except as otherwise spec-  
7 ified, amendments made by this title to a section or other  
8 provision of law are amendments to such section or other  
9 provision of the Federal Food, Drug, and Cosmetic Act  
10 (21 U.S.C. 301 et seq.).

## 11 **SEC. 102. DEFINITIONS.**

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

13 (1) in paragraph (1)—

14 (A) in subparagraph (A), by striking  
15 “505(b)(1),” and inserting “505(b), or”;

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

17 (C) by redesignating subparagraph (C) as  
18 subparagraph (B);

19 (2) in paragraph (3)(C)—

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

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

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

7 (4) by amending paragraph (6)(F) to read as  
8 follows:

9 “(F) Postmarket safety activities with re-  
10 spect to drugs approved under human drug ap-  
11 plications or supplements, including the fol-  
12 lowing activities:

13 “(i) Collecting, developing, and re-  
14 viewing safety information on approved  
15 drugs, including adverse event reports.

16 “(ii) Developing and using improved  
17 adverse-event data-collection systems, in-  
18 cluding information technology systems.

19 “(iii) Developing and using improved  
20 analytical tools to assess potential safety  
21 problems, including access to external data  
22 bases.

23 “(iv) Preparing and making publicly  
24 available (including on the website of the  
25 Food and Drug Administration) a sum-

1           mary analysis of the adverse drug reaction  
2           reports received for recently approved  
3           drugs, including identification of any new  
4           risks not previously identified, potential  
5           new risks, or known risks reported in un-  
6           usual number not previously identified  
7           within 18 months of the drug’s initial mar-  
8           keting or after exposure of 10,000 individ-  
9           uals to the drug, whichever is later.

10           “(v) Conducting regular, bi-weekly  
11           screening of the Adverse Event Reporting  
12           System database and developing a report  
13           every 15 days on any new safety concerns.

14           “(vi) Ensuring that the reports avail-  
15           able to the public under the Adverse Event  
16           Reporting System are updated at least  
17           every 6 months.

18           “(vii) Reporting to the Congress on—

19           “(I) the recommendations re-  
20           ceived in consultations with, and re-  
21           ports from, the Office of Surveillance  
22           and Epidemiology within the Food  
23           and Drug Administration on  
24           postmarket safety activities;

1 “(II) a description of the actions  
2 taken on those recommendations; and

3 “(III) if no action is taken, or a  
4 different action is taken relative to the  
5 action recommended by the Office of  
6 Surveillance and Epidemiology, an ex-  
7 planation of why no action or a dif-  
8 ferent action was taken.

9 “(viii) On an annual basis, reviewing  
10 the entire backlog of postmarket safety  
11 commitments to determine which commit-  
12 ments require revision or should be elimi-  
13 nated, reporting to the Congress on these  
14 determinations, and assigning start dates  
15 and estimated completion dates for such  
16 commitments.

17 “(ix) Developing postmarket safety  
18 performance measures, including those list-  
19 ed in clauses (iv) through (viii), that are as  
20 measurable and rigorous as the ones al-  
21 ready developed for premarket review.”;

22 (5) in paragraph (8)—

23 (A) by striking “April of the preceding fis-  
24 cal year” and inserting “October of the pre-  
25 ceding fiscal year”; and

1 (B) by striking “April 1997” and inserting  
2 “October 1996”;

3 (6) by redesignating paragraph (9) as para-  
4 graph (11); and

5 (7) by inserting after paragraph (8) the fol-  
6 lowing paragraphs:

7 “(9) The term ‘person’ includes an affiliate  
8 thereof.

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

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

14 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.  
15 379h(a)) is amended—

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

18 (2) in paragraph (1)—

19 (A) in subparagraph (D)—

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

23 (ii) by inserting before the period at  
24 the end the following: “or withdrawn with-  
25 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 subparagraph  
10 (1)(B) 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, subject to subparagraph (C), be applied  
8       by substituting the amount determined under  
9       subparagraph (B) for ‘\$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) an amount equal to—

16                              “(I)(aa) for fiscal year 2008,  
17                              \$25,000,000;

18                              “(bb) for fiscal year 2009,  
19                              \$35,000,000;

20                              “(cc) for fiscal year 2010,  
21                              \$45,000,000;

22                              “(dd) for fiscal year 2011,  
23                              \$55,000,000; and

24                              “(ee) for fiscal year 2012,  
25                              \$65,000,000; minus

1           “(II) the amount equal to the ex-  
2           cess amount in item (bb), provided  
3           that—

4                   “(aa) the amount of the  
5                   total appropriation for the Food  
6                   and Drug Administration for  
7                   such fiscal year (excluding the  
8                   amount of fees appropriated for  
9                   such fiscal year) exceeds the  
10                  amount of the total appropriation  
11                  for the Food and Drug Adminis-  
12                  tration for fiscal year 2007 (ex-  
13                  cluding the amount of fees appro-  
14                  priated for such fiscal year), ad-  
15                  justed as provided under sub-  
16                  section (c)(1); and

17                   “(bb) the amount of the  
18                   total appropriations for the proc-  
19                   ess of human drug review at the  
20                   Food and Drug Administration  
21                   for such fiscal year (excluding  
22                   the amount of fees appropriated  
23                   for such fiscal year) exceeds the  
24                   amount of appropriations for the  
25                   process of human drug review at

1 the Food and Drug Administra-  
2 tion for fiscal year 2007 (exclud-  
3 ing the amount of fees appro-  
4 priated for such fiscal year), ad-  
5 justed as provided under sub-  
6 section (c)(1).

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

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

16 (c) ADJUSTMENTS TO FEES.—

17 (1) INFLATION ADJUSTMENT.—Section  
18 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

19 (A) in the matter preceding subparagraph  
20 (A), by striking “The revenues established in  
21 subsection (b)” and inserting “For fiscal year  
22 2009 and subsequent fiscal years, the revenues  
23 established in subsection (b)”;

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

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

3 (D) by inserting after subparagraph (B)  
4 the following:

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

11 (E) in the matter following subparagraph  
12 (C) (as added under this paragraph), by strik-  
13 ing “fiscal year 2003” and inserting “fiscal  
14 year 2008”.

15 (2) WORKLOAD ADJUSTMENT.—Section  
16 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

17 (A) in the matter preceding subparagraph  
18 (A), by striking “Beginning with fiscal year  
19 2004,” and inserting “For fiscal year 2009 and  
20 subsequent fiscal years,”;

21 (B) in subparagraph (A), in the first sen-  
22 tence—

23 (i) by striking “human drug applica-  
24 tions,” and inserting “human drug applica-  
25 tions (adjusted for changes in review ac-



1 activities, as described in the notice that the  
2 Secretary is required to publish in the  
3 Federal Register under this subpara-  
4 graph),”;

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

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

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

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

24 “(C) The Secretary shall contract with an  
25 independent accounting firm to study the ad-

1           justment for changes in review activities applied  
2           in setting fees and revenue amounts for fiscal  
3           year 2009 and to make recommendations, if  
4           warranted, for future changes in the method-  
5           ology for calculating the adjustment. After re-  
6           view of the recommendations, the Secretary  
7           shall, if warranted, make appropriate changes  
8           to the methodology, and the changes shall be ef-  
9           fective for each of the fiscal years 2010 through  
10          2012. The Secretary shall not make any adjust-  
11          ment for changes in review activities for any  
12          fiscal year after 2009 unless such study has  
13          been completed.”.

14           (3) RENT AND RENT-RELATED COST ADJUST-  
15          MENT.—Section 736(c) (21 U.S.C. 379h(c)) is  
16          amended—

17                   (A) by redesignating paragraphs (3), (4),  
18                   and (5) as paragraphs (4), (5), and (6), respec-  
19                   tively; and

20                   (B) by inserting after paragraph (2) the  
21                   following:

22                   “(3) RENT AND RENT-RELATED COST ADJUST-  
23                   MENT.—For fiscal year 2010 and each subsequent  
24                   fiscal year, the Secretary shall, before making ad-  
25                   justments under paragraphs (1) and (2), decrease

1 the fee revenue amount established in subsection (b)  
2 if actual costs paid for rent and rent-related ex-  
3 penses for the preceding fiscal year are less than es-  
4 timates made for such year in fiscal year 2006. Any  
5 reduction made under this paragraph shall not ex-  
6 ceed the amount by which such costs fall below the  
7 estimates made in fiscal year 2006 for such fiscal  
8 year, and shall not exceed \$11,721,000 for any fiscal  
9 year.”.

10 (4) FINAL YEAR ADJUSTMENT.—Section 736(c)  
11 (21 U.S.C. 379h(c)) is amended—

12 (A) in paragraph (4) (as redesignated by  
13 paragraph (3)(A))—

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

16 (ii) by striking “paragraphs (1) and  
17 (2)” and inserting “paragraphs (1), (2),  
18 and (3)”;

19 (iii) by striking “2008” and inserting  
20 “2013”;

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

23 (d) FEE WAIVER OR REDUCTION.—Section 736(d)  
24 (21 U.S.C. 379h(d)) is amended—

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

3                   (A) by inserting after “The Secretary shall  
4                   grant” the following: “to a person who is  
5                   named as the applicant in a human drug appli-  
6                   cation”; and

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

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

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

13                   “(2) CONSIDERATIONS.—In determining wheth-  
14                   er to grant a waiver or reduction of a fee under  
15                   paragraph (1), the Secretary shall consider only the  
16                   circumstances and assets of the applicant involved  
17                   and any affiliate of the applicant.”; and

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

24           (e) CREDITING AND AVAILABILITY OF FEES.—

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

4           “(3) AUTHORIZATION OF APPROPRIATIONS.—  
5           For each of the fiscal years 2008 through 2012,  
6           there is authorized to be appropriated for fees under  
7           this section an amount equal to the total revenue  
8           amount determined under subsection (b) for the fis-  
9           cal year, as adjusted or otherwise affected under  
10          subsection (c) and paragraph (4) of this sub-  
11          section.”.

12          (2) OFFSET.—Section 736(g)(4) (21 U.S.C.  
13          379h(g)(4)) is amended to read as follows:

14          “(4) OFFSET.—If the sum of the cumulative  
15          amount of fees collected under this section for the  
16          fiscal years 2008 through 2010 and the amount of  
17          fees estimated to be collected under this section for  
18          fiscal year 2011 exceeds the cumulative amount ap-  
19          propriated under paragraph (3) for the fiscal years  
20          2008 through 2011, the excess shall be credited to  
21          the appropriation account of the Food and Drug Ad-  
22          ministration as provided in paragraph (1), and shall  
23          be subtracted from the amount of fees that would  
24          otherwise be authorized to be collected under this

1 section pursuant to appropriation Acts for fiscal  
2 year 2012.”.

3 (f) EXEMPTION FOR ORPHAN DRUGS.—Section 736  
4 (21 U.S.C. 379h) is further amended by adding at the  
5 end the following:

6 “(k) ORPHAN DRUGS.—A drug designated under sec-  
7 tion 526 for a rare disease or condition and approved  
8 under section 505 or under section 351 of the Public  
9 Health Service Act shall be exempt from product and facil-  
10 ity fees under this section, provided that the drug meets  
11 all of the following:

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

17 “(2) The drug meets the public health require-  
18 ments contained in this Act as such requirements  
19 are applied to requests for waivers for product and  
20 facility fees.

21 “(3) The drug is owned or licensed and mar-  
22 keted by a company that had less than  
23 \$100,000,000 in gross worldwide revenue during the  
24 previous year.”.

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

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

7 Part 2 of subchapter C of chapter VII (21 U.S.C.  
8 379g et seq.) is amended by adding after section 736 the  
9 following:

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

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

16 “(1) ADVISORY REVIEW FEE.—

17 “(A) IN GENERAL.—With respect to a pro-  
18 posed direct-to-consumer television advertise-  
19 ment (referred to in this section as a ‘DTC ad-  
20 vertisement’), each person that on or after Oc-  
21 tober 1, 2007, submits such an advertisement  
22 for advisory review by the Secretary prior to its  
23 initial public broadcast (referred to in this sec-  
24 tion as ‘prebroadcast advisory review’) shall, ex-

1           cept as provided in subparagraph (B), be sub-  
2           ject to a fee established under subsection (c)(3).

3           “(B) EXCEPTION FOR REQUIRED SUBMIS-  
4           SIONS.—A DTC advertisement that is required  
5           under section 502(n) to be submitted to the  
6           Secretary prior to initial public broadcast is not  
7           subject to a fee under subparagraph (A) unless  
8           the sponsor designates the submission as a sub-  
9           mission for prebroadcast advisory review.

10          “(C) NOTICE TO SECRETARY OF NUMBER  
11          OF ADVERTISEMENTS.—Not later than June 1  
12          of each fiscal year, the Secretary shall publish  
13          a notice in the Federal Register requesting any  
14          person to notify the Secretary within 30 days of  
15          the number of DTC advertisements the person  
16          intends to submit for prebroadcast advisory re-  
17          view in the next fiscal year.

18          “(D) PAYMENT.—

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



1 prebroadcast advisory review, subject to  
2 subparagraph (F)(i).

3 “(ii) EFFECT OF SUBMISSION.—Noti-  
4 fication of the Secretary under subpara-  
5 graph (C) of the number of DTC adver-  
6 tisements a person intends to submit for  
7 prebroadcast advisory review is a legally  
8 binding commitment by that person to pay  
9 the annual advisory review fee for that  
10 number of submissions on or before Octo-  
11 ber 1 of the fiscal year in which the adver-  
12 tisement is intended to be submitted.

13 “(iii) NOTICE REGARDING CARRYOVER  
14 SUBMISSIONS.—In making a notification  
15 under subparagraph (C), the person in-  
16 volved shall in addition notify the Sec-  
17 retary if under subparagraph (F)(i) the  
18 person intends to submit a DTC advertise-  
19 ment for which the advisory review fee has  
20 already been paid. If the person does not  
21 so notify the Secretary, each DTC adver-  
22 tisement submitted by the person for  
23 prebroadcast advisory review in the fiscal  
24 year involved shall be subject to the advi-  
25 sory review fee.

1                   “(E) MODIFICATION OF ADVISORY REVIEW  
2 FEE.—

3                   “(i) LATE PAYMENT.—If a person has  
4 submitted a notification under subpara-  
5 graph (C) with respect to a fiscal year and  
6 has not paid all advisory review fees due  
7 under subparagraph (D) on or before No-  
8 vember 1 of such fiscal year, the fees are  
9 regarded as late and a revised due date  
10 and an increase in the amount of fees ap-  
11 plies in accordance with this clause, not-  
12 withstanding any other provision of this  
13 section. For such person, the advisory re-  
14 view fee for each DTC advertisement sub-  
15 mitted in such fiscal year for prebroadcast  
16 advisory review shall be due and payable  
17 20 days before the advertisement is sub-  
18 mitted to the Secretary, and each such fee  
19 shall be revised to be equal to 150 percent  
20 of the fee that otherwise would have ap-  
21 plied pursuant to subsection (c)(3).

22                   “(ii) EXCEEDING IDENTIFIED NUM-  
23 BER OF SUBMISSIONS.—If a person sub-  
24 mits a number of DTC ads for  
25 prebroadcast advisory review in a fiscal

1 year that exceeds the number identified by  
2 the person under subparagraph (C), a re-  
3 vised due date and an increase in the  
4 amount of fees applies under this clause  
5 for each submission in excess of such num-  
6 ber, notwithstanding any other provision of  
7 this section. For each such DTC ad, the  
8 advisory review fee shall be due and pay-  
9 able 20 days before the advertisement is  
10 submitted to the Secretary, and the fee  
11 shall be revised to be equal to 150 percent  
12 of the fee that otherwise would have ap-  
13 plied pursuant to subsection (c)(3).

14 “(F) LIMITS.—

15 “(i) SUBMISSIONS.—For each advi-  
16 sory review fee paid by a person for a fis-  
17 cal year, the person is entitled to accept-  
18 ance for advisory review by the Secretary  
19 of one DTC advertisement and acceptance  
20 of one resubmission for advisory review of  
21 the same advertisement. The advertisement  
22 shall be submitted for review in the fiscal  
23 year for which the fee was assessed, except  
24 that a person may carry over not more  
25 than one paid advisory review submission

1 to the next fiscal year. Resubmissions may  
2 be submitted without regard to the fiscal  
3 year of the initial advisory review submis-  
4 sion.

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

8 “(iii) NO WAIVERS, EXEMPTIONS, OR  
9 REDUCTIONS.—The Secretary shall not  
10 grant a waiver, exemption, or reduction of  
11 any fees due or payable under this section.

12 “(iv) RIGHT TO ADVISORY REVIEW  
13 NOT TRANSFERABLE.—The right to an ad-  
14 visory review under this paragraph is not  
15 transferable, except to a successor in inter-  
16 est.

17 “(2) OPERATING RESERVE FEE.—

18 “(A) IN GENERAL.—Each person that on  
19 or after October 1, 2007, is assessed an advi-  
20 sory review fee under paragraph (1) shall be  
21 subject to fee established under subsection  
22 (d)(2) referred to in this section as an ‘oper-  
23 ating reserve fee’ for the first fiscal year in  
24 which an advisory review fee is assessed to such

1 person. The person is not subject to an oper-  
2 ating reserve fee for any other fiscal year.

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

8 “(C) LATE NOTICE OF SUBMISSION.—If, in  
9 the first fiscal year of a person’s participation  
10 in the program under this section, that person  
11 submits any DTC advertisements for  
12 prebroadcast advisory review that are in excess  
13 of the number identified by that person in re-  
14 sponse to the Federal Register notice described  
15 in subsection (a)(1)(C), that person shall pay  
16 an operating reserve fee for each of those advi-  
17 sory reviews equal to the advisory review fee for  
18 each submission established under paragraph  
19 (1)(D)(ii). Fees required by this subparagraph  
20 shall be in addition to any fees required by sub-  
21 paragraph (A). Fees under this subparagraph  
22 shall be due 20 days before any DTC advertise-  
23 ment is submitted by such person to the Sec-  
24 retary for prebroadcast advisory review.

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

6       “(c) ADJUSTMENTS.—

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

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

18                   “(B) the total percentage change for the  
19 previous fiscal year in basic pay under the Gen-  
20 eral Schedule in accordance with section 5332  
21 of title 5, United States Code, as adjusted by  
22 any locality-based comparability payment pur-  
23 suant to section 5304 of such title for Federal  
24 employees stationed in the District of Columbia;  
25 or

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

7           The adjustment made each fiscal year by this sub-  
8           section will be added on a compounded basis to the  
9           sum of all adjustments made each fiscal year after  
10          fiscal year 2008 under this subsection.

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

20                 “(A) The adjustment shall be determined  
21                 by the Secretary based upon the number of  
22                 DTC advertisements identified pursuant to sub-  
23                 section (a)(1)(C) for the upcoming fiscal year,  
24                 excluding allowable previously paid carry over  
25                 submissions. The adjustment shall be deter-

1           mined by multiplying the number of such adver-  
2           tisements projected for that fiscal year that ex-  
3           ceeds 150 by \$27,600 (adjusted each year be-  
4           ginning with fiscal year 2009 for inflation in  
5           accordance with paragraph (1)). The Secretary  
6           shall publish in the Federal Register the fee  
7           revenues and fees resulting from the adjust-  
8           ment and the supporting methodologies.

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

13          “(3) ANNUAL FEE SETTING FOR ADVISORY RE-  
14          VIEW.—

15          “(A) IN GENERAL.—Not later than August  
16          1 of each fiscal year, the Secretary shall estab-  
17          lish for the next fiscal year the DTC advertise-  
18          ment advisory review fee under subsection  
19          (a)(1), based on the revenue amounts estab-  
20          lished under subsection (b), the adjustments  
21          provided under paragraphs (1) and (2), and the  
22          number of DTC advertisements identified pur-  
23          suant to subsection (a)(1)(C), excluding allow-  
24          able previously-paid carry over submissions.  
25          The annual advisory review fee shall be estab-



1           lished by dividing the fee revenue for a fiscal  
2           year (as adjusted pursuant to this subsection)  
3           by the number of DTC advertisements so iden-  
4           tified, excluding allowable previously-paid carry  
5           over submissions.

6           “(B) FISCAL YEAR 2008 FEE LIMIT.—Not-  
7           withstanding subsection (b) and the adjust-  
8           ments pursuant to this subsection, the fee es-  
9           tablished under subparagraph (A) for fiscal  
10          year 2008 may not be more than \$83,000 per  
11          submission for advisory review.

12          “(C) ANNUAL FEE LIMIT.—Notwith-  
13          standing subsection (b) and the adjustments  
14          pursuant to this subsection, the fee established  
15          under subparagraph (A) for a fiscal year after  
16          fiscal year 2008 may not be more than 50 per-  
17          cent more than the fee established for the prior  
18          fiscal year.

19          “(D) LIMIT.—The total amount of fees ob-  
20          ligated for a fiscal year may not exceed the  
21          total costs for such fiscal year for the resources  
22          allocated for the process for the advisory review  
23          of prescription drug advertising.

24          “(d) OPERATING RESERVES.—

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

11          “(2) FEE SETTING.—The Secretary shall estab-  
12          lish the operating reserve fee under subsection  
13          (a)(2)(A) for each person required to pay the fee by  
14          multiplying the number of DTC advertisements iden-  
15          tified by that person pursuant to subsection  
16          (a)(1)(C) by the advisory review fee established pur-  
17          suant to subsection (c)(3) for that fiscal year, except  
18          that in no case shall the operating reserve fee as-  
19          sessed be less than the operating reserve fee as-  
20          sessed if the person had first participated in the pro-  
21          gram under this section in fiscal year 2008.

22          “(3) USE OF OPERATING RESERVE.—The Sec-  
23          retary may use funds from the reserves only to the  
24          extent necessary in any fiscal year to make up the  
25          difference between the fee revenue amount estab-

1 lished for that fiscal year under subsections (b) and  
2 (c) and the amount of fees actually collected for that  
3 fiscal year pursuant to subsection (a)(1), or to pay  
4 costs of ending the program under this section if it  
5 is terminated pursuant to subsection (f) or not reau-  
6 thorized beyond fiscal year 2012.

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

19 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-  
20 standing any other requirement, a submission for  
21 prebroadcast advisory review of a DTC advertisement sub-  
22 mitted by a person subject to fees under subsection (a)  
23 shall be considered incomplete and shall not be accepted  
24 for review by the Secretary until all fees owed by such  
25 person under this section have been paid.

1       “(f) EFFECT OF INADEQUATE FUNDING OF PRO-  
2 GRAM.—

3           “(1) INITIAL FUNDING.—If on November 1,  
4       2007, or 120 days after enactment of this provision,  
5       whichever is later, the Secretary has not received at  
6       least \$11,250,000 in advisory review fees and oper-  
7       ating reserve fees combined, the program under this  
8       section shall not commence and all collected fees  
9       shall be refunded.

10          “(2) LATER FISCAL YEARS.—Beginning in fis-  
11       cal year 2009, if, on November 1 of the fiscal year,  
12       the combination of the operating reserves, annual fee  
13       revenues from that fiscal year, and unobligated fee  
14       revenues from prior fiscal years falls below  
15       \$9,000,000, adjusted for inflation (as described in  
16       subsection (c)(1)), the program under this section  
17       shall cease to exist, and the Secretary shall notify all  
18       participants, retain any money from the unused ad-  
19       visory review fees and the operating reserves needed  
20       to close down the program under this section, and  
21       refund the remainder of the unused fees and oper-  
22       ating reserves. To the extent required to close down  
23       the program under this section, the Secretary shall  
24       first use unobligated advisory review fee revenues  
25       from prior fiscal years, then the operating reserves,

1 and finally, unused advisory review fees from the rel-  
2 evant fiscal year.

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

4 “(1) IN GENERAL.—Fees authorized under sub-  
5 section (a) of this section shall be collected and  
6 available for obligation only to the extent and in the  
7 amount provided in advance in appropriations Acts.  
8 Such fees are authorized to remain available until  
9 expended. Such sums as may be necessary may be  
10 transferred from the Food and Drug Administration  
11 salaries and expenses appropriation account without  
12 fiscal year limitation to such appropriation account  
13 for salaries and expenses with such fiscal year limi-  
14 tation. The sums transferred shall be available solely  
15 for the process for the advisory review of prescrip-  
16 tion drug advertising.

17 “(2) COLLECTIONS AND APPROPRIATION  
18 ACTS.—

19 “(A) IN GENERAL.—The fees authorized  
20 by this section—

21 “(i) shall be retained in each fiscal  
22 year in an amount not to exceed the  
23 amount specified in appropriation Acts, or  
24 otherwise made available for obligation for  
25 such fiscal year; and

1           “(ii) shall be available for obligation  
2           only if the amounts appropriated as budget  
3           authority for such fiscal year are sufficient  
4           to support a number of full-time equivalent  
5           review employees that is not fewer than the  
6           number of such employees supported in fis-  
7           cal year 2007.

8           “(B) REVIEW EMPLOYEES.—For purposes  
9           of subparagraph (A)(ii), the term ‘full-time  
10          equivalent review employees’ means the total  
11          combined number of full-time equivalent em-  
12          ployees in—

13                 “(i) the Center for Drug Evaluation  
14                 and Research, Division of Drug Marketing,  
15                 Advertising, and Communications, Food  
16                 and Drug Administration; and

17                 “(ii) the Center for Biologics Evalua-  
18                 tion and Research, Advertising and Pro-  
19                 motional Labeling Branch, Food and Drug  
20                 Administration.

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

1 cal year, as adjusted pursuant to subsection (c) and  
2 paragraph (4) of this subsection, plus amounts col-  
3 lected for the reserve fund under subsection (d).

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

13 “(h) DEFINITIONS.—For purposes of this sub-  
14 chapter:

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

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

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

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

6           “(5) The term ‘DTC advertisement’ has the  
7           meaning indicated for such term in subsection  
8           (a)(1)(A).

9           “(6) The term ‘operating reserve fee’ has the  
10          meaning indicated for such term in subsection  
11          (a)(2)(A).

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

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

18          “(9) The term ‘process for the advisory review  
19          of prescription drug advertising’ means the activities  
20          necessary to review and provide advisory comments  
21          on DTC advertisements prior to public broadcast  
22          and, to the extent the Secretary has additional staff  
23          resources available under the program under this  
24          section that are not necessary for the advisory re-  
25          view of DTC advertisements, the activities necessary



1 to review and provide advisory comments on other  
2 proposed advertisements and promotional material  
3 prior to public broadcast.

4 “(10) The term ‘resources allocated for the  
5 process for the advisory review of prescription drug  
6 advertising’ means the expenses incurred in connec-  
7 tion with the process for the advisory review of pre-  
8 scription drug advertising for—

9 “(A) officers and employees of the Food  
10 and Drug Administration, contractors of the  
11 Food and Drug Administration, advisory com-  
12 mittees, and costs related to such officers, em-  
13 ployees, and committees, and to contracts with  
14 such contractors;

15 “(B) management of information, and the  
16 acquisition, maintenance, and repair of com-  
17 puter resources;

18 “(C) leasing, maintenance, renovation, and  
19 repair of facilities and acquisition, maintenance,  
20 and repair of fixtures, furniture, scientific  
21 equipment, and other necessary materials and  
22 supplies;

23 “(D) collection of fees under this section  
24 and accounting for resources allocated for the

1 advisory review of prescription drug advertising;  
2 and

3 “(E) closing down the program under this  
4 section pursuant to subsection (f)(2) if that be-  
5 comes necessary.

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

13 “(12) The term ‘submission for advisory review’  
14 means an original submission of a direct-to-con-  
15 sumer television advertisement for which the sponsor  
16 voluntarily requests advisory comments before the  
17 advertisement is publicly disseminated.”.

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

19 (a) PERFORMANCE REPORT.—Beginning with fiscal  
20 year 2008, not later than 120 days after the end of each  
21 fiscal year for which fees are collected under part 2 of  
22 subchapter C of chapter VII of the Federal Food, Drug,  
23 and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary  
24 of Health and Human Services (referred to in this section  
25 as the “Secretary”) shall prepare and submit to the Com-

1 mittee on Energy and Commerce of the House of Rep-  
2 resentatives and the Committee on Health, Education,  
3 Labor, and Pensions of the Senate a report concerning  
4 the progress of the Food and Drug Administration in  
5 achieving the goals identified in the letters described in  
6 section 502(4) of the Prescription Drug User Fee Amend-  
7 ments of 2002 (Subtitle A of title V of Public Law 107-  
8 188) during such fiscal year and the future plans of the  
9 Food and Drug Administration for meeting the goals.

10 (b) FISCAL REPORT.—Beginning with fiscal year  
11 2008, not later than 120 days after the end of each fiscal  
12 year for which fees are collected under the part described  
13 in subsection (a), the Secretary shall prepare and submit  
14 to the Committee on Energy and Commerce of the House  
15 of Representatives and the Committee on Health, Edu-  
16 cation, Labor, and Pensions of the Senate a report on the  
17 implementation of the authority for such fees during such  
18 fiscal year and the use, by the Food and Drug Administra-  
19 tion, of the fees collected for such fiscal year.

20 (c) REAUTHORIZATION.—

21 (1) CONSULTATION.—In developing rec-  
22 ommendations to present to the Congress with re-  
23 spect to the goals, and plans for meeting the goals,  
24 for the process for the review of human drug appli-  
25 cations for the first 5 fiscal years after fiscal year

1 2012, and for the reauthorization of this part for  
2 such fiscal years, the Secretary shall consult with—

3 (A) the Committee on Energy and Com-  
4 merce of the House of Representatives;

5 (B) the Committee on Health, Education,  
6 Labor, and Pensions of the Senate;

7 (C) scientific and academic experts;

8 (D) health care professionals;

9 (E) representatives of patient and con-  
10 sumer advocacy groups; and

11 (F) the regulated industry.

12 (2) PUBLIC REVIEW OF RECOMMENDATIONS.—

13 After negotiations with the regulated industry and  
14 representatives of patient and consumer advocacy  
15 groups, the Secretary shall—

16 (A) present the recommendations devel-  
17 oped under paragraph (1) to the congressional  
18 committees specified in such paragraph;

19 (B) publish such recommendations in the  
20 Federal Register;

21 (C) provide for a period of 30 days for the  
22 public to provide written comments on such rec-  
23 ommendations;

1           (D) hold a meeting at which the public  
2           may present its views on such recommenda-  
3           tions; and

4           (E) after consideration of such public  
5           views and comments, revise such recommenda-  
6           tions as necessary.

7           (3) TRANSMITTAL OF RECOMMENDATIONS.—  
8           Not later than January 15, 2012, the Secretary  
9           shall transmit to Congress the revised recommenda-  
10          tions under paragraph (2), a summary of the views  
11          and comments received under such paragraph, and  
12          any changes made to the recommendations in re-  
13          sponse to such views and comments.

14          (4) PUBLIC AVAILABILITY OF MINUTES.—Be-  
15          fore presenting the recommendations developed  
16          under paragraphs (1) and (2) to the Congress, the  
17          Secretary shall make publicly available, on the public  
18          website of the Food and Drug Administration, the  
19          minutes of all negotiations conducted under para-  
20          graph (1) or (2), as applicable, between the Food  
21          and Drug Administration and the regulated industry  
22          and representatives of patient and consumer advoca-  
23          cacy groups.

1 **SEC. 106. SUNSET DATES.**

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

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

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

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

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

14 **Subtitle A—Fees Related to**  
15 **Medical Devices**

16 **SEC. 211. DEFINITIONS.**

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

18 (1) in paragraph (4)—

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

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

24 “(F) The term ‘30-day notice’ means a supple-  
25 ment to an approved premarket application or pre-  
26 market report under section 515 that is limited to

1 a request to make modifications to manufacturing  
2 procedures or methods of manufacture affecting the  
3 safety and effectiveness of the device.”;

4 (2) by redesignating paragraphs (5), (6), (7),  
5 and (8) as paragraphs (7), (8), (9), and (11), re-  
6 spectively;

7 (3) by inserting after paragraph (4), as amend-  
8 ed by paragraph (1) of this section, the following:

9 “(5) The term ‘request for classification infor-  
10 mation’ means a request made under section 513(g)  
11 for information respecting the class in which a de-  
12 vice has been classified or the requirements applica-  
13 ble to a device.

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

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

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

24 (B) by striking “April 2002” and inserting  
25 “October 2001”;

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

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

5           (6) by inserting after paragraph (11), as reded-  
6 icated by paragraph (2) of this section, the fol-  
7 lowing:

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

12           “(A) MANUFACTURER.—An establishment  
13 that makes by any means any article that is a  
14 device, as defined in section 201(h), including  
15 an establishment that sterilizes or otherwise  
16 makes such article for or on behalf of a speci-  
17 fication developer or any other person.

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

21           “(C) SPECIFICATION DEVELOPER.—An es-  
22 tablishment that develops specifications for a  
23 device that is distributed under the establish-  
24 ment’s name but which performs no manufac-  
25 turing, including an establishment that, in addi-



1           tion to developing specifications, also arranges  
2           for the manufacturing of devices labeled with  
3           another establishment’s name by a contract  
4           manufacturer.”.

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

6           (a) TYPES OF FEES.—

7           (1) IN GENERAL.—The designation and heading  
8           of paragraph (2) of section 738(a) (21 U.S.C.  
9           379j(a)(2)) are amended to read as follows:

10           “(2) PREMARKET APPLICATION, PREMARKET  
11           REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND  
12           ANNUAL FEE FOR PERIODIC REPORTING CON-  
13           CERNING A CLASS III DEVICE.—”.

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

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

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

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

23           (D) by redesignating clauses (vi) and (vii)  
24           as clauses (vii) and (viii), respectively;

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

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

6 (F) in clause (viii), as so redesignated, by  
7 striking “1.42 percent” and inserting “1.84  
8 percent”; and

9 (G) by inserting after such clause (viii) the  
10 following:

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

14 “(x) For periodic reporting concerning  
15 a class III device, the annual fee shall be  
16 equal to 3.5 percent of the fee that applies  
17 under clause (i).”.

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

20 “(C) PAYMENT.—The fee required by sub-  
21 paragraph (A) shall be due upon submission of  
22 the premarket application, premarket report,  
23 supplement, premarket notification submission,  
24 30-day notice, request for classification infor-  
25 mation, or periodic reporting concerning a class

1           III device. Applicants submitting portions of  
2           applications pursuant to section 515(c)(3) shall  
3           pay such fees upon submission of the first por-  
4           tion of such applications.”.

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

8                   “(iv) MODULAR APPLICATIONS WITH-  
9                   DRAWN BEFORE FIRST ACTION.—The Sec-  
10                  retary shall refund 75 percent of the appli-  
11                  cation fee paid for a modular application  
12                  submitted under section 515(c)(4) that is  
13                  withdrawn before a second module is sub-  
14                  mitted and before a first action on the first  
15                  module. If the modular application is with-  
16                  drawn after a second or subsequent module  
17                  is submitted but before any first action,  
18                  the Secretary may return a portion of the  
19                  fee. The amount of refund, if any, shall be  
20                  based on the level of effort already ex-  
21                  pended on the review of the modules sub-  
22                  mitted.”.

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

1           “(3) ANNUAL ESTABLISHMENT REGISTRATION  
2 FEE.—

3           “(A) IN GENERAL.—Except as provided in  
4 subparagraph (B), each establishment subject  
5 to registration shall be subject to a fee for each  
6 initial or annual registration under section 510  
7 beginning with its registration for fiscal year  
8 2008.

9           “(B) EXCEPTION.—No fee shall be re-  
10 quired under subparagraph (A) for an estab-  
11 lishment operated by a State or Federal govern-  
12 mental entity or an Indian tribe (as defined in  
13 the Indian Self Determination and Educational  
14 Assistance Act), unless a device manufactured  
15 by the establishment is to be distributed com-  
16 mercially.

17           “(C) PAYMENT.—The fee required under  
18 subparagraph (A) shall be due once each fiscal  
19 year, upon the initial registration of the estab-  
20 lishment or upon the annual registration under  
21 section 510.”.

22           (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.  
23 379j(b)) is amended to read as follows:

24           “(b) FEE AMOUNTS.—Except as provided in  
25 subsections (c), (d), and (e), the fees under sub-

1 section (a) shall be based on the following fee  
2 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.”.

3 (c) ANNUAL FEE SETTING.—

4 (1) IN GENERAL.—Section 738(c) (21 U.S.C.  
5 379j(c)(1)) is amended—

6 (A) in the subsection heading, by striking  
7 “Annual Fee Setting” and inserting “ANNUAL  
8 FEE SETTING”; and

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

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

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

16 (B) by inserting after paragraph (1) the  
17 following:

18 “(2) ADJUSTMENT.—

1           “(A) IN GENERAL.—When setting fees for  
2           fiscal year 2010, the Secretary may increase the  
3           fee under subsection (a)(3)(A) (applicable to es-  
4           tablishments subject to registration) only if the  
5           Secretary estimates that the number of estab-  
6           lishments submitting fees for fiscal year 2009 is  
7           less than 12,250. The percentage increase shall  
8           be the percentage by which the estimate of es-  
9           tablishments submitting fees in fiscal year 2009  
10          is less than 12,750, but in no case may the per-  
11          centage increase be more than 8.5 percent over  
12          that specified in subsection (b) for fiscal year  
13          2010. If the Secretary makes any adjustment to  
14          the fee under subsection (a)(3)(A) for fiscal  
15          year 2010, then such fee for fiscal years 2011  
16          and 2012 shall be adjusted so that such fee for  
17          fiscal year 2011 is equal to the adjusted fee for  
18          fiscal year 2010 increased by 8.5 percent, and  
19          such fee for fiscal year 2012 is equal to the ad-  
20          justed fee for fiscal year 2011 increased by 8.5  
21          percent.

22           “(B) PUBLICATION.—For any adjustment  
23          made under subparagraph (A), the Secretary  
24          shall publish in the Federal Register the Sec-

1           retary’s determination to make the adjustment  
2           and the rationale for the determination.”; and

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

5           (i) by striking “For fiscal years 2006  
6           and 2007, the Secretary” and inserting  
7           “‘The Secretary’”; and

8           (ii) by striking “for the first month of  
9           fiscal year 2008” and inserting “for the  
10          first month of the next fiscal year”.

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

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

15           (A) by striking “, partners, and parent  
16           firms”; and

17           (B) by striking “clauses (i) through (vi) of  
18           subsection (a)(2)(A)” and inserting “clauses (i)  
19           through (v) and clauses (vii), (ix), and (x) of  
20           subsection (a)(2)(A)”.

21          (2) RULES RELATING TO PREMARKET AP-  
22          PROVAL FEES.—

23           (A) DEFINITION.—Section 738(d)(2)(A)  
24           (21 U.S.C. 379j(d)(2)(A)) is amended by strik-  
25           ing “, partners, and parent firms”.

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

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

7 “(B) EVIDENCE OF QUALIFICATION.—

8 “(i) IN GENERAL.—An applicant”;

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

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

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

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

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

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



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

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

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

6           “(C) REDUCED FEES.—Where the Sec-  
7           retary finds that the applicant involved meets  
8           the definition under subparagraph (A), the fees  
9           established under subsection (c)(1) may be paid  
10          at a reduced rate of—

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

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

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

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

1 (A) by striking “2004” and inserting  
2 “2008”; and

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

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

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

10 (B) EVIDENCE OF QUALIFICATION.—Sec-  
11 tion 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(A)) 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 and 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 and sales were col-  
8 lected. The applicant shall also submit a  
9 statement signed by the head of the appli-  
10 cant's firm or by its chief financial officer  
11 that the applicant has submitted certifi-  
12 cations for all of its affiliates, or that the  
13 applicant has no affiliates.”.

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

16 “(C) REDUCED FEES.—For fiscal year  
17 2008 and each subsequent fiscal year, where  
18 the Secretary finds that the applicant involved  
19 meets the definition under subparagraph (A),  
20 the fee for a premarket notification submission  
21 may be paid at 50 percent of the fee that ap-  
22 plies under subsection (a)(2)(A)(viii), and as es-  
23 tablished under subsection (c)(1).”.

24 (f) EFFECT OF FAILURE TO PAY FEES.—Section  
25 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

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

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

11 “(2) NO REGISTRATION.—Registration informa-  
12 tion submitted under section 510 by an establish-  
13 ment subject to registration shall be considered in-  
14 complete and shall not be accepted by the Secretary  
15 until the registration fee under subsection (a)(3)  
16 owed for the establishment has been paid. Until the  
17 fee is paid and the registration is complete, the es-  
18 tablishment is deemed to have failed to register in  
19 accordance with section 510.”.

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

22 (1) in paragraph (1)(D)—

23 (A) in the matter preceding clause (i), by  
24 striking “For fiscal year 2007” and inserting

1           “For fiscal year 2007 and for each subsequent  
2           year”;

3           (B) in clause (i), by striking “applicable to  
4           fiscal year 2007” and inserting “applicable to  
5           such fiscal year”; and

6           (C) in clause (ii)—

7           (i) by striking “subparagraph (C)”  
8           and inserting “this subparagraph”; and

9           (ii) by striking “for fiscal year 2006”  
10          and inserting “for the previous fiscal  
11          year”; and

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

14           “(2) AUTHORITY.—If the Secretary does not  
15           assess fees under subsection (a) during any portion  
16           of a fiscal year because of subparagraph (C) or (D)  
17           of paragraph (1) and if at a later date in such fiscal  
18           year the Secretary may assess such fees, the Sec-  
19           retary may assess and collect such fees, without any  
20           modification in the rate for premarket applications,  
21           supplements, premarket reports, premarket notifica-  
22           tion submissions, 30-day notices, requests for classi-  
23           fication information, periodic reporting concerning a  
24           class III device, and establishment registrations at  
25           any time in such fiscal year, notwithstanding the

1 provisions of subsection (a) relating to the date fees  
2 are to be paid.”.

3 (h) CREDITING AND AVAILABILITY OF FEES.—

4 (1) AUTHORIZATION OF APPROPRIATIONS.—

5 Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amend-  
6 ed to read as follows:

7 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—

8 There are authorized to be appropriated for fees  
9 under this section—

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

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

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

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

14 and

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

16 (2) OFFSET.—Section 738(h)(4) (21 U.S.C.  
17 379j(h)(3)) is amended to read as follows:

18 “(4) OFFSET.—If the cumulative amount of  
19 fees collected during fiscal years 2008, 2009, and  
20 2010, added to the amount estimated to be collected  
21 for fiscal year 2011, which estimate shall be based  
22 upon the amount of fees received by the Secretary  
23 through June 30, 2011, exceeds the amount of fees  
24 specified in aggregate in paragraph (3) for these  
25 four fiscal years, the aggregate amount in excess



1 shall be credited to the appropriation account of the  
2 Food and Drug Administration as provided in para-  
3 graph (1), and shall be subtracted from the amount  
4 of fees that would otherwise be authorized to be col-  
5 lected under this section pursuant to appropriation  
6 Acts for fiscal year 2012.”.

7 **SEC. 213. ANNUAL REPORTS.**

8 Beginning with fiscal year 2008, the Secretary shall  
9 prepare and submit to the Committee on Energy and  
10 Commerce of the House of Representatives and the Com-  
11 mittee on Health, Education, Labor, and Pensions of the  
12 Senate a report concerning—

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

1           (2) the implementation of the authority for  
2           such fees during such fiscal year, and the use, by  
3           the Food and Drug Administration, of the fees col-  
4           lected during such fiscal year (including a descrip-  
5           tion of the use of such fees for postmarket safety ac-  
6           tivities), not later than 120 days after the end of  
7           each fiscal year during which fees are collected  
8           under the medical device user-fee program reauthor-  
9           ized by this title.

10 **SEC. 214. CONSULTATION.**

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

1           (b) RECOMMENDATIONS.—The Secretary shall pub-  
2 lish in the Federal Register recommendations under sub-  
3 section (a), after negotiations with the regulated industry  
4 and patient and consumer advocacy groups; shall present  
5 such recommendations to the congressional committees  
6 specified in such subsection; shall hold a meeting at which  
7 the public may present its views on such recommenda-  
8 tions; and shall provide for a period of 30 days for the  
9 public to provide written comments on such recommenda-  
10 tions.

11 **SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIA-**  
12 **TIONS FOR POSTMARKET SAFETY INFORMA-**  
13 **TION.**

14           For the purpose of collecting, developing, reviewing,  
15 and evaluating postmarket safety information on medical  
16 devices, there are authorized to be appropriated to the  
17 Food and Drug Administration, in addition to the  
18 amounts authorized by other provisions of law for such  
19 purpose, \$7,100,000 for fiscal year 2008, and for each of  
20 the fiscal years 2009 through 2012, \$7,100,000 increased  
21 by the amount necessary to offset the effects of inflation  
22 occurring after October 1, 2007.

23 **SEC. 216. EFFECTIVE DATE.**

24           The amendments made by this title shall take effect  
25 on the date of the enactment of this title, except that fees

1 shall be assessed for all premarket applications, premarket  
2 reports, supplements, and premarket notification submis-  
3 sions received on or after October 1, 2007, regardless of  
4 the date of enactment.

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

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

9 **Subtitle B—Amendments Regarding**  
10 **Regulation of Medical De-**  
11 **vices**

12 **SEC. 221. EXTENSION OF AUTHORITY FOR THIRD PARTY**  
13 **REVIEW OF PREMARKET NOTIFICATION.**

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

16 **SEC. 222. REGISTRATION.**

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

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

21 “(1) On or before”;

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

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

24 “(2) During the period beginning on October 1 and  
25 ending on December 31 of each year, every person who

1 owns or operates any establishment in any State engaged  
2 in the manufacture, preparation, propagation,  
3 compounding, or processing of a device or devices shall  
4 register with the Secretary his name, places of business,  
5 and all such establishments.”.

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

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

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

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

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

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

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

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

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

1       “(p)(1) Registrations and listings under this section  
2 (including the submission of updated information) shall be  
3 submitted to the Secretary by electronic means unless the  
4 Secretary grants a request for waiver of such requirement  
5 because use of electronic means is not reasonable for the  
6 person requesting such waiver.

7       “(2) With regard to any establishment engaged in the  
8 manufacture, preparation, propagation, compounding, or  
9 processing of a device, the registration and listing infor-  
10 mation required by this section shall be submitted to the  
11 Secretary by electronic means, unless the Secretary grants  
12 a waiver because electronic registration and listing is not  
13 reasonable for the person requesting such waiver.”.

14 **SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OF-**  
15 **FICE.**

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

22       (b) CONSIDERATION.—In determining the effective-  
23 ness of the premarket notification and classification au-  
24 thority under section 510(k) and subsections (f) and (i)  
25 of section 513, the study under subsection (a) shall con-

1 sider the Secretary's evaluation of the respective intended  
2 uses and technologies of such devices, including the effec-  
3 tiveness of the Secretary's comparative assessment of  
4 technological characteristics such as device materials,  
5 principles of operations, and power sources.

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

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

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

12 (1) by redesignating subsection (f) as sub-  
13 section (g); and

14 (2) by inserting after subsection (e) the fol-  
15 lowing:

16 “Unique Device Identification System

17 “(f) The Secretary shall promulgate regulations es-  
18 tablishing a unique device identification system for med-  
19 ical devices requiring the labeling of devices to bear a  
20 unique identifier.”.

21 **SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DE-**  
22 **VICES.**

23 Subparagraph (B) of section 519(a)(1) (21 U.S.C.  
24 360i(a)(1)) is amended by striking “were to recur;” and



1 inserting the following: “were to recur, which report under  
2 this subparagraph—

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

7 “(I) a class III device;

8 “(II) a class II device that is per-  
9 manently implantable, is life sup-  
10 porting, or is life sustaining; or

11 “(III) a type of device that the  
12 Secretary has by regulation deter-  
13 mined should be subject to such part  
14 803 in order to protect the public  
15 health; or

16 “(ii) shall, if the device is not subject  
17 to clause (i), be submitted in accordance  
18 with criteria established by the Secretary  
19 for reports made pursuant to this clause,  
20 which criteria shall require the reports to  
21 be in summary form and made on a quar-  
22 terly basis;”.

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

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

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

5           (2) in paragraph (2), by—

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

10          (B) striking the fifth sentence;

11          (3) in paragraph (3), by adding at the end the  
12 following:

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

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

23          (4) by amending paragraph (6) to read as fol-  
24 lows:

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

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

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

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

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

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

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

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

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

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

18                 “(I) denies clearance to participate as provided  
19                 under subparagraph (C); or

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

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

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

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

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

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

1 facilitated consistent compliance by promptly correcting  
2 any compliance problems identified in such inspections.

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

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

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

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

1           “(iii)(I) The Secretary may reject the selection of the  
2 accredited person identified in the notice under subpara-  
3 graph (A)(ii) if the Secretary provides to the owner or op-  
4 erator of the establishment a statement of the reasons for  
5 such rejection. Reasons for the rejection may include that  
6 the establishment or the accredited person, as the case  
7 may be, has failed to fully respond to the request, or that  
8 the Secretary has concerns regarding the relationship be-  
9 tween the establishment and such accredited person.

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

21           “(iv) In the case of a device establishment that is de-  
22 nied clearance under clause (i) or (ii) or with respect to  
23 which the selection of the accredited person is rejected  
24 under clause (iii), the Secretary shall designate a person  
25 to review the statement of reasons, or statement summa-

1 rizing such evidence, as the case may be, of the Secretary  
2 under such clause if, during the 30-day period beginning  
3 on the date on which the owner or operator of the estab-  
4 lishment receives such statement, the owner or operator  
5 requests the review. The review shall commence not later  
6 than 30 days after the owner or operator requests the re-  
7 view, unless the Secretary and the owner or operator oth-  
8 erwise agree.”;

9 (5) in paragraph (7)—

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



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

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

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

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

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

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

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

22 (A) Reprocessed single use devices.

23 (B) Handling of sterilized medical devices.

24 (C) In-hospital sterilization of medical de-  
25 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 **TITLE III—PEDIATRIC MEDICAL**  
18 **DEVICE SAFETY AND IM-**  
19 **PROVEMENT ACT OF 2007**

20 **SEC. 301. SHORT TITLE.**

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

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

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

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

6 “(a) NEW DEVICES.—

7 “(1) IN GENERAL.—A person that submits to  
8 the Secretary an application under section 520(m),  
9 or an application (or supplement to an application)  
10 or a product development protocol under section  
11 515, shall include in the application or protocol the  
12 information described in paragraph (2).

13 “(2) REQUIRED INFORMATION.—The applica-  
14 tion or protocol described in paragraph (1) shall in-  
15 clude, with respect to the device for which approval  
16 is sought and if readily available—

17 “(A) a description of any pediatric sub-  
18 populations that suffer from the disease or con-  
19 dition that the device is intended to treat, diag-  
20 nose, or cure; and

21 “(B) the number of affected pediatric pa-  
22 tients.

23 “(3) ANNUAL REPORT.—Not later than 18  
24 months after the date of enactment of this section,  
25 and annually thereafter, the Secretary shall submit  
26 to the Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Committee on En-  
2 ergy and Commerce of the House of Representatives  
3 a report that includes—

4 “(A) the number of devices approved in the  
5 year preceding the year in which the report is  
6 submitted, for which there is a pediatric sub-  
7 population that suffers from the disease or con-  
8 dition that the device is intended to treat, diag-  
9 nose, or cure;

10 “(B) the number of devices approved in  
11 the year preceding the year in which the report  
12 is submitted, labeled for use in pediatric pa-  
13 tients;

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

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

20 “(b) DETERMINATION OF PEDIATRIC EFFECTIVE-  
21 NESS BASED ON SIMILAR COURSE OF DISEASE OR CONDI-  
22 TION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

23 “(1) IN GENERAL.—If the course of the disease  
24 or condition and the effects of the device are suffi-  
25 ciently similar in adults and pediatric patients, the

1 Secretary may conclude that adult data may be used  
2 to support a determination of a reasonable assur-  
3 ance of effectiveness in pediatric populations, as ap-  
4 propriate.

5 “(2) EXTRAPOLATION BETWEEN SUBPOPULA-  
6 TIONS.—A study may not be needed in each pedi-  
7 atric subpopulation if data from one subpopulation  
8 can be extrapolated to another subpopulation.

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

12 **SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EX-**  
13 **EMPTION.**

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

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

19 (2) in paragraph (5)—

20 (A) by inserting “, if the Secretary has  
21 reason to believe that the requirements of para-  
22 graph (6) are no longer met,” after “public  
23 health”; and

24 (B) by adding at the end the following: “If  
25 the person granted an exemption under para-

1 graph (2) fails to demonstrate continued com-  
2 pliance with the requirements of this sub-  
3 section, the Secretary may suspend or withdraw  
4 the exemption from the effectiveness require-  
5 ments of sections 514 and 515 for a humani-  
6 tarian device only after providing notice and an  
7 opportunity for an informal hearing.”; and

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

10 “(6)(A) Except as provided in subparagraph (D), the  
11 prohibition in paragraph (3) shall not apply with respect  
12 to a person granted an exemption under paragraph (2)  
13 if each of the following conditions apply:

14 “(i)(I) The device with respect to which the ex-  
15 emption is granted is intended for the treatment or  
16 diagnosis of a disease or condition that occurs in pe-  
17 diatric patients or in a pediatric subpopulation, and  
18 such device is labeled for use in pediatric patients or  
19 in a pediatric subpopulation in which the disease or  
20 condition occurs.

21 “(II) The device was not previously approved  
22 under this subsection for the pediatric patients or  
23 the pediatric subpopulation described in subclause  
24 (I) prior to the date of enactment of the Pediatric

1 Medical Device Safety and Improvement Act of  
2 2007.

3 “(ii) During any calendar year, the number of  
4 such devices distributed during that year does not  
5 exceed the annual distribution number specified by  
6 the Secretary when the Secretary grants such ex-  
7 emption. The annual distribution number shall be  
8 based on the number of individuals affected by the  
9 disease or condition that such device is intended to  
10 treat, diagnose, or cure, and of that number, the  
11 number of individuals likely to use the device, and  
12 the number of devices reasonably necessary to treat  
13 such individuals. In no case shall the annual dis-  
14 tribution number exceed the number identified in  
15 paragraph (2)(A).

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

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

22 “(B) The Secretary may inspect the records relating  
23 to the number of devices distributed during any calendar  
24 year of a person granted an exemption under paragraph

1 (2) for which the prohibition in paragraph (3) does not  
2 apply.

3 “(C) A person may petition the Secretary to modify  
4 the annual distribution number specified by the Secretary  
5 under subparagraph (A)(ii) with respect to a device if ad-  
6 ditional information on the number of individuals affected  
7 by the disease or condition arises, and the Secretary may  
8 modify such number but in no case shall the annual dis-  
9 tribution number exceed the number identified in para-  
10 graph (2)(A).

11 “(D) If a person notifies the Secretary, or the Sec-  
12 retary determines through an inspection under subpara-  
13 graph (B), that the number of devices distributed during  
14 any calendar year exceeds the annual distribution number,  
15 as required under subparagraph (A)(iii), and modified  
16 under subparagraph (C), if applicable, then the prohibi-  
17 tion in paragraph (3) shall apply with respect to such per-  
18 son for such device for any sales of such device after such  
19 notification.

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

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

25 “(I) Neonates.



1           “(II) Infants.

2           “(III) Children.

3           “(IV) Adolescents.

4           “(7) The Secretary shall refer any report of an ad-  
5 verse event regarding a device for which the prohibition  
6 under paragraph (3) does not apply pursuant to para-  
7 graph (6)(A) that the Secretary receives to the Office of  
8 Pediatric Therapeutics, established under section 6 of the  
9 Best Pharmaceuticals for Children Act (Public Law 107-  
10 109). In considering the report, the Director of the Office  
11 of Pediatric Therapeutics, in consultation with experts in  
12 the Center for Devices and Radiological Health, shall pro-  
13 vide for periodic review of the report by the Pediatric Ad-  
14 visory Committee, including obtaining any recommenda-  
15 tions of such committee regarding whether the Secretary  
16 should take action under this Act in response to the re-  
17 port.

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

1 (b) REPORT.—Not later than January 1, 2012, the  
2 Comptroller General of the United States shall submit to  
3 the Committee on Health, Education, Labor, and Pen-  
4 sions of the Senate and the Committee on Energy and  
5 Commerce of the House of Representatives a report on  
6 the impact of allowing persons granted an exemption  
7 under section 520(m)(2) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a  
9 device to profit from such device pursuant to section  
10 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amend-  
11 ed by subsection (a)), including—

12 (1) an assessment of whether such section  
13 520(m)(6) (as amended by subsection (a)) has in-  
14 creased the availability of pediatric devices for condi-  
15 tions that occur in small numbers of children, in-  
16 cluding any increase or decrease in the number of—

17 (A) exemptions granted under such section  
18 520(m)(2) for pediatric devices; and

19 (B) applications approved under section  
20 515 of such Act (21 U.S.C. 360e) for devices  
21 intended to treat, diagnose, or cure conditions  
22 that occur in pediatric patients or for devices  
23 labeled for use in a pediatric population;

24 (2) the conditions or diseases the pediatric de-  
25 vices were intended to treat or diagnose and the esti-

1 mated size of the pediatric patient population for  
2 each condition or disease;

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

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

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

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

11 (7) an estimate of the extent of the use of the  
12 pediatric devices by both adults and pediatric popu-  
13 lations for a condition or disease other than the con-  
14 dition or disease on the label of such devices;

15 (8) recommendations of the Comptroller Gen-  
16 eral of the United States regarding the effectiveness  
17 of such section 520(m)(6) (as amended by sub-  
18 section (a)) and whether any modifications to such  
19 section 520(m)(6) (as amended by subsection (a))  
20 should be made;

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

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

1 (c) GUIDANCE.—Not later than 180 days after the  
2 date of enactment of this Act, the Commissioner of Food  
3 and Drugs shall issue guidance for institutional review  
4 committees on how to evaluate requests for approval for  
5 devices for which a humanitarian device exemption under  
6 section 520(m)(2) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 360j(m)(2)) has been granted.

8 **SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RE-**  
9 **SEARCH.**

10 (a) ACCESS TO FUNDING.—The Director of the Na-  
11 tional Institutes of Health shall designate a contact point  
12 or office at the National Institutes of Health to help  
13 innovators and physicians access funding for pediatric  
14 medical device development.

15 (b) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-  
16 SEARCH.—

17 (1) IN GENERAL.—Not later than 180 days  
18 after the date of enactment of this Act, the Commis-  
19 sioner of Food and Drugs, in collaboration with the  
20 Director of the National Institutes of Health and the  
21 Director of the Agency for Healthcare Research and  
22 Quality, shall submit to the Committee on Health,  
23 Education, Labor, and Pensions of the Senate and  
24 the Committee on Energy and Commerce of the  
25 House of Representatives a plan for expanding pedi-

1 atric medical device research and development. In  
2 developing such plan, the Commissioner of Food and  
3 Drugs shall consult with individuals and organiza-  
4 tions with appropriate expertise in pediatric medical  
5 devices.

6 (2) CONTENTS.—The plan under paragraph (1)  
7 shall include—

8 (A) the current status of federally funded  
9 pediatric medical device research;

10 (B) any gaps in such research, which may  
11 include a survey of pediatric medical providers  
12 regarding unmet pediatric medical device needs,  
13 as needed; and

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

20 **SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**  
21 **ATRIC DEVICE AVAILABILITY.**

22 (a) IN GENERAL.—

23 (1) REQUEST FOR PROPOSALS.—Not later than  
24 90 days after the date of enactment of this Act, the  
25 Secretary of Health and Human Services shall issue

1 a request for proposals for 1 or more grants or con-  
2 tracts to nonprofit consortia for demonstration  
3 projects to promote pediatric device development.

4 (2) DETERMINATION ON GRANTS OR CON-  
5 TRACTS.—Not later than 180 days after the date the  
6 Secretary of Health and Human Services issues a  
7 request for proposals under paragraph (1), the Sec-  
8 retary shall make a determination on the grants or  
9 contracts under this section.

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

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

17 (1) encourage innovation by connecting quali-  
18 fied individuals with pediatric device ideas with po-  
19 tential manufacturers;

20 (2) mentor and manage pediatric device  
21 projects through the development process, including  
22 product identification, prototype design, device devel-  
23 opment, and marketing;

24 (3) connect innovators and physicians to exist-  
25 ing Federal resources, including resources from the

1 Food and Drug Administration, the National Insti-  
2 tutes of Health, the Small Business Administration,  
3 the Department of Energy, the Department of Edu-  
4 cation, the National Science Foundation, the De-  
5 partment of Veterans Affairs, the Agency for  
6 Healthcare Research and Quality, and the National  
7 Institute of Standards and Technology;

8 (4) assess the scientific and medical merit of  
9 proposed pediatric device projects;

10 (5) assess business feasibility and provide busi-  
11 ness advice;

12 (6) provide assistance with prototype develop-  
13 ment; and

14 (7) provide assistance with postmarket needs,  
15 including training, logistics, and reporting.

16 (d) COORDINATION.—

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

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

23 (B) provide to the National Institutes of  
24 Health any identified pediatric device needs  
25 that the consortium lacks sufficient capacity to

1 address or those needs in which the consortium  
2 has been unable to stimulate manufacturer in-  
3 terest.

4 (2) FOOD AND DRUG ADMINISTRATION.—Each  
5 consortium that receives a grant or contract under  
6 this section shall coordinate with the Commissioner  
7 of Food and Drugs and device companies to facili-  
8 tate the application for approval or clearance of de-  
9 vices labeled for pediatric use.

10 (e) AUTHORIZATION OF APPROPRIATIONS.—There  
11 are authorized to be appropriated to carry out this section  
12 \$6,000,000 for each of fiscal years 2008 through 2012.

13 **SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**  
14 **PEUTICS AND PEDIATRIC ADVISORY COM-**  
15 **MITTEE.**

16 (a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section  
17 6(b) of the Best Pharmaceuticals for Children Act (21  
18 U.S.C. 393a(b)) is amended by inserting “, including in-  
19 creasing pediatric access to medical devices” after “pedi-  
20 atric issues”.

21 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14  
22 of the Best Pharmaceuticals for Children Act (42 U.S.C.  
23 284m note) is amended—



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

4 (2) in subsection (b)—

5 (A) in paragraph (1), by inserting “(in-  
6 cluding drugs and biological products) and med-  
7 ical devices” after “therapeutics”; and

8 (B) in paragraph (2)—

9 (i) in subparagraph (A), by striking  
10 “and 505B” and inserting “505B, 510(k),  
11 515, and 520(m)”;

12 (ii) by striking subparagraph (B) and  
13 inserting the following:

14 “(B) identification of research priorities re-  
15 lated to therapeutics (including drugs and bio-  
16 logical products) and medical devices for pedi-  
17 atric populations and the need for additional  
18 diagnostics and treatments for specific pediatric  
19 diseases or conditions;” and

20 (iii) in subparagraph (C), by inserting  
21 “(including drugs and biological products)  
22 and medical devices” after “therapeutics”.

23 **SEC. 307. POSTMARKET STUDIES.**

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

1 (1) in subsection (a)—

2 (A) by inserting “, or as a condition to ap-  
3 proval of an application (or a supplement to an  
4 application) or a product development protocol  
5 under section 515 or as a condition to clearance  
6 of a premarket notification under section  
7 510(k), for a pediatric population or pediatric  
8 subpopulation,” after “The Secretary may by  
9 order”; and

10 (B) by inserting “, or that is indicated for  
11 pediatric populations or subpopulations or is ex-  
12 pected to have significant use in pediatric popu-  
13 lations,” after “health consequences”; and

14 (2) in subsection (b)—

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

17 “(b) SURVEILLANCE APPROVAL.—

18 “(1) IN GENERAL.—Each”;

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

22 (C) by striking “Any determination” and  
23 inserting “Except as provided in paragraph (2),  
24 any determination”; and

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

1           “(2) LONGER STUDIES FOR PEDIATRIC DE-  
2           VICES.—The Secretary may by order require a pro-  
3           spective surveillance period of more than 36 months  
4           with respect to a device that is expected to have sig-  
5           nificant use in pediatric populations if such period of  
6           more than 36 months is necessary in order to assess  
7           the impact of the device on growth and development,  
8           or the effects of growth, development, activity level,  
9           or other factors on the safety or efficacy of the de-  
10          vice.

11          “(c) DISPUTE RESOLUTION.—A manufacturer may  
12          request review under section 562 of any order or condition  
13          requiring postmarket surveillance under this section. Dur-  
14          ing the pendency of such review, the device subject to such  
15          a postmarket surveillance order or condition shall not be  
16          deemed misbranded under section 502(t) or otherwise in  
17          violation of such order or condition or a related require-  
18          ment of this Act unless deemed necessary to protect the  
19          public health.”.

20                           **TITLE IV—PEDIATRIC**  
21           **RESEARCH EQUITY ACT OF 2007**

22   **SEC. 401. SHORT TITLE.**

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

1 **SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQ-**  
2 **UITY ACT.**

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

6 **“SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS**  
7 **AND BIOLOGICAL PRODUCTS.**

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

9 “(1) IN GENERAL.—A person that submits, on  
10 or after the date of enactment of the Pediatric Re-  
11 search Equity Act of 2007, an application (or sup-  
12 plement to an application)—

13 “(A) under section 505 for a new active in-  
14 gredient, new indication, new dosage form, new  
15 dosing regimen, or new route of administration,  
16 or

17 “(B) under section 351 of the Public  
18 Health Service Act (42 U.S.C. 262) for a new  
19 active ingredient, new indication, new dosage  
20 form, new dosing regimen, or new route of ad-  
21 ministration,

22 shall submit with the application the assessments de-  
23 scribed in paragraph (2).

24 “(2) ASSESSMENTS.—

25 “(A) IN GENERAL.—The assessments re-  
26 ferred to in paragraph (1) shall contain data,

1 gathered using appropriate formulations for  
2 each age group for which the assessment is re-  
3 quired, that are adequate—

4 “(i) to assess the safety and effective-  
5 ness of the drug or the biological product  
6 for the claimed indications in all relevant  
7 pediatric subpopulations; and

8 “(ii) to support dosing and adminis-  
9 tration for each pediatric subpopulation for  
10 which the drug or the biological product is  
11 safe and effective.

12 “(B) SIMILAR COURSE OF DISEASE OR  
13 SIMILAR EFFECT OF DRUG OR BIOLOGICAL  
14 PRODUCT.—

15 “(i) IN GENERAL.—If the course of  
16 the disease and the effects of the drug are  
17 sufficiently similar in adults and pediatric  
18 patients, the Secretary may conclude that  
19 pediatric effectiveness can be extrapolated  
20 from adequate and well-controlled studies  
21 in adults, usually supplemented with other  
22 information obtained in pediatric patients,  
23 such as pharmacokinetic studies.

24 “(ii) EXTRAPOLATION BETWEEN AGE  
25 GROUPS.—A study may not be needed in

1 each pediatric age group if data from one  
2 age group can be extrapolated to another  
3 age group.

4 “(iii) INFORMATION ON EXTRAPO-  
5 LATION.—A brief documentation of the sci-  
6 entific data supporting the conclusion  
7 under clauses (i) and (ii) shall be included  
8 in the medical review that is collected as  
9 part of the application under section 505  
10 of this Act or section 351 of the Public  
11 Health Service Act (42 U.S.C. 262).

12 “(3) DEFERRAL.—

13 “(A) IN GENERAL.—On the initiative of  
14 the Secretary or at the request of the applicant,  
15 the Secretary may defer submission of some or  
16 all assessments required under paragraph (1)  
17 until a specified date after approval of the drug  
18 or issuance of the license for a biological prod-  
19 uct if—

20 “(i) the Secretary finds that—

21 “(I) the drug or biological prod-  
22 uct is ready for approval for use in  
23 adults before pediatric studies are  
24 complete;

1           “(II) pediatric studies should be  
2           delayed until additional safety or ef-  
3           fectiveness data have been collected;  
4           or

5           “(III) there is another appro-  
6           priate reason for deferral; and

7           “(ii) the applicant submits to the Sec-  
8           retary—

9           “(I) certification of the grounds  
10          for deferring the assessments;

11          “(II) a description of the planned  
12          or ongoing studies;

13          “(III) evidence that the studies  
14          are being conducted or will be con-  
15          ducted with due diligence and at the  
16          earliest possible time; and

17          “(IV) a timeline for the comple-  
18          tion of such studies.

19          “(B) ANNUAL REVIEW.—

20          “(i) IN GENERAL.—On an annual  
21          basis following the approval of a deferral  
22          under subparagraph (A), the applicant  
23          shall submit to the Secretary the following  
24          information:

1                   “(I) Information detailing the  
2                   progress made in conducting pediatric  
3                   studies.

4                   “(II) If no progress has been  
5                   made in conducting such studies, evi-  
6                   dence and documentation that such  
7                   studies will be conducted with due  
8                   diligence and at the earliest possible  
9                   time.

10                  “(ii) PUBLIC AVAILABILITY.—The in-  
11                  formation submitted through the annual  
12                  review under clause (i) shall promptly be  
13                  made available to the public in an easily  
14                  accessible manner, including through the  
15                  website of the Food and Drug Administra-  
16                  tion.

17                  “(4) WAIVERS.—

18                  “(A) FULL WAIVER.—On the initiative of  
19                  the Secretary or at the request of an applicant,  
20                  the Secretary shall grant a full waiver, as ap-  
21                  propriate, of the requirement to submit assess-  
22                  ments for a drug or biological product under  
23                  this subsection if the applicant certifies and the  
24                  Secretary finds that—



1           “(i) necessary studies are impossible  
2           or highly impracticable (because, for exam-  
3           ple, the number of patients is so small or  
4           the patients are geographically dispersed);

5           “(ii) there is evidence strongly sug-  
6           gesting that the drug or biological product  
7           would be ineffective or unsafe in all pedi-  
8           atric age groups; or

9           “(iii) The drug or biological product—  
10           “(I) does not represent a mean-  
11           ingful therapeutic benefit over existing  
12           therapies for pediatric patients; and

13           “(II) is not likely to be used in a  
14           substantial number of pediatric pa-  
15           tients.

16           “(B) PARTIAL WAIVER.—On the initiative  
17           of the Secretary or at the request of an appli-  
18           cant, the Secretary shall grant a partial waiver,  
19           as appropriate, of the requirement to submit as-  
20           sessments for a drug or biological product  
21           under this subsection with respect to a specific  
22           pediatric age group if the applicant certifies  
23           and the Secretary finds that—

24           “(i) necessary studies are impossible  
25           or highly impracticable (because, for exam-

1           ple, the number of patients in that age  
2           group is so small or patients in that age  
3           group are geographically dispersed);

4           “(ii) there is evidence strongly sug-  
5           gesting that the drug or biological product  
6           would be ineffective or unsafe in that age  
7           group;

8           “(iii) the drug or biological product—

9           “(I) does not represent a mean-  
10          ingful therapeutic benefit over existing  
11          therapies for pediatric patients in that  
12          age group; and

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

16          “(iv) the applicant can demonstrate  
17          that reasonable attempts to produce a pe-  
18          diatric formulation necessary for that age  
19          group have failed.

20          “(C) PEDIATRIC FORMULATION NOT POS-  
21          SIBLE.—If a waiver is granted on the ground  
22          that it is not possible to develop a pediatric for-  
23          mulation, the waiver shall cover only the pedi-  
24          atric groups requiring that formulation. An ap-  
25          plicant seeking either a full or partial waiver

1 shall submit to the Secretary documentation de-  
2 tailing why a pediatric formulation cannot be  
3 developed and, if the waiver is granted, the ap-  
4 plicant's submission shall promptly be made  
5 available to the public in an easily accessible  
6 manner, including through posting on the  
7 website of the Food and Drug Administration.

8 “(D) LABELING REQUIREMENT.—If the  
9 Secretary grants a full or partial waiver because  
10 there is evidence that a drug or biological prod-  
11 uct would be ineffective or unsafe in pediatric  
12 populations, the information shall be included  
13 in the labeling for the drug or biological prod-  
14 uct.

15 “(b) MARKETED DRUGS AND BIOLOGICAL PROD-  
16 UCTS.—

17 “(1) IN GENERAL.—Beginning on the date of  
18 enactment of the Pediatric Research Equity Act of  
19 2007, after providing notice in the form of a letter  
20 and an opportunity for written response and a meet-  
21 ing, which may include an advisory committee meet-  
22 ing, the Secretary may (by order in the form of a  
23 letter) require the sponsor or holder of an approved  
24 application for a drug under section 505 or the hold-  
25 er of a license for a biological product under section

1 351 of the Public Health Service Act to submit by  
2 a specified date the assessments described in sub-  
3 section (a)(2), if the Secretary finds that—

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

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

9 “(B) there is reason to believe that the  
10 drug or biological product would represent a  
11 meaningful therapeutic benefit over existing  
12 therapies for pediatric patients for 1 or more of  
13 the claimed indications; or

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

16 “(2) WAIVERS.—

17 “(A) FULL WAIVER.—At the request of an  
18 applicant, the Secretary shall grant a full waiv-  
19 er, as appropriate, of the requirement to submit  
20 assessments under this subsection if the appli-  
21 cant certifies and the Secretary finds that—

22 “(i) necessary studies are impossible  
23 or highly impracticable (because, for exam-  
24 ple, the number of patients in that age

1 group is so small or patients in that age  
2 group are geographically dispersed); or

3 “(ii) there is evidence strongly sug-  
4 gesting that the drug or biological product  
5 would be ineffective or unsafe in all pedi-  
6 atric age groups.

7 “(B) PARTIAL WAIVER.—At the request of  
8 an applicant, the Secretary shall grant a partial  
9 waiver, as appropriate, of the requirement to  
10 submit assessments under this subsection with  
11 respect to a specific pediatric age group if the  
12 applicant certifies and the Secretary finds  
13 that—

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

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

23 “(iii)(I) the drug or biological prod-  
24 uct—

1                   “(aa) does not represent a mean-  
2                   ingful therapeutic benefit over existing  
3                   therapies for pediatric patients in that  
4                   age group; and

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

8                   “(II) the absence of adequate labeling  
9                   could not pose significant risks to pediatric  
10                  patients; or

11                  “(iv) the applicant can demonstrate  
12                  that reasonable attempts to produce a pe-  
13                  diatric formulation necessary for that age  
14                  group have failed.

15                  “(C) PEDIATRIC FORMULATION NOT POS-  
16                  SIBLE.—If a waiver is granted on the ground  
17                  that it is not possible to develop a pediatric for-  
18                  mulation, the waiver shall cover only the pedi-  
19                  atric groups requiring that formulation. An ap-  
20                  plicant seeking either a full or partial waiver  
21                  shall submit to the Secretary documentation de-  
22                  tailing why a pediatric formulation cannot be  
23                  developed and, if the waiver is granted, the ap-  
24                  plicant’s submission shall promptly be made  
25                  available to the public in an easily accessible

1 manner, including through posting on the  
2 website of the Food and Drug Administration.

3 “(D) LABELING REQUIREMENT.—If the  
4 Secretary grants a full or partial waiver because  
5 there is evidence that a drug or biological prod-  
6 uct would be ineffective or unsafe in pediatric  
7 populations, the information shall be included  
8 in the labeling for the drug or biological prod-  
9 uct.

10 “(c) MEANINGFUL THERAPEUTIC BENEFIT.—For  
11 the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I)  
12 of subsection (a) and paragraphs (1)(B)(I) and  
13 (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological  
14 product shall be considered to represent a meaningful  
15 therapeutic benefit over existing therapies if the Secretary  
16 determines that—

17 “(1) if approved, the drug or biological product  
18 could represent an improvement in the treatment,  
19 diagnosis, or prevention of a disease, compared with  
20 marketed products adequately labeled for that use in  
21 the relevant pediatric population; or

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

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

6               “(1) the drug or biological product that is the  
7 subject of the assessment or request may be consid-  
8 ered misbranded solely because of that failure and  
9 subject to relevant enforcement action (except that  
10 the drug or biological product shall not be subject to  
11 action under section 303); but

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

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

16                       “(B) to revoke the license for a biological  
17 product under section 351 of the Public Health  
18 Service Act.

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

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



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

3           “(f) REVIEW OF PEDIATRIC PLANS, DEFERRALS,  
4           AND WAIVERS.—

5           “(1) REVIEW.—Beginning not later than 30  
6           days after the date of enactment of the Pediatric  
7           Research Equity Act of 2007, the Secretary shall  
8           utilize an internal committee to provide consultation  
9           to reviewing divisions on all pediatric plans and as-  
10          sessments prior to approval of an application or sup-  
11          plement for which a pediatric assessment is required  
12          under this section and all deferral and waiver re-  
13          quests granted pursuant to this section. Such inter-  
14          nal committee shall include employees of the Food  
15          and Drug Administration, with expertise in pediat-  
16          rics (including representation from the Office of Pe-  
17          diatric Therapeutics), biopharmacology, statistics,  
18          chemistry, legal issues, pediatric ethics, and the ap-  
19          propriate expertise pertaining to the pediatric prod-  
20          uct under review, and other individuals designated  
21          by the Secretary.

22          “(2) ACTIVITY BY COMMITTEE.—The committee  
23          referred to in paragraph (1) may operate using ap-  
24          propriate members of such committee and need not  
25          convene all members of the committee.

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

7           “(4) REVIEW OF PEDIATRIC PLANS, DEFERRALS  
8           AND WAIVERS.—Consultation on pediatric plans and  
9           assessments by the internal committee pursuant to  
10          this section shall occur prior to approval of an appli-  
11          cation or supplement for which a pediatric assess-  
12          ment is required under this section. The internal  
13          committee shall review all requests for deferrals and  
14          waivers from the requirement to submit a pediatric  
15          assessment granted under this section and shall pro-  
16          vide recommendations as needed to reviewing divi-  
17          sions.

18          “(5) RETROSPECTIVE REVIEW OF PEDIATRIC  
19          PLANS, DEFERRALS AND WAIVERS.—Within one year  
20          after enactment of the Pediatric Research Equity  
21          Act of 2007, the committee shall conduct a retro-  
22          spective review and analysis of a representative sam-  
23          ple of assessments submitted and deferrals and  
24          waivers approved under this section since enactment  
25          of the Pediatric Research Equity Act of 2003. Such

1 review shall include an analysis of the quality and  
2 consistency of pediatric information in pediatric as-  
3 sessments and the appropriateness of waivers and  
4 deferrals granted. Based on such review, the Sec-  
5 retary shall issue recommendations to the review di-  
6 visions for improvements and initiate guidance to in-  
7 dustry related to the scope of pediatric studies re-  
8 quired under this section.

9 “(6) TRACKING OF ASSESSMENTS AND LABEL-  
10 ING CHANGES.—Beginning on the date of enactment  
11 of the Pediatric Research Equity Act of 2007, the  
12 Secretary shall track and make available to the pub-  
13 lic in an easily accessible manner, including through  
14 posting on the website of the Food and Drug Ad-  
15 ministration—

16 “(A) the number of assessments conducted  
17 under this section;

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

20 “(C) the types of assessments conducted  
21 under this section, including trial design, the  
22 number of pediatric patients studied, and the  
23 number of centers and countries involved;

24 “(D) the total number of deferrals re-  
25 quested and granted under this section and, if

1 granted, the reasons for such deferrals, the  
2 timeline for completion, and the number com-  
3 pleted and pending by the specified date, as  
4 outlined in subsection (a)(3);

5 “(E) the number of waivers requested and  
6 granted under this section and, if granted, the  
7 reasons for the waivers;

8 “(F) the number of pediatric formulations  
9 developed and the number of pediatric formula-  
10 tions not developed and the reasons any such  
11 formulation was not developed;

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

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

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

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

23 “(g) LABELING CHANGES.—

24 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-  
25 CATIONS.—Any supplement to an application under

1 section 505 and section 351 of the Public Health  
2 Service Act proposing a labeling change as a result  
3 of any pediatric assessments conducted pursuant to  
4 this section—

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

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

10 “(2) DISPUTE RESOLUTION.—

11 “(A) REQUEST FOR LABELING CHANGE  
12 AND FAILURE TO AGREE.—If, on or after the  
13 date of enactment of the Pediatric Research  
14 Equity Act of 2007, the Commissioner deter-  
15 mines that a sponsor and the Commissioner  
16 have been unable to reach agreement on appro-  
17 priate changes to the labeling for the drug that  
18 is the subject of the application or supplement,  
19 not later than 180 days after the date of the  
20 submission of the application or supplement—

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

1           “(ii) if the sponsor does not agree  
2           within 30 days after the Commissioner’s  
3           request to make a labeling change re-  
4           quested by the Commissioner, the Commis-  
5           sioner shall refer the matter to the Pedi-  
6           atric Advisory Committee.

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

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

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

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

24           “(D) MISBRANDING.—If the sponsor of the  
25           application, within 30 days after receiving a re-

1           quest under subparagraph (C), does not agree  
2           to make a labeling change requested by the  
3           Commissioner, the Commissioner may deem the  
4           drug that is the subject of the application to be  
5           misbranded.

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

15          “(3) OTHER LABELING CHANGES.—If, on or  
16          after the date of enactment of the Pediatric Re-  
17          search Equity Act of 2007, the Secretary makes a  
18          determination that a pediatric assessment conducted  
19          under this section does or does not demonstrate that  
20          the drug that is the subject of such assessment is  
21          safe and effective in pediatric populations or sub-  
22          populations, including whether such assessment re-  
23          sults are inconclusive, the Secretary shall order the  
24          label of such product to include information about

1 the results of the assessment and a statement of the  
2 Secretary's determination.

3 “(h) DISSEMINATION OF PEDIATRIC INFORMA-  
4 TION.—

5 “(1) IN GENERAL.—Not later than 180 days  
6 after the date of submission of a pediatric assess-  
7 ment under this section, the Secretary shall make  
8 available to the public in an easily accessible manner  
9 the medical, statistical, and clinical pharmacology re-  
10 views of such pediatric assessments, and shall post  
11 such assessments on the website of the Food and  
12 Drug Administration.

13 “(2) DISSEMINATION OF INFORMATION RE-  
14 GARDING LABELING CHANGES.—Beginning on the  
15 date of enactment of the Pediatric Research Equity  
16 Act of 2007, the Secretary shall require that the  
17 sponsors of the assessments that result in labeling  
18 changes that are reflected in the annual summary  
19 developed pursuant to subsection (f)(6)(H) dis-  
20 tribute such information to physicians and other  
21 health care providers.

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



1 “(i) ADVERSE EVENT REPORTING.—

2 “(1) REPORTING IN YEAR ONE.—Beginning on  
3 the date of enactment of the Pediatric Research Eq-  
4 uity Act of 2007, during the one-year period begin-  
5 ning on the date a labeling change is made pursuant  
6 to subsection (g), the Secretary shall ensure that all  
7 adverse event reports that have been received for  
8 such drug (regardless of when such report was re-  
9 ceived) are referred to the Office of Pediatric Thera-  
10 peutics. In considering the report, the Director of  
11 such Office shall provide for the review of the report  
12 by the Pediatric Advisory Committee, including ob-  
13 taining any recommendations of such committee re-  
14 garding whether the Secretary should take action  
15 under this Act in response to such report.

16 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-  
17 lowing the one-year period described in paragraph  
18 (1), the Secretary shall, as appropriate, refer to the  
19 Office of Pediatric Therapeutics all pediatric adverse  
20 event reports for a drug for which a pediatric study  
21 was conducted under this section. In considering the  
22 report, the Director of such Office may provide for  
23 the review of the report by the Pediatric Advisory  
24 Committee, including obtaining any recommendation

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

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

6 “(j) SCOPE OF AUTHORITY.—Nothing in this section  
7 provides to the Secretary any authority to require a pedi-  
8 atric assessment of any drug or biological product, or any  
9 assessment regarding other populations or uses of a drug  
10 or biological product, other than the pediatric assessments  
11 described in this section.

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

16 “(l) INSTITUTE OF MEDICINE STUDY.—

17 “(1) IN GENERAL.—Not later than three years  
18 after the date of the enactment of the Pediatric Re-  
19 search Equity Act of 2007, the Secretary shall con-  
20 tract with the Institute of Medicine to conduct a  
21 study and report to Congress regarding the pediatric  
22 studies conducted pursuant to this section since  
23 1997 and labeling changes made as a result of such  
24 studies.

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

8           “(3) REPRESENTATIVE SAMPLE.—The Institute  
9           of Medicine may devise an appropriate mechanism to  
10          review a representative sample of studies conducted  
11          pursuant to this section from each review division  
12          within the Center for Drug Evaluation and Research  
13          in order to make the requested assessment.”.

14          (b) APPLICABILITY.—The amendment made in sub-  
15          section (a) applies to assessments required under section  
16          505B on or after the date of enactment of this Act.

17       **SEC. 403. GOVERNMENT ACCOUNTABILITY OFFICE RE-**  
18                               **PORT.**

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

1 that medicines used by children are tested and properly  
2 labeled. Such report shall include—

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

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

19           (3) the number of drugs and biological products  
20 for which testing is being done and labeling changes  
21 required, including the date labeling changes are  
22 made and which labeling changes required the use of  
23 the dispute resolution process established pursuant  
24 to the amendments made by this title, together with  
25 a description of the outcomes of such process, in-

1 including a description of the disputes and the rec-  
2 ommendations of the Pediatric Advisory Committee;

3 (4) any recommendations for modifications to  
4 the programs established under sections 505A and  
5 505B of the Federal Food, Drug, and Cosmetic Act  
6 (21 U.S.C. 355a) and section 409I of the Public  
7 Health Service Act (42 U.S.C. 284m) that the Sec-  
8 retary determines to be appropriate, including a de-  
9 tailed rationale for each recommendation; and

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

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

18 **TITLE V—BEST PHARMA-**  
19 **CEUTICALS FOR CHILDREN**  
20 **ACT OF 2007**

21 **SEC. 501. SHORT TITLE.**

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

1 **SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS**  
2 **FOR CHILDREN ACT.**

3 (a) PEDIATRIC STUDIES OF DRUGS.—

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

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

8 “(a) DEFINITIONS.—As used in this section, the term  
9 ‘pediatric studies’ or ‘studies’ means at least one clinical  
10 investigation (that, at the Secretary’s discretion, may in-  
11 clude pharmacokinetic studies) in pediatric age groups (in-  
12 cluding neonates in appropriate cases) in which a drug  
13 is anticipated to be used, and at the discretion of the Sec-  
14 retary, may include preclinical studies.

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

16 “(1) IN GENERAL.—Except as provided in para-  
17 graph (2), if, prior to approval of an application that  
18 is submitted under section 505(b)(1), the Secretary  
19 determines that information relating to the use of a  
20 new drug in the pediatric population may produce  
21 health benefits in that population, the Secretary  
22 makes a written request for pediatric studies (which  
23 shall include a timeframe for completing such stud-  
24 ies), the applicant agrees to the request, such stud-  
25 ies are completed using appropriate formulations for  
26 each age group for which the study is requested

1 within any such timeframe, and the reports thereof  
2 are submitted and accepted in accordance with sub-  
3 section (d)(3), and if the Secretary has determined  
4 that labeling changes are appropriate, such changes  
5 are approved within the timeframe requested by the  
6 Secretary—

7 “(A)(i)(I) the period referred to in sub-  
8 section (c)(3)(E)(ii) of section 505, and in sub-  
9 section (j)(5)(F)(ii) of such section, is deemed  
10 to be five years and six months rather than five  
11 years, and the references in subsections  
12 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to  
13 four years, to forty-eight months, and to seven  
14 and one-half years are deemed to be four and  
15 one-half years, fifty-four months, and eight  
16 years, respectively; or

17 “(II) the period referred to in clauses (iii)  
18 and (iv) of subsection (c)(3)(E) of such section,  
19 and in clauses (iii) and (iv) of subsection  
20 (j)(5)(F) of such section, is deemed to be three  
21 years and six months rather than three years;  
22 and

23 “(ii) if the drug is designated under sec-  
24 tion 526 for a rare disease or condition, the pe-  
25 riod referred to in section 527(a) is deemed to

1 be seven years and six months rather than  
2 seven years; and

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

4 “(I) a listed patent for which a certifi-  
5 cation has been submitted under sub-  
6 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of  
7 section 505 and for which pediatric studies  
8 were submitted prior to the expiration of  
9 the patent (including any patent exten-  
10 sions); or

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

15 the period during which an application may not  
16 be approved under section 505(c)(3) or section  
17 505(j)(5)(B) shall be extended by a period of  
18 six months after the date the patent expires (in-  
19 cluding any patent extensions); or

20 “(ii) if the drug is the subject of a listed  
21 patent for which a certification has been sub-  
22 mitted under subsection (b)(2)(A)(iv) or  
23 (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
24 ent infringement litigation resulting from the  
25 certification the court determines that the pat-



1           ent is valid and would be infringed, the period  
2           during which an application may not be ap-  
3           proved under section 505(c)(3) or section  
4           505(j)(5)(B) shall be extended by a period of  
5           six months after the date the patent expires (in-  
6           cluding any patent extensions).

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

11          “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-  
12          KETED DRUGS.—

13                 “(1) IN GENERAL.—Except as provided in para-  
14                 graph (2), if the Secretary determines that informa-  
15                 tion relating to the use of an approved drug in the  
16                 pediatric population may produce health benefits in  
17                 that population and makes a written request to the  
18                 holder of an approved application under section  
19                 505(b)(1) for pediatric studies (which shall include  
20                 a timeframe for completing such studies), the holder  
21                 agrees to the request, such studies are completed  
22                 using appropriate formulations for each age group  
23                 for which the study is requested within any such  
24                 timeframe and the reports thereof are submitted and  
25                 accepted in accordance with subsection (d)(3), and if

1 the Secretary determines that labeling changes are  
2 appropriate and such changes are approved within  
3 the timeframe requested by the Secretary—

4 “(A)(i)(I) the period referred to in sub-  
5 section (c)(3)(E)(ii) of section 505, and in sub-  
6 section (j)(5)(F)(ii) of such section, is deemed  
7 to be five years and six months rather than five  
8 years, and the references in subsections  
9 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to  
10 four years, to forty-eight months, and to seven  
11 and one-half years are deemed to be four and  
12 one-half years, fifty-four months, and eight  
13 years, respectively; or

14 “(II) the period referred to in clauses (iii)  
15 and (iv) of subsection (c)(3)(D) of such section,  
16 and in clauses (iii) and (iv) of subsection  
17 (j)(5)(F) of such section, is deemed to be three  
18 years and six months rather than three years;  
19 and

20 “(ii) if the drug is designated under sec-  
21 tion 526 for a rare disease or condition, the pe-  
22 riod referred to in section 527(a) is deemed to  
23 be seven years and six months rather than  
24 seven years; and

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

1           “(I) a listed patent for which a certifi-  
2           cation has been submitted under sub-  
3           section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of  
4           section 505 and for which pediatric studies  
5           were submitted prior to the expiration of  
6           the patent (including any patent exten-  
7           sions); or

8           “(II) a listed patent for which a cer-  
9           tification has been submitted under sub-  
10          section (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)  
11          of section 505,

12          the period during which an application may not  
13          be approved under section 505(c)(3) or section  
14          505(j)(5)(B)(ii) shall be extended by a period of  
15          six months after the date the patent expires (in-  
16          cluding any patent extensions); or

17          “(ii) if the drug is the subject of a listed  
18          patent for which a certification has been sub-  
19          mitted under subsection (b)(2)(A)(iv) or  
20          (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
21          ent infringement litigation resulting from the  
22          certification the court determines that the pat-  
23          ent is valid and would be infringed, the period  
24          during which an application may not be ap-  
25          proved under section 505(c)(3) or section

1           505(j)(5)(B) shall be extended by a period of  
2           six months after the date the patent expires (in-  
3           cluding any patent extensions)

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

8           “(d) CONDUCT OF PEDIATRIC STUDIES.—

9           “(1) REQUEST FOR STUDIES.—

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

1           “(B) SINGLE WRITTEN REQUEST.—A sin-  
2           gle written request—

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

5                   “(ii) may include uses that are both  
6                   approved and unapproved.

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

9                   “(A) REQUEST AND RESPONSE.—

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

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

23                           “(II) indicating that the appli-  
24                           cant or holder does not agree to the

1 request and stating the reasons for  
2 declining the request.

3 “(ii) DISAGREE WITH REQUEST.—If,  
4 on or after the date of the enactment of  
5 the Best Pharmaceuticals for Children Act  
6 of 2007, the applicant or holder does not  
7 agree to the request on the grounds that it  
8 is not possible to develop the appropriate  
9 pediatric formulation, the applicant or  
10 holder shall submit to the Secretary the  
11 reasons such pediatric formulation cannot  
12 be developed.

13 “(B) ADVERSE EVENT REPORTS.—An ap-  
14 plicant or holder that, on or after the date of  
15 the enactment of the Best Pharmaceuticals for  
16 Children Act of 2007, agrees to the request for  
17 such studies shall provide the Secretary, at the  
18 same time as the submission of the reports of  
19 such studies, with all postmarket adverse event  
20 reports regarding the drug that is the subject  
21 of such studies and are available prior to sub-  
22 mission of such reports.

23 “(3) MEETING THE STUDIES REQUIREMENT.—  
24 Not later than 180 days after the submission of the  
25 reports of the studies, the Secretary shall accept or

1 reject such reports and so notify the sponsor or  
2 holder. The Secretary's only responsibility in accept-  
3 ing or rejecting the reports shall be to determine,  
4 within the 180-day period, whether the studies fairly  
5 respond to the written request, have been conducted  
6 in accordance with commonly accepted scientific  
7 principles and protocols, and have been reported in  
8 accordance with the requirements of the Secretary  
9 for filing.

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

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

16 “(1) IN GENERAL.—The Secretary shall publish  
17 a notice of any determination, made on or after the  
18 date of the enactment of the Best Pharmaceuticals  
19 for Children Act of 2007, that the requirements of  
20 subsection (d) have been met and that submissions  
21 and approvals under subsection (b)(2) or (j) of sec-  
22 tion 505 for a drug will be subject to the provisions  
23 of this section. Such notice shall be published not  
24 later than 30 days after the date of the Secretary's  
25 determination regarding market exclusivity and shall

1 include a copy of the written request made under  
2 subsection (b) or (c).

3 “(2) IDENTIFICATION OF CERTAIN DRUGS.—

4 The Secretary shall publish a notice identifying any  
5 drug for which, on or after the date of the enact-  
6 ment of the Best Pharmaceuticals for Children Act  
7 of 2007, a pediatric formulation was developed,  
8 studied, and found to be safe and effective in the pe-  
9 diatric population (or specified subpopulation) if the  
10 pediatric formulation for such drug is not introduced  
11 onto the market within one year after the date that  
12 the Secretary publishes the notice described in para-  
13 graph (1). Such notice identifying such drug shall be  
14 published not later than 30 days after the date of  
15 the expiration of such one year period.

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

18 “(1) INTERNAL REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall  
20 establish an internal review committee to review  
21 all written requests issued on or after the date  
22 of the enactment of the Best Pharmaceuticals  
23 for Children Act of 2007, in accordance with  
24 paragraph (2).



1           “(B) MEMBERS.—The committee estab-  
2           lished under subparagraph (A) shall include in-  
3           dividuals with expertise in pediatrics, biophar-  
4           macology, statistics, drugs and drug formula-  
5           tions, legal issues, pediatric ethics, the appro-  
6           priate expertise, such as expertise in child and  
7           adolescent psychiatry, pertaining to the pedi-  
8           atric product under review, one or more experts  
9           from the Office of Pediatric Therapeutics, and  
10          other individuals designated by the Secretary.

11          “(2) REVIEW OF WRITTEN REQUESTS.—The  
12          committee established under paragraph (1) shall re-  
13          view all written requests issued pursuant to this sec-  
14          tion prior to being issued.

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

20                 “(A) the number of studies conducted  
21                 under this section and under section 409I of  
22                 the Public Health Service Act;

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

1           “(C) the types of studies conducted under  
2 such sections, including trial design, the num-  
3 ber of pediatric patients studied, and the num-  
4 ber of centers and countries involved;

5           “(D) the number of pediatric formulations  
6 developed and the number of pediatric formula-  
7 tions not developed and the reasons such for-  
8 mulations were not developed;

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

11           “(F) an annual summary of labeling  
12 changes made as a result of studies conducted  
13 under such sections for distribution pursuant to  
14 subsection (k)(2); and

15           “(G) information regarding reports sub-  
16 mitted on or after the date of the enactment of  
17 the Best Pharmaceuticals for Children Act of  
18 2007.

19           “(4) COMMITTEE.—The committee established  
20 under paragraph (1) shall be the committee utilized  
21 under section 505B(f)(1).

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

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

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

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

15          “(i) LABELING CHANGES.—

16                 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-  
17                 CATIONS AND SUPPLEMENTS.—Any application or  
18                 supplement to an application under section 505 pro-  
19                 posing a labeling change as a result of any pediatric  
20                 study conducted pursuant to this section—

21                         “(A) shall be considered to be a priority  
22                         application or supplement; and

23                         “(B) shall be subject to the performance  
24                         goals established by the Commissioner for pri-  
25                         ority drugs.

1 “(2) DISPUTE RESOLUTION.—

2 “(A) REQUEST FOR LABELING CHANGE  
3 AND FAILURE TO AGREE.—If, on or after the  
4 date of the enactment of the Best Pharma-  
5 ceuticals for Children Act of 2007, the Commis-  
6 sioner determines that the sponsor and the  
7 Commissioner have been unable to reach agree-  
8 ment on appropriate changes to the labeling for  
9 the drug that is the subject of the application,  
10 not later than 180 days after the date of sub-  
11 mission of the application—

12 “(i) the Commissioner shall request  
13 that the sponsor of the application make  
14 any labeling change that the Commissioner  
15 determines to be appropriate; and

16 “(ii) if the sponsor of the application  
17 does not agree within 30 days after the  
18 Commissioner’s request to make a labeling  
19 change requested by the Commissioner, the  
20 Commissioner shall refer the matter to the  
21 Pediatric Advisory Committee.

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

1 “(i) review the pediatric study reports;

2 and

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

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

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

21 “(E) NO EFFECT ON AUTHORITY.—Noth-  
22 ing in this subsection limits the authority of the  
23 United States to bring an enforcement action  
24 under this Act when a drug lacks appropriate  
25 pediatric labeling. Neither course of action (the

1 Pediatric Advisory Committee process or an en-  
2 forcement action referred to in the preceding  
3 sentence) shall preclude, delay, or serve as the  
4 basis to stay the other course of action.

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

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

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

23 “(2) DISSEMINATION OF INFORMATION RE-  
24 GARDING LABELING CHANGES.—Beginning on the  
25 date of the enactment of the Best Pharmaceuticals

1 for Children Act of 2007, the Secretary shall include  
2 as a requirement of a written request that the spon-  
3 sors of the studies that result in labeling changes  
4 that are reflected in the annual summary developed  
5 pursuant to subsection (f)(3)(F) distribute, at least  
6 annually (or more frequently if the Secretary deter-  
7 mines that it would be beneficial to the public  
8 health), such information to physicians and other  
9 health care providers.

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

14 “(1) ADVERSE EVENT REPORTING.—

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

1 rector of such Office shall provide for the review of  
2 the reports by the Pediatric Advisory Committee, in-  
3 cluding obtaining any recommendations of such  
4 Committee regarding whether the Secretary should  
5 take action under this Act in response to such re-  
6 ports.

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

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

22 “(m) CLARIFICATION OF INTERACTION OF MARKET  
23 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-  
24 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL  
25 OF A DRUG UNDER SECTION 505(j).—If a 180-day period



1 under section 505(j)(5)(B)(iv) overlaps with a 6-month ex-  
2 clusivity period under this section, so that the applicant  
3 for approval of a drug under section 505(j) entitled to the  
4 180-day period under that section loses a portion of the  
5 180-day period to which the applicant is entitled for the  
6 drug, the 180-day period shall be extended from—

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

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

17           “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-  
18 PLETED.—

19           “(1) IN GENERAL.—Beginning on the date of  
20 the enactment of the Best Pharmaceuticals for Chil-  
21 dren Act of 2007, if pediatric studies have not been  
22 completed under subsection (d) and if the Secretary,  
23 through the committee established under subsection  
24 (f), determines that there is a continuing need for  
25 information relating to the use of the drug in the pe-

1       diatric population (including neonates, as appro-  
2       priate), the Secretary shall—

3               “(A) for a drug for which listed patents  
4               have not expired, make a determination regard-  
5               ing whether an assessment shall be required to  
6               be submitted under section 505B; or

7               “(B) for a drug that has no listed patents  
8               or has 1 or more listed patents that have ex-  
9               pired, determine whether there are funds avail-  
10              able under section 736 to award a grant to con-  
11              duct the requested studies pursuant to para-  
12              graph (2).

13              “(2) FUNDING OF STUDIES.—If, pursuant to  
14              paragraph (1), the Secretary determines that there  
15              are funds available under section 736 to award a  
16              grant to conduct the requested pediatric studies,  
17              then the Secretary shall issue a proposal to award  
18              a grant to conduct the requested studies. If the Sec-  
19              retary determines that funds are not available under  
20              section 736, the Secretary shall refer the drug for  
21              inclusion on the list established under section 409I  
22              of the Public Health Service Act or the conduct of  
23              studies.

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

1           “(A) a decision under paragraph (1)(A)  
2           not to require an assessment under section  
3           505B and the basis for such decision;

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

7           “(C) any decision under paragraph (2) to  
8           include a drug on the list established under sec-  
9           tion 409I of the Public Health Service Act.

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

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

17          “(1) GENERAL RULE.—A drug for which an ap-  
18          plication has been submitted or approved under sec-  
19          tion 505(j) shall not be considered ineligible for ap-  
20          proval under that section or misbranded under sec-  
21          tion 502 on the basis that the labeling of the drug  
22          omits a pediatric indication or any other aspect of  
23          labeling pertaining to pediatric use when the omitted  
24          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; and

7 “(4) make recommendations regarding appro-  
8 priate incentives for encouraging pediatric studies of  
9 biologics.

10 “(q) SUNSET.—A drug may not receive any 6-month  
11 period under subsection (b) or (c) unless—

12 “(1) on or before October 1, 2012, the Sec-  
13 retary makes a written request for pediatric studies  
14 of the drug;

15 “(2) on or before October 1, 2012, an applica-  
16 tion for the drug is accepted for filing under section  
17 505(b); and

18 “(3) all requirements of this section are met.”.

19 (2) EFFECTIVE DATE.—The amendment made  
20 by this subsection shall apply to written requests  
21 under section 505A of the Federal Food, Drug, and  
22 Cosmetic Act (21 U.S.C. 355a) made after the date  
23 of the enactment of this Act.

1 (b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—  
2 Section 409I of the Public Health Service Act (42 U.S.C.  
3 284m) is amended to read as follows:

4 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

5 “(a) LIST OF PRIORITY ISSUES IN PEDIATRIC  
6 THERAPEUTICS.—

7 “(1) IN GENERAL.—Not later than one year  
8 after the date of the enactment of the Best Pharma-  
9 ceuticals for Children Act of 2007, the Secretary,  
10 acting through the Director of the National Insti-  
11 tutes of Health and in consultation with the Com-  
12 missioner of Food and Drugs and experts in pedi-  
13 atric research, shall develop and publish a priority  
14 list of needs in pediatric therapeutics, including  
15 drugs or indications that require study. The list  
16 shall be revised every three years.

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

20 “(A) therapeutic gaps in pediatrics that  
21 may include developmental pharmacology,  
22 pharmacogenetic determinants of drug re-  
23 sponse, metabolism of drugs and biologics in  
24 children, and pediatric clinical trials;

1           “(B) particular pediatric diseases, dis-  
2           orders or conditions where more complete  
3           knowledge and testing of therapeutics, including  
4           drugs and biologics, may be beneficial in pedi-  
5           atric populations; and

6           “(C) the adequacy of necessary infrastruc-  
7           ture to conduct pediatric pharmacological re-  
8           search, including research networks and trained  
9           pediatric investigators.

10       “(b) PEDIATRIC STUDIES AND RESEARCH.—The  
11       Secretary, acting through the National Institutes of  
12       Health, shall award funds to entities that have the exper-  
13       tise to conduct pediatric clinical trials or other research  
14       (including qualified universities, hospitals, laboratories,  
15       contract research organizations, practice groups, federally  
16       funded programs such as pediatric pharmacology research  
17       units, other public or private institutions, or individuals)  
18       to enable the entities to conduct the drug studies or other  
19       research on the issues described in subsection (a). The  
20       Secretary may use contracts, grants, or other appropriate  
21       funding mechanisms to award funds under this subsection.

22       “(c) PROCESS FOR PROPOSED PEDIATRIC STUDY  
23       REQUESTS AND LABELING CHANGES.—

24           “(1) SUBMISSION OF PROPOSED PEDIATRIC  
25       STUDY REQUEST.—The Director of the National In-



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

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

17               “(ii) there is a submitted application that  
18               could be approved under the criteria of such  
19               section; and

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

1           “(C) additional studies are needed to as-  
2           sess the safety and effectiveness of the use of  
3           the drug in the pediatric population.

4           “(2) WRITTEN REQUEST TO HOLDERS OF AP-  
5           PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-  
6           SIVITY.—The Commissioner of Food and Drugs, in  
7           consultation with the Director of the National Insti-  
8           tutes of Health, may issue a written request based  
9           on the proposed pediatric study request for the indi-  
10          cation or indications submitted pursuant to para-  
11          graph (1) (which shall include a timeframe for nego-  
12          tiations for an agreement) for pediatric studies con-  
13          cerning a drug identified under subsection (a) to all  
14          holders of an approved application for the drug  
15          under section 505 of the Federal Food, Drug, and  
16          Cosmetic Act. Such a written request shall be made  
17          in a manner equivalent to the manner in which a  
18          written request is made under subsection (b) or (c)  
19          of section 505A of such Act, including with respect  
20          to information provided on the pediatric studies to  
21          be conducted pursuant to the request and using ap-  
22          propriate formulations for each age group for which  
23          the study is requested.

24          “(3) REQUESTS FOR PROPOSALS.—If the Com-  
25          missioner of Food and Drugs does not receive a re-

1 sponse to a written request issued under paragraph  
2 (2) not later than 30 days after the date on which  
3 a request was issued, the Secretary, acting through  
4 the Director of the National Institutes of Health and  
5 in consultation with the Commissioner of Food and  
6 Drugs, shall publish a request for proposals to con-  
7 duct the pediatric studies described in the written  
8 request in accordance with subsection (b).

9 “(4) DISQUALIFICATION.—A holder that re-  
10 ceives a first right of refusal shall not be entitled to  
11 respond to a request for proposals under paragraph  
12 (3).

13 “(5) CONTRACTS, GRANTS, OR OTHER FUNDING  
14 MECHANISMS.—A contract, grant, or other funding  
15 may be awarded under this section only if a proposal  
16 is submitted to the Secretary in such form and man-  
17 ner, and containing such agreements, assurances,  
18 and information as the Secretary determines to be  
19 necessary to carry out this section.

20 “(6) REPORTING OF STUDIES.—

21 “(A) IN GENERAL.—On completion of a  
22 pediatric study in accordance with an award  
23 under this section, a report concerning the  
24 study shall be submitted to the Director of the  
25 National Institutes of Health and the Commis-

1 sioner of Food and Drugs. The report shall in-  
2 clude all data generated in connection with the  
3 study, including a written request if issued.

4 “(B) AVAILABILITY OF REPORTS.—Each  
5 report submitted under subparagraph (A) shall  
6 be considered to be in the public domain (sub-  
7 ject to section 505A(d)(4) of the Federal Food,  
8 Drug, and Cosmetic Act) and shall be assigned  
9 a docket number by the Commissioner of Food  
10 and Drugs. An interested person may submit  
11 written comments concerning such pediatric  
12 studies to the Commissioner of Food and  
13 Drugs, and the written comments shall become  
14 part of the docket file with respect to each of  
15 the drugs.

16 “(C) ACTION BY COMMISSIONER.—The  
17 Commissioner of Food and Drugs shall take ap-  
18 propriate action in response to the reports sub-  
19 mitted under subparagraph (A) in accordance  
20 with paragraph (7).

21 “(7) REQUESTS FOR LABELING CHANGE.—Dur-  
22 ing the 180-day period after the date on which a re-  
23 port is submitted under paragraph (6)(A), the Com-  
24 missioner of Food and Drugs shall—

1           “(A) review the report and such other data  
2 as are available concerning the safe and effec-  
3 tive use in the pediatric population of the drug  
4 studied;

5           “(B) negotiate with the holders of ap-  
6 proved applications for the drug studied for any  
7 labeling changes that the Commissioner of Food  
8 and Drugs determines to be appropriate and re-  
9 quests the holders to make; and

10           “(C)(i) place in the public docket file a  
11 copy of the report and of any requested labeling  
12 changes; and

13           “(ii) publish in the Federal Register and  
14 through a posting on the website of the Food  
15 and Drug Administration a summary of the re-  
16 port and a copy of any requested labeling  
17 changes.

18           “(8) DISPUTE RESOLUTION.—

19           “(A) REFERRAL TO PEDIATRIC ADVISORY  
20 COMMITTEE.—If, not later than the end of the  
21 180-day period specified in paragraph (7), the  
22 holder of an approved application for the drug  
23 involved does not agree to any labeling change  
24 requested by the Commissioner of Food and  
25 Drugs under that paragraph, the Commissioner

1 of Food and Drugs shall refer the request to  
2 the Pediatric Advisory Committee.

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

7 “(i) review the available information  
8 on the safe and effective use of the drug  
9 in the pediatric population, including study  
10 reports submitted under this section; and

11 “(ii) make a recommendation to the  
12 Commissioner of Food and Drugs as to ap-  
13 propriate labeling changes, if any.

14 “(9) FDA DETERMINATION.—Not later than 30  
15 days after receiving a recommendation from the Pe-  
16 diatric Advisory Committee under paragraph  
17 (8)(B)(ii) with respect to a drug, the Commissioner  
18 of Food and Drugs shall consider the recommenda-  
19 tion and, if appropriate, make a request to the hold-  
20 ers of approved applications for the drug to make  
21 any labeling change that the Commissioner of Food  
22 and Drugs determines to be appropriate.

23 “(10) FAILURE TO AGREE.—If a holder of an  
24 approved application for a drug, within 30 days  
25 after receiving a request to make a labeling change

1 under paragraph (9), does not agree to make a re-  
2 requested labeling change, the Commissioner of Food  
3 and Drugs may deem the drug to be misbranded  
4 under the Federal Food, Drug, and Cosmetic Act.

5 “(11) NO EFFECT ON AUTHORITY.—Nothing in  
6 this subsection limits the authority of the United  
7 States to bring an enforcement action under the  
8 Federal Food, Drug, and Cosmetic Act when a drug  
9 lacks appropriate pediatric labeling. Neither course  
10 of action (the Pediatric Advisory Committee process  
11 or an enforcement action referred to in the pre-  
12 ceding sentence) shall preclude, delay, or serve as  
13 the basis to stay the other course of action.

14 “(d) DISSEMINATION OF PEDIATRIC INFORMA-  
15 TION.—Not later than one year after the date of the enact-  
16 ment of the Best Pharmaceuticals for Children Act of  
17 2007, the Secretary, acting through the Director of the  
18 National Institutes of Health, shall study the feasibility  
19 of establishing a compilation of information on pediatric  
20 drug use and report the findings to Congress.

21 “(e) AUTHORIZATION OF APPROPRIATIONS.—

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

24 “(A) \$200,000,000 for fiscal year 2008;

25 and

1           “(B) such sums as are necessary for each  
2           of the four succeeding fiscal years.

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

6           (c) FEES RELATING TO DRUGS.—Section 735(6) of  
7           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8           379(6)) is amended by adding at the end the following  
9           new subparagraph:

10           “(G) Activities relating to the support of  
11           studies of drugs on pediatric populations under  
12           section 505A(n)(1).”.

13           (d) FOUNDATION FOR THE NATIONAL INSTITUTES  
14           OF HEALTH.—Section 499(c)(1)(C) of the Public Health  
15           Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by  
16           striking “and studies listed by the Secretary pursuant to  
17           section 409I(a)(1)(A) of this Act and referred under sec-  
18           tion 505A(d)(4)(C) of the Federal Food, Drug, and Cos-  
19           metic Act (21 U.S.C. 355(a)(d)(4)(C))”.

20           (e) CONTINUATION OF OPERATION OF COM-  
21           MITTEE.—Section 14 of the Best Pharmaceuticals for  
22           Children Act (42 U.S.C. 284m note) is amended by adding  
23           at the end the following new subsection:

24           “(d) CONTINUATION OF OPERATION OF COM-  
25           MITTEE.—Notwithstanding section 14 of the Federal Ad-



1 visory Committee Act, the advisory committee shall con-  
2 tinue to operate during the five-year period beginning on  
3 the date of the enactment of the Best Pharmaceuticals for  
4 Children Act of 2007.”.

5 (f) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC  
6 DRUGS ADVISORY COMMITTEE.—Section 15 of the Best  
7 Pharmaceuticals for Children Act (42 U.S.C. 284m note)  
8 is amended—

9 (1) in subsection (a)—

10 (A) in paragraph (1)—

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

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

16 (iii) by adding at the end the fol-  
17 lowing new subparagraph:

18 “(D) provide recommendations to the in-  
19 ternal review committee created under section  
20 505A(f) of the Federal Food, Drug, and Cos-  
21 metic Act regarding the implementation of  
22 amendments to sections 505A and 505B of the  
23 Federal Food, Drug, and Cosmetic Act with re-  
24 spect to the treatment of pediatric cancers.”;  
25 and

1 (B) by adding at the end the following new  
2 paragraph:

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

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

11 (g) EFFECTIVE DATE AND LIMITATION FOR RULE  
12 RELATING TO TOLL-FREE NUMBER FOR ADVERSE  
13 EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

14 (1) IN GENERAL.—Notwithstanding subchapter  
15 II of chapter 5, and chapter 7, of title 5, United  
16 States Code (commonly known as the “Administra-  
17 tive Procedure Act”) and any other provision of law,  
18 the proposed rule issued by the Commissioner of  
19 Food and Drugs entitled “Toll-Free Number for Re-  
20 porting Adverse Events on Labeling for Human  
21 Drug Products,” 69 Fed. Reg. 21778, (April 22,  
22 2004) shall take effect on January 1, 2008, unless  
23 such Commissioner issues the final rule before such  
24 date.

1           (2) LIMITATION.—The proposed rule that takes  
2 effect under subsection (a), or the final rule de-  
3 scribed under subsection (a), shall, notwithstanding  
4 section 17(a) of the Best Pharmaceuticals for Chil-  
5 dren Act (21 U.S.C. 355b(a)), not apply to a drug—

6           (A) for which an application is approved  
7 under section 505 of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 355);

9           (B) that is not described under section  
10 503(b)(1) of such Act (21 U.S.C. 353(b)(1));

11 and

12           (C) the packaging of which includes a toll-  
13 free number through which consumers can re-  
14 port complaints to the manufacturer or dis-  
15 tributor of the drug.

## 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 12 individuals, from a list of can-  
16                   didates to be provided by the National  
17                   Academy of Sciences. Of such appointed  
18                   members—

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

23                           “(II) 3 shall be representatives of  
24                           academic research organizations;



1                   “(III) 2 shall be representatives  
2                   of Government agencies, including the  
3                   Food and Drug Administration and  
4                   the National Institutes of Health;

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

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

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

19                  “(D) INITIAL MEETING.—

20                  “(i) IN GENERAL.—Not later than 30  
21                  days after the date of the enactment of  
22                  this Act, the Secretary shall convene a  
23                  meeting of the ex officio members of the  
24                  Board to—

1                   “(I) incorporate the Foundation;  
2                   and

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

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

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

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

17                         “(A) establish bylaws for the Foundation  
18                         that—

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

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

24                                 “(iii) establish policies, including eth-  
25                                 ical standards, for the acceptance, sollicita-

1 tion, and disposition of donations and  
2 grants to the Foundation and for the dis-  
3 position of the assets of the Foundation,  
4 including appropriate limits on the ability  
5 of donors to designate, by stipulation or re-  
6 striction, the use or recipient of donated  
7 funds;

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

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

23 “(vi) specify principles for the review  
24 of proposals and awarding of grants and  
25 contracts that include peer review and that

1 are consistent with those of the Founda-  
2 tion for the National Institutes of Health,  
3 to the extent determined practicable and  
4 appropriate by the Board;

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

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

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

1           “(x) specify a process for annual  
2           Board review of the operations of the  
3           Foundation; and

4           “(xi) establish specific duties of the  
5           Executive Director;

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

8           “(C) evaluate the performance of the Exec-  
9           utive Director; and

10          “(D) carry out any other necessary activi-  
11          ties regarding the functioning of the Founda-  
12          tion.

13          “(3) TERMS AND VACANCIES.—

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

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

22                       “(i) shall not affect the power of the  
23                       remaining members to execute the duties  
24                       of the Board; and

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

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

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

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

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

24                  “(f) NONPROFIT STATUS.—The Foundation shall be  
25                  considered to be a corporation under section 501(c) of the

1 Internal Revenue Code of 1986, and shall be subject to  
2 the provisions of such section.

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          “(1) 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       “(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(1)(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 shall have no effect on any grant, contract,  
11 memorandum of understanding, or cooperative agreement  
12 between the Food and Drug Administration and any other  
13 entity entered into before, on, or after the date of enact-  
14 ment of this subchapter.”.

15       (c) CONFORMING AMENDMENT.—Section 742(b) of  
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 3791(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; and

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.”.

11 **SEC. 603. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.**

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

15 **“SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNER-**  
16 **SHIPS.**

17           “(a) ESTABLISHMENT.—The Secretary, acting  
18           through the Commissioner of Food and Drugs, shall enter  
19           into collaborative agreements, to be known as Critical  
20           Path Public-Private Partnerships, with one or more eligi-  
21           ble entities to implement the Critical Path Initiative of the  
22           Food and Drug Administration by developing innovative,  
23           collaborative projects in research, education, and outreach  
24           for the purpose of fostering medical product innovation,

1 enabling the acceleration of medical product development,  
2 and enhancing medical product safety.

3 “(b) ELIGIBLE ENTITY.—In this section, the term  
4 ‘eligible entity’ means an entity that meets each of the  
5 following:

6 “(1) The entity is—

7 “(A) an institution of higher education (as  
8 such term is defined in section 101 of the High-  
9 er Education Act of 1965); or

10 “(B) an organization described in section  
11 501(c)(3) of the Internal Revenue Code of 1986  
12 and exempt from tax under section 501(a) of  
13 such Code.

14 “(2) The entity has experienced personnel and  
15 clinical and other technical expertise in the bio-  
16 medical sciences.

17 “(3) The entity demonstrates to the Secretary’s  
18 satisfaction that the entity is capable of—

19 “(A) developing and critically evaluating  
20 tools, methods, and processes—

21 “(i) to increase efficiency, predict-  
22 ability, and productivity of medical product  
23 development; and



1                   “(ii) to more accurately identify the  
2                   benefits and risks of new and existing med-  
3                   ical products;

4                   “(B) establishing partnerships, consortia,  
5                   and collaborations with health care practitioners  
6                   and other providers of health care goods or  
7                   services; pharmacists; pharmacy benefit man-  
8                   agers and purchasers; health maintenance orga-  
9                   nizations and other managed health care orga-  
10                  nizations; health care insurers; government  
11                  agencies; patients and consumers; manufactur-  
12                  ers of prescription drugs, biological products,  
13                  diagnostic technologies, and devices; and aca-  
14                  demic scientists; and

15                  “(C) securing funding for the projects of a  
16                  Critical Path Public-Private Partnership from  
17                  Federal and nonfederal governmental sources,  
18                  foundations, and private individuals.

19                  “(c) FUNDING.—The Secretary may not enter into  
20 a collaborative agreement under subsection (a) unless the  
21 eligible entity involved provides an assurance that the enti-  
22 ty will not accept funding for a Critical Path Public-Pri-  
23 vate Partnership project from any organization that man-  
24 ufactures or distributes products regulated by the Food  
25 and Drug Administration unless—

1           “(1) the entity accepts such funding for such  
2 project from 2 or more such organizations; and

3           “(2) the entity provides assurances in its agree-  
4 ment with the Food and Drug Administration that  
5 the results of the Critical Path Public-Private Part-  
6 nership project will not be influenced by any source  
7 of funding.

8           “(d) ANNUAL REPORT.—Not later than 18 months  
9 after the date of the enactment of this section, and annu-  
10 ally thereafter, the Secretary, in collaboration with the  
11 parties to each Critical Path Public-Private Partnership,  
12 shall submit a report to the Committee on Health, Edu-  
13 cation, Labor, and Pensions of the Senate and the Com-  
14 mittee on Energy and Commerce of the House of Rep-  
15 resentatives—

16           “(1) reviewing the operations and activities of  
17 the Partnerships in the previous year; and

18           “(2) addressing such other issues relating to  
19 this section as the Secretary determines to be appro-  
20 priate.

21           “(e) DEFINITION.—In this section, the term ‘medical  
22 product’ includes a drug, a biological product, a device,  
23 and any combination of such products.

24           “(f) AUTHORIZATION OF APPROPRIATIONS.—To  
25 carry out this section, there are authorized to be appro-

1 priated \$5,000,000 for fiscal year 2008 and such sums  
2 as may be necessary for each of fiscal years 2009 through  
3 2012.”.

4           **TITLE VII—CONFLICTS OF**  
5                           **INTEREST**

6   **SEC. 701. CONFLICTS OF INTEREST.**

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

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

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

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

17                   “(2) FINANCIAL INTEREST.—The term ‘finan-  
18 cial interest’ means a financial interest under section  
19 208(a) of title 18, United States Code.

20           “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

21                   “(1) RECRUITMENT.—

22                           “(A) IN GENERAL.—Given the importance  
23 of advisory committees to the review process at  
24 the Food and Drug Administration, the Sec-  
25 retary, through the Office of Women’s Health,

1 the Office of Orphan Product Development, the  
2 Office of Pediatric Therapeutics, and other of-  
3 fices within the Food and Drug Administration  
4 with relevant expertise, shall develop and imple-  
5 ment strategies on effective outreach to poten-  
6 tial members of advisory committees at univer-  
7 sities, colleges, other academic research centers,  
8 professional and medical societies, and patient  
9 and consumer groups. The Secretary shall seek  
10 input from professional medical and scientific  
11 societies to determine the most effective infor-  
12 mational and recruitment activities. The Sec-  
13 retary shall also take into account the advisory  
14 committees with the greatest number of vacan-  
15 cies.

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

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

22 “(ii) making widely available, includ-  
23 ing by using existing electronic commu-  
24 nications channels, the contact information  
25 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)(3) of this section

1 for service on the committee at a meeting of the  
2 committee.

3 “(3) PARTICIPATION OF GUEST EXPERT WITH  
4 FINANCIAL INTEREST.—Notwithstanding any other  
5 provision of this section, an individual with a finan-  
6 cial interest with respect to any matter considered  
7 by an advisory committee may be allowed to partici-  
8 pate in a meeting of an advisory committee as a  
9 guest expert if the Secretary determines that the in-  
10 dividual has particular expertise required for the  
11 meeting. An individual participating as a guest ex-  
12 pert may provide information and expert opinion,  
13 but shall not participate in the discussion or voting  
14 by the members of the advisory committee.

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

16 “(1) IN GENERAL.—Prior to a meeting of an  
17 advisory committee regarding a ‘particular matter’  
18 (as that term is used in section 208 of title 18,  
19 United States Code), each member of the committee  
20 who is a full-time Government employee or special  
21 Government employee shall disclose to the Secretary  
22 financial interests in accordance with subsection (b)  
23 of such section 208.

24 “(2) FINANCIAL INTEREST OF ADVISORY COM-  
25 MITTEE MEMBER OR FAMILY MEMBER.—No member

1 of an advisory committee may vote with respect to  
2 any matter considered by the advisory committee if  
3 such member (or an immediate family member of  
4 such member) has a financial interest that could be  
5 affected by the advice given to the Secretary with re-  
6 spect to such matter, excluding interests exempted  
7 in regulations issued by the Director of the Office of  
8 Government Ethics as too remote or inconsequential  
9 to affect the integrity of the services of the Govern-  
10 ment officers or employees to which such regulations  
11 apply.

12 “(3) WAIVER.—The Secretary may grant a  
13 waiver of the prohibition in paragraph (2) if such  
14 waiver is necessary to afford the advisory committee  
15 essential expertise.

16 “(4) LIMITATIONS.—

17 “(A) ONE WAIVER PER COMMITTEE MEET-  
18 ING.—Notwithstanding any other provision of  
19 this section, with respect to each advisory com-  
20 mittee, the Secretary shall not grant more than  
21 1 waiver under paragraph (3) per committee  
22 meeting.

23 “(B) SCIENTIFIC WORK.—The Secretary  
24 may not grant a waiver under paragraph (3)

1           for a member of an advisory committee when  
2           the member's own scientific work is involved.

3           “(5) DISCLOSURE OF WAIVER.—Notwith-  
4           standing section 107(a)(2) of the Ethics in Govern-  
5           ment Act (5 U.S.C. App.), the following shall apply:

6                   “(A) 15 OR MORE DAYS IN ADVANCE.—As  
7                   soon as practicable, but in no case later than  
8                   15 days prior to a meeting of an advisory com-  
9                   mittee to which a written determination as re-  
10                  ferred to in section 208(b)(1) of title 18, United  
11                  States Code, a written certification as referred  
12                  to in section 208(b)(3) of title 18, United  
13                  States Code, or a waiver as referred to in para-  
14                  graph (3) applies, the Secretary shall disclose  
15                  (other than information exempted from disclo-  
16                  sure under section 552 of title 5, United States  
17                  Code, and section 552a of title 5, United States  
18                  Code (popularly known as the Freedom of In-  
19                  formation Act and the Privacy Act of 1974, re-  
20                  spectively)) on the Internet website of the Food  
21                  and Drug Administration—

22                           “(i) the type, nature, and magnitude  
23                           of the financial interests of the advisory  
24                           committee member to which such deter-



1           mination, certification, or waiver applies;  
2           and

3           “(ii) the reasons of the Secretary for  
4           such determination, certification, or waiv-  
5           er.

6           “(B) LESS THAN 30 DAYS IN ADVANCE.—

7           In the case of a financial interest that becomes  
8           known to the Secretary less than 30 days prior  
9           to a meeting of an advisory committee to which  
10          a written determination as referred to in section  
11          208(b)(1) of title 18, United States Code, a  
12          written certification as referred to in section  
13          208(b)(3) of title 18, United States Code, or a  
14          waiver as referred to in paragraph (3) applies,  
15          the Secretary shall disclose (other than infor-  
16          mation exempted from disclosure under section  
17          552 of title 5, United States Code, and section  
18          552a of title 5, United States Code) on the  
19          Internet website of the Food and Drug Admin-  
20          istration, the information described in clauses  
21          (i) and (ii) of subparagraph (A) as soon as  
22          practicable after the Secretary makes such de-  
23          termination, certification, or waiver, but in no  
24          case later than the date of such meeting.

1       “(d) PUBLIC RECORD.—The Secretary shall ensure  
2 that the public record and transcript of each meeting of  
3 an advisory committee includes the disclosure required  
4 under subsection (c)(5) (other than information exempted  
5 from disclosure under section 552 of title 5, United States  
6 Code, and section 552a of title 5, United States Code).

7       “(e) ANNUAL REPORT.—Not later than February 1  
8 of each year, the Secretary shall submit to the Committee  
9 on Appropriations and the Committee on Health, Edu-  
10 cation, Labor, and Pensions of the Senate, and the Com-  
11 mittee on Appropriations and the Committee on Energy  
12 and Commerce of the House of Representatives a report  
13 that describes—

14               “(1) with respect to the fiscal year that ended  
15 on September 30 of the previous year, the number  
16 of vacancies on each advisory committee, the number  
17 of nominees received for each committee, and the  
18 number of such nominees willing to serve;

19               “(2) with respect to such year, the aggregate  
20 number of disclosures required under subsection  
21 (c)(5) for each meeting of each advisory committee  
22 and the percentage of individuals to whom such dis-  
23 closures did not apply who served on such committee  
24 for each such meeting;

1           “(3) with respect to such year, the number of  
2 times the disclosures required under subsection  
3 (c)(5) occurred under subparagraph (B) of such sub-  
4 section; and

5           “(4) how the Secretary plans to reduce the  
6 number of vacancies reported under paragraph (1)  
7 during the fiscal year following such year, and mech-  
8 anisms to encourage the nomination of individuals  
9 for service on an advisory committee, including those  
10 who are classified by the Food and Drug Adminis-  
11 tration as academicians or practitioners.

12       “(f) PERIODIC REVIEW OF GUIDANCE.—Not less  
13 than once every 5 years, the Secretary shall review guid-  
14 ance of the Food and Drug Administration regarding con-  
15 flict of interest waiver determinations with respect to advi-  
16 sory committees and update such guidance as necessary.”.

17       (b) CONFORMING AMENDMENT.—Section 505(n) of  
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 355(n)) is amended—

20           (1) by striking paragraph (4); and

21           (2) by redesignating paragraphs (5), (6), (7),  
22 and (8) as paragraphs (4), (5), (6), and (7), respec-  
23 tively.

24       (c) EFFECTIVE DATE.—The amendments made by  
25 this section shall take effect on October 1, 2007.

1           **TITLE VIII—CLINICAL TRIAL**  
2                           **DATABASES**

3   **SEC. 801. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-**  
4                           **ICAL TRIAL RESULTS DATABASE.**

5           (a) IN GENERAL.—Title IV of the Public Health  
6 Service Act (42 U.S.C. 281 et seq.) is amended—

7                   (1) in section 402, by striking subsection (i);

8                   and

9                   (2) by inserting after section 492B the fol-

10                  lowing new section:

11   **“SEC. 492C. CLINICAL TRIAL REGISTRY DATABASE; CLIN-**  
12                           **ICAL TRIAL RESULTS DATABASE.**

13           “(a) DEFINITIONS.—In this section:

14                   “(1) APPLICABLE CLINICAL TRIAL.—The term  
15                   ‘applicable clinical trial’—

16                           “(A) means a clinical trial that is con-  
17                           ducted to test the safety or effectiveness (in-  
18                           cluding comparative effectiveness) of a drug or  
19                           device (irrespective of whether the clinical trial  
20                           is federally or privately funded, and whether the  
21                           clinical trial involves an approved or unap-  
22                           proved drug or device);

23                           “(B) includes such a clinical trial that is  
24                           conducted outside of the United States if—

1           “(i) there is an application or pre-  
2           market notification pending before the  
3           Food and Drug Administration for ap-  
4           proval or clearance of the drug or device  
5           involved under section 505, 510(k), or 515  
6           of the Federal Food, Drug, and Cosmetic  
7           Act or section 351 of this Act; or

8           “(ii) the drug or device involved is so  
9           approved or cleared; and

10           “(C) notwithstanding subparagraphs (A)  
11           and (B), excludes—

12           “(i) a clinical trial to determine the  
13           safety of a use of a drug that is designed  
14           solely to detect major toxicities in the drug  
15           or to investigate pharmacokinetics, unless  
16           the clinical trial is designed to investigate  
17           pharmacokinetics in a special population or  
18           populations; and

19           “(ii) a small clinical trial to determine  
20           the feasibility of a device, or a clinical trial  
21           to test prototype devices where the primary  
22           focus is feasibility.

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

1 ical trial registry database under subsection (b) or  
2 the clinical trial results database under subsection  
3 (c), as applicable.

4 “(3) COMPLETION DATE.—The term ‘comple-  
5 tion date’ means the date of the final collection of  
6 data from subjects in the clinical trial for the pri-  
7 mary and secondary outcomes to be examined in the  
8 trial.

9 “(4) DEVICE.—The term ‘device’ has the mean-  
10 ing given to that term in section 201(h) of the Fed-  
11 eral Food, Drug, and Cosmetic Act.

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

16 “(6) RESPONSIBLE PARTY.—The term ‘respon-  
17 sible party’, with respect to an applicable clinical  
18 trial, means—

19 “(A) the primary sponsor (as defined in  
20 the International Clinical Trials Registry Plat-  
21 form trial registration data set of the World  
22 Health Organization) of the clinical trial; or

23 “(B) the principal investigator of such clin-  
24 ical trial if so designated by such sponsor, so  
25 long as the principal investigator is responsible

1 for conducting the trial, has access to and con-  
2 trol over the data, has the right to publish the  
3 results of the trial, and has the responsibility to  
4 meet all of the requirements under this section  
5 that are applicable to responsible parties.

6 “(b) CLINICAL TRIALS REGISTRY DATABASE.—

7 “(1) ESTABLISHMENT.—To enhance patient en-  
8 rollment and provide a mechanism to track subse-  
9 quent progress of clinical trials, the Secretary, act-  
10 ing through the Director of NIH, shall establish and  
11 administer a clinical trial registry database in ac-  
12 cordance with this section (referred to in this section  
13 as the ‘registry database’). The Director of NIH  
14 shall ensure that the registry database is made pub-  
15 licly available through the Internet.

16 “(2) CONTENT.—The Secretary shall promul-  
17 gate regulations for the submission to the registry  
18 database of clinical trial information that—

19 “(A) conforms to the International Clinical  
20 Trials Registry Platform trial registration data  
21 set of the World Health Organization;

22 “(B) includes the city, State, and zip code  
23 for each clinical trial location or a toll free  
24 number through which such location informa-  
25 tion may be accessed;

1           “(C) includes a statement of the estimated  
2 completion date for the clinical trial;

3           “(D) includes the identity and contact in-  
4 formation of the responsible party;

5           “(E) if the drug is not approved under sec-  
6 tion 505 of the Federal Food, Drug, and Cos-  
7 metic Act or licensed under section 351 of this  
8 Act, or the device is not cleared under section  
9 510(k) or approved under section 515 of the  
10 Federal Food, Drug, and Cosmetic Act, speci-  
11 fies whether or not there is expanded access to  
12 the drug or device under section 561 of the  
13 Federal Food, Drug, and Cosmetic Act for  
14 those who do not qualify for enrollment in the  
15 clinical trial and how to obtain information  
16 about such access;

17           “(F) includes, with respect to any indi-  
18 vidual who is not an employee of the responsible  
19 party for the clinical trial or of the manufac-  
20 turer of the drug or device involved, information  
21 on whether the responsible party or manufac-  
22 turer has entered into any agreement with such  
23 individual that restricts in any manner the abil-  
24 ity of the individual—



1           “(i) to discuss the results of the trial  
2           at a scientific meeting or any other public  
3           or private forum; or

4           “(ii) to publish the results of the trial,  
5           or a description or discussion of the results  
6           of the trial, in a scientific or academic  
7           journal; and

8           “(G) requires the inclusion of such other  
9           data elements to the registry database as ap-  
10          propriate.

11          “(3) FORMAT AND STRUCTURE.—

12           “(A) SEARCHABLE CATEGORIES.—The Di-  
13          rector of NIH shall ensure that the public may  
14          search the entries in the registry database by 1  
15          or more of the following criteria:

16           “(i) The indication being studied in  
17           the clinical trial, using Medical Subject  
18           Headers (MeSH) descriptors.

19           “(ii) The safety issue being studied in  
20           the clinical trial.

21           “(iii) The enrollment status of the  
22           clinical trial.

23           “(iv) The sponsor of the clinical trial.

24           “(B) FORMAT.—The Director of the NIH  
25          shall ensure that the registry database is easily

1           used by patients, and that entries are easily  
2           compared.

3           “(4) DATA SUBMISSION.—The responsible party  
4           for an applicable clinical trial shall submit to the Di-  
5           rector of NIH for inclusion in the registry database  
6           the clinical trial information described in paragraph  
7           (2).

8           “(5) TRUTHFUL CLINICAL TRIAL INFORMA-  
9           TION.—

10           “(A) IN GENERAL.—The clinical trial in-  
11           formation submitted by a responsible party  
12           under this subsection shall not be false or mis-  
13           leading.

14           “(B) EFFECT.—Subparagraph (A) shall  
15           not have the effect of requiring clinical trial in-  
16           formation to include information from any  
17           source other than the clinical trial involved.

18           “(6) TIMING OF SUBMISSION.—Except as pro-  
19           vided in paragraph (7), the clinical trial information  
20           for a clinical trial required to be submitted under  
21           this subsection shall be submitted not later than 14  
22           days after the first patient is enrolled in such clin-  
23           ical trial.

24           “(7) UPDATES.—The responsible party for an  
25           applicable clinical trial shall submit to the Director

1 of NIH for inclusion in the registry database peri-  
2 odic updates to reflect changes to the clinical trial  
3 information submitted under this subsection. Such  
4 updates—

5 “(A) shall be provided not less than once  
6 every 6 months until information on the results  
7 of the trial is submitted under subsection (c);

8 “(B) shall include identification of the  
9 dates of any such changes;

10 “(C) not later than 30 days after the en-  
11 rollment status of such clinical trial changes,  
12 shall include an update of the enrollment sta-  
13 tus; and

14 “(D) not later than 30 days after the com-  
15 pletion date of the clinical trial, shall include a  
16 report to the Director that such clinical trial is  
17 complete.

18 “(8) APPLICABILITY OF DEVICE TRIALS.—In  
19 the case of an applicable clinical trial regarding a  
20 device, the responsible person for the trial shall sub-  
21 mit to the Director of NIH the clinical trial informa-  
22 tion as required in paragraph (4), but the Director  
23 may not make the information publicly available  
24 through the registry database until the device is ap-  
25 proved or cleared (as the case may be).

1 “(c) CLINICAL TRIALS RESULTS DATABASE.—

2 “(1) ESTABLISHMENT.—To ensure that results  
3 of clinical trials are made public and that patients  
4 and providers have current information regarding  
5 the results of clinical trials, the Secretary, acting  
6 through the Director of NIH, shall establish and ad-  
7 minister a clinical trial results database in accord-  
8 ance with this section (referred to in this section as  
9 the ‘results database’). The Director of NIH shall  
10 ensure that the results database is made publicly  
11 available through the Internet.

12 “(2) SEARCHABLE CATEGORIES.—The Director  
13 of NIH shall ensure that the public may search the  
14 entries in the results database by 1 or more of the  
15 following:

16 “(A) The indication studied in the clinical  
17 trial, using Medical Subject Headers (MeSH)  
18 descriptors.

19 “(B) The safety issue studied in the clin-  
20 ical trial.

21 “(C) Whether an application for the tested  
22 indication is approved, pending approval, with-  
23 drawn, or not submitted.

24 “(D) The phase of the clinical trial.

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

3           “(F) Within the documents described in  
4           clauses (i) and (ii) of paragraph (3)(B), the fol-  
5           lowing information, as applicable:

6                   “(i) The sponsor of the clinical trial.

7                   “(ii) Each financial sponsor of the  
8                   clinical trial.

9           “(3) CONTENTS.—

10                   “(A) IN GENERAL.—The responsible party  
11                   for an applicable clinical trial shall submit to  
12                   the Director of NIH for inclusion in the results  
13                   database the clinical trial information described  
14                   in subparagraph (B).

15                   “(B) REQUIRED ELEMENTS.—In submit-  
16                   ting clinical trial information for a clinical trial  
17                   to the Director of NIH for inclusion in the re-  
18                   sults database, the responsible party shall in-  
19                   clude, with respect to such clinical trial, the fol-  
20                   lowing information:

21                           “(i) The information described in sub-  
22                           paragraphs (A) through (E) of subsection  
23                           (b)(2).

1           “(ii) A summary that is written in  
2 non-technical, understandable language for  
3 patients that includes the following:

4                   “(I) The purpose of the clinical  
5 trial.

6                   “(II) The sponsor of the clinical  
7 trial.

8                   “(III) A point of contact for in-  
9 formation about the clinical trial.

10                   “(IV) A description of the patient  
11 population tested in the clinical trial.

12                   “(V) A general description of the  
13 clinical trial and results, including a  
14 description of and the reasons for any  
15 changes in the clinical trial design  
16 that occurred since the date of sub-  
17 mission of clinical trial information  
18 for inclusion in the registry database  
19 established under subsection (b) and a  
20 description of any significant safety  
21 information.

22           “(iii) A summary that is technical in  
23 nature that includes the following:

24                   “(I) The purpose of the clinical  
25 trial.

1                   “(II) The sponsor of the clinical  
2 trial.

3                   “(III) Each financial sponsor of  
4 the clinical trial.

5                   “(IV) A point of contact for sci-  
6 entific information about the clinical  
7 trial.

8                   “(V) A description of the patient  
9 population tested in the clinical trial.

10                   “(VI) A general description of  
11 the clinical trial and results, including  
12 a description of and the reasons for  
13 any changes in the clinical trial design  
14 that occurred since the date of sub-  
15 mission of clinical trial information  
16 for the clinical trial in the registry  
17 database established under subsection  
18 (b).

19                   “(VII) Summary data describing  
20 the results, including—

21                   “(aa) whether the primary  
22 endpoint was achieved, including  
23 relevant statistics;

24                   “(bb) an assessment of any  
25 secondary endpoints, if applica-

1 ble, including relevant statistics;  
2 and

3 “(cc) any significant safety  
4 information, including a sum-  
5 mary of the incidence of serious  
6 adverse events observed in the  
7 clinical trial and a summary of  
8 the most common adverse events  
9 observed in the clinical trial and  
10 the frequencies of such events.

11 “(iv) With respect to the group of  
12 subjects receiving the drug or device in-  
13 volved, and each comparison group of sub-  
14 jects, the percentage of individuals who  
15 ceased participation as subjects and the  
16 reasons for ceasing participation.

17 “(v) With respect to an individual who  
18 is not an employee of the responsible party  
19 for the clinical trial or of the manufacturer  
20 of the drug or device involved, information  
21 (to the extent not submitted under sub-  
22 section (b)(2)(F)) on any agreement that  
23 the responsible party or manufacturer has  
24 entered into with such individual that re-



1                   stricts in any manner the ability of the in-  
2                   dividual—

3                   “(I) to discuss the results of the  
4                   trial at a scientific meeting or any  
5                   other public or private forum; or

6                   “(II) to publish the results of the  
7                   trial, or a description or discussion of  
8                   the results of the trial, in a scientific  
9                   or academic journal.

10                  “(vi) The completion date of the clin-  
11                  ical trial.

12                  “(vii) A link to the Internet web post-  
13                  ing of any adverse regulatory actions taken  
14                  by the Food and Drug Administration,  
15                  such as a warning letter, that was sub-  
16                  stantively based on the clinical trial design,  
17                  outcome, or representation made by the  
18                  applicant about the design or outcome of  
19                  the clinical trial.

20                  “(C) LINKS IN DATABASE.—The Director  
21                  of NIH shall ensure that the results database  
22                  includes the following:

23                  “(i) Links to Medline citations to pub-  
24                  lications reporting results from each appli-

1 cable drug clinical trial and applicable de-  
2 vice clinical trial.

3 “(ii) Links to the entry for the prod-  
4 uct that is the subject of an applicable  
5 drug clinical trial in the National Library  
6 of Medicine database of structured product  
7 labels, if available.

8 “(iii) Links described in clauses (i)  
9 and (ii) for data bank entries for clinical  
10 trials submitted to the data bank prior to  
11 enactment of this section, as available.

12 “(4) TIMING.—

13 “(A) IN GENERAL.—Except as provided in  
14 subparagraphs (B) and (C), a responsible party  
15 shall submit to the Director of NIH for inclu-  
16 sion in the results database clinical trial infor-  
17 mation for an applicable clinical trial not later  
18 than 1 year after the earlier of—

19 “(i) the estimated completion date of  
20 the trial, as submitted under subsection  
21 (b)(2); or

22 “(ii) the actual date of the completion,  
23 or termination before completion, of the  
24 trial, as applicable.

1           “(B) EXTENSIONS.—The Director of NIH  
2           may provide an extension of the deadline for  
3           submission of clinical trial information under  
4           subparagraph (A) if the responsible party for  
5           the trial submits to the Director a written re-  
6           quest that demonstrates good cause for the ex-  
7           tension and provides an estimate of the date on  
8           which the information will be submitted. The  
9           Director of NIH may grant more than one such  
10          extension for the clinical trial involved.

11          “(C) UPDATES.—The responsible party for  
12          an applicable clinical trial shall submit to the  
13          Director of NIH for inclusion in the results  
14          database periodic updates to reflect changes in  
15          the clinical trial information submitted under  
16          this subsection. Such updates—

17                 “(i) shall be provided not less fre-  
18                 quently than once every 6 months during  
19                 the 10-year period beginning on the date  
20                 on which information is due under sub-  
21                 paragraph (A);

22                 “(ii) shall identify the dates on which  
23                 the changes were made; and

24                 “(iii) shall include, not later than 30  
25                 days after any change in the regulatory

1 status of the drug or device involved, an  
2 update informing the Director of NIH of  
3 such change.

4 “(5) TRUTHFUL CLINICAL TRIAL INFORMA-  
5 TION.—

6 “(A) IN GENERAL.—The clinical trial in-  
7 formation submitted by a responsible party  
8 under this subsection shall not be false or mis-  
9 leading in any particular.

10 “(B) EFFECT.—Subparagraph (A) shall  
11 not have the effect of requiring clinical trial in-  
12 formation with respect to a clinical trial to in-  
13 clude information from any source other than  
14 such clinical trial.

15 “(6) PUBLIC AVAILABILITY OF RESULTS.—

16 “(A) PRE-APPROVAL STUDIES.—Except as  
17 provided in subparagraph (E), with respect to  
18 an applicable clinical trial that is completed be-  
19 fore the drug is initially approved under section  
20 505 of the Federal Food, Drug, and Cosmetic  
21 Act or initially licensed under section 351 of  
22 this Act, or the device is initially cleared under  
23 section 510(k) or approved under section 515 of  
24 the Federal Food, Drug, and Cosmetic Act, the  
25 Director of NIH shall make publicly available

1 on the results database the clinical trial infor-  
2 mation submitted for such clinical trial not  
3 later than 30 days after—

4 “(i) the drug or device is approved  
5 under such section 505, licensed under  
6 such section 351, cleared under such sec-  
7 tion 510(k), or approved under such sec-  
8 tion 515, as applicable; or

9 “(ii) the Secretary issues a not ap-  
10 provable letter or a not substantially equiv-  
11 alent letter for the drug or device under  
12 such section 505, 351, 510(k), or 515, as  
13 applicable.

14 “(B) MEDICAL AND CLINICAL PHARMA-  
15 COLOGY REVIEWS OF PRE-APPROVAL STUD-  
16 IES.—Not later than 90 days after the date ap-  
17 plicable under clause (i) or (ii) of subparagraph  
18 (A) with respect to an applicable clinical trial,  
19 the Director of NIH shall make publicly avail-  
20 able on the results database a summary of the  
21 available medical and clinical pharmacology re-  
22 views conducted by the Food and Drug Admin-  
23 istration for such trial.

24 “(C) POST-APPROVAL STUDIES.—Except  
25 as provided in subparagraphs (D) and (E), with

1 respect to an applicable clinical trial that is  
2 completed after the drug is initially approved  
3 under such section 505 or licensed under such  
4 section 351, or the device is initially cleared  
5 under such section 510(k) or approved under  
6 such section 515, the Director of NIH shall  
7 make publicly available on the results database  
8 the clinical trial information submitted for such  
9 clinical trial not later than 30 days after the  
10 date of such submission.

11 “(D) SEEKING APPROVAL OF A NEW USE  
12 FOR THE DRUG OR DEVICE.—

13 “(i) IN GENERAL.—If the manufac-  
14 turer of the drug or device is the sponsor  
15 or a financial sponsor of an applicable clin-  
16 ical trial, and such manufacturer certifies  
17 to the Director of NIH that such manufac-  
18 turer has filed, or will file within 1 year,  
19 an application seeking approval under such  
20 section 505, licensing under such section  
21 351, clearance under such section 510(k),  
22 or approval under such section 515 for the  
23 use studied in such clinical trial (which use  
24 is not included in the labeling of the ap-  
25 proved drug or device), then the Director

1 of NIH shall make publicly available on  
2 the results database the clinical trial infor-  
3 mation submitted for such clinical trial on  
4 the earlier of the date that is 30 days after  
5 the date—

6 “(I) the new use of the drug or  
7 device is approved under such section  
8 505, licensed under such section 351,  
9 cleared under such section 510(k), or  
10 approved under such section 515;

11 “(II) the Secretary issues a not  
12 approvable letter or a not substan-  
13 tially equivalent letter for the new use  
14 of the drug or device under such sec-  
15 tion 505, 351, 510(k), or 515; or

16 “(III) the application or pre-  
17 market notification under such section  
18 505, 351, 510(k), or 515 is with-  
19 drawn.

20 “(ii) LIMITATION ON CERTIFI-  
21 CATION.—If a manufacturer makes a cer-  
22 tification under clause (i) with respect to a  
23 clinical trial, the manufacturer shall make  
24 such a certification with respect to each  
25 applicable clinical trial that is required to

1 be submitted in an application for approval  
2 of the use studied in the clinical trial.

3 “(iii) 2-YEAR LIMITATION.—The clin-  
4 ical trial information subject to clause (i)  
5 shall be made publicly available on the re-  
6 sults database on the date that is 2 years  
7 after the date the certification referred to  
8 in clause (i) was made to the Director of  
9 NIH, if a regulatory action referred to in  
10 subclause (I), (II), or (III) of clause (i) has  
11 not occurred by such date.

12 “(iv) MEDICAL AND CLINICAL PHAR-  
13 MACOLOGY REVIEWS.—Not later than 90  
14 days after the date applicable under sub-  
15 clause (I), (II), or (III) of clause (i) or  
16 clause (iii) with respect to an applicable  
17 clinical trial, the Director of NIH shall  
18 make publicly available on the results data-  
19 base a summary of the available medical  
20 and clinical pharmacology reviews con-  
21 ducted by the Food and Drug Administra-  
22 tion for such trial.

23 “(E) SEEKING PUBLICATION.—

24 “(i) IN GENERAL.—If the principal in-  
25 vestigator of an applicable clinical trial is



1 seeking publication in a peer-reviewed bio-  
2 medical journal of a manuscript based on  
3 the results of the clinical trial and the re-  
4 sponsible party so certifies to the Director  
5 of NIH—

6 “(I) the responsible party shall  
7 notify the Director of NIH of the pub-  
8 lication date of such manuscript not  
9 later than 15 days after such date;  
10 and

11 “(II) the Director of NIH shall  
12 make publicly available on the results  
13 database the clinical trial information  
14 submitted for such clinical trial on the  
15 date that is 30 days after the publica-  
16 tion date of such manuscript.

17 “(ii) LIMITATIONS.—The clinical trial  
18 information subject to clause (i)—

19 “(I) shall be made publicly avail-  
20 able on the results database on the  
21 date that is 2 years after the date  
22 that the clinical trial information was  
23 required to be submitted to the Direc-  
24 tor of NIH if the manuscript referred

1 to in such clause has not been pub-  
2 lished by such date; and

3 “(II) shall not be required to be  
4 made publicly available under section  
5 552 of title 5, United States Code  
6 (commonly known as the ‘Freedom of  
7 Information Act’), prior to the date  
8 applicable to such clinical trial infor-  
9 mation under this subparagraph.

10 “(7) VERIFICATION OF SUBMISSION PRIOR TO  
11 PUBLIC AVAILABILITY.—In the case of clinical trial  
12 information that is submitted under this subsection,  
13 but is not made publicly available pending either  
14 regulatory action or publication under subparagraph  
15 (D) or (E) of paragraph (6), as applicable, the Di-  
16 rector of NIH shall respond to inquiries from other  
17 Federal agencies and peer-reviewed journals to con-  
18 firm that such clinical trial information has been  
19 submitted but has not yet been made publicly avail-  
20 able on the results database.

21 “(d) UPDATES; TRACKING OF CHANGES IN SUB-  
22 MITTED INFORMATION.—The Director of NIH shall en-  
23 sure that updates submitted to the Director under sub-  
24 sections (b)(7) and (c)(4) do not result in the removal  
25 from the registry database or the results database of the

1 original submissions or of any preceding updates, and that  
2 information in such databases is presented in a manner  
3 that enables users to readily access each original submis-  
4 sion and to track the changes made by the updates.

5 “(e) COORDINATION AND COMPLIANCE.—

6 “(1) CONSULTATION WITH OTHER FEDERAL  
7 AGENCIES.—The Secretary shall—

8 “(A) consult with other agencies that con-  
9 duct human studies in accordance with part 46  
10 of title 45, Code of Federal Regulations (or any  
11 successor regulations), to determine if any such  
12 studies are applicable clinical trials; and

13 “(B) develop with such agencies appro-  
14 priate procedures to ensure that clinical trial in-  
15 formation for such applicable clinical trials is  
16 submitted under subsection (b) and (c).

17 “(2) COORDINATION OF REGISTRY DATABASE  
18 AND RESULTS DATABASE.—

19 “(A) IN GENERAL.—Each entry in the reg-  
20 istry database under subsection (b) or the re-  
21 sults database under subsection (c) shall in-  
22 clude a link to the corresponding entry in the  
23 results database or the registry database, re-  
24 spectively.

25 “(B) MISSING ENTRIES.—

1           “(i) IN GENERAL.—If, based on a re-  
2 view of the entries in the registry database  
3 under subsection (b), the Director of NIH  
4 determines that a responsible party has  
5 failed to submit required clinical trial in-  
6 formation to the results database under  
7 subsection (c), the Director of NIH shall  
8 inform the responsible party involved of  
9 such failure and permit the responsible  
10 party to correct the failure within 30 days.

11           “(ii) FAILURE TO CORRECT.—If the  
12 responsible party does not correct a failure  
13 to submit required clinical trial informa-  
14 tion within the 30-day period described  
15 under clause (i), the Director of NIH shall  
16 report such noncompliance to the scientific  
17 peer review committees of the Federal re-  
18 search agencies and to the Office of  
19 Human Research Protections.

20           “(iii) PUBLIC NOTICE OF FAILURE TO  
21 CORRECT.—The Director of NIH shall in-  
22 clude in the clinical trial registry database  
23 entry and the clinical trial results database  
24 entry for each applicable clinical trial a no-  
25 tice of any uncorrected failure to submit

1 required clinical trial information and shall  
2 provide that the public may easily search  
3 for such entries.

4 “(3) ACTION ON APPLICATIONS.—

5 “(A) VERIFICATION PRIOR TO FILING.—

6 The Secretary, acting through the Commis-  
7 sioner of Food and Drugs, shall verify that the  
8 clinical trial information required under sub-  
9 sections (b) and (c) for an applicable clinical  
10 trial is submitted pursuant to such subsections,  
11 as applicable—

12 “(i) when considering a drug or device  
13 for an exemption under section 505(i) or  
14 section 520(g) of the Federal Food, Drug,  
15 and Cosmetic Act; and

16 “(ii) prior to filing an application or  
17 premarket notification under section 505,  
18 510(k), or 515 of the Federal Food, Drug,  
19 and Cosmetic Act or section 351 of this  
20 Act, that includes information from such  
21 clinical trial.

22 “(B) NOTIFICATION.—If the Secretary de-  
23 termines under subparagraph (A) that clinical  
24 trial information has not been submitted as re-  
25 quired by subsection (b) or (c), the Secretary

1 shall notify the applicant and the responsible  
2 party of such noncompliance and require sub-  
3 mission of such information within 30 days.

4 “(C) REFUSAL TO FILE.—If the respon-  
5 sible party does not remedy such noncompliance  
6 within 30 days of receipt of notification under  
7 subparagraph (B), the Secretary shall refuse to  
8 file, approve, or clear such application or pre-  
9 market notification.

10 “(4) CONTENT REVIEW.—

11 “(A) IN GENERAL.—To ensure that the  
12 summary documents described in subsection  
13 (c)(3) are non-promotional, and are not false or  
14 misleading in any particular under subsection  
15 (c)(5), the Secretary shall compare such docu-  
16 ments to the results data of the clinical trial for  
17 a representative sample of applicable clinical  
18 trials by—

19 “(i) acting through the Commissioner  
20 of Food and Drugs to examine the results  
21 data for such clinical trials submitted to  
22 Secretary when such data are submitted—

23 “(I) for review as part of an ap-  
24 plication under section 505 or 515 of  
25 the Federal Food, Drug, and Cos-

1                    metic Act or under section 351 of this  
2                    Act or a premarket notification under  
3                    section 510(k) of the Federal Food,  
4                    Drug, and Cosmetic Act; or

5                    “(II) in an annual status report  
6                    on the drug or device under such ap-  
7                    plication;

8                    “(ii) acting with the Federal agency  
9                    that funds such clinical trial in whole or in  
10                   part by a grant to examine the results data  
11                   for such clinical trials; and

12                   “(iii) acting through inspections under  
13                   section 704 of the Federal Food, Drug,  
14                   and Cosmetic Act to examine results data  
15                   for such clinical trials not described in  
16                   clause (i) or (ii).

17                   “(B) NOTICE OF NONCOMPLIANCE.—If the  
18                   Secretary determines that the clinical trial in-  
19                   formation submitted in such a summary docu-  
20                   ment is false or misleading in any particular,  
21                   the Secretary shall notify the responsible party  
22                   and give such party an opportunity to remedy  
23                   such noncompliance by submitting the required  
24                   revised clinical trial information within 30 days  
25                   of such notification.

1 “(f) PENALTIES FOR NONCOMPLIANCE.—

2 “(1) IN GENERAL.—The following acts and the  
3 causing thereof are unlawful:

4 “(A) The failure to submit clinical trial in-  
5 formation as required by this section.

6 “(B) The submission of clinical trial infor-  
7 mation under this section that is false or mis-  
8 leading in any particular in violation of sub-  
9 section (b)(5) or (c)(5).

10 “(2) CERTAIN PENALTIES.—Section 303(a) of  
11 the Federal Food, Drug, and Cosmetic Act applies  
12 with respect to a violation of paragraph (1) to the  
13 same extent and in the same manner as such section  
14 303(a) applies with respect to a violation of section  
15 301 of such Act.

16 “(3) CONSIDERATIONS.—In determining wheth-  
17 er to apply a penalty under paragraph (2) or under  
18 paragraph (4) for a violation described in paragraph  
19 (1), the Secretary, acting through the Commissioner  
20 of Food and Drugs, shall consider—

21 “(A) whether the responsible party  
22 promptly corrects the noncompliance when pro-  
23 vided notice;



1           “(B) whether the responsible party has en-  
2           gaged in a pattern or practice of noncompli-  
3           ance; and

4           “(C) the extent to which the noncompli-  
5           ance involved may have significantly misled  
6           health care providers or patients concerning the  
7           safety or effectiveness of the drug involved.

8           “(4) CIVIL PENALTIES.—

9           “(A) IN GENERAL.—A person is subject to  
10          a civil penalty in accordance with this para-  
11          graph if the person commits a violation de-  
12          scribed in paragraph (1) and fails to correct the  
13          violation by the end of the 30-day period de-  
14          scribed in subparagraph (B).

15          “(B) NOTIFICATION.—If a person is in vio-  
16          lation of paragraph (1), the Secretary shall no-  
17          tify the person of such noncompliance and give  
18          the person a 30-day period to correct such vio-  
19          lation before imposing a civil penalty under this  
20          paragraph.

21          “(C) AMOUNT OF PENALTY.—The amount  
22          of a civil penalty under this subsection shall be  
23          not more than a total of \$15,000 for all viola-  
24          tions adjudicated in a single proceeding in the  
25          case of an individual, and not more than

1           \$10,000 per day until the violation is corrected  
2           in the case of any other person, except that if  
3           the person is a nonprofit entity the penalty may  
4           not exceed a total of \$15,000 for all violations  
5           adjudicated in a single proceeding.

6           “(D) PROCEDURES.—The provisions of  
7           paragraphs (4) through (6) of section 303(f) of  
8           the Federal Food, Drug, and Cosmetic Act  
9           apply to the imposition of a penalty under this  
10          subsection to the same extent and in the same  
11          manner as such provisions apply to a penalty  
12          imposed under such section 303(f).

13          “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
14          are authorized to be appropriated to carry out this section  
15          \$10,000,000 for each fiscal year.”.

16          (b) CONFORMING AMENDMENTS.—

17                  (1) INVESTIGATIONAL NEW DRUGS.—Section  
18                  505(i) of the Federal Food, Drug, and Cosmetic Act  
19                  (21 U.S.C. 355(i)) is amended—

20                          (A) in paragraph (1)—

21                                  (i) in subparagraph (C), by striking  
22                                  “and” after the semicolon;

23                                  (ii) in subparagraph (D)—

24    (I) by aligning the indentation of  
25    such subparagraph with the indenta-

1                   tion of subparagraphs (A), (B), and  
2                   (C); and

3                   (II) by striking the period at the  
4                   end and inserting “; and”; and

5                   (iii) by adding at the end the fol-  
6                   lowing:

7                   “(E) the submission to the Director of NIH of  
8                   clinical trial information for the clinical investigation  
9                   at issue required under section 492C of the Public  
10                  Health Service Act for inclusion in the registry data-  
11                  base and the results database described in such sec-  
12                  tion.”;

13                  (B) in paragraph (3)(B)—

14                   (i) in clause (i), by striking “or” after  
15                   the semicolon;

16                   (ii) in clause (ii), by striking the pe-  
17                   riod at the end and inserting “; or”; and

18                   (iii) by adding at the end the fol-  
19                   lowing:

20                   “(iii) clinical trial information for the clinical  
21                   investigation at issue was not submitted in compli-  
22                   ance with section 492C of the Public Health Service  
23                   Act.”; and

24                   (C) in paragraph (4), by adding at the end  
25                   the following: “The Secretary shall update such

1 regulations to require inclusion in the informed  
2 consent form a statement that clinical trial in-  
3 formation for such clinical investigation will be  
4 submitted for inclusion in the registry database  
5 and results database, as applicable, described in  
6 section 492C of the Public Health Service  
7 Act.”.

8 (2) REFUSAL TO APPROVE NEW DRUG APPLICA-  
9 TION.—Section 505(d) of the Federal Food, Drug,  
10 and Cosmetic Act (21 U.S.C. 355(d)) is amended—

11 (A) in the first sentence, by inserting after  
12 “in any particular;” the following: “or (8) the  
13 applicant failed to submit the clinical trial in-  
14 formation for any applicable clinical trial as re-  
15 quired by section 492C of the Public Health  
16 Service Act;”; and

17 (B) in the second sentence, by striking  
18 “clauses (1) through (6)” and inserting “para-  
19 graphs (1) through (8)”.

20 (3) INVESTIGATIONAL NEW DEVICES.—Sub-  
21 paragraph (B) of section 520(g)(2) of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C.  
23 360j(g)(2)) is amended—

24 (A) by redesignating clause (iii) as clause  
25 (iv); and

1 (B) by inserting after clause (ii) the fol-  
2 lowing:

3 “(iii) A requirement that the person applying  
4 for an exemption for a device assure that such per-  
5 son is in compliance with the requirements of section  
6 492C of the Public Health Service Act for the sub-  
7 mission of clinical trial information for inclusion in  
8 the registry database and the results database de-  
9 scribed in such section.”.

10 (4) REFUSAL TO CLEAR NEW DEVICE PRE-  
11 MARKET NOTIFICATION REPORT.—Subsection (k) of  
12 section 510 of the Federal Food, Drug, and Cos-  
13 metic Act (21 U.S.C. 360) is amended—

14 (A) in paragraph (1), by striking “and” at  
15 the end; and

16 (B) in paragraph (2), by striking the pe-  
17 riod at the end and inserting “, and”; and

18 (C) by adding at the end the following:

19 “(3) action taken by such person to comply  
20 with requirements under section 492C of the Public  
21 Health Service Act for the submission of clinical  
22 trial information for inclusion in the registry data-  
23 base and the results database described in such sec-  
24 tion.”.

1           (5) REFUSAL TO APPROVE NEW DEVICE APPLI-  
2           CATION.—Paragraph (2) of section 515(d) of the  
3           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4           360e(d)) is amended—

5                   (A) in subparagraph (D), by striking “or”  
6                   at the end;

7                   (B) in subparagraph (E), by striking the  
8                   period at the end and inserting “; or”; and

9                   (C) by inserting after subparagraph (E)  
10                  the following:

11                  “(F) the applicant is in violation of the require-  
12                  ments under section 492C of the Public Health  
13                  Service Act for the submission of clinical trial infor-  
14                  mation for inclusion in the registry database or the  
15                  results database described in such section.”.

16           (c) GUIDANCE.—Not later than 180 days after the  
17           date of the enactment of this Act, the Commissioner of  
18           Food and Drugs, in consultation with the Director of the  
19           National Institutes of Health, shall issue guidance to clar-  
20           ify which clinical trials are applicable clinical trials (as de-  
21           fined in section 492C of the Public Health Service Act,  
22           as amended by this section) and required to be submitted  
23           for inclusion in the clinical trial registry database de-  
24           scribed in such section.

25           (d) PREEMPTION.—

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

6           (2) RULE OF CONSTRUCTION.—The fact of sub-  
7           mission of clinical trial information, if submitted in  
8           compliance with section 492C of the Public Health  
9           Service Act (as amended by this section), that re-  
10          lates to a use of a drug or device not included in the  
11          official labeling of the approved drug or device shall  
12          not be construed by the Secretary or in any adminis-  
13          trative or judicial proceeding, as evidence of a new  
14          intended use of the drug or device that is different  
15          from the intended use of the drug or device set forth  
16          in the official labeling of the drug or device. The  
17          availability of clinical trial information through the  
18          databases under subsections (b) and (c) of such sec-  
19          tion 492C, if submitted in compliance with such sec-  
20          tion 492C, shall not be considered as labeling, adul-  
21          teration, or misbranding of the drug or device under  
22          the Federal Food, Drug, and Cosmetic Act (21  
23          U.S.C. 301 et seq.).

24          (e) EFFECTIVE DATES.—

1           (1) ESTABLISHMENT OF REGISTRY DATABASE  
2           AND RESULTS DATABASE.—Not later than 1 year  
3           after the date of the enactment of this Act, the Di-  
4           rector of NIH shall establish the registry database  
5           and the results database of clinical trials of drugs  
6           and devices in accordance with section 492C of the  
7           Public Health Service Act (as amended by sub-  
8           section (a)).

9           (2) CLINICAL TRIALS INITIATED PRIOR TO OP-  
10          ERATION OF REGISTRY DATABASE.—The responsible  
11          party (as defined in such section 492C) for an appli-  
12          cable clinical trial (as defined in such section 492C)  
13          that is initiated after the date of the enactment of  
14          this Act and before the date such registry database  
15          is established under paragraph (1) of this sub-  
16          section, shall submit required clinical trial informa-  
17          tion not later than 120 days after the date such reg-  
18          istry database is established.

19          (3) CLINICAL TRIALS INITIATED AFTER OPER-  
20          ATION OF REGISTRY DATABASE.—The responsible  
21          party (as defined in such section 492C) for an appli-  
22          cable clinical trial (as defined in such section 492C)  
23          that is initiated after the date such registry database  
24          is established under paragraph (1) of this subsection



1 shall submit required clinical trial information in ac-  
2 cordance with subsection (b) of such section 492C.

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

5 (A) IN GENERAL.—Subsection (c) of such  
6 section 492C shall take effect 90 days after the  
7 date the results database is established under  
8 paragraph (1) of this subsection with respect to  
9 any applicable clinical trial (as defined in such  
10 section 492C) that—

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

13 (ii) is completed between the date of  
14 the enactment of this Act and such date of  
15 establishment under paragraph (1) of this  
16 subsection.

17 (B) OTHER TRIALS.—Except as provided  
18 in subparagraph (A), subsection (c) of such sec-  
19 tion 492C shall take effect 180 days after the  
20 date that the results database is established  
21 under paragraph (1) of this subsection with re-  
22 spect to any applicable clinical trial that is com-  
23 pleted between the date of the enactment of this  
24 Act and such date of establishment under para-  
25 graph (1).

1           (5) TRIALS COMPLETED AFTER ESTABLISH-  
2           MENT OF RESULTS DATABASE.—Subsection (c) of  
3           such section 492C shall apply to any clinical trial  
4           that is completed after the date that the results  
5           database is established under paragraph (1) of this  
6           subsection.

7           (6) RETROACTIVITY OF DATABASE.—

8                   (A) VOLUNTARY SUBMISSIONS.—The Sec-  
9           retary of Health and Human Services (referred  
10          to in this paragraph as the “Secretary”) shall  
11          establish procedures and mechanisms to allow  
12          for the voluntary submission to the Secretary—

13                       (i) of clinical trial information for in-  
14                       clusion in the registry database (as defined  
15                       in such section 492C) on applicable clinical  
16                       trials (as defined in such section 492C)  
17                       initiated before the date of the enactment  
18                       of this Act; and

19                       (ii) of clinical trial information for in-  
20                       clusion in the results database (as defined  
21                       in such section 492C) on applicable clinical  
22                       trials (as defined in such section 492C)  
23                       completed before the date of the enactment  
24                       of this Act.

1 (B) REQUIRED SUBMISSIONS.—Notwith-  
2 standing the preceding paragraphs of this sub-  
3 section, in any case in which the Secretary de-  
4 termines that submission of clinical trial infor-  
5 mation for an applicable clinical trial (as de-  
6 fined in such section 492C) described in clause  
7 (i) or (ii) of subparagraph (A) is in the interest  
8 of the public health—

9 (i) the Secretary may require that  
10 such information be submitted to the Sec-  
11 retary in accordance with such section  
12 492C; and

13 (ii) failure to comply with such a re-  
14 quirement shall be treated as a violation of  
15 the corresponding requirement of such sec-  
16 tion 492C.

17 (7) STATUS OF CLINICALTRIALS.GOV  
18 WEBSITE.—

19 (A) IN GENERAL.—After receiving public  
20 comment and not later than 90 days after the  
21 date of the enactment of this Act, the Secretary  
22 shall publish in the Federal Register a notice  
23 determining the more efficient approach to es-  
24 tablishing the registry database described in

1 subsection (b) of such section 492C and wheth-  
2 er such approach is—

3 (i) that such registry database should  
4 expand and build upon the data bank de-  
5 scribed in section 402(i) of the Public  
6 Health Service Act (as in effect on the day  
7 before the date of the enactment of this  
8 Act); or

9 (ii) that such registry database should  
10 supplant the data bank described in such  
11 section 402(i) (as in effect on the day be-  
12 fore the date of the enactment of this Act).

13 (B) CLINICALTRIALS.GOV SUPPLANTED.—

14 If the Secretary determines to apply the ap-  
15 proach described under subparagraph (A)(ii),  
16 the Secretary shall maintain an archive of the  
17 data bank described in such section 402(i) (as  
18 in effect on the day before the date of the en-  
19 actment of this Act) on the Internet website of  
20 the National Library of Medicine.

21 **SEC. 802. STUDY BY GOVERNMENT ACCOUNTABILITY OF-**  
22 **FICE.**

23 (a) IN GENERAL.—The Comptroller General of the  
24 United States shall conduct a study to determine whether  
25 information on the trials registry and database is consid-

1 ered promotional and to evaluate the implementation of  
2 this database.

3 (b) REPORT.—Not later than one year after the date  
4 of the enactment of this Act, the Comptroller General shall  
5 complete the study under subsection (a) and submit to the  
6 Congress a report on the results of such study.

7 **TITLE IX—ENHANCED AUTHORITIES**  
8 **REGARDING**  
9 **POSTMARKET SAFETY OF**  
10 **DRUGS**

11 **SEC. 901. POSTMARKET STUDIES AND CLINICAL TRIALS RE-**  
12 **GARDING HUMAN DRUGS; RISK EVALUATION**  
13 **AND MITIGATION STRATEGIES.**

14 (a) IN GENERAL.—Section 505 of the Federal Food,  
15 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by  
16 adding at the end the following subsections:

17 “(o) POSTMARKET STUDIES AND CLINICAL TRIALS;  
18 LABELING.—

19 “(1) IN GENERAL.—A responsible person may  
20 not introduce or deliver for introduction into inter-  
21 state commerce the new drug involved if the person  
22 is in violation of a requirement established under  
23 paragraph (3) or (4) with respect to the drug.

24 “(2) DEFINITIONS.—For purposes of this sub-  
25 section:

1           “(A) RESPONSIBLE PERSON.—The term  
2 ‘responsible person’ means a person who—

3           “(i) has submitted to the Secretary a  
4 covered application that is pending; or

5           “(ii) is the holder of an approved cov-  
6 ered application.

7           “(B) COVERED APPLICATION.—The term  
8 ‘covered application’ means—

9           “(i) an application under subsection  
10 (b) for a drug that is subject to section  
11 503(b); and

12           “(ii) an application under section 351  
13 of the Public Health Service Act.

14           “(C) NEW SAFETY INFORMATION; SERIOUS  
15 RISK.—The terms ‘new safety information’, ‘se-  
16 rious risk’, and ‘signal of a serious risk’ have  
17 the meanings given such terms in section 505-  
18 1(b).

19           “(3) STUDIES AND CLINICAL TRIALS.—

20           “(A) IN GENERAL.—For any or all of the  
21 purposes specified in subparagraph (B), the  
22 Secretary may, subject to subparagraph (C), re-  
23 quire a responsible person for a drug to conduct  
24 a postapproval study or studies of the drug, or  
25 a postapproval clinical trial or trials of the

1 drug, on the basis of scientific information, in-  
2 cluding information regarding chemically-re-  
3 lated or pharmacologically-related drugs.

4 “(B) PURPOSES OF STUDY OR TRIAL.—

5 The purposes referred to in this subparagraph  
6 with respect to a postapproval study or post-  
7 approval clinical trial are the following:

8 “(i) To assess a known serious risk  
9 related to the use of the drug involved.

10 “(ii) To assess signals of serious risk  
11 related to the use of the drug.

12 “(iii) To identify a serious risk.

13 “(C) ESTABLISHMENT OF REQUIREMENT  
14 AFTER APPROVAL OF COVERED APPLICATION.—

15 The Secretary may require a postapproval study  
16 or studies or postapproval trial or trials for a  
17 drug for which an approved covered application  
18 is in effect as of the date on which the Sec-  
19 retary seeks to establish such requirement only  
20 if the Secretary becomes aware of new safety  
21 information. For each study required to be con-  
22 ducted under this subparagraph, the Secretary  
23 shall require that the applicant submit a time-  
24 table for completion of the study and shall re-  
25 quire the applicant to periodically report to the

1 Secretary on the status of the study. Unless the  
2 applicant demonstrates good cause for failure to  
3 comply with such timeline, the applicant shall  
4 be in violation of this subsection. The Secretary  
5 shall determine what constitutes good cause  
6 under the preceding sentence.

7 “(4) SAFETY LABELING CHANGES REQUESTED  
8 BY SECRETARY.—

9 “(A) NEW SAFETY INFORMATION.—The  
10 Secretary shall promptly notify the responsible  
11 person if the Secretary becomes aware of new  
12 safety information that the Secretary believes  
13 should be included in the labeling of the drug.

14 “(B) RESPONSE TO NOTIFICATION.—Fol-  
15 lowing notification pursuant to subparagraph  
16 (A), the responsible person shall within 30  
17 days—

18 “(i) submit a supplement proposing  
19 changes to the approved labeling to reflect  
20 the new safety information, including  
21 changes to boxed warnings, contraindica-  
22 tions, warnings, precautions, or adverse re-  
23 actions; or

24 “(ii) notify the Secretary that the re-  
25 sponsible person does not believe a labeling



1 change is warranted and submit a state-  
2 ment detailing the reasons why such a  
3 change is not warranted.

4 “(C) REVIEW.—Upon receipt of such sup-  
5 plement, the Secretary shall promptly review  
6 and act upon such supplement. If the Secretary  
7 disagrees with the proposed changes in the sup-  
8 plement or with the statement setting forth the  
9 responsible person’s reasons why no labeling  
10 change is necessary, the Secretary shall initiate  
11 discussions with the responsible person to reach  
12 agreement on whether the labeling for the drug  
13 should be modified to reflect the new safety in-  
14 formation, and if so, the contents of such label-  
15 ing changes.

16 “(D) DISCUSSIONS.—Such discussions  
17 shall not extend for more than 30 days after  
18 the response to the notification under subpara-  
19 graph (B), unless the Secretary determines an  
20 extension of such discussion period is war-  
21 ranted.

22 “(E) ORDER.—Within 15 days of the con-  
23 clusion of the discussions under subparagraph  
24 (D), the Secretary may issue an order directing  
25 the responsible person to make such a labeling

1 change as the Secretary deems appropriate to  
2 address the new safety information. Within 15  
3 days of such an order, the responsible person  
4 shall submit a supplement containing the label-  
5 ing change.

6 “(F) DISPUTE RESOLUTION.—Within 5  
7 days of receiving an order under subparagraph  
8 (E), the responsible person may appeal using  
9 the Food and Drug Administration’s normal  
10 dispute resolution procedures established by the  
11 Secretary in regulation and guidance.

12 “(G) VIOLATION.—If the change required  
13 by an order under subparagraph (E) is not  
14 made by the date so specified, the responsible  
15 person shall be considered to be in violation of  
16 this section.

17 “(H) SERIOUS PUBLIC HEALTH THREAT.—  
18 Notwithstanding subparagraphs (A) through  
19 (F), if the Secretary concludes that failure to  
20 make such a labeling change is necessary to  
21 protect against a serious public health threat,  
22 the Secretary may accelerate the timelines in  
23 such subparagraphs.

24 “(I) RULE OF CONSTRUCTION.—This para-  
25 graph shall not be construed to affect the re-

1           sponsibility of the responsible person to main-  
2           tain its label in accordance with existing re-  
3           quirements, including subpart B and section  
4           314.70 of title 21, Code of Federal Regulations  
5           (or any successor regulations).

6           “(p) RISK EVALUATION AND MITIGATION STRAT-  
7 EGY.—

8           “(1) IN GENERAL.—A person may not intro-  
9           duce or deliver for introduction into interstate com-  
10          merce a new drug if—

11                   “(A)(i) the application for such drug is ap-  
12                   proved under subsection (b) or (j) and is sub-  
13                   ject to section 503(b); or

14                   “(ii) the application for such drug is ap-  
15                   proved under section 351 of the Public Health  
16                   Service Act; and

17                   “(B) a risk evaluation and mitigation  
18                   strategy is required under section 505–1 with  
19                   respect to the drug and—

20                           “(i) the person fails to maintain com-  
21                           pliance with the requirements of the ap-  
22                           proved strategy or with other requirements  
23                           under section 505–1, including require-  
24                           ments regarding assessments of approved  
25                           strategies; or

1           “(ii) in the case of a requirement for  
2           such a strategy that is first established  
3           after the applicable application referred to  
4           in subparagraph (A) was approved with re-  
5           spect to the drug, the Secretary, after no-  
6           tice and opportunity for a hearing, pub-  
7           lishes in the Federal Register a statement  
8           that the person is not cooperating with the  
9           Secretary in developing such a strategy for  
10          the drug.

11           “(2) REQUIRED STATEMENT DURING APPROVAL  
12          PROCESS.—In the case of an application approved  
13          under subsection (b) or (j) for a new drug that is  
14          subject to section 503(b), or an application approved  
15          under section 351 of the Public Health Service Act,  
16          or a supplement to such an application that requires  
17          substantive data, the Secretary may not approve the  
18          application or supplement unless the person involved  
19          has complied with the following:

20           “(A) The person has submitted to the Sec-  
21          retary a statement that provides the following  
22          information:

23           “(i) Whether the person believes that  
24          a risk evaluation and mitigation strategy  
25          should be required under section 505–1.

1           “(ii) Whether a postmarket study or  
2           clinical trial should be required under sub-  
3           section (o)(3).

4           “(B) In making the statement under sub-  
5           paragraph (A), the person took into account  
6           each of the following factors:

7                   “(i) The estimated size of the popu-  
8                   lation likely to use the drug involved.

9                   “(ii) The seriousness of the disease or  
10                  condition that is to be treated with the  
11                  drug.

12                  “(iii) The expected benefit of the drug  
13                  with respect to such disease or condition.

14                  “(iv) The expected or actual duration  
15                  of treatment with the drug.

16                  “(v) The seriousness of any known or  
17                  potential adverse events that may be re-  
18                  lated to the drug and the background inci-  
19                  dence of such events in the population like-  
20                  ly to use the drug.

21           “(3) CERTAIN POSTMARKET STUDIES.—The  
22           failure to conduct a postmarket study under subpart  
23           H of part 314 of title 21, Code of Federal Regula-  
24           tions (or any successor regulation), is deemed to be  
25           a violation of paragraph (1).”.

1 (b) REQUIREMENTS REGARDING STRATEGIES.—  
2 Chapter V of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 351 et seq.) is amended by inserting after sec-  
4 tion 505 the following section:

5 **“SEC. 505-1. RISK EVALUATION AND MITIGATION STRATE-**  
6 **GIES.**

7 “(a) SUBMISSION OF PROPOSED STRATEGY.—

8 “(1) INITIAL APPROVAL.—A person who sub-  
9 mits an application referred to in section  
10 505(p)(1)(A) (referred to in this section as a ‘cov-  
11 ered application’) shall submit to the Secretary as  
12 part of the application a proposed risk evaluation  
13 and mitigation strategy if the Secretary determines  
14 such a strategy is necessary to ensure that the bene-  
15 fits of the drug involved outweigh the risks of the  
16 drug. In making such a determination, the Secretary  
17 shall consider the statement submitted by the person  
18 under section 505(p)(2) with respect to the drug and  
19 shall consider the following factors:

20 “(A) The estimated size of the population  
21 likely to use the drug involved.

22 “(B) The seriousness of the disease or con-  
23 dition that is to be treated with the drug.

24 “(C) The expected benefit of the drug with  
25 respect to such disease or condition.

1           “(D) The expected or actual duration of  
2 treatment with the drug.

3           “(E) The seriousness of any known or po-  
4 tential adverse events that may be related to  
5 the drug and the background incidence of such  
6 events in the population likely to use the drug.

7           “(F) The availability and safety of a drug  
8 or other treatment, if any, for such disease or  
9 condition to which the safety of the drug may  
10 be compared.

11           “(G) Whether the drug is a new molecular  
12 entity.

13           “(2) POSTAPPROVAL REQUIREMENT.—

14           “(A) IN GENERAL.—If the Secretary ap-  
15 proves a covered application and does not when  
16 approving the application require a risk evalua-  
17 tion and mitigation strategy under paragraph  
18 (1), the Secretary may subsequently require  
19 such a strategy for the drug involved if the Sec-  
20 retary becomes aware of new safety information  
21 and makes a determination that such a strategy  
22 is necessary to ensure that the benefits of the  
23 drug outweigh the risks of the drug.

24           “(B) SUBMISSION OF PROPOSED STRAT-  
25 EGY.—Not later than 120 days after the Sec-

1           retary notifies the holder of an approved cov-  
2           ered application that the Secretary has made a  
3           determination under subparagraph (A) with re-  
4           spect to the drug involved, or within such other  
5           time as the Secretary requires to protect the  
6           public health, the holder shall submit to the  
7           Secretary a proposed risk evaluation and miti-  
8           gation strategy.

9           “(3) APPROVAL OF NEW INDICATION FOR  
10          USE.—The applicability of paragraph (2) includes  
11          applicability to a drug for which an approved cov-  
12          ered application was in effect on the day before the  
13          effective date of this section and for which, on or  
14          after such effective date, the holder of the approved  
15          application submits to the Secretary a supplemental  
16          application seeking approval of a new indication for  
17          use of the drug.

18          “(4) ABBREVIATED NEW DRUG APPLICA-  
19          TIONS.—The applicability of this section to an appli-  
20          cation under section 505(j) is subject to subsection  
21          (i).

22          “(b) DEFINITIONS.—For purposes of this section:

23                 “(1) ADVERSE DRUG EXPERIENCE.—The term  
24                 ‘adverse drug experience’ means any adverse event



1 associated with the use of a drug in humans, wheth-  
2 er or not considered drug related, including—

3 “(A) an adverse event occurring in the  
4 course of the use of the drug in professional  
5 practice;

6 “(B) an adverse event occurring from an  
7 overdose of the drug, whether accidental or in-  
8 tentional;

9 “(C) an adverse event occurring from  
10 abuse of the drug;

11 “(D) an adverse event occurring from  
12 withdrawal of the drug; and

13 “(E) any failure of expected pharma-  
14 cological action of the drug.

15 “(2) COVERED APPLICATION.—The term ‘cov-  
16 ered application’ has the meaning indicated for such  
17 term in subsection (a)(1).

18 “(3) NEW SAFETY INFORMATION.—The term  
19 ‘new safety information’ with respect to a drug  
20 means information about—

21 “(A) a serious risk or an unexpected seri-  
22 ous risk associated with use of the drug that  
23 the Secretary has become aware of since the  
24 drug was approved, since the risk evaluation  
25 and mitigation strategy was required, or since

1 the last assessment of the approved risk evalua-  
2 tion and mitigation strategy for the drug; or

3 “(B) the effectiveness of the approved risk  
4 evaluation and mitigation strategy for the drug  
5 obtained since the last assessment of such  
6 strategy.

7 “(4) SERIOUS ADVERSE DRUG EXPERIENCE.—  
8 The term ‘serious adverse drug experience’ is an ad-  
9 verse event that—

10 “(A) results in—

11 “(i) death;

12 “(ii) an adverse drug experience that  
13 places the patient at immediate risk of  
14 death from the adverse drug experience as  
15 it occurred (not including an adverse drug  
16 experience that might have caused death  
17 had it occurred in a more severe form);

18 “(iii) inpatient hospitalization or pro-  
19 longation of existing hospitalization;

20 “(iv) a persistent or significant inca-  
21 pacity or substantial disruption of the abil-  
22 ity to conduct normal life functions; or

23 “(v) a congenital anomaly or birth de-  
24 fect; or

1           “(B) based on appropriate medical judg-  
2           ment, may jeopardize the patient and may re-  
3           quire a medical or surgical intervention to pre-  
4           vent an outcome described under subparagraph  
5           (A).

6           “(5) SERIOUS RISK.—The term ‘serious risk’  
7           means a risk of a serious adverse drug experience.

8           “(6) SIGNAL OF A SERIOUS RISK.—The term  
9           ‘signal of a serious risk’ means information related  
10          to a serious adverse drug experience associated with  
11          use of a drug and derived from—

12                   “(A) a clinical trial;

13                   “(B) adverse event reports;

14                   “(C) a postapproval study, including a  
15                   study under section 505(o)(3);

16                   “(D) peer-reviewed biomedical literature;

17                   or

18                   “(E) data derived from a postmarket risk  
19                   identification and analysis system under section  
20                   505(k)(3).

21           “(7) RESPONSIBLE PERSON.—The term ‘re-  
22           sponsible person’ has the meaning indicated for such  
23           term in subsection (e)(2).

24           “(8) UNEXPECTED SERIOUS RISK.—The term  
25           ‘unexpected serious risk’ means a serious adverse

1 drug experience that is not listed in the labeling of  
2 a drug, or that may be symptomatically and  
3 pathophysiologically related to an adverse drug expe-  
4 rience identified in the labeling, but differs from  
5 such adverse drug experience because of greater se-  
6 verity, specificity, or prevalence.

7 “(c) CONTENTS.—A proposed risk evaluation and  
8 mitigation strategy under subsection (a) shall—

9 “(1) include the timetable required under sub-  
10 section (d); and

11 “(2) to the extent required by the Secretary, in-  
12 clude additional elements described in subsections  
13 (e) and (f).

14 “(d) MINIMAL STRATEGY.—For purposes of sub-  
15 section (c)(1), the risk evaluation and mitigation strategy  
16 for a drug shall require a timetable for submission of as-  
17 sessments of the strategy that—

18 “(1) is not less frequent than once annually for  
19 the first 3 years after the strategy is initially ap-  
20 proved;

21 “(2) includes an assessment in the seventh year  
22 after the strategy is so approved; and

23 “(3) subject to paragraph (2), for subsequent  
24 years—

1           “(A) is at a frequency specified in the  
2 strategy;

3           “(B) is increased or reduced in frequency  
4 as necessary as provided for in subsection  
5 (g)(4)(A); and

6           “(C) is eliminated after the 3-year period  
7 described in paragraph (1) if the Secretary de-  
8 termines that serious risks of the drug have  
9 been adequately identified and assessed and are  
10 being adequately managed.

11       “(e) ADDITIONAL POTENTIAL ELEMENTS OF STRAT-  
12 EGY.—

13           “(1) IN GENERAL.—The Secretary may under  
14 subsection (c)(2) require that the risk evaluation  
15 and mitigation strategy for a drug include 1 or more  
16 of the additional elements described in this sub-  
17 section if the Secretary makes the determination re-  
18 quired with respect to the element involved.

19           “(2) MEDGUIDE; PATIENT PACKAGE INSERT.—  
20 The risk evaluation and mitigation strategy for a  
21 drug may require that, as applicable, the person sub-  
22 mitting the covered application or the holder of the  
23 approved such application (referred to in this section  
24 as the ‘responsible person’) develop for distribution  
25 to each patient when the drug is dispensed—

1           “(A) a Medication Guide, as provided for  
2           under part 208 of title 21, Code of Federal  
3           Regulations (or any successor regulations); and

4           “(B) a patient package insert, if the Sec-  
5           retary determines that such insert may help  
6           mitigate a serious risk of the drug.

7           “(3) COMMUNICATION PLAN.—The risk evalua-  
8           tion and mitigation strategy for a drug may require  
9           that the responsible person conduct a communica-  
10          tion plan to health care providers, if, with respect to  
11          such drug, the Secretary determines that such plan  
12          may support implementation of an element of the  
13          strategy. Such plan may include—

14               “(A) sending letters to health care pro-  
15               viders;

16               “(B) disseminating information about the  
17               elements of the risk evaluation and mitigation  
18               strategy to encourage implementation by health  
19               care providers of components that apply to such  
20               health care providers, or to explain certain safe-  
21               ty protocols (such as medical monitoring by  
22               periodic laboratory tests); or

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

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

3           “(f) RESTRICTIONS ON DISTRIBUTION OR USE.—

4           “(1) IN GENERAL.—If the Secretary determines  
5           that a drug shown to be effective can be safely used  
6           only if distribution or use of such drug is restricted,  
7           the Secretary may under subsection (c)(2) require as  
8           elements of the risk evaluation and mitigation strat-  
9           egy such restrictions on distribution or use as are  
10          needed to ensure safe use of the drug.

11          “(2) ASSURING ACCESS AND MINIMIZING BUR-  
12          DEN.—Elements of a risk evaluation and mitigation  
13          strategy included under paragraph (1) shall—

14                 “(A) be commensurate with a specific seri-  
15                 ous risk listed in the labeling of the drug;

16                 “(B) be posted publicly by the Secretary  
17                 with an explanation of how such elements will  
18                 mitigate the observed safety risk, which posting  
19                 shall be made within 30 days after the date on  
20                 which the Secretary requires the element in-  
21                 volved;

22                 “(C) considering the risk referred to in  
23                 subparagraph (A), not be unduly burdensome  
24                 on patient access to the drug, considering in  
25                 particular—

1           “(i) patients with serious or life-  
2           threatening diseases or conditions; and

3           “(ii) patients who have difficulty ac-  
4           cessing health care (such as patients in  
5           rural or medically underserved areas); and

6           “(D) to the extent practicable, so as to  
7           minimize the burden on the health care delivery  
8           system—

9           “(i) conform with elements to assure  
10          safe use for other drugs with similar, seri-  
11          ous risks; and

12          “(ii) be designed to be compatible  
13          with established distribution, procurement,  
14          and dispensing systems for drugs.

15          “(3) ELEMENTS.—The restrictions on distribu-  
16          tion or use described in paragraph (1) shall include  
17          1 or more goals to evaluate or mitigate a serious  
18          risk listed in the labeling of the drug, and may re-  
19          quire that—

20          “(A) health care providers that prescribe  
21          the drug have special training or experience, or  
22          are specially certified, which training or certifi-  
23          cation with respect to the drug is available to  
24          any willing provider from a frontier area;



1           “(B) pharmacies, practitioners, or health  
2 care settings that dispense the drug are spe-  
3 cially certified, which training or certification  
4 with respect to the drug is available to any will-  
5 ing provider from a frontier area;

6           “(C) the drug be dispensed to patients only  
7 in certain health care settings, such as hos-  
8 pitals;

9           “(D) the drug be dispensed to patients  
10 with evidence or other documentation of safe-  
11 use conditions, such as laboratory test results;

12           “(E) each patient using the drug be sub-  
13 ject to certain monitoring; or

14           “(F) each patient using the drug be en-  
15 rolled in a registry.

16           “(4) IMPLEMENTATION SYSTEM.—The restric-  
17 tions on distribution or use described in paragraph  
18 (1) may require a system through which the respon-  
19 sible person is able to—

20           “(A) monitor and evaluate implementation  
21 of the restrictions by health care providers,  
22 pharmacists, patients, and other parties in the  
23 health care system who are responsible for im-  
24 plementing the restrictions;

1           “(B) work to improve implementation of  
2           the restrictions by health care providers, phar-  
3           macists, patients, and other parties in the  
4           health care system who are responsible for im-  
5           plementing the restrictions; and

6           “(C) notify wholesalers of the drug of  
7           those health care providers—

8                   “(i) who are responsible for imple-  
9                   menting the restrictions; and

10                   “(ii) whom the responsible person  
11                   knows have failed to meet their responsibil-  
12                   ities for implementing the restrictions,  
13                   after the responsible person has informed  
14                   such party of such failure and such party  
15                   has not remedied such failure.

16           “(5) LIMITATION.—No holder of an approved  
17           application shall use any restriction on distribution  
18           required by the Secretary as necessary to assure safe  
19           use of the drug to block or delay approval of an ap-  
20           plication under section 505(b)(2) or (j) or to prevent  
21           application of such restriction under subsection  
22           (i)(1)(B) to a drug that is the subject of an abbrevi-  
23           ated new drug application.

24           “(6) BIOEQUIVALENCE TESTING.—Notwith-  
25           standing any other provisions in this subsection, the

1 holder of an approved application that is subject to  
2 distribution restrictions required under this sub-  
3 section that limit the ability of a sponsor seeking ap-  
4 proval of an application under subsection 505(b)(2)  
5 or (j) to purchase on the open market a sufficient  
6 quantity of drug to conduct bioequivalence testing  
7 shall provide to such a sponsor a sufficient amount  
8 of drug to conduct bioequivalence testing if the spon-  
9 sor seeking approval under section 505(b)(2) or  
10 (j)—

11 “(A) agrees to such restrictions on dis-  
12 tribution as the Secretary finds necessary to as-  
13 sure safe use of the drug during bioequivalence  
14 testing; and

15 “(B) pays the holder of the approved appli-  
16 cation the fair market value of the drug pur-  
17 chased for bioequivalence testing.

18 “(7) LETTER BY SECRETARY.—Upon a showing  
19 by the sponsor seeking approval under section  
20 505(b)(2) or (j) that the sponsor has agreed to such  
21 restrictions necessary to assure safe use of the drug  
22 during bioequivalence testing, the Secretary shall  
23 issue to the sponsor seeking to conduct bioequiva-  
24 lence testing a letter that describes the Secretary’s  
25 finding which shall serve as proof that the sponsor

1 has satisfied the requirements of subparagraph  
2 (6)(A).

3 “(8) EVALUATION OF ELEMENTS TO ASSURE  
4 SAFE USE.—The Secretary, acting through the Drug  
5 Safety and Risk Management Advisory Committee  
6 (or any successor committee) of the Food and Drug  
7 Administration, shall—

8 “(A) seek input from patients, physicians,  
9 pharmacists, and other health care providers  
10 about how elements to assure safe use under  
11 this subsection for 1 or more drugs may be  
12 standardized so as not to be—

13 “(i) unduly burdensome on patient ac-  
14 cess to the drug; and

15 “(ii) to the extent practicable, mini-  
16 mize the burden on the health care delivery  
17 system;

18 “(B) at least annually, evaluate, for 1 or  
19 more drugs, the elements to assure safe use of  
20 such drug to assess whether the elements—

21 “(i) assure safe use of the drug;

22 “(ii) are not unduly burdensome on  
23 patient access to the drug; and

1 “(iii) to the extent practicable, mini-  
2 mize the burden on the health care delivery  
3 system; and

4 “(C) considering such input and evalua-  
5 tions—

6 “(i) issue or modify agency guidance  
7 about how to implement the requirements  
8 of this subsection; and

9 “(ii) modify elements under this sub-  
10 section for 1 or more drugs as appropriate.

11 “(9) WAIVER IN PUBLIC HEALTH EMER-  
12 GENCIES.—The Secretary may waive any restriction  
13 on distribution or use under this subsection during  
14 the period described in section 319(a) of the Public  
15 Health Service Act with respect to a qualified coun-  
16 termeasure described under section 319F–1(a)(2) of  
17 such Act, to which a restriction or use under this  
18 subsection has been applied, if the Secretary has—

19 “(A) declared a public health emergency  
20 under such section 319; and

21 “(B) determined that such waiver is re-  
22 quired to mitigate the effects of, or reduce the  
23 severity of, such public health emergency.

24 “(g) ASSESSMENT AND MODIFICATION OF APPROVED  
25 STRATEGY.—

1           “(1) VOLUNTARY ASSESSMENTS.—After the ap-  
2           proval of a risk evaluation and mitigation strategy  
3           under subsection (a), the responsible person involved  
4           may, subject to paragraph (2), submit to the Sec-  
5           retary an assessment of, and propose a modification  
6           to, the approved strategy for the drug involved at  
7           any time.

8           “(2) REQUIRED ASSESSMENTS.—A responsible  
9           person shall, subject to paragraph (5), submit an as-  
10          sessment of, and may propose a modification to, the  
11          approved risk evaluation and mitigation strategy for  
12          a drug—

13                 “(A) when submitting a supplemental ap-  
14                 plication for a new indication for use under sec-  
15                 tion 505(b) or under section 351 of the Public  
16                 Health Service Act, unless the drug is not sub-  
17                 ject to section 503(b) and the risk evaluation  
18                 and mitigation strategy for the drug includes  
19                 only the timetable under subsection (d);

20                 “(B) when required by the strategy, as  
21                 provided for in such timetable under subsection  
22                 (d);

23                 “(C) within a time period to be determined  
24                 by the Secretary, if the Secretary determines

1 that new safety or effectiveness information in-  
2 dicates that—

3 “(i) an element under subsection (d)  
4 or (e) should be modified or included in  
5 the strategy; or

6 “(ii) an element under subsection (f)  
7 should be modified or included in the strat-  
8 egy; or

9 “(D) within 15 days when ordered by the  
10 Secretary, if the Secretary determines that  
11 there may be a cause for action by the Sec-  
12 retary under section 505(e).

13 “(3) REQUIREMENTS FOR ASSESSMENTS.—An  
14 assessment under paragraph (1) or (2) of an ap-  
15 proved risk evaluation and mitigation strategy for a  
16 drug shall include—

17 “(A) with respect to any goal under sub-  
18 section (f), an assessment of the extent to  
19 which the restrictions on distribution or use are  
20 meeting the goal or whether the goal or such  
21 restrictions should be modified;

22 “(B) with respect to any postapproval  
23 study required under section 505(o)(3), the sta-  
24 tus of such study, including whether any dif-

1           difficulties completing the study have been en-  
2           countered; and

3           “(C) with respect to any postapproval clin-  
4           ical trial required under section 505(o), the sta-  
5           tus of such clinical trial, including whether en-  
6           rollment has begun, the number of participants  
7           enrolled, the expected completion date, whether  
8           any difficulties completing the clinical trial have  
9           been encountered, and registration information  
10          with respect to requirements under section  
11          492C of the Public Health Service Act.

12          “(4) MODIFICATION.—A modification (whether  
13          an enhancement or a reduction) to the approved risk  
14          evaluation and mitigation strategy for a drug may  
15          include the addition or modification of any element  
16          under subsection (d) or the addition, modification,  
17          or removal of any element under subsection (e) or  
18          (f), such as—

19                  “(A) modifying the timetable for assess-  
20                  ments of the strategy under subsection (d), in-  
21                  cluding to eliminate assessments; or

22                  “(B) adding, modifying, or removing a re-  
23                  striction on distribution or use under subsection  
24                  (f).



1           “(5) NO EFFECT ON LABELING CHANGES THAT  
2           DO NOT REQUIRE PREAPPROVAL.—In the case of a  
3           labeling change to which section 314.70 of title 21,  
4           Code of Federal Regulations (or any successor regu-  
5           lation), applies for which the submission of a supple-  
6           mental application is not required or for which dis-  
7           tribution of the drug involved may commence upon  
8           the receipt by the Secretary of a supplemental appli-  
9           cation for the change, the submission of an assess-  
10          ment of the approved risk evaluation and mitigation  
11          strategy for the drug under paragraph (2) is not re-  
12          quired.

13          “(h) REVIEW OF PROPOSED STRATEGIES; REVIEW  
14          OF ASSESSMENTS OF APPROVED STRATEGIES.—

15                 “(1) IN GENERAL.—The Secretary shall  
16                 promptly review each proposed risk evaluation and  
17                 mitigation strategy for a drug submitted under sub-  
18                 section (a) and each assessment of an approved risk  
19                 evaluation and mitigation strategy for a drug sub-  
20                 mitted under subsection (g).

21                 “(2) MARKETING PLAN.—As part of a review  
22                 conducted under this subsection, the Secretary may  
23                 require the applicant to submit information regard-  
24                 ing its marketing plan and practices for the drug, so  
25                 as to allow the Secretary to determine whether any

1 of the proposed or ongoing marketing activities un-  
2 dermine any of the requirements of the risk evalua-  
3 tion and mitigation strategy.

4 “(3) DISCUSSION.—The Secretary shall initiate  
5 discussions with a responsible person for purposes of  
6 this subsection to determine a strategy—

7 “(A) if the proposed strategy is submitted  
8 as part of an application or supplemental appli-  
9 cation under subsection (a) or subsection  
10 (g)(2)(A), not less than 60 days before the ac-  
11 tion deadline for the application that has been  
12 agreed to by the Secretary and that has been  
13 set forth in goals identified in letters of the  
14 Secretary (relating to the use of fees collected  
15 under section 736 to expedite the drug develop-  
16 ment process and the process for the review of  
17 human drug applications);

18 “(B) if the assessment is submitted under  
19 subparagraph (B) or (C) or subsection (g)(2),  
20 not later than 20 days after such submission;

21 “(C) if the assessment is submitted under  
22 subsection (g)(1) or subsection (g)(2)(D) , not  
23 later than 30 days after such submission; or

1           “(D) if the assessment is submitted under  
2 subsection (g)(2)(D), not later than 10 days  
3 after such submission.

4           “(4) ACTION.—

5           “(A) IN GENERAL.—Unless the responsible  
6 person requests the dispute resolution process  
7 described under paragraph (5), the Secretary  
8 shall approve and describe the risk evaluation  
9 and mitigation strategy for a drug, or any  
10 modification to the strategy—

11           “(i) as part of the action letter on the  
12 application, when a proposed strategy is  
13 submitted under subsection (a) or an as-  
14 sessment of the strategy is submitted  
15 under subsection (g)(1); or

16           “(ii) in an order issued not later than  
17 50 days after the date discussions of such  
18 modification begin under paragraph (3),  
19 when an assessment of the strategy is sub-  
20 mitted under subsection (g)(1) or under  
21 any of subparagraphs (B) through (D) of  
22 subsection (g)(2).

23           “(B) INACTION.—An approved risk evalua-  
24 tion and mitigation strategy shall remain in ef-  
25 fect until the Secretary acts, if the Secretary

1 fails to act as provided under subparagraph  
2 (A).

3 “(C) PUBLIC AVAILABILITY.—Any action  
4 letter described in subparagraph (A)(i) or order  
5 described in subparagraph (A)(ii) shall be made  
6 publicly available.

7 “(5) DISPUTE RESOLUTION.—

8 “(A) REQUEST FOR REVIEW.—

9 “(i) IN GENERAL.—Not earlier than  
10 15 days, and not later than 35 days, after  
11 discussions under paragraph (3) have  
12 begun, the responsible person may request  
13 in writing that a dispute about the strat-  
14 egy be reviewed by the Drug Safety Over-  
15 sight Board under subsection (j), except  
16 that the determination of the Secretary to  
17 require a risk evaluation and mitigation  
18 strategy is not subject to review under this  
19 paragraph. The preceding sentence does  
20 not prohibit review under this paragraph of  
21 the particular elements of such a strategy.

22 “(ii) SCHEDULING.—Upon receipt of  
23 a request under clause (i), the Secretary  
24 shall schedule the dispute involved for re-  
25 view under subparagraph (B) and, not

1 later than 5 business days of scheduling  
2 the dispute for review, shall publish by  
3 posting on the Internet or otherwise a no-  
4 tice that the dispute will be reviewed by  
5 the Drug Safety Oversight Board.

6 “(B) SCHEDULING REVIEW.—If a respon-  
7 sible person requests review under subpara-  
8 graph (A), the Secretary—

9 “(i) shall schedule the dispute for re-  
10 view at 1 of the next 2 regular meetings of  
11 the Drug Safety Oversight Board, which-  
12 ever meeting date is more practicable; or

13 “(ii) may convene a special meeting of  
14 the Drug Safety Oversight Board to review  
15 the matter more promptly, including to  
16 meet an action deadline on an application  
17 (including a supplemental application).

18 “(C) AGREEMENT AFTER DISCUSSION OR  
19 ADMINISTRATIVE APPEALS.—

20 “(i) FURTHER DISCUSSION OR ADMIN-  
21 ISTRATIVE APPEALS.—A request for review  
22 under subparagraph (A) shall not preclude  
23 further discussions to reach agreement on  
24 the risk evaluation and mitigation strategy,  
25 and such a request shall not preclude the

1 use of administrative appeals within the  
2 Food and Drug Administration to reach  
3 agreement on the strategy, including ap-  
4 peals as described in letters of the Sec-  
5 retary (relating to the use of fees collected  
6 under section 736 to expedite the drug de-  
7 velopment process and the process for the  
8 review of human drug applications) for  
9 procedural or scientific matters involving  
10 the review of human drug applications and  
11 supplemental applications that cannot be  
12 resolved at the divisional level.

13 “(ii) AGREEMENT TERMINATES DIS-  
14 PUTE RESOLUTION.—At any time before a  
15 decision and order is issued under sub-  
16 paragraph (G) , the Secretary and the re-  
17 sponsible person may reach an agreement  
18 on the risk evaluation and mitigation strat-  
19 egy through further discussion or adminis-  
20 trative appeals, terminating the dispute  
21 resolution process, and the Secretary shall  
22 issue an action letter or order, as appro-  
23 priate, that describes the strategy.

24 “(D) MEETING OF THE BOARD.—At a  
25 meeting of the Drug Safety Oversight Board

1 described in subparagraph (B), the Board  
2 shall—

3 “(i) hear from both parties; and

4 “(ii) review the dispute.

5 “(E) RECORD OF PROCEEDINGS.—The  
6 Secretary shall ensure that the proceedings of  
7 any such meeting are recorded, transcribed, and  
8 made public within 30 days of the meeting. The  
9 Secretary shall redact the transcript to protect  
10 any trade secrets or other confidential informa-  
11 tion described in section 552(b)(4) of title 5,  
12 United States Code.

13 “(F) RECOMMENDATION OF THE  
14 BOARD.—Not later than 5 days after any such  
15 meeting, the Drug Safety Oversight Board shall  
16 provide a written recommendation on resolving  
17 the dispute to the Secretary. Not later than 5  
18 days after the Board provides such written rec-  
19 ommendation to the Secretary, the Secretary  
20 shall make the recommendation available to the  
21 public.

22 “(G) ACTION BY THE SECRETARY.—

23 “(i) ACTION LETTER.—With respect  
24 to a proposal or assessment referred to in  
25 paragraph (1), the Secretary shall issue an

1 action letter that resolves the dispute not  
2 later than the later of—

3 “(I) the action deadline referred  
4 to in paragraph (3)(A); or

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

8 “(ii) ORDER.—With respect to an as-  
9 sessment of an approved risk evaluation  
10 and mitigation strategy under subsection  
11 (g)(1) or under any of subparagraphs (B)  
12 through (D) of subsection (g)(2), the Sec-  
13 retary shall issue an order, which shall be  
14 made public, that resolves the dispute not  
15 later than 7 days after receiving the rec-  
16 ommendation of the Drug Safety Oversight  
17 Board.

18 “(H) INACTION.—An approved risk evalua-  
19 tion and mitigation strategy shall remain in ef-  
20 fect until the Secretary acts, if the Secretary  
21 fails to act as provided for under subparagraph  
22 (G).

23 “(I) EFFECT ON ACTION DEADLINE.—  
24 With respect to a proposal or assessment re-  
25 ferred to in paragraph (1), the Secretary shall



1 be considered to have met the action deadline  
2 referred to in paragraph (3)(A) with respect to  
3 the application involved if the responsible per-  
4 son requests the dispute resolution process de-  
5 scribed in this paragraph and if the Secretary—

6 “(i) has initiated the discussions de-  
7 scribed under paragraph (3) not less than  
8 60 days before such action deadline; and

9 “(ii) has complied with the timing re-  
10 quirements of scheduling review by the  
11 Drug Safety Oversight Board, providing a  
12 written recommendation, and issuing an  
13 action letter under subparagraphs (B),  
14 (F), and (G), respectively.

15 “(J) DISQUALIFICATION.—No individual  
16 who is an employee of the Food and Drug Ad-  
17 ministration and who reviews a drug or who  
18 participated in an administrative appeal under  
19 subparagraph (C)(i) with respect to such drug  
20 may serve on the Drug Safety Oversight Board  
21 at a meeting under subparagraph (D) to review  
22 a dispute about the risk evaluation and mitiga-  
23 tion strategy for such drug.

24 “(K) ADDITIONAL EXPERTISE.—The Drug  
25 Safety Oversight Board may add members with

1 relevant expertise from the Food and Drug Ad-  
2 ministration, including the Office of Pediatrics,  
3 the Office of Women’s Health, or the Office of  
4 Rare Diseases, or from other Federal public  
5 health or health care agencies, for a meeting  
6 under subparagraph (D) of the Drug Safety  
7 Oversight Board.

8 “(6) USE OF ADVISORY COMMITTEES.—The  
9 Secretary may convene a meeting of 1 or more advi-  
10 sory committees of the Food and Drug Administra-  
11 tion to—

12 “(A) review a concern about the safety of  
13 a drug or class of drugs, including before an as-  
14 sessment of the risk evaluation and mitigation  
15 strategy or strategies of such drug or drugs is  
16 required to be submitted under any of subpara-  
17 graphs (B) through (D) of subsection (g)(2);

18 “(B) review the risk evaluation and mitiga-  
19 tion strategy or strategies of a drug or group  
20 of drugs; or

21 “(C) review a dispute under paragraph (5).

22 “(7) PROCESS FOR ADDRESSING DRUG CLASS  
23 EFFECTS.—

24 “(A) IN GENERAL.—When a concern about  
25 a serious risk of a drug may be related to the

1 pharmacological class of the drug, the Secretary  
2 may defer assessments of the approved risk  
3 evaluation and mitigation strategies for such  
4 drugs until the Secretary has convened 1 or  
5 more public meetings to consider possible re-  
6 sponses to such concern. If the Secretary defers  
7 an assessment under this subparagraph, the  
8 Secretary shall give notice to the public of the  
9 deferral not later than 5 days of the deferral.

10 “(B) PUBLIC MEETINGS.—Such public  
11 meetings may include—

12 “(i) 1 or more meetings of the re-  
13 viewed entities 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 “(C) ACTION.—After considering the dis-  
21 cussions from any meetings under subpara-  
22 graph (B), 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 may coordinate the timetable for submis-  
10 sion of assessments under subsection (d), or a study  
11 or clinical trial under section 505(o)(3), with efforts  
12 to identify and assess the serious risks of such drug  
13 by the marketing authorities of other countries  
14 whose drug approval and risk management processes  
15 the Secretary deems comparable to the drug ap-  
16 proval and risk management processes of the United  
17 States. If the Secretary takes action to coordinate  
18 such timetable, the Secretary shall give notice to the  
19 public of the action not later than 5 days after the  
20 action.

21 “(9) EFFECT.—Use of the processes described  
22 in paragraphs (7) and (8) shall not delay action on  
23 an application or a supplement to an application for  
24 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) Restrictions on distribution or use, if  
10 required under subsection (f) for the listed  
11 drug. A drug that is the subject of an abbrevi-  
12 ated new drug application and the listed drug  
13 shall use a single, shared system under sub-  
14 section (f)(4). The Secretary may waive the re-  
15 quirement under the preceding sentence for a  
16 drug that is the subject of an abbreviated new  
17 drug application if the Secretary determines  
18 that—

19           “(i) it is not practical for the drug to  
20 use such single, shared system; or

21           “(ii) the burden of using the single,  
22 shared system outweighs the benefit of  
23 using the single system.

1           “(2) ACTION BY SECRETARY.—For an applica-  
2           ble listed drug for which a drug is approved under  
3           section 505(j), the Secretary—

4                   “(A) shall undertake any communication  
5                   plan to health care providers required under  
6                   subsection (e)(3) for the applicable listed drug;  
7                   and

8                   “(B) shall inform the responsible person  
9                   for the drug that is so approved if the risk eval-  
10                  uation and mitigation strategy for the applica-  
11                  ble listed drug is modified.

12          “(j) DRUG SAFETY OVERSIGHT BOARD.—

13                  “(1) IN GENERAL.—There is established a  
14                  Drug Safety Oversight Board.

15                  “(2) COMPOSITION; MEETINGS.—The Drug  
16                  Safety Oversight Board shall—

17                          “(A) be composed of scientists and health  
18                          care practitioners appointed by the Secretary,  
19                          each of whom is an employee of the Federal  
20                          Government;

21                          “(B) include representatives from offices  
22                          throughout the Food and Drug Administration;

23                          “(C) include at least 1 representative from  
24                          each of the National Institutes of Health and  
25                          the Department of Health and Human Services

1 (other than the Food and Drug Administra-  
2 tion);

3 “(D) include such representatives as the  
4 Secretary shall designate from other appro-  
5 priate agencies that wish to provide representa-  
6 tives; and

7 “(E) meet at least monthly to provide  
8 oversight and advice to the Secretary on the  
9 management of important drug safety issues.”.

10 (c) REGULATION OF BIOLOGICAL PRODUCTS.—Sec-  
11 tion 351 of the Public Health Service Act (42 U.S.C. 262)  
12 is amended—

13 (1) in subsection (a)(2), by adding at the end  
14 the following:

15 “(D) RISK EVALUATION AND MITIGATION STRAT-  
16 EGY.—A person that submits an application for a license  
17 under this paragraph is subject to section 505(p) of the  
18 Federal Food, Drug, and Cosmetic Act.”; and

19 (2) in subsection (j), by inserting “, including  
20 the requirements under section 505(p) of such Act,”  
21 after “, and Cosmetic Act”.

22 (d) PREREVIEW OF ADVERTISEMENTS.—

23 (1) SENSE OF CONGRESS.—It is the sense of  
24 the Congress that—

1 (A) “Guidance for Industry Consumer-Di-  
2 rected Broadcast Advertisements” issued by the  
3 Food and Drug Administration in August,  
4 1999, represents generally good guidance for di-  
5 rect-to-consumer (DTC) advertising of prescrip-  
6 tion medicines and other treatments;

7 (B) direct-to-consumer advertising as an  
8 accurate source of health information for all  
9 populations, specifically including the elderly  
10 populations, children, chronically ill and racial  
11 and ethnic minority populations, should be  
12 made more reliable by ensuring the truth and  
13 credibility of information provided through such  
14 advertising; and

15 (C) the Congress will work with the Food  
16 and Drug Administration to ensure that infor-  
17 mation provided through direct-to-consumer ad-  
18 vertising of prescription medicines and other  
19 treatments is not false or misleading and com-  
20 municates clearly and sensitively to all commu-  
21 nities.

22 (2) PREREVIEW.—The Federal Food, Drug,  
23 and Cosmetic Act (21 U.S.C. 301 et seq.) is amend-  
24 ed—



1 (A) in section 301 (21 U.S.C. 331), by  
2 adding at the end the following:

3 “(jj) The dissemination of a television advertisement  
4 without complying with section 503B.”; and

5 (B) by inserting after section 503A the fol-  
6 lowing:

7 **“SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.**

8 “(a) IN GENERAL.—The Secretary may require the  
9 submission of any television advertisement for a drug (in-  
10 cluding any script, story board, rough, or a completed  
11 video production of the television advertisement) to the  
12 Secretary for review under this section not later than 45  
13 days before dissemination of the television advertisement.

14 “(b) REVIEW.—In conducting a review of a television  
15 advertisement under this section, the Secretary may make  
16 recommendations—

17 “(1) on changes that are—

18 “(A) necessary to protect the consumer  
19 good and well-being; or

20 “(B) consistent with prescribing informa-  
21 tion for the product under review; and

22 “(2) if appropriate and if information exists, on  
23 statements for inclusion in the advertisement to ad-  
24 dress the specific efficacy of the drug as it relates  
25 to a specific population group, including elderly pop-

1       ulations, children, and racially and ethnically diverse  
2       populations.

3       “(c) NO AUTHORITY TO REQUIRE CHANGES.—This  
4       section does not authorize the Secretary to make or direct  
5       changes in any material submitted pursuant to subsection  
6       (a).

7       “(d) ELDERLY POPULATIONS, CHILDREN, RACIALLY  
8       AND ETHNICALLY DIVERSE COMMUNITIES.—In formu-  
9       lating recommendations under subsection (b), the Sec-  
10      retary shall take into consideration the impact of the ad-  
11      vertised drug on elderly populations, children, and racially  
12      and ethnically diverse communities.

13      “(e) SPECIFIC DISCLOSURES.—

14           “(1) SERIOUS RISK; SAFETY PROTOCOL.—In  
15      conducting a review of a television advertisement  
16      under this section, if the Secretary determines that  
17      the advertisement would be false or misleading with-  
18      out a specific disclosure about a serious risk listed  
19      in the labeling of the drug involved, the Secretary  
20      may require inclusion of such disclosure in the ad-  
21      vertisement.

22           “(2) DATE OF APPROVAL.—In conducting a re-  
23      view of a television advertisement under this section,  
24      the Secretary may require the advertisement to in-  
25      clude, for a period not to exceed 2 years from the

1 date of the approval of the drug under section 505,  
2 a specific disclosure of such date of approval if the  
3 Secretary determines that the advertisement would  
4 otherwise be false or misleading.

5 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
6 tion may be construed as having any effect on the author-  
7 ity of the Secretary under section 314.550, 314.640,  
8 601.45, or 601.94 of title 21, Code of Federal Regulations  
9 (or successor regulations).”.

10 (3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

11 (A) IN GENERAL.—Section 502(n) of the  
12 Federal Food, Drug, and Cosmetic Act (21  
13 U.S.C. 352(n)) is amended by adding at the  
14 end the following: “In the case of an advertise-  
15 ment for a drug subject to section 503(b)(1)  
16 presented directly to consumers in television or  
17 radio format and stating the name of the drug  
18 and its conditions of use, the major statement  
19 relating to side effects and contraindications  
20 shall be presented in a clear and conspicuous  
21 manner.”.

22 (B) REGULATIONS TO DETERMINE CLEAR  
23 AND CONSPICUOUS MANNER.—The Secretary of  
24 Health and Human Services shall by regulation  
25 establish standards for determining whether a

1 major statement relating to side effects and  
2 contraindications of a drug, described in section  
3 502(n) of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 352(n)) (as amended by  
5 subparagraph (A)) is presented in the manner  
6 required under such section.

7 (4) CIVIL PENALTIES.—Section 303 of the Fed-  
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333)  
9 is amended—

10 (A) by redesignating subsection (g) (relat-  
11 ing to civil penalties) as subsection (f); and

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

13 “(g)(1) With respect to a person who is a holder of  
14 an approved application under section 505 for a drug sub-  
15 ject to section 503(b) or under section 351 of the Public  
16 Health Service Act, any such person who disseminates a  
17 direct-to-consumer advertisement that is false or mis-  
18 leading shall be liable to the United States for a civil pen-  
19 alty in an amount not to exceed \$250,000 for the first  
20 such violation in any 3-year period, and not to exceed  
21 \$500,000 for each subsequent violation in any 3-year pe-  
22 riod. No other civil monetary penalties in this Act (includ-  
23 ing the civil penalty in section 303(f)(3)) shall apply to  
24 a violation regarding direct-to-consumer advertising. For  
25 purposes of this paragraph: (A) Repeated dissemination

1 of the same or similar advertisement prior to the receipt  
2 of the written notice referred to in paragraph (2) for such  
3 advertisements shall be considered one violation. (B) On  
4 and after the date of the receipt of such a notice, all viola-  
5 tions under this paragraph occurring in a single day shall  
6 be considered one violation

7       “(2) A civil penalty under paragraph (1) shall be as-  
8 sessed by the Secretary by an order made on the record  
9 after providing written notice to the person to be assessed  
10 a civil penalty and an opportunity for a hearing in accord-  
11 ance with this paragraph and section 554 of title 5, United  
12 States Code. If upon receipt of the written notice, the per-  
13 son to be assessed a civil penalty objects and requests a  
14 hearing, then in the course of any investigation related  
15 to such hearing, the Secretary may issue subpoenas re-  
16 quiring the attendance and testimony of witnesses and the  
17 production of evidence that relates to the matter under  
18 investigation, including information pertaining to the fac-  
19 tors described in paragraph (3).

20       “(3) Upon the request of the person to be assessed  
21 a civil penalty under paragraph (1), the Secretary, in de-  
22 termining the amount of the civil penalty, shall take into  
23 account the nature, circumstances, extent, and gravity of  
24 the violation or violations, including the following factors:

1           “(A) Whether the person submitted the adver-  
2           tisement or a similar advertisement for review under  
3           section 736A.

4           “(B) Whether the person submitted the adver-  
5           tisement for review if required under section 503B.

6           “(C) Whether, after submission of the adver-  
7           tisement as described in subparagraph (A) or (B),  
8           the person disseminated the advertisement before  
9           the end of the 45-day comment period.

10          “(D) Whether the person incorporated any com-  
11          ments made by the Secretary with regard to the ad-  
12          vertisement into the advertisement prior to its dis-  
13          semination.

14          “(E) Whether the person ceased distribution of  
15          the advertisement upon receipt of the written notice  
16          referred to in paragraph (2) for such advertisement.

17          “(F) Whether the person had the advertisement  
18          reviewed by qualified medical, regulatory, and legal  
19          reviewers prior to its dissemination.

20          “(G) Whether the violations were material.

21          “(H) Whether the person who created the ad-  
22          vertisement acted in good faith.

23          “(I) Whether the person who created the adver-  
24          tisement has been assessed a civil penalty under this  
25          provision within the previous 1-year period.

1           “(J) The scope and extent of any voluntary,  
2           subsequent remedial action by the person.

3           “(K) Such other matters, as justice may re-  
4           quire.

5           “(4)(A) Subject to subparagraph (B), no person shall  
6           be required to pay a civil penalty under paragraph (1) if  
7           the person submitted the advertisement to the Secretary  
8           and disseminated such advertisement after incorporating  
9           any comment received from the Secretary other than a  
10          recommendation subject to subsection 503B(c).

11          “(B) The Secretary may retract or modify any prior  
12          comments the Secretary has provided to an advertisement  
13          submitted to the Secretary based on new information or  
14          changed circumstances, so long as the Secretary provides  
15          written notice to the person of the new views of the Sec-  
16          retary on the advertisement and provides a reasonable  
17          time for modification or correction of the advertisement  
18          prior to seeking any civil penalty under paragraph (1).

19          “(5) The Secretary may compromise, modify, or  
20          remit, with or without conditions, any civil penalty which  
21          may be assessed under paragraph (1). The amount of such  
22          penalty, when finally determined, or the amount charged  
23          upon in compromise, may be deducted from any sums  
24          owed by the United States to the person charged.

1       “(6) Any person who requested, in accordance with  
2 paragraph (2), a hearing with respect to the assessment  
3 of a civil penalty and who is aggrieved by an order assess-  
4 ing a civil penalty, may file a petition for de novo judicial  
5 review of such order with the United States Court of Ap-  
6 peals for the District of Columbia Circuit or for any other  
7 circuit in which such person resides or transacts business.  
8 Such a petition may only be filed within the 60-day period  
9 beginning on the date the order making such assessments  
10 was issued.

11       “(7) On an annual basis, the Secretary shall report  
12 to the Congress on direct-to-consumer advertising and its  
13 ability to communicate to subsets of the general popu-  
14 lation, including elderly populations, children, and racial  
15 and ethnic minority communities. The Secretary shall es-  
16 tablish a permanent advisory committee to advise the Sec-  
17 retary with respect to such report. The membership of the  
18 advisory committee shall consist of nationally recognized  
19 medical, advertising, and communications experts, includ-  
20 ing experts representing subsets of the general population.  
21 The members of the advisory committee shall serve with-  
22 out pay, but may receive travel expenses, including per  
23 diem in lieu of subsistence in accordance with applicable  
24 provisions under subchapter I of chapter 57 of title 5,  
25 United States Code. The advisory committee shall study



1 direct-to-consumer advertising as it relates to increased  
2 access to health information and decreased health dispari-  
3 ties for these populations. The annual report required by  
4 this paragraph shall recommend effective ways to present  
5 and disseminate information to these populations. Such  
6 report shall also make recommendations regarding impedi-  
7 ments to the participation of elderly populations, children,  
8 racially and ethnically diverse communities, and medically  
9 underserved populations in clinical drug trials and shall  
10 recommend best practice approaches for increasing the in-  
11 clusion of such subsets of the general population. The Sec-  
12 retary shall submit the first annual report under this para-  
13 graph to the Committee on Health, Education, Labor, and  
14 Pensions of the Senate and the Committee on Energy and  
15 Commerce of the House of Representatives not later than  
16 18 months after the advisory committee has been con-  
17 vened by the Secretary.

18       “(8) If any person fails to pay an assessment of a  
19 civil penalty under paragraph (1)—

20               “(A) after the order making the assessment be-  
21 comes final, and if such person does not file a peti-  
22 tion for judicial review of the order in accordance  
23 with paragraph (6), or

1           “(B) after a court in an action brought under  
2           paragraph (6) has entered a final judgment in favor  
3           of the Secretary,  
4           the Attorney General of the United States shall recover  
5           the amount assessed (plus interest at currently prevailing  
6           rates from the date of the expiration of the 60-day period  
7           referred to in paragraph (6) or the date of such final judg-  
8           ment, as the case may be) in an action brought in any  
9           appropriate district court of the United States. In such  
10          an action, the validity, amount, and appropriateness of  
11          such penalty shall not be subject to review.”.

12          (e) **RULE OF CONSTRUCTION REGARDING PEDIATRIC**  
13 **STUDIES.**—This title and the amendments made by this  
14 title may not be construed as affecting the authority of  
15 the Secretary of Health and Human Services to request  
16 pediatric studies under section 505A of the Federal Food,  
17 Drug, and Cosmetic Act or to require such studies under  
18 section 505B of such Act.

19 **SEC. 902. ENFORCEMENT.**

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

23           “(y) If it is a drug subject to an approved risk evalua-  
24 tion and mitigation strategy pursuant to section 505(p)  
25 and the person responsible for complying with the strategy

1 fails to comply with a requirement of such strategy pro-  
2 vided for under subsection (d), (e), or (f) of section 505–  
3 1.

4 “(z) If it is a drug, and the responsible person (as  
5 such term is used in section 505(o)) is in violation of a  
6 requirement established under paragraph (3) (relating to  
7 postmarket studies and clinical trials) or paragraph (4)  
8 (relating to labeling) of section 505(o) with respect to such  
9 drug.”.

10 (b) CIVIL PENALTIES.—Section 303(f) of the Federal  
11 Food, Drug, and Cosmetic Act, as redesignated by section  
12 901(d)(4), is amended—

13 (1) by redesignating paragraphs (3), (4), and  
14 (5) as paragraphs (4), (5), and (6), respectively;

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

17 “(3) Any applicant (as such term is used in section  
18 505–1) who violates a requirement of section 505(o), sec-  
19 tion 505(p), or section 505–1 shall be subject to a civil  
20 monetary penalty of—

21 “(A) not more than \$250,000 per violation, and  
22 not to exceed \$1,000,000 for all such violations ad-  
23 judicated in a single proceeding; or

24 “(B) in the case of a violation that continues  
25 after the Secretary provides notice of such violation

1 to the applicant, not more than \$10,000,000 per vio-  
2 lation, and not to exceed \$50,000,000 for all such  
3 violations adjudicated in a single proceeding.

4 If a violation referred to in subparagraph (A) or (B) is  
5 continuing in nature and poses a substantial threat to the  
6 public health, the Secretary may impose a civil penalty not  
7 to exceed \$1,000,000 per day during such time period  
8 such person is in violation.”;

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

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

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

18 **SEC. 903. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**

19 **APPROVAL.**

20 Section 505(e) of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C. 355(e)) is amended by adding at  
22 the end the following: “The Secretary may withdraw the  
23 approval of an application submitted under this section,  
24 or suspend the approval of such an application, as pro-  
25 vided under this subsection, without first ordering the ap-

1 plicant to submit an assessment of the approved risk eval-  
2 uation and mitigation strategy for the drug under section  
3 505–1(g)(2)(D).”.

4 **SEC. 904. BENEFIT-RISK ASSESSMENTS.**

5 Not later than 1 year after the date of the enactment  
6 of this Act, the Commissioner of Food and Drugs shall  
7 submit to the Congress a report on how best to commu-  
8 nicate to the public the risks and benefits of new drugs  
9 and the role of the risk evaluation and mitigation strategy  
10 in assessing such risks and benefits. As part of such study,  
11 the Commissioner shall consider the possibility of includ-  
12 ing in the labeling and any direct-to-consumer advertise-  
13 ments of a newly approved drug or indication a unique  
14 symbol indicating the newly approved status of the drug  
15 or indication for a period after approval.

16 **SEC. 905. POSTMARKET RISK IDENTIFICATION AND ANAL-**  
17 **YSIS SYSTEM FOR ACTIVE SURVEILLANCE**  
18 **AND ASSESSMENT.**

19 (a) FINDINGS.—Congress finds the following:

20 (1) It is in the best interests of healthcare pro-  
21 viders and patients that a postmarketing surveil-  
22 lance system be developed that will enable active sur-  
23 veillance of disparate sources of data to identify sig-  
24 nals of unexpected adverse events and trends in the  
25 frequency of known adverse events, to provide data

1 on the outcomes of off label uses, and to enable  
2 identification of safety issues earlier than can be  
3 done today.

4 (2) Such a system can best be developed  
5 through public private partnerships to develop meth-  
6 ods and tools for conducting surveillance using elec-  
7 tronic databases that currently contain data on mil-  
8 lions of patient encounters and are expected to grow  
9 significantly in the next decade, as well as electronic  
10 databases that contain millions of medical product  
11 purchases, health care claims, and similar informa-  
12 tion relevant to product use, efficacy, and safety.

13 (3) Therefore, this section directs the Secretary  
14 of Health and Human Services to enter into such  
15 public private partnerships as are necessary to de-  
16 velop such a surveillance system and the tools and  
17 methods necessary to conduct active surveillance  
18 using the system.

19 (b) DEVELOPMENT OF THE POSTMARKET RISK  
20 IDENTIFICATION AND ANALYSIS SYSTEM.—Subsection (k)  
21 of section 505 of the Federal Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 355) is amended by adding at the end the  
23 following:

24 “(3) The Secretary shall establish public private part-  
25 nerships to develop tools and methods to enable the Sec-

1   retary and others to use available electronic databases to  
2   create a robust surveillance system that will support active  
3   surveillance on important drug safety questions including  
4   detecting and assessing drug safety signals; monitoring  
5   the frequency of known adverse events; and evaluating the  
6   outcomes of off label uses. Such surveillance shall provide  
7   for adverse event surveillance using the following data  
8   sources:

9           “(A) Federal health-related electronic data  
10       (such as data from the Medicare program and the  
11       health systems of the Department of Veterans Af-  
12       fairs).

13           “(B) Private sector health-related electronic  
14       data (such as pharmaceutical purchase data and  
15       health insurance claims data).

16           “(C) Other information as the Secretary deems  
17       useful to create a robust system to identify and as-  
18       sess adverse events and potential drug safety signals  
19       and to evaluate the extent and outcomes of off label  
20       uses of drugs.

21           “(4) Not later than 1 year after the date of the enact-  
22       ment of this paragraph, the Secretary, in consultation  
23       with experts including individuals who are recognized in  
24       the field of data privacy and security, shall develop meth-  
25       ods for integrating and analyzing safety data from mul-

1 tiple sources and mechanisms for obtaining access to such  
2 data. Such methods and mechanisms shall not compromise  
3 the protection of individually identifiable health informa-  
4 tion.

5       “(5) Not later than 2 years after the date of the en-  
6 actment of this paragraph, the Secretary shall have en-  
7 tered into partnerships that will allow the analysis of avail-  
8 able data from the various data sources using the stand-  
9 ards and methods to identify drug safety signals and  
10 trends. Such analysis shall not disclose individually identi-  
11 fiable health information when presenting such drug safe-  
12 ty signals and trends or when responding to inquiries re-  
13 garding such drug safety signals and trends.

14       “(6) Not later than 4 years after the date of the en-  
15 actment of this paragraph, the Secretary shall report to  
16 the Congress on the ways in which the Secretary has used  
17 the surveillance system described in this subsection to  
18 identify specific drug safety signals and to better under-  
19 stand the outcomes associated with drugs marketed in the  
20 United States.

21       “(7) Disclosure of individually identifiable informa-  
22 tion is prohibited in the surveillance system described in  
23 this subsection. Nothing in this subsection prohibits lawful  
24 disclosure of such information for other purposes.



1           “(8) Nothing in this subsection shall be construed as  
2 limiting public health activities authorized under law.”.

3           (c) AUTHORIZATION OF APPROPRIATIONS.—To carry  
4 out activities under the amendment made by subsection  
5 (b) for which funds are made available under section 736  
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 379h), there are authorized to be appropriated, in addition  
8 to such funds, \$25,000,000 for each of fiscal years 2008  
9 through 2012.

10          (d) GAO REPORT.—Not later than 18 months after  
11 the date of the enactment of this Act, the Comptroller  
12 General of the United States shall evaluate data confiden-  
13 tiality and security issues relating to collection, trans-  
14 mission, and maintenance of data for the surveillance sys-  
15 tem developed pursuant to this section, and make rec-  
16 ommendations to the Committee on Energy and Com-  
17 merce of the House of Representatives and the Committee  
18 on Health, Education, Labor and Pensions of the Senate,  
19 and any other congressional committees of relevant juris-  
20 diction, regarding the need for any additional legislative  
21 or regulatory actions to ensure confidentiality and security  
22 of this data or otherwise address confidentiality and secu-  
23 rity issues to ensure the effective operation of the surveil-  
24 lance system.

1 **SEC. 907. STATEMENT FOR INCLUSION IN DIRECT-TO-CON-**  
2 **SUMER ADVERTISEMENTS OF DRUGS.**

3 Section 502(n) of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 352), as amended by section  
5 901(d)(3), is further amended by striking “of this Act,  
6 except that” and inserting “of this Act, and in the case  
7 of any direct-to-consumer advertisement the following  
8 statement: ‘You are encouraged to report adverse effects  
9 of prescription drug medication to the FDA. Log onto  
10 [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1–800-FDA-1088.’, except  
11 that”.

12 **SEC. 908. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC**  
13 **DRUGS.**

14 Chapter V of the Federal Food, Drug, and Cosmetic  
15 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
16 section 510 the following:

17 **“SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC**  
18 **DRUGS.**

19 “(a) IN GENERAL.—Not later than 1 year after the  
20 date of enactment of this section, the Secretary, acting  
21 through the Commissioner of Food and Drugs, shall issue  
22 guidance for the conduct of clinical trials with respect to  
23 antibiotic drugs, including antimicrobials to treat acute  
24 bacterial sinusitis, acute bacterial otitis media, and acute  
25 bacterial exacerbation of chronic bronchitis. Such guide-  
26 lines shall indicate the appropriate animal models of infec-

1 tion, in vitro techniques, and valid microbiologic surrogate  
2 markers.

3 “(b) REVIEW.—Not later than 5 years after the date  
4 of enactment of this section, the Secretary, acting through  
5 the Commissioner of Food and Drugs, shall review and  
6 update the guidance described under subsection (a) to re-  
7 flect developments in scientific and medical information  
8 and technology.”.

9 **SEC. 909. PROHIBITION AGAINST FOOD TO WHICH DRUGS**  
10 **OR BIOLOGICAL PRODUCTS HAVE BEEN**  
11 **ADDED.**

12 Section 301 of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 331), as amended by section 901(d)(2)(A),  
14 is amended by adding at the end the following:

15 “(kk) The introduction or delivery for introduction  
16 into interstate commerce of any food to which has been  
17 added—

18 “(1) a drug approved under section 505,

19 “(2) a biological product licensed under section  
20 351 of the Public Health Service Act, or

21 “(3) a drug or biological product for which sub-  
22 stantial clinical investigations have been instituted  
23 and for which the existence of such investigations  
24 has been made public,

1 unless such drug or biological product was marketed in  
2 food before any approval of the drug under section 505  
3 of this Act, before licensure of the biological product under  
4 section 351 of the Public Health Service Act, and before  
5 any substantial clinical investigations involving the drug  
6 or biological product have been instituted, or unless the  
7 Secretary, in the Secretary's discretion, has issued a regu-  
8 lation, after notice and comment, approving the addition  
9 of such drug or biological product to the food.”.

10 **SEC. 910. ASSURING PHARMACEUTICAL SAFETY.**

11 Chapter V of the Federal Food, Drug, and Cosmetic  
12 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
13 section 505B the following:

14 **“SEC. 505C. PHARMACEUTICAL SECURITY.**

15 “(a) IN GENERAL.—The Secretary shall develop  
16 standards and identify and validate effective technologies  
17 for the purpose of securing the prescription drug distribu-  
18 tion system against counterfeit, diverted, subpotent, sub-  
19 standard, adulterated, misbranded, or expired drugs.

20 “(b) STANDARDS DEVELOPMENT.—

21 “(1) IN GENERAL.—The Secretary shall, in con-  
22 sultation with the agencies specified in paragraph  
23 (3), prioritize and develop standards for the identi-  
24 fication, validation, authentication, and tracking of  
25 prescription drugs.

1           “(2) PROMISING TECHNOLOGIES.—The stand-  
2           ards developed under this subsection shall address  
3           promising technologies, including—

4                   “(A) radio frequency identification tech-  
5                   nology;

6                   “(B) nanotechnology;

7                   “(C) encryption technologies; and

8                   “(D) other track-and-trace technologies.

9           “(3) INTERAGENCY COLLABORATION.—In car-  
10           rying out this subsection, the Secretary shall consult  
11           with Federal health and security agencies, includ-  
12           ing—

13                   “(A) the Administrator of the Drug En-  
14                   forcement Administration;

15                   “(B) the Secretary of the Department of  
16                   Homeland Security;

17                   “(C) the Secretary 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 the Office  
23                   of Regulatory Affairs of the Food and Drug Admin-  
24                   istration to protect the prescription drug distribution

1 system against counterfeit, diverted, subpotent, sub-  
2 standard, adulterated, misbranded, or expired drugs.

3 “(2) ACTIVITIES.—The Secretary shall under-  
4 take enhanced and joint enforcement activities with  
5 other Federal agencies and State officials, and es-  
6 tablish regional capacities for the validation of pre-  
7 scription drugs and the inspection of the prescrip-  
8 tion drug distribution system.

9 “(d) DEFINITION.—In this section, the term ‘pre-  
10 scription drug’ means a drug subject to section  
11 503(b)(1).”.

12 **SEC. 911. ORPHAN ANTIBIOTIC DRUGS.**

13 (a) PUBLIC MEETING.—The Commissioner of Food  
14 and Drugs shall convene a public meeting regarding which  
15 serious and life threatening infectious diseases, such as  
16 diseases due to gram-negative bacteria and other diseases  
17 due to antibiotic-resistant bacteria, potentially qualify for  
18 available grants and contracts under section 5(a) of the  
19 Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives  
20 for development.

21 (b) GRANTS AND CONTRACTS FOR THE DEVELOP-  
22 MENT OF ORPHAN DRUGS.—Section 5(c) of the Orphan  
23 Drug Act (21 U.S.C. 360ee(c)) is amended to read as fol-  
24 lows:

1       “(c) For grants and contracts under subsection (a),  
2 there is authorized to be appropriated \$30,000,000 for  
3 each of fiscal years 2008 through 2012.”.

4 **SEC. 912. AUTHORIZATION OF APPROPRIATIONS.**

5       (a) IN GENERAL.—For carrying out this title and the  
6 amendments made by this title, there is authorized to be  
7 appropriated \$25,000,000 for each of fiscal years 2008  
8 through 2012.

9       (b) RELATION TO OTHER FUNDING.—The authoriza-  
10 tion of appropriations under subsection (a) is in addition  
11 to any other funds available for carrying out this title and  
12 the amendments made by this title.

13 **SEC. 913. EFFECTIVE DATE AND APPLICABILITY.**

14       (a) EFFECTIVE DATE.—This title takes effect 180  
15 days after the date of the enactment of this Act.

16       (b) DRUGS DEEMED TO HAVE RISK EVALUATION  
17 AND MITIGATION STRATEGIES.—

18           (1) IN GENERAL.—A drug that was approved  
19 before the effective date of this Act is, in accordance  
20 with paragraph (2), deemed to have in effect an ap-  
21 proved risk evaluation and mitigation strategy under  
22 section 505–1 of the Federal Food, Drug, and Cos-  
23 metic Act (as added by section 901 of this title) (re-  
24 ferred to in this section as the “Act” ) if there are

1 in effect on the effective date of this Act restrictions  
2 on distribution or use—

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

6 (B) otherwise agreed to by the applicant  
7 and the Secretary for such drug.

8 (2) ELEMENTS OF STRATEGY; ENFORCE-  
9 MENT.—The approved risk evaluation and mitigation  
10 strategy in effect for a drug under paragraph (1)—

11 (A) is deemed to consist of the elements  
12 described in paragraphs (1) and (2) of section  
13 505–1(d) of the Act and any additional ele-  
14 ments under subsections (d) and (e) of such  
15 section in effect for such drug on the effective  
16 date of this Act; and

17 (B) is subject to enforcement by the Sec-  
18 retary to the same extent as any other risk  
19 evaluation and mitigation strategy under sec-  
20 tion 505–1 of the Act.

21 (3) SUBMISSION.—Not later than 180 days  
22 after the effective date of this Act, the holder of an  
23 approved application for which a risk evaluation and  
24 mitigation strategy is deemed to be in effect under  
25 paragraph (1) shall submit to the Secretary a pro-



1 posed risk evaluation and mitigation strategy. Such  
2 proposed strategy is subject to section 505–1 of the  
3 Act as if included in such application at the time of  
4 submission of the application to the Secretary.

5 (c) OTHER DRUGS APPROVED BEFORE THE EFFEC-  
6 TIVE DATE.—The Secretary, on a case-by-case basis, may  
7 require the holder of an application approved before the  
8 effective date of this Act to which subsection (b) does not  
9 apply to submit a proposed risk evaluation and mitigation  
10 strategy in accordance with the timeframes provided for  
11 in subparagraphs (C) through (D) of section 505–1(g)(2)  
12 of the Act if the Secretary determines (with respect to  
13 such drug or with respect to the group of drugs to which  
14 such drug belongs) that—

15 (1) an element described under section 505–  
16 1(d)(1) of the Act may require modification; or

17 (2) a standard for adding an element described  
18 in subsection (e) or (d) of section 505–1 of the Act  
19 that is not in effect with respect to such drug or  
20 class of drugs may apply.

21 (d) USE OF ADVISORY COMMITTEES; PROCESS FOR  
22 ADDRESSING DRUG CLASS EFFECTS.—In imposing a re-  
23 quirement under subsection (c), the Secretary—

24 (1) may convene a meeting of 1 or more advi-  
25 sory committees of the Food and Drug Administra-

1       tion in accordance with paragraph (6) of section  
2       505–1(h) of the Act; and

3               (2) may use the process described in paragraph  
4       (7) of such section 505–1(h) (relating to addressing  
5       drug class effects).



Union Calendar No. 140

110<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**H. R. 2900**

[Report No. 110-225]

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**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.

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JULY 11, 2007

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed