

Suspend the Rules and Pass the Bill, S. 3187, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

112TH CONGRESS
2^D SESSION

S. 3187

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, 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 Safety and Innovation Act”.

6 **SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.**

7 (a) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Sunset dates.

Sec. 106. Effective date.

Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; findings.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Savings clause.
- Sec. 206. Effective date.
- Sec. 207. Sunset clause.
- Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Amendment with respect to misbranding.
- Sec. 307. Streamlined hiring authority to support activities related to human generic drugs.
- Sec. 308. Additional reporting requirements.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Fees relating to biosimilar biological products.
- Sec. 403. Reauthorization; reporting requirements.
- Sec. 404. Sunset dates.
- Sec. 405. Effective date.
- Sec. 406. Savings clause.
- Sec. 407. Conforming amendment.
- Sec. 408. Additional reporting requirements.

TITLE V—PEDIATRIC DRUGS AND DEVICES

- Sec. 501. Permanence.
- Sec. 502. Written requests.
- Sec. 503. Communication with Pediatric Review Committee.
- Sec. 504. Access to data.
- Sec. 505. Ensuring the completion of pediatric studies.
- Sec. 506. Pediatric study plans.
- Sec. 507. Reauthorizations.
- Sec. 508. Report.
- Sec. 509. Technical amendments.
- Sec. 510. Pediatric rare diseases.
- Sec. 511. Staff of Office of Pediatric Therapeutics.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

- Sec. 601. Investigational device exemptions.
- Sec. 602. Clarification of least burdensome standard.
- Sec. 603. Agency documentation and review of significant decisions.
- Sec. 604. Device modifications requiring premarket notification prior to marketing.

- Sec. 605. Program to improve the device recall system.
- Sec. 606. Clinical holds on investigational device exemptions.
- Sec. 607. Modification of de novo application process.
- Sec. 608. Reclassification procedures.
- Sec. 609. Harmonization of device premarket review, inspection, and labeling symbols.
- Sec. 610. Participation in international fora.
- Sec. 611. Reauthorization of third-party review.
- Sec. 612. Reauthorization of third-party inspection.
- Sec. 613. Humanitarian device exemptions.
- Sec. 614. Unique device identifier.
- Sec. 615. Sentinel.
- Sec. 616. Postmarket surveillance.
- Sec. 617. Custom devices.
- Sec. 618. Health information technology.
- Sec. 619. Good guidance practices relating to devices.
- Sec. 620. Pediatric device consortia.

TITLE VII—DRUG SUPPLY CHAIN

- Sec. 701. Registration of domestic drug establishments.
- Sec. 702. Registration of foreign establishments.
- Sec. 703. Identification of drug excipient information with product listing.
- Sec. 704. Electronic system for registration and listing.
- Sec. 705. Risk-based inspection frequency.
- Sec. 706. Records for inspection.
- Sec. 707. Prohibition against delaying, denying, limiting, or refusing inspection.
- Sec. 708. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.
- Sec. 709. Administrative detention.
- Sec. 710. Exchange of information.
- Sec. 711. Enhancing the safety and quality of the drug supply.
- Sec. 712. Recognition of foreign government inspections.
- Sec. 713. Standards for admission of imported drugs.
- Sec. 714. Registration of commercial importers.
- Sec. 715. Notification.
- Sec. 716. Protection against intentional adulteration.
- Sec. 717. Penalties for counterfeiting drugs.
- Sec. 718. Extraterritorial jurisdiction.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

- Sec. 801. Extension of exclusivity period for drugs.
- Sec. 802. Priority review.
- Sec. 803. Fast track product.
- Sec. 804. Clinical trials.
- Sec. 805. Reassessment of qualified infectious disease product incentives in 5 years.
- Sec. 806. Guidance on pathogen-focused antibacterial drug development.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

- Sec. 901. Enhancement of accelerated patient access to new medical treatments.
- Sec. 902. Breakthrough therapies.

- Sec. 903. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
- Sec. 904. Accessibility of information on prescription drug container labels by visually impaired and blind consumers.
- Sec. 905. Risk-benefit framework.
- Sec. 906. Grants and Contracts for the Development of Orphan Drugs.
- Sec. 907. Reporting of inclusion of demographic subgroups in clinical trials and data analysis in applications for drugs, biologics, and devices.
- Sec. 908. Rare pediatric disease priority review voucher incentive program.

TITLE X—DRUG SHORTAGES

- Sec. 1001. Discontinuance or interruption in the production of life-saving drugs.
- Sec. 1002. Annual reporting on drug shortages.
- Sec. 1003. Coordination; task force and strategic plan.
- Sec. 1004. Drug shortage list.
- Sec. 1005. Quotas applicable to drugs in shortage.
- Sec. 1006. Attorney General report on drug shortages.
- Sec. 1007. Hospital repackaging of drugs in shortage.
- Sec. 1008. Study on drug shortages.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

- Sec. 1101. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
- Sec. 1102. Reauthorization of the critical path public-private partnerships.

Subtitle B—Medical Gas Product Regulation

- Sec. 1111. Regulation of medical gases.
- Sec. 1112. Changes to regulations.
- Sec. 1113. Rules of construction.

Subtitle C—Miscellaneous Provisions

- Sec. 1121. Guidance document regarding product promotion using the Internet.
- Sec. 1122. Combating prescription drug abuse.
- Sec. 1123. Optimizing global clinical trials.
- Sec. 1124. Advancing regulatory science to promote public health innovation.
- Sec. 1125. Information technology.
- Sec. 1126. Nanotechnology.
- Sec. 1127. Online pharmacy report to Congress.
- Sec. 1128. Report on small businesses.
- Sec. 1129. Protections for the commissioned corps of the public health service act.
- Sec. 1130. Compliance date for rule relating to sunscreen drug products for over-the-counter human use.
- Sec. 1131. Strategic integrated management plan.
- Sec. 1132. Assessment and modification of REMS.
- Sec. 1133. Extension of period for first applicant to obtain tentative approval without forfeiting 180-day-exclusivity period.
- Sec. 1134. Deadline for determination on certain petitions.
- Sec. 1135. Final agency action relating to petitions and civil actions.
- Sec. 1136. Electronic submission of applications.

1 Act, in the letters from the Secretary of Health and
2 Human Services to the Chairman of the Committee on
3 Health, Education, Labor, and Pensions of the Senate and
4 the Chairman of the Committee on Energy and Commerce
5 of the House of Representatives, as set forth in the Con-
6 gressional Record.

7 **SEC. 102. DEFINITIONS.**

8 Section 735(7) (21 U.S.C. 379g) is amended by strik-
9 ing “expenses incurred in connection with” and inserting
10 “expenses in connection with”.

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

12 Section 736 (21 U.S.C. 379h) is amended—

13 (1) in subsection (a)—

14 (A) in the matter preceding paragraph (1),
15 by striking “fiscal year 2008” and inserting
16 “fiscal year 2013”;

17 (B) in paragraph (1)(A)—

18 (i) in clause (i), by striking “(c)(5)”
19 and inserting “(c)(4)”; and

20 (ii) in clause (ii), by striking “(c)(5)”
21 and inserting “(c)(4)”;

22 (C) in the matter following clause (ii) in
23 paragraph (2)(A)—

24 (i) by striking “(c)(5)” and inserting
25 “(c)(4)”; and

- 1 (ii) by striking “payable on or before
2 October 1 of each year” and inserting
3 “due on the later of the first business day
4 on or after October 1 of each fiscal year or
5 the first business day after the enactment
6 of an appropriations Act providing for the
7 collection and obligation of fees for such
8 fiscal year under this section”;
- 9 (D) in paragraph (3)—
- 10 (i) in subparagraph (A)—
- 11 (I) by striking “subsection
12 (c)(5)” and inserting “subsection
13 (c)(4)”; and
- 14 (II) by striking “payable on or
15 before October 1 of each year.” and
16 inserting “due on the later of the first
17 business day on or after October 1 of
18 each fiscal year or the first business
19 day after the enactment of an appro-
20 priations Act providing for the collec-
21 tion and obligation of fees for such
22 fiscal year under this section.”; and
- 23 (ii) by amending subparagraph (B) to
24 read as follows:

1 “(B) EXCEPTION.—A prescription drug
2 product shall not be assessed a fee under sub-
3 paragraph (A) if such product is—

4 “(i) identified on the list compiled
5 under section 505(j)(7) with a potency de-
6 scribed in terms of per 100 mL;

7 “(ii) the same product as another
8 product that—

9 “(I) was approved under an ap-
10 plication filed under section 505(b) or
11 505(j); and

12 “(II) is not in the list of discon-
13 tinued products compiled under sec-
14 tion 505(j)(7);

15 “(iii) the same product as another
16 product that was approved under an abbrevi-
17 ated application filed under section 507
18 (as in effect on the day before the date of
19 enactment of the Food and Drug Adminis-
20 tration Modernization Act of 1997); or

21 “(iv) the same product as another
22 product that was approved under an abbrevi-
23 ated new drug application pursuant to
24 regulations in effect prior to the implemen-

1 tation of the Drug Price Competition and
2 Patent Term Restoration Act of 1984.”;

3 (2) in subsection (b)—

4 (A) in paragraph (1)—

5 (i) in the matter preceding subpara-
6 graph (A), by striking “fiscal years 2008
7 through 2012” and inserting “fiscal years
8 2013 through 2017”;

9 (ii) in subparagraph (A), by striking
10 “\$392,783,000; and” and inserting
11 “\$693,099,000;”; and

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

14 “(B) the dollar amount equal to the infla-
15 tion adjustment for fiscal year 2013 (as deter-
16 mined under paragraph (3)(A)); and

17 “(C) the dollar amount equal to the work-
18 load adjustment for fiscal year 2013 (as deter-
19 mined under paragraph (3)(B)).”; and

20 (B) by striking paragraphs (3) and (4) and
21 inserting the following:

22 “(3) FISCAL YEAR 2013 INFLATION AND WORK-
23 LOAD ADJUSTMENTS.—For purposes of paragraph
24 (1), the dollar amount of the inflation and workload

1 adjustments for fiscal year 2013 shall be determined
2 as follows:

3 “(A) INFLATION ADJUSTMENT.—The infla-
4 tion adjustment for fiscal year 2013 shall be
5 the sum of—

6 “(i) \$652,709,000 multiplied by the
7 result of an inflation adjustment calcula-
8 tion determined using the methodology de-
9 scribed in subsection (c)(1)(B); and

10 “(ii) \$652,709,000 multiplied by the
11 result of an inflation adjustment calcula-
12 tion determined using the methodology de-
13 scribed in subsection (c)(1)(C).

14 “(B) WORKLOAD ADJUSTMENT.—Subject
15 to subparagraph (C), the workload adjustment
16 for fiscal 2013 shall be—

17 “(i) \$652,709,000 plus the amount of
18 the inflation adjustment calculated under
19 subparagraph (A); multiplied by

20 “(ii) the amount (if any) by which a
21 percentage workload adjustment for fiscal
22 year 2013, as determined using the meth-
23 odology described in subsection (c)(2)(A),
24 would exceed the percentage workload ad-
25 justment (as so determined) for fiscal year

1 2012, if both such adjustment percentages
2 were calculated using the 5-year base pe-
3 riod consisting of fiscal years 2003
4 through 2007.

5 “(C) LIMITATION.—Under no cir-
6 cumstances shall the adjustment under sub-
7 paragraph (B) result in fee revenues for fiscal
8 year 2013 that are less than the sum of the
9 amount under paragraph (1)(A) and the
10 amount under paragraph (1)(B).”;

11 (3) by striking subsection (c) and inserting the
12 following:

13 “(c) ADJUSTMENTS.—

14 “(1) INFLATION ADJUSTMENT.—For fiscal year
15 2014 and subsequent fiscal years, the revenues es-
16 tablished in subsection (b) shall be adjusted by the
17 Secretary by notice, published in the Federal Reg-
18 ister, for a fiscal year by the amount equal to the
19 sum of—

20 “(A) one;

21 “(B) the average annual percent change in
22 the cost, per full-time equivalent position of the
23 Food and Drug Administration, of all personnel
24 compensation and benefits paid with respect to
25 such positions for the first 3 years of the pre-

1 ceding 4 fiscal years, multiplied by the propor-
2 tion of personnel compensation and benefits
3 costs to total costs of the process for the review
4 of human drug applications (as defined in sec-
5 tion 735(6)) for the first 3 years of the pre-
6 ceding 4 fiscal years, and

7 “(C) the average annual percent change
8 that occurred in the Consumer Price Index for
9 urban consumers (Washington-Baltimore, DC-
10 MD-VA-WV; Not Seasonally Adjusted; All
11 items; Annual Index) for the first 3 years of the
12 preceding 4 years of available data multiplied
13 by the proportion of all costs other than per-
14 sonnel compensation and benefits costs to total
15 costs of the process for the review of human
16 drug applications (as defined in section 735(6))
17 for the first 3 years of the preceding 4 fiscal
18 years.

19 The adjustment made each fiscal year under this
20 paragraph shall be added on a compounded basis to
21 the sum of all adjustments made each fiscal year
22 after fiscal year 2013 under this paragraph.

23 “(2) WORKLOAD ADJUSTMENT.—For fiscal
24 year 2014 and subsequent fiscal years, after the fee
25 revenues established in subsection (b) are adjusted

1 for a fiscal year for inflation in accordance with
2 paragraph (1), the fee revenues shall be adjusted
3 further for such fiscal year to reflect changes in the
4 workload of the Secretary for the process for the re-
5 view of human drug applications. With respect to
6 such adjustment:

7 “(A) The adjustment shall be determined
8 by the Secretary based on a weighted average
9 of the change in the total number of human
10 drug applications (adjusted for changes in re-
11 view activities, as described in the notice that
12 the Secretary is required to publish in the Fed-
13 eral Register under this subparagraph), efficacy
14 supplements, and manufacturing supplements
15 submitted to the Secretary, and the change in
16 the total number of active commercial investiga-
17 tional new drug applications (adjusted for
18 changes in review activities, as so described)
19 during the most recent 12-month period for
20 which data on such submissions is available.
21 The Secretary shall publish in the Federal Reg-
22 ister the fee revenues and fees resulting from
23 the adjustment and the supporting methodolo-
24 gies.

1 “(B) Under no circumstances shall the ad-
2 justment result in fee revenues for a fiscal year
3 that are less than the sum of the amount under
4 subsection (b)(1)(A) and the amount under
5 subsection (b)(1)(B), as adjusted for inflation
6 under paragraph (1).

7 “(C) The Secretary shall contract with an
8 independent accounting or consulting firm to
9 periodically review the adequacy of the adjust-
10 ment and publish the results of those reviews.
11 The first review shall be conducted and pub-
12 lished by the end of fiscal year 2013 (to exam-
13 ine the performance of the adjustment since fis-
14 cal year 2009), and the second review shall be
15 conducted and published by the end of fiscal
16 year 2015 (to examine the continued perform-
17 ance of the adjustment). The reports shall
18 evaluate whether the adjustment reasonably
19 represents actual changes in workload volume
20 and complexity and present options to dis-
21 continue, retain, or modify any elements of the
22 adjustment. The reports shall be published for
23 public comment. After review of the reports and
24 receipt of public comments, the Secretary shall,
25 if warranted, adopt appropriate changes to the

1 methodology. If the Secretary adopts changes to
2 the methodology based on the first report, the
3 changes shall be effective for the first fiscal
4 year for which fees are set after the Secretary
5 adopts such changes and each subsequent fiscal
6 year.

7 “(3) FINAL YEAR ADJUSTMENT.—For fiscal
8 year 2017, the Secretary may, in addition to adjust-
9 ments under this paragraph and paragraphs (1) and
10 (2), further increase the fee revenues and fees estab-
11 lished in subsection (b) if such an adjustment is nec-
12 essary to provide for not more than 3 months of op-
13 erating reserves of carryover user fees for the proc-
14 ess for the review of human drug applications for
15 the first 3 months of fiscal year 2018. If such an
16 adjustment is necessary, the rationale for the
17 amount of the increase shall be contained in the an-
18 nual notice establishing fee revenues and fees for fis-
19 cal year 2017. If the Secretary has carryover bal-
20 ances for such process in excess of 3 months of such
21 operating reserves, the adjustment under this para-
22 graph shall not be made.

23 “(4) ANNUAL FEE SETTING.—The Secretary
24 shall, not later than 60 days before the start of each
25 fiscal year that begins after September 30, 2012, es-

1 tabish, for the next fiscal year, application, product,
2 and establishment fees under subsection (a), based
3 on the revenue amounts established under subsection
4 (b) and the adjustments provided under this sub-
5 section.

6 “(5) LIMIT.—The total amount of fees charged,
7 as adjusted under this subsection, for a fiscal year
8 may not exceed the total costs for such fiscal year
9 for the resources allocated for the process for the re-
10 view of human drug applications.”; and

11 (4) in subsection (g)—

12 (A) in paragraph (1), by striking “Fees
13 authorized” and inserting “Subject to para-
14 graph (2)(C), fees authorized”;

15 (B) in paragraph (2)—

16 (i) in subparagraph (A)(i), by striking
17 “shall be retained” and inserting “subject
18 to subparagraph (C), shall be collected and
19 available”;

20 (ii) in subparagraph (A)(ii), by strik-
21 ing “shall only be collected and available”
22 and inserting “shall be available”; and

23 (iii) by adding at the end the fol-
24 lowing new subparagraph:

1 “(C) PROVISION FOR EARLY PAYMENTS.—
2 Payment of fees authorized under this section
3 for a fiscal year, prior to the due date for such
4 fees, may be accepted by the Secretary in ac-
5 cordance with authority provided in advance in
6 a prior year appropriations Act.”;

7 (C) in paragraph (3), by striking “fiscal
8 years 2008 through 2012” and inserting “fiscal
9 years 2013 through 2017”; and

10 (D) in paragraph (4)—

11 (i) by striking “fiscal years 2008
12 through 2010” and inserting “fiscal years
13 2013 through 2015”;

14 (ii) by striking “fiscal year 2011” and
15 inserting “fiscal year 2016”;

16 (iii) by striking “fiscal years 2008
17 through 2011” and inserting “fiscal years
18 2013 through 2016”; and

19 (iv) by striking “fiscal year 2012”
20 and inserting “fiscal year 2017”.

21 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

22 Section 736B (21 U.S.C. 379h–2) is amended—

23 (1) by amending subsection (a) to read as fol-
24 lows:

25 “(a) PERFORMANCE REPORT.—

1 “(1) IN GENERAL.—Beginning with fiscal year
2 2013, not later than 120 days after the end of each
3 fiscal year for which fees are collected under this
4 part, the Secretary shall prepare and submit to the
5 Committee on Energy and Commerce of the House
6 of Representatives and the Committee on Health,
7 Education, Labor, and Pensions of the Senate a re-
8 port concerning—

9 “(A) the progress of the Food and Drug
10 Administration in achieving the goals identified
11 in the letters described in section 101(b) of the
12 Prescription Drug User Fee Amendments of
13 2012 during such fiscal year and the future
14 plans of the Food and Drug Administration for
15 meeting the goals, including the status of the
16 independent assessment described in such let-
17 ters; and

18 “(B) the progress of the Center for Drug
19 Evaluation and Research and the Center for
20 Biologics Evaluation and Research in achieving
21 the goals, and future plans for meeting the
22 goals, including, for each review division—

23 “(i) the number of original standard
24 new drug applications and biologics license

1 applications filed per fiscal year for each
2 review division;

3 “(ii) the number of original priority
4 new drug applications and biologics license
5 applications filed per fiscal year for each
6 review division;

7 “(iii) the number of standard efficacy
8 supplements filed per fiscal year for each
9 review division;

10 “(iv) the number of priority efficacy
11 supplements filed per fiscal year for each
12 review division;

13 “(v) the number of applications filed
14 for review under accelerated approval per
15 fiscal year for each review division;

16 “(vi) the number of applications filed
17 for review as fast track products per fiscal
18 year for each review division;

19 “(vii) the number of applications filed
20 for orphan-designated products per fiscal
21 year for each review division; and

22 “(viii) the number of breakthrough
23 designations for a fiscal year for each re-
24 view division.

1 “(2) INCLUSION.—The report under this sub-
2 section for a fiscal year shall include information on
3 all previous cohorts for which the Secretary has not
4 given a complete response on all human drug appli-
5 cations and supplements in the cohort.”.

6 (2) in subsection (b), by striking “2008” and
7 inserting “2013”; and

8 (3) in subsection (d), by striking “2012” each
9 place it appears and inserting “2017”.

10 **SEC. 105. SUNSET DATES.**

11 (a) AUTHORIZATION.—Sections 735 and 736 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
13 379h) shall cease to be effective October 1, 2017.

14 (b) REPORTING REQUIREMENTS.—Section 736B of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379h–2) shall cease to be effective January 31, 2018.

17 (c) PREVIOUS SUNSET PROVISION.—

18 (1) IN GENERAL.—Section 106 of the Food and
19 Drug Administration Amendments Act of 2007
20 (Public Law 110–85) is repealed.

21 (2) CONFORMING AMENDMENT.—The Food and
22 Drug Administration Amendments Act of 2007
23 (Public Law 110–85) is amended in the table of con-
24 tents in section 2, by striking the item relating to
25 section 106.

1 (d) TECHNICAL CLARIFICATIONS.—

2 (1) Effective September 30, 2007—

3 (A) section 509 of the Prescription Drug
4 User Fee Amendments Act of 2002 (Title V of
5 Public Law 107–188) is repealed; and

6 (B) the Public Health Security and Bioter-
7 rorism Preparedness and Response Act of 2002
8 (Public Law 107–188) is amended in the table
9 of contents in section 1(b), by striking the item
10 relating to section 509.

11 (2) Effective September 30, 2002—

12 (A) section 107 of the Food and Drug Ad-
13 ministration Modernization Act of 1997 (Public
14 Law 105–115) is repealed; and

15 (B) the table of contents in section 1(c) of
16 such Act is amended by striking the item re-
17 lated to section 107.

18 (3) Effective September 30, 1997, section 105
19 of the Prescription Drug User Fee Act of 1992
20 (Public Law 102–571) is repealed.

21 **SEC. 106. EFFECTIVE DATE.**

22 The amendments made by this title shall take effect
23 on October 1, 2012, or the date of the enactment of this
24 Act, whichever is later, except that fees under part 2 of
25 subchapter C of chapter VII of the Federal Food, Drug,

1 and Cosmetic Act shall be assessed for all human drug
2 applications received on or after October 1, 2012, regard-
3 less of the date of the enactment of this Act.

4 **SEC. 107. SAVINGS CLAUSE.**

5 Notwithstanding the amendments made by this title,
6 part 2 of subchapter C of chapter VII of the Federal Food,
7 Drug, and Cosmetic Act, as in effect on the day before
8 the date of the enactment of this title, shall continue to
9 be in effect with respect to human drug applications and
10 supplements (as defined in such part as of such day) that
11 on or after October 1, 2007, but before October 1, 2012,
12 were accepted by the Food and Drug Administration for
13 filing with respect to assessing and collecting any fee re-
14 quired by such part for a fiscal year prior to fiscal year
15 2012.

16 **TITLE II—FEES RELATING TO**
17 **DEVICES**

18 **SEC. 201. SHORT TITLE; FINDINGS.**

19 (a) **SHORT TITLE.**—This title may be cited as the
20 “Medical Device User Fee Amendments of 2012”.

21 (b) **FINDINGS.**—The Congress finds that the fees au-
22 thorized under the amendments made by this title will be
23 dedicated toward expediting the process for the review of
24 device applications and for assuring the safety and effec-
25 tiveness of devices, as set forth in the goals identified for

1 purposes of part 3 of subchapter C of chapter VII of the
2 Federal Food, Drug, and Cosmetic Act in the letters from
3 the Secretary of Health and Human Services to the Chair-
4 man of the Committee on Health, Education, Labor, and
5 Pensions of the Senate and the Chairman of the Com-
6 mittee on Energy and Commerce of the House of Rep-
7 resentatives, as set forth in the Congressional Record.

8 **SEC. 202. DEFINITIONS.**

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

10 (1) in paragraph (9), by striking “incurred”
11 after “expenses”;

12 (2) in paragraph (10), by striking “October
13 2001” and inserting “October 2011”; and

14 (3) in paragraph (13), by striking “is required
15 to register” and all that follows through the end of
16 paragraph (13) and inserting the following: “is reg-
17 istered (or is required to register) with the Secretary
18 under section 510 because such establishment is en-
19 gaged in the manufacture, preparation, propagation,
20 compounding, or processing of a device.”.

21 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

22 (a) **TYPES OF FEES.**—Section 738(a) (21 U.S.C.
23 379j(a)) is amended—

24 (1) in paragraph (1), by striking “fiscal year
25 2008” and inserting “fiscal year 2013”;

1 (2) in paragraph (2)(A)—

2 (A) in the matter preceding clause (i)—

3 (i) by striking “subsections (d) and
4 (e)” and inserting “subsections (d), (e),
5 and (f)”;

6 (ii) by striking “October 1, 2002” and
7 inserting “October 1, 2012”; and

8 (iii) by striking “subsection (c)(1)”
9 and inserting “subsection (c)”;

10 (B) in clause (viii), by striking “1.84” and
11 inserting “2”;

12 (3) in paragraph (3)—

13 (A) in subparagraph (A), by inserting
14 “and subsection (f)” after “subparagraph (B)”;
15 and

16 (B) in subparagraph (C), by striking “ini-
17 tial registration” and all that follows through
18 “section 510.” and inserting “later of—

19 “(i) the initial or annual registration
20 (as applicable) of the establishment under
21 section 510; or

22 “(ii) the first business day after the
23 date of enactment of an appropriations Act
24 providing for the collection and obligation
25 of fees for such year under this section.”.

1 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.
2 379j(b)) is amended to read as follows:

3 “(b) FEE AMOUNTS.—

4 “(1) IN GENERAL.—Subject to subsections (c),
5 (d), (e), (f), and (i), for each of fiscal years 2013
6 through 2017, fees under subsection (a) shall be de-
7 rived from the base fee amounts specified in para-
8 graph (2), to generate the total revenue amounts
9 specified in paragraph (3).

10 “(2) BASE FEE AMOUNTS SPECIFIED.—For
11 purposes of paragraph (1), the base fee amounts
12 specified in this paragraph are as follows:

| “Fee Type | Fiscal Year 2013 | Fiscal Year 2014 | Fiscal Year 2015 | Fiscal Year 2016 | Fiscal Year 2017 |
|----------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Premarket Application | \$248,000 | \$252,960 | \$258,019 | \$263,180 | \$268,443 |
| Establishment Registration | \$2,575 | \$3,200 | \$3,750 | \$3,872 | \$3,872 |

13 “(3) TOTAL REVENUE AMOUNTS SPECIFIED.—
14 For purposes of paragraph (1), the total revenue
15 amounts specified in this paragraph are as follows:

16 “(A) \$97,722,301 for fiscal year 2013.

17 “(B) \$112,580,497 for fiscal year 2014.

18 “(C) \$125,767,107 for fiscal year 2015.

19 “(D) \$129,339,949 for fiscal year 2016.

20 “(E) \$130,184,348 for fiscal year 2017.”.

21 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
22 738(c) (21 U.S.C. 379j(c)) is amended—

1 (1) in the subsection heading, by inserting “;
2 ADJUSTMENTS” after “SETTING”;

3 (2) by striking paragraphs (1) and (2);

4 (3) by redesignating paragraphs (3) and (4) as
5 paragraphs (4) and (5), respectively; and

6 (4) by inserting before paragraph (4), as so re-
7 designated, the following:

8 “(1) IN GENERAL.—The Secretary shall, 60
9 days before the start of each fiscal year after Sep-
10 tember 30, 2012, establish fees under subsection (a),
11 based on amounts specified under subsection (b) and
12 the adjustments provided under this subsection, and
13 publish such fees, and the rationale for any adjust-
14 ments to such fees, in the Federal Register.

15 “(2) INFLATION ADJUSTMENTS.—

16 “(A) ADJUSTMENT TO TOTAL REVENUE
17 AMOUNTS.—For fiscal year 2014 and each sub-
18 sequent fiscal year, the Secretary shall adjust
19 the total revenue amount specified in subsection
20 (b)(3) for such fiscal year by multiplying such
21 amount by the applicable inflation adjustment
22 under subparagraph (B) for such year.

23 “(B) APPLICABLE INFLATION ADJUST-
24 MENT TO TOTAL REVENUE AMOUNTS.—The ap-

1 applicable inflation adjustment for a fiscal year
2 is—

3 “(i) for fiscal year 2014, the base in-
4 flation adjustment under subparagraph (C)
5 for such fiscal year; and

6 “(ii) for fiscal year 2015 and each
7 subsequent fiscal year, the product of—

8 “(I) the base inflation adjust-
9 ment under subparagraph (C) for
10 such fiscal year; and

11 “(II) the product of the base in-
12 flation adjustment under subpara-
13 graph (C) for each of the fiscal years
14 preceding such fiscal year, beginning
15 with fiscal year 2014.

16 “(C) BASE INFLATION ADJUSTMENT TO
17 TOTAL REVENUE AMOUNTS.—

18 “(i) IN GENERAL.—Subject to further
19 adjustment under clause (ii), the base in-
20 flation adjustment for a fiscal year is the
21 sum of one plus—

22 “(I) the average annual percent
23 change in the cost, per full-time equiv-
24 alent position of the Food and Drug
25 Administration, of all personnel com-

1 pensation and benefits paid with re-
2 spect to such positions for the first 3
3 years of the preceding 4 fiscal years,
4 multiplied by 0.60; and

5 “(II) the average annual percent
6 change that occurred in the Consumer
7 Price Index for urban consumers
8 (Washington-Baltimore, DC–MD–VA–
9 WV; Not Seasonally Adjusted; All
10 items; Annual Index) for the first 3
11 years of the preceding 4 years of
12 available data multiplied by 0.40.

13 “(ii) LIMITATIONS.—For purposes of
14 subparagraph (B), if the base inflation ad-
15 justment for a fiscal year under clause
16 (i)—

17 “(I) is less than 1, such adjust-
18 ment shall be considered to be equal
19 to 1; or

20 “(II) is greater than 1.04, such
21 adjustment shall be considered to be
22 equal to 1.04.

23 “(D) ADJUSTMENT TO BASE FEE
24 AMOUNTS.—For each of fiscal years 2014
25 through 2017, the base fee amounts specified in

1 subsection (b)(2) shall be adjusted as needed,
2 on a uniform proportionate basis, to generate
3 the total revenue amounts under subsection
4 (b)(3), as adjusted for inflation under subpara-
5 graph (A).

6 “(3) VOLUME-BASED ADJUSTMENTS TO ESTAB-
7 LISHMENT REGISTRATION BASE FEES.—For each of
8 fiscal years 2014 through 2017, after the base fee
9 amounts specified in subsection (b)(2) are adjusted
10 under paragraph (2)(D), the base establishment reg-
11 istration fee amounts specified in such subsection
12 shall be further adjusted, as the Secretary estimates
13 is necessary in order for total fee collections for such
14 fiscal year to generate the total revenue amounts, as
15 adjusted under paragraph (2).”.

16 (d) FEE WAIVER OR REDUCTION.—Section 738 (21
17 U.S.C. 379j) is amended by—

18 (1) redesignating subsections (f) through (k) as
19 subsections (g) through (l), respectively; and

20 (2) by inserting after subsection (e) the fol-
21 lowing new subsection:

22 “(f) FEE WAIVER OR REDUCTION.—

23 “(1) IN GENERAL.—The Secretary may, at the
24 Secretary’s sole discretion, grant a waiver or reduc-
25 tion of fees under subsection (a)(2) or (a)(3) if the

1 Secretary finds that such waiver or reduction is in
2 the interest of public health.

3 “(2) LIMITATION.—The sum of all fee waivers
4 or reductions granted by the Secretary in any fiscal
5 year under paragraph (1) shall not exceed 2 percent
6 of the total fee revenue amounts established for such
7 year under subsection (c).

8 “(3) DURATION.—The authority provided by
9 this subsection terminates October 1, 2017.”.

10 (e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C.
11 379j(h)(1)(A)), as redesignated by subsection (d)(1), is
12 amended by striking “\$205,720,000” and inserting
13 “\$280,587,000”.

14 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
15 tion 738(i) (21 U.S.C. 379j(i)), as redesignated by sub-
16 section (d)(1), is amended—

17 (1) in paragraph (1), by striking “Fees author-
18 ized” and inserting “Subject to paragraph (2)(C),
19 fees authorized”;

20 (2) in paragraph (2)—

21 (A) in subparagraph (A)—

22 (i) in clause (i), by striking “shall be
23 retained” and inserting “subject to sub-
24 paragraph (C), shall be collected and avail-
25 able”; and

1 (ii) in clause (ii)—

2 (I) by striking “collected and”
3 after “shall only be”; and

4 (II) by striking “fiscal year
5 2002” and inserting “fiscal year
6 2009”; and

7 (B) by adding at the end, the following:

8 “(C) PROVISION FOR EARLY PAYMENTS.—

9 Payment of fees authorized under this section
10 for a fiscal year, prior to the due date for such
11 fees, may be accepted by the Secretary in ac-
12 cordance with authority provided in advance in
13 a prior year appropriations Act.”;

14 (3) by amending paragraph (3) to read as fol-
15 lows:

16 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—

17 For each of the fiscal years 2013 through 2017,
18 there is authorized to be appropriated for fees under
19 this section an amount equal to the total revenue
20 amount specified under subsection (b)(3) for the fis-
21 cal year, as adjusted under subsection (c) and, for
22 fiscal year 2017 only, as further adjusted under
23 paragraph (4).”; and

24 (4) in paragraph (4)—

1 (A) by striking “fiscal years 2008, 2009,
2 and 2010” and inserting “fiscal years 2013,
3 2014, and 2015”;

4 (B) by striking “fiscal year 2011” and in-
5 serting “fiscal year 2016”;

6 (C) by striking “June 30, 2011” and in-
7 serting “June 30, 2016”;

8 (D) by striking “the amount of fees speci-
9 fied in aggregate in” and inserting “the cumu-
10 lative amount appropriated pursuant to”;

11 (E) by striking “aggregate amount in” be-
12 fore “excess shall be credited”; and

13 (F) by striking “fiscal year 2012” and in-
14 serting “fiscal year 2017”.

15 (g) CONFORMING AMENDMENT.—Section
16 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by
17 striking “738(g)” and inserting “738(h)”.

18 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

19 (a) REAUTHORIZATION.—Section 738A(b) (21
20 U.S.C. 379j–1(b)) is amended—

21 (1) in paragraph (1), by striking “2012” and
22 inserting “2017”; and

23 (2) in paragraph (5), by striking “2012” and
24 inserting “2017”.

1 (b) PERFORMANCE REPORTS.—Section 738A(a) (21
2 U.S.C. 379j–1(a)) is amended—

3 (1) by striking paragraph (1) and inserting the
4 following:

5 “(1) PERFORMANCE REPORT.—

6 “(A) IN GENERAL.—Beginning with fiscal
7 year 2013, for each fiscal year for which fees
8 are collected under this part, the Secretary
9 shall prepare and submit to the Committee on
10 Health, Education, Labor, and Pensions of the
11 Senate and the Committee on Energy and Com-
12 merce of the House of Representatives annual
13 reports concerning the progress of the Food
14 and Drug Administration in achieving the goals
15 identified in the letters described in section
16 201(b) of the Medical Device User Fee Amend-
17 ments of 2012 during such fiscal year and the
18 future plans of the Food and Drug Administra-
19 tion for meeting the goals.

20 “(B) PUBLICATION.—With regard to infor-
21 mation to be reported by the Food and Drug
22 Administration to industry on a quarterly and
23 annual basis pursuant to the letters described
24 in section 201(b) of the Medical Device User
25 Fee Amendments Act of 2012, the Secretary

1 shall make such information publicly available
2 on the Internet Web site of the Food and Drug
3 Administration not later than 60 days after the
4 end of each quarter or 120 days after the end
5 of each fiscal year, respectively, to which such
6 information applies. This information shall in-
7 clude the status of the independent assessment
8 identified in the letters described in such sec-
9 tion 201(b).

10 “(C) UPDATES.—The Secretary shall in-
11 clude in each report under subparagraph (A)
12 information on all previous cohorts for which
13 the Secretary has not given a complete response
14 on all device premarket applications and re-
15 ports, supplements, and premarket notifications
16 in the cohort.”; and

17 (2) in paragraph (2), by striking “2008
18 through 2012” and inserting “2013 through 2017”.

19 **SEC. 205. SAVINGS CLAUSE.**

20 Notwithstanding the amendments made by this title,
21 part 3 of subchapter C of chapter VII of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
23 effect on the day before the date of the enactment of this
24 title, shall continue to be in effect with respect to the sub-
25 missions listed in section 738(a)(2)(A) of such Act (in ef-

1 fect as of such day) that on or after October 1, 2007,
2 but before October 1, 2012, were accepted by the Food
3 and Drug Administration for filing with respect to assess-
4 ing and collecting any fee required by such part for a fiscal
5 year prior to fiscal year 2013.

6 **SEC. 206. EFFECTIVE DATE.**

7 The amendments made by this title shall take effect
8 on October 1, 2012, or the date of the enactment of this
9 Act, whichever is later, except that fees under part 3 of
10 subchapter C of chapter VII of the Federal Food, Drug,
11 and Cosmetic Act shall be assessed for all submissions list-
12 ed in section 738(a)(2)(A) of such Act received on or after
13 October 1, 2012, regardless of the date of the enactment
14 of this Act.

15 **SEC. 207. SUNSET CLAUSE.**

16 (a) IN GENERAL.—Sections 737 and 738 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j)
18 shall cease to be effective October 1, 2017. Section 738A
19 (21 U.S.C. 739j–1) of the Federal Food, Drug, and Cos-
20 metic Act (regarding reauthorization and reporting re-
21 quirements) shall cease to be effective January 31, 2018.

22 (b) PREVIOUS SUNSET PROVISION.—

23 (1) IN GENERAL.—Section 217 of the Food and
24 Drug Administration Amendments Act of 2007
25 (Title II of Public Law 110–85) is repealed.

1 (2) CONFORMING AMENDMENT.—The Food and
2 Drug Administration Amendments Act of 2007
3 (Public Law 110–85) is amended in the table of con-
4 tents in section 2, by striking the item relating to
5 section 217.

6 (c) TECHNICAL CLARIFICATION.—Effective Sep-
7 tember 30, 2007—

8 (1) section 107 of the Medical Device User Fee
9 and Modernization Act of 2002 (Public Law 107–
10 250) is repealed; and

11 (2) the table of contents in section 1(b) of such
12 Act is amended by striking the item related to sec-
13 tion 107.

14 **SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT**
15 **ACTIVITIES RELATED TO THE PROCESS FOR**
16 **THE REVIEW OF DEVICE APPLICATIONS.**

17 Subchapter A of chapter VII (21 U.S.C. 371 et seq.)
18 is amended by inserting after section 713 the following
19 new section:

20 **“SEC. 714. STREAMLINED HIRING AUTHORITY.**

21 “(a) IN GENERAL.—In addition to any other per-
22 sonnel authorities under other provisions of law, the Sec-
23 retary may, without regard to the provisions of title 5,
24 United States Code, governing appointments in the com-
25 petitive service, appoint employees to positions in the Food

1 and Drug Administration to perform, administer, or sup-
2 port activities described in subsection (b), if the Secretary
3 determines that such appointments are needed to achieve
4 the objectives specified in subsection (c).

5 “(b) ACTIVITIES DESCRIBED.—The activities de-
6 scribed in this subsection are activities under this Act re-
7 lated to the process for the review of device applications
8 (as defined in section 737(8)).

9 “(c) OBJECTIVES SPECIFIED.—The objectives speci-
10 fied in this subsection are with respect to the activities
11 under subsection (b), the goals referred to in section
12 738A(a)(1).

13 “(d) INTERNAL CONTROLS.—The Secretary shall in-
14 stitute appropriate internal controls for appointments
15 under this section.

16 “(e) SUNSET.—The authority to appoint employees
17 under this section shall terminate on the date that is 3
18 years after the date of enactment of this section.”.

19 **TITLE III—FEES RELATING TO** 20 **GENERIC DRUGS**

21 **SEC. 301. SHORT TITLE.**

22 (a) SHORT TITLE.—This title may be cited as the
23 “Generic Drug User Fee Amendments of 2012”.

24 (b) FINDING.—The Congress finds that the fees au-
25 thorized by the amendments made in this title will be dedi-

1 cated to human generic drug activities, as set forth in the
2 goals identified for purposes of part 7 of subchapter C
3 of chapter VII of the Federal Food, Drug, and Cosmetic
4 Act, in the letters from the Secretary of Health and
5 Human Services to the Chairman of the Committee on
6 Health, Education, Labor, and Pensions of the Senate and
7 the Chairman of the Committee on Energy and Commerce
8 of the House of Representatives, as set forth in the Con-
9 gressional Record.

10 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
11 **NERIC DRUG FEES.**

12 Subchapter C of chapter VII (21 U.S.C. 379f et seq.)
13 is amended by adding at the end the following:

14 **“PART 7—FEES RELATING TO GENERIC DRUGS**
15 **“SEC. 744A. DEFINITIONS.**

16 “For purposes of this part:

17 “(1) The term ‘abbreviated new drug applica-
18 tion’—

19 “(A) means an application submitted
20 under section 505(j), an abbreviated application
21 submitted under section 507 (as in effect on the
22 day before the date of enactment of the Food
23 and Drug Administration Modernization Act of
24 1997), or an abbreviated new drug application
25 submitted pursuant to regulations in effect

1 prior to the implementation of the Drug Price
2 Competition and Patent Term Restoration Act
3 of 1984; and

4 “(B) does not include an application for a
5 positron emission tomography drug.

6 “(2) The term ‘active pharmaceutical ingre-
7 dient’ means—

8 “(A) a substance, or a mixture when the
9 substance is unstable or cannot be transported
10 on its own, intended—

11 “(i) to be used as a component of a
12 drug; and

13 “(ii) to furnish pharmacological activ-
14 ity or other direct effect in the diagnosis,
15 cure, mitigation, treatment, or prevention
16 of disease, or to affect the structure or any
17 function of the human body; or

18 “(B) a substance intended for final crys-
19 tallization, purification, or salt formation, or
20 any combination of those activities, to become a
21 substance or mixture described in subparagraph
22 (A).

23 “(3) The term ‘adjustment factor’ means a fac-
24 tor applicable to a fiscal year that is the Consumer
25 Price Index for all urban consumers (all items;

1 United States city average) for October of the pre-
2 ceding fiscal year divided by such Index for October
3 2011.

4 “(4) The term ‘affiliate’ means a business enti-
5 ty that has a relationship with a second business en-
6 tity if, directly or indirectly—

7 “(A) one business entity controls, or has
8 the power to control, the other business entity;
9 or

10 “(B) a third party controls, or has power
11 to control, both of the business entities.

12 “(5)(A) The term ‘facility’—

13 “(i) means a business or other entity—

14 “(I) under one management, either di-
15 rect or indirect; and

16 “(II) at one geographic location or ad-
17 dress engaged in manufacturing or proc-
18 essing an active pharmaceutical ingredient
19 or a finished dosage form; and

20 “(ii) does not include a business or other
21 entity whose only manufacturing or processing
22 activities are one or more of the following: re-
23 packaging, relabeling, or testing.

24 “(B) For purposes of subparagraph (A), sepa-
25 rate buildings within close proximity are considered

1 to be at one geographic location or address if the ac-
2 tivities in them are—

3 “(i) closely related to the same business
4 enterprise;

5 “(ii) under the supervision of the same
6 local management; and

7 “(iii) capable of being inspected by the
8 Food and Drug Administration during a single
9 inspection.

10 “(C) If a business or other entity would meet
11 the definition of a facility under this paragraph but
12 for being under multiple management, the business
13 or other entity is deemed to constitute multiple fa-
14 cilities, one per management entity, for purposes of
15 this paragraph.

16 “(6) The term ‘finished dosage form’ means—

17 “(A) a drug product in the form in which
18 it will be administered to a patient, such as a
19 tablet, capsule, solution, or topical application;

20 “(B) a drug product in a form in which re-
21 constitution is necessary prior to administration
22 to a patient, such as oral suspensions or
23 lyophilized powders; or

24 “(C) any combination of an active pharma-
25 ceutical ingredient with another component of a

1 drug product for purposes of production of a
2 drug product described in subparagraph (A) or
3 (B).

4 “(7) The term ‘generic drug submission’ means
5 an abbreviated new drug application, an amendment
6 to an abbreviated new drug application, or a prior
7 approval supplement to an abbreviated new drug ap-
8 plication.

9 “(8) The term ‘human generic drug activities’
10 means the following activities of the Secretary asso-
11 ciated with generic drugs and inspection of facilities
12 associated with generic drugs:

13 “(A) The activities necessary for the re-
14 view of generic drug submissions, including re-
15 view of drug master files referenced in such
16 submissions.

17 “(B) The issuance of—

18 “(i) approval letters which approve
19 abbreviated new drug applications or sup-
20 plements to such applications; or

21 “(ii) complete response letters which
22 set forth in detail the specific deficiencies
23 in such applications and, where appro-
24 priate, the actions necessary to place such
25 applications in condition for approval.

1 “(C) The issuance of letters related to
2 Type II active pharmaceutical drug master files
3 which—

4 “(i) set forth in detail the specific de-
5 ficiencies in such submissions, and where
6 appropriate, the actions necessary to re-
7 solve those deficiencies; or

8 “(ii) document that no deficiencies
9 need to be addressed.

10 “(D) Inspections related to generic drugs.

11 “(E) Monitoring of research conducted in
12 connection with the review of generic drug sub-
13 missions and drug master files.

14 “(F) Postmarket safety activities with re-
15 spect to drugs approved under abbreviated new
16 drug applications or supplements, including the
17 following activities:

18 “(i) Collecting, developing, and re-
19 viewing safety information on approved
20 drugs, including adverse event reports.

21 “(ii) Developing and using improved
22 adverse-event data-collection systems, in-
23 cluding information technology systems.

24 “(iii) Developing and using improved
25 analytical tools to assess potential safety

1 problems, including access to external data
2 bases.

3 “(iv) Implementing and enforcing sec-
4 tion 505(o) (relating to postapproval stud-
5 ies and clinical trials and labeling changes)
6 and section 505(p) (relating to risk evalua-
7 tion and mitigation strategies) insofar as
8 those activities relate to abbreviated new
9 drug applications.

10 “(v) Carrying out section 505(k)(5)
11 (relating to adverse-event reports and
12 postmarket safety activities).

13 “(G) Regulatory science activities related
14 to generic drugs.

15 “(9) The term ‘positron emission tomography
16 drug’ has the meaning given to the term ‘com-
17 pounded positron emission tomography drug’ in sec-
18 tion 201(ii), except that paragraph (1)(B) of such
19 section shall not apply.

20 “(10) The term ‘prior approval supplement’
21 means a request to the Secretary to approve a
22 change in the drug substance, drug product, produc-
23 tion process, quality controls, equipment, or facilities
24 covered by an approved abbreviated new drug appli-
25 cation when that change has a substantial potential

1 to have an adverse effect on the identity, strength,
2 quality, purity, or potency of the drug product as
3 these factors may relate to the safety or effective-
4 ness of the drug product.

5 “(11) The term ‘resources allocated for human
6 generic drug activities’ means the expenses for—

7 “(A) officers and employees of the Food
8 and Drug Administration, contractors of the
9 Food and Drug Administration, advisory com-
10 mittees, and costs related to such officers and
11 employees and to contracts with such contrac-
12 tors;

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

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

21 “(D) collecting fees under subsection (a)
22 and accounting for resources allocated for the
23 review of abbreviated new drug applications and
24 supplements and inspection related to generic
25 drugs.

1 fee shall be calculated by dividing \$50,000,000
2 by the total number of abbreviated new drug
3 applications pending on October 1, 2012, that
4 have not received a tentative approval as of that
5 date.

6 “(C) NOTICE.—Not later than October 31,
7 2012, the Secretary shall publish in the Federal
8 Register a notice announcing the amount of the
9 fee required by subparagraph (A).

10 “(D) FEE DUE DATE.—The fee required
11 by subparagraph (A) shall be due no later than
12 30 calendar days after the date of the publica-
13 tion of the notice specified in subparagraph (C).

14 “(2) DRUG MASTER FILE FEE.—

15 “(A) IN GENERAL.—Each person that
16 owns a Type II active pharmaceutical ingre-
17 dient drug master file that is referenced on or
18 after October 1, 2012, in a generic drug sub-
19 mission by any initial letter of authorization
20 shall be subject to a drug master file fee.

21 “(B) ONE-TIME PAYMENT.—If a person
22 has paid a drug master file fee for a Type II
23 active pharmaceutical ingredient drug master
24 file, the person shall not be required to pay a
25 subsequent drug master file fee when that Type

1 II active pharmaceutical ingredient drug master
2 file is subsequently referenced in generic drug
3 submissions.

4 “(C) NOTICE.—

5 “(i) FISCAL YEAR 2013.—Not later
6 than October 31, 2012, the Secretary shall
7 publish in the Federal Register a notice
8 announcing the amount of the drug master
9 file fee for fiscal year 2013.

10 “(ii) FISCAL YEAR 2014 THROUGH
11 2017.—Not later than 60 days before the
12 start of each of fiscal years 2014 through
13 2017, the Secretary shall publish in the
14 Federal Register the amount of the drug
15 master file fee established by this para-
16 graph for such fiscal year.

17 “(D) AVAILABILITY FOR REFERENCE.—

18 “(i) IN GENERAL.—Subject to sub-
19 section (g)(2)(C), for a generic drug sub-
20 mission to reference a Type II active phar-
21 maceutical ingredient drug master file, the
22 drug master file must be deemed available
23 for reference by the Secretary.

1 “(ii) CONDITIONS.—A drug master
2 file shall be deemed available for reference
3 by the Secretary if—

4 “(I) the person that owns a Type
5 II active pharmaceutical ingredient
6 drug master file has paid the fee re-
7 quired under subparagraph (A) within
8 20 calendar days after the applicable
9 due date under subparagraph (E);
10 and

11 “(II) the drug master file has not
12 failed an initial completeness assess-
13 ment by the Secretary, in accordance
14 with criteria to be published by the
15 Secretary.

16 “(iii) LIST.—The Secretary shall
17 make publicly available on the Internet
18 Web site of the Food and Drug Adminis-
19 tration a list of the drug master file num-
20 bers that correspond to drug master files
21 that have successfully undergone an initial
22 completeness assessment, in accordance
23 with criteria to be published by the Sec-
24 retary, and are available for reference.

25 “(E) FEE DUE DATE.—

1 “(i) IN GENERAL.—Subject to clause
2 (ii), a drug master file fee shall be due no
3 later than the date on which the first ge-
4 neric drug submission is submitted that
5 references the associated Type II active
6 pharmaceutical ingredient drug master file.

7 “(ii) LIMITATION.—No fee shall be
8 due under subparagraph (A) for a fiscal
9 year until the later of—

10 “(I) 30 calendar days after publi-
11 cation of the notice provided for in
12 clause (i) or (ii) of subparagraph (C),
13 as applicable; or

14 “(II) 30 calendar days after the
15 date of enactment of an appropria-
16 tions Act providing for the collection
17 and obligation of fees under this sec-
18 tion.

19 “(3) ABBREVIATED NEW DRUG APPLICATION
20 AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

21 “(A) IN GENERAL.—Each applicant that
22 submits, on or after October 1, 2012, an abbrevi-
23 ated new drug application or a prior approval
24 supplement to an abbreviated new drug applica-
25 tion shall be subject to a fee for each such sub-

1 mission in the amount established under sub-
2 section (d).

3 “(B) NOTICE.—

4 “(i) FISCAL YEAR 2013.—Not later
5 than October 31, 2012, the Secretary shall
6 publish in the Federal Register a notice
7 announcing the amount of the fees under
8 subparagraph (A) for fiscal year 2013.

9 “(ii) FISCAL YEARS 2014 THROUGH
10 2017.—Not later than 60 days before the
11 start of each of fiscal years 2014 through
12 2017, the Secretary shall publish in the
13 Federal Register the amount of the fees
14 under subparagraph (A) for such fiscal
15 year.

16 “(C) FEE DUE DATE.—

17 “(i) IN GENERAL.—Except as pro-
18 vided in clause (ii), the fees required by
19 subparagraphs (A) and (F) shall be due no
20 later than the date of submission of the
21 abbreviated new drug application or prior
22 approval supplement for which such fee ap-
23 plies.

1 “(ii) SPECIAL RULE FOR 2013.—For
2 fiscal year 2013, such fees shall be due on
3 the later of—

4 “(I) the date on which the fee is
5 due under clause (i);

6 “(II) 30 calendar days after pub-
7 lication of the notice referred to in
8 subparagraph (B)(i); or

9 “(III) if an appropriations Act is
10 not enacted providing for the collec-
11 tion and obligation of fees under this
12 section by the date of submission of
13 the application or prior approval sup-
14 plement for which the fees under sub-
15 paragraphs (A) and (F) apply, 30 cal-
16 endar days after the date that such an
17 appropriations Act is enacted.

18 “(D) REFUND OF FEE IF ABBREVIATED
19 NEW DRUG APPLICATION IS NOT CONSIDERED
20 TO HAVE BEEN RECEIVED.—The Secretary
21 shall refund 75 percent of the fee paid under
22 subparagraph (A) for any abbreviated new drug
23 application or prior approval supplement to an
24 abbreviated new drug application that the Sec-
25 retary considers not to have been received with-

1 in the meaning of section 505(j)(5)(A) for a
2 cause other than failure to pay fees.

3 “(E) FEE FOR AN APPLICATION THE SEC-
4 RETARY CONSIDERS NOT TO HAVE BEEN RE-
5 CEIVED, OR THAT HAS BEEN WITHDRAWN.—An
6 abbreviated new drug application or prior ap-
7 proval supplement that was submitted on or
8 after October 1, 2012, and that the Secretary
9 considers not to have been received, or that has
10 been withdrawn, shall, upon resubmission of the
11 application or a subsequent new submission fol-
12 lowing the applicant’s withdrawal of the appli-
13 cation, be subject to a full fee under subpara-
14 graph (A).

15 “(F) ADDITIONAL FEE FOR ACTIVE PHAR-
16 MACEUTICAL INGREDIENT INFORMATION NOT
17 INCLUDED BY REFERENCE TO TYPE II ACTIVE
18 PHARMACEUTICAL INGREDIENT DRUG MASTER
19 FILE.—An applicant that submits a generic
20 drug submission on or after October 1, 2012,
21 shall pay a fee, in the amount determined under
22 subsection (d)(3), in addition to the fee re-
23 quired under subparagraph (A), if—

24 “(i) such submission contains infor-
25 mation concerning the manufacture of an

1 active pharmaceutical ingredient at a facil-
2 ity by means other than reference by a let-
3 ter of authorization to a Type II active
4 pharmaceutical drug master file; and

5 “(ii) a fee in the amount equal to the
6 drug master file fee established in para-
7 graph (2) has not been previously paid
8 with respect to such information.

9 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
10 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

11 “(A) IN GENERAL.—Facilities identified,
12 or intended to be identified, in at least one ge-
13 neric drug submission that is pending or ap-
14 proved to produce a finished dosage form of a
15 human generic drug or an active pharma-
16 ceutical ingredient contained in a human ge-
17 neric drug shall be subject to fees as follows:

18 “(i) GENERIC DRUG FACILITY.—Each
19 person that owns a facility which is identi-
20 fied or intended to be identified in at least
21 one generic drug submission that is pend-
22 ing or approved to produce one or more
23 finished dosage forms of a human generic
24 drug shall be assessed an annual fee for
25 each such facility.

1 “(ii) ACTIVE PHARMACEUTICAL IN-
2 GREDIENT FACILITY.—Each person that
3 owns a facility which produces, or which is
4 pending review to produce, one or more ac-
5 tive pharmaceutical ingredients identified,
6 or intended to be identified, in at least one
7 generic drug submission that is pending or
8 approved or in a Type II active pharma-
9 ceutical ingredient drug master file ref-
10 erenced in such a generic drug submission,
11 shall be assessed an annual fee for each
12 such facility.

13 “(iii) FACILITIES PRODUCING BOTH
14 ACTIVE PHARMACEUTICAL INGREDIENTS
15 AND FINISHED DOSAGE FORMS.—Each
16 person that owns a facility identified, or
17 intended to be identified, in at least one
18 generic drug submission that is pending or
19 approved to produce both one or more fin-
20 ished dosage forms subject to clause (i)
21 and one or more active pharmaceutical in-
22 gredients subject to clause (ii) shall be
23 subject to fees under both such clauses for
24 that facility.

1 “(B) AMOUNT.—The amount of fees estab-
2 lished under subparagraph (A) shall be estab-
3 lished under subsection (d).

4 “(C) NOTICE.—

5 “(i) FISCAL YEAR 2013.—For fiscal
6 year 2013, the Secretary shall publish in
7 the Federal Register a notice announcing
8 the amount of the fees provided for in sub-
9 paragraph (A) within the timeframe speci-
10 fied in subsection (d)(1)(B).

11 “(ii) FISCAL YEARS 2014 THROUGH
12 2017.—Within the timeframe specified in
13 subsection (d)(2), the Secretary shall pub-
14 lish in the Federal Register the amount of
15 the fees under subparagraph (A) for such
16 fiscal year.

17 “(D) FEE DUE DATE.—

18 “(i) FISCAL YEAR 2013.—For fiscal
19 year 2013, the fees under subparagraph
20 (A) shall be due on the later of—

21 “(I) not later than 45 days after
22 the publication of the notice under
23 subparagraph (B); or

24 “(II) if an appropriations Act is
25 not enacted providing for the collec-

1 tion and obligation of fees under this
2 section by the date of the publication
3 of such notice, 30 days after the date
4 that such an appropriations Act is en-
5 acted.

6 “(ii) FISCAL YEARS 2014 THROUGH
7 2017.—For each of fiscal years 2014
8 through 2017, the fees under subpara-
9 graph (A) for such fiscal year shall be due
10 on the later of—

11 “(I) the first business day on or
12 after October 1 of each such year; or

13 “(II) the first business day after
14 the enactment of an appropriations
15 Act providing for the collection and
16 obligation of fees under this section
17 for such year.

18 “(5) DATE OF SUBMISSION.—For purposes of
19 this Act, a generic drug submission or Type II phar-
20 maceutical master file is deemed to be ‘submitted’ to
21 the Food and Drug Administration—

22 “(A) if it is submitted via a Food and
23 Drug Administration electronic gateway, on the
24 day when transmission to that electronic gate-
25 way is completed, except that a submission or

1 master file that arrives on a weekend, Federal
2 holiday, or day when the Food and Drug Ad-
3 ministration office that will review that submis-
4 sion is not otherwise open for business shall be
5 deemed to be submitted on the next day when
6 that office is open for business; or

7 “(B) if it is submitted in physical media
8 form, on the day it arrives at the appropriate
9 designated document room of the Food and
10 Drug Administration.

11 “(b) FEE REVENUE AMOUNTS.—

12 “(1) IN GENERAL.—

13 “(A) FISCAL YEAR 2013.—For fiscal year
14 2013, fees under subsection (a) shall be estab-
15 lished to generate a total estimated revenue
16 amount under such subsection of \$299,000,000.
17 Of that amount—

18 “(i) \$50,000,000 shall be generated
19 by the one-time backlog fee for generic
20 drug applications pending on October 1,
21 2012, established in subsection (a)(1); and

22 “(ii) \$249,000,000 shall be generated
23 by the fees under paragraphs (2) through
24 (4) of subsection (a).

1 “(B) FISCAL YEARS 2014 THROUGH 2017.—
2 For each of the fiscal years 2014 through 2017,
3 fees under paragraphs (2) through (4) of sub-
4 section (a) shall be established to generate a
5 total estimated revenue amount under such sub-
6 section that is equal to \$299,000,000, as ad-
7 justed pursuant to subsection (c).

8 “(2) TYPES OF FEES.—In establishing fees
9 under paragraph (1) to generate the revenue
10 amounts specified in paragraph (1)(A)(ii) for fiscal
11 year 2013 and paragraph (1)(B) for each of fiscal
12 years 2014 through 2017, such fees shall be derived
13 from the fees under paragraphs (2) through (4) of
14 subsection (a) as follows:

15 “(A) Six percent shall be derived from fees
16 under subsection (a)(2) (relating to drug mas-
17 ter files).

18 “(B) Twenty-four percent shall be derived
19 from fees under subsection (a)(3) (relating to
20 abbreviated new drug applications and supple-
21 ments). The amount of a fee for a prior ap-
22 proval supplement shall be half the amount of
23 the fee for an abbreviated new drug application.

24 “(C) Fifty-six percent shall be derived
25 from fees under subsection (a)(4)(A)(i) (relat-

1 ing to generic drug facilities). The amount of
2 the fee for a facility located outside the United
3 States and its territories and possessions shall
4 be not less than \$15,000 and not more than
5 \$30,000 higher than the amount of the fee for
6 a facility located in the United States and its
7 territories and possessions, as determined by
8 the Secretary on the basis of data concerning
9 the difference in cost between inspections of fa-
10 cilities located in the United States, including
11 its territories and possessions, and those located
12 outside of the United States and its territories
13 and possessions.

14 “(D) Fourteen percent shall be derived
15 from fees under subsection (a)(4)(A)(ii) (relat-
16 ing to active pharmaceutical ingredient facili-
17 ties). The amount of the fee for a facility lo-
18 cated outside the United States and its terri-
19 tories and possessions shall be not less than
20 \$15,000 and not more than \$30,000 higher
21 than the amount of the fee for a facility located
22 in the United States, including its territories
23 and possessions, as determined by the Secretary
24 on the basis of data concerning the difference
25 in cost between inspections of facilities located

1 in the United States and its territories and pos-
2 sessions and those located outside of the United
3 States and its territories and possessions.

4 “(c) ADJUSTMENTS.—

5 “(1) INFLATION ADJUSTMENT.—For fiscal year
6 2014 and subsequent fiscal years, the revenues es-
7 tablished in subsection (b) shall be adjusted by the
8 Secretary by notice, published in the Federal Reg-
9 ister, for a fiscal year, by an amount equal to the
10 sum of—

11 “(A) one;

12 “(B) the average annual percent change in
13 the cost, per full-time equivalent position of the
14 Food and Drug Administration, of all personnel
15 compensation and benefits paid with respect to
16 such positions for the first 3 years of the pre-
17 ceding 4 fiscal years multiplied by the propor-
18 tion of personnel compensation and benefits
19 costs to total costs of human generic drug ac-
20 tivities for the first 3 years of the preceding 4
21 fiscal years; and

22 “(C) the average annual percent change
23 that occurred in the Consumer Price Index for
24 urban consumers (Washington-Baltimore, DC-
25 MD-VA-WV; Not Seasonally Adjusted; All

1 items; Annual Index) for the first 3 years of the
2 preceding 4 years of available data multiplied
3 by the proportion of all costs other than per-
4 sonnel compensation and benefits costs to total
5 costs of human generic drug activities for the
6 first 3 years of the preceding 4 fiscal years.

7 The adjustment made each fiscal year under this
8 subsection shall be added on a compounded basis to
9 the sum of all adjustments made each fiscal year
10 after fiscal year 2013 under this subsection.

11 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
12 year 2017, the Secretary may, in addition to adjust-
13 ments under paragraph (1), further increase the fee
14 revenues and fees established in subsection (b) if
15 such an adjustment is necessary to provide for not
16 more than 3 months of operating reserves of carry-
17 over user fees for human generic drug activities for
18 the first 3 months of fiscal year 2018. Such fees
19 may only be used in fiscal year 2018. If such an ad-
20 justment is necessary, the rationale for the amount
21 of the increase shall be contained in the annual no-
22 tice establishing fee revenues and fees for fiscal year
23 2017. If the Secretary has carryover balances for
24 such activities in excess of 3 months of such oper-

1 ating reserves, the adjustment under this subpara-
2 graph shall not be made.

3 “(d) ANNUAL FEE SETTING.—

4 “(1) FISCAL YEAR 2013.—For fiscal year
5 2013—

6 “(A) the Secretary shall establish, by Octo-
7 ber 31, 2012, the one-time generic drug backlog
8 fee for generic drug applications pending on Oc-
9 tober 1, 2012, the drug master file fee, the ab-
10 breviated new drug application fee, and the
11 prior approval supplement fee under subsection
12 (a), based on the revenue amounts established
13 under subsection (b); and

14 “(B) the Secretary shall establish, not
15 later than 45 days after the date to comply
16 with the requirement for identification of facili-
17 ties in subsection (f)(2), the generic drug facil-
18 ity fee and active pharmaceutical ingredient fa-
19 cility fee under subsection (a) based on the rev-
20 enue amounts established under subsection (b).

21 “(2) FISCAL YEARS 2014 THROUGH 2017.—Not
22 more than 60 days before the first day of each of
23 fiscal years 2014 through 2017, the Secretary shall
24 establish the drug master file fee, the abbreviated
25 new drug application fee, the prior approval supple-

1 ment fee, the generic drug facility fee, and the active
2 pharmaceutical ingredient facility fee under sub-
3 section (a) for such fiscal year, based on the revenue
4 amounts established under subsection (b) and the
5 adjustments provided under subsection (c).

6 “(3) FEE FOR ACTIVE PHARMACEUTICAL IN-
7 GREDIENT INFORMATION NOT INCLUDED BY REF-
8 ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-
9 GREDIENT DRUG MASTER FILE.—In establishing the
10 fees under paragraphs (1) and (2), the amount of
11 the fee under subsection (a)(3)(F) shall be deter-
12 mined by multiplying—

13 “(A) the sum of—

14 “(i) the total number of such active
15 pharmaceutical ingredients in such submis-
16 sion; and

17 “(ii) for each such ingredient that is
18 manufactured at more than one such facil-
19 ity, the total number of such additional fa-
20 cilities; and

21 “(B) the amount equal to the drug master
22 file fee established in subsection (a)(2) for such
23 submission.

24 “(e) LIMIT.—The total amount of fees charged, as
25 adjusted under subsection (c), for a fiscal year may not

1 exceed the total costs for such fiscal year for the resources
2 allocated for human generic drug activities.

3 “(f) IDENTIFICATION OF FACILITIES.—

4 “(1) PUBLICATION OF NOTICE; DEADLINE FOR
5 COMPLIANCE.—Not later than October 1, 2012, the
6 Secretary shall publish in the Federal Register a no-
7 tice requiring each person that owns a facility de-
8 scribed in subsection (a)(4)(A), or a site or organi-
9 zation required to be identified by paragraph (4), to
10 submit to the Secretary information on the identity
11 of each such facility, site, or organization. The no-
12 tice required by this paragraph shall specify the type
13 of information to be submitted and the means and
14 format for submission of such information.

15 “(2) REQUIRED SUBMISSION OF FACILITY
16 IDENTIFICATION.—Each person that owns a facility
17 described in subsection (a)(4)(A) or a site or organi-
18 zation required to be identified by paragraph (4)
19 shall submit to the Secretary the information re-
20 quired under this subsection each year. Such infor-
21 mation shall—

22 “(A) for fiscal year 2013, be submitted not
23 later than 60 days after the publication of the
24 notice under paragraph (1); and

1 “(B) for each subsequent fiscal year, be
2 submitted, updated, or reconfirmed on or before
3 June 1 of the previous year.

4 “(3) CONTENTS OF NOTICE.—At a minimum,
5 the submission required by paragraph (2) shall in-
6 clude for each such facility—

7 “(A) identification of a facility identified or
8 intended to be identified in an approved or
9 pending generic drug submission;

10 “(B) whether the facility manufactures ac-
11 tive pharmaceutical ingredients or finished dos-
12 age forms, or both;

13 “(C) whether or not the facility is located
14 within the United States and its territories and
15 possessions;

16 “(D) whether the facility manufactures
17 positron emission tomography drugs solely, or
18 in addition to other drugs; and

19 “(E) whether the facility manufactures
20 drugs that are not generic drugs.

21 “(4) CERTAIN SITES AND ORGANIZATIONS.—

22 “(A) IN GENERAL.—Any person that owns
23 or operates a site or organization described in
24 subparagraph (B) shall submit to the Secretary

1 information concerning the ownership, name,
2 and address of the site or organization.

3 “(B) SITES AND ORGANIZATIONS.—A site
4 or organization is described in this subpara-
5 graph if it is identified in a generic drug sub-
6 mission and is—

7 “(i) a site in which a bioanalytical
8 study is conducted;

9 “(ii) a clinical research organization;

10 “(iii) a contract analytical testing site;

11 or

12 “(iv) a contract repackager site.

13 “(C) NOTICE.—The Secretary may, by no-
14 tice published in the Federal Register, specify
15 the means and format for submission of the in-
16 formation under subparagraph (A) and may
17 specify, as necessary for purposes of this sec-
18 tion, any additional information to be sub-
19 mitted.

20 “(D) INSPECTION AUTHORITY.—The Sec-
21 retary’s inspection authority under section
22 704(a)(1) shall extend to all such sites and or-
23 ganizations.

24 “(g) EFFECT OF FAILURE TO PAY FEES.—

1 “(1) GENERIC DRUG BACKLOG FEE.—Failure
2 to pay the fee under subsection (a)(1) shall result in
3 the Secretary placing the person that owns the ab-
4 breviated new drug application subject to that fee on
5 a publicly available arrears list, such that no new ab-
6 breviated new drug applications or supplement sub-
7 mitted on or after October 1, 2012, from that per-
8 son, or any affiliate of that person, will be received
9 within the meaning of section 505(j)(5)(A) until
10 such outstanding fee is paid.

11 “(2) DRUG MASTER FILE FEE.—

12 “(A) Failure to pay the fee under sub-
13 section (a)(2) within 20 calendar days after the
14 applicable due date under subparagraph (E) of
15 such subsection (as described in subsection
16 (a)(2)(D)(ii)(I)) shall result in the Type II ac-
17 tive pharmaceutical ingredient drug master file
18 not being deemed available for reference.

19 “(B)(i) Any generic drug submission sub-
20 mitted on or after October 1, 2012, that ref-
21 erences, by a letter of authorization, a Type II
22 active pharmaceutical ingredient drug master
23 file that has not been deemed available for ref-
24 erence shall not be received within the meaning

1 of section 505(j)(5)(A) unless the condition
2 specified in clause (ii) is met.

3 “(ii) The condition specified in this clause
4 is that the fee established under subsection
5 (a)(2) has been paid within 20 calendar days of
6 the Secretary providing the notification to the
7 sponsor of the abbreviated new drug application
8 or supplement of the failure of the owner of the
9 Type II active pharmaceutical ingredient drug
10 master file to pay the drug master file fee as
11 specified in subparagraph (C).

12 “(C)(i) If an abbreviated new drug applica-
13 tion or supplement to an abbreviated new drug
14 application references a Type II active pharma-
15 ceutical ingredient drug master file for which a
16 fee under subsection (a)(2)(A) has not been
17 paid by the applicable date under subsection
18 (a)(2)(E), the Secretary shall notify the sponsor
19 of the abbreviated new drug application or sup-
20 plement of the failure of the owner of the Type
21 II active pharmaceutical ingredient drug master
22 file to pay the applicable fee.

23 “(ii) If such fee is not paid within 20 cal-
24 endar days of the Secretary providing the noti-
25 fication, the abbreviated new drug application

1 or supplement to an abbreviated new drug ap-
2 plication shall not be received within the mean-
3 ing of 505(j)(5)(A).

4 “(3) ABBREVIATED NEW DRUG APPLICATION
5 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—
6 Failure to pay a fee under subparagraph (A) or (F)
7 of subsection (a)(3) within 20 calendar days of the
8 applicable due date under subparagraph (C) of such
9 subsection shall result in the abbreviated new drug
10 application or the prior approval supplement to an
11 abbreviated new drug application not being received
12 within the meaning of section 505(j)(5)(A) until
13 such outstanding fee is paid.

14 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
15 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

16 “(A) IN GENERAL.—Failure to pay the fee
17 under subsection (a)(4) within 20 calendar days
18 of the due date as specified in subparagraph
19 (D) of such subsection shall result in the fol-
20 lowing:

21 “(i) The Secretary shall place the fa-
22 cility on a publicly available arrears list,
23 such that no new abbreviated new drug ap-
24 plication or supplement submitted on or
25 after October 1, 2012, from the person

1 that is responsible for paying such fee, or
2 any affiliate of that person, will be received
3 within the meaning of section 505(j)(5)(A).

4 “(ii) Any new generic drug submission
5 submitted on or after October 1, 2012,
6 that references such a facility shall not be
7 received, within the meaning of section
8 505(j)(5)(A) if the outstanding facility fee
9 is not paid within 20 calendar days of the
10 Secretary providing the notification to the
11 sponsor of the failure of the owner of the
12 facility to pay the facility fee under sub-
13 section (a)(4)(C).

14 “(iii) All drugs or active pharma-
15 ceutical ingredients manufactured in such
16 a facility or containing an ingredient man-
17 ufactured in such a facility shall be deemed
18 misbranded under section 502(aa).

19 “(B) APPLICATION OF PENALTIES.—The
20 penalties under this paragraph shall apply until
21 the fee established by subsection (a)(4) is paid
22 or the facility is removed from all generic drug
23 submissions that refer to the facility.

24 “(C) NONRECEIVAL FOR NONPAYMENT.—

1 “(i) NOTICE.—If an abbreviated new
2 drug application or supplement to an ab-
3 breivated new drug application submitted
4 on or after October 1, 2012, references a
5 facility for which a facility fee has not been
6 paid by the applicable date under sub-
7 section (a)(4)(C), the Secretary shall notify
8 the sponsor of the generic drug submission
9 of the failure of the owner of the facility
10 to pay the facility fee.

11 “(ii) NONRECEIVAL.—If the facility
12 fee is not paid within 20 calendar days of
13 the Secretary providing the notification
14 under clause (i), the abbreviated new drug
15 application or supplement to an abbre-
16 viated new drug application shall not be re-
17 ceived within the meaning of section
18 505(j)(5)(A).

19 “(h) LIMITATIONS.—

20 “(1) IN GENERAL.—Fees under subsection (a)
21 shall be refunded for a fiscal year beginning after
22 fiscal year 2012, unless appropriations for salaries
23 and expenses of the Food and Drug Administration
24 for such fiscal year (excluding the amount of fees
25 appropriated for such fiscal year) are equal to or

1 greater than the amount of appropriations for the
2 salaries and expenses of the Food and Drug Admin-
3 istration for fiscal year 2009 (excluding the amount
4 of fees appropriated for such fiscal year) multiplied
5 by the adjustment factor (as defined in section
6 744A) applicable to the fiscal year involved.

7 “(2) AUTHORITY.—If the Secretary does not
8 assess fees under subsection (a) during any portion
9 of a fiscal year and if at a later date in such fiscal
10 year the Secretary may assess such fees, the Sec-
11 retary may assess and collect such fees, without any
12 modification in the rate, for Type II active pharma-
13 ceutical ingredient drug master files, abbreviated
14 new drug applications and prior approval supple-
15 ments, and generic drug facilities and active phar-
16 maceutical ingredient facilities at any time in such
17 fiscal year notwithstanding the provisions of sub-
18 section (a) relating to the date fees are to be paid.

19 “(i) CREDITING AND AVAILABILITY OF FEES.—

20 “(1) IN GENERAL.—Fees authorized under sub-
21 section (a) shall be collected and available for obliga-
22 tion only to the extent and in the amount provided
23 in advance in appropriations Acts, subject to para-
24 graph (2). Such fees are authorized to remain avail-
25 able until expended. Such sums as may be necessary

1 may be transferred from the Food and Drug Admin-
2 istration salaries and expenses appropriation account
3 without fiscal year limitation to such appropriation
4 account for salaries and expenses with such fiscal
5 year limitation. The sums transferred shall be avail-
6 able solely for human generic drug activities.

7 “(2) COLLECTIONS AND APPROPRIATION
8 ACTS.—

9 “(A) IN GENERAL.—The fees authorized
10 by this section—

11 “(i) subject to subparagraphs (C) and
12 (D), shall be collected and available in each
13 fiscal year in an amount not to exceed the
14 amount specified in appropriation Acts, or
15 otherwise made available for obligation for
16 such fiscal year; and

17 “(ii) shall be available for a fiscal year
18 beginning after fiscal year 2012 to defray
19 the costs of human generic drug activities
20 (including such costs for an additional
21 number of full-time equivalent positions in
22 the Department of Health and Human
23 Services to be engaged in such activities),
24 only if the Secretary allocates for such
25 purpose an amount for such fiscal year

1 (excluding amounts from fees collected
2 under this section) no less than
3 \$97,000,000 multiplied by the adjustment
4 factor defined in section 744A(3) applica-
5 ble to the fiscal year involved.

6 “(B) COMPLIANCE.—The Secretary shall
7 be considered to have met the requirements of
8 subparagraph (A)(ii) in any fiscal year if the
9 costs funded by appropriations and allocated for
10 human generic activities are not more than 10
11 percent below the level specified in such sub-
12 paragraph.

13 “(C) FEE COLLECTION DURING FIRST
14 PROGRAM YEAR.—Until the date of enactment
15 of an Act making appropriations through Sep-
16 tember 30, 2013 for the salaries and expenses
17 account of the Food and Drug Administration,
18 fees authorized by this section for fiscal year
19 2013, may be collected and shall be credited to
20 such account and remain available until ex-
21 pended.

22 “(D) PROVISION FOR EARLY PAYMENTS IN
23 SUBSEQUENT YEARS.—Payment of fees author-
24 ized under this section for a fiscal year (after
25 fiscal year 2013), prior to the due date for such

1 fees, may be accepted by the Secretary in ac-
2 cordance with authority provided in advance in
3 a prior year appropriations Act.

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—
5 For each of the fiscal years 2013 through 2017,
6 there is authorized to be appropriated for fees under
7 this section an amount equivalent to the total rev-
8 enue amount determined under subsection (b) for
9 the fiscal year, as adjusted under subsection (c), if
10 applicable, or as otherwise affected under paragraph
11 (2) of this subsection.

12 “(j) COLLECTION OF UNPAID FEES.—In any case
13 where the Secretary does not receive payment of a fee as-
14 sessed under subsection (a) within 30 calendar days after
15 it is due, such fee shall be treated as a claim of the United
16 States Government subject to subchapter II of chapter 37
17 of title 31, United States Code.

18 “(k) CONSTRUCTION.—This section may not be con-
19 strued to require that the number of full-time equivalent
20 positions in the Department of Health and Human Serv-
21 ices, for officers, employees, and advisory committees not
22 engaged in human generic drug activities, be reduced to
23 offset the number of officers, employees, and advisory
24 committees so engaged.

25 “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

1 “(1) EXEMPTION FROM FEES.—Submission of
2 an application for a positron emission tomography
3 drug or active pharmaceutical ingredient for a
4 positron emission tomography drug shall not require
5 the payment of any fee under this section. Facilities
6 that solely produce positron emission tomography
7 drugs shall not be required to pay a facility fee as
8 established in subsection (a)(4).

9 “(2) IDENTIFICATION REQUIREMENT.—Facili-
10 ties that produce positron emission tomography
11 drugs or active pharmaceutical ingredients of such
12 drugs are required to be identified pursuant to sub-
13 section (f).

14 “(m) DISPUTES CONCERNING FEES.—To qualify for
15 the return of a fee claimed to have been paid in error
16 under this section, a person shall submit to the Secretary
17 a written request justifying such return within 180 cal-
18 endar days after such fee was paid.

19 “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—
20 An abbreviated new drug application that is not consid-
21 ered to be received within the meaning of section
22 505(j)(5)(A) because of failure to pay an applicable fee
23 under this provision within the time period specified in
24 subsection (g) shall be deemed not to have been ‘substan-
25 tially complete’ on the date of its submission within the

1 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbrev-
2 viated new drug application that is not substantially com-
3 plete on the date of its submission solely because of failure
4 to pay an applicable fee under the preceding sentence shall
5 be deemed substantially complete and received within the
6 meaning of section 505(j)(5)(A) as of the date such appli-
7 cable fee is received.”.

8 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

9 Part 7 of subchapter C of chapter VII, as added by
10 section 302 of this Act, is amended by inserting after sec-
11 tion 744B the following:

12 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**
13 **MENTS.**

14 “(a) PERFORMANCE REPORT.—Beginning with fiscal
15 year 2013, not later than 120 days after the end of each
16 fiscal year for which fees are collected under this part,
17 the Secretary shall prepare and submit to the Committee
18 on Energy and Commerce of the House of Representatives
19 and the Committee on Health, Education, Labor, and
20 Pensions of the Senate a report concerning the progress
21 of the Food and Drug Administration in achieving the
22 goals identified in the letters described in section 301(b)
23 of the Generic Drug User Fee Amendments of 2012 dur-
24 ing such fiscal year and the future plans of the Food and
25 Drug Administration for meeting the goals.

1 “(b) FISCAL REPORT.—Beginning with fiscal year
2 2013, not later than 120 days after the end of each fiscal
3 year for which fees are collected under this part, the Sec-
4 retary shall prepare and submit to the Committee on En-
5 ergy and Commerce of the House of Representatives and
6 the Committee on Health, Education, Labor, and Pen-
7 sions of the Senate a report on the implementation of the
8 authority for such fees during such fiscal year and the
9 use, by the Food and Drug Administration, of the fees
10 collected for such fiscal year.

11 “(c) PUBLIC AVAILABILITY.—The Secretary shall
12 make the reports required under subsections (a) and (b)
13 available to the public on the Internet Web site of the
14 Food and Drug Administration.

15 “(d) REAUTHORIZATION.—

16 “(1) CONSULTATION.—In developing rec-
17 ommendations to present to the Congress with re-
18 spect to the goals, and plans for meeting the goals,
19 for human generic drug activities for the first 5 fis-
20 cal years after fiscal year 2017, and for the reau-
21 thORIZATION of this part for such fiscal years, the Sec-
22 retary shall consult with—

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

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

3 “(C) scientific and academic experts;

4 “(D) health care professionals;

5 “(E) representatives of patient and con-
6 sumer advocacy groups; and

7 “(F) the generic drug industry.

8 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
9 negotiations with the generic drug industry on the
10 reauthorization of this part, the Secretary shall—

11 “(A) publish a notice in the Federal Reg-
12 ister requesting public input on the reauthoriza-
13 tion;

14 “(B) hold a public meeting at which the
15 public may present its views on the reauthoriza-
16 tion, including specific suggestions for changes
17 to the goals referred to in subsection (a);

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

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

23 “(3) PERIODIC CONSULTATION.—Not less fre-
24 quently than once every month during negotiations
25 with the generic drug industry, the Secretary shall

1 hold discussions with representatives of patient and
2 consumer advocacy groups to continue discussions of
3 their views on the reauthorization and their sugges-
4 tions for changes to this part as expressed under
5 paragraph (2).

6 “(4) PUBLIC REVIEW OF RECOMMENDA-
7 TIONS.—After negotiations with the generic drug in-
8 dustry, the Secretary shall—

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

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

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

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

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

23 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
24 Not later than January 15, 2017, the Secretary
25 shall transmit to the Congress the revised rec-

1 ommendations under paragraph (4), a summary of
2 the views and comments received under such para-
3 graph, and any changes made to the recommenda-
4 tions in response to such views and comments.

5 “(6) MINUTES OF NEGOTIATION MEETINGS.—

6 “(A) PUBLIC AVAILABILITY.—Before pre-
7 senting the recommendations developed under
8 paragraphs (1) through (5) to the Congress, the
9 Secretary shall make publicly available, on the
10 Internet Web site of the Food and Drug Ad-
11 ministration, minutes of all negotiation meet-
12 ings conducted under this subsection between
13 the Food and Drug Administration and the ge-
14 neric drug industry.

15 “(B) CONTENT.—The minutes described
16 under subparagraph (A) shall summarize any
17 substantive proposal made by any party to the
18 negotiations as well as significant controversies
19 or differences of opinion during the negotiations
20 and their resolution.”.

21 **SEC. 304. SUNSET DATES.**

22 (a) AUTHORIZATION.—Sections 744A and 744B of
23 the Federal Food, Drug, and Cosmetic Act, as added by
24 section 302 of this Act, shall cease to be effective October
25 1, 2017.

1 (b) REPORTING REQUIREMENTS.—Section 744C of
2 the Federal Food, Drug, and Cosmetic Act, as added by
3 section 303 of this Act, shall cease to be effective January
4 31, 2018.

5 **SEC. 305. EFFECTIVE DATE.**

6 The amendments made by this title shall take effect
7 on October 1, 2012, or the date of the enactment of this
8 title, whichever is later, except that fees under section 302
9 shall be assessed for all human generic drug submissions
10 and Type II active pharmaceutical drug master files re-
11 ceived on or after October 1, 2012, regardless of the date
12 of enactment of this title.

13 **SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.**

14 Section 502 (21 U.S.C. 352) is amended by adding
15 at the end the following:

16 “(aa) If it is a drug, or an active pharmaceutical in-
17 gredient, and it was manufactured, prepared, propagated,
18 compounded, or processed in a facility for which fees have
19 not been paid as required by section 744A(a)(4) or for
20 which identifying information required by section 744B(f)
21 has not been submitted, or it contains an active pharma-
22 ceutical ingredient that was manufactured, prepared,
23 propagated, compounded, or processed in such a facility.”.

1 **SEC. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT**
2 **ACTIVITIES RELATED TO HUMAN GENERIC**
3 **DRUGS.**

4 Section 714, as added by section 208 of this Act, is
5 amended—

6 (1) by amending subsection (b) to read as fol-
7 lows:

8 “(b) **ACTIVITIES DESCRIBED.**—The activities de-
9 scribed in this subsection are—

10 “(1) activities under this Act related to the
11 process for the review of device applications (as de-
12 fined in section 737(8)); and

13 “(2) activities under this Act related to human
14 generic drug activities (as defined in section
15 744A).”; and

16 (2) by amending subsection (c) to read as fol-
17 lows:

18 “(c) **OBJECTIVES SPECIFIED.**—The objectives speci-
19 fied in this subsection are—

20 “(1) with respect to the activities under sub-
21 section (b)(1), the goals referred to in section
22 738A(a)(1); and

23 “(2) with respect to the activities under sub-
24 section (b)(2), the goals referred to in section
25 744C(a).”.

1 **SEC. 308. ADDITIONAL REPORTING REQUIREMENTS.**

2 Subchapter A of chapter VII (21 U.S.C. 371 et seq.),
3 as amended by section 208, is further amended by adding
4 at the end the following:

5 **“SEC. 715. REPORTING REQUIREMENTS.**

6 “(a) **GENERIC DRUGS.**—Beginning with fiscal year
7 2013 and ending after fiscal year 2017, not later than
8 120 days after the end of each fiscal year for which fees
9 are collected under part 7 of subchapter C, the Secretary
10 shall prepare and submit to the Committee on Health,
11 Education, Labor, and Pensions of the Senate and the
12 Committee on Energy and Commerce of the House of
13 Representatives a report concerning, for all applications
14 for approval of a generic drug under section 505(j),
15 amendments to such applications, and prior approval sup-
16 plements with respect to such applications filed in the pre-
17 vious fiscal year—

18 “(1) the number of such applications that met
19 the goals identified for purposes of part 7 of sub-
20 chapter C, in the letters from the Secretary of
21 Health and Human Services to the Chairman of the
22 Committee on Health, Education, Labor, and Pen-
23 sions of the Senate and the Chairman of the Com-
24 mittee on Energy and Commerce of the House of
25 Representatives, as set forth in the Congressional
26 Record;

1 “(2) the average total time to decision by the
2 Secretary for applications for approval of a generic
3 drug under section 505(j), amendments to such ap-
4 plications, and prior approval supplements with re-
5 spect to such applications filed in the previous fiscal
6 year, including the number of calendar days spent
7 during the review by the Food and Drug Adminis-
8 tration and the number of calendar days spent by
9 the sponsor responding to a complete response let-
10 ter;

11 “(3) the total number of applications under sec-
12 tion 505(j), amendments to such applications, and
13 prior approval supplements with respect to such ap-
14 plications that were pending with the Secretary for
15 more than 10 months on the date of enactment of
16 the Food and Drug Administration Safety and Inno-
17 vation Act; and

18 “(4) the number of applications described in
19 paragraph (3) on which the Food and Drug Admin-
20 istration took final regulatory action in the previous
21 fiscal year.”.

1 **TITLE IV—FEES RELATING TO**
2 **BIOSIMILAR BIOLOGICAL**
3 **PRODUCTS**

4 **SEC. 401. SHORT TITLE; FINDING.**

5 (a) **SHORT TITLE.**—This title may be cited as the
6 “Biosimilar User Fee Act of 2012”.

7 (b) **FINDING.**—The Congress finds that the fees au-
8 thorized by the amendments made in this title will be dedi-
9 cated to expediting the process for the review of biosimilar
10 biological product applications, including postmarket safe-
11 ty activities, as set forth in the goals identified for pur-
12 poses of part 8 of subchapter C of chapter VII of the Fed-
13 eral Food, Drug, and Cosmetic Act, in the letters from
14 the Secretary of Health and Human Services to the Chair-
15 man of the Committee on Health, Education, Labor, and
16 Pensions of the Senate and the Chairman of the Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives, as set forth in the Congressional Record.

19 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
20 **PRODUCTS.**

21 Subchapter C of chapter VII (21 U.S.C. 379f et seq.)
22 is amended by inserting after part 7, as added by title
23 III of this Act, the following:

1 **“PART 8—FEES RELATING TO BIOSIMILAR**

2 **BIOLOGICAL PRODUCTS**

3 **“SEC. 744G. DEFINITIONS.**

4 “For purposes of this part:

5 “(1) The term ‘adjustment factor’ applicable to
6 a fiscal year that is the Consumer Price Index for
7 all urban consumers (Washington-Baltimore, DC–
8 MD–VA–WV; Not Seasonally Adjusted; All items) of
9 the preceding fiscal year divided by such Index for
10 September 2011.

11 “(2) The term ‘affiliate’ means a business enti-
12 ty that has a relationship with a second business en-
13 tity if, directly or indirectly—

14 “(A) one business entity controls, or has
15 the power to control, the other business entity;
16 or

17 “(B) a third party controls, or has power
18 to control, both of the business entities.

19 “(3) The term ‘biosimilar biological product’
20 means a product for which a biosimilar biological
21 product application has been approved.

22 “(4)(A) Subject to subparagraph (B), the term
23 ‘biosimilar biological product application’ means an
24 application for licensure of a biological product
25 under section 351(k) of the Public Health Service
26 Act.

1 “(B) Such term does not include—

2 “(i) a supplement to such an application;

3 “(ii) an application filed under section
4 351(k) of the Public Health Service Act that
5 cites as the reference product a bovine blood
6 product for topical application licensed before
7 September 1, 1992, or a large volume paren-
8 teral drug product approved before such date;

9 “(iii) an application filed under section
10 351(k) of the Public Health Service Act with
11 respect to—

12 “(I) whole blood or a blood component
13 for transfusion;

14 “(II) an allergenic extract product;

15 “(III) an in vitro diagnostic biological
16 product; or

17 “(IV) a biological product for further
18 manufacturing use only; or

19 “(iv) an application for licensure under
20 section 351(k) of the Public Health Service Act
21 that is submitted by a State or Federal Govern-
22 ment entity for a product that is not distributed
23 commercially.

24 “(5) The term ‘biosimilar biological product de-
25 velopment meeting’ means any meeting, other than

1 a biosimilar initial advisory meeting, regarding the
2 content of a development program, including a pro-
3 posed design for, or data from, a study intended to
4 support a biosimilar biological product application.

5 “(6) The term ‘biosimilar biological product de-
6 velopment program’ means the program under this
7 part for expediting the process for the review of sub-
8 missions in connection with biosimilar biological
9 product development.

10 “(7)(A) The term ‘biosimilar biological product
11 establishment’ means a foreign or domestic place of
12 business—

13 “(i) that is at one general physical location
14 consisting of one or more buildings, all of which
15 are within 5 miles of each other; and

16 “(ii) at which one or more biosimilar bio-
17 logical products are manufactured in final dos-
18 age form.

19 “(B) For purposes of subparagraph (A)(ii), the
20 term ‘manufactured’ does not include packaging.

21 “(8) The term ‘biosimilar initial advisory meet-
22 ing’—

23 “(A) means a meeting, if requested, that is
24 limited to—

1 “(i) a general discussion regarding
2 whether licensure under section 351(k) of
3 the Public Health Service Act may be fea-
4 sible for a particular product; and

5 “(ii) if so, general advice on the ex-
6 pected content of the development pro-
7 gram; and

8 “(B) does not include any meeting that in-
9 volves substantive review of summary data or
10 full study reports.

11 “(9) The term ‘costs of resources allocated for
12 the process for the review of biosimilar biological
13 product applications’ means the expenses in connec-
14 tion with the process for the review of biosimilar bio-
15 logical product applications for—

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

22 “(B) management of information, and the
23 acquisition, maintenance, and repair of com-
24 puter resources;

1 “(C) leasing, maintenance, renovation, and
2 repair of facilities and acquisition, maintenance,
3 and repair of fixtures, furniture, scientific
4 equipment, and other necessary materials and
5 supplies; and

6 “(D) collecting fees under section 744H
7 and accounting for resources allocated for the
8 review of submissions in connection with bio-
9 similar biological product development, bio-
10 similar biological product applications, and sup-
11 plements.

12 “(10) The term ‘final dosage form’ means, with
13 respect to a biosimilar biological product, a finished
14 dosage form which is approved for administration to
15 a patient without substantial further manufacturing
16 (such as lyophilized products before reconstitution).

17 “(11) The term ‘financial hold’—

18 “(A) means an order issued by the Sec-
19 retary to prohibit the sponsor of a clinical in-
20 vestigation from continuing the investigation if
21 the Secretary determines that the investigation
22 is intended to support a biosimilar biological
23 product application and the sponsor has failed
24 to pay any fee for the product required under

1 subparagraph (A), (B), or (D) of section
2 744H(a)(1); and

3 “(B) does not mean that any of the bases
4 for a ‘clinical hold’ under section 505(i)(3) have
5 been determined by the Secretary to exist con-
6 cerning the investigation.

7 “(12) The term ‘person’ includes an affiliate of
8 such person.

9 “(13) The term ‘process for the review of bio-
10 similar biological product applications’ means the
11 following activities of the Secretary with respect to
12 the review of submissions in connection with bio-
13 similar biological product development, biosimilar bi-
14 ological product applications, and supplements:

15 “(A) The activities necessary for the re-
16 view of submissions in connection with bio-
17 similar biological product development, bio-
18 similar biological product applications, and sup-
19 plements.

20 “(B) Actions related to submissions in con-
21 nection with biosimilar biological product devel-
22 opment, the issuance of action letters which ap-
23 prove biosimilar biological product applications
24 or which set forth in detail the specific defi-
25 ciencies in such applications, and where appro-

1 appropriate, the actions necessary to place such ap-
2 plications in condition for approval.

3 “(C) The inspection of biosimilar biological
4 product establishments and other facilities un-
5 dertaken as part of the Secretary’s review of
6 pending biosimilar biological product applica-
7 tions and supplements.

8 “(D) Activities necessary for the release of
9 lots of biosimilar biological products under sec-
10 tion 351(k) of the Public Health Service Act.

11 “(E) Monitoring of research conducted in
12 connection with the review of biosimilar biologi-
13 cal product applications.

14 “(F) Postmarket safety activities with re-
15 spect to biologics approved under biosimilar bio-
16 logical product applications or supplements, in-
17 cluding the following activities:

18 “(i) Collecting, developing, and re-
19 viewing safety information on biosimilar bi-
20 ological products, including adverse-event
21 reports.

22 “(ii) Developing and using improved
23 adverse-event data-collection systems, in-
24 cluding information technology systems.

1 “(iii) Developing and using improved
2 analytical tools to assess potential safety
3 problems, including access to external data
4 bases.

5 “(iv) Implementing and enforcing sec-
6 tion 505(o) (relating to postapproval stud-
7 ies and clinical trials and labeling changes)
8 and section 505(p) (relating to risk evalua-
9 tion and mitigation strategies).

10 “(v) Carrying out section 505(k)(5)
11 (relating to adverse-event reports and
12 postmarket safety activities).

13 “(14) The term ‘supplement’ means a request
14 to the Secretary to approve a change in a biosimilar
15 biological product application which has been ap-
16 proved, including a supplement requesting that the
17 Secretary determine that the biosimilar biological
18 product meets the standards for interchangeability
19 described in section 351(k)(4) of the Public Health
20 Service Act.

21 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
22 **BIOLOGICAL PRODUCT FEES.**

23 “(a) TYPES OF FEES.—Beginning in fiscal year
24 2013, the Secretary shall assess and collect fees in accord-
25 ance with this section as follows:

1 “(1) BIOSIMILAR DEVELOPMENT PROGRAM
2 FEES.—

3 “(A) INITIAL BIOSIMILAR BIOLOGICAL
4 PRODUCT DEVELOPMENT FEE.—

5 “(i) IN GENERAL.—Each person that
6 submits to the Secretary a meeting request
7 described under clause (ii) or a clinical
8 protocol for an investigational new drug
9 protocol described under clause (iii) shall
10 pay for the product named in the meeting
11 request or the investigational new drug ap-
12 plication the initial biosimilar biological
13 product development fee established under
14 subsection (b)(1)(A).

15 “(ii) MEETING REQUEST.—The meet-
16 ing request described in this clause is a re-
17 quest for a biosimilar biological product
18 development meeting for a product.

19 “(iii) CLINICAL PROTOCOL FOR IND.—
20 A clinical protocol for an investigational
21 new drug protocol described in this clause
22 is a clinical protocol consistent with the
23 provisions of section 505(i), including any
24 regulations promulgated under section
25 505(i), (referred to in this section as ‘in-

1 vestigational new drug application’) de-
2 scribing an investigation that the Secretary
3 determines is intended to support a bio-
4 similar biological product application for a
5 product.

6 “(iv) DUE DATE.—The initial bio-
7 similar biological product development fee
8 shall be due by the earlier of the following:

9 “(I) Not later than 5 days after
10 the Secretary grants a request for a
11 biosimilar biological product develop-
12 ment meeting.

13 “(II) The date of submission of
14 an investigational new drug applica-
15 tion describing an investigation that
16 the Secretary determines is intended
17 to support a biosimilar biological
18 product application.

19 “(v) TRANSITION RULE.—Each per-
20 son that has submitted an investigational
21 new drug application prior to the date of
22 enactment of the Biosimilars User Fee Act
23 of 2012 shall pay the initial biosimilar bio-
24 logical product development fee by the ear-
25 lier of the following:

1 “(I) Not later than 60 days after
2 the date of the enactment of the
3 Biosimilars User Fee Act of 2012, if
4 the Secretary determines that the in-
5 vestigational new drug application de-
6 scribes an investigation that is in-
7 tended to support a biosimilar biologi-
8 cal product application.

9 “(II) Not later than 5 days after
10 the Secretary grants a request for a
11 biosimilar biological product develop-
12 ment meeting.

13 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
14 PRODUCT DEVELOPMENT FEE.—

15 “(i) IN GENERAL.—A person that
16 pays an initial biosimilar biological product
17 development fee for a product shall pay for
18 such product, beginning in the fiscal year
19 following the fiscal year in which the initial
20 biosimilar biological product development
21 fee was paid, an annual fee established
22 under subsection (b)(1)(B) for biosimilar
23 biological product development (referred to
24 in this section as ‘annual biosimilar bio-
25 logical product development fee’).

1 “(ii) DUE DATE.—The annual bio-
2 similar biological product development pro-
3 gram fee for each fiscal year will be due on
4 the later of—

5 “(I) the first business day on or
6 after October 1 of each such year; or

7 “(II) the first business day after
8 the enactment of an appropriations
9 Act providing for the collection and
10 obligation of fees for such year under
11 this section.

12 “(iii) EXCEPTION.—The annual bio-
13 similar development program fee for each
14 fiscal year will be due on the date specified
15 in clause (ii), unless the person has—

16 “(I) submitted a marketing appli-
17 cation for the biological product that
18 was accepted for filing; or

19 “(II) discontinued participation
20 in the biosimilar biological product de-
21 velopment program for the product
22 under subparagraph (C).

23 “(C) DISCONTINUATION OF FEE OBLIGA-
24 TION.—A person may discontinue participation
25 in the biosimilar biological product development

1 program for a product effective October 1 of a
2 fiscal year by, not later than August 1 of the
3 preceding fiscal year—

4 “(i) if no investigational new drug ap-
5 plication concerning the product has been
6 submitted, submitting to the Secretary a
7 written declaration that the person has no
8 present intention of further developing the
9 product as a biosimilar biological product;
10 or

11 “(ii) if an investigational new drug
12 application concerning the product has
13 been submitted, withdrawing the investiga-
14 tional new drug application in accordance
15 with part 312 of title 21, Code of Federal
16 Regulations (or any successor regulations).

17 “(D) REACTIVATION FEE.—

18 “(i) IN GENERAL.—A person that has
19 discontinued participation in the biosimilar
20 biological product development program for
21 a product under subparagraph (C) shall
22 pay a fee (referred to in this section as ‘re-
23 activation fee’) by the earlier of the fol-
24 lowing:

1 “(I) Not later than 5 days after
2 the Secretary grants a request for a
3 biosimilar biological product develop-
4 ment meeting for the product (after
5 the date on which such participation
6 was discontinued).

7 “(II) Upon the date of submis-
8 sion (after the date on which such
9 participation was discontinued) of an
10 investigational new drug application
11 describing an investigation that the
12 Secretary determines is intended to
13 support a biosimilar biological product
14 application for that product.

15 “(ii) APPLICATION OF ANNUAL
16 FEE.—A person that pays a reactivation
17 fee for a product shall pay for such prod-
18 uct, beginning in the next fiscal year, the
19 annual biosimilar biological product devel-
20 opment fee under subparagraph (B).

21 “(E) EFFECT OF FAILURE TO PAY BIO-
22 SIMILAR DEVELOPMENT PROGRAM FEES.—

23 “(i) NO BIOSIMILAR BIOLOGICAL
24 PRODUCT DEVELOPMENT MEETINGS.—If a
25 person has failed to pay an initial or an-

1 nual biosimilar biological product develop-
2 ment fee as required under subparagraph
3 (A) or (B), or a reactivation fee as re-
4 quired under subparagraph (D), the Sec-
5 retary shall not provide a biosimilar bio-
6 logical product development meeting relat-
7 ing to the product for which fees are owed.

8 “(ii) NO RECEIPT OF INVESTIGA-
9 TIONAL NEW DRUG APPLICATIONS.—Ex-
10 cept in extraordinary circumstances, the
11 Secretary shall not consider an investiga-
12 tional new drug application to have been
13 received under section 505(i)(2) if—

14 “(I) the Secretary determines
15 that the investigation is intended to
16 support a biosimilar biological product
17 application; and

18 “(II) the sponsor has failed to
19 pay an initial or annual biosimilar bio-
20 logical product development fee for
21 the product as required under sub-
22 paragraph (A) or (B), or a reactiva-
23 tion fee as required under subpara-
24 graph (D).

1 “(iii) FINANCIAL HOLD.—Notwith-
2 standing section 505(i)(2), except in ex-
3 traordinary circumstances, the Secretary
4 shall prohibit the sponsor of a clinical in-
5 vestigation from continuing the investiga-
6 tion if—

7 “(I) the Secretary determines
8 that the investigation is intended to
9 support a biosimilar biological product
10 application; and

11 “(II) the sponsor has failed to
12 pay an initial or annual biosimilar bio-
13 logical product development fee for
14 the product as required under sub-
15 paragraph (A) or (B), or a reactiva-
16 tion fee for the product as required
17 under subparagraph (D).

18 “(iv) NO ACCEPTANCE OF BIOSIMILAR
19 BIOLOGICAL PRODUCT APPLICATIONS OR
20 SUPPLEMENTS.—If a person has failed to
21 pay an initial or annual biosimilar biologi-
22 cal product development fee as required
23 under subparagraph (A) or (B), or a reac-
24 tivation fee as required under subpara-
25 graph (D), any biosimilar biological prod-

1 uct application or supplement submitted by
2 that person shall be considered incomplete
3 and shall not be accepted for filing by the
4 Secretary until all such fees owed by such
5 person have been paid.

6 “(F) LIMITS REGARDING BIOSIMILAR DE-
7 VELOPMENT PROGRAM FEES.—

8 “(i) NO REFUNDS.—The Secretary
9 shall not refund any initial or annual bio-
10 similar biological product development fee
11 paid under subparagraph (A) or (B), or
12 any reactivation fee paid under subpara-
13 graph (D).

14 “(ii) NO WAIVERS, EXEMPTIONS, OR
15 REDUCTIONS.—The Secretary shall not
16 grant a waiver, exemption, or reduction of
17 any initial or annual biosimilar biological
18 product development fee due or payable
19 under subparagraph (A) or (B), or any re-
20 activation fee due or payable under sub-
21 paragraph (D).

22 “(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
23 CATION AND SUPPLEMENT FEE.—

24 “(A) IN GENERAL.—Each person that sub-
25 mits, on or after October 1, 2012, a biosimilar

1 biological product application or a supplement
2 shall be subject to the following fees:

3 “(i) A fee for a biosimilar biological
4 product application that is equal to—

5 “(I) the amount of the fee estab-
6 lished under subsection (b)(1)(D) for
7 a biosimilar biological product applica-
8 tion for which clinical data (other
9 than comparative bioavailability stud-
10 ies) with respect to safety or effective-
11 ness are required for approval; minus

12 “(II) the cumulative amount of
13 fees paid, if any, under subparagraphs
14 (A), (B), and (D) of paragraph (1)
15 for the product that is the subject of
16 the application.

17 “(ii) A fee for a biosimilar biological
18 product application for which clinical data
19 (other than comparative bioavailability
20 studies) with respect to safety or effective-
21 ness are not required, that is equal to—

22 “(I) half of the amount of the fee
23 established under subsection (b)(1)(D)
24 for a biosimilar biological product ap-
25 plication; minus

1 “(II) the cumulative amount of
2 fees paid, if any, under subparagraphs
3 (A), (B), and (D) of paragraph (1)
4 for that product.

5 “(iii) A fee for a supplement for which
6 clinical data (other than comparative bio-
7 availability studies) with respect to safety
8 or effectiveness are required, that is equal
9 to half of the amount of the fee established
10 under subsection (b)(1)(D) for a biosimilar
11 biological product application.

12 “(B) REDUCTION IN FEES.—Notwith-
13 standing section 404 of the Biosimilars User
14 Fee Act of 2012, any person who pays a fee
15 under subparagraph (A), (B), or (D) of para-
16 graph (1) for a product before October 1, 2017,
17 but submits a biosimilar biological product ap-
18 plication for that product after such date, shall
19 be entitled to the reduction of any biosimilar bi-
20 ological product application fees that may be
21 assessed at the time when such biosimilar bio-
22 logical product application is submitted, by the
23 cumulative amount of fees paid under subpara-
24 graphs (A), (B), and (D) of paragraph (1) for
25 that product.

1 “(C) PAYMENT DUE DATE.—Any fee re-
2 quired by subparagraph (A) shall be due upon
3 submission of the application or supplement for
4 which such fee applies.

5 “(D) EXCEPTION FOR PREVIOUSLY FILED
6 APPLICATION OR SUPPLEMENT.—If a biosimilar
7 biological product application or supplement
8 was submitted by a person that paid the fee for
9 such application or supplement, was accepted
10 for filing, and was not approved or was with-
11 drawn (without a waiver), the submission of a
12 biosimilar biological product application or a
13 supplement for the same product by the same
14 person (or the person’s licensee, assignee, or
15 successor) shall not be subject to a fee under
16 subparagraph (A).

17 “(E) REFUND OF APPLICATION FEE IF AP-
18 PLICATION REFUSED FOR FILING OR WITH-
19 DRAWN BEFORE FILING.—The Secretary shall
20 refund 75 percent of the fee paid under this
21 paragraph for any application or supplement
22 which is refused for filing or withdrawn without
23 a waiver before filing.

24 “(F) FEES FOR APPLICATIONS PRE-
25 VIOUSLY REFUSED FOR FILING OR WITHDRAWN

1 BEFORE FILING.—A biosimilar biological prod-
2 uct application or supplement that was sub-
3 mitted but was refused for filing, or was with-
4 drawn before being accepted or refused for fil-
5 ing, shall be subject to the full fee under sub-
6 paragraph (A) upon being resubmitted or filed
7 over protest, unless the fee is waived under sub-
8 section (c).

9 “(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTAB-
10 LISHMENT FEE.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (E), each person that is named
13 as the applicant in a biosimilar biological prod-
14 uct application shall be assessed an annual fee
15 established under subsection (b)(1)(E) for each
16 biosimilar biological product establishment that
17 is listed in the approved biosimilar biological
18 product application as an establishment that
19 manufactures the biosimilar biological product
20 named in such application.

21 “(B) ASSESSMENT IN FISCAL YEARS.—The
22 establishment fee shall be assessed in each fis-
23 cal year for which the biosimilar biological prod-
24 uct named in the application is assessed a fee
25 under paragraph (4) unless the biosimilar bio-

1 logical product establishment listed in the appli-
2 cation does not engage in the manufacture of
3 the biosimilar biological product during such
4 fiscal year.

5 “(C) DUE DATE.—The establishment fee
6 for a fiscal year shall be due on the later of—

7 “(i) the first business day on or after
8 October 1 of such fiscal year; or

9 “(ii) the first business day after the
10 enactment of an appropriations Act pro-
11 viding for the collection and obligation of
12 fees for such fiscal year under this section.

13 “(D) APPLICATION TO ESTABLISHMENT.—

14 “(i) Each biosimilar biological product
15 establishment shall be assessed only one
16 fee per biosimilar biological product estab-
17 lishment, notwithstanding the number of
18 biosimilar biological products manufac-
19 tured at the establishment, subject to
20 clause (ii).

21 “(ii) In the event an establishment is
22 listed in a biosimilar biological product ap-
23 plication by more than one applicant, the
24 establishment fee for the fiscal year shall
25 be divided equally and assessed among the

1 applicants whose biosimilar biological prod-
2 ucts are manufactured by the establish-
3 ment during the fiscal year and assessed
4 biosimilar biological product fees under
5 paragraph (4).

6 “(E) EXCEPTION FOR NEW PRODUCTS.—
7 If, during the fiscal year, an applicant initiates
8 or causes to be initiated the manufacture of a
9 biosimilar biological product at an establish-
10 ment listed in its biosimilar biological product
11 application—

12 “(i) that did not manufacture the bio-
13 similar biological product in the previous
14 fiscal year; and

15 “(ii) for which the full biosimilar bio-
16 logical product establishment fee has been
17 assessed in the fiscal year at a time before
18 manufacture of the biosimilar biological
19 product was begun,

20 the applicant shall not be assessed a share of
21 the biosimilar biological product establishment
22 fee for the fiscal year in which the manufacture
23 of the product began.

24 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

1 “(A) IN GENERAL.—Each person who is
2 named as the applicant in a biosimilar biologi-
3 cal product application shall pay for each such
4 biosimilar biological product the annual fee es-
5 tablished under subsection (b)(1)(F).

6 “(B) DUE DATE.—The biosimilar biologi-
7 cal product fee for a fiscal year shall be due on
8 the later of—

9 “(i) the first business day on or after
10 October 1 of each such year; or

11 “(ii) the first business day after the
12 enactment of an appropriations Act pro-
13 viding for the collection and obligation of
14 fees for such year under this section.

15 “(C) ONE FEE PER PRODUCT PER YEAR.—
16 The biosimilar biological product fee shall be
17 paid only once for each product for each fiscal
18 year.

19 “(b) FEE SETTING AND AMOUNTS.—

20 “(1) IN GENERAL.—Subject to paragraph (2),
21 the Secretary shall, 60 days before the start of each
22 fiscal year that begins after September 30, 2012, es-
23 tablish, for the next fiscal year, the fees under sub-
24 section (a). Except as provided in subsection (c),
25 such fees shall be in the following amounts:

1 “(A) INITIAL BIOSIMILAR BIOLOGICAL
2 PRODUCT DEVELOPMENT FEE.—The initial bio-
3 similar biological product development fee under
4 subsection (a)(1)(A) for a fiscal year shall be
5 equal to 10 percent of the amount established
6 under section 736(c)(4) for a human drug ap-
7 plication described in section 736(a)(1)(A)(i)
8 for that fiscal year.

9 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
10 PRODUCT DEVELOPMENT FEE.—The annual
11 biosimilar biological product development fee
12 under subsection (a)(1)(B) for a fiscal year
13 shall be equal to 10 percent of the amount es-
14 tablished under section 736(c)(4) for a human
15 drug application described in section
16 736(a)(1)(A)(i) for that fiscal year.

17 “(C) REACTIVATION FEE.—The reactiva-
18 tion fee under subsection (a)(1)(D) for a fiscal
19 year shall be equal to 20 percent of the amount
20 of the fee established under section 736(c)(4)
21 for a human drug application described in sec-
22 tion 736(a)(1)(A)(i) for that fiscal year.

23 “(D) BIOSIMILAR BIOLOGICAL PRODUCT
24 APPLICATION FEE.—The biosimilar biological
25 product application fee under subsection (a)(2)

1 for a fiscal year shall be equal to the amount
2 established under section 736(c)(4) for a
3 human drug application described in section
4 736(a)(1)(A)(i) for that fiscal year.

5 “(E) BIOSIMILAR BIOLOGICAL PRODUCT
6 ESTABLISHMENT FEE.—The biosimilar biologi-
7 cal product establishment fee under subsection
8 (a)(3) for a fiscal year shall be equal to the
9 amount established under section 736(c)(4) for
10 a prescription drug establishment for that fiscal
11 year.

12 “(F) BIOSIMILAR BIOLOGICAL PRODUCT
13 FEE.—The biosimilar biological product fee
14 under subsection (a)(4) for a fiscal year shall be
15 equal to the amount established under section
16 736(c)(4) for a prescription drug product for
17 that fiscal year.

18 “(2) LIMIT.—The total amount of fees charged
19 for a fiscal year under this section may not exceed
20 the total amount for such fiscal year of the costs of
21 resources allocated for the process for the review of
22 biosimilar biological product applications.

23 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-
24 NESS.—

1 “(1) WAIVER OF APPLICATION FEE.—The Sec-
2 retary shall grant to a person who is named in a bio-
3 similar biological product application a waiver from
4 the application fee assessed to that person under
5 subsection (a)(2)(A) for the first biosimilar biological
6 product application that a small business or its
7 affiliate submits to the Secretary for review. After a
8 small business or its affiliate is granted such a waiver,
9 the small business or its affiliate shall pay—

10 “(A) application fees for all subsequent
11 biosimilar biological product applications sub-
12 mitted to the Secretary for review in the same
13 manner as an entity that is not a small busi-
14 ness; and

15 “(B) all supplement fees for all supple-
16 ments to biosimilar biological product applica-
17 tions submitted to the Secretary for review in
18 the same manner as an entity that is not a
19 small business.

20 “(2) CONSIDERATIONS.—In determining wheth-
21 er to grant a waiver of a fee under paragraph (1),
22 the Secretary shall consider only the circumstances
23 and assets of the applicant involved and any affiliate
24 of the applicant.

1 “(3) SMALL BUSINESS DEFINED.—In this sub-
2 section, the term ‘small business’ means an entity
3 that has fewer than 500 employees, including em-
4 ployees of affiliates, and does not have a drug prod-
5 uct that has been approved under a human drug ap-
6 plication (as defined in section 735) or a biosimilar
7 biological product application (as defined in section
8 744G(4)) and introduced or delivered for introduc-
9 tion into interstate commerce.

10 “(d) EFFECT OF FAILURE TO PAY FEES.—A bio-
11 similar biological product application or supplement sub-
12 mitted by a person subject to fees under subsection (a)
13 shall be considered incomplete and shall not be accepted
14 for filing by the Secretary until all fees owed by such per-
15 son have been paid.

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

17 “(1) IN GENERAL.—Subject to paragraph (2),
18 fees authorized under subsection (a) shall be col-
19 lected and available for obligation only to the extent
20 and in the amount provided in advance in appropria-
21 tions Acts. Such fees are authorized to remain avail-
22 able until expended. Such sums as may be necessary
23 may be transferred from the Food and Drug Admin-
24 istration salaries and expenses appropriation account
25 without fiscal year limitation to such appropriation

1 account for salaries and expenses with such fiscal
2 year limitation. The sums transferred shall be avail-
3 able solely for the process for the review of bio-
4 similar biological product applications.

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

7 “(A) IN GENERAL.—Subject to subpara-
8 graphs (C) and (D), the fees authorized by this
9 section shall be collected and available in each
10 fiscal year in an amount not to exceed the
11 amount specified in appropriation Acts, or oth-
12 erwise made available for obligation for such
13 fiscal year.

14 “(B) USE OF FEES AND LIMITATION.—
15 The fees authorized by this section shall be
16 available for a fiscal year beginning after fiscal
17 year 2012 to defray the costs of the process for
18 the review of biosimilar biological product appli-
19 cations (including such costs for an additional
20 number of full-time equivalent positions in the
21 Department of Health and Human Services to
22 be engaged in such process), only if the Sec-
23 retary allocates for such purpose an amount for
24 such fiscal year (excluding amounts from fees
25 collected under this section) no less than

1 \$20,000,000, multiplied by the adjustment fac-
2 tor applicable to the fiscal year involved.

3 “(C) FEE COLLECTION DURING FIRST
4 PROGRAM YEAR.—Until the date of enactment
5 of an Act making appropriations through Sep-
6 tember 30, 2013, for the salaries and expenses
7 account of the Food and Drug Administration,
8 fees authorized by this section for fiscal year
9 2013 may be collected and shall be credited to
10 such account and remain available until ex-
11 pended.

12 “(D) PROVISION FOR EARLY PAYMENTS IN
13 SUBSEQUENT YEARS.—Payment of fees author-
14 ized under this section for a fiscal year (after
15 fiscal year 2013), prior to the due date for such
16 fees, may be accepted by the Secretary in ac-
17 cordance with authority provided in advance in
18 a prior year appropriations Act.

19 “(3) AUTHORIZATION OF APPROPRIATIONS.—
20 For each of fiscal years 2013 through 2017, there
21 is authorized to be appropriated for fees under this
22 section an amount equivalent to the total amount of
23 fees assessed for such fiscal year under this section.

24 “(f) COLLECTION OF UNPAID FEES.—In any case
25 where the Secretary does not receive payment of a fee as-

1 sessed under subsection (a) within 30 days after it is due,
2 such fee shall be treated as a claim of the United States
3 Government subject to subchapter II of chapter 37 of title
4 31, United States Code.

5 “(g) WRITTEN REQUESTS FOR WAIVERS AND RE-
6 FUNDS.—To qualify for consideration for a waiver under
7 subsection (c), or for a refund of any fee collected in ac-
8 cordance with subsection (a)(2)(A), a person shall submit
9 to the Secretary a written request for such waiver or re-
10 fund not later than 180 days after such fee is due.

11 “(h) CONSTRUCTION.—This section may not be con-
12 strued to require that the number of full-time equivalent
13 positions in the Department of Health and Human Serv-
14 ices, for officers, employers, and advisory committees not
15 engaged in the process of the review of biosimilar biologi-
16 cal product applications, be reduced to offset the number
17 of officers, employees, and advisory committees so en-
18 gaged.”.

19 **SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.**

20 Part 8 of subchapter C of chapter VII, as added by
21 section 402, is further amended by inserting after section
22 744H the following:

1 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**
2 **MENTS.**

3 “(a) **PERFORMANCE REPORT.**—Beginning with fiscal
4 year 2013, not later than 120 days after the end of each
5 fiscal year for which fees are collected under this part,
6 the Secretary shall prepare and submit to the Committee
7 on Energy and Commerce of the House of Representatives
8 and the Committee on Health, Education, Labor, and
9 Pensions of the Senate a report concerning the progress
10 of the Food and Drug Administration in achieving the
11 goals identified in the letters described in section 401(b)
12 of the Biosimilar User Fee Act of 2012 during such fiscal
13 year and the future plans of the Food and Drug Adminis-
14 tration for meeting such goals. The report for a fiscal year
15 shall include information on all previous cohorts for which
16 the Secretary has not given a complete response on all
17 biosimilar biological product applications and supplements
18 in the cohort.

19 “(b) **FISCAL REPORT.**—Not later than 120 days after
20 the end of fiscal year 2013 and each subsequent fiscal year
21 for which fees are collected under this part, the Secretary
22 shall prepare and submit to the Committee on Energy and
23 Commerce of the House of Representatives and the Com-
24 mittee on Health, Education, Labor, and Pensions of the
25 Senate a report on the implementation of the authority
26 for such fees during such fiscal year and the use, by the

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

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

7 “(d) STUDY.—

8 “(1) IN GENERAL.—The Secretary shall con-
9 tract with an independent accounting or consulting
10 firm to study the workload volume and full costs as-
11 sociated with the process for the review of biosimilar
12 biological product applications.

13 “(2) INTERIM RESULTS.—Not later than June
14 1, 2015, the Secretary shall publish, for public com-
15 ment, interim results of the study described under
16 paragraph (1).

17 “(3) FINAL RESULTS.—Not later than Sep-
18 tember 30, 2016, the Secretary shall publish, for
19 public comment, the final results of the study de-
20 scribed under paragraph (1).

21 “(e) REAUTHORIZATION.—

22 “(1) CONSULTATION.—In developing rec-
23 ommendations to present to the Congress with re-
24 spect to the goals described in subsection (a), and
25 plans for meeting the goals, for the process for the

1 review of biosimilar biological product applications
2 for the first 5 fiscal years after fiscal year 2017, and
3 for the reauthorization of this part for such fiscal
4 years, the Secretary shall consult with—

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

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

9 “(C) scientific and academic experts;

10 “(D) health care professionals;

11 “(E) representatives of patient and con-
12 sumer advocacy groups; and

13 “(F) the regulated industry.

14 “(2) PUBLIC REVIEW OF RECOMMENDA-
15 TIONS.—After negotiations with the regulated indus-
16 try, the Secretary shall—

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

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

22 “(C) provide for a period of 30 days for
23 the public to provide written comments on such
24 recommendations;

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, 2017, the Secretary
9 shall transmit to the Congress the revised rec-
10 ommendations under paragraph (2), a summary of
11 the views and comments received under such para-
12 graph, and any changes made to the recommenda-
13 tions in response to such views and comments.”.

14 **SEC. 404. SUNSET DATES.**

15 (a) AUTHORIZATION.—Sections 744G and 744H of
16 the Federal Food, Drug, and Cosmetic Act, as added by
17 section 402 of this Act, shall cease to be effective October
18 1, 2017.

19 (b) REPORTING REQUIREMENTS.—Section 744I of
20 the Federal Food, Drug, and Cosmetic Act, as added by
21 section 403 of this Act, shall cease to be effective January
22 31, 2018.

1 **SEC. 405. EFFECTIVE DATE.**

2 (a) IN GENERAL.—Except as provided under sub-
3 section (b), the amendments made by this title shall take
4 effect on the later of—

5 (1) October 1, 2012; or

6 (2) the date of the enactment of this title.

7 (b) EXCEPTION.—Fees under part 8 of subchapter
8 C of chapter VII of the Federal Food, Drug, and Cosmetic
9 Act, as added by this title, shall be assessed for all bio-
10 similar biological product applications received on or after
11 October 1, 2012, regardless of the date of the enactment
12 of this title.

13 **SEC. 406. SAVINGS CLAUSE.**

14 Notwithstanding the amendments made by this title,
15 part 2 of subchapter C of chapter VII of the Federal Food,
16 Drug, and Cosmetic Act, as in effect on the day before
17 the date of the enactment of this title, shall continue to
18 be in effect with respect to human drug applications and
19 supplements (as defined in such part as of such day) that
20 were accepted by the Food and Drug Administration for
21 filing on or after October 1, 2007, but before October 1,
22 2012, with respect to assessing and collecting any fee re-
23 quired by such part for a fiscal year prior to fiscal year
24 2013.

1 **SEC. 407. CONFORMING AMENDMENT.**

2 Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amend-
3 ed by striking “or (k)”.

4 **SEC. 408. ADDITIONAL REPORTING REQUIREMENTS.**

5 Section 715, as added by section 308 of this Act, is
6 amended by adding at the end the following:

7 “(b) BIOSIMILAR BIOLOGICAL PRODUCTS.—

8 “(1) IN GENERAL.—Beginning with fiscal year
9 2014, not later than 120 days after the end of each
10 fiscal year for which fees are collected under part 8
11 of subchapter C, the Secretary shall prepare and
12 submit to the Committee on Health, Education,
13 Labor, and Pensions of the Senate and the Com-
14 mittee on Energy and Commerce of the House of
15 Representatives a report concerning—

16 “(A) the number of applications for ap-
17 proval filed under section 351(k) of the Public
18 Health Service Act; and

19 “(B) the percentage of applications de-
20 scribed in subparagraph (A) that were approved
21 by the Secretary.

22 “(2) ADDITIONAL INFORMATION.—As part of
23 the performance report described in paragraph (1),
24 the Secretary shall include an explanation of how the
25 Food and Drug Administration is managing the bio-
26 logical product review program to ensure that the

1 user fees collected under part 2 are not used to re-
2 view an application under section 351(k) of the Pub-
3 lic Health Service Act.”.

4 **TITLE V—PEDIATRIC DRUGS** 5 **AND DEVICES**

6 **SEC. 501. PERMANENCE.**

7 (a) PEDIATRIC STUDIES OF DRUGS.—Section 505A
8 (21 U.S.C. 355a) is amended by striking subsection (q)
9 (relating to a sunset).

10 (b) RESEARCH INTO PEDIATRIC USES FOR DRUGS
11 AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C.
12 355e) is amended—

13 (1) by striking subsection (m); and

14 (2) by redesignating subsection (n) as sub-
15 section (m).

16 **SEC. 502. WRITTEN REQUESTS.**

17 (a) IN GENERAL.—

18 (1) FEDERAL FOOD, DRUG, AND COSMETIC
19 ACT.—Subsection (h) of section 505A (21 U.S.C.
20 355a) is amended to read as follows:

21 “(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-
22 QUIREMENTS.—Exclusivity under this section shall only be
23 granted for the completion of a study or studies that are
24 the subject of a written request and for which reports are
25 submitted and accepted in accordance with subsection

1 (d)(3). Written requests under this section may consist of
2 a study or studies required under section 505B.”

3 (2) PUBLIC HEALTH SERVICE ACT.—Section
4 351(m)(1) of the Public Health Service Act (42
5 U.S.C. 262(m)(1)) is amended by striking “(f), (i),
6 (j), (k), (l), (p), and (q)” and inserting “(f), (h), (i),
7 (j), (k), (l), (n), and (p)”.

8 (b) NEONATES.—Subparagraph (A) of section
9 505A(d)(1) is amended by adding at the end the following:
10 “If a request under this subparagraph does not request
11 studies in neonates, such request shall include a statement
12 describing the rationale for not requesting studies in neo-
13 nates.”.

14 **SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COM-**
15 **MITTEE.**

16 Not later than 1 year after the date of enactment
17 of this Act, the Secretary of Health and Human Services
18 (referred to in this title as the “Secretary”) shall issue
19 internal standard operating procedures that provide for
20 the review by the internal review committee established
21 under section 505C of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 355d) of any significant modifica-
23 tions to initial pediatric study plans, agreed initial pedi-
24 atric study plans, and written requests under sections
25 505A and 505B of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 355a, 355c). Such internal standard oper-
2 ating procedures shall be made publicly available on the
3 Internet Web site of the Food and Drug Administration.

4 **SEC. 504. ACCESS TO DATA.**

5 Not later than 3 years after the date of enactment
6 of this Act, the Secretary shall make available to the pub-
7 lic, including through posting on the Internet Web site of
8 the Food and Drug Administration, the medical, statis-
9 tical, and clinical pharmacology reviews of, and cor-
10 responding written requests issued to an applicant, spon-
11 sor, or holder for, pediatric studies submitted between
12 January 4, 2002, and September 27, 2007, under sub-
13 section (b) or (c) of section 505A of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355a) for which 6
15 months of market exclusivity was granted and that re-
16 sulted in a labeling change. The Secretary shall make pub-
17 lic the information described in the preceding sentence in
18 a manner consistent with how the Secretary releases infor-
19 mation under section 505A(k) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 355a(k)).

21 **SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC**
22 **STUDIES.**

23 (a) EXTENSION OF DEADLINE FOR DEFERRED
24 STUDIES.—Section 505B (21 U.S.C. 355c) is amended—

25 (1) in subsection (a)(3)—

1 (A) by redesignating subparagraph (B) as
2 subparagraph (C);

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

5 “(B) DEFERRAL EXTENSION.—

6 “(i) IN GENERAL.—On the initiative
7 of the Secretary or at the request of the
8 applicant, the Secretary may grant an ex-
9 tension of a deferral approved under sub-
10 subparagraph (A) for submission of some or
11 all assessments required under paragraph
12 (1) if—

13 “(I) the Secretary determines
14 that the conditions described in sub-
15 clause (II) or (III) of subparagraph
16 (A)(i) continue to be met; and

17 “(II) the applicant submits a new
18 timeline under subparagraph
19 (A)(ii)(IV) and any significant up-
20 dates to the information required
21 under subparagraph (A)(ii).

22 “(ii) TIMING AND INFORMATION.—If
23 the deferral extension under this subpara-
24 graph is requested by the applicant, the
25 applicant shall submit the deferral exten-

1 sion request containing the information de-
2 scribed in this subparagraph not less than
3 90 days prior to the date that the deferral
4 would expire. The Secretary shall respond
5 to such request not later than 45 days
6 after the receipt of such letter. If the Sec-
7 retary grants such an extension, the speci-
8 fied date shall be the extended date. The
9 sponsor of the required assessment under
10 paragraph (1) shall not be issued a letter
11 described in subsection (d) unless the spec-
12 ified or extended date of submission for
13 such required studies has passed or if the
14 request for an extension is pending. For a
15 deferral that has expired prior to the date
16 of enactment of the Food and Drug Ad-
17 ministration Safety and Innovation Act or
18 that will expire prior to 270 days after the
19 date of enactment of such Act, a deferral
20 extension shall be requested by an appli-
21 cant not later than 180 days after the date
22 of enactment of such Act. The Secretary
23 shall respond to any such request as soon
24 as practicable, but not later than 1 year
25 after the date of enactment of such Act.

1 Nothing in this clause shall prevent the
2 Secretary from updating the status of a
3 study or studies publicly if components of
4 such study or studies are late or delayed.”;
5 and

6 (C) in subparagraph (C), as so redesign-
7 nated—

8 (i) in clause (i), by adding at the end
9 the following:

10 “(III) Projected completion date
11 for pediatric studies.

12 “(IV) The reason or reasons why
13 a deferral or deferral extension con-
14 tinues to be necessary.”; and

15 (ii) by amending clause (ii) to read as
16 follows:

17 “(ii) PUBLIC AVAILABILITY.—Not
18 later than 90 days after the submission to
19 the Secretary of the information submitted
20 through the annual review under clause (i),
21 the Secretary shall make available to the
22 public in an easily accessible manner, in-
23 cluding through the Internet Web site of
24 the Food and Drug Administration—

25 “(I) such information;

1 “(II) the name of the applicant
2 for the product subject to the assess-
3 ment;

4 “(III) the date on which the
5 product was approved; and

6 “(IV) the date of each deferral or
7 deferral extension under this para-
8 graph for the product.”; and

9 (2) in subsection (f)—

10 (A) in the subsection heading, by inserting
11 “DEFERRAL EXTENSIONS,” after “DEFER-
12 RALS,”;

13 (B) in paragraph (1), by inserting “, deferr-
14 al extension,” after “deferral”; and

15 (C) in paragraph (4)—

16 (i) in the paragraph heading, by in-
17 serting “DEFERRAL EXTENSIONS,” after
18 “DEFERRALS,”; and

19 (ii) by inserting “, deferral exten-
20 sions,” after “deferrals”.

21 (b) TRACKING OF EXTENSIONS; ANNUAL INFORMA-
22 TION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D))
23 is amended to read as follows:

24 “(D) aggregated on an annual basis—

1 “(i) the total number of deferrals and
2 deferral extensions requested and granted
3 under this section and, if granted, the rea-
4 sons for each such deferral or deferral ex-
5 tension;

6 “(ii) the timeline for completion of the
7 assessments; and

8 “(iii) the number of assessments com-
9 pleted and pending;”.

10 (c) ACTION ON FAILURE TO COMPLETE STUDIES.—

11 (1) ISSUANCE OF LETTER.—Subsection (d) of
12 section 505B (21 U.S.C. 355c) is amended to read
13 as follows:

14 “(d) SUBMISSION OF ASSESSMENTS.—If a person
15 fails to submit a required assessment described in sub-
16 section (a)(2), fails to meet the applicable requirements
17 in subsection (a)(3), or fails to submit a request for ap-
18 proval of a pediatric formulation described in subsection
19 (a) or (b), in accordance with applicable provisions of sub-
20 sections (a) and (b), the following shall apply:

21 “(1) Beginning 270 days after the date of en-
22 actment of the Food and Drug Administration Safe-
23 ty and Innovation Act, the Secretary shall issue a
24 non-compliance letter to such person informing them
25 of such failure to submit or meet the requirements

1 of the applicable subsection. Such letter shall require
2 the person to respond in writing within 45 calendar
3 days of issuance of such letter. Such response may
4 include the person's request for a deferral extension
5 if applicable. Such letter and the person's written re-
6 sponse to such letter shall be made publicly available
7 on the Internet Web site of the Food and Drug Ad-
8 ministration 60 calendar days after issuance, with
9 redactions for any trade secrets and confidential
10 commercial information. If the Secretary determines
11 that the letter was issued in error, the requirements
12 of this paragraph shall not apply.

13 “(2) The drug or biological product that is the
14 subject of an assessment described in subsection
15 (a)(2), applicable requirements in subsection (a)(3),
16 or request for approval of a pediatric formulation,
17 may be considered misbranded solely because of that
18 failure and subject to relevant enforcement action
19 (except that the drug or biological product shall not
20 be subject to action under section 303), but such
21 failure shall not be the basis for a proceeding—

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

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

4 (2) TRACKING OF LETTERS ISSUED.—Subpara-
5 graph (D) of section 505B(f)(6) (21 U.S.C.
6 355c(f)(6)), as amended by subsection (b), is further
7 amended—

8 (A) in clause (ii), by striking “; and” and
9 inserting a semicolon;

10 (B) in clause (iii), by adding “and” at the
11 end; and

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

13 “(iv) the number of postmarket non-
14 compliance letters issued pursuant to sub-
15 section (d), and the recipients of such let-
16 ters;”.

17 **SEC. 506. PEDIATRIC STUDY PLANS.**

18 (a) IN GENERAL.—Subsection (e) of section 505B
19 (21 U.S.C. 355c) is amended to read as follows:

20 “(e) PEDIATRIC STUDY PLANS.—

21 “(1) IN GENERAL.—An applicant subject to
22 subsection (a) shall submit to the Secretary an ini-
23 tial pediatric study plan prior to the submission of
24 the assessments described under subsection (a)(2).

25 “(2) TIMING; CONTENT; MEETING.—

1 “(A) TIMING.—An applicant shall submit
2 the initial pediatric plan under paragraph (1)—

3 “(i) before the date on which the ap-
4 plicant submits the assessments under sub-
5 section (a)(2); and

6 “(ii) not later than—

7 “(I) 60 calendar days after the
8 date of the end-of-Phase 2 meeting
9 (as such term is used in section
10 312.47 of title 21, Code of Federal
11 Regulations, or successor regulations);
12 or

13 “(II) such other time as may be
14 agreed upon between the Secretary
15 and the applicant.

16 Nothing in this section shall preclude the Sec-
17 retary from accepting the submission of an ini-
18 tial pediatric plan earlier than the date other-
19 wise applicable under this subparagraph.

20 “(B) CONTENT OF INITIAL PLAN.—The
21 initial pediatric study plan shall include—

22 “(i) an outline of the pediatric study
23 or studies that the applicant plans to con-
24 duct (including, to the extent practicable
25 study objectives and design, age groups,

1 relevant endpoints, and statistical ap-
2 proach);

3 “(ii) any request for a deferral, partial
4 waiver, or waiver under this section, if ap-
5 plicable, along with any supporting infor-
6 mation; and

7 “(iii) other information specified in
8 the regulations promulgated under para-
9 graph (7).

10 “(C) MEETING.—The Secretary—

11 “(i) shall meet with the applicant to
12 discuss the initial pediatric study plan as
13 soon as practicable, but not later than 90
14 calendar days after the receipt of such plan
15 under subparagraph (A);

16 “(ii) may determine that a written re-
17 sponse to the initial pediatric study plan is
18 sufficient to communicate comments on the
19 initial pediatric study plan, and that no
20 meeting is necessary; and

21 “(iii) if the Secretary determines that
22 no meeting is necessary, shall so notify the
23 applicant and provide written comments of
24 the Secretary as soon as practicable, but

1 not later than 90 calendar days after the
2 receipt of the initial pediatric study plan.

3 “(3) AGREED INITIAL PEDIATRIC STUDY
4 PLAN.—Not later than 90 calendar days following
5 the meeting under paragraph (2)(C)(i) or the receipt
6 of a written response from the Secretary under para-
7 graph (2)(C)(iii), the applicant shall document
8 agreement on the initial pediatric study plan in a
9 submission to the Secretary marked ‘Agreed Initial
10 Pediatric Study Plan’, and the Secretary shall con-
11 firm such agreement to the applicant in writing not
12 later than 30 calendar days of receipt of such agreed
13 initial pediatric study plan.

14 “(4) DEFERRAL AND WAIVER.—If the agreed
15 initial pediatric study plan contains a request from
16 the applicant for a deferral, partial waiver, or waiver
17 under this section, the written confirmation under
18 paragraph (3) shall include a recommendation from
19 the Secretary as to whether such request meets the
20 standards under paragraphs (3) or (4) of subsection
21 (a).

22 “(5) AMENDMENTS TO THE PLAN.—At the ini-
23 tiative of the Secretary or the applicant, the agreed
24 initial pediatric study plan may be amended at any
25 time. The requirements of paragraph (2)(C) shall

1 apply to any such proposed amendment in the same
2 manner and to the same extent as such require-
3 ments apply to an initial pediatric study plan under
4 paragraph (1). The requirements of paragraphs (3)
5 and (4) shall apply to any agreement resulting from
6 such proposed amendment in the same manner and
7 to the same extent as such requirements apply to an
8 agreed initial pediatric study plan.

9 “(6) INTERNAL COMMITTEE.—The Secretary
10 shall consult the internal committee under section
11 505C on the review of the initial pediatric study
12 plan, agreed initial pediatric plan, and any signifi-
13 cant amendments to such plans.

14 “(7) REQUIRED RULEMAKING.—Not later than
15 1 year after the date of enactment of the Food and
16 Drug Administration Safety and Innovation Act, the
17 Secretary shall promulgate proposed regulations and
18 issue guidance to implement the provisions of this
19 subsection.”.

20 (b) CONFORMING AMENDMENTS.—Section 505B (21
21 U.S.C. 355e) is amended—

22 (1) by amending subclause (II) of subsection
23 (a)(3)(A)(ii) to read as follows:

24 “(II) a pediatric study plan as
25 described in subsection (e);” and

1 (2) in subsection (f)—

2 (A) in the subsection heading, by striking
3 “PEDIATRIC PLANS,” and inserting “PEDI-
4 ATRIC STUDY PLANS,”;

5 (B) in paragraph (1), by striking “all pedi-
6 atric plans” and inserting “initial pediatric
7 study plans, agreed initial pediatric study
8 plans,”; and

9 (C) in paragraph (4)—

10 (i) in the paragraph heading, by strik-
11 ing “PEDIATRIC PLANS,” and inserting
12 “PEDIATRIC STUDY PLANS,”; and

13 (ii) by striking “pediatric plans” and
14 inserting “initial pediatric study plans,
15 agreed initial pediatric study plans,”.

16 (c) EFFECTIVE DATE.—

17 (1) IN GENERAL.—Subject to paragraph (2),
18 the amendments made by this section shall take ef-
19 fect 180 calendar days after the date of enactment
20 of this Act, irrespective of whether the Secretary has
21 promulgated final regulations to carry out such
22 amendments.

23 (2) RULE OF CONSTRUCTION.—Paragraph (1)
24 shall not be construed to affect the deadline for pro-
25 mulgation of proposed regulations under section

1 505B(e)(7) of the Federal Food, Drug, and Cos-
2 metic Act, as added by subsection (a) of this section.

3 **SEC. 507. REAUTHORIZATIONS.**

4 (a) PEDIATRIC ADVISORY COMMITTEE.—Section
5 14(d) of the Best Pharmaceuticals for Children Act (42
6 U.S.C. 284m note) is amended by striking “during the
7 five-year period beginning on the date of the enactment
8 of the Best Pharmaceuticals for Children Act of 2007”
9 and inserting “to carry out the advisory committee’s re-
10 sponsibilities under sections 505A, 505B, and 520(m) of
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 355a, 355c, and 360j(m))”.

13 (b) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
14 DRUGS ADVISORY COMMITTEE.—Section 15(a)(3) of the
15 Best Pharmaceuticals for Children Act (Public Law 107–
16 109), as amended by section 502(e) of the Food and Drug
17 Administration Amendments Act of 2007 (Public Law
18 110–85), is amended by striking “during the five-year pe-
19 riod beginning on the date of the enactment of the Best
20 Pharmaceuticals for Children Act of 2007” and inserting
21 “for the duration of the operation of the Oncologic Drugs
22 Advisory Committee”.

23 (c) HUMANITARIAN DEVICE EXEMPTION EXTEN-
24 SION.—Section 520(m)(6)(A)(iv) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is
2 amended by striking “2012” and inserting “2017”.

3 (d) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN
4 PHSA.—Section 409I(e)(1) of the Public Health Service
5 Act (42 U.S.C. 284m(e)(1)) is amended by striking “to
6 carry out this section” and all that follows through the
7 end of paragraph (1) and inserting “to carry out this sec-
8 tion, \$25,000,000 for each of fiscal years 2013 through
9 2017.”.

10 **SEC. 508. REPORT.**

11 (a) IN GENERAL.—Not later than four years after
12 the date of enactment of this Act and every five years
13 thereafter, the Secretary shall prepare and submit to the
14 Committee on Health, Education, Labor, and Pensions of
15 the Senate and the Committee on Energy and Commerce
16 of the House of Representatives, and make publicly avail-
17 able, including through posting on the Internet Web site
18 of the Food and Drug Administration, a report on the im-
19 plementation of sections 505A and 505B of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

21 (b) CONTENTS.—Each report under subsection (a)
22 shall include—

23 (1) an assessment of the effectiveness of sec-
24 tions 505A and 505B of the Federal Food, Drug,
25 and Cosmetic Act in improving information about

1 pediatric uses for approved drugs and biological
2 products, including the number and type of labeling
3 changes made since the date of enactment of this
4 Act and the importance of such uses in the improve-
5 ment of the health of children;

6 (2) the number of required studies under such
7 section 505B that have not met the initial deadline
8 provided under such section 505B, including—

9 (A) the number of deferrals and deferral
10 extensions granted and the reasons such exten-
11 sions were granted;

12 (B) the number of waivers and partial
13 waivers granted; and

14 (C) the number of letters issued under
15 subsection (d) of such section 505B;

16 (3) an assessment of the timeliness and effec-
17 tiveness of pediatric study planning since the date of
18 enactment of this Act, including the number of ini-
19 tial pediatric study plans not submitted in accord-
20 ance with the requirements of subsection (e) of such
21 section 505B and any resulting rulemaking;

22 (4) the number of written requests issued, ac-
23 cepted, and declined under such section 505A since
24 the date of enactment of this Act, and a listing of

1 any important gaps in pediatric information as a re-
2 sult of such declined requests;

3 (5) a description and current status of referrals
4 made under subsection (n) of such section 505A;

5 (6) an assessment of the effectiveness of study-
6 ing biological products in pediatric populations
7 under such sections 505A and 505B and section
8 409I of the Public Health Service Act (42 U.S.C.
9 284m);

10 (7)(A) the efforts made by the Secretary to in-
11 crease the number of studies conducted in the neo-
12 natal population (including efforts made to encour-
13 age the conduct of appropriate studies in neonates
14 by companies with products that have sufficient
15 safety and other information to make the conduct of
16 the studies ethical and safe); and

17 (B) the results of such efforts;

18 (8)(A) the number and importance of drugs and
19 biological products for children with cancer that are
20 being tested as a result of the programs under such
21 sections 505A and 505B and under section 409I of
22 the Public Health Service Act; and

23 (B) any recommendations for modifications to
24 such programs that would lead to new and better

1 therapies for children with cancer, including a de-
2 tailed rationale for each recommendation;

3 (9) any recommendations for modification to
4 such programs that would improve pediatric drug re-
5 search and increase pediatric labeling of drugs and
6 biological products;

7 (10) an assessment of the successes of and limi-
8 tations to studying drugs for rare diseases under
9 such sections 505A and 505B; and

10 (11) an assessment of the Secretary's efforts to
11 address the suggestions and options described in any
12 prior report issued by the Comptroller General, In-
13 stitute of Medicine, or the Secretary, and any subse-
14 quent reports, including recommendations therein,
15 regarding the topics addressed in the reports under
16 this section, including with respect to—

17 (A) improving public access to information
18 from pediatric studies conducted under such
19 sections 505A and 505B; and

20 (B) improving the timeliness of pediatric
21 studies and pediatric study planning under such
22 sections 505A and 505B.

23 (c) **STAKEHOLDER COMMENT.**—At least 180 days
24 prior to the submission of each report under subsection
25 (a), the Secretary shall consult with representatives of pa-

1 tient groups (including pediatric patient groups), con-
2 sumer groups, regulated industry, academia, and other in-
3 terested parties to obtain any recommendations or infor-
4 mation relevant to the report including suggestions for
5 modifications that would improve pediatric drug research
6 and pediatric labeling of drugs and biological products.

7 **SEC. 509. TECHNICAL AMENDMENTS.**

8 (a) **PEDIATRIC STUDIES OF DRUGS IN FFDCA.**—
9 Section 505A (21 U.S.C. 355a) is amended—

10 (1) in subsection (k)(2), by striking “subsection
11 (f)(3)(F)” and inserting “subsection (f)(6)(F)”;

12 (2) in subsection (l)—

13 (A) in paragraph (1)—

14 (i) in the paragraph heading, by strik-
15 ing “YEAR ONE” and inserting “FIRST 18-
16 MONTH PERIOD”; and

17 (ii) by striking “one-year” and insert-
18 ing “18-month”;

19 (B) in paragraph (2)—

20 (i) in the paragraph heading, by strik-
21 ing “YEARS” and inserting “PERIODS”;
22 and

23 (ii) by striking “one-year period” and
24 inserting “18-month period”;

1 (C) by redesignating paragraph (3) as
2 paragraph (4); and

3 (D) by inserting after paragraph (2) the
4 following:

5 “(3) PRESERVATION OF AUTHORITY.—Nothing
6 in this subsection shall prohibit the Office of Pedi-
7 atric Therapeutics from providing for the review of
8 adverse event reports by the Pediatric Advisory
9 Committee prior to the 18-month period referred to
10 in paragraph (1), if such review is necessary to en-
11 sure safe use of a drug in a pediatric population.”;

12 (3) in subsection (n)—

13 (A) in the subsection heading, by striking
14 “COMPLETED” and inserting “SUBMITTED”;
15 and

16 (B) in paragraph (1)—

17 (i) in the matter preceding subpara-
18 graph (A), by striking “have not been com-
19 pleted” and inserting “have not been sub-
20 mitted by the date specified in the written
21 request issued or if the applicant or holder
22 does not agree to the request”;

23 (ii) in subparagraph (A)—

24 (I) in the first sentence, by in-
25 serting “, or for which a period of ex-

1 clusivity eligible for extension under
2 subsection (b)(1) or (c)(1) of this sec-
3 tion or under subsection (m)(2) or
4 (m)(3) of section 351 of the Public
5 Health Service Act has not ended”
6 after “expired”; and

7 (II) by striking “Prior to” and
8 all that follows through the period at
9 the end; and

10 (iii) in subparagraph (B), by striking
11 “no listed patents or has 1 or more listed
12 patents that have expired,” and inserting
13 “no unexpired listed patents and for which
14 no unexpired periods of exclusivity eligible
15 for extension under subsection (b)(1) or
16 (c)(1) of this section or under subsection
17 (m)(2) or (m)(3) of section 351 of the
18 Public Health Service Act apply,”; and

19 (4) in subsection (o)(2), by amending subpara-
20 graph (B) to read as follows:

21 “(B) a statement of any appropriate pedi-
22 atric contraindications, warnings, precautions,
23 or other information that the Secretary con-
24 siders necessary to assure safe use.”.

1 (b) RESEARCH INTO PEDIATRIC USES FOR DRUGS
2 AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B
3 (21 U.S.C. 355e) is amended—

4 (1) in subsection (a)—

5 (A) in paragraph (1), in the matter before
6 subparagraph (A), by inserting “for a drug”
7 after “(or supplement to an application)”; and

8 (B) in paragraph (4)(C)—

9 (i) in the first sentence, by inserting
10 “partial” before “waiver is granted”; and

11 (ii) in the second sentence, by striking
12 “either a full or” and inserting “such a”;

13 (2) in subsection (b)(1), in the matter pre-
14 ceding subparagraph (A), by striking “After pro-
15 viding notice” and all that follows through “studies),
16 the” and inserting “The”;

17 (3) in subsection (g)—

18 (A) in paragraph (1)(A), by inserting
19 “that receives a priority review or 330 days
20 after the date of the submission of an applica-
21 tion or supplement that receives a standard re-
22 view” after “after the date of the submission of
23 the application or supplement”; and

1 (B) in paragraph (2), by striking “the
2 label of such product” and inserting “the label-
3 ing of such product”;

4 (4) in subsection (h)(1)—

5 (A) by inserting “an application (or sup-
6 plement to an application) that contains” after
7 “date of submission of”; and

8 (B) by inserting “if the application (or
9 supplement) receives a priority review, or not
10 later than 330 days after the date of submis-
11 sion of an application (or supplement to an ap-
12 plication) that contains a pediatric assessment
13 under this section, if the application (or supple-
14 ment) receives a standard review,” after “under
15 this section,”; and

16 (5) in subsection (i)—

17 (A) in paragraph (1)—

18 (i) in the paragraph heading, by strik-
19 ing “YEAR ONE” and inserting “FIRST 18-
20 MONTH PERIOD”; and

21 (ii) by striking “one-year” and insert-
22 ing “18-month”;

23 (B) in paragraph (2)—

1 (i) in the paragraph heading, by strik-
2 ing “YEARS” and inserting “PERIODS”;
3 and

4 (ii) by striking “one-year period” and
5 inserting “18-month period”;

6 (C) by redesignating paragraph (3) as
7 paragraph (4); and

8 (D) by inserting after paragraph (2) the
9 following:

10 “(3) PRESERVATION OF AUTHORITY.—Nothing
11 in this subsection shall prohibit the Office of Pedi-
12 atric Therapeutics from providing for the review of
13 adverse event reports by the Pediatric Advisory
14 Committee prior to the 18-month period referred to
15 in paragraph (1), if such review is necessary to en-
16 sure safe use of a drug in a pediatric population.”.

17 (c) INTERNAL COMMITTEE FOR REVIEW OF PEDI-
18 ATRIC PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL
19 EXTENSIONS, AND WAIVERS.—Section 505C (21 U.S.C.
20 355d) is amended—

21 (1) in the section heading, by inserting “**DE-**
22 **FERRAL EXTENSIONS,**” after “**DEFERRALS,**”;
23 and

24 (2) by inserting “neonatology,” after “pediatric
25 ethics,”.

1 (d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—

2 Section 409I(c) of the Public Health Service Act (42

3 U.S.C. 284m(c)) is amended—

4 (1) in paragraph (1)—

5 (A) in the matter preceding subparagraph

6 (A), by inserting “or section 351(m) of this

7 Act,” after “Cosmetic Act,”;

8 (B) in subparagraph (A)(i), by inserting

9 “or section 351(k) of this Act” after “Cosmetic

10 Act”; and

11 (C) by amending subparagraph (B) to read

12 as follows:

13 “(B) there remains no patent listed pursu-

14 ant to section 505(b)(1) of the Federal Food,

15 Drug, and Cosmetic Act, and every three-year

16 and five-year period referred to in subsection

17 (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv),

18 (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of

19 section 505 of the Federal Food, Drug, and

20 Cosmetic Act, or applicable twelve-year period

21 referred to in section 351(k)(7) of this Act, and

22 any seven-year period referred to in section 527

23 of the Federal Food, Drug, and Cosmetic Act

24 has ended for at least one form of the drug;

25 and”;

1 (2) in paragraph (2)—

2 (A) in the paragraph heading, by striking
3 “FOR DRUGS LACKING EXCLUSIVITY”;

4 (B) by striking “under section 505 of the
5 Federal Food, Drug, and Cosmetic Act”; and

6 (C) by striking “505A of such Act” and
7 inserting “505A of the Federal Food, Drug,
8 and Cosmetic Act or section 351(m) of this
9 Act”.

10 (e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
11 ADVISORY COMMITTEE.—Section 15(a) of the Best Phar-
12 maceuticals for Children Act (Public Law 107–109), as
13 amended by section 502(e) of the Food and Drug Admin-
14 istration Amendments Act of 2007 (Public Law 110–85),
15 is amended in paragraph (1)(D), by striking “section
16 505B(f)” and inserting “section 505C”.

17 (f) FOUNDATION OF NATIONAL INSTITUTES OF
18 HEALTH.—Section 499(c)(1)(C) of the Public Health
19 Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by
20 striking “for which the Secretary issues a certification in
21 the affirmative under section 505A(n)(1)(A) of the Fed-
22 eral Food, Drug, and Cosmetic Act”.

23 (g) APPLICATION; TRANSITION RULE.—

24 (1) APPLICATION.—Notwithstanding any provi-
25 sion of section 505A and 505B of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355a, 355c)
2 stating that a provision applies beginning on the
3 date of the enactment of the Best Pharmaceuticals
4 for Children Act of 2007 or the date of the enact-
5 ment of the Pediatric Research Equity Act of 2007,
6 any amendment made by this Act to such a provi-
7 sion applies beginning on the date of the enactment
8 of this Act.

9 (2) TRANSITIONAL RULE FOR ADVERSE EVENT
10 REPORTING.—With respect to a drug for which a la-
11 beling change described under section 505A(l)(1) or
12 505B(i)(1) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved
14 or made, respectively, during the one-year period
15 that ends on the day before the date of enactment
16 of this Act, the Secretary shall apply section 505A(l)
17 and section 505B(i), as applicable, to such drug, as
18 such sections were in effect on such day.

19 **SEC. 510. PEDIATRIC RARE DISEASES.**

20 (a) PUBLIC MEETING.—Not later than 18 months
21 after the date of enactment of this Act, the Secretary shall
22 hold at least one public meeting to discuss ways to encour-
23 age and accelerate the development of new therapies for
24 pediatric rare diseases.

1 (b) REPORT.—Not later than 180 days after the date
2 of the public meeting under subsection (a), the Secretary
3 shall issue a report that includes a strategic plan for en-
4 couraging and accelerating the development of new thera-
5 pies for treating pediatric rare diseases.

6 **SEC. 511. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.**

7 Section 6 of the Best Pharmaceuticals for Children
8 Act (21 U.S.C. 393a) is amended—

9 (1) in subsection (c)—

10 (A) in paragraph (1), by striking “and” at
11 the end;

12 (B) by redesignating paragraph (2) as
13 paragraph (4); and

14 (C) by inserting after paragraph (1) the
15 following:

16 “(2) subject to subsection (d), one or more ad-
17 ditional individuals with necessary expertise in a pe-
18 diatric subpopulation that is, as determined through
19 consideration of the reports and recommendations
20 issued by the Institute of Medicine and the Comp-
21 troller General of the United States, less likely to be
22 studied as a part of a written request issued under
23 section 505A of the Federal Food, Drug, and Cos-
24 metic Act or an assessment under section 505B of
25 such Act;

1 “(3) one or more additional individuals with ex-
2 pertise in pediatric epidemiology; and”;

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

4 “(d) NEONATOLOGY EXPERTISE.—For the 5-year pe-
5 riod beginning on the date of enactment of this subsection,
6 at least one of the individuals described in subsection
7 (c)(2) shall have expertise in neonatology.”.

8 **TITLE VI—MEDICAL DEVICE** 9 **REGULATORY IMPROVEMENTS**

10 **SEC. 601. INVESTIGATIONAL DEVICE EXEMPTIONS.**

11 Section 520(g) (21 U.S.C. 360j(g)) is amended—

12 (1) in paragraph (2)(B)(ii), by inserting “safety
13 or effectiveness” before “data obtained”; and

14 (2) in paragraph (4), by adding at the end the
15 following:

16 “(C) Consistent with paragraph (1), the Secretary
17 shall not disapprove an application under this subsection
18 because the Secretary determines that—

19 “(i) the investigation may not support a sub-
20 stantial equivalence or de novo classification deter-
21 mination or approval of the device;

22 “(ii) the investigation may not meet a require-
23 ment, including a data requirement, relating to the
24 approval or clearance of a device; or

1 “(iii) an additional or different investigation
2 may be necessary to support clearance or approval
3 of the device.”.

4 **SEC. 602. CLARIFICATION OF LEAST BURDENSOME STAND-**
5 **ARD.**

6 (a) **PREMARKET APPROVAL.**—Section 513(a)(3)(D)
7 (21 U.S.C. 360c(a)(3)(D)) is amended—

8 (1) by redesignating clause (iii) as clause (v);
9 and

10 (2) by inserting after clause (ii) the following:

11 “(iii) For purposes of clause (ii), the term ‘necessary’
12 means the minimum required information that would sup-
13 port a determination by the Secretary that an application
14 provides reasonable assurance of the effectiveness of the
15 device.

16 “(iv) Nothing in this subparagraph shall alter the cri-
17 teria for evaluating an application for premarket approval
18 of a device.”.

19 (b) **PREMARKET NOTIFICATION UNDER SECTION**
20 **510(k).**—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D))
21 is amended—

22 (1) by striking “(D) Whenever” and inserting
23 “(D)(i) Whenever”; and

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

1 “(ii) For purposes of clause (i), the term ‘necessary’
2 means the minimum required information that would sup-
3 port a determination of substantial equivalence between
4 a new device and a predicate device.

5 “(iii) Nothing in this subparagraph shall alter the
6 standard for determining substantial equivalence between
7 a new device and a predicate device.”.

8 **SEC. 603. AGENCY DOCUMENTATION AND REVIEW OF SIG-**
9 **NIFICANT DECISIONS.**

10 Chapter V is amended by inserting after section 517
11 (21 U.S.C. 360g) the following:

12 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**
13 **SIGNIFICANT DECISIONS REGARDING DE-**
14 **VICES.**

15 “(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-
16 CANT DECISIONS.—

17 “(1) IN GENERAL.—The Secretary shall provide
18 a substantive summary of the scientific and regu-
19 latory rationale for any significant decision of the
20 Center for Devices and Radiological Health regard-
21 ing submission or review of a report under section
22 510(k), an application under section 515, or an ap-
23 plication for an exemption under section 520(g), in-
24 cluding documentation of significant controversies or

1 differences of opinion and the resolution of such con-
2 troversies or differences of opinion.

3 “(2) PROVISION OF DOCUMENTATION.—Upon
4 request, the Secretary shall furnish such substantive
5 summary to the person who is seeking to submit, or
6 who has submitted, such report or application.

7 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

8 “(1) REQUEST FOR SUPERVISORY REVIEW OF
9 SIGNIFICANT DECISION.—Any person may request a
10 supervisory review of the significant decision de-
11 scribed in subsection (a)(1). Such review may be
12 conducted at the next supervisory level or higher
13 above the individual who made the significant deci-
14 sion.

15 “(2) SUBMISSION OF REQUEST.—A person re-
16 questing a supervisory review under paragraph (1)
17 shall submit such request to the Secretary not later
18 than 30 days after such decision and shall indicate
19 in the request whether such person seeks an in-per-
20 son meeting or a teleconference review.

21 “(3) TIMEFRAME.—

22 “(A) IN GENERAL.—Except as provided in
23 subparagraph (B), the Secretary shall schedule
24 an in-person or teleconference review, if so re-
25 quested, not later than 30 days after such re-

1 quest is made. The Secretary shall issue a deci-
2 sion to the person requesting a review under
3 this subsection not later than 45 days after the
4 request is made under paragraph (1), or, in the
5 case of a person who requests an in-person
6 meeting or teleconference, 30 days after such
7 meeting or teleconference.

8 “(B) EXCEPTION.—Subparagraph (A)
9 shall not apply in cases that are referred to ex-
10 perts outside of the Food and Drug Adminis-
11 tration.”.

12 **SEC. 604. DEVICE MODIFICATIONS REQUIRING PREMARKET**
13 **NOTIFICATION PRIOR TO MARKETING.**

14 Section 510(n) (21 U.S.C. 360(n)) is amended by—

15 (1) striking “(n) The Secretary” and inserting
16 “(n)(1) The Secretary”; and

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

18 “(2)(A) Not later than 18 months after the
19 date of enactment of this paragraph, the Secretary
20 shall submit to the Committee on Energy and Com-
21 merce of the House of Representatives and the Com-
22 mittee on Health, Education, Labor, and Pensions
23 of the Senate a report regarding when a premarket
24 notification under subsection (k) should be sub-
25 mitted for a modification or change to a legally mar-

1 keted device. The report shall include the Secretary's
2 interpretation of the following terms: 'could signifi-
3 cantly affect the safety or effectiveness of the de-
4 vice', 'a significant change or modification in design,
5 material, chemical composition, energy source, or
6 manufacturing process', and 'major change or modi-
7 fication in the intended use of the device'. The re-
8 port also shall discuss possible processes for industry
9 to use to determine whether a new submission under
10 subsection (k) is required and shall analyze how to
11 leverage existing quality system requirements to re-
12 duce premarket burden, facilitate continual device
13 improvement, and provide reasonable assurance of
14 safety and effectiveness of modified devices. In de-
15 veloping such report, the Secretary shall consider the
16 input of interested stakeholders.

17 “(B) The Secretary shall withdraw the Food
18 and Drug Administration draft guidance entitled
19 ‘Guidance for Industry and FDA Staff—510(k) De-
20 vice Modifications: Deciding When to Submit a
21 510(k) for a Change to an Existing Device’, dated
22 July 27, 2011, and shall not use this draft guidance
23 as part of, or for the basis of, any premarket review
24 or any compliance or enforcement decisions or ac-
25 tions. The Secretary shall not issue—

1 “(i) any draft guidance or proposed regula-
2 tion that addresses when to submit a premarket
3 notification submission for changes and modi-
4 fications made to a manufacturer’s previously
5 cleared device before the receipt by the Com-
6 mittee on Energy and Commerce of the House
7 of Representatives and the Committee on
8 Health, Education, Labor, and Pensions of the
9 Senate of the report required in subparagraph
10 (A); and

11 “(ii) any final guidance or regulation on
12 that topic for one year after date of receipt of
13 such report by the Committee on Energy and
14 Commerce of the House of Representatives and
15 the Committee on Health, Education, Labor,
16 and Pensions of the Senate.

17 “(C) The Food and Drug Administration guid-
18 ance entitled ‘Deciding When to Submit a 510(k) for
19 a Change to an Existing Device’, dated January 10,
20 1997, shall be in effect until the subsequent issuance
21 of guidance or promulgation, if appropriate, of a
22 regulation described in subparagraph (B), and the
23 Secretary shall interpret such guidance in a manner
24 that is consistent with the manner in which the Sec-
25 retary has interpreted such guidance since 1997.”.

1 **SEC. 605. PROGRAM TO IMPROVE THE DEVICE RECALL SYS-**
2 **TEM.**

3 Chapter V is amended by inserting after section 518
4 (21 U.S.C. 360h) the following:

5 **“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**
6 **SYSTEM.**

7 “(a) IN GENERAL.—The Secretary shall—

8 “(1) establish a program to routinely and sys-
9 tematically assess information relating to device re-
10 calls and use such information to proactively identify
11 strategies for mitigating health risks presented by
12 defective or unsafe devices;

13 “(2) clarify procedures for conducting device re-
14 call audit checks to improve the ability of investiga-
15 tors to perform those checks in a consistent manner;

16 “(3) develop detailed criteria for assessing
17 whether a person performing a device recall has per-
18 formed an effective correction or action plan for the
19 recall; and

20 “(4) document the basis for each termination
21 by the Food and Drug Administration of a device re-
22 call.

23 “(b) ASSESSMENT CONTENT.—The program estab-
24 lished under subsection (a)(1) shall, at a minimum, iden-
25 tify—

1 “(1) trends in the number and types of device
2 recalls;

3 “(2) devices that are most frequently the sub-
4 ject of a recall; and

5 “(3) underlying causes of device recalls.

6 “(c) TERMINATION OF RECALLS.—The Secretary
7 shall document the basis for the termination by the Food
8 and Drug Administration of a device recall.

9 “(d) DEFINITION.—In this section, the term ‘recall’
10 means—

11 “(1) the removal from the market of a device
12 pursuant to an order of the Secretary under sub-
13 section (b) or (e) of section 518; or

14 “(2) the correction or removal from the market
15 of a device at the initiative of the manufacturer or
16 importer of the device that is required to be reported
17 to the Secretary under section 519(g).”.

18 **SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE**

19 **EXEMPTIONS.**

20 Section 520(g) (21 U.S.C. 360j(g)) is amended by
21 adding at the end the following:

22 “(8)(A) At any time, the Secretary may prohibit the
23 sponsor of an investigation from conducting the investiga-
24 tion (referred to in this paragraph as a ‘clinical hold’) if
25 the Secretary makes a determination described in sub-

1 paragraph (B). The Secretary shall specify the basis for
2 the clinical hold, including the specific information avail-
3 able to the Secretary which served as the basis for such
4 clinical hold, and confirm such determination in writing.

5 “(B) For purposes of subparagraph (A), a determina-
6 tion described in this subparagraph with respect to a clin-
7 ical hold is a determination that—

8 “(i) the device involved represents an unreason-
9 able risk to the safety of the persons who are the
10 subjects of the clinical investigation, taking into ac-
11 count the qualifications of the clinical investigators,
12 information about the device, the design of the clin-
13 ical investigation, the condition for which the device
14 is to be investigated, and the health status of the
15 subjects involved; or

16 “(ii) the clinical hold should be issued for such
17 other reasons as the Secretary may by regulation es-
18 tablish.

19 “(C) Any written request to the Secretary from the
20 sponsor of an investigation that a clinical hold be removed
21 shall receive a decision, in writing and specifying the rea-
22 sons therefor, within 30 days after receipt of such request.
23 Any such request shall include sufficient information to
24 support the removal of such clinical hold.”.

1 **SEC. 607. MODIFICATION OF DE NOVO APPLICATION PROC-**
2 **ESS.**

3 (a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.
4 360c(f)(2)) is amended—

5 (1) by inserting “(i)” after “(2)(A)”;

6 (2) in subparagraph (A)(i), as so designated by
7 paragraph (1), by striking “under the criteria set
8 forth” and all that follows through the end of sub-
9 paragraph (A) and inserting a period;

10 (3) by adding at the end of subparagraph (A)
11 the following:

12 “(ii) In lieu of submitting a report under section
13 510(k) and submitting a request for classification under
14 clause (i) for a device, if a person determines there is no
15 legally marketed device upon which to base a determina-
16 tion of substantial equivalence (as defined in subsection
17 (i)), a person may submit a request under this clause for
18 the Secretary to classify the device.

19 “(iii) Upon receipt of a request under clause (i) or
20 (ii), the Secretary shall classify the device subject to the
21 request under the criteria set forth in subparagraphs (A)
22 through (C) of subsection (a)(1) within 120 days.

23 “(iv) Notwithstanding clause (iii), the Secretary may
24 decline to undertake a classification request submitted
25 under clause (ii) if the Secretary identifies a legally mar-
26 keted device that could provide a reasonable basis for re-

1 view of substantial equivalence under paragraph (1), or
2 when the Secretary determines that the device submitted
3 is not of low-moderate risk or that general controls would
4 be inadequate to control the risks and special controls to
5 mitigate the risks cannot be developed.

6 “(v) The person submitting the request for classifica-
7 tion under this subparagraph may recommend to the Sec-
8 retary a classification for the device and shall, if recom-
9 mending classification in class II, include in the request
10 an initial draft proposal for applicable special controls, as
11 described in subsection (a)(1)(B), that are necessary, in
12 conjunction with general controls, to provide reasonable
13 assurance of safety and effectiveness and a description of
14 how the special controls provide such assurance. Any such
15 request shall describe the device and provide detailed in-
16 formation and reasons for the recommended classifica-
17 tion.”; and

18 (4) in subparagraph (B), by striking “Not later
19 than 60 days after the date of the submission of the
20 request under subparagraph (A), the Secretary” and
21 inserting “The Secretary”.

22 (b) CONFORMING AMENDMENTS.—Section 513(f)
23 (21 U.S.C. 360c(f)) is amended in paragraph (1)—

24 (1) in subparagraph (A), by striking “, or” at
25 the end and inserting a semicolon;

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

3 (3) by inserting after subparagraph (B) the fol-
4 lowing:

5 “(C) the device is classified pursuant to a re-
6 quest submitted under paragraph (2).”.

7 **SEC. 608. RECLASSIFICATION PROCEDURES.**

8 (a) CLASSIFICATION CHANGES.—

9 (1) IN GENERAL.—Section 513(e)(1) (21
10 U.S.C. 360c(e)(1)) is amended to read as follows:

11 “(e)(1)(A)(i) Based on new information respecting a
12 device, the Secretary may, upon the initiative of the Sec-
13 retary or upon petition of an interested person, change
14 the classification of such device, and revoke, on account
15 of the change in classification, any regulation or require-
16 ment in effect under section 514 or 515 with respect to
17 such device, by administrative order published in the Fed-
18 eral Register following publication of a proposed reclassi-
19 fication order in the Federal Register, a meeting of a de-
20 vice classification panel described in subsection (b), and
21 consideration of comments to a public docket, notwith-
22 standing subchapter II of chapter 5 of title 5, United
23 States Code. The proposed reclassification order published
24 in the Federal Register shall set forth the proposed reclas-
25 sification, and a substantive summary of the valid sci-

1 entific evidence concerning the proposed reclassification,
2 including—

3 “(I) the public health benefit of the use of the
4 device, and the nature and, if known, incidence of
5 the risk of the device;

6 “(II) in the case of a reclassification from class
7 II to class III, why general controls pursuant to sub-
8 section (a)(1)(A) and special controls pursuant to
9 subsection (a)(1)(B) together are not sufficient to
10 provide a reasonable assurance of safety and effec-
11 tiveness for such device; and

12 “(III) in the case of reclassification from class
13 III to class II, why general controls pursuant to sub-
14 section (a)(1)(A) and special controls pursuant to
15 subsection (a)(1)(B) together are sufficient to pro-
16 vide a reasonable assurance of safety and effective-
17 ness for such device.

18 “(ii) An order under this subsection changing the
19 classification of a device from class III to class II may
20 provide that such classification shall not take effect until
21 the effective date of a performance standard established
22 under section 514 for such device.

23 “(B) Authority to issue such administrative order
24 shall not be delegated below the Director of the Center

1 for Devices and Radiological Health, acting in consulta-
2 tion with the Commissioner.”.

3 (2) TECHNICAL AND CONFORMING AMEND-
4 MENTS.—

5 (A) Section 513(e)(2) (21 U.S.C.
6 360c(e)(2)) is amended by striking “regulation
7 promulgated” and inserting “an order issued”.

8 (B) Section 514(a)(1) (21 U.S.C.
9 360d(a)(1)) is amended by striking “under a
10 regulation under section 513(e) but such regu-
11 lation” and inserting “under an administrative
12 order under section 513(e) (or a regulation pro-
13 mulgated under such section prior to the date
14 of enactment of the Food and Drug Adminis-
15 tration Safety and Innovation Act) but such
16 order (or regulation)”.

17 (C) Section 517(a)(1) (21 U.S.C.
18 360g(a)(1)) is amended by striking “or chang-
19 ing the classification of a device to class I” and
20 inserting “, an administrative order changing
21 the classification of a device to class I”.

22 (3) DEVICES RECLASSIFIED PRIOR TO THE
23 DATE OF ENACTMENT OF THIS ACT.—

24 (A) IN GENERAL.—The amendments made
25 by this subsection shall have no effect on a reg-

1 ulation promulgated with respect to the classi-
2 fication of a device under section 513(e) of the
3 Federal Food, Drug, and Cosmetic Act prior to
4 the date of enactment of this Act.

5 (B) APPLICABILITY OF OTHER PROVI-
6 SIONS.—In the case of a device reclassified
7 under section 513(e) of the Federal Food,
8 Drug, and Cosmetic Act by regulation prior to
9 the date of enactment of this Act, section
10 517(a)(1) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 360g(a)(1)) shall apply to
12 such regulation promulgated under section
13 513(e) of such Act with respect to such device
14 in the same manner such section 517(a)(1) ap-
15 plies to an administrative order issued with re-
16 spect to a device reclassified after the date of
17 enactment of this Act.

18 (b) DEVICES MARKETED BEFORE MAY 28, 1976.—

19 (1) PREMARKET APPROVAL.—Section 515 (21
20 U.S.C. 360e) is amended—

21 (A) in subsection (a), by striking “regula-
22 tion promulgated under subsection (b)” and in-
23 serting “an order issued under subsection (b)
24 (or a regulation promulgated under such sub-
25 section prior to the date of enactment of the

1 Food and Drug Administration Safety and In-
2 novation Act)”;

3 (B) in subsection (b)—

4 (i) in paragraph (1)—

5 (I) in the heading, by striking
6 “Regulation” and inserting “Order”;
7 and

8 (II) in the matter following sub-
9 paragraph (B)—

10 (aa) by striking “by regula-
11 tion, promulgated in accordance
12 with this subsection” and insert-
13 ing “by administrative order fol-
14 lowing publication of a proposed
15 order in the Federal Register, a
16 meeting of a device classification
17 panel described in section 513(b),
18 and consideration of comments
19 from all affected stakeholders, in-
20 cluding patients, payors, and pro-
21 viders, notwithstanding sub-
22 chapter II of chapter 5 of title 5,
23 United States Code”; and

24 (bb) by adding at the end
25 the following: “Authority to issue

1 such administrative order shall
2 not be delegated below the Direc-
3 tor of the Center for Devices and
4 Radiological Health, acting in
5 consultation with the Commis-
6 sioner.”;

7 (ii) in paragraph (2)—

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

10 (II) in subparagraph (A)—

11 (aa) by striking “(2)(A) A
12 proceeding for the promulgation
13 of a regulation under paragraph
14 (1) respecting a device shall be
15 initiated by the publication in the
16 Federal Register of a notice of
17 proposed rulemaking. Such notice
18 shall contain—” and inserting
19 “(2) A proposed order required
20 under paragraph (1) shall con-
21 tain—”;

22 (bb) by redesignating
23 clauses (i) through (iv) as sub-
24 paragraphs (A) through (D), re-
25 spectively;

1 (cc) in subparagraph (A), as
2 so redesignated, by striking “reg-
3 ulation” and inserting “order”;
4 and

5 (dd) in subparagraph (C), as
6 so redesignated, by striking “reg-
7 ulation” and inserting “order”;

8 (iii) in paragraph (3)—

9 (I) by striking “proposed regula-
10 tion” each place such term appears
11 and inserting “proposed order”;

12 (II) by striking “paragraph (2)
13 and after” and inserting “paragraph
14 (2),”;

15 (III) by inserting “and a meeting
16 of a device classification panel de-
17 scribed in section 513(b),” after “such
18 proposed regulation and findings,”;

19 (IV) by striking “(A) promulgate
20 such regulation” and inserting “(A)
21 issue an administrative order under
22 paragraph (1)”;

23 (V) by striking “paragraph
24 (2)(A)(ii)” and inserting “paragraph
25 (2)(B)”;

1 (VI) by striking “promulgation of
2 the regulation” and inserting
3 “issuance of the administrative
4 order”; and
5 (iv) by striking paragraph (4); and
6 (C) in subsection (i)—
7 (i) in paragraph (2)—
8 (I) in the matter preceding sub-
9 paragraph (A)—
10 (aa) by striking “December
11 1, 1995” and inserting “the date
12 that is 2 years after the date of
13 enactment of the Food and Drug
14 Administration Safety and Inno-
15 vation Act”; and
16 (bb) by striking “publish a
17 regulation in the Federal Reg-
18 ister” and inserting “issue an ad-
19 ministrative order following pub-
20 lication of a proposed order in
21 the Federal Register, a meeting
22 of a device classification panel
23 described in section 513(b), and
24 consideration of comments from
25 all affected stakeholders, includ-

1 ing patients, payors, and pro-
2 viders, notwithstanding sub-
3 chapter II of chapter 5 of title 5,
4 United States Code,”;

5 (II) in subparagraph (B), by
6 striking “final regulation has been
7 promulgated under section 515(b)”
8 and inserting “administrative order
9 has been issued under subsection (b)
10 (or no regulation has been promul-
11 gated under such subsection prior to
12 the date of enactment of the Food
13 and Drug Administration Safety and
14 Innovation Act)”;

15 (III) in the matter following sub-
16 paragraph (B), by striking “regula-
17 tion requires” and inserting “adminis-
18 trative order issued under this para-
19 graph requires”; and

20 (IV) by striking the third and
21 fourth sentences; and

22 (ii) in paragraph (3)—

23 (I) by striking “regulation requir-
24 ing” each place such term appears
25 and inserting “order requiring”; and

1 (II) by striking “promulgation of
2 a section 515(b) regulation” and in-
3 serting “issuance of an administrative
4 order under subsection (b)”.

5 (2) TECHNICAL AND CONFORMING AMEND-
6 MENTS.—Section 501(f) (21 U.S.C. 351(f)) is
7 amended—

8 (A) in subparagraph (1)(A)—

9 (i) in subclause (i), by striking “a reg-
10 ulation promulgated” and inserting “an
11 order issued”; and

12 (ii) in subclause (ii), by striking “pro-
13 mulgation of such regulation” and insert-
14 ing “issuance of such order”;

15 (B) in subparagraph (2)(B)—

16 (i) by striking “a regulation promul-
17 gated” and inserting “an order issued”;
18 and

19 (ii) by striking “promulgation of such
20 regulation” and inserting “issuance of
21 such order”; and

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

23 “(3) In the case of a device with respect to which
24 a regulation was promulgated under section 515(b) prior
25 to the date of enactment of the Food and Drug Adminis-

1 tration Safety and Innovation Act, a reference in this sub-
2 section to an order issued under section 515(b) shall be
3 deemed to include such regulation.”.

4 (3) APPROVAL BY REGULATION PRIOR TO THE
5 DATE OF ENACTMENT OF THIS ACT.—The amend-
6 ments made by this subsection shall have no effect
7 on a regulation that was promulgated prior to the
8 date of enactment of this Act requiring that a device
9 have an approval under section 515 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of
11 an application for premarket approval.

12 (c) REPORTING.—The Secretary of Health and
13 Human Services shall annually post on the Internet Web
14 site of the Food and Drug Administration—

15 (1) the number and type of class I and class II
16 devices reclassified as class II or class III in the pre-
17 vious calendar year under section 513(e)(1) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 360c(e)(1));

20 (2) the number and type of class II and class
21 III devices reclassified as class I or class II in the
22 previous calendar year under such section 513(e)(1);
23 and

24 (3) the number and type of devices reclassified
25 in the previous calendar year under section 515 of

1 the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 360e).

3 **SEC. 609. HARMONIZATION OF DEVICE PREMARKET RE-**
4 **VIEW, INSPECTION, AND LABELING SYMBOLS.**

5 Paragraph (4) of section 803(c) (21 U.S.C. 383(c))
6 is amended to read as follows:

7 “(4) With respect to devices, the Secretary may,
8 when appropriate, enter into arrangements with nations
9 regarding methods and approaches to harmonizing regu-
10 latory requirements for activities, including inspections
11 and common international labeling symbols.”.

12 **SEC. 610. PARTICIPATION IN INTERNATIONAL FORA.**

13 Paragraph (3) of section 803(c) (21 U.S.C. 383(c))
14 is amended—

15 (1) by striking “(3)” and inserting “(3)(A)”;

16 and

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

18 “(B) In carrying out subparagraph (A), the Secretary
19 may participate in appropriate fora, including the Inter-
20 national Medical Device Regulators Forum, and may—

21 “(i) provide guidance to such fora on strategies,
22 policies, directions, membership, and other activities
23 of a forum as appropriate;

24 “(ii) to the extent appropriate, solicit, review,
25 and consider comments from industry, academia,

1 health care professionals, and patient groups regard-
2 ing the activities of such fora; and

3 “(iii) to the extent appropriate, inform the pub-
4 lic of the Secretary’s activities within such fora, and
5 share with the public any documentation relating to
6 a forum’s strategies, policies, and other activities of
7 such fora.”.

8 **SEC. 611. REAUTHORIZATION OF THIRD-PARTY REVIEW.**

9 (a) PERIODIC REACCREDITATION.—Section
10 523(b)(2) (21 U.S.C. 360m(b)(2)) is amended by adding
11 at the end of the following:

12 “(E) PERIODIC REACCREDITATION.—

13 “(i) PERIOD.—Subject to suspension
14 or withdrawal under subparagraph (B),
15 any accreditation under this section shall
16 be valid for a period of 3 years after its
17 issuance.

18 “(ii) RESPONSE TO REACCREDITATION
19 REQUEST.—Upon the submission of a re-
20 quest by an accredited person for re-
21 accreditation under this section, the Sec-
22 retary shall approve or deny such request
23 not later than 60 days after receipt of the
24 request.

1 “(iii) CRITERIA.—Not later than 120
2 days after the date of the enactment of
3 this subparagraph, the Secretary shall es-
4 tablish and publish in the Federal Register
5 criteria to reaccredit or deny reaccredita-
6 tion to persons under this section. The re-
7 accreditation of persons under this section
8 shall specify the particular activities under
9 subsection (a), and the devices, for which
10 such persons are reaccredited.”.

11 (b) DURATION OF AUTHORITY.—Section 523(c) (21
12 U.S.C. 360m(c)) is amended by striking “October 1,
13 2012” and inserting “October 1, 2017”.

14 **SEC. 612. REAUTHORIZATION OF THIRD-PARTY INSPEC-**
15 **TION.**

16 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-
17 ed by striking “October 1, 2012” and inserting “October
18 1, 2017”.

19 **SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.**

20 (a) IN GENERAL.—Section 520(m) (21 U.S.C.
21 360j(m)) is amended—

22 (1) in paragraph (6)—

23 (A) in subparagraph (A)—

24 (i) by striking clause (i) and inserting
25 the following:

1 “(i) The device with respect to which the ex-
2 emption is granted—

3 “(I) is intended for the treatment or diag-
4 nosis of a disease or condition that occurs in
5 pediatric patients or in a pediatric subpopula-
6 tion, and such device is labeled for use in pedi-
7 atric patients or in a pediatric subpopulation in
8 which the disease or condition occurs; or

9 “(II) is intended for the treatment or diag-
10 nosis of a disease or condition that does not
11 occur in pediatric patients or that occurs in pe-
12 diatric patients in such numbers that the devel-
13 opment of the device for such patients is impos-
14 sible, highly impracticable, or unsafe.”; and

15 (ii) by striking clause (ii) and insert-
16 ing the following:

17 “(ii) During any calendar year, the number of
18 such devices distributed during that year under each
19 exemption granted under this subsection does not
20 exceed the annual distribution number for such de-
21 vice. In this paragraph, the term ‘annual distribu-
22 tion number’ means the number of such devices rea-
23 sonably needed to treat, diagnose, or cure a popu-
24 lation of 4,000 individuals in the United States. The
25 Secretary shall determine the annual distribution

1 number when the Secretary grants such exemp-
2 tion.”; and

3 (B) by amending subparagraph (C) to read
4 as follows:

5 “(C) A person may petition the Secretary to modify
6 the annual distribution number determined by the Sec-
7 retary under subparagraph (A)(ii) with respect to a device
8 if additional information arises, and the Secretary may
9 modify such annual distribution number.”;

10 (2) in paragraph (7), by striking “regarding a
11 device” and inserting “regarding a device described
12 in paragraph (6)(A)(i)(I)”;

13 (3) in paragraph (8), by striking “of all devices
14 described in paragraph (6)” and inserting “of all de-
15 vices described in paragraph (6)(A)(i)(I)”.

16 (b) **APPLICABILITY TO EXISTING DEVICES.**—A spon-
17 sor of a device for which an exemption was approved under
18 paragraph (2) of section 520(m) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the
20 date of enactment of this Act may seek a determination
21 under subclause (I) or (II) of section 520(m)(6)(A)(i) (as
22 amended by subsection (a)). If the Secretary of Health
23 and Human Services determines that such subclause (I)
24 or (II) applies with respect to a device, clauses (ii), (iii),
25 and (iv) of subparagraph (A) and subparagraphs (B), (C),

1 (D), and (E) of paragraph (6) of such section 520(m)
2 shall apply to such device, and the Secretary shall deter-
3 mine the annual distribution number for purposes of
4 clause (ii) of such subparagraph (A) when making the de-
5 termination under this subsection.

6 **SEC. 614. UNIQUE DEVICE IDENTIFIER.**

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

8 (1) by striking “The Secretary shall promul-
9 gate” and inserting “Not later than December 31,
10 2012, the Secretary shall issue proposed”; and

11 (2) by adding at the end the following: “The
12 Secretary shall finalize the proposed regulations not
13 later than 6 months after the close of the comment
14 period and shall implement the final regulations with
15 respect to devices that are implantable, life-saving,
16 and life sustaining not later than 2 years after the
17 regulations are finalized, taking into account patient
18 access to medical devices and therapies.”.

19 **SEC. 615. SENTINEL.**

20 Section 519 (21 U.S.C. 360i) is amended by adding
21 at the end the following:

22 “(h) INCLUSION OF DEVICES IN THE POSTMARKET
23 RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

24 “(1) IN GENERAL.—

1 “(A) APPLICATION TO DEVICES.—The Sec-
2 retary shall amend the procedures established
3 and maintained under clauses (i), (ii), (iii), and
4 (v) of section 505(k)(3)(C) in order to expand
5 the postmarket risk identification and analysis
6 system established under such section to include
7 and apply to devices.

8 “(B) EXCEPTION.—Subclause (II) of
9 clause (i) of section 505(k)(3)(C) shall not
10 apply to devices.

11 “(C) CLARIFICATION.—With respect to de-
12 vices, the private sector health-related electronic
13 data provided under section
14 505(k)(3)(C)(i)(III)(bb) may include medical
15 device utilization data, health insurance claims
16 data, and procedure and device registries.

17 “(2) DATA.—In expanding the system as de-
18 scribed in paragraph (1)(A), the Secretary shall use
19 relevant data with respect to devices cleared under
20 section 510(k) or approved under section 515, in-
21 cluding claims data, patient survey data, and any
22 other data deemed appropriate by the Secretary.

23 “(3) STAKEHOLDER INPUT.—To help ensure ef-
24 fective implementation of the system as described in
25 paragraph (1) with respect to devices, the Secretary

1 shall engage outside stakeholders in development of
2 the system, and gather information from outside
3 stakeholders regarding the content of an effective
4 sentinel program, through a public hearing, advisory
5 committee meeting, maintenance of a public docket,
6 or other similar public measures.

7 “(4) VOLUNTARY SURVEYS.—Chapter 35 of
8 title 44, United States Code, shall not apply to the
9 collection of voluntary information from health care
10 providers, such as voluntary surveys or question-
11 naires, initiated by the Secretary for purposes of
12 postmarket risk identification, mitigation, and anal-
13 ysis for devices.”.

14 **SEC. 616. POSTMARKET SURVEILLANCE.**

15 Section 522 (21 U.S.C. 360l) is amended—

16 (1) in subsection (a)(1)(A), in the matter pre-
17 ceding clause (i), by inserting “, at the time of ap-
18 proval or clearance of a device or at any time there-
19 after,” after “by order”; and

20 (2) in subsection (b)(1), by inserting “The
21 manufacturer shall commence surveillance under this
22 section not later than 15 months after the day on
23 which the Secretary issues an order under this sec-
24 tion.” after the second sentence.

1 **SEC. 617. CUSTOM DEVICES.**

2 Section 520(b) (21 U.S.C. 360j(b)) is amended to
3 read as follows:

4 “(b) CUSTOM DEVICES.—

5 “(1) IN GENERAL.—The requirements of sec-
6 tions 514 and 515 shall not apply to a device that—

7 “(A) is created or modified in order to
8 comply with the order of an individual physician
9 or dentist (or any other specially qualified per-
10 son designated under regulations promulgated
11 by the Secretary after an opportunity for an
12 oral hearing);

13 “(B) in order to comply with an order de-
14 scribed in subparagraph (A), necessarily devi-
15 ates from an otherwise applicable performance
16 standard under section 514 or requirement
17 under section 515;

18 “(C) is not generally available in the
19 United States in finished form through labeling
20 or advertising by the manufacturer, importer,
21 or distributor for commercial distribution;

22 “(D) is designed to treat a unique pathol-
23 ogy or physiological condition that no other de-
24 vice is domestically available to treat;

25 “(E)(i) is intended to meet the special
26 needs of such physician or dentist (or other spe-

1 cially qualified person so designated) in the
2 course of the professional practice of such phy-
3 sician or dentist (or other specially qualified
4 person so designated); or

5 “(ii) is intended for use by an individual
6 patient named in such order of such physician
7 or dentist (or other specially qualified person so
8 designated);

9 “(F) is assembled from components or
10 manufactured and finished on a case-by-case
11 basis to accommodate the unique needs of indi-
12 viduals described in clause (i) or (ii) of subpara-
13 graph (E); and

14 “(G) may have common, standardized de-
15 sign characteristics, chemical and material com-
16 positions, and manufacturing processes as com-
17 mercially distributed devices.

18 “(2) LIMITATIONS.—Paragraph (1) shall apply
19 to a device only if—

20 “(A) such device is for the purpose of
21 treating a sufficiently rare condition, such that
22 conducting clinical investigations on such device
23 would be impractical;

24 “(B) production of such device under para-
25 graph (1) is limited to no more than 5 units per

1 year of a particular device type, provided that
2 such replication otherwise complies with this
3 section; and

4 “(C) the manufacturer of such device noti-
5 fies the Secretary on an annual basis, in a man-
6 ner prescribed by the Secretary, of the manu-
7 facture of such device.

8 “(3) GUIDANCE.—Not later than 2 years after
9 the date of enactment of this section, the Secretary
10 shall issue final guidance on replication of multiple
11 devices described in paragraph (2)(B).”.

12 **SEC. 618. HEALTH INFORMATION TECHNOLOGY.**

13 (a) REPORT.—Not later than 18 months after the
14 date of enactment of this Act, the Secretary of Health and
15 Human Services (referred to in this section as the “Sec-
16 retary”), acting through the Commissioner of Food and
17 Drugs, and in consultation with the National Coordinator
18 for Health Information Technology and the Chairman of
19 the Federal Communications Commission, shall post on
20 the Internet Web sites of the Food and Drug Administra-
21 tion, the Federal Communications Commission, and the
22 Office of the National Coordinator for Health Information
23 Technology, a report that contains a proposed strategy
24 and recommendations on an appropriate, risk-based regu-
25 latory framework pertaining to health information tech-

1 nology, including mobile medical applications, that pro-
2 motes innovation, protects patient safety, and avoids regu-
3 latory duplication.

4 (b) WORKING GROUP.—

5 (1) IN GENERAL.—In carrying out subsection
6 (a), the Secretary may convene a working group of
7 external stakeholders and experts to provide appro-
8 priate input on the strategy and recommendations
9 required for the report under subsection (a).

10 (2) REPRESENTATIVES.—If the Secretary con-
11 venes the working group under paragraph (1), the
12 Secretary, in consultation with the Commissioner of
13 Food and Drugs, the National Coordinator for
14 Health Information Technology, and the Chairman
15 of the Federal Communications Commission, shall
16 determine the number of representatives partici-
17 pating in the working group, and shall, to the extent
18 practicable, ensure that the working group is geo-
19 graphically diverse and includes representatives of
20 patients, consumers, health care providers, startup
21 companies, health plans or other third-party payers,
22 venture capital investors, information technology
23 vendors, health information technology vendors,
24 small businesses, purchasers, employers, and other

1 stakeholders with relevant expertise, as determined
2 by the Secretary.

3 **SEC. 619. GOOD GUIDANCE PRACTICES RELATING TO DE-**
4 **VICES.**

5 Subparagraph (C) of section 701(h)(1) (21 U.S.C.
6 371(h)(1)) is amended—

7 (1) by striking “(C) For guidance documents”
8 and inserting “(C)(i) For guidance documents”; and
9 (2) by adding at the end the following:

10 “(ii) With respect to devices, if a notice to in-
11 dustry guidance letter, a notice to industry advisory
12 letter, or any similar notice sets forth initial inter-
13 pretations of a regulation or policy or sets forth
14 changes in interpretation or policy, such notice shall
15 be treated as a guidance document for purposes of
16 this subparagraph.”.

17 **SEC. 620. PEDIATRIC DEVICE CONSORTIA.**

18 (a) **IN GENERAL.**—Section 305(e) of Pediatric Med-
19 ical Device Safety and Improvement Act (Public Law
20 110–85; 42 U.S.C. 282 note)) is amended by striking
21 “\$6,000,000 for each of fiscal years 2008 through 2012”
22 and inserting “\$5,250,000 for each of fiscal years 2013
23 through 2017”.

1 (b) FINAL RULE RELATING TO TRACKING OF PEDI-
2 ATRIC USES OF DEVICES.—The Secretary of Health and
3 Human Services shall issue—

4 (1) a proposed rule implementing section
5 515A(a)(2) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 360e–1(a)(2)) not later than
7 December 31, 2012; and

8 (2) a final rule implementing such section not
9 later than December 31, 2013.

10 **TITLE VII—DRUG SUPPLY CHAIN**

11 **SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISH-** 12 **MENTS.**

13 Section 510 (21 U.S.C. 360) is amended—

14 (1) in subsection (b)—

15 (A) in paragraph (1), by striking “On or
16 before” and all that follows through the period
17 at the end and inserting the following: “During
18 the period beginning on October 1 and ending
19 on December 31 of each year, every person who
20 owns or operates any establishment in any
21 State engaged in the manufacture, preparation,
22 propagation, compounding, or processing of a
23 drug or drugs shall register with the Secretary
24 the name of such person, places of business of
25 such person, all such establishments, the unique

1 facility identifier of each such establishment,
2 and a point of contact e-mail address.; and

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

4 “(3) The Secretary shall specify the unique facility
5 identifier system that shall be used by registrants under
6 paragraph (1). The requirement to include a unique facil-
7 ity identifier in a registration under paragraph (1) shall
8 not apply until the date that the identifier system is speci-
9 fied by the Secretary under the preceding sentence.”; and

10 (2) in subsection (c), by striking “with the Sec-
11 retary his name, place of business, and such estab-
12 lishment” and inserting “with the Secretary—

13 “(1) with respect to drugs, the information de-
14 scribed under subsection (b)(1); and

15 “(2) with respect to devices, the information de-
16 scribed under subsection (b)(2).”.

17 **SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

18 (a) ENFORCEMENT OF REGISTRATION OF FOREIGN
19 ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is
20 amended by striking “in any State”.

21 (b) REGISTRATION OF FOREIGN DRUG ESTABLISH-
22 MENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

23 (1) in paragraph (1)—

24 (A) by amending the matter preceding sub-
25 paragraph (A) to read as follows: “Every per-

1 son who owns or operates any establishment
2 within any foreign country engaged in the man-
3 ufacture, preparation, propagation,
4 compounding, or processing of a drug or device
5 that is imported or offered for import into the
6 United States shall, through electronic means
7 in accordance with the criteria of the Sec-
8 retary—”;

9 (B) by amending subparagraph (A) to read
10 as follows:

11 “(A) upon first engaging in any such activity,
12 immediately submit a registration to the Secretary
13 that includes—

14 “(i) with respect to drugs, the name and
15 place of business of such person, all such estab-
16 lishments, the unique facility identifier of each
17 such establishment, a point of contact e-mail
18 address, the name of the United States agent of
19 each such establishment, the name of each im-
20 porter of such drug in the United States that
21 is known to the establishment, and the name of
22 each person who imports or offers for import
23 such drug to the United States for purposes of
24 importation; and

1 “(ii) with respect to devices, the name and
2 place of business of the establishment, the name
3 of the United States agent for the establish-
4 ment, the name of each importer of such device
5 in the United States that is known to the estab-
6 lishment, and the name of each person who im-
7 ports or offers for import such device to the
8 United States for purposes of importation;
9 and”;

10 (C) by amending subparagraph (B) to read
11 as follows:

12 “(B) each establishment subject to the require-
13 ments of subparagraph (A) shall thereafter register
14 with the Secretary during the period beginning on
15 October 1 and ending on December 31 of each
16 year.”;

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

18 “(4) The Secretary shall specify the unique facility
19 identifier system that shall be used by registrants under
20 paragraph (1) with respect to drugs. The requirement to
21 include a unique facility identifier in a registration under
22 paragraph (1) with respect to drugs shall not apply until
23 the date that the identifier system is specified by the Sec-
24 retary under the preceding sentence.”.

1 **SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMA-**
2 **TION WITH PRODUCT LISTING.**

3 Section 510(j) (21 U.S.C. 360(j)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (C), by striking “;
6 and” and inserting a semicolon;

7 (B) in subparagraph (D), by striking the
8 period at the end and inserting “; and”; and

9 (C) by adding at the end the following:

10 “(E) in the case of a drug contained in the ap-
11 plicable list, the name and place of business of each
12 manufacturer of an excipient of the listed drug with
13 which the person listing the drug conducts business,
14 including all establishments used in the production
15 of such excipient, the unique facility identifier of
16 each such establishment, and a point of contact e-
17 mail address for each such excipient manufacturer.”;
18 and

19 (2) by adding at the end the following:

20 “(4) The Secretary shall require persons subject to
21 this subsection to use, for purposes of this subsection, the
22 unique facility identifier systems specified under sub-
23 sections (b)(3) and (i)(4) with respect to drugs. Such re-
24 quirement shall not apply until the date that the identifier
25 system under subsection (b)(3) or (i)(4), as applicable, is
26 specified by the Secretary.”.

1 **SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND**
2 **LISTING.**

3 Section 510(p) (21 U.S.C. 360(p)) is amended—

4 (1) by striking “(p) Registrations and listings”
5 and inserting the following:

6 “(p) **ELECTRONIC REGISTRATION AND LISTING.**—

7 “(1) **IN GENERAL.**—Registrations and listings”;

8 and

9 (2) by adding at the end the following:

10 “(2) **ELECTRONIC DATABASE.**—Not later than
11 2 years after the Secretary specifies a unique facility
12 identifier system under subsections (b) and (i), the
13 Secretary shall maintain an electronic database,
14 which shall not be subject to inspection under sub-
15 section (f), populated with the information submitted
16 as described under paragraph (1) that—

17 “(A) enables personnel of the Food and
18 Drug Administration to search the database by
19 any field of information submitted in a registra-
20 tion described under paragraph (1), or com-
21 bination of such fields; and

22 “(B) uses the unique facility identifier sys-
23 tem to link with other relevant databases within
24 the Food and Drug Administration, including
25 the database for submission of information
26 under section 801(r).

1 “(3) RISK-BASED INFORMATION AND COORDI-
2 NATION.—The Secretary shall ensure the accuracy
3 and coordination of relevant Food and Drug Admin-
4 istration databases in order to identify and inform
5 risk-based inspections under section 510(h).”.

6 **SEC. 705. RISK-BASED INSPECTION FREQUENCY.**

7 Section 510(h) (21 U.S.C. 360(h)) is amended to
8 read as follows:

9 “(h) INSPECTIONS.—

10 “(1) IN GENERAL.—Every establishment that is
11 required to be registered with the Secretary under
12 this section shall be subject to inspection pursuant
13 to section 704.

14 “(2) BIENNIAL INSPECTIONS FOR DEVICES.—
15 Every establishment described in paragraph (1), in
16 any State, that is engaged in the manufacture, prop-
17 agation, compounding, or processing of a device or
18 devices classified in class II or III shall be so in-
19 spected by one or more officers or employees duly
20 designated by the Secretary, or by persons accred-
21 ited to conduct inspections under section 704(g), at
22 least once in the 2-year period beginning with the
23 date of registration of such establishment pursuant
24 to this section and at least once in every successive
25 2-year period thereafter.

1 “(3) RISK-BASED SCHEDULE FOR DRUGS.—The
2 Secretary, acting through one or more officers or
3 employees duly designated by the Secretary, shall in-
4 spect establishments described in paragraph (1) that
5 are engaged in the manufacture, preparation, propa-
6 gation, compounding, or processing of a drug or
7 drugs (referred to in this subsection as ‘drug estab-
8 lishments’) in accordance with a risk-based schedule
9 established by the Secretary.

10 “(4) RISK FACTORS.—In establishing the risk-
11 based scheduled under paragraph (3), the Secretary
12 shall inspect establishments according to the known
13 safety risks of such establishments, which shall be
14 based on the following factors:

15 “(A) The compliance history of the estab-
16 lishment.

17 “(B) The record, history, and nature of re-
18 calls linked to the establishment.

19 “(C) The inherent risk of the drug manu-
20 factured, prepared, propagated, compounded, or
21 processed at the establishment.

22 “(D) The inspection frequency and history
23 of the establishment, including whether the es-
24 tablishment has been inspected pursuant to sec-
25 tion 704 within the last 4 years.

1 “(E) Whether the establishment has been
2 inspected by a foreign government or an agency
3 of a foreign government recognized under sec-
4 tion 809.

5 “(F) Any other criteria deemed necessary
6 and appropriate by the Secretary for purposes
7 of allocating inspection resources.

8 “(5) EFFECT OF STATUS.—In determining the
9 risk associated with an establishment for purposes of
10 establishing a risk-based schedule under paragraph
11 (3), the Secretary shall not consider whether the
12 drugs manufactured, prepared, propagated, com-
13 pounded, or processed by such establishment are
14 drugs described in section 503(b).

15 “(6) ANNUAL REPORT ON INSPECTIONS OF ES-
16 TABLISHMENTS.—Beginning in 2014, not later than
17 February 1 of each year, the Secretary shall make
18 available on the Internet Web site of the Food and
19 Drug Administration a report regarding—

20 “(A)(i) the number of domestic and foreign
21 establishments registered pursuant to this sec-
22 tion in the previous fiscal year; and

23 “(ii) the number of such domestic estab-
24 lishments and the number of such foreign es-

1 tablishments that the Secretary inspected in the
2 previous fiscal year;

3 “(B) with respect to establishments that
4 manufacture, prepare, propagate, compound, or
5 process an active ingredient of a drug, a fin-
6 ished drug product, or an excipient of a drug,
7 the number of each such type of establishment;
8 and

9 “(C) the percentage of the budget of the
10 Food and Drug Administration used to fund
11 the inspections described under subparagraph
12 (A).”.

13 **SEC. 706. RECORDS FOR INSPECTION.**

14 Section 704(a) (21 U.S.C. 374(a)) is amended by
15 adding at the end the following:

16 “(4)(A) Any records or other information that the
17 Secretary may inspect under this section from a person
18 that owns or operates an establishment that is engaged
19 in the manufacture, preparation, propagation,
20 compounding, or processing of a drug shall, upon the re-
21 quest of the Secretary, be provided to the Secretary by
22 such person, in advance of or in lieu of an inspection, with-
23 in a reasonable timeframe, within reasonable limits, and
24 in a reasonable manner, and in either electronic or phys-
25 ical form, at the expense of such person. The Secretary’s

1 request shall include a sufficient description of the records
2 requested.

3 “(B) Upon receipt of the records requested under
4 subparagraph (A), the Secretary shall provide to the per-
5 son confirmation of receipt.

6 “(C) Nothing in this paragraph supplants the author-
7 ity of the Secretary to conduct inspections otherwise per-
8 mitted under this Act in order to ensure compliance with
9 this Act.”.

10 **SEC. 707. PROHIBITION AGAINST DELAYING, DENYING, LIM-**
11 **ITING, OR REFUSING INSPECTION.**

12 (a) IN GENERAL.—Section 501 (21 U.S.C. 351) is
13 amended by adding at the end the following:

14 “(j) If it is a drug and it has been manufactured,
15 processed, packed, or held in any factory, warehouse, or
16 establishment and the owner, operator, or agent of such
17 factory, warehouse, or establishment delays, denies, or
18 limits an inspection, or refuses to permit entry or inspec-
19 tion.”.

20 (b) GUIDANCE.—Not later than 1 year after the date
21 of enactment of this section, the Secretary of Health and
22 Human Services shall issue guidance that defines the cir-
23 cumstances that would constitute delaying, denying, or
24 limiting inspection, or refusing to permit entry or inspec-

1 tion, for purposes of section 501(j) of the Federal Food,
2 Drug, and Cosmetic Act (as added by subsection (a)).

3 **SEC. 708. DESTRUCTION OF ADULTERATED, MISBRANDED,**
4 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
5 **PORT.**

6 (a) IN GENERAL.—The sixth sentence of section
7 801(a) (21 U.S.C. 381(a)) is amended by inserting before
8 the period at the end the following: “, except that the Sec-
9 retary of Health and Human Services may destroy, with-
10 out the opportunity for export, any drug refused admission
11 under this section, if such drug is valued at an amount
12 that is \$2,500 or less (or such higher amount as the Sec-
13 retary of the Treasury may set by regulation pursuant to
14 section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C.
15 1498(a)(1)) and was not brought into compliance as de-
16 scribed under subsection (b).”.

17 (b) NOTICE.—Subsection (a) of section 801 (21
18 U.S.C. 381), as amended by subsection (a), is further
19 amended by inserting after the sixth sentence the fol-
20 lowing: “The Secretary of Health and Human Services
21 shall issue regulations providing for notice and an oppor-
22 tunity to appear before the Secretary of Health and
23 Human Services and introduce testimony, as described in
24 the first sentence of this subsection, on destruction of a
25 drug under the sixth sentence of this subsection. The regu-

1 lations shall provide that prior to destruction, appropriate
2 due process is available to the owner or consignee seeking
3 to challenge the decision to destroy the drug. Where the
4 Secretary of Health and Human Services provides notice
5 and an opportunity to appear and introduce testimony on
6 the destruction of a drug, the Secretary of Health and
7 Human Services shall store and, as applicable, dispose of
8 the drug after the issuance of the notice, except that the
9 owner and consignee shall remain liable for costs pursuant
10 to subsection (c). Such process may be combined with the
11 notice and opportunity to appear before the Secretary and
12 introduce testimony, as described in the first sentence of
13 this subsection, as long as appropriate notice is provided
14 to the owner or consignee.”.

15 (c) APPLICABILITY.—The amendment made by sub-
16 section (a) shall apply beginning on the effective date of
17 the regulations promulgated pursuant to the amendment
18 made by subsection (b).

19 (d) REGULATIONS.—

20 (1) IN GENERAL.—Not later than 2 years after
21 the date of enactment of this Act, the Secretary of
22 Health and Human Services shall adopt final regula-
23 tions implementing the amendments made this sec-
24 tion.

1 (2) PROCEDURE.—In promulgating a regulation
2 implementing the amendments made by this section,
3 the Secretary of Health and Human Services shall—

4 (A) issue a notice of proposed rulemaking
5 that includes a copy of the proposed regulation;

6 (B) provide a period of not less than 60
7 days for comments on the proposed regulation;
8 and

9 (C) publish the final regulation not less
10 than 30 days before the effective date of the
11 regulation.

12 (3) RESTRICTIONS.—Notwithstanding any other
13 provision of law, the Secretary of Health and
14 Human Services shall promulgate regulations imple-
15 menting the amendments made by this section only
16 as described in paragraph (2).

17 **SEC. 709. ADMINISTRATIVE DETENTION.**

18 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
19 335a(g)) is amended—

20 (1) in paragraph (1), by inserting “, drug,”
21 after “device”, each place it appears;

22 (2) in paragraph (2)(A), by inserting “, drug,”
23 after “(B), a device”; and

24 (3) in paragraph (2)(B), by inserting “or drug”
25 after “device” each place it appears.

1 (b) REGULATIONS.—

2 (1) IN GENERAL.—Not later than 2 years after
3 the date of the enactment of this Act, the Secretary
4 of Health and Human Services shall promulgate reg-
5 ulations in accordance with section 304(i) of the
6 Federal Food, Drug, and Cosmetic Act, as added by
7 paragraph (2) of this subsection, to implement ad-
8 ministrative detention authority with respect to
9 drugs, as authorized by the amendments made by
10 subsection (a). Before promulgating such regula-
11 tions, the Secretary shall consult with stakeholders,
12 including manufacturers of drugs.

13 (2) IN GENERAL.—Section 304 (21 U.S.C. 334)
14 is amended by adding at the end the following:

15 “(i) PROCEDURES FOR PROMULGATING REGULA-
16 TIONS.—

17 “(1) IN GENERAL.—In promulgating a regula-
18 tion implementing this section, the Secretary shall—

19 “(A) issue a notice of proposed rulemaking
20 that includes the proposed regulation;

21 “(B) provide a period of not less than 60
22 days for comments on the proposed regulation;
23 and

1 “(C) publish the final regulation not less
2 than 30 days before the regulation’s effective
3 date.

4 “(2) RESTRICTIONS.—Notwithstanding any
5 other provision of Federal law, in implementing this
6 section, the Secretary shall only promulgate regula-
7 tions as described in paragraph (1).”.

8 (c) EFFECTIVE DATE.—The amendments made by
9 subsection (a) shall not take effect until the Secretary has
10 issued a final regulation under subsection (b).

11 **SEC. 710. EXCHANGE OF INFORMATION.**

12 Section 708 (21 U.S.C. 379) is amended—

13 (1) by striking “CONFIDENTIAL INFORMATION”
14 and all that follows through “The Secretary may
15 provide” and inserting the following:

16 **“SEC. 708. CONFIDENTIAL INFORMATION.**

17 “(a) CONTRACTORS.—The Secretary may provide”;
18 and

19 (2) by adding at the end the following:

20 “(b) ABILITY TO RECEIVE AND PROTECT CON-
21 FIDENTIAL INFORMATION OBTAINED FROM FOREIGN
22 GOVERNMENTS.—

23 “(1) IN GENERAL.—The Secretary shall not be
24 required to disclose under section 552 of title 5,
25 United States Code (commonly referred to as the

1 ‘Freedom of Information Act’), or any other provi-
2 sion of law, any information relating to drugs ob-
3 tained from a foreign government agency, if—

4 “(A) the information concerns the inspec-
5 tion of a facility, is part of an investigation,
6 alerts the United States to the potential need
7 for an investigation, or concerns a drug that
8 has a reasonable probability of causing serious
9 adverse health consequences or death to hu-
10 mans or animals;

11 “(B) the information is provided or made
12 available to the United States Government vol-
13 untarily on the condition that it not be released
14 to the public; and

15 “(C) the information is covered by, and
16 subject to, a written agreement between the
17 Secretary and the foreign government.

18 “(2) TIME LIMITATIONS.—The written agree-
19 ment described in paragraph (1)(C) shall specify the
20 time period for which paragraph (1) shall apply to
21 the voluntarily disclosed information. Paragraph
22 (1) shall not apply with respect to such information
23 after the date specified in such agreement, but all
24 other applicable legal protections, including the pro-
25 visions of section 552 of title 5, United States Code,

1 and section 319L(e)(1) of the Public Health Service
2 Act, as applicable, shall continue to apply to such in-
3 formation. If no date is specified in the written
4 agreement, paragraph (1) shall not apply with re-
5 spect to such information for a period of more than
6 36 months.

7 “(3) DISCLOSURES NOT AFFECTED.—Nothing
8 in this section authorizes any official to withhold, or
9 to authorize the withholding of, information from
10 Congress or information required to be disclosed
11 pursuant to an order of a court of the United
12 States.

13 “(4) RELATION TO OTHER LAW.—For purposes
14 of section 552 of title 5, United States Code, this
15 subsection shall be considered a statute described in
16 subsection (b)(3)(B) of such section 552.

17 “(c) AUTHORITY TO ENTER INTO MEMORANDA OF
18 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-
19 CHANGE.—The Secretary may enter into written agree-
20 ments to provide information referenced in section 301(j)
21 to foreign governments subject to the following criteria:

22 “(1) CERTIFICATION.—The Secretary may
23 enter into a written agreement to provide informa-
24 tion under this subsection to a foreign government
25 only if the Secretary has certified such government

1 as having the authority and demonstrated ability to
2 protect trade secret information from disclosure. Re-
3 sponsibility for this certification shall not be dele-
4 gated to any officer or employee other than the
5 Commissioner of Food and Drugs.

6 “(2) WRITTEN AGREEMENT.—The written
7 agreement to provide information to the foreign gov-
8 ernment under this subsection shall include a com-
9 mitment by the foreign government to protect infor-
10 mation exchanged under this subsection from disclo-
11 sure unless and until the sponsor gives written per-
12 mission for disclosure or the Secretary makes a dec-
13 laration of a public health emergency pursuant to
14 section 319 of the Public Health Service Act that is
15 relevant to the information.

16 “(3) INFORMATION EXCHANGE.—The Secretary
17 may provide to a foreign government that has been
18 certified under paragraph (1) and that has executed
19 a written agreement under paragraph (2) informa-
20 tion referenced in section 301(j) in only the fol-
21 lowing circumstances:

22 “(A) Information concerning the inspection
23 of a facility may be provided to a foreign gov-
24 ernment if—

1 “(i) the Secretary reasonably believes,
2 or the written agreement described in
3 paragraph (2) establishes, that the govern-
4 ment has authority to otherwise obtain
5 such information; and

6 “(ii) the written agreement executed
7 under paragraph (2) limits the recipient’s
8 use of the information to the recipient’s
9 civil regulatory purposes.

10 “(B) Information not described in sub-
11 paragraph (A) may be provided as part of an
12 investigation, or to alert the foreign government
13 to the potential need for an investigation, if the
14 Secretary has reasonable grounds to believe
15 that a drug has a reasonable probability of
16 causing serious adverse health consequences or
17 death to humans or animals.

18 “(4) EFFECT OF SUBSECTION.—Nothing in this
19 subsection affects the ability of the Secretary to
20 enter into any written agreement authorized by
21 other provisions of law to share confidential informa-
22 tion.”.

1 **SEC. 711. ENHANCING THE SAFETY AND QUALITY OF THE**
2 **DRUG SUPPLY.**

3 Section 501 (21 U.S.C. 351) is amended by adding
4 at the end the following flush text:

5 “For purposes of paragraph (a)(2)(B), the term ‘current
6 good manufacturing practice’ includes the implementation
7 of oversight and controls over the manufacture of drugs
8 to ensure quality, including managing the risk of and es-
9 tablishing the safety of raw materials, materials used in
10 the manufacturing of drugs, and finished drug products.”.

11 **SEC. 712. RECOGNITION OF FOREIGN GOVERNMENT IN-**
12 **SPECTIONS.**

13 Chapter VIII (21 U.S.C. 381 et seq.) is amended by
14 adding at the end the following:

15 **“SEC. 809. RECOGNITION OF FOREIGN GOVERNMENT IN-**
16 **SPECTIONS.**

17 “(a) INSPECTION.—The Secretary—

18 “(1) may enter into arrangements and agree-
19 ments with a foreign government or an agency of a
20 foreign government to recognize the inspection of
21 foreign establishments registered under section
22 510(i) in order to facilitate risk-based inspections in
23 accordance with the schedule established in section
24 510(h)(3);

25 “(2) may enter into arrangements and agree-
26 ments with a foreign government or an agency of a

1 foreign government under this section only with a
2 foreign government or an agency of a foreign gov-
3 ernment that the Secretary has determined as hav-
4 ing the capability of conduction inspections that
5 meet the applicable requirements of this Act; and

6 “(3) shall perform such reviews and audits of
7 drug safety programs, systems, and standards of a
8 foreign government or agency for the foreign govern-
9 ment as the Secretary deems necessary to determine
10 that the foreign government or agency of the foreign
11 government is capable of conducting inspections that
12 meet the applicable requirements of this Act.

13 “(b) RESULTS OF INSPECTION.—The results of in-
14 spections performed by a foreign government or an agency
15 of a foreign government under this section may be used
16 as—

17 “(1) evidence of compliance with section
18 501(a)(2)(B) or section 801(r); and

19 “(2) for any other purposes as determined ap-
20 propriate by the Secretary.”.

21 **SEC. 713. STANDARDS FOR ADMISSION OF IMPORTED**
22 **DRUGS.**

23 Section 801 (21 U.S.C. 381) is amended—

24 (1) in subsection (o), by striking “drug or”;
25 and

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

2 “(r)(1) The Secretary may require, pursuant to the
3 regulations promulgated under paragraph (4)(A), as a
4 condition of granting admission to a drug imported or of-
5 fered for import into the United States, that the importer
6 electronically submit information demonstrating that the
7 drug complies with applicable requirements of this Act.

8 “(2) The information described under paragraph (1)
9 may include—

10 “(A) information demonstrating the regulatory
11 status of the drug, such as the new drug application,
12 abbreviated new drug application, or investigational
13 new drug or drug master file number;

14 “(B) facility information, such as proof of reg-
15 istration and the unique facility identifier;

16 “(C) indication of compliance with current good
17 manufacturing practice, testing results, certifications
18 relating to satisfactory inspections, and compliance
19 with the country of export regulations; and

20 “(D) any other information deemed necessary
21 and appropriate by the Secretary to assess compli-
22 ance of the article being offered for import.

23 “(3) Information requirements referred to in para-
24 graph (2)(C) may, at the discretion of the Secretary, be
25 satisfied—

1 “(A) through representation by a foreign gov-
2 ernment, if an inspection is conducted by a foreign
3 government using standards and practices as deter-
4 mined appropriate by the Secretary;

5 “(B) through representation by a foreign gov-
6 ernment or an agency of a foreign government rec-
7 ognized under section 809; or

8 “(C) other appropriate documentation or evi-
9 dence as described by the Secretary.

10 “(4)(A) Not later than 18 months after the date of
11 enactment of the Food and Drug Administration Safety
12 and Innovation Act, the Secretary shall adopt final regula-
13 tions implementing this subsection. Such requirements
14 shall be appropriate for the type of import, such as wheth-
15 er the drug is for import into the United States for use
16 in preclinical research or in a clinical investigation under
17 an investigational new drug exemption under 505(i).

18 “(B) In promulgating the regulations under subpara-
19 graph (A), the Secretary—

20 “(i) may, as appropriate, take into account dif-
21 ferences among importers and types of imports, and,
22 based on the level of risk posed by the imported
23 drug, provide for expedited clearance for those im-
24 porters that volunteer to participate in partnership
25 programs for highly compliant companies and pass

1 a review of internal controls, including sourcing of
2 foreign manufacturing inputs, and plant inspections;
3 and

4 “(ii) shall—

5 “(I) issue a notice of proposed rulemaking
6 that includes the proposed regulation;

7 “(II) provide a period of not less than 60
8 days for comments on the proposed regulation;
9 and

10 “(III) publish the final regulation not less
11 than 30 days before the effective date of the
12 regulation.

13 “(C) Notwithstanding any other provision of law, the
14 Secretary shall promulgate regulations implementing this
15 subsection only as described in subparagraph (B).”.

16 **SEC. 714. REGISTRATION OF COMMERCIAL IMPORTERS.**

17 (a) PROHIBITIONS.—Section 301 (21 U.S.C. 331) is
18 amended by adding at the end the following:

19 “(aaa) The failure to register in accordance with sec-
20 tion 801(s).”.

21 (b) REGISTRATION.—Section 801 (21 U.S.C. 381),
22 as amended by section 713 of this Act, is further amended
23 by adding at the end the following:

24 “(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

1 “(1) REGISTRATION.—The Secretary shall re-
2 quire a commercial importer of drugs—

3 “(A) to be registered with the Secretary in
4 a form and manner specified by the Secretary;
5 and

6 “(B) subject to paragraph (4), to submit,
7 at the time of registration, a unique identifier
8 for the principal place of business for which the
9 importer is required to register under this sub-
10 section.

11 “(2) REGULATIONS.—

12 “(A) IN GENERAL.—The Secretary, in con-
13 sultation with the Secretary of Homeland Secu-
14 rity acting through U.S. Customs and Border
15 Protection, shall promulgate regulations to es-
16 tablish good importer practices that specify the
17 measures an importer shall take to ensure im-
18 ported drugs are in compliance with the re-
19 quirements of this Act and the Public Health
20 Service Act.

21 “(B) PROCEDURE.—In promulgating a
22 regulation under subparagraph (A), the Sec-
23 retary shall—

1 “(i) issue a notice of proposed rule-
2 making that includes the proposed regula-
3 tion;

4 “(ii) provide a period of not less than
5 60 days for comments on the proposed reg-
6 ulation; and

7 “(iii) publish the final regulation not
8 less than 30 days before the regulation’s
9 effective date.

10 “(C) RESTRICTIONS.—Notwithstanding
11 any other provision of Federal law, in imple-
12 menting this subsection, the Secretary shall
13 only promulgate regulations as described in
14 subparagraph (B).

15 “(3) DISCONTINUANCE OF REGISTRATION.—
16 The Secretary shall discontinue the registration of
17 any commercial importer of drugs that fails to com-
18 ply with the regulations promulgated under this sub-
19 section.

20 “(4) UNIQUE FACILITY IDENTIFIER.—The Sec-
21 retary shall specify the unique facility identifier sys-
22 tem that shall be used by registrants under para-
23 graph (1). The requirement to include a unique fa-
24 cility identifier in a registration under paragraph (1)
25 shall not apply until the date that the identifier sys-

1 tem is specified by the Secretary under the pre-
2 ceding sentence.

3 “(5) EXEMPTIONS.—The Secretary, by notice
4 in the Federal Register, may establish exemptions
5 from the requirements of this subsection.”.

6 (c) MISBRANDING.—Section 502(o) (21 U.S.C. 352)
7 is amended by inserting “if it is a drug and was imported
8 or offered for import by a commercial importer of drugs
9 not duly registered under section 801(s),” after “not duly
10 registered under section 510,”.

11 (d) REGULATIONS.—

12 (1) IN GENERAL.—Not later than 36 months
13 after the date of the enactment of this Act, the Sec-
14 retary of Health and Human Services, in consulta-
15 tion with the Secretary of Homeland Security acting
16 through U.S. Customs and Border Protection, shall
17 promulgate the regulations required to carry out sec-
18 tion 801(s) of the Federal Food, Drug, and Cos-
19 metic Act, as added by subsection (b).

20 (2) PROCEDURES FOR PROMULGATING REGULA-
21 TIONS.—

22 (A) IN GENERAL.—In promulgating a reg-
23 ulation under paragraph (1), the Secretary
24 shall—

1 (i) issue a notice of proposed rule-
2 making that includes the proposed regula-
3 tion;

4 (ii) provide a period of not less than
5 60 days for comments on the proposed reg-
6 ulation; and

7 (iii) publish the final regulation not
8 less than 30 days before the regulation's
9 effective date.

10 (B) RESTRICTIONS.—Notwithstanding any
11 other provision of Federal law, in implementing
12 section 801(s) of the Federal Food, Drug, and
13 Cosmetic Act, as added by subsection (b), the
14 Secretary shall promulgate regulations only as
15 described in subparagraph (A).

16 (3) EFFECTIVE DATE.—In establishing the ef-
17 fective date of the regulations under paragraph (1),
18 the Secretary of Health and Human Services shall,
19 in consultation with the Secretary of Homeland Se-
20 curity acting through U.S. Customs and Border Pro-
21 tection, as determined appropriate by the Secretary
22 of Health and Human Services, provide a reasonable
23 period of time for an importer of a drug to comply
24 with good importer practices, taking into account
25 differences among importers and types of imports,

1 including based on the level of risk posed by the im-
2 ported product.

3 **SEC. 715. NOTIFICATION.**

4 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
5 331), as amended by section 714 of this Act, is further
6 amended by adding at the end the following:

7 “(bbb) The failure to notify the Secretary in violation
8 of section 568.”.

9 (b) NOTIFICATION.—Subchapter E of chapter V (21
10 U.S.C. 360bbb et seq.) is amended by adding at the end
11 the following:

12 **“SEC. 568. NOTIFICATION.**

13 “(a) NOTIFICATION TO SECRETARY.—With respect
14 to a drug, the Secretary may require notification to the
15 Secretary by a regulated person if the regulated person
16 knows—

17 “(1) that the use of such drug in the United
18 States may result in serious injury or death;

19 “(2) of a significant loss or known theft of such
20 drug intended for use in the United States; or

21 “(3) that—

22 “(A) such drug has been or is being coun-
23 terfeited; and

24 “(B)(i) the counterfeit product is in com-
25 merce in the United States or could be reason-

1 ably expected to be introduced into commerce in
2 the United States; or

3 “(ii) such drug has been or is being im-
4 ported into the United States or may reason-
5 ably be expected to be offered for import into
6 the United States.

7 “(b) MANNER OF NOTIFICATION.—Notification
8 under this section shall be made in such manner and by
9 such means as the Secretary may specify by regulation
10 or guidance.

11 “(c) SAVINGS CLAUSE.—Nothing in this section shall
12 be construed as limiting any other authority of the Sec-
13 retary to require notifications related to a drug under any
14 other provision of this Act or the Public Health Service
15 Act.

16 “(d) DEFINITION.—In this section, the term ‘regu-
17 lated person’ means—

18 “(1) a person who is required to register under
19 section 510 or 801(s);

20 “(2) a wholesale distributor of a drug product;
21 or

22 “(3) any other person that distributes drugs ex-
23 cept a person that distributes drugs exclusively for
24 retail sale.”.

1 **SEC. 716. PROTECTION AGAINST INTENTIONAL ADULTERA-**
2 **TION.**

3 Section 303(b) (21 U.S.C. 333(b)) is amended by
4 adding at the end the following:

5 “(7) Notwithstanding subsection (a)(2), any person
6 that knowingly and intentionally adulterates a drug such
7 that the drug is adulterated under subsection (a)(1), (b),
8 (c), or (d) of section 501 and has a reasonable probability
9 of causing serious adverse health consequences or death
10 to humans or animals shall be imprisoned for not more
11 than 20 years or fined not more than \$1,000,000, or
12 both.”.

13 **SEC. 717. PENALTIES FOR COUNTERFEITING DRUGS.**

14 (a) COUNTERFEIT DRUG PENALTY ENHANCE-
15 MENT.—

16 (1) OFFENSE.—Section 2320(a) of title 18,
17 United States Code, is amended—

18 (A) by striking “or” at the end of para-
19 graph (2);

20 (B) by inserting “or” at the end of para-
21 graph (3);

22 (C) by inserting after paragraph (3) the
23 following:

24 “(4) traffics in a counterfeit drug;” and

25 (D) by striking “through (3)” and insert-
26 ing “through (4)”.

1 (2) PENALTIES.—Section 2320(b)(3) of title
2 18, United States Code, is amended—

3 (A) in the heading, by inserting “AND
4 COUNTERFEIT DRUGS” after “SERVICES”; and

5 (B) by inserting “or counterfeit drug”
6 after “service”.

7 (3) DEFINITION.—Section 2320(f) of title 18,
8 United States Code, is amended—

9 (A) by striking “and” at the end of para-
10 graph (4);

11 (B) by striking the period at the end of
12 paragraph (5) and inserting “; and”; and

13 (C) by adding at the end the following:

14 “(6) the term ‘counterfeit drug’ means a drug,
15 as defined by section 201 of the Federal Food,
16 Drug, and Cosmetic Act, that uses a counterfeit
17 mark on or in connection with the drug.”.

18 (4) PRIORITY GIVEN TO CERTAIN INVESTIGA-
19 TIONS AND PROSECUTIONS.—The Attorney General
20 shall give increased priority to efforts to investigate
21 and prosecute offenses under section 2320 of title
22 18, United States Code, that involve counterfeit
23 drugs.

24 (b) SENTENCING COMMISSION DIRECTIVE.—

1 (1) DIRECTIVE TO SENTENCING COMMISSION.—

2 Pursuant to its authority under section 994(p) of
3 title 28, United States Code, and in accordance with
4 this subsection, the United States Sentencing Com-
5 mission shall review and amend, if appropriate, its
6 guidelines and its policy statements applicable to
7 persons convicted of an offense described in section
8 2320(a)(4) of title 18, United States Code, as
9 amended by subsection (a), in order to reflect the in-
10 tent of Congress that such penalties be increased in
11 comparison to those currently provided by the guide-
12 lines and policy statements.

13 (2) REQUIREMENTS.—In carrying out this sub-
14 section, the Commission shall—

15 (A) ensure that the sentencing guidelines
16 and policy statements reflect the intent of Con-
17 gress that the guidelines and policy statements
18 reflect the serious nature of the offenses de-
19 scribed in paragraph (1) and the need for an ef-
20 fective deterrent and appropriate punishment to
21 prevent such offenses;

22 (B) consider the extent to which the guide-
23 lines may or may not appropriately account for
24 the potential and actual harm to the public re-
25 sulting from the offense;

1 (C) assure reasonable consistency with
2 other relevant directives and with other sen-
3 tencing guidelines;

4 (D) account for any additional aggravating
5 or mitigating circumstances that might justify
6 exceptions to the generally applicable sentencing
7 ranges;

8 (E) make any necessary conforming
9 changes to the sentencing guidelines; and

10 (F) assure that the guidelines adequately
11 meet the purposes of sentencing as set forth in
12 section 3553(a)(2) of title 18, United States
13 Code.

14 **SEC. 718. EXTRATERRITORIAL JURISDICTION.**

15 Chapter III (21 U.S.C. 331 et seq.) is amended by
16 adding at the end the following:

17 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

18 “There is extraterritorial jurisdiction over any viola-
19 tion of this Act relating to any article regulated under this
20 Act if such article was intended for import into the United
21 States or if any act in furtherance of the violation was
22 committed in the United States.”.

1 **TITLE VIII—GENERATING**
2 **ANTIBIOTIC INCENTIVES NOW**

3 **SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

4 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.)
5 is amended by inserting after section 505D the following:

6 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**
7 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

8 “(a) EXTENSION.—If the Secretary approves an ap-
9 plication pursuant to section 505 for a drug that has been
10 designated as a qualified infectious disease product under
11 subsection (d), the 4- and 5-year periods described in sub-
12 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the
13 3-year periods described in clauses (iii) and (iv) of sub-
14 section (c)(3)(E) and clauses (iii) and (iv) of subsection
15 (j)(5)(F) of section 505, or the 7-year period described
16 in section 527, as applicable, shall be extended by 5 years.

17 “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
18 extension under subsection (a) of a period shall be in addi-
19 tion to any extension of the period under section 505A
20 with respect to the drug.

21 “(c) LIMITATIONS.—Subsection (a) does not apply to
22 the approval of—

23 “(1) a supplement to an application under sec-
24 tion 505(b) for any qualified infectious disease prod-

1 uct for which an extension described in subsection
2 (a) is in effect or has expired;

3 “(2) a subsequent application filed with respect
4 to a product approved under section 505 for a
5 change that results in a new indication, route of ad-
6 ministration, dosing schedule, dosage form, delivery
7 system, delivery device, or strength; or

8 “(3) a product that does not meet the definition
9 of a qualified infectious disease product under sub-
10 section (g) based upon its approved uses.

11 “(d) DESIGNATION.—

12 “(1) IN GENERAL.—The manufacturer or spon-
13 sor of a drug may request the Secretary to designate
14 a drug as a qualified infectious disease product at
15 any time before the submission of an application
16 under section 505(b) for such drug. The Secretary
17 shall, not later than 60 days after the submission of
18 such a request, determine whether the drug is a
19 qualified infectious disease product.

20 “(2) LIMITATION.—Except as provided in para-
21 graph (3), a designation under this subsection shall
22 not be withdrawn for any reason, including modifica-
23 tions to the list of qualifying pathogens under sub-
24 section (f)(2)(C).

1 “(3) REVOCATION OF DESIGNATION.—The Sec-
2 retary may revoke a designation of a drug as a
3 qualified infectious disease product if the Secretary
4 finds that the request for such designation contained
5 an untrue statement of material fact.

6 “(e) REGULATIONS.—

7 “(1) IN GENERAL.—Not later than 2 years
8 after the date of enactment of the Food and Drug
9 Administration Safety and Innovation Act, the Sec-
10 retary shall adopt final regulations implementing
11 this section, including developing the list of quali-
12 fying pathogens described in subsection (f).

13 “(2) PROCEDURE.—In promulgating a regula-
14 tion implementing this section, the Secretary shall—

15 “(A) issue a notice of proposed rulemaking
16 that includes the proposed regulation;

17 “(B) provide a period of not less than 60
18 days for comments on the proposed regulation;
19 and

20 “(C) publish the final regulation not less
21 than 30 days before the effective date of the
22 regulation.

23 “(3) RESTRICTIONS.—Notwithstanding any
24 other provision of law, the Secretary shall promul-
25 gate regulations implementing this section only as

1 described in paragraph (2), except that the Sec-
2 retary may issue interim guidance for sponsors seek-
3 ing designation under subsection (d) prior to the
4 promulgation of such regulations.

5 “(4) DESIGNATION PRIOR TO REGULATIONS.—
6 The Secretary shall designate drugs as qualified in-
7 fectionous disease products under subsection (d) prior
8 to the promulgation of regulations under this sub-
9 section, if such drugs meet the definition of a quali-
10 fied infectious disease product described in sub-
11 section (g).

12 “(f) QUALIFYING PATHOGEN.—

13 “(1) DEFINITION.—In this section, the term
14 ‘qualifying pathogen’ means a pathogen identified
15 and listed by the Secretary under paragraph (2) that
16 has the potential to pose a serious threat to public
17 health, such as—

18 “(A) resistant gram positive pathogens, in-
19 cluding methicillin-resistant *Staphylococcus*
20 *aureus*, vancomycin-resistant *Staphylococcus*
21 *aureus*, and vancomycin-resistant enterococcus;

22 “(B) multi-drug resistant gram negative
23 bacteria, including *Acinetobacter*, *Klebsiella*,
24 *Pseudomonas*, and *E. coli* species;

25 “(C) multi-drug resistant tuberculosis; and

1 “(D) *Clostridium difficile*.

2 “(2) LIST OF QUALIFYING PATHOGENS.—

3 “(A) IN GENERAL.—The Secretary shall
4 establish and maintain a list of qualifying
5 pathogens, and shall make public the method-
6 ology for developing such list.

7 “(B) CONSIDERATIONS.—In establishing
8 and maintaining the list of pathogens described
9 under this section, the Secretary shall—

10 “(i) consider—

11 “(I) the impact on the public
12 health due to drug-resistant orga-
13 nisms in humans;

14 “(II) the rate of growth of drug-
15 resistant organisms in humans;

16 “(III) the increase in resistance
17 rates in humans; and

18 “(IV) the morbidity and mor-
19 tality in humans; and

20 “(ii) consult with experts in infectious
21 diseases and antibiotic resistance, includ-
22 ing the Centers for Disease Control and
23 Prevention, the Food and Drug Adminis-
24 tration, medical professionals, and the clin-
25 ical research community.

1 “(C) REVIEW.—Every 5 years, or more
2 often as needed, the Secretary shall review, pro-
3 vide modifications to, and publish the list of
4 qualifying pathogens under subparagraph (A)
5 and shall by regulation revise the list as nec-
6 essary, in accordance with subsection (e).

7 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
8 The term ‘qualified infectious disease product’ means an
9 antibacterial or antifungal drug for human use intended
10 to treat serious or life-threatening infections, including
11 those caused by—

12 “(1) an antibacterial or antifungal resistant
13 pathogen, including novel or emerging infectious
14 pathogens; or

15 “(2) qualifying pathogens listed by the Sec-
16 retary under subsection (f).”.

17 (b) APPLICATION.—Section 505E of the Federal
18 Food, Drug, and Cosmetic Act, as added by subsection
19 (a), applies only with respect to a drug that is first ap-
20 proved under section 505(c) of such Act (21 U.S.C.
21 355(c)) on or after the date of the enactment of this Act.

22 **SEC. 802. PRIORITY REVIEW.**

23 (a) AMENDMENT.—Chapter V (21 U.S.C. 351 et
24 seq.) is amended by inserting after section 524 the fol-
25 lowing:

1 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**
2 **DISEASE PRODUCTS.**

3 “If the Secretary designates a drug under section
4 505E(d) as a qualified infectious disease product, then the
5 Secretary shall give priority review to any application sub-
6 mitted for approval for such drug under section 505(b).”.

7 (b) APPLICATION.—Section 524A of the Federal
8 Food, Drug, and Cosmetic Act, as added by subsection
9 (a), applies only with respect to an application that is sub-
10 mitted under section 505(b) of such Act (21 U.S.C.
11 355(b)) on or after the date of the enactment of this Act.

12 **SEC. 803. FAST TRACK PRODUCT.**

13 Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended
14 by section 901(b) of this Act, is amended by inserting “,
15 or if the Secretary designates the drug as a qualified infec-
16 tious disease product under section 505E(d)” before the
17 period at the end of the first sentence.

18 **SEC. 804. CLINICAL TRIALS.**

19 (a) REVIEW AND REVISION OF GUIDANCE DOCU-
20 MENTS.—

21 (1) IN GENERAL.—The Secretary of Health and
22 Human Services (referred to in this section as the
23 “Secretary”) shall review and, as appropriate, revise
24 not fewer than 3 guidance documents per year,
25 which shall include—

1 (A) reviewing the guidance documents of
2 the Food and Drug Administration for the con-
3 duct of clinical trials with respect to anti-
4 bacterial and antifungal drugs; and

5 (B) as appropriate, revising such guidance
6 documents to reflect developments in scientific
7 and medical information and technology and to
8 ensure clarity regarding the procedures and re-
9 quirements for approval of antibacterial and
10 antifungal drugs under chapter V of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C.
12 351 et seq.).

13 (2) ISSUES FOR REVIEW.—At a minimum, the
14 review under paragraph (1) shall address the appro-
15 priate animal models of infection, in vitro tech-
16 niques, valid microbiological surrogate markers, the
17 use of noninferiority versus superiority trials, trial
18 enrollment, data requirements, and appropriate delta
19 values for noninferiority trials.

20 (3) RULE OF CONSTRUCTION.—Except to the
21 extent to which the Secretary makes revisions under
22 paragraph (1)(B), nothing in this section shall be
23 construed to repeal or otherwise effect the guidance
24 documents of the Food and Drug Administration.

25 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

1 (1) REQUEST.—The sponsor of a drug intended
2 to be designated as a qualified infectious disease
3 product may request that the Secretary provide writ-
4 ten recommendations for nonclinical and clinical in-
5 vestigations which the Secretary believes may be
6 necessary to be conducted with the drug before such
7 drug may be approved under section 505 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)
9 for use in treating, detecting, preventing, or identi-
10 fying a qualifying pathogen, as defined in section
11 505E of such Act.

12 (2) RECOMMENDATIONS.—If the Secretary has
13 reason to believe that a drug for which a request is
14 made under this subsection is a qualified infectious
15 disease product, the Secretary shall provide the per-
16 son making the request written recommendations for
17 the nonclinical and clinical investigations which the
18 Secretary believes, on the basis of information avail-
19 able to the Secretary at the time of the request,
20 would be necessary for approval under section 505
21 of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 355) of such drug for the use described in
23 paragraph (1).

24 (c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
25 For purposes of this section, the term “qualified infectious

1 disease product” has the meaning given such term in sec-
2 tion 505E(g) of the Federal Food, Drug, and Cosmetic
3 Act, as added by section 801 of this Act.

4 **SEC. 805. REASSESSMENT OF QUALIFIED INFECTIOUS DIS-**
5 **EASE PRODUCT INCENTIVES IN 5 YEARS.**

6 (a) IN GENERAL.—Not later than 5 years after the
7 date of enactment of this Act, the Secretary of Health and
8 Human Services shall, in consultation with the Food and
9 Drug Administration, the Centers for Disease Control and
10 Prevention, and other appropriate agencies, submit to the
11 Committee on Energy and Commerce of the House of
12 Representatives and the Committee on Health, Education,
13 Labor, and Pensions of the Senate a report that contains
14 the following:

15 (1)(A) The number of initial designations of
16 drugs as qualified infectious disease products under
17 section 505E of the Federal Food, Drug, and Cos-
18 metic Act.

19 (B) The number of qualified infectious disease
20 products approved under such section 505E.

21 (C) Whether such products address the need for
22 antibacterial and antifungal drugs to treat serious
23 and life-threatening infections.

24 (D) A list of qualified infectious disease prod-
25 ucts with information on the types of exclusivity

1 granted for each product, consistent with the infor-
2 mation published under section 505(j)(7)(A)(iii) of
3 the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 355(j)(7)(A)(iii)).

5 (E) The progress made regarding the review
6 and revision of the clinical trial guidance documents
7 required under section 804 and the impact such re-
8 view and revision has had on the review and ap-
9 proval of qualified infectious disease products.

10 (F) The Federal contribution, if any, to funding
11 of the clinical trials for each qualified infectious dis-
12 ease product for each phase.

13 (2) Recommendations—

14 (A) based on the information under para-
15 graph (1) and any other relevant data, on any
16 changes that should be made to the list of
17 pathogens that are defined as qualifying patho-
18 gens under section 505E(f)(2) of the Federal
19 Food, Drug, and Cosmetic Act, as added by
20 section 801 of this Act; and

21 (B) on whether any additional program
22 (such as the development of public-private col-
23 laborations to advance antibacterial drug inno-
24 vation) or changes to the incentives under this

1 subtitle may be needed to promote the develop-
2 ment of antibacterial drugs.

3 (3) An examination of—

4 (A) the adoption of programs to measure
5 the use of antibacterial drugs in health care set-
6 tings; and

7 (B) the implementation and effectiveness
8 of antimicrobial stewardship protocols across all
9 health care settings.

10 (4) Any recommendations for ways to encour-
11 age further development and establishment of stew-
12 ardship programs.

13 (5) A description of the regulatory challenges
14 and impediments to clinical development, approval,
15 and licensure of qualified infectious disease prod-
16 ucts, and the steps the Secretary has taken and will
17 take to address such challenges and ensure regu-
18 latory certainty and predictability with respect to
19 qualified infectious disease products.

20 (b) DEFINITION.—For purposes of this section, the
21 term “qualified infectious disease product” has the mean-
22 ing given such term in section 505E(g) of the Federal
23 Food, Drug, and Cosmetic Act, as added by section 801
24 of this Act.

1 **SEC. 806. GUIDANCE ON PATHOGEN-FOCUSED ANTI-**
2 **BACTERIAL DRUG DEVELOPMENT.**

3 (a) DRAFT GUIDANCE.—Not later than June 30,
4 2013, in order to facilitate the development of anti-
5 bacterial drugs for serious or life-threatening bacterial in-
6 fections, particularly in areas of unmet need, the Secretary
7 of Health and Human Services shall publish draft guid-
8 ance that—

9 (1) specifies how preclinical and clinical data
10 can be utilized to inform an efficient and stream-
11 lined pathogen-focused antibacterial drug develop-
12 ment program that meets the approval standards of
13 the Food and Drug Administration; and

14 (2) provides advice on approaches for the devel-
15 opment of antibacterial drugs that target a more
16 limited spectrum of pathogens.

17 (b) FINAL GUIDANCE.—Not later than December 31,
18 2014, after notice and opportunity for public comment on
19 the draft guidance under subsection (a), the Secretary of
20 Health and Human Services shall publish final guidance
21 consistent with this section.

22 **TITLE IX—DRUG APPROVAL AND**
23 **PATIENT ACCESS**

24 **SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT AC-**
25 **CESS TO NEW MEDICAL TREATMENTS.**

26 (a) FINDINGS; SENSE OF CONGRESS.—

1 (1) FINDINGS.—Congress finds as follows:

2 (A) The Food and Drug Administration
3 (referred to in this section as the “FDA”)
4 serves a critical role in helping to assure that
5 new medicines are safe and effective. Regu-
6 latory innovation is 1 element of the Nation’s
7 strategy to address serious and life-threatening
8 diseases or conditions by promoting investment
9 in and development of innovative treatments for
10 unmet medical needs.

11 (B) During the 2 decades following the es-
12 tablishment of the accelerated approval mecha-
13 nism, advances in medical sciences, including
14 genomics, molecular biology, and bioinformatics,
15 have provided an unprecedented understanding
16 of the underlying biological mechanism and
17 pathogenesis of disease. A new generation of
18 modern, targeted medicines is under develop-
19 ment to treat serious and life-threatening dis-
20 eases, some applying drug development strate-
21 gies based on biomarkers or pharmacogenomics,
22 predictive toxicology, clinical trial enrichment
23 techniques, and novel clinical trial designs, such
24 as adaptive clinical trials.

1 (C) As a result of these remarkable sci-
2 entific and medical advances, the FDA should
3 be encouraged to implement more broadly effec-
4 tive processes for the expedited development
5 and review of innovative new medicines in-
6 tended to address unmet medical needs for seri-
7 ous or life-threatening diseases or conditions,
8 including those for rare diseases or conditions,
9 using a broad range of surrogate or clinical
10 endpoints and modern scientific tools earlier in
11 the drug development cycle when appropriate.
12 This may result in fewer, smaller, or shorter
13 clinical trials for the intended patient popu-
14 lation or targeted subpopulation without com-
15 promising or altering the high standards of the
16 FDA for the approval of drugs.

17 (D) Patients benefit from expedited access
18 to safe and effective innovative therapies to
19 treat unmet medical needs for serious or life-
20 threatening diseases or conditions.

21 (E) For these reasons, the statutory au-
22 thority in effect on the day before the date of
23 enactment of this Act governing expedited ap-
24 proval of drugs for serious or life-threatening
25 diseases or conditions should be amended in

1 “(1) IN GENERAL.—The Secretary shall, at the
2 request of the sponsor of a new drug, facilitate the
3 development and expedite the review of such drug if
4 it is intended, whether alone or in combination with
5 one or more other drugs, for the treatment of a seri-
6 ous or life-threatening disease or condition, and it
7 demonstrates the potential to address unmet medical
8 needs for such a disease or condition. (In this sec-
9 tion, such a drug is referred to as a ‘fast track prod-
10 uct’.)

11 “(2) REQUEST FOR DESIGNATION.—The spon-
12 sor of a new drug may request the Secretary to des-
13 ignate the drug as a fast track product. A request
14 for the designation may be made concurrently with,
15 or at any time after, submission of an application
16 for the investigation of the drug under section 505(i)
17 or section 351(a)(3) of the Public Health Service
18 Act.

19 “(3) DESIGNATION.—Within 60 calendar days
20 after the receipt of a request under paragraph (2),
21 the Secretary shall determine whether the drug that
22 is the subject of the request meets the criteria de-
23 scribed in paragraph (1). If the Secretary finds that
24 the drug meets the criteria, the Secretary shall des-
25 ignate the drug as a fast track product and shall

1 take such actions as are appropriate to expedite the
2 development and review of the application for ap-
3 proval of such product.

4 “(b) ACCELERATED APPROVAL OF A DRUG FOR A
5 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
6 TION, INCLUDING A FAST TRACK PRODUCT.—

7 “(1) IN GENERAL.—

8 “(A) ACCELERATED APPROVAL.—The Sec-
9 retary may approve an application for approval
10 of a product for a serious or life-threatening
11 disease or condition, including a fast track
12 product, under section 505(c) or section 351(a)
13 of the Public Health Service Act upon a deter-
14 mination that the product has an effect on a
15 surrogate endpoint that is reasonably likely to
16 predict clinical benefit, or on a clinical endpoint
17 that can be measured earlier than irreversible
18 morbidity or mortality, that is reasonably likely
19 to predict an effect on irreversible morbidity or
20 mortality or other clinical benefit, taking into
21 account the severity, rarity, or prevalence of the
22 condition and the availability or lack of alter-
23 native treatments. The approval described in
24 the preceding sentence is referred to in this sec-
25 tion as ‘accelerated approval’.

1 “(B) EVIDENCE.—The evidence to support
2 that an endpoint is reasonably likely to predict
3 clinical benefit under subparagraph (A) may in-
4 clude epidemiological, pathophysiological, thera-
5 peutic, pharmacologic, or other evidence devel-
6 oped using biomarkers, for example, or other
7 scientific methods or tools.

8 “(2) LIMITATION.—Approval of a product
9 under this subsection may be subject to 1 or both
10 of the following requirements:

11 “(A) That the sponsor conduct appropriate
12 postapproval studies to verify and describe the
13 predicted effect on irreversible morbidity or
14 mortality or other clinical benefit.

15 “(B) That the sponsor submit copies of all
16 promotional materials related to the product
17 during the preapproval review period and, fol-
18 lowing approval and for such period thereafter
19 as the Secretary determines to be appropriate,
20 at least 30 days prior to dissemination of the
21 materials.

22 “(3) EXPEDITED WITHDRAWAL OF AP-
23 PROVAL.—The Secretary may withdraw approval of
24 a product approved under accelerated approval using
25 expedited procedures (as prescribed by the Secretary

1 in regulations which shall include an opportunity for
2 an informal hearing) if—

3 “(A) the sponsor fails to conduct any re-
4 quired postapproval study of the drug with due
5 diligence;

6 “(B) a study required to verify and de-
7 scribe the predicted effect on irreversible mor-
8 bidity or mortality or other clinical benefit of
9 the product fails to verify and describe such ef-
10 fect or benefit;

11 “(C) other evidence demonstrates that the
12 product is not safe or effective under the condi-
13 tions of use; or

14 “(D) the sponsor disseminates false or
15 misleading promotional materials with respect
16 to the product.

17 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR
18 APPROVAL OF A FAST TRACK PRODUCT.—

19 “(1) IN GENERAL.—If the Secretary deter-
20 mines, after preliminary evaluation of clinical data
21 submitted by the sponsor, that a fast track product
22 may be effective, the Secretary shall evaluate for fil-
23 ing, and may commence review of portions of, an ap-
24 plication for the approval of the product before the
25 sponsor submits a complete application. The Sec-

1 retary shall commence such review only if the appli-
2 cant—

3 “(A) provides a schedule for submission of
4 information necessary to make the application
5 complete; and

6 “(B) pays any fee that may be required
7 under section 736.

8 “(2) EXCEPTION.—Any time period for review
9 of human drug applications that has been agreed to
10 by the Secretary and that has been set forth in goals
11 identified in letters of the Secretary (relating to the
12 use of fees collected under section 736 to expedite
13 the drug development process and the review of
14 human drug applications) shall not apply to an ap-
15 plication submitted under paragraph (1) until the
16 date on which the application is complete.

17 “(d) AWARENESS EFFORTS.—The Secretary shall—

18 “(1) develop and disseminate to physicians, pa-
19 tient organizations, pharmaceutical and bio-
20 technology companies, and other appropriate persons
21 a description of the provisions of this section appli-
22 cable to accelerated approval and fast track prod-
23 ucts; and

24 “(2) establish a program to encourage the de-
25 velopment of surrogate and clinical endpoints, in-

1 including biomarkers, and other scientific methods and
2 tools that can assist the Secretary in determining
3 whether the evidence submitted in an application is
4 reasonably likely to predict clinical benefit for seri-
5 ous or life-threatening conditions for which signifi-
6 cant unmet medical needs exist.

7 “(e) CONSTRUCTION.—

8 “(1) PURPOSE.—The amendments made by the
9 Food and Drug Administration Safety and Innova-
10 tion Act to this section are intended to encourage
11 the Secretary to utilize innovative and flexible ap-
12 proaches to the assessment of products under accel-
13 erated approval for treatments for patients with seri-
14 ous or life-threatening diseases or conditions and
15 unmet medical needs.

16 “(2) CONSTRUCTION.—Nothing in this section
17 shall be construed to alter the standards of evidence
18 under subsection (c) or (d) of section 505 (including
19 the substantial evidence standard in section 505(d))
20 of this Act or under section 351(a) of the Public
21 Health Service Act. Such sections and standards of
22 evidence apply to the review and approval of prod-
23 ucts under this section, including whether a product
24 is safe and effective. Nothing in this section alters
25 the ability of the Secretary to rely on evidence that

1 does not come from adequate and well-controlled in-
2 vestigations for the purpose of determining whether
3 an endpoint is reasonably likely to predict clinical
4 benefit as described in subsection (b)(1)(B).”.

5 (c) GUIDANCE; AMENDED REGULATIONS.—

6 (1) DRAFT GUIDANCE.—Not later than 1 year
7 after the date of enactment of this Act, the Sec-
8 retary of Health and Human Services (referred to in
9 this section as the “Secretary”) shall issue draft
10 guidance to implement the amendments made by
11 this section. In developing such guidance, the Sec-
12 retary shall specifically consider issues arising under
13 the accelerated approval and fast track processes
14 under section 506 of the Federal Food, Drug, and
15 Cosmetic Act, as amended by subsection (b), for
16 drugs designated for a rare disease or condition
17 under section 526 of such Act (21 U.S.C. 360bb)
18 and shall also consider any unique issues associated
19 with very rare diseases.

20 (2) FINAL GUIDANCE.—Not later than 1 year
21 after the issuance of draft guidance under para-
22 graph (1), and after an opportunity for public com-
23 ment, the Secretary shall—

24 (A) issue final guidance; and

1 (B) amend the regulations governing accel-
2 erated approval in parts 314 and 601 of title
3 21, Code of Federal Regulations, as necessary
4 to conform such regulations with the amend-
5 ment made by subsection (b).

6 (3) CONSIDERATION.—In developing the guid-
7 ance under paragraphs (1) and (2)(A) and the
8 amendments under paragraph (2)(B), the Secretary
9 shall consider how to incorporate novel approaches
10 to the review of surrogate endpoints based on patho-
11 physiologic and pharmacologic evidence in such guid-
12 ance, especially in instances where the low preva-
13 lence of a disease renders the existence or collection
14 of other types of data unlikely or impractical.

15 (4) CONFORMING CHANGES.—The Secretary
16 shall issue, as necessary, conforming amendments to
17 the applicable regulations under title 21, Code of
18 Federal Regulations, governing accelerated approval.

19 (5) NO EFFECT OF INACTION ON REQUESTS.—
20 The issuance (or nonissuance) of guidance or con-
21 forming regulations implementing the amendment
22 made by subsection (b) shall not preclude the review
23 of, or action on, a request for designation or an ap-
24 plication for approval submitted pursuant to section

1 506 of the Federal Food, Drug, and Cosmetic Act,
2 as amended by subsection (b).

3 (d) INDEPENDENT REVIEW.—The Secretary may, in
4 conjunction with other planned reviews, contract with an
5 independent entity with expertise in assessing the quality
6 and efficiency of biopharmaceutical development and regu-
7 latory review programs to evaluate the Food and Drug Ad-
8 ministration’s application of the processes described in
9 section 506 of the Federal Food, Drug, and Cosmetic Act,
10 as amended by subsection (b), and the impact of such
11 processes on the development and timely availability of in-
12 novative treatments for patients suffering from serious or
13 life-threatening conditions. Any such evaluation shall in-
14 clude consultation with regulated industries, patient advo-
15 cacy and disease research foundations, and relevant aca-
16 demic medical centers.

17 **SEC. 902. BREAKTHROUGH THERAPIES.**

18 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as
19 amended by section 901 of this Act, is further amended—

20 (1) by redesignating subsections (a) through (c)
21 as subsections (b) through (d), respectively;

22 (2) by redesignating subsection (d) as sub-
23 section (f);

24 (3) by inserting before subsection (b), as so re-
25 designated, the following:

1 “(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH
2 THERAPY.—

3 “(1) IN GENERAL.—The Secretary shall, at the
4 request of the sponsor of a drug, expedite the devel-
5 opment and review of such drug if the drug is in-
6 tended, alone or in combination with 1 or more other
7 drugs, to treat a serious or life-threatening disease
8 or condition and preliminary clinical evidence indi-
9 cates that the drug may demonstrate substantial im-
10 provement over existing therapies on 1 or more clini-
11 cally significant endpoints, such as substantial treat-
12 ment effects observed early in clinical development.
13 (In this section, such a drug is referred to as a
14 ‘breakthrough therapy’.)

15 “(2) REQUEST FOR DESIGNATION.—The spon-
16 sor of a drug may request the Secretary to designate
17 the drug as a breakthrough therapy. A request for
18 the designation may be made concurrently with, or
19 at any time after, the submission of an application
20 for the investigation of the drug under section 505(i)
21 or section 351(a)(3) of the Public Health Service
22 Act.

23 “(3) DESIGNATION.—

24 “(A) IN GENERAL.—Not later than 60 cal-
25 endar days after the receipt of a request under

1 paragraph (2), the Secretary shall determine
2 whether the drug that is the subject of the re-
3 quest meets the criteria described in paragraph
4 (1). If the Secretary finds that the drug meets
5 the criteria, the Secretary shall designate the
6 drug as a breakthrough therapy and shall take
7 such actions as are appropriate to expedite the
8 development and review of the application for
9 approval of such drug.

10 “(B) ACTIONS.—The actions to expedite
11 the development and review of an application
12 under subparagraph (A) may include, as appro-
13 priate—

14 “(i) holding meetings with the sponsor
15 and the review team throughout the devel-
16 opment of the drug;

17 “(ii) providing timely advice to, and
18 interactive communication with, the spon-
19 sor regarding the development of the drug
20 to ensure that the development program to
21 gather the nonclinical and clinical data
22 necessary for approval is as efficient as
23 practicable;

1 “(iii) involving senior managers and
2 experienced review staff, as appropriate, in
3 a collaborative, cross-disciplinary review;

4 “(iv) assigning a cross-disciplinary
5 project lead for the Food and Drug Ad-
6 ministration review team to facilitate an
7 efficient review of the development pro-
8 gram and to serve as a scientific liaison be-
9 tween the review team and the sponsor;
10 and

11 “(v) taking steps to ensure that the
12 design of the clinical trials is as efficient as
13 practicable, when scientifically appropriate,
14 such as by minimizing the number of pa-
15 tients exposed to a potentially less effica-
16 cious treatment.”; and

17 (4) in subsection (f)(1), as so redesignated, by
18 striking “applicable to accelerated approval” and in-
19 serting “applicable to breakthrough therapies, accel-
20 erated approval, and”.

21 (b) GUIDANCE; AMENDED REGULATIONS.—

22 (1) IN GENERAL.—

23 (A) GUIDANCE.—Not later than 18
24 months after the date of enactment of this Act,
25 the Secretary of Health and Human Services

1 (referred to in this section as the “Secretary”)
2 shall issue draft guidance on implementing the
3 requirements with respect to breakthrough
4 therapies, as set forth in section 506(a) of the
5 Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 356(a)), as amended by this section.
7 The Secretary shall issue final guidance not
8 later than 1 year after the close of the comment
9 period for the draft guidance.

10 (B) AMENDED REGULATIONS.—

11 (i) IN GENERAL.—If the Secretary de-
12 termines that it is necessary to amend the
13 regulations under title 21, Code of Federal
14 Regulations in order to implement the
15 amendments made by this section to sec-
16 tion 506(a) of the Federal Food, Drug,
17 and Cosmetic Act, the Secretary shall
18 amend such regulations not later than 2
19 years after the date of enactment of this
20 Act.

21 (ii) PROCEDURE.—In amending regu-
22 lations under clause (i), the Secretary
23 shall—

1 (I) issue a notice of proposed
2 rulemaking that includes the proposed
3 regulation;

4 (II) provide a period of not less
5 than 60 days for comments on the
6 proposed regulation; and

7 (III) publish the final regulation
8 not less than 30 days before the effec-
9 tive date of the regulation.

10 (iii) RESTRICTIONS.—Notwithstanding
11 any other provision of law, the Secretary
12 shall promulgate regulations implementing
13 the amendments made by this section only
14 as described in clause (ii).

15 (2) REQUIREMENTS.—Guidance issued under
16 this section shall—

17 (A) specify the process and criteria by
18 which the Secretary makes a designation under
19 section 506(a)(3) of the Federal Food, Drug,
20 and Cosmetic Act; and

21 (B) specify the actions the Secretary shall
22 take to expedite the development and review of
23 a breakthrough therapy pursuant to such des-
24 ignation under such section 506(a)(3), includ-

1 ing updating good review management practices
2 to reflect breakthrough therapies.

3 (c) CONFORMING AMENDMENTS.—Section 506B(e)
4 (21 U.S.C. 356b) is amended by striking “section
5 506(b)(2)(A)” each place such term appears and inserting
6 “section 506(c)(2)(A)”.

7 **SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON**
8 **RARE DISEASES, TARGETED THERAPIES, AND**
9 **GENETIC TARGETING OF TREATMENTS.**

10 Subchapter E of chapter V (21 U.S.C. 360bbb et
11 seq.), as amended by section 715 of this Act, is further
12 amended by adding at the end the following:

13 **“SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON**
14 **RARE DISEASES, TARGETED THERAPIES, AND**
15 **GENETIC TARGETING OF TREATMENTS.**

16 “(a) IN GENERAL.—For the purpose of promoting
17 the efficiency of and informing the review by the Food
18 and Drug Administration of new drugs and biological
19 products for rare diseases and drugs and biological prod-
20 ucts that are genetically targeted, the following shall
21 apply:

22 “(1) CONSULTATION WITH STAKEHOLDERS.—
23 Consistent with sections X.C and IX.E.4 of the
24 PDUFA Reauthorization Performance Goals and
25 Procedures Fiscal Years 2013 through 2017, as ref-

1 erenced in the letters described in section 101(b) of
2 the Prescription Drug User Fee Amendments of
3 2012, the Secretary shall ensure that opportunities
4 exist, at a time the Secretary determines appro-
5 priate, for consultations with stakeholders on the
6 topics described in subsection (b).

7 “(2) CONSULTATION WITH EXTERNAL EX-
8 PERTS.—

9 “(A) IN GENERAL.—The Secretary shall
10 develop and maintain a list of external experts
11 who, because of their special expertise, are
12 qualified to provide advice on rare disease
13 issues, including topics described in subsection
14 (c). The Secretary may, when appropriate to
15 address a specific regulatory question, consult
16 such external experts on issues related to the
17 review of new drugs and biological products for
18 rare diseases and drugs and biological products
19 that are genetically targeted, including the top-
20 ics described in subsection (b), when such con-
21 sultation is necessary because the Secretary
22 lacks the specific scientific, medical, or tech-
23 nical expertise necessary for the performance of
24 the Secretary’s regulatory responsibilities and

1 the necessary expertise can be provided by the
2 external experts.

3 “(B) EXTERNAL EXPERTS.—For purposes
4 of subparagraph (A), external experts are indi-
5 viduals who possess scientific or medical train-
6 ing that the Secretary lacks with respect to one
7 or more rare diseases.

8 “(b) TOPICS FOR CONSULTATION.—Topics for con-
9 sultation pursuant to this section may include—

10 “(1) rare diseases;

11 “(2) the severity of rare diseases;

12 “(3) the unmet medical need associated with
13 rare diseases;

14 “(4) the willingness and ability of individuals
15 with a rare disease to participate in clinical trials;

16 “(5) an assessment of the benefits and risks of
17 therapies to treat rare diseases;

18 “(6) the general design of clinical trials for rare
19 disease populations and subpopulations; and

20 “(7) the demographics and the clinical descrip-
21 tion of patient populations.

22 “(c) CLASSIFICATION AS SPECIAL GOVERNMENT EM-
23 PLOYEES.—The external experts who are consulted under
24 this section may be considered special government employ-

1 ees, as defined under section 202 of title 18, United States
2 Code.

3 “(d) PROTECTION OF CONFIDENTIAL INFORMATION
4 AND TRADE SECRETS.—

5 “(1) RULE OF CONSTRUCTION.—Nothing in
6 this section shall be construed to alter the protec-
7 tions offered by laws, regulations, and policies gov-
8 erning disclosure of confidential commercial or trade
9 secret information, and any other information ex-
10 empt from disclosure pursuant to section 552(b) of
11 title 5, United States Code, as such provisions would
12 be applied to consultation with individuals and orga-
13 nizations prior to the date of enactment of this sec-
14 tion.

15 “(2) CONSENT REQUIRED FOR DISCLOSURE.—
16 The Secretary shall not disclose confidential com-
17 mercial or trade secret information to an expert con-
18 sulted under this section without the written consent
19 of the sponsor unless the expert is a special govern-
20 ment employee (as defined under section 202 of title
21 18, United States Code) or the disclosure is other-
22 wise authorized by law.

23 “(e) OTHER CONSULTATION.—Nothing in this sec-
24 tion shall be construed to limit the ability of the Secretary

1 to consult with individuals and organizations as authorized
2 prior to the date of enactment of this section.

3 “(f) NO RIGHT OR OBLIGATION.—

4 “(1) NO RIGHT TO CONSULTATION.—Nothing
5 in this section shall be construed to create a legal
6 right for a consultation on any matter or require the
7 Secretary to meet with any particular expert or
8 stakeholder.

9 “(2) NO ALTERING OF GOALS.—Nothing in this
10 section shall be construed to alter agreed upon goals
11 and procedures identified in the letters described in
12 section 101(b) of the Prescription Drug User Fee
13 Amendments of 2012.

14 “(3) NO CHANGE TO NUMBER OF REVIEW CY-
15 CLES.—Nothing in this section is intended to in-
16 crease the number of review cycles as in effect before
17 the date of enactment of this section.

18 “(g) NO DELAY IN PRODUCT REVIEW.—

19 “(1) IN GENERAL.—Prior to a consultation
20 with an external expert, as described in this section,
21 relating to an investigational new drug application
22 under section 505(i), a new drug application under
23 section 505(b), or a biologics license application
24 under section 351 of the Public Health Service Act,
25 the Director of the Center for Drug Evaluation and

1 Research or the Director of the Center for Biologics
2 Evaluation and Research (or appropriate Division
3 Director), as appropriate, shall determine that—

4 “(A) such consultation will—

5 “(i) facilitate the Secretary’s ability to
6 complete the Secretary’s review; and

7 “(ii) address outstanding deficiencies
8 in the application; or

9 “(B) the sponsor authorized such consulta-
10 tion.

11 “(2) LIMITATION.—The requirements of this
12 subsection shall apply only in instances where the
13 consultation is undertaken solely under the authority
14 of this section. The requirements of this subsection
15 shall not apply to any consultation initiated under
16 any other authority.”.

17 **SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIP-**
18 **TION DRUG CONTAINER LABELS BY VIS-**
19 **UALLY IMPAIRED AND BLIND CONSUMERS.**

20 (a) ESTABLISHMENT OF WORKING GROUP.—

21 (1) IN GENERAL.—The Architectural and
22 Transportation Barriers Compliance Board (referred
23 to in this section as the “Access Board”) shall con-
24 vene a stakeholder working group (referred to in this
25 section as the “working group”) to develop best

1 practices on access to information on prescription
2 drug container labels for individuals who are blind
3 or visually impaired.

4 (2) MEMBERS.—The working group shall be
5 comprised of representatives of national organiza-
6 tions representing blind and visually impaired indi-
7 viduals, national organizations representing the el-
8 derly, and industry groups representing stake-
9 holders, including retail, mail-order, and independent
10 community pharmacies, who would be impacted by
11 such best practices. Representation within the work-
12 ing group shall be divided equally between consumer
13 and industry advocates.

14 (3) BEST PRACTICES.—

15 (A) IN GENERAL.—The working group
16 shall develop, not later than 1 year after the
17 date of the enactment of this Act, best practices
18 for pharmacies to ensure that blind and visually
19 impaired individuals have safe, consistent, reli-
20 able, and independent access to the information
21 on prescription drug container labels.

22 (B) PUBLIC AVAILABILITY.—The best
23 practices developed under subparagraph (A)
24 may be made publicly available, including
25 through the Internet Web sites of the working

1 group participant organizations, and through
2 other means, in a manner that provides access
3 to interested individuals, including individuals
4 with disabilities.

5 (C) LIMITATIONS.—The best practices de-
6 veloped under subparagraph (A) shall not be
7 construed as accessibility guidelines or stand-
8 ards of the Access Board, and shall not confer
9 any rights or impose any obligations on working
10 group participants or other persons. Nothing in
11 this section shall be construed to limit or condi-
12 tion any right, obligation, or remedy available
13 under the Americans with Disabilities Act of
14 1990 (42 U.S.C. 12101 et seq.) or any other
15 Federal or State law requiring effective commu-
16 nication, barrier removal, or nondiscrimination
17 on the basis of disability.

18 (4) CONSIDERATIONS.—In developing and
19 issuing the best practices under paragraph (3)(A),
20 the working group shall consider—

21 (A) the use of—

22 (i) Braille;

23 (ii) auditory means, such as—

24 (I) “talking bottles” that provide
25 audible container label information;

1 (II) digital voice recorders at-
2 tached to the prescription drug con-
3 tainer; and

4 (III) radio frequency identifica-
5 tion tags;

6 (iii) enhanced visual means, such as—

7 (I) large font labels or large font
8 “duplicate” labels that are affixed or
9 matched to a prescription drug con-
10 tainer;

11 (II) high-contrast printing; and

12 (III) sans-serif font; and

13 (iv) other relevant alternatives as de-
14 termined by the working group;

15 (B) whether there are technical, financial,
16 manpower, or other factors unique to phar-
17 macies with 20 or fewer retail locations which
18 may pose significant challenges to the adoption
19 of the best practices; and

20 (C) such other factors as the working
21 group determines to be appropriate.

22 (5) INFORMATION CAMPAIGN.—Upon comple-
23 tion of development of the best practices under sub-
24 section (a)(3), the National Council on Disability, in
25 consultation with the working group, shall conduct

1 an informational and educational campaign designed
2 to inform individuals with disabilities, pharmacists,
3 and the public about such best practices.

4 (6) FACA WAIVER.—The Federal Advisory
5 Committee Act (5 U.S.C. App.) shall not apply to
6 the working group.

7 (b) GAO STUDY.—

8 (1) IN GENERAL.—Beginning 18 months after
9 the completion of the development of best practices
10 under subsection (a)(3)(A), the Comptroller General
11 of the United States shall conduct a review of the
12 extent to which pharmacies are utilizing such best
13 practices, and the extent to which barriers to acces-
14 sible information on prescription drug container la-
15 bels for blind and visually impaired individuals con-
16 tinue.

17 (2) REPORT.—Not later than September 30,
18 2016, the Comptroller General of the United States
19 shall submit to Congress a report on the review con-
20 ducted under paragraph (1). Such report shall in-
21 clude recommendations about how best to reduce the
22 barriers experienced by blind and visually impaired
23 individuals to independently accessing information
24 on prescription drug container labels.

25 (c) DEFINITIONS.—In this section—

1 (1) the term “pharmacy” includes a pharmacy
2 that receives prescriptions and dispenses prescription
3 drugs through an Internet Web site or by mail;

4 (2) the term “prescription drug” means a drug
5 subject to section 503(b)(1) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

7 (3) the term “prescription drug container label”
8 means the label with the directions for use that is
9 affixed to the prescription drug container by the
10 pharmacist and dispensed to the consumer.

11 **SEC. 905. RISK-BENEFIT FRAMEWORK.**

12 Section 505(d) (21 U.S.C. 355(d)) is amended by
13 adding at the end the following: “The Secretary shall im-
14 plement a structured risk-benefit assessment framework
15 in the new drug approval process to facilitate the balanced
16 consideration of benefits and risks, a consistent and sys-
17 tematic approach to the discussion and regulatory deci-
18 sionmaking, and the communication of the benefits and
19 risks of new drugs. Nothing in the preceding sentence
20 shall alter the criteria for evaluating an application for
21 premarket approval of a drug.”.

22 **SEC. 906. GRANTS AND CONTRACTS FOR THE DEVELOP-**
23 **MENT OF ORPHAN DRUGS.**

24 (a) **QUALIFIED TESTING DEFINITION.**—Section
25 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.

1 360ee(b)(1)(A)(ii) is amended by striking “after the date
2 such drug is designated under section 526 of such Act
3 and”.

4 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
5 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is
6 amended to read as follows:

7 “(c) AUTHORIZATION OF APPROPRIATIONS.—For
8 grants and contracts under subsection (a), there is author-
9 ized to be appropriated \$30,000,000 for each of fiscal
10 years 2013 through 2017.”.

11 **SEC. 907. REPORTING OF INCLUSION OF DEMOGRAPHIC**
12 **SUBGROUPS IN CLINICAL TRIALS AND DATA**
13 **ANALYSIS IN APPLICATIONS FOR DRUGS, BIO-**
14 **LOGICS, AND DEVICES.**

15 (a) REPORT.—

16 (1) IN GENERAL.—Not later than 1 year after
17 the date of enactment of this Act, the Secretary, act-
18 ing through the Commissioner, shall publish on the
19 Internet Web site of the Food and Drug Administra-
20 tion a report, consistent with the regulations of the
21 Food and Drug Administration pertaining to the
22 protection of sponsors’ confidential commercial infor-
23 mation as of the date of enactment of this Act, ad-
24 dressing the extent to which clinical trial participa-
25 tion and the inclusion of safety and effectiveness

1 data by demographic subgroups including sex, age,
2 race, and ethnicity, is included in applications sub-
3 mitted to the Food and Drug Administration, and
4 shall provide such publication to Congress.

5 (2) CONTENTS OF REPORT.—The report de-
6 scribed in paragraph (1) shall contain the following:

7 (A) A description of existing tools to en-
8 sure that data to support demographic analyses
9 are submitted in applications for drugs, biologi-
10 cal products, and devices, and that these anal-
11 yses are conducted by applicants consistent
12 with applicable Food and Drug Administration
13 requirements and Guidance for Industry. The
14 report shall address how the Food and Drug
15 Administration makes available information
16 about differences in safety and effectiveness of
17 medical products according to demographic sub-
18 groups, such as sex, age, racial, and ethnic sub-
19 groups, to health care providers, researchers,
20 and patients.

21 (B) An analysis of the extent to which de-
22 mographic data subset analyses on sex, age,
23 race, and ethnicity is presented in applications
24 for new drug applications for new molecular en-
25 tities under section 505 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355), in
2 biologics license applications under section 351
3 of the Public Health Service Act (42 U.S.C.
4 262), and in premarket approval applications
5 under section 515 of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 360e) for prod-
7 ucts approved or licensed by the Food and
8 Drug Administration, consistent with applicable
9 requirements and Guidance for Industry, and
10 consistent with the regulations of the Food and
11 Drug Administration pertaining to the protec-
12 tion of sponsors' confidential commercial infor-
13 mation as of the date of enactment of this Act.

14 (C) An analysis of the extent to which de-
15 mographic subgroups, including sex, age, racial,
16 and ethnic subgroups, are represented in clin-
17 ical studies to support applications for approved
18 or licensed new molecular entities, biological
19 products, and devices.

20 (D) An analysis of the extent to which a
21 summary of product safety and effectiveness
22 data by demographic subgroups including sex,
23 age, race, and ethnicity is readily available to
24 the public in a timely manner by means of the

1 product labeling or the Food and Drug Admin-
2 istration's Internet Web site.

3 (b) ACTION PLAN.—

4 (1) IN GENERAL.—Not later than 1 year after
5 the publication of the report described in subsection
6 (a), the Secretary, acting through the Commissioner,
7 shall publish an action plan on the Internet Web site
8 of the Food and Drug Administration, and provide
9 such publication to Congress.

10 (2) CONTENT OF ACTION PLAN.—The plan de-
11 scribed in paragraph (1) shall include—

12 (A) recommendations, as appropriate, to
13 improve the completeness and quality of anal-
14 yses of data on demographic subgroups in sum-
15 maries of product safety and effectiveness data
16 and in labeling;

17 (B) recommendations, as appropriate, on
18 the inclusion of such data, or the lack of avail-
19 ability of such data in labeling;

20 (C) recommendations, as appropriate, to
21 otherwise improve the public availability of such
22 data to patients, health care providers, and re-
23 searchers; and

24 (D) a determination with respect to each
25 recommendation identified in subparagraphs

1 (A) through (C) that distinguishes between
2 product types referenced in subsection
3 (a)(2)(B) insofar as the applicability of each
4 such recommendation to each type of product.

5 (c) DEFINITIONS.—In this section:

6 (1) The term “Commissioner” means the Com-
7 missioner of Food and Drugs.

8 (2) The term “device” has the meaning given
9 such term in section 201(h) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 321(h)).

11 (3) The term “drug” has the meaning given
12 such term in section 201(g) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 321(g)).

14 (4) The term “biological product” has the
15 meaning given such term in section 351(i) of the
16 Public Health Service Act (42 U.S.C. 262(i)).

17 (5) The term “Secretary” means the Secretary
18 of Health and Human Services.

19 **SEC. 908. RARE PEDIATRIC DISEASE PRIORITY REVIEW**
20 **VOUCHER INCENTIVE PROGRAM.**

21 Subchapter B of chapter V (21 U.S.C. 360aa et seq.)

22 is amended by adding at the end the following:

23 **“SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
24 **FOR RARE PEDIATRIC DISEASES.**

25 “(a) DEFINITIONS.—In this section:

1 “(1) PRIORITY REVIEW.—The term ‘priority re-
2 view’, with respect to a human drug application as
3 defined in section 735(1), means review and action
4 by the Secretary on such application not later than
5 6 months after receipt by the Secretary of such ap-
6 plication, as described in the Manual of Policies and
7 Procedures of the Food and Drug Administration
8 and goals identified in the letters described in sec-
9 tion 101(b) of the Prescription Drug User Fee
10 Amendments of 2012.

11 “(2) PRIORITY REVIEW VOUCHER.—The term
12 ‘priority review voucher’ means a voucher issued by
13 the Secretary to the sponsor of a rare pediatric dis-
14 ease product application that entitles the holder of
15 such voucher to priority review of a single human
16 drug application submitted under section 505(b)(1)
17 or section 351(a) of the Public Health Service Act
18 after the date of approval of the rare pediatric dis-
19 ease product application.

20 “(3) RARE PEDIATRIC DISEASE.—The term
21 ‘rare pediatric disease’ means a disease that meets
22 each of the following criteria:

23 “(A) The disease primarily affects individ-
24 uals aged from birth to 18 years, including age

1 groups often called neonates, infants, children,
2 and adolescents.

3 “(B) The disease is a rare disease or con-
4 dition, within the meaning of section 526.

5 “(4) RARE PEDIATRIC DISEASE PRODUCT AP-
6 PPLICATION.—The term ‘rare pediatric disease prod-
7 uct application’ means a human drug application, as
8 defined in section 735(1), that—

9 “(A) is for a drug or biological product—

10 “(i) that is for the prevention or
11 treatment of a rare pediatric disease; and

12 “(ii) that contains no active ingredient
13 (including any ester or salt of the active
14 ingredient) that has been previously ap-
15 proved in any other application under sec-
16 tion 505(b)(1), 505(b)(2), or 505(j) of this
17 Act or section 351(a) or 351(k) of the
18 Public Health Service Act;

19 “(B) is submitted under section 505(b)(1)
20 of this Act or section 351(a) of the Public
21 Health Service Act;

22 “(C) the Secretary deems eligible for pri-
23 ority review;

24 “(D) that relies on clinical data derived
25 from studies examining a pediatric population

1 and dosages of the drug intended for that popu-
2 lation;

3 “(E) that does not seek approval for an
4 adult indication in the original rare pediatric
5 disease product application; and

6 “(F) is approved after the date of the en-
7 actment of the Prescription Drug User Fee
8 Amendments of 2012.

9 “(b) PRIORITY REVIEW VOUCHER.—

10 “(1) IN GENERAL.—The Secretary shall award
11 a priority review voucher to the sponsor of a rare pe-
12 diatric disease product application upon approval by
13 the Secretary of such rare pediatric disease product
14 application.

15 “(2) TRANSFERABILITY.—

16 “(A) IN GENERAL.—The sponsor of a rare
17 pediatric disease product application that re-
18 ceives a priority review voucher under this sec-
19 tion may transfer (including by sale) the enti-
20 tlement to such voucher. There is no limit on
21 the number of times a priority review voucher
22 may be transferred before such voucher is used.

23 “(B) NOTIFICATION OF TRANSFER.—Each
24 person to whom a voucher is transferred shall
25 notify the Secretary of such change in owner-

1 ship of the voucher not later than 30 days after
2 such transfer.

3 “(3) LIMITATION.—A sponsor of a rare pedi-
4 atric disease product application may not receive a
5 priority review voucher under this section if the rare
6 pediatric disease product application was submitted
7 to the Secretary prior to the date that is 90 days
8 after the date of enactment of the Prescription Drug
9 User Fee Amendments of 2012.

10 “(4) NOTIFICATION.—

11 “(A) IN GENERAL.—The sponsor of a
12 human drug application shall notify the Sec-
13 retary not later than 90 days prior to submis-
14 sion of the human drug application that is the
15 subject of a priority review voucher of an intent
16 to submit the human drug application, includ-
17 ing the date on which the sponsor intends to
18 submit the application. Such notification shall
19 be a legally binding commitment to pay for the
20 user fee to be assessed in accordance with this
21 section.

22 “(B) TRANSFER AFTER NOTICE.—The
23 sponsor of a human drug application that pro-
24 vides notification of the intent of such sponsor
25 to use the voucher for the human drug applica-

1 tion under subparagraph (A) may transfer the
2 voucher after such notification is provided, if
3 such sponsor has not yet submitted the human
4 drug application described in the notification.

5 “(5) TERMINATION OF AUTHORITY.—The Sec-
6 retary may not award any priority review vouchers
7 under paragraph (1) after the last day of the 1-year
8 period that begins on the date that the Secretary
9 awards the third rare pediatric disease priority
10 voucher under this section.

11 “(c) PRIORITY REVIEW USER FEE.—

12 “(1) IN GENERAL.—The Secretary shall estab-
13 lish a user fee program under which a sponsor of a
14 human drug application that is the subject of a pri-
15 ority review voucher shall pay to the Secretary a fee
16 determined under paragraph (2). Such fee shall be
17 in addition to any fee required to be submitted by
18 the sponsor under chapter VII.

19 “(2) FEE AMOUNT.—The amount of the pri-
20 ority review user fee shall be determined each fiscal
21 year by the Secretary, based on the difference be-
22 tween—

23 “(A) the average cost incurred by the Food
24 and Drug Administration in the review of a

1 human drug application subject to priority re-
2 view in the previous fiscal year; and

3 “(B) the average cost incurred by the
4 Food and Drug Administration in the review of
5 a human drug application that is not subject to
6 priority review in the previous fiscal year.

7 “(3) ANNUAL FEE SETTING.—The Secretary
8 shall establish, before the beginning of each fiscal
9 year beginning after September 30, 2012, the
10 amount of the priority review user fee for that fiscal
11 year.

12 “(4) PAYMENT.—

13 “(A) IN GENERAL.—The priority review
14 user fee required by this subsection shall be due
15 upon the notification by a sponsor of the intent
16 of such sponsor to use the voucher, as specified
17 in subsection (b)(4)(A). All other user fees as-
18 sociated with the human drug application shall
19 be due as required by the Secretary or under
20 applicable law.

21 “(B) COMPLETE APPLICATION.—An appli-
22 cation described under subparagraph (A) for
23 which the sponsor requests the use of a priority
24 review voucher shall be considered incomplete if
25 the fee required by this subsection and all other

1 applicable user fees are not paid in accordance
2 with the Secretary's procedures for paying such
3 fees.

4 “(C) NO WAIVERS, EXEMPTIONS, REDUC-
5 TIONS, OR REFUNDS.—The Secretary may not
6 grant a waiver, exemption, reduction, or refund
7 of any fees due and payable under this section.

8 “(5) OFFSETTING COLLECTIONS.—Fees col-
9 lected pursuant to this subsection for any fiscal
10 year—

11 “(A) shall be deposited and credited as off-
12 setting collections to the account providing ap-
13 propriations to the Food and Drug Administra-
14 tion; and

15 “(B) shall not be collected for any fiscal
16 year except to the extent provided in advance in
17 appropriations Acts.

18 “(d) DESIGNATION PROCESS.—

19 “(1) IN GENERAL.—Upon the request of the
20 manufacturer or the sponsor of a new drug, the Sec-
21 retary may designate—

22 “(A) the new drug as a drug for a rare pe-
23 diatric disease; and

24 “(B) the application for the new drug as a
25 rare pediatric disease product application.

1 “(2) REQUEST FOR DESIGNATION.—The re-
2 quest for a designation under paragraph (1) shall be
3 made at the same time a request for designation of
4 orphan disease status under section 526 or fast-
5 track designation under section 506 is made. Re-
6 questing designation under this subsection is not a
7 prerequisite to receiving a priority review voucher
8 under this section.

9 “(3) DETERMINATION BY SECRETARY.—Not
10 later than 60 days after a request is submitted
11 under paragraph (1), the Secretary shall determine
12 whether—

13 “(A) the disease or condition that is the
14 subject of such request is a rare pediatric dis-
15 ease; and

16 “(B) the application for the new drug is a
17 rare pediatric disease product application.

18 “(e) MARKETING OF RARE PEDIATRIC DISEASE
19 PRODUCTS.—

20 “(1) REVOCATION.—The Secretary may revoke
21 any priority review voucher awarded under sub-
22 section (b) if the rare pediatric disease product for
23 which such voucher was awarded is not marketed in
24 the United States within the 365-day period begin-
25 ning on the date of the approval of such drug under

1 section 505 of this Act or section 351 of the Public
2 Health Service Act.

3 “(2) POSTAPPROVAL PRODUCTION REPORT.—

4 The sponsor of an approved rare pediatric disease
5 product shall submit a report to the Secretary not
6 later than 5 years after the approval of the applica-
7 ble rare pediatric disease product application. Such
8 report shall provide the following information, with
9 respect to each of the first 4 years after approval of
10 such product:

11 “(A) The estimated population in the
12 United States suffering from the rare pediatric
13 disease.

14 “(B) The estimated demand in the United
15 States for such rare pediatric disease product.

16 “(C) The actual amount of such rare pedi-
17 atric disease product distributed in the United
18 States.

19 “(f) NOTICE AND REPORT.—

20 “(1) NOTICE OF ISSUANCE OF VOUCHER AND
21 APPROVAL OF PRODUCTS UNDER VOUCHER.—The
22 Secretary shall publish a notice in the Federal Reg-
23 ister and on the Internet Web site of the Food and
24 Drug Administration not later than 30 days after
25 the occurrence of each of the following:

1 “(A) The Secretary issues a priority review
2 voucher under this section.

3 “(B) The Secretary approves a drug pur-
4 suant to an application submitted under section
5 505(b) of this Act or section 351(a) of the Pub-
6 lic Health Service Act for which the sponsor of
7 the application used a priority review voucher
8 under this section.

9 “(2) NOTIFICATION.—If, after the last day of
10 the 1-year period that begins on the date that the
11 Secretary awards the third rare pediatric disease
12 priority voucher under this section, a sponsor of an
13 application submitted under section 505(b) of this
14 Act or section 351(a) of the Public Health Service
15 Act for a drug uses a priority review voucher under
16 this section for such application, the Secretary shall
17 submit to the Committee on Energy and Commerce
18 of the House of Representatives and the Committee
19 on Health, Education, Labor, and Pensions of the
20 Senate a document—

21 “(A) notifying such Committees of the use
22 of such voucher; and

23 “(B) identifying the drug for which such
24 priority review voucher is used.

1 “(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing
2 in this section precludes a sponsor who seeks a priority
3 review voucher under this section from participating in
4 any other incentive program, including under this Act.

5 “(h) RELATION TO OTHER PROVISIONS.—The provi-
6 sions of this section shall supplement, not supplant, any
7 other provisions of this Act or the Public Health Service
8 Act that encourage the development of drugs for tropical
9 diseases and rare pediatric diseases.

10 “(i) GAO STUDY AND REPORT.—

11 “(1) STUDY.—

12 “(A) IN GENERAL.—Beginning on the date
13 that the Secretary awards the third rare pedi-
14 atric disease priority voucher under this section,
15 the Comptroller General of the United States
16 shall conduct a study of the effectiveness of
17 awarding rare pediatric disease priority vouch-
18 ers under this section in the development of
19 human drug products that treat or prevent such
20 diseases.

21 “(B) CONTENTS OF STUDY.—In con-
22 ducting the study under subparagraph (A), the
23 Comptroller General shall examine the fol-
24 lowing:

1 “(i) The indications for which each
2 rare disease product for which a priority
3 review voucher was awarded was approved
4 under section 505 or section 351 of the
5 Public Health Service Act.

6 “(ii) Whether, and to what extent, an
7 unmet need related to the treatment or
8 prevention of a rare pediatric disease was
9 met through the approval of such a rare
10 disease product.

11 “(iii) The value of the priority review
12 voucher if transferred.

13 “(iv) Identification of each drug for
14 which a priority review voucher was used.

15 “(v) The length of the period of time
16 between the date on which a priority re-
17 view voucher was awarded and the date on
18 which it was used.

19 “(2) REPORT.—Not later than 1 year after the
20 date under paragraph (1)(A), the Comptroller Gen-
21 eral shall submit to the Committee on Energy and
22 Commerce of the House of Representatives and the
23 Committee on Health, Education, Labor, and Pen-
24 sions of the Senate, a report containing the results
25 of the study under paragraph (1).”.

1 **TITLE X—DRUG SHORTAGES**

2 **SEC. 1001. DISCONTINUANCE OR INTERRUPTION IN THE**
3 **PRODUCTION OF LIFE-SAVING DRUGS.**

4 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)
5 is amended to read as follows:

6 **“SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE**
7 **PRODUCTION OF LIFE-SAVING DRUGS.**

8 “(a) IN GENERAL.—A manufacturer of a drug—

9 “(1) that is—

10 “(A) life-supporting;

11 “(B) life-sustaining; or

12 “(C) intended for use in the prevention or
13 treatment of a debilitating disease or condition,
14 including any such drug used in emergency
15 medical care or during surgery; and

16 “(2) that is not a radio pharmaceutical drug
17 product or any other product as designated by the
18 Secretary,

19 shall notify the Secretary, in accordance with subsection
20 (b), of a permanent discontinuance in the manufacture of
21 the drug or an interruption of the manufacture of the drug
22 that is likely to lead to a meaningful disruption in the sup-
23 ply of that drug in the United States, and the reasons
24 for such discontinuance or interruption.

1 “(b) TIMING.—A notice required under subsection (a)
2 shall be submitted to the Secretary—

3 “(1) at least 6 months prior to the date of the
4 discontinuance or interruption; or

5 “(2) if compliance with paragraph (1) is not
6 possible, as soon as practicable.

7 “(c) DISTRIBUTION.—To the maximum extent prac-
8 ticable, the Secretary shall distribute, through such means
9 as the Secretary deems appropriate, information on the
10 discontinuation or interruption of the manufacture of the
11 drugs described in subsection (a) to appropriate organiza-
12 tions, including physician, health provider, and patient or-
13 ganizations, as described in section 506E.

14 “(d) CONFIDENTIALITY.—Nothing in this section
15 shall be construed as authorizing the Secretary to disclose
16 any information that is a trade secret or confidential infor-
17 mation subject to section 552(b)(4) of title 5, United
18 States Code, or section 1905 of title 18, United States
19 Code.

20 “(e) COORDINATION WITH ATTORNEY GENERAL.—
21 Not later than 30 days after the receipt of a notification
22 described in subsection (a), the Secretary shall—

23 “(1) determine whether the notification pertains
24 to a controlled substance subject to a production

1 quota under section 306 of the Controlled Sub-
2 stances Act; and

3 “(2) if necessary, as determined by the Sec-
4 retary—

5 “(A) notify the Attorney General that the
6 Secretary has received such a notification;

7 “(B) request that the Attorney General in-
8 crease the aggregate and individual production
9 quotas under section 306 of the Controlled Sub-
10 stances Act applicable to such controlled sub-
11 stance and any ingredient therein to a level the
12 Secretary deems necessary to address a short-
13 age of a controlled substance based on the best
14 available market data; and

15 “(C) if the Attorney General determines
16 that the level requested is not necessary to ad-
17 dress a shortage of a controlled substance, the
18 Attorney General shall provide to the Secretary
19 a written response detailing the basis for the
20 Attorney General’s determination.

21 The Secretary shall make the written response pro-
22 vided under subparagraph (C) available to the public
23 on the Internet Web site of the Food and Drug Ad-
24 ministration.

1 “(f) FAILURE TO MEET REQUIREMENTS.—If a per-
2 son fails to submit information required under subsection
3 (a) in accordance with subsection (b)—

4 “(1) the Secretary shall issue a letter to such
5 person informing such person of such failure;

6 “(2) not later than 30 calendar days after the
7 issuance of a letter under paragraph (1), the person
8 who receives such letter shall submit to the Sec-
9 retary a written response to such letter setting forth
10 the basis for noncompliance and providing informa-
11 tion required under subsection (a); and

12 “(3) not later than 45 calendar days after the
13 issuance of a letter under paragraph (1), the Sec-
14 retary shall make such letter and any response to
15 such letter under paragraph (2) available to the pub-
16 lic on the Internet Web site of the Food and Drug
17 Administration, with appropriate redactions made to
18 protect information described in subsection (d), ex-
19 cept that, if the Secretary determines that the letter
20 under paragraph (1) was issued in error or, after re-
21 view of such response, the person had a reasonable
22 basis for not notifying as required under subsection
23 (a), the requirements of this paragraph shall not
24 apply.

1 “(g) EXPEDITED INSPECTIONS AND REVIEWS.—If,
2 based on notifications described in subsection (a) or any
3 other relevant information, the Secretary concludes that
4 there is, or is likely to be, a drug shortage of a drug de-
5 scribed in subsection (a), the Secretary may—

6 “(1) expedite the review of a supplement to a
7 new drug application submitted under section
8 505(b), an abbreviated new drug application sub-
9 mitted under section 505(j), or a supplement to such
10 an application submitted under section 505(j) that
11 could help mitigate or prevent such shortage; or

12 “(2) expedite an inspection or reinspection of
13 an establishment that could help mitigate or prevent
14 such drug shortage.

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

16 “(1) the term ‘drug’—

17 “(A) means a drug (as defined in section
18 201(g)) that is intended for human use and
19 that is subject to section 503(b)(1); and

20 “(B) does not include biological products
21 (as defined in section 351 of the Public Health
22 Service Act), unless otherwise provided by the
23 Secretary in the regulations promulgated under
24 subsection (i);

1 “(2) the term ‘drug shortage’ or ‘shortage’,
2 with respect to a drug, means a period of time when
3 the demand or projected demand for the drug within
4 the United States exceeds the supply of the drug;
5 and

6 “(3) the term ‘meaningful disruption’—

7 “(A) means a change in production that is
8 reasonably likely to lead to a reduction in the
9 supply of a drug by a manufacturer that is
10 more than negligible and affects the ability of
11 the manufacturer to fill orders or meet expected
12 demand for its product; and

13 “(B) does not include interruptions in
14 manufacturing due to matters such as routine
15 maintenance or insignificant changes in manu-
16 facturing so long as the manufacturer expects
17 to resume operations in a short period of time.

18 “(i) REGULATIONS.—

19 “(1) IN GENERAL.—Not later than 18 months
20 after the date of enactment of the Food and Drug
21 Administration Safety and Innovation Act, the Sec-
22 retary shall adopt a final regulation implementing
23 this section.

24 “(2) CONTENTS.—Such regulation shall define,
25 for purposes of this section, the terms ‘life-sup-

1 porting’, ‘life-sustaining’, and ‘intended for use in
2 the prevention or treatment of a debilitating disease
3 or condition’.

4 “(3) INCLUSION OF BIOLOGICAL PRODUCTS.—

5 “(A) IN GENERAL.—The Secretary may by
6 regulation apply this section to biological prod-
7 ucts (as defined in section 351 of the Public
8 Health Service Act), including plasma products
9 derived from human plasma protein and their
10 recombinant analogs, if the Secretary deter-
11 mines such inclusion would benefit the public
12 health. Such regulation shall take into account
13 any supply reporting programs and shall aim to
14 reduce duplicative notification.

15 “(B) RULE FOR VACCINES.—If the Sec-
16 retary applies this section to vaccines pursuant
17 to subparagraph (A), the Secretary shall—

18 “(i) consider whether the notification
19 requirement under subsection (a) may be
20 satisfied by submitting a notification to the
21 Centers for Disease Control and Preven-
22 tion under the vaccine shortage notification
23 program of such Centers; and

1 “(ii) explain the determination made
2 by the Secretary under clause (i) in the
3 regulation.

4 “(4) PROCEDURE.—In promulgating a regula-
5 tion implementing this section, the Secretary shall—

6 “(A) issue a notice of proposed rulemaking
7 that includes the proposed regulation;

8 “(B) provide a period of not less than 60
9 days for comments on the proposed regulation;
10 and

11 “(C) publish the final regulation not less
12 than 30 days before the regulation’s effective
13 date.

14 “(5) RESTRICTIONS.—Notwithstanding any
15 other provision of Federal law, in implementing this
16 section, the Secretary shall only promulgate regula-
17 tions as described in paragraph (4).”.

18 (b) EFFECT OF NOTIFICATION.—The submission of
19 a notification to the Secretary of Health and Human Serv-
20 ices (referred to in this title as the “Secretary”) for pur-
21 poses of complying with the requirement in section
22 506C(a) of the Federal Food, Drug, and Cosmetic Act (as
23 amended by subsection (a)) shall not be construed—

24 (1) as an admission that any product that is
25 the subject of such notification violates any provision

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

3 (2) as evidence of an intention to promote or
4 market the product for an indication or use for
5 which the product has not been approved by the Sec-
6 retary.

7 **SEC. 1002. ANNUAL REPORTING ON DRUG SHORTAGES.**

8 Chapter V (21 U.S.C. 351 et seq.) is amended by
9 inserting after section 506C, as amended by section 1001
10 of this Act, the following:

11 **“SEC. 506C-1. ANNUAL REPORTING ON DRUG SHORTAGES.**

12 “(a) ANNUAL REPORTS TO CONGRESS.—Not later
13 than the end of calendar year 2013, and not later than
14 the end of each calendar year thereafter, the Secretary
15 shall submit to the Committee on Energy and Commerce
16 of the House of Representatives and the Committee on
17 Health, Education, Labor, and Pensions of the Senate a
18 report on drug shortages that—

19 “(1) specifies the number of manufacturers that
20 submitted a notification to the Secretary under sec-
21 tion 506C(a) during such calendar year;

22 “(2) describes the communication between the
23 field investigators of the Food and Drug Administra-
24 tion and the staff of the Center for Drug Evaluation
25 and Research’s Office of Compliance and Drug

1 Shortage Program, including the Food and Drug
2 Administration's procedures for enabling and ensur-
3 ing such communication;

4 “(3)(A) lists the major actions taken by the
5 Secretary to prevent or mitigate the drug shortages
6 described in paragraph (7);

7 “(B) in the list under subparagraph (A), in-
8 cludes—

9 “(i) the number of applications and supple-
10 ments for which the Secretary expedited review
11 under section 506C(g)(1) during such calendar
12 year; and

13 “(ii) the number of establishment inspec-
14 tions or reinspections that the Secretary expe-
15 dited under section 506C(g)(2) during such cal-
16 endar year;

17 “(4) describes the coordination between the
18 Food and Drug Administration and the Drug En-
19 forcement Administration on efforts to prevent or al-
20 leviate drug shortages;

21 “(5) identifies the number of and describes the
22 instances in which the Food and Drug Administra-
23 tion exercised regulatory flexibility and discretion to
24 prevent or alleviate a drug shortage;

1 “(6) lists the names of manufacturers that were
2 issued letters under section 506C(f); and

3 “(7) specifies the number of drug shortages oc-
4 ccurring during such calendar year, as identified by
5 the Secretary.

6 “(b) TREND ANALYSIS.—The Secretary is authorized
7 to retain a third party to conduct a study, if the Secretary
8 believes such a study would help clarify the causes, trends,
9 or solutions related to drug shortages.

10 “(c) DEFINITION.—In this section, the term ‘drug
11 shortage’ or ‘shortage’ has the meaning given such term
12 in section 506C.”.

13 **SEC. 1003. COORDINATION; TASK FORCE AND STRATEGIC**
14 **PLAN.**

15 Chapter V (21 U.S.C. 351 et seq.) is amended by
16 inserting after section 506C–1, as added by section 1002
17 of this Act, the following:

18 **“SEC. 506D. COORDINATION; TASK FORCE AND STRATEGIC**
19 **PLAN.**

20 “(a) TASK FORCE AND STRATEGIC PLAN.—

21 “(1) IN GENERAL.—

22 “(A) TASK FORCE.—As soon as practicable
23 after the date of enactment of the Food and
24 Drug Administration Safety and Innovation
25 Act, the Secretary shall establish a task force to

1 develop and implement a strategic plan for en-
2 hancing the Secretary’s response to preventing
3 and mitigating drug shortages.

4 “(B) STRATEGIC PLAN.—The strategic
5 plan described in subparagraph (A) shall in-
6 clude—

7 “(i) plans for enhanced interagency
8 and intra-agency coordination, communica-
9 tion, and decisionmaking;

10 “(ii) plans for ensuring that drug
11 shortages are considered when the Sec-
12 retary initiates a regulatory action that
13 could precipitate a drug shortage or exac-
14 erbate an existing drug shortage;

15 “(iii) plans for effective communica-
16 tion with outside stakeholders, including
17 who the Secretary should alert about po-
18 tential or actual drug shortages, how the
19 communication should occur, and what
20 types of information should be shared;

21 “(iv) plans for considering the impact
22 of drug shortages on research and clinical
23 trials; and

24 “(v) an examination of whether to es-
25 tablish a ‘qualified manufacturing partner

1 program', as described in subparagraph
2 (C).

3 “(C) DESCRIPTION OF PROGRAM.—In con-
4 ducting the examination of a ‘qualified manu-
5 facturing partner program’ under subparagraph
6 (B)(v), the Secretary—

7 “(i) shall take into account that—

8 “(I) a ‘qualified manufacturer’,
9 for purposes of such program, would
10 need to have the capability and capaci-
11 ty to supply products determined or
12 anticipated to be in shortage; and

13 “(II) in examining the capability
14 and capacity to supply products in
15 shortage, the ‘qualified manufacturer’
16 could have a site that manufactures a
17 drug listed under section 506E or
18 have the capacity to produce drugs in
19 response to a shortage within a rapid
20 timeframe; and

21 “(ii) shall examine whether incentives
22 are necessary to encourage the participa-
23 tion of ‘qualified manufacturers’ in such a
24 program.

1 “(D) CONSULTATION.—In carrying out
2 this paragraph, the task force shall ensure con-
3 sultation with the appropriate offices within the
4 Food and Drug Administration, including the
5 Office of the Commissioner, the Center for
6 Drug Evaluation and Research, the Office of
7 Regulatory Affairs, and employees within the
8 Department of Health and Human Services
9 with expertise regarding drug shortages. The
10 Secretary shall engage external stakeholders
11 and experts as appropriate.

12 “(2) TIMING.—Not later than 1 year after the
13 date of enactment of the Food and Drug Adminis-
14 tration Safety and Innovation Act, the task force
15 shall—

16 “(A) publish the strategic plan described in
17 paragraph (1); and

18 “(B) submit such plan to Congress.

19 “(b) COMMUNICATION.—The Secretary shall ensure
20 that, prior to any enforcement action or issuance of a
21 warning letter that the Secretary determines could reason-
22 ably be anticipated to lead to a meaningful disruption in
23 the supply in the United States of a drug described under
24 section 506C(a), there is communication with the appro-
25 priate office of the Food and Drug Administration with

1 expertise regarding drug shortages regarding whether the
2 action or letter could cause, or exacerbate, a shortage of
3 the drug.

4 “(c) ACTION.—If the Secretary determines, after the
5 communication described in subsection (b), that an en-
6 forcement action or a warning letter could reasonably
7 cause or exacerbate a shortage of a drug described under
8 section 506C(a), then the Secretary shall evaluate the
9 risks associated with the impact of such shortage upon
10 patients and those risks associated with the violation in-
11 volved before taking such action or issuing such letter, un-
12 less there is imminent risk of serious adverse health con-
13 sequences or death to humans.

14 “(d) REPORTING BY OTHER ENTITIES.—The Sec-
15 retary shall identify or establish a mechanism by which
16 health care providers and other third-party organizations
17 may report to the Secretary evidence of a drug shortage.

18 “(e) REVIEW AND CONSTRUCTION.—No determina-
19 tion, finding, action, or omission of the Secretary under
20 this section shall—

21 “(1) be subject to judicial review; or

22 “(2) be construed to establish a defense to an
23 enforcement action by the Secretary.

24 “(f) SUNSET.—Subsections (a), (b), (c), and (e) shall
25 cease to be effective on the date that is 5 years after the

1 date of enactment of the Food and Drug Administration
2 Safety and Innovation Act.”.

3 **SEC. 1004. DRUG SHORTAGE LIST.**

4 Chapter V (21 U.S.C. 351 et seq.) is amended by
5 inserting after section 506D, as added by section 1003
6 of this Act, the following:

7 **“SEC. 506E. DRUG SHORTAGE LIST.**

8 “(a) ESTABLISHMENT.—The Secretary shall main-
9 tain an up-to-date list of drugs that are determined by
10 the Secretary to be in shortage in the United States.

11 “(b) CONTENTS.—For each drug on such list, the
12 Secretary shall include the following information:

13 “(1) The name of the drug in shortage, includ-
14 ing the National Drug Code number for such drug.

15 “(2) The name of each manufacturer of such
16 drug.

17 “(3) The reason for the shortage, as determined
18 by the Secretary, selecting from the following cat-
19 egories:

20 “(A) Requirements related to complying
21 with good manufacturing practices.

22 “(B) Regulatory delay.

23 “(C) Shortage of an active ingredient.

24 “(D) Shortage of an inactive ingredient
25 component.

1 “(E) Discontinuation of the manufacture
2 of the drug.

3 “(F) Delay in shipping of the drug.

4 “(G) Demand increase for the drug.

5 “(4) The estimated duration of the shortage as
6 determined by the Secretary.

7 “(c) PUBLIC AVAILABILITY.—

8 “(1) IN GENERAL.—Subject to paragraphs (2)
9 and (3), the Secretary shall make the information in
10 such list publicly available.

11 “(2) TRADE SECRETS AND CONFIDENTIAL IN-
12 FORMATION.—Nothing in this section alters or
13 amends section 1905 of title 18, United States Code,
14 or section 552(b)(4) of title 5 of such Code.

15 “(3) PUBLIC HEALTH EXCEPTION.—The Sec-
16 retary may choose not to make information collected
17 under this section publicly available under paragraph
18 (1) or section 506C(e) if the Secretary determines
19 that disclosure of such information would adversely
20 affect the public health (such as by increasing the
21 possibility of hoarding or other disruption of the
22 availability of drug products to patients).”.

1 **SEC. 1005. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

2 Section 306 of the Controlled Substances Act (21
3 U.S.C. 826) is amended by adding at the end the fol-
4 lowing:

5 “(h)(1) Not later than 30 days after the receipt of
6 a request described in paragraph (2), the Attorney Gen-
7 eral shall—

8 “(A) complete review of such request; and

9 “(B)(i) as necessary to address a shortage of a
10 controlled substance, increase the aggregate and in-
11 dividual production quotas under this section appli-
12 cable to such controlled substance and any ingre-
13 dient therein to the level requested; or

14 “(ii) if the Attorney General determines that
15 the level requested is not necessary to address a
16 shortage of a controlled substance, the Attorney
17 General shall provide a written response detailing
18 the basis for the Attorney General’s determination.
19 The Secretary shall make the written response pro-
20 vided under subparagraph (B)(ii) available to the
21 public on the Internet Web site of the Food and
22 Drug Administration.

23 “(2) A request is described in this paragraph if—

24 “(A) the request pertains to a controlled sub-
25 stance on the list of drugs in shortage maintained

1 under section 506E of the Federal Food, Drug, and
2 Cosmetic Act;

3 “(B) the request is submitted by the manufac-
4 turer of the controlled substance; and

5 “(C) the controlled substance is in schedule
6 II.”.

7 **SEC. 1006. ATTORNEY GENERAL REPORT ON DRUG SHORT-**
8 **AGES.**

9 Not later than 6 months after the date of the enact-
10 ment of this Act, and annually thereafter, the Attorney
11 General shall submit to the Committee on Energy and
12 Commerce of the House of Representatives and the Com-
13 mittee on the Judiciary of the Senate a report on drug
14 shortages that—

15 (1) identifies the number of requests received
16 under section 306(h) of the Controlled Substances
17 Act (as added by section 1005 of this Act), the aver-
18 age review time for such requests, the number of re-
19 quests granted and denied under such section, and,
20 for each of the requests denied under such section,
21 the basis for such denial;

22 (2) describes the coordination between the Drug
23 Enforcement Administration and Food and Drug
24 Administration on efforts to prevent or alleviate
25 drug shortages; and

1 “(A) extend the supply of a drug in re-
2 sponse to the placement of the drug on a drug
3 shortage list under section 506E; and

4 “(B) facilitate access to the drug by hos-
5 pitals within the same health system.

6 “(b) EXCLUSION FROM REGISTRATION.—Notwith-
7 standing any other provision of this Act, a hospital shall
8 not be considered an establishment for which registration
9 is required under section 510 solely because it repackages
10 a drug and transfers it to another hospital within the same
11 health system in accordance with the conditions in sub-
12 section (c)—

13 “(1) during any period in which the drug is list-
14 ed on the drug shortage list under section 506E; or

15 “(2) during the 60-day period following any pe-
16 riod described in paragraph (1).

17 “(c) CONDITIONS.—Subsection (b) shall only apply to
18 a hospital, with respect to the repackaging of a drug for
19 transfer to another hospital within the same health sys-
20 tem, if the following conditions are met:

21 “(1) DRUG FOR INTRASYSTEM USE ONLY.—In
22 no case may a drug that has been repackaged in ac-
23 cordance with this section be sold or otherwise dis-
24 tributed by the health system or a hospital within

1 the system to an entity or individual that is not a
2 hospital within such health system.

3 “(2) COMPLIANCE WITH STATE RULES.—Re-
4 packaging of a drug under this section shall be done
5 in compliance with applicable State requirements of
6 each State in which the drug is repackaged and re-
7 ceived.

8 “(d) TERMINATION.—This section shall not apply on
9 or after the date on which the Secretary issues final guid-
10 ance that clarifies the policy of the Food and Drug Admin-
11 istration regarding hospital pharmacies repackaging and
12 safely transferring repackaged drugs to other hospitals
13 within the same health system during a drug shortage.”.

14 **SEC. 1008. STUDY ON DRUG SHORTAGES.**

15 (a) STUDY.—The Comptroller General of the United
16 States shall conduct a study to examine the cause of drug
17 shortages and formulate recommendations on how to pre-
18 vent or alleviate such shortages.

19 (b) CONSIDERATION.—In conducting the study under
20 this section, the Comptroller General shall consider the
21 following questions:

22 (1) What are the dominant characteristics of
23 drugs that have gone into a drug shortage over the
24 preceding 3 years?

1 (2) Are there systemic high-risk factors (such
2 as drug pricing structure, including Federal reim-
3 bursements, or the number of manufacturers pro-
4 ducing a drug product) that have led to the con-
5 centration of drug shortages in certain drug prod-
6 ucts that have made such products vulnerable to
7 drug shortages?

8 (3) Is there a reason why drug shortages have
9 occurred primarily in the sterile injectable market
10 and in certain therapeutic areas?

11 (4)(A) How have regulations, guidance docu-
12 ments, regulatory practices, policies, and other ac-
13 tions of Federal departments and agencies (includ-
14 ing the effectiveness of interagency and intra-agency
15 coordination, communication, strategic planning, and
16 decisionmaking), including those used to enforce
17 statutory requirements, affected drug shortages?

18 (B) Do any such regulations, guidances, poli-
19 cies, or practices cause, exacerbate, prevent, or miti-
20 gate drug shortages?

21 (C) How can regulations, guidances, policies, or
22 practices be modified, streamlined, expanded, or dis-
23 continued in order to reduce or prevent such drug
24 shortages?

1 (D) What effect would the changes described in
2 subparagraph (C) have on the public health?

3 (5) How does hoarding affect drug shortages?

4 (6) How would incentives alleviate or prevent
5 drug shortages?

6 (7) To what extent are health care providers,
7 including hospitals and physicians responding to
8 drug shortages, able to adjust care effectively to
9 compensate for such shortages, and what impedi-
10 ments exist that hinder provider ability to adjust to
11 such shortages?

12 (8)(A) Have drug shortages led market partici-
13 pants to stockpile affected drugs or sell such drugs
14 at inflated prices?

15 (B) What has been the impact of any such ac-
16 tivities described in subparagraph (A) on Federal
17 revenue, and are there any economic factors that
18 have exacerbated or created a market for such ac-
19 tivities?

20 (C) Is there a need for any additional reporting
21 or enforcement actions to address such activities?

22 (9)(A) How have the activities under section
23 506D of the Federal Food, Drug, and Cosmetic Act
24 (as added by section 1003 of this Act) improved the

1 efforts of the Food and Drug Administration to
2 mitigate and prevent drug shortages?

3 (B) Is there a need to continue the task force
4 and strategic plan under such section 506D, or are
5 there any other recommendations to increase com-
6 munication and coordination inside the Food and
7 Drug Administration, between the Food and Drug
8 Administration and other agencies, and between the
9 Food and Drug Administration and stakeholders?

10 (c) CONSULTATION WITH STAKEHOLDERS.—In con-
11 ducting the study under this section, the Comptroller Gen-
12 eral shall consult with relevant stakeholders, including
13 physicians, pharmacists, hospitals, patients, drug manu-
14 facturers, and other health providers.

15 (d) REPORT.—Not later than 18 months after the
16 date of the enactment of this Act, the Comptroller General
17 shall submit a report to the Committee on Energy and
18 Commerce of the House of Representatives and the Com-
19 mittee on Health, Education, Labor, and Pensions of the
20 Senate on the results of the study under this section.

1 **TITLE XI—OTHER PROVISIONS**

2 **Subtitle A—Reauthorizations**

3 **SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO** 4 **EXCLUSIVITY OF CERTAIN DRUGS CON-** 5 **TAINING SINGLE ENANTIOMERS.**

6 (a) IN GENERAL.—Section 505(u)(4) (21 U.S.C.
7 355(u)(4)) is amended by striking “2012” and inserting
8 “2017”.

9 (b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21
10 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting
11 “clinical” after “any”.

12 **SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH** 13 **PUBLIC-PRIVATE PARTNERSHIPS.**

14 Subsection (f) of section 566 (21 U.S.C. 360bbb–5)
15 is amended to read as follows:

16 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
17 carry out this section, there is authorized to be appro-
18 priated \$6,000,000 for each of fiscal years 2013 through
19 2017.”.

20 **Subtitle B—Medical Gas Product** 21 **Regulation**

22 **SEC. 1111. REGULATION OF MEDICAL GASES.**

23 Chapter V (21 U.S.C. 351 et seq.) is amended by
24 adding at the end the following:

1 **“Subchapter G—Medical Gases**

2 **“SEC. 575. DEFINITIONS.**

3 “In this subchapter:

4 “(1) The term ‘designated medical gas’ means
5 any of the following:

6 “(A) Oxygen that meets the standards set
7 forth in an official compendium.

8 “(B) Nitrogen that meets the standards
9 set forth in an official compendium.

10 “(C) Nitrous oxide that meets the stand-
11 ards set forth in an official compendium.

12 “(D) Carbon dioxide that meets the stand-
13 ards set forth in an official compendium.

14 “(E) Helium that meets the standards set
15 forth in an official compendium.

16 “(F) Carbon monoxide that meets the
17 standards set forth in an official compendium.

18 “(G) Medical air that meets the standards
19 set forth in an official compendium.

20 “(H) Any other medical gas deemed appro-
21 priate by the Secretary, after taking into ac-
22 count any investigational new drug application
23 or investigational new animal drug application
24 for the same medical gas submitted in accord-
25 ance with regulations applicable to such appli-

1 cations in title 21 of the Code of Federal Regu-
2 lations, unless any period of exclusivity under
3 section 505(c)(3)(E)(ii) or section
4 505(j)(5)(F)(ii), or the extension of any such
5 period under section 505A, applicable to such
6 medical gas has not expired.

7 “(2) The term ‘medical gas’ means a drug
8 that—

9 “(A) is manufactured or stored in a lique-
10 fied, nonliquefied, or cryogenic state; and

11 “(B) is administered as a gas.

12 **“SEC. 576. REGULATION OF MEDICAL GASES.**

13 “(a) CERTIFICATION OF DESIGNATED MEDICAL
14 GASES.—

15 “(1) SUBMISSION.—Beginning 180 days after
16 the date of enactment of this section, any person
17 may file with the Secretary a request for certifi-
18 cation of a medical gas as a designated medical gas.
19 Any such request shall contain the following infor-
20 mation:

21 “(A) A description of the medical gas.

22 “(B) The name and address of the spon-
23 sor.

1 “(C) The name and address of the facility
2 or facilities where the medical gas is or will be
3 manufactured.

4 “(D) Any other information deemed appro-
5 priate by the Secretary to determine whether
6 the medical gas is a designated medical gas.

7 “(2) GRANT OF CERTIFICATION.—The certifi-
8 cation requested under paragraph (1) is deemed to
9 be granted unless, within 60 days of the filing of
10 such request, the Secretary finds that—

11 “(A) the medical gas subject to the certifi-
12 cation is not a designated medical gas;

13 “(B) the request does not contain the in-
14 formation required under paragraph (1) or oth-
15 erwise lacks sufficient information to permit the
16 Secretary to determine that the medical gas is
17 a designated medical gas; or

18 “(C) denying the request is necessary to
19 protect the public health.

20 “(3) EFFECT OF CERTIFICATION.—

21 “(A) IN GENERAL.—

22 “(i) APPROVED USES.—A designated
23 medical gas for which a certification is
24 granted under paragraph (2) is deemed,
25 alone or in combination, as medically ap-

1 appropriate, with another designated medical
2 gas or gases for which a certification or
3 certifications have been granted, to have in
4 effect an approved application under sec-
5 tion 505 or 512, subject to all applicable
6 postapproval requirements, for the fol-
7 lowing indications for use:

8 “(I) In the case of oxygen, the
9 treatment or prevention of hypoxemia
10 or hypoxia.

11 “(II) In the case of nitrogen, use
12 in hypoxic challenge testing.

13 “(III) In the case of nitrous
14 oxide, analgesia.

15 “(IV) In the case of carbon diox-
16 ide, use in extracorporeal membrane
17 oxygenation therapy or respiratory
18 stimulation.

19 “(V) In the case of helium, the
20 treatment of upper airway obstruction
21 or increased airway resistance.

22 “(VI) In the case of medical air,
23 to reduce the risk of hyperoxia.

1 “(VII) In the case of carbon
2 monoxide, use in lung diffusion test-
3 ing.

4 “(VIII) Any other indication for
5 use for a designated medical gas or
6 combination of designated medical
7 gases deemed appropriate by the Sec-
8 retary, unless any period of exclusivity
9 under clause (iii) or (iv) of section
10 505(c)(3)(E), clause (iii) or (iv) of
11 section 505(j)(5)(F), or section 527,
12 or the extension of any such period
13 under section 505A, applicable to
14 such indication for use for such gas or
15 combination of gases has not expired.

16 “(ii) LABELING.—The requirements
17 of sections 503(b)(4) and 502(f) are
18 deemed to have been met for a designated
19 medical gas if the labeling on final use
20 container for such medical gas bears—

21 “(I) the information required by
22 section 503(b)(4);

23 “(II) a warning statement con-
24 cerning the use of the medical gas as

1 determined by the Secretary by regu-
2 lation; and

3 “(III) appropriate directions and
4 warnings concerning storage and han-
5 dling.

6 “(B) INAPPLICABILITY OF EXCLUSIVITY
7 PROVISIONS.—

8 “(i) NO EXCLUSIVITY FOR A CER-
9 TIFIED MEDICAL GAS.—No designated
10 medical gas deemed under subparagraph
11 (A)(i) to have in effect an approved appli-
12 cation is eligible for any period of exclu-
13 sivity under section 505(c), 505(j), or 527,
14 or the extension of any such period under
15 section 505A, on the basis of such deemed
16 approval.

17 “(ii) EFFECT ON CERTIFICATION.—
18 No period of exclusivity under section
19 505(c), 505(j), or section 527, or the ex-
20 tension of any such period under section
21 505A, with respect to an application for a
22 drug product shall prohibit, limit, or other-
23 wise affect the submission, grant, or effect
24 of a certification under this section, except

1 as provided in subsection (a)(3)(A)(i)(VIII)
2 and section 575(1)(H).

3 “(4) WITHDRAWAL, SUSPENSION, OR REVOCA-
4 TION OF APPROVAL.—

5 “(A) WITHDRAWAL, SUSPENSION OF AP-
6 PROVAL.—Nothing in this subchapter limits the
7 Secretary’s authority to withdraw or suspend
8 approval of a drug product, including a des-
9 ignated medical gas deemed under this section
10 to have in effect an approved application under
11 section 505 or section 512 of this Act.

12 “(B) REVOCATION OF CERTIFICATION.—
13 The Secretary may revoke the grant of a certifi-
14 cation under paragraph (2) if the Secretary de-
15 termines that the request for certification con-
16 tains any material omission or falsification.

17 “(b) PRESCRIPTION REQUIREMENT.—

18 “(1) IN GENERAL.—A designated medical gas
19 shall be subject to the requirements of section
20 503(b)(1) unless the Secretary exercises the author-
21 ity provided in section 503(b)(3) to remove such
22 medical gas from the requirements of section
23 503(b)(1), the gas is approved for use without a pre-
24 scription pursuant to an application under section
25 505 or 512, or the use in question is authorized pur-

1 suant to another provision of this Act relating to use
2 of medical products in emergencies.

3 “(2) OXYGEN.—

4 “(A) NO PRESCRIPTION REQUIRED FOR
5 CERTAIN USES.—Notwithstanding paragraph
6 (1), oxygen may be provided without a prescrip-
7 tion for the following uses:

8 “(i) For use in the event of depres-
9 surization or other environmental oxygen
10 deficiency.

11 “(ii) For oxygen deficiency or for use
12 in emergency resuscitation, when adminis-
13 tered by properly trained personnel.

14 “(B) LABELING.—For oxygen provided
15 pursuant to subparagraph (A), the require-
16 ments of section 503(b)(4) shall be deemed to
17 have been met if its labeling bears a warning
18 that the oxygen can be used for emergency use
19 only and for all other medical applications a
20 prescription is required.

21 **“SEC. 577. INAPPLICABILITY OF DRUG FEES TO DES-**
22 **IGNATED MEDICAL GASES.**

23 “A designated medical gas, alone or in combination
24 with another designated gas or gases (as medically appro-
25 priate) deemed under section 576 to have in effect an ap-

1 proved application shall not be assessed fees under section
2 736(a) on the basis of such deemed approval.”.

3 **SEC. 1112. CHANGES TO REGULATIONS.**

4 (a) REPORT.—Not later than 18 months after the
5 date of the enactment of this Act, the Secretary, after ob-
6 taining input from medical gas manufacturers and any
7 other interested members of the public, shall—

8 (1) determine whether any changes to the Fed-
9 eral drug regulations are necessary for medical
10 gases; and

11 (2) submit to the Committee on Health, Edu-
12 cation, Labor, and Pensions of the Senate and the
13 Committee on Energy and Commerce of the House
14 of Representatives a report regarding any such
15 changes.

16 (b) REGULATIONS.—If the Secretary determines
17 under subsection (a) that changes to the Federal drug reg-
18 ulations are necessary for medical gases, the Secretary
19 shall issue final regulations revising the Federal drug reg-
20 ulations with respect to medical gases not later than 48
21 months after the date of the enactment of this Act.

22 (c) DEFINITIONS.—In this section:

23 (1) The term “Federal drug regulations” means
24 regulations in title 21 of the Code of Federal Regu-
25 lations pertaining to drugs.

1 (2) The term “medical gas” has the meaning
2 given to such term in section 575 of the Federal
3 Food, Drug, and Cosmetic Act, as added by section
4 1111 of this Act.

5 (3) The term “Secretary” means the Secretary
6 of Health and Human Services, acting through the
7 Commissioner of Food and Drugs.

8 **SEC. 1113. RULES OF CONSTRUCTION.**

9 Nothing in this subtitle and the amendments made
10 by this subtitle applies with respect to—

11 (1) a drug that is approved prior to May 1,
12 2012, pursuant to an application submitted under
13 section 505 or 512 of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 355, 360b);

15 (2) any gas listed in subparagraphs (A) through
16 (G) of section 575(1) of the Federal Food, Drug,
17 and Cosmetic Act, as added by section 1111 of this
18 Act, or any combination of any such gases, for an
19 indication that—

20 (A) is not included in, or is different from,
21 those specified in subclauses (I) through (VII)
22 of section 576(a)(3)(A)(i) of such Act; and

23 (B) is approved on or after May 1, 2012,
24 pursuant to an application submitted under sec-
25 tion 505 or 512; or

1 (3) any designated medical gas added pursuant
2 to subparagraph (H) of section 575(1) of such Act
3 for an indication that—

4 (A) is not included in, or is different from,
5 those originally added pursuant to subpara-
6 graph (H) of section 575(1) and section
7 576(a)(3)(A)(i)(VIII); and

8 (B) is approved on or after May 1, 2012,
9 pursuant to an application submitted under sec-
10 tion 505 or 512 of such Act.

11 **Subtitle C—Miscellaneous** 12 **Provisions**

13 **SEC. 1121. GUIDANCE DOCUMENT REGARDING PRODUCT** 14 **PROMOTION USING THE INTERNET.**

15 Not later than 2 years after the date of enactment
16 of this Act, the Secretary of Health and Human Services
17 shall issue guidance that describes Food and Drug Admin-
18 istration policy regarding the promotion, using the Inter-
19 net (including social media), of medical products that are
20 regulated by such Administration.

21 **SEC. 1122. COMBATING PRESCRIPTION DRUG ABUSE.**

22 (a) **IN GENERAL.**—To combat the significant rise in
23 prescription drug abuse and the consequences of such
24 abuse, the Secretary of Health and Human Services (re-
25 ferred to in this section as the “Secretary”), in coordina-

1 tion with other Federal agencies, as appropriate, shall re-
2 view current Federal initiatives and identify gaps and op-
3 portunities with respect to—

4 (1) ensuring the safe use of prescription drugs
5 with the potential for abuse; and

6 (2) the treatment of prescription drug
7 dependance.

8 (b) REPORT.—Not later than 1 year after the date
9 of enactment of this Act, the Secretary shall post on the
10 Department of Health and Human Service’s Internet Web
11 site a report on the findings of the review under subsection

12 (a). Such report shall include findings and recommenda-
13 tions on—

14 (1) how best to leverage and build upon existing
15 Federal and federally funded data sources, such as
16 prescription drug monitoring program data and the
17 sentinel initiative of the Food and Drug Administra-
18 tion under section 505(k)(3) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as
20 it relates to collection of information relevant to ad-
21 verse events, patient safety, and patient outcomes, to
22 create a centralized data clearinghouse and early
23 warning tool;

24 (2) how best to develop and disseminate widely
25 best practices models and suggested standard re-

1 requirements to States for achieving greater interoper-
2 ability and effectiveness of prescription drug moni-
3 toring programs, especially with respect to provider
4 participation, producing standardized data on ad-
5 verse events, patient safety, and patient outcomes;
6 and

7 (3) how best to develop provider, pharmacist,
8 and patient education tools and a strategy to widely
9 disseminate such tools and assess the efficacy of
10 such tools.

11 (c) **GUIDANCE ON ABUSE-DETERRENT PRODUCTS.**—
12 Not later than 6 months after the date of enactment of
13 this Act, the Secretary shall promulgate guidance on the
14 development of abuse-deterrent drug products.

15 **SEC. 1123. OPTIMIZING GLOBAL CLINICAL TRIALS.**

16 Subchapter E of chapter V (21 U.S.C. 360bbb et
17 seq.), as amended by section 903 of this Act, is further
18 amended by adding at the end the following:

19 **“SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.**

20 “(a) **IN GENERAL.**—The Secretary shall—

21 “(1) work with other regulatory authorities of
22 similar standing, medical research companies, and
23 international organizations to foster and encourage
24 uniform, scientifically driven clinical trial standards

1 with respect to medical products around the world;
2 and

3 “(2) enhance the commitment to provide con-
4 sistent parallel scientific advice to manufacturers
5 seeking simultaneous global development of new
6 medical products in order to—

7 “(A) enhance medical product develop-
8 ment;

9 “(B) facilitate the use of foreign data; and

10 “(C) minimize the need to conduct duplica-
11 tive clinical studies, preclinical studies, or non-
12 clinical studies.

13 “(b) **MEDICAL PRODUCT.**—In this section, the term
14 ‘medical product’ means a drug, as defined in subsection
15 (g) of section 201, a device, as defined in subsection (h)
16 of such section, or a biological product, as defined in sec-
17 tion 351(i) of the Public Health Service Act.

18 “(c) **SAVINGS CLAUSE.**—Nothing in this section shall
19 alter the criteria for evaluating the safety or effectiveness
20 of a medical product under this Act.

21 **“SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM**
22 **OUTSIDE THE UNITED STATES.**

23 “(a) **IN GENERAL.**—In determining whether to ap-
24 prove, license, or clear a drug or device pursuant to an
25 application submitted under this chapter, the Secretary

1 shall accept data from clinical investigations conducted
2 outside of the United States, including the European
3 Union, if the applicant demonstrates that such data are
4 adequate under applicable standards to support approval,
5 licensure, or clearance of the drug or device in the United
6 States.

7 “(b) NOTICE TO SPONSOR.—If the Secretary finds
8 under subsection (a) that the data from clinical investiga-
9 tions conducted outside the United States, including in the
10 European Union, are inadequate for the purpose of mak-
11 ing a determination on approval, clearance, or licensure
12 of a drug or device pursuant to an application submitted
13 under this chapter, the Secretary shall provide written no-
14 tice to the sponsor of the application of such finding and
15 include the rationale for such finding.”.

16 **SEC. 1124. ADVANCING REGULATORY SCIENCE TO PRO-**
17 **MOTE PUBLIC HEALTH INNOVATION.**

18 (a) IN GENERAL.—Not later than 1 year after the
19 date of enactment of this Act, the Secretary of Health and
20 Human Services (referred to in this section as the “Sec-
21 retary”) shall develop a strategy and implementation plan
22 for advancing regulatory science for medical products in
23 order to promote the public health and advance innovation
24 in regulatory decisionmaking.

1 (b) REQUIREMENTS.—The strategy and implementa-
2 tion plan developed under subsection (a) shall be con-
3 sistent with the user fee performance goals in the Pre-
4 scription Drug User Fee Agreement commitment letter,
5 the Generic Drug User Fee Agreement commitment letter,
6 and the Biosimilar User Fee Agreement commitment let-
7 ter transmitted by the Secretary to Congress on January
8 13, 2012, and the Medical Device User Fee Agreement
9 commitment letter transmitted by the Secretary to Con-
10 gress on April 20, 2012, and shall—

11 (1) identify a clear vision of the fundamental
12 role of efficient, consistent, and predictable, science-
13 based decisions throughout regulatory decision-
14 making of the Food and Drug Administration with
15 respect to medical products;

16 (2) identify the regulatory science priorities of
17 the Food and Drug Administration directly related
18 to fulfilling the mission of the agency with respect
19 to decisionmaking concerning medical products and
20 allocation of resources toward such regulatory
21 science priorities;

22 (3) identify regulatory and scientific gaps that
23 impede the timely development and review of, and
24 regulatory certainty with respect to, the approval, li-
25 censure, or clearance of medical products, including

1 with respect to companion products and new tech-
2 nologies, and facilitating the timely introduction and
3 adoption of new technologies and methodologies in a
4 safe and effective manner;

5 (4) identify clear, measurable metrics by which
6 progress on the priorities identified under paragraph
7 (2) and gaps identified under paragraph (3) will be
8 measured by the Food and Drug Administration, in-
9 cluding metrics specific to the integration and adop-
10 tion of advances in regulatory science described in
11 paragraph (5) and improving medical product deci-
12 sionmaking, in a predictable and science-based man-
13 ner; and

14 (5) set forth how the Food and Drug Adminis-
15 tration will ensure that advances in regulatory
16 science for medical products are adopted, as appro-
17 priate, on an ongoing basis and in an manner inte-
18 grated across centers, divisions, and branches of the
19 Food and Drug Administration, including by senior
20 managers and reviewers, including through the—

21 (A) development, updating, and consistent
22 application of guidance documents that support
23 medical product decisionmaking; and

24 (B) adoption of the tools, methods, and
25 processes under section 566 of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 360bbb-5).

3 (c) PERFORMANCE REPORTS.—The annual perform-
4 ance reports submitted to Congress under sections
5 736B(a) (as amended by section 104 of this Act), 738A(a)
6 (as amended by section 204 of this Act), 744C(a) (as
7 added by section 303 of this Act), and 744I(a) (as added
8 by section 403 of this Act) of the Federal Food, Drug,
9 and Cosmetic Act for each of fiscal years 2014 and 2016,
10 shall include a report from the Secretary on the progress
11 made with respect to—

12 (1) advancing the regulatory science priorities
13 identified under paragraph (2) of subsection (b) and
14 resolving the gaps identified under paragraph (3) of
15 such subsection, including reporting on specific
16 metrics identified under paragraph (4) of such sub-
17 section;

18 (2) the integration and adoption of advances in
19 regulatory science as set forth in paragraph (5) of
20 such subsection; and

21 (3) the progress made in advancing the regu-
22 latory science goals outlined in the Prescription
23 Drug User Fee Agreement commitment letter, the
24 Generic Drug User Fee Agreement commitment let-
25 ter, and the Biosimilar User Fee Agreement commit-

1 ment letter transmitted by the Secretary to Congress
2 on January 13, 2012, and the Medical Device User
3 Fee Agreement transmitted by the Secretary to Con-
4 gress on April 20, 2012.

5 (d) **MEDICAL PRODUCT.**—In this section, the term
6 “medical product” means a drug, as defined in subsection
7 (g) of section 201 of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 321), a device, as defined in sub-
9 section (h) of such section, or a biological product, as de-
10 fined in section 351(i) of the Public Health Service Act.

11 **SEC. 1125. INFORMATION TECHNOLOGY.**

12 (a) **HHS REPORT.**—Not later than 1 year after the
13 date of enactment of this Act, the Secretary of Health and
14 Human Services shall—

15 (1) report to Congress on—

16 (A) the milestones and a completion date
17 for developing and implementing a comprehen-
18 sive information technology strategic plan to
19 align the information technology systems mod-
20 ernization projects with the strategic goals of
21 the Food and Drug Administration, including
22 results-oriented goals, strategies, milestones,
23 performance measures;

24 (B) efforts to finalize and approve a com-
25 prehensive inventory of the information tech-

1 nology systems of the Food and Drug Adminis-
2 tration that includes information describing
3 each system, such as costs, system function or
4 purpose, and status information, and incor-
5 porate use of the system portfolio into the in-
6 formation investment management process of
7 the Food and Drug Administration;

8 (C) the ways in which the Food and Drug
9 Administration uses the plan described in sub-
10 paragraph (A) to guide and coordinate the
11 modernization projects and activities of the
12 Food and Drug Administration, including the
13 interdependencies among projects and activities;
14 and

15 (D) the extent to which the Food and
16 Drug Administration has fulfilled or is imple-
17 menting recommendations of the Government
18 Accountability Office with respect to the Food
19 and Drug Administration and information tech-
20 nology; and

21 (2) develop—

22 (A) a documented enterprise architecture
23 program management plan that includes the
24 tasks, activities, and timeframes associated with
25 developing and using the architecture and ad-

1 dresses how the enterprise architecture program
2 management will be performed in coordination
3 with other management disciplines, such as or-
4 ganizational strategic planning, capital planning
5 and investment control, and performance man-
6 agement; and

7 (B) a skills inventory, needs assessment,
8 gap analysis, and initiatives to address skills
9 gaps as part of a strategic approach to informa-
10 tion technology human capital planning.

11 (b) GAO REPORT.—Not later than January 1, 2016,
12 the Comptroller General of the United States shall issue
13 a report regarding the strategic plan described in sub-
14 section (a)(1)(A) and related actions carried out by the
15 Food and Drug Administration. Such report shall assess
16 the progress the Food and Drug Administration has made
17 on—

18 (1) the development and implementation of a
19 comprehensive information technology strategic plan,
20 including the results-oriented goals, strategies, mile-
21 stones, and performance measures identified in sub-
22 section (a)(1)(A);

23 (2) the effectiveness of the comprehensive infor-
24 mation technology strategic plan described in sub-

1 section (a)(1)(A), including the results-oriented
2 goals and performance measures; and

3 (3) the extent to which the Food and Drug Ad-
4 ministration has fulfilled recommendations of the
5 Government Accountability Office with respect to
6 such agency and information technology.

7 **SEC. 1126. NANOTECHNOLOGY.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”) shall intensify and expand activities related to en-
11 hancing scientific knowledge regarding nanomaterials in-
12 cluded or intended for inclusion in products regulated
13 under the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 301 et seq.) or other statutes administered by the
15 Food and Drug Administration, to address issues relevant
16 to the regulation of those products, including the potential
17 toxicology of such nanomaterials, the potential benefit of
18 new therapies derived from nanotechnology, the effects of
19 such nanomaterials on biological systems, and the inter-
20 action of such nanomaterials with biological systems.

21 (b) ACTIVITIES.—In conducting activities related to
22 nanotechnology, the Secretary may—

23 (1) assess scientific literature and data on gen-
24 eral nanomaterials interactions with biological sys-

1 tems and on specific nanomaterials of concern to the
2 Food and Drug Administration;

3 (2) in cooperation with other Federal agencies,
4 develop and organize information using databases
5 and models that will facilitate the identification of
6 generalized principles and characteristics regarding
7 the behavior of classes of nanomaterials with biologi-
8 cal systems;

9 (3) promote Food and Drug Administration
10 programs and participate in collaborative efforts, to
11 further the understanding of the science of novel
12 properties of nanomaterials that might contribute to
13 toxicity;

14 (4) promote and participate in collaborative ef-
15 forts to further the understanding of measurement
16 and detection methods for nanomaterials;

17 (5) collect, synthesize, interpret, and dissemi-
18 nate scientific information and data related to the
19 interactions of nanomaterials with biological sys-
20 tems;

21 (6) build scientific expertise on nanomaterials
22 within the Food and Drug Administration, including
23 field and laboratory expertise, for monitoring the
24 production and presence of nanomaterials in domes-
25 tic and imported products regulated under this Act;

1 (7) ensure ongoing training, as well as dissemi-
2 nation of new information within the centers of the
3 Food and Drug Administration, and more broadly
4 across the Food and Drug Administration, to ensure
5 timely, informed consideration of the most current
6 science pertaining to nanomaterials;

7 (8) encourage the Food and Drug Administra-
8 tion to participate in international and national con-
9 sensus standards activities pertaining to
10 nanomaterials; and

11 (9) carry out other activities that the Secretary
12 determines are necessary and consistent with the
13 purposes described in paragraphs (1) through (8).

14 **SEC. 1127. ONLINE PHARMACY REPORT TO CONGRESS.**

15 Not later than 1 year after the date of enactment
16 of this Act, the Comptroller General of the United States
17 shall submit to the Committee on Health, Education,
18 Labor, and Pensions of the Senate and the Committee on
19 Energy and Commerce of the House of Representatives
20 a report that describes any problems posed by pharmacy
21 Internet Web sites that violate Federal or State law, in-
22 cluding—

23 (1) the methods by which Internet Web sites
24 are used to sell prescription drugs in violation of

1 Federal or State law or established industry stand-
2 ards;

3 (2) the harmful health effects that patients ex-
4 perience when they consume prescription drugs pur-
5 chased through such pharmacy Internet Web sites;

6 (3) efforts by the Federal Government and
7 State and local governments to investigate and pros-
8 ecute the owners or operators of pharmacy Internet
9 Web sites, to address the threats such Web sites
10 pose, and to protect patients;

11 (4) the level of success that Federal, State, and
12 local governments have experienced in investigating
13 and prosecuting such cases;

14 (5) whether the law, as in effect on the date of
15 the report, provides sufficient authorities to Federal,
16 State, and local governments to investigate and
17 prosecute the owners and operators of pharmacy
18 Internet Web sites that violate Federal or State law
19 or established industry standards;

20 (6) additional authorities that could assist Fed-
21 eral, State, and local governments in investigating
22 and prosecuting the owners and operators of phar-
23 macy Internet Web sites that violate Federal or
24 State law or established industry standards;

1 (7) laws, policies, and activities that would edu-
2 cate consumers about how to distinguish pharmacy
3 Internet Web sites that comply with Federal and
4 State laws and established industry standards from
5 those pharmacy Internet Web sites that do not com-
6 ply with such laws and standards; and

7 (8) activities that private sector actors are tak-
8 ing to address the prevalence of illegitimate phar-
9 macy Internet Web sites, and any policies to encour-
10 age further activities.

11 **SEC. 1128. REPORT ON SMALL BUSINESSES.**

12 Not later than 1 year after the date of enactment
13 of this Act, the Commissioner of Food and Drugs shall
14 submit a report to Congress that includes—

15 (1) a listing of and staffing levels of all small
16 business offices at the Food and Drug Administra-
17 tion, including the small business liaison program;

18 (2) the status of partnership efforts between
19 the Food and Drug Administration and the Small
20 Business Administration;

21 (3) a summary of outreach efforts to small
22 businesses and small business associations, including
23 availability of toll-free telephone help lines;

24 (4) with respect to the program under the Or-
25 phan Drug Act (Public Law 97–414), the number of

1 applications made by small businesses and number
2 of applications approved for research grants and the
3 number of companies receiving protocol assistance
4 for the development of drugs for rare diseases and
5 disorders;

6 (5) the number of small businesses submitting
7 applications and receiving approval for unsolicited
8 grant applications from the Food and Drug Admin-
9 istration;

10 (6) the number of small businesses submitting
11 applications and receiving approval for solicited
12 grant applications from the Food and Drug Admin-
13 istration; and

14 (7) barriers small businesses encounter in the
15 drug and medical device approval process.

16 **SEC. 1129. PROTECTIONS FOR THE COMMISSIONED CORPS**
17 **OF THE PUBLIC HEALTH SERVICE ACT.**

18 (a) IN GENERAL.—Section 221(a) of the Public
19 Health Service Act (42 U.S.C. 213a(a)) is amended by
20 adding at the end the following:

21 “(18) Section 1034, Protected Communications;
22 Prohibition of Retaliatory Personnel Actions.”.

23 (b) CONFORMING AMENDMENT.—Section 221(b) of
24 the Public Health Service Act (42 U.S.C. 213a(b)) is
25 amended by adding at the end the following: “For pur-

1 poses of paragraph (18) of subsection (a), the term ‘In-
2 spector General’ in section 1034 of such title 10 shall
3 mean the Inspector General of the Department of Health
4 and Human Services.”.

5 **SEC. 1130. COMPLIANCE DATE FOR RULE RELATING TO**
6 **SUNSCREEN DRUG PRODUCTS FOR OVER-**
7 **THE-COUNTER HUMAN USE.**

8 In accordance with the final rule issued by the Com-
9 missioner of Food and Drug entitled “Labeling and Effec-
10 tiveness Testing; Sunscreen Drug Products for Over-the-
11 Counter Human Use; Delay of Compliance Dates” (77
12 Fed. Reg. 27591 (May 11, 2012)), a product subject to
13 the final rule issued by the Commissioner entitled “Label-
14 ing and Effectiveness Testing; Sunscreen Drug Products
15 for Over-the-Counter Human Use” (76 Fed. Reg. 35620
16 (June 17, 2011)), shall comply with such rule not later
17 than—

- 18 (1) December 17, 2013, for products subject to
19 such rule with annual sales of less than \$25,000 and
20 (2) December 17, 2012, for all other products
21 subject to such rule.

22 **SEC. 1131. STRATEGIC INTEGRATED MANAGEMENT PLAN.**

23 Not later than 1 year after the date of enactment
24 of this Act, the Secretary of Health and Human Services
25 shall submit to Congress a strategic integrated manage-

1 ment plan for the Center for Drug Evaluation and Re-
2 search, the Center for Biologics Evaluation and Research,
3 and the Center for Devices and Radiological Health. Such
4 strategic management plan shall—

5 (1) identify strategic institutional goals, prior-
6 ities, and mechanisms to improve efficiency, for the
7 Center for Drug Evaluation and Research, the Cen-
8 ter for Biologics Evaluation and Research, and the
9 Center for Devices and Radiological Health;

10 (2) describe the actions the Secretary will take
11 to recruit, retain, train, and continue to develop the
12 workforce at the Center for Drug Evaluation and
13 Research, the Center for Biologics Evaluation and
14 Research, and the Center for Devices and Radio-
15 logical Health to fulfill the public health mission of
16 the Food and Drug Administration; and

17 (3) identify results-oriented, outcome-based
18 measures that the Secretary will use to measure the
19 progress of achieving the strategic goals, priorities,
20 and mechanisms identified under paragraph (1) and
21 the effectiveness of the actions identified under para-
22 graph (2), including metrics to ensure that man-
23 agers and reviewers of the Center for Drug Evalua-
24 tion and Research, the Center for Biologics Evalua-
25 tion and Research, and the Center for Devices and

1 Radiological Health are familiar with and appro-
2 priately and consistently apply the requirements
3 under the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 301 et seq.), including new requirements
5 under parts 2, 3, 7, and 8 of subchapter C of title
6 VII of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 379f et seq.).

8 **SEC. 1132. ASSESSMENT AND MODIFICATION OF REMS.**

9 (a) ASSESSMENT AND MODIFICATION OF APPROVED
10 STRATEGY.—Section 505–1(g) (21 U.S.C. 355–1(g)) is
11 amended—

12 (1) in paragraph (1), by striking “, and propose
13 a modification to,”;

14 (2) in paragraph (2)—

15 (A) in the matter before subparagraph

16 (A)—

17 (i) by striking “, subject to paragraph
18 (5),”; and

19 (ii) by striking “, and may propose a
20 modification to,”;

21 (B) in subparagraph (C), by striking “new
22 safety or effectiveness information indicates
23 that” and all that follows and inserting the fol-
24 lowing: “an assessment is needed to evaluate

1 whether the approved strategy should be modi-
2 fied to—

3 “(i) ensure the benefits of the drug
4 outweigh the risks of the drug; or

5 “(ii) minimize the burden on the
6 health care delivery system of complying
7 with the strategy.”; and

8 (C) by striking subparagraph (D);

9 (3) in paragraph (3), by striking “for a drug
10 shall include—” and all that follows and inserting
11 the following “for a drug shall include, with respect
12 to each goal included in the strategy, an assessment
13 of the extent to which the approved strategy, includ-
14 ing each element of the strategy, is meeting the goal
15 or whether 1 or more such goals or such elements
16 should be modified.”; and

17 (4) by amending paragraph (4) to read as fol-
18 lows:

19 “(4) MODIFICATION.—

20 “(A) ON INITIATIVE OF RESPONSIBLE
21 PERSON.—After the approval of a risk evalua-
22 tion and mitigation strategy by the Secretary,
23 the responsible person may, at any time, submit
24 to the Secretary a proposal to modify the ap-
25 proved strategy. Such proposal may propose the

1 addition, modification, or removal of any goal
2 or element of the approved strategy and shall
3 include an adequate rationale to support such
4 proposed addition, modification, or removal of
5 any goal or element of the strategy.

6 “(B) ON INITIATIVE OF SECRETARY.—
7 After the approval of a risk evaluation and
8 mitigation strategy by the Secretary, the Sec-
9 retary may, at any time, require a responsible
10 person to submit a proposed modification to the
11 strategy within 120 days or within such reason-
12 able time as the Secretary specifies, if the Sec-
13 retary, in consultation with the offices described
14 in subsection (c)(2), determines that 1 or more
15 goals or elements should be added, modified, or
16 removed from the approved strategy to—

17 “(i) ensure the benefits of the drug
18 outweigh the risks of the drug; or

19 “(ii) minimize the burden on the
20 health care delivery system of complying
21 with the strategy.”.

22 (b) REVIEW OF PROPOSED STRATEGIES; REVIEW OF
23 ASSESSMENTS AND MODIFICATIONS OF APPROVED
24 STRATEGIES.—Section 505–1(h) (21 U.S.C. 355–1(h)) is
25 amended—

1 (1) in the subsection heading by inserting “AND
2 MODIFICATIONS” after “REVIEW OF ASSESS-
3 MENTS”;

4 (2) in paragraph (1)—

5 (A) by inserting “and proposed modifica-
6 tion to” after “under subsection (a) and each
7 assessment of”; and

8 (B) by inserting “, and, if necessary,
9 promptly initiate discussions with the respon-
10 sible person about such proposed strategy, as-
11 sessment, or modification” after “subsection
12 (g)”;

13 (3) by striking paragraph (2);

14 (4) by redesignating paragraphs (3) through
15 (9) as paragraphs (2) through (8), respectively;

16 (5) in paragraph (2), as redesignated by para-
17 graph (4)—

18 (A) by amending subparagraph (A) to read
19 as follows:

20 “(A) IN GENERAL.—

21 “(i) TIMEFRAME.—Unless the dispute
22 resolution process described under para-
23 graph (3) or (4) applies, and, except as
24 provided in clause (ii) or clause (iii) below,
25 the Secretary, in consultation with the of-

1 fices described in subsection (c)(2), shall
2 review and act on the proposed risk evalua-
3 tion and mitigation strategy for a drug or
4 any proposed modification to any required
5 strategy within 180 days of receipt of the
6 proposed strategy or modification.

7 “(ii) MINOR MODIFICATIONS.—The
8 Secretary shall review and act on a pro-
9 posed minor modification, as defined by
10 the Secretary in guidance, within 60 days
11 of receipt of such modification.

12 “(iii) REMS MODIFICATION DUE TO
13 SAFETY LABEL CHANGES.—Not later than
14 60 days after the Secretary receives a pro-
15 posed modification to an approved risk
16 evaluation and mitigation strategy to con-
17 form the strategy to approved safety label
18 changes, including safety labeling changes
19 initiated by the sponsor in accordance with
20 FDA regulatory requirements, or to a safe-
21 ty label change that the Secretary has di-
22 rected the holder of the application to
23 make pursuant to section 505(o)(4), the
24 Secretary shall review and act on such pro-

1 posed modification to the approved strat-
2 egy.

3 “(iv) GUIDANCE.—The Secretary shall
4 establish, through guidance, that respon-
5 sible persons may implement certain modi-
6 fications to an approved risk evaluation
7 and mitigation strategy following notifica-
8 tion to the Secretary.”; and

9 (B) by amending subparagraph (C) to read
10 as follows:

11 “(C) PUBLIC AVAILABILITY.—Upon acting
12 on a proposed risk evaluation and mitigation
13 strategy or proposed modification to a risk eval-
14 uation and mitigation strategy under subpara-
15 graph (A), the Secretary shall make publicly
16 available an action letter describing the actions
17 taken by the Secretary under such subpara-
18 graph (A).”;

19 (6) in paragraph (4), as redesignated by para-
20 graph (4)—

21 (A) in subparagraph (A)(i)—

22 (i) by striking “Not earlier than 15
23 days, and not later than 35 days, after dis-
24 cussions under paragraph (2) have begun,
25 the” and inserting “The”; and

1 (ii) by inserting “, after the sponsor is
2 required to make a submission under sub-
3 section (a)(2) or (g),” before “request in
4 writing”; and

5 (B) in subparagraph (I)—

6 (i) by striking clauses (i) and (ii); and

7 (ii) by striking “if the Secretary—”
8 and inserting “if the Secretary has com-
9 plied with the timing requirements of
10 scheduling review by the Drug Safety
11 Oversight Board, providing a written rec-
12 ommendation, and issuing an action letter
13 under subparagraphs (B), (F), and (G),
14 respectively.”;

15 (7) in paragraph (5), as redesignated by para-
16 graph (4)—

17 (A) in subparagraph (A), by striking “any
18 of subparagraphs (B) through (D)” and insert-
19 ing “subparagraph (B) or (C)”; and

20 (B) in subparagraph (C), by striking
21 “paragraph (4) or (5)” and inserting “para-
22 graph (3) or (4)”; and

23 (8) in paragraph (8), as redesignated by para-
24 graph (4), by striking “paragraphs (7) and (8)” and
25 inserting “paragraphs (6) and (7).”.

1 (c) GUIDANCE.—Not later than 1 year after the date
2 of enactment of this Act, the Secretary of Health and
3 Human Services shall issue guidance that, for purposes
4 of section 505–1(h)(2)(A) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 355–1(h)(2)(A)), describes the
6 types of modifications to approved risk evaluation and
7 mitigation strategies that shall be considered to be minor
8 modifications of such strategies.

9 **SEC. 1133. EXTENSION OF PERIOD FOR FIRST APPLICANT**
10 **TO OBTAIN TENTATIVE APPROVAL WITHOUT**
11 **FORFEITING 180-DAY-EXCLUSIVITY PERIOD.**

12 (a) EXTENSION.—

13 (1) IN GENERAL.—If a first applicant files an
14 application during the 30-month period ending on
15 the date of enactment of this Act and such applica-
16 tion initially contains a certification described in
17 paragraph (2)(A)(vii)(IV) of section 505(j) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(j)), or if a first applicant files an application
20 and the application is amended during such period
21 to first contain such a certification, the phrase “30
22 months” in paragraph (5)(D)(i)(IV) of such section
23 shall, with respect to such application, be read as
24 meaning—

1 (A) during the period beginning on the
2 date of enactment of this Act, and ending on
3 September 30, 2015, “40 months”; and

4 (B) during the period beginning on Octo-
5 ber 1, 2015, and ending on September 30,
6 2016, “36 months”.

7 (2) CONFORMING AMENDMENT.—In the case of
8 an application to which an extended period under
9 paragraph (1) applies, the reference to the 30-month
10 period under section 505(q)(1)(G) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C.
12 355(q)(1)(G)) shall be read to be the applicable pe-
13 riod under paragraph (1).

14 (b) PERIOD FOR OBTAINING TENTATIVE APPROVAL
15 OF CERTAIN APPLICATIONS.—If an application is filed on
16 or before the date of enactment of this Act and such appli-
17 cation is amended during the period beginning on the day
18 after the date of enactment of this Act and ending on Sep-
19 tember 30, 2017, to first contain a certification described
20 in paragraph (2)(A)(vii)(IV) of section 505(j) of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)),
22 the date of the filing of such amendment (rather than the
23 date of the filing of such application) shall be treated as
24 the beginning of the 30-month period described in para-
25 graph (5)(D)(i)(IV) of such section 505(j).

1 (c) DEFINITIONS.—For the purposes of this section,
2 the terms “application” and “first applicant” mean appli-
3 cation and first applicant, as such terms are used in sec-
4 tion 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)).

6 **SEC. 1134. DEADLINE FOR DETERMINATION ON CERTAIN**
7 **PETITIONS.**

8 (a) IN GENERAL.—Section 505 (21 U.S.C. 355) is
9 amended by adding at the end the following:

10 “(w) DEADLINE FOR DETERMINATION ON CERTAIN
11 PETITIONS.—The Secretary shall issue a final, substantive
12 determination on a petition submitted pursuant to sub-
13 section (b) of section 314.161 of title 21, Code of Federal
14 Regulations (or any successor regulations), no later than
15 270 days after the date the petition is submitted.”.

16 (b) APPLICATION.—The amendment made by sub-
17 section (a) shall apply to any petition that is submitted
18 pursuant to subsection (b) of section 314.161 of title 21,
19 Code of Federal Regulations (or any successor regula-
20 tions), on or after the date of enactment of this Act.

21 **SEC. 1135. FINAL AGENCY ACTION RELATING TO PETITIONS**
22 **AND CIVIL ACTIONS.**

23 Section 505(q) (21 U.S.C. 355(q)) is amended—
24 (1) in paragraph (1)—

1 (A) in subparagraph (A), by striking “sub-
2 section (b)(2) or (j)” and inserting “subsection
3 (b)(2) or (j) of this section or section 351(k) of
4 the Public Health Service Act”; and

5 (B) in subparagraph (F), by striking “180
6 days” and inserting “150 days”;

7 (2) in paragraph (2)(A)—

8 (A) in the subparagraph heading, by strik-
9 ing “180” and inserting “150”; and

10 (B) in clause (i), by striking “180-day”
11 and inserting “150-day”;

12 (3) in paragraph (4)—

13 (A) by redesignating subparagraphs (A)
14 and (B) as clauses (i) and (ii), respectively, and
15 moving such clauses, as so redesignated, 2 ems
16 to the right;

17 (B) by striking “This subsection does not
18 apply to—” and inserting the following:

19 “(A) This subsection does not apply to—
20 ”; and

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

22 “(B) Paragraph (2) does not apply to a
23 petition addressing issues concerning an appli-
24 cation submitted pursuant to section 351(k) of
25 the Public Health Service Act.”; and

1 (4) in paragraph (5), by striking “subsection
2 (b)(2) or (j)” inserting “subsection (b)(2) or (j) of
3 the Act or 351(k) of the Public Health Service Act”.

4 **SEC. 1136. ELECTRONIC SUBMISSION OF APPLICATIONS.**

5 Subchapter D of chapter VII (21 U.S.C. 379k et
6 seq.) is amended by inserting after section 745 the fol-
7 lowing:

8 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

9 “(a) DRUGS AND BIOLOGICS.—

10 “(1) IN GENERAL.—Beginning no earlier than
11 24 months after the issuance of a final guidance
12 issued after public notice and opportunity for com-
13 ment, submissions under subsection (b), (i), or (j) of
14 section 505 of this Act or subsection (a) or (k) of
15 section 351 of the Public Health Service Act shall
16 be submitted in such electronic format as specified
17 by the Secretary in such guidance.

18 “(2) GUIDANCE CONTENTS.—In the guidance
19 under paragraph (1), the Secretary may—

20 “(A) provide a timetable for establishment
21 by the Secretary of further standards for elec-
22 tronic submission as required by such para-
23 graph; and

1 “(B) set forth criteria for waivers of and
2 exemptions from the requirements of this sub-
3 section.

4 “(3) EXCEPTION.—This subsection shall not
5 apply to submissions described in section 561.

6 “(b) DEVICES.—

7 “(1) IN GENERAL.—Beginning after the
8 issuance of final guidance implementing this para-
9 graph, presubmissions and submissions for devices
10 under section 510(k), 513(f)(2)(A), 515(c), 515(d),
11 515(f), 520(g), 520(m), or 564 of this Act or section
12 351 of the Public Health Service Act, and any sup-
13 plements to such presubmissions or submissions,
14 shall include an electronic copy of such
15 presubmissions or submissions.

16 “(2) GUIDANCE CONTENTS.—In the guidance
17 under paragraph (1), the Secretary may—

18 “(A) provide standards for the electronic
19 copy required under such paragraph; and

20 “(B) set forth criteria for waivers of and
21 exemptions from the requirements of this sub-
22 section.”.

1 **SEC. 1137. PATIENT PARTICIPATION IN MEDICAL PRODUCT**
2 **DISCUSSIONS.**

3 Subchapter E of chapter V (21 U.S.C. 360bbb et
4 seq.), as amended by section 1123 of this Act, is further
5 amended by adding at the end the following:

6 **“SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PROD-**
7 **UCT DISCUSSION.**

8 “(a) IN GENERAL.—The Secretary shall develop and
9 implement strategies to solicit the views of patients during
10 the medical product development process and consider the
11 perspectives of patients during regulatory discussions, in-
12 cluding by—

13 “(1) fostering participation of a patient rep-
14 resentative who may serve as a special government
15 employee in appropriate agency meetings with med-
16 ical product sponsors and investigators; and

17 “(2) exploring means to provide for identifica-
18 tion of patient representatives who do not have any,
19 or have minimal, financial interests in the medical
20 products industry.

21 “(b) PROTECTION OF PROPRIETARY INFORMA-
22 TION.—Nothing in this section shall be construed to alter
23 the protections offered by laws, regulations, or policies
24 governing disclosure of confidential commercial or trade
25 secret information and any other information exempt from
26 disclosure pursuant to section 552(b) of title 5, United

1 States Code, as such laws, regulations, or policies would
2 apply to consultation with individuals and organizations
3 prior to the date of enactment of this section.

4 “(c) OTHER CONSULTATION.—Nothing in this sec-
5 tion shall be construed to limit the ability of the Secretary
6 to consult with individuals and organizations as authorized
7 prior to the date of enactment of this section.

8 “(d) NO RIGHT OR OBLIGATION.—Nothing in this
9 section shall be construed to create a legal right for a con-
10 sultation on any matter or require the Secretary to meet
11 with any particular expert or stakeholder. Nothing in this
12 section shall be construed to alter agreed upon goals and
13 procedures identified in the letters described in section
14 101(b) of the Prescription Drug User Fee Amendments
15 of 2012. Nothing in this section is intended to increase
16 the number of review cycles as in effect before the date
17 of enactment of this section.

18 “(e) FINANCIAL INTEREST.—In this section, the
19 term ‘financial interest’ means a financial interest under
20 section 208(a) of title 18, United States Code.”.

1 **SEC. 1138. ENSURING ADEQUATE INFORMATION REGARD-**
2 **ING PHARMACEUTICALS FOR ALL POPU-**
3 **LATIONS, PARTICULARLY UNDERREP-**
4 **RESENTED SUBPOPULATIONS, INCLUDING**
5 **RACIAL SUBGROUPS.**

6 (a) **COMMUNICATION PLAN.**—The Secretary of
7 Health and Human Services (referred to in this section
8 as the “Secretary”), acting through the Commissioner of
9 Food and Drugs, shall review and modify, as necessary,
10 the Food and Drug Administration’s communication plan
11 to inform and educate health care providers and patients
12 on the benefits and risks of medical products, with par-
13 ticular focus on underrepresented subpopulations, includ-
14 ing racial subgroups.

15 (b) **CONTENT.**—The communication plan described
16 under subsection (a)—

17 (1) shall take into account—

18 (A) the goals and principles set forth in
19 the Strategic Action Plan to Reduce Racial and
20 Ethnic Health Disparities issued by the Depart-
21 ment of Health and Human Services;

22 (B) the nature of the medical product; and

23 (C) health and disease information avail-
24 able from other agencies within such Depart-
25 ment, as well as any new means of commu-

1 n icating health and safety benefits and risks re-
2 lated to medical products;

3 (2) taking into account the nature of the med-
4 ical product, shall address the best strategy for com-
5 municating safety alerts, labeled indications for the
6 medical products, changes to the label or labeling of
7 medical products (including black-box warnings,
8 health advisories, health and safety benefits and
9 risks), particular actions to be taken by health care
10 professionals and patients, any information identi-
11 fying particular subpopulations, and any other rel-
12 evant information as determined appropriate to en-
13 hance communication, including varied means of
14 electronic communication; and

15 (3) shall include a process for implementation
16 of any improvements or other modifications deter-
17 mined to be necessary.

18 (c) ISSUANCE AND POSTING OF COMMUNICATION
19 PLAN.—

20 (1) COMMUNICATION PLAN.—Not later than 1
21 year after the date of enactment of this Act, the
22 Secretary, acting through the Commissioner of Food
23 and Drugs, shall issue the communication plan de-
24 scribed under this section.

1 (2) POSTING OF COMMUNICATION PLAN ON THE
2 OFFICE OF MINORITY HEALTH WEB SITE.—The Sec-
3 retary, acting through the Commissioner of Food
4 and Drugs, shall publicly post the communication
5 plan on the Internet Web site of the Office of Minor-
6 ity Health of the Food and Drug Administration,
7 and provide links to any other appropriate Internet
8 Web site, and seek public comment on the commu-
9 nication plan.

10 **SEC. 1139. SCHEDULING OF HYDROCODONE.**

11 (a) IN GENERAL.—Not later than 60 days after the
12 date of enactment of this Act, if practicable, the Secretary
13 of Health and Human Services (referred to in this section
14 as the “Secretary”) shall hold a public meeting to solicit
15 advice and recommendations to assist in conducting a sci-
16 entific and medical evaluation in connection with a sched-
17 uling recommendation to the Drug Enforcement Adminis-
18 tration regarding drug products containing hydrocodone,
19 combined with other analgesics or as an antitussive.

20 (b) STAKEHOLDER INPUT.—In conducting the eval-
21 uation under subsection (a), the Secretary shall solicit
22 input from a variety of stakeholders including patients,
23 health care providers, harm prevention experts, the Na-
24 tional Institute on Drug Abuse, the Centers for Disease
25 Control and Prevention, and the Drug Enforcement Ad-

1 ministration regarding the health benefits and risks, in-
2 cluding the potential for abuse and the impact of up-
3 scheduling of these products.

4 (c) TRANSCRIPT.—The transcript of any public meet-
5 ing conducted pursuant to this section shall be published
6 on the Internet Web site of the Food and Drug Adminis-
7 tration.

8 **SEC. 1140. STUDY ON DRUG LABELING BY ELECTRONIC**
9 **MEANS.**

10 (a) STUDY.—The Comptroller General of the United
11 States shall conduct a study on the benefits and effi-
12 ciencies of electronic patient labeling of prescription drugs,
13 as a complete or partial substitute for patient labeling in
14 paper form. The study shall address the implementation
15 costs to the different levels of the distribution system,
16 logistical barriers to utilizing a system of electronic patient
17 labeling, and any anticipated public health impact of
18 movement to electronic labeling.

19 (b) REPORT.—Not later than 1 year after the date
20 of enactment of this Act, the Comptroller General shall
21 submit to Congress a report on the results of the study
22 under subsection (a).

1 **SEC. 1141. RECOMMENDATIONS ON INTEROPERABILITY**
2 **STANDARDS.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services may facilitate, and, as appropriate, may
5 consult with the Attorney General to facilitate, the devel-
6 opment of recommendations on interoperability standards
7 to inform and facilitate the exchange of prescription drug
8 information across State lines by States receiving grant
9 funds under—

10 (1) the Harold Rogers Prescription Drug Moni-
11 toring Program established under the Departments
12 of Commerce, Justice, and State, the Judiciary, and
13 Related Agencies Appropriations Act, 2002 (Public
14 Law 107–77; 115 Stat. 748); and

15 (2) the Controlled Substance Monitoring Pro-
16 gram established under section 3990 of the Public
17 Health Service Act (42 U.S.C. 280g–3).

18 (b) REQUIREMENTS.—The Secretary of Health and
19 Human Services shall consider the following in facilitating
20 the development of recommendations on interoperability of
21 prescription drug monitoring programs under subsection
22 (a)—

23 (1) open standards that are freely available,
24 without cost and without restriction, in order to pro-
25 mote broad implementation;

1 (2) the use of exchange intermediaries, or hubs,
2 as necessary to facilitate interstate interoperability
3 by accommodating State-to-hub, hub-to-hub, and di-
4 rect State-to-State communication;

5 (3) the support of transmissions that are fully
6 secured as required, using industry standard meth-
7 ods of encryption, to ensure that protected health in-
8 formation and personally identifiable information are
9 not compromised at any point during such trans-
10 mission;

11 (4) access control methodologies to share pro-
12 tected information solely in accordance with State
13 laws and regulations; and

14 (5) consider model interoperability standards
15 developed by the Alliance of States with Prescription
16 Monitoring Programs.

17 (c) REPORT.—

18 (1) IN GENERAL.—Not later than 1 year after
19 the date of enactment of this Act, the Secretary of
20 Health and Human Services shall submit to the
21 Committee on Health, Education, Labor, and Pen-
22 sions of the Senate and the Committee on Energy
23 and Commerce of the House of Representatives a re-
24 port on enhancing the interoperability of State pre-
25 scription drug monitoring programs with other tech-

1 nologies and databases used for detecting and reduc-
2 ing fraud, diversion, and abuse of prescription
3 drugs.

4 (2) CONTENTS.—The report required under
5 paragraph (1) shall include—

6 (A) an assessment of legal, technical, fis-
7 cal, privacy, or security challenges that have an
8 impact on interoperability;

9 (B) a discussion of how State prescription
10 drug monitoring programs could increase the
11 production and distribution of unsolicited re-
12 ports to prescribers and dispensers of prescrip-
13 tion drugs, law enforcement officials, and health
14 professional licensing agencies, including the
15 enhancement of such reporting through inter-
16 operability with other States and relevant tech-
17 nology and databases;

18 (C) any recommendations for addressing
19 challenges that impact interoperability of State
20 prescription drug monitoring programs in order
21 to reduce fraud, diversion, and abuse of pre-
22 scription drugs; and

23 (D) an assessment of the extent to which
24 providers use prescription drug management

1 programs in delivering care and preventing pre-
2 scription drug abuse.

3 **SEC. 1142. CONFLICTS OF INTEREST.**

4 (a) IN GENERAL.—Section 712 (21 U.S.C. 379d–1)
5 is amended—

6 (1) by striking subsections (b) and (c) and in-
7 serting the following subsections:

8 “(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

9 “(1) IN GENERAL.—The Secretary shall—

10 “(A) develop and implement strategies on
11 effective outreach to potential members of advi-
12 sory committees at universities, colleges, other
13 academic research centers, professional and
14 medical societies, and patient and consumer
15 groups;

16 “(B) seek input from professional medical
17 and scientific societies to determine the most ef-
18 fective informational and recruitment activities;

19 “(C) at least every 180 days, request refer-
20 rals for potential members of advisory commit-
21 tees from a variety of stakeholders, including—

22 “(i) product developers, patient
23 groups, and disease advocacy organiza-
24 tions; and

25 “(ii) relevant—

- 1 “(I) professional societies;
- 2 “(II) medical societies;
- 3 “(III) academic organizations;
- 4 and
- 5 “(IV) governmental organiza-
- 6 tions; and

7 “(D) in carrying out subparagraphs (A)
8 and (B), take into account the levels of activity
9 (including the numbers of annual meetings) and
10 the numbers of vacancies of the advisory com-
11 mittees.

12 “(2) RECRUITMENT ACTIVITIES.—The recruit-
13 ment activities under paragraph (1) may include—

14 “(A) advertising the process for becoming
15 an advisory committee member at medical and
16 scientific society conferences;

17 “(B) making widely available, including by
18 using existing electronic communications chan-
19 nels, the contact information for the Food and
20 Drug Administration point of contact regarding
21 advisory committee nominations; and

22 “(C) developing a method through which
23 an entity receiving funding from the National
24 Institutes of Health, the Agency for Healthcare
25 Research and Quality, the Centers for Disease

1 Control and Prevention, or the Veterans Health
2 Administration can identify a person whom the
3 Food and Drug Administration can contact re-
4 garding the nomination of individuals to serve
5 on advisory committees.

6 “(3) EXPERTISE.—In carrying out this sub-
7 section, the Secretary shall seek to ensure that the
8 Secretary has access to the most current expert ad-
9 vice.

10 “(c) DISCLOSURE OF DETERMINATIONS AND CER-
11 TIFICATIONS.—Notwithstanding section 107(a)(2) of the
12 Ethics in Government Act of 1978, the following shall
13 apply:

14 “(1) 15 OR MORE DAYS IN ADVANCE.—As soon
15 as practicable, but (except as provided in paragraph
16 (2)) not later than 15 days prior to a meeting of an
17 advisory committee to which a written determination
18 as referred to in section 208(b)(1) of title 18,
19 United States Code, or a written certification as re-
20 ferred to in section 208(b)(3) of such title, applies,
21 the Secretary shall disclose (other than information
22 exempted from disclosure under section 552 or sec-
23 tion 552a of title 5, United States Code (popularly
24 known as the Freedom of Information Act and the

1 Privacy Act of 1974, respectively)) on the Internet
2 Web site of the Food and Drug Administration—

3 “(A) the type, nature, and magnitude of
4 the financial interests of the advisory committee
5 member to which such determination or certifi-
6 cation applies; and

7 “(B) the reasons of the Secretary for such
8 determination or certification, including, as ap-
9 propriate, the public health interest in having
10 the expertise of the member with respect to the
11 particular matter before the advisory com-
12 mittee.

13 “(2) LESS THAN 30 DAYS IN ADVANCE.—In the
14 case of a financial interest that becomes known to
15 the Secretary less than 30 days prior to a meeting
16 of an advisory committee to which a written deter-
17 mination as referred to in section 208(b)(1) of title
18 18, United States Code, or a written certification as
19 referred to in section 208(b)(3) of such title applies,
20 the Secretary shall disclose (other than information
21 exempted from disclosure under section 552 or 552a
22 of title 5, United States Code) on the Internet Web
23 site of the Food and Drug Administration, the infor-
24 mation described in subparagraphs (A) and (B) of
25 paragraph (1) as soon as practicable after the Sec-

1 retary makes such determination or certification, but
2 in no case later than the date of such meeting.”;

3 (2) in subsection (d), by striking “subsection
4 (c)(3)” and inserting “subsection (e)”;

5 (3) by amending subsection (e) to read as fol-
6 lows:

7 “(e) ANNUAL REPORT.—

8 “(1) IN GENERAL.—Not later than February 1
9 of each year, the Secretary shall submit to the Com-
10 mittee on Appropriations and the Committee on
11 Health, Education, Labor, and Pensions of the Sen-
12 ate, and the Committee on Appropriations and the
13 Committee on Energy and Commerce of the House
14 of Representatives, a report that describes—

15 “(A) with respect to the fiscal year that
16 ended on September 30 of the previous year,
17 the number of persons nominated for participa-
18 tion at meetings for each advisory committee,
19 the number of persons so nominated, and will-
20 ing to serve, the number of vacancies on each
21 advisory committee, and the number of persons
22 contacted for service as members on each advi-
23 sory committee meeting for each advisory com-
24 mittee who did not participate because of the
25 potential for such participation to constitute a

1 disqualifying financial interest under section
2 208 of title 18, United States Code;

3 “(B) with respect to such year, the number
4 of persons contacted for services as members
5 for each advisory committee meeting for each
6 advisory committee who did not participate be-
7 cause of reasons other than the potential for
8 such participation to constitute a disqualifying
9 financial interest under section 208 of title 18,
10 United States Code;

11 “(C) with respect to such year, the number
12 of members attending meetings for each advi-
13 sory committee; and

14 “(D) with respect to such year, the aggre-
15 gate number of disclosures required under sub-
16 section (d) and the percentage of individuals to
17 whom such disclosures did not apply who served
18 on such committee.

19 “(2) PUBLIC AVAILABILITY.—Not later than 30
20 days after submitting any report under paragraph
21 (1) to the committees specified in such paragraph,
22 the Secretary shall make each such report available
23 to the public.”;

1 (4) in subsection (f), by striking “shall review
2 guidance” and all that follows through the end of
3 the subsection and inserting the following: “shall—

4 “(1) review guidance of the Food and Drug Ad-
5 ministration with respect to advisory committees re-
6 garding disclosure of conflicts of interest and the ap-
7 plication of section 208 of title 18, United States
8 Code; and

9 “(2) update such guidance as necessary to en-
10 sure that the Food and Drug Administration re-
11 ceives appropriate access to needed scientific exper-
12 tise, with due consideration of the requirements of
13 such section 208.”; and

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

15 “(g) GUIDANCE ON REPORTED DISCLOSED FINAN-
16 CIAL INTEREST OR INVOLVEMENT.—The Secretary shall
17 issue guidance that describes how the Secretary reviews
18 the financial interests and involvement of advisory com-
19 mittee members that are disclosed under subsection (c)
20 but that the Secretary determines not to meet the defini-
21 tion of a disqualifying interest under section 208 of title
22 18, United States Code for the purposes of participating
23 in a particular matter.”.

24 (b) APPLICABILITY.—The amendments made by sub-
25 section (a) apply beginning on October 1, 2012.

1 **SEC. 1143. NOTIFICATION OF FDA INTENT TO REGULATE**
2 **LABORATORY-DEVELOPED TESTS.**

3 (a) IN GENERAL.—The Food and Drug Administra-
4 tion may not issue any draft or final guidance on the regu-
5 lation of laboratory-developed tests under the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
7 without, at least 60 days prior to such issuance—

8 (1) notifying the Committee on Energy and
9 Commerce of the House of Representatives and the
10 Committee on Health, Education, Labor, and Pen-
11 sions of the Senate of the Administration’s intent to
12 take such action; and

13 (2) including in such notification the antici-
14 pated details of such action.

15 (b) SUNSET.—Subsection (a) shall cease to have force
16 or effect on the date that is 5 years after the date of enact-
17 ment of this Act.

18 **Subtitle D—Synthetic Drugs**

19 **SEC. 1151. SHORT TITLE.**

20 This subtitle may be cited as the “Synthetic Drug
21 Abuse Prevention Act of 2012”.

22 **SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE**
23 **I OF THE CONTROLLED SUBSTANCES ACT.**

24 (a) CANNABIMIMETIC AGENTS.—Schedule I, as set
25 forth in section 202(c) of the Controlled Substances Act

1 (21 U.S.C. 812(c)) is amended by adding at the end the
2 following:

3 “(d)(1) Unless specifically exempted or unless listed
4 in another schedule, any material, compound, mixture, or
5 preparation which contains any quantity of
6 cannabimimetic agents, or which contains their salts, iso-
7 mers, and salts of isomers whenever the existence of such
8 salts, isomers, and salts of isomers is possible within the
9 specific chemical designation.

10 “(2) In paragraph (1):

11 “(A) The term ‘cannabimimetic agents’ means
12 any substance that is a cannabinoid receptor type 1
13 (CB1 receptor) agonist as demonstrated by binding
14 studies and functional assays within any of the fol-
15 lowing structural classes:

16 “(i) 2-(3-hydroxycyclohexyl)phenol with
17 substitution at the 5-position of the phenolic
18 ring by alkyl or alkenyl, whether or not sub-
19 stituted on the cyclohexyl ring to any extent.

20 “(ii) 3-(1-naphthoyl)indole or 3-(1-
21 naphthylmethane)indole by substitution at the
22 nitrogen atom of the indole ring, whether or not
23 further substituted on the indole ring to any ex-
24 tent, whether or not substituted on the naph-
25 thoyl or naphthyl ring to any extent.

1 “(iii) 3-(1-naphthoyl)pyrrole by substi-
2 tution at the nitrogen atom of the pyrrole ring,
3 whether or not further substituted in the
4 pyrrole ring to any extent, whether or not sub-
5 stituted on the naphthoyl ring to any extent.

6 “(iv) 1-(1-naphthylmethylene)indene by
7 substitution of the 3-position of the indene ring,
8 whether or not further substituted in the indene
9 ring to any extent, whether or not substituted
10 on the naphthyl ring to any extent.

11 “(v) 3-phenylacetylindole or 3-
12 benzoylindole by substitution at the nitrogen
13 atom of the indole ring, whether or not further
14 substituted in the indole ring to any extent,
15 whether or not substituted on the phenyl ring
16 to any extent.

17 “(B) Such term includes—

18 “(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-
19 hydroxycyclohexyl]-phenol (CP-47,497);

20 “(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-
21 hydroxycyclohexyl]-phenol (cannabicyclohexanol
22 or CP-47,497 C8-homolog);

23 “(iii) 1-pentyl-3-(1-naphthoyl)indole
24 (JWH-018 and AM678);

1 (b) OTHER DRUGS.—Schedule I of section 202(c) of
2 the Controlled Substances Act (21 U.S.C. 812(c)) is
3 amended in subsection (c) by adding at the end the fol-
4 lowing:

5 “(18) 4-methylmethcathinone (Mephedrone).

6 “(19) 3,4-methylenedioxypropylvalerone (MDPV).

7 “(20) 2-(2,5-Dimethoxy-4-
8 ethylphenyl)ethanamine (2C-E).

9 “(21) 2-(2,5-Dimethoxy-4-
10 methylphenyl)ethanamine (2C-D).

11 “(22) 2-(4-Chloro-2,5-
12 dimethoxyphenyl)ethanamine (2C-C).

13 “(23) 2-(4-Iodo-2,5-
14 dimethoxyphenyl)ethanamine (2C-I).

15 “(24) 2-[4-(Ethylthio)-2,5-
16 dimethoxyphenyl]ethanamine (2C-T-2).

17 “(25) 2-[4-(Isopropylthio)-2,5-
18 dimethoxyphenyl]ethanamine (2C-T-4).

19 “(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-
20 H).

21 “(27) 2-(2,5-Dimethoxy-4-nitro-
22 phenyl)ethanamine (2C-N).

23 “(28) 2-(2,5-Dimethoxy-4-(n)-
24 propylphenyl)ethanamine (2C-P).”.

1 **SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT**
2 **HAZARDS TO PUBLIC SAFETY EXPANSION.**

3 Section 201(h)(2) of the Controlled Substances Act
4 (21 U.S.C. 811(h)(2)) is amended—

5 (1) by striking “one year” and inserting “2
6 years”; and

7 (2) by striking “six months” and inserting “1
8 year”.