

Calendar No. 400

112TH CONGRESS
2^D SESSION

S. 3187

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.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2012

Mr. HARKIN (for himself and Mr. ENZI) introduced the following bill; which was read the first time

MAY 16, 2012

Read the second time and placed on the calendar

A BILL

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”.

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

2 (a) TABLE OF CONTENTS.—The table of contents of
 3 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 dates.
- 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 of the Food and Drug Administration to support activities related to human generic drugs.

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.

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. Relationship Between Pediatric Labeling and New Clinical Investigation Exclusivity.
- Sec. 511. Pediatric rare diseases.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

- Sec. 601. Reclassification procedures.
- Sec. 602. Condition of approval studies.
- Sec. 603. Postmarket surveillance.
- Sec. 604. Sentinel.
- Sec. 605. Recalls.
- Sec. 606. Clinical holds on investigational device exemptions.
- Sec. 607. Unique device identifier.
- Sec. 608. Clarification of least burdensome standard.
- Sec. 609. Custom devices.
- Sec. 610. Agency documentation and review of certain decisions regarding devices.
- Sec. 611. Good guidance practices relating to devices.
- Sec. 612. Modification of de novo application process.
- Sec. 613. Humanitarian device exemptions.
- Sec. 614. Reauthorization of third-party review and inspections.
- Sec. 615. 510(k) device modifications.
- Sec. 616. Health information technology.

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. Failure to allow foreign inspection.
- Sec. 708. Exchange of information.
- Sec. 709. Enhancing the safety and quality of the drug supply.
- Sec. 710. Accreditation of third-party auditors for drug establishments.
- Sec. 711. Standards for admission of imported drugs.
- Sec. 712. Notification.
- Sec. 713. Protection against intentional adulteration.
- Sec. 714. Enhanced criminal penalty for counterfeiting drugs.
- Sec. 715. Extraterritorial jurisdiction.
- Sec. 716. Compliance with international agreements.

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. GAO study.

- Sec. 805. Clinical trials.
- Sec. 806. Regulatory certainty and predictability.

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. Independent study on medical innovation inducement model.
- Sec. 907. Orphan product grants program.

TITLE X—DRUG SHORTAGES

- Sec. 1001. 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 gas products.
- Sec. 1112. Regulations.
- Sec. 1113. Applicability.

Subtitle C—Miscellaneous Provisions

- Sec. 1121. Advisory committee conflicts of interest.
- Sec. 1122. Guidance document regarding product promotion using the Internet.
- Sec. 1123. Electronic submission of applications.
- Sec. 1124. Combating prescription drug abuse.
- Sec. 1125. Tanning bed labeling.
- Sec. 1126. Optimizing global clinical trials.
- Sec. 1127. Advancing regulatory science to promote public health innovation.
- Sec. 1128. Information technology.
- Sec. 1129. Reporting requirements.
- Sec. 1130. Strategic integrated management plan.
- Sec. 1131. Drug development and bioequivalence testing.
- Sec. 1132. Patient participation in medical product discussions.

1 (b) REFERENCES IN ACT.—Except as otherwise spec-
 2 ified, amendments made by this Act to a section or other
 3 provision of law are amendments to such section or other

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

3 **TITLE I—FEES RELATING TO**
4 **DRUGS**

5 **SEC. 101. SHORT TITLE; FINDING.**

6 (a) **SHORT TITLE.**—This title may be cited as the
7 “Prescription Drug User Fee Amendments of 2012”.

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

21 **SEC. 102. DEFINITIONS.**

22 Paragraph (7) of section 735 (21 U.S.C. 379g) is
23 amended, in the matter preceding subparagraph (A), by
24 striking “incurred”.

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

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

3 (1) in subsection (a)—

4 (A) in the matter preceding paragraph (1),
5 by striking “fiscal year 2008” and inserting
6 “fiscal year 2013”;

7 (B) in paragraph (1), in clauses (i) and (ii)
8 of subparagraph (A), by striking “subsection
9 (c)(5)” each place such term appears and in-
10 serting “subsection (c)(4)”;

11 (C) in the matter following clause (ii) in
12 paragraph (2)(A)—

13 (i) by striking “subsection (c)(5)” and
14 inserting “subsection (c)(4)”; and

15 (ii) by striking “payable on or before
16 October 1 of each year” and inserting
17 “due on the later of the first business day
18 on or after October 1 of each fiscal year or
19 the first business day after the enactment
20 of an appropriations Act providing for the
21 collection and obligation of fees for such
22 fiscal year under this section”; and

23 (D) in paragraph (3)—

24 (i) in subparagraph (A)—

1 (I) by striking “subsection
2 (c)(5)” and inserting “subsection
3 (c)(4)”; and

4 (II) by striking “payable on or
5 before October 1 of each year.” and
6 inserting “due on the later of the first
7 business day on or after October 1 of
8 each fiscal year or the first business
9 day after the enactment of an appro-
10 priations Act providing for the collec-
11 tion and obligation of fees for such
12 fiscal year under this section.”; and

13 (ii) by amending subparagraph (B) to
14 read as follows:

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

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

21 “(ii) the same product as another
22 product that—

23 “(I) was approved under an ap-
24 plication filed under section 505(b) or
25 505(j); and

1 “(II) is not in the list of discon-
2 tinued products compiled under sec-
3 tion 505(j)(7);

4 “(iii) the same product as another
5 product that was approved under an abbrevi-
6 ated application filed under section 507
7 (as in effect on the day before the date of
8 enactment of the Food and Drug Adminis-
9 tration Modernization Act of 1997); or

10 “(iv) the same product as another
11 product that was approved under an abbrevi-
12 ated new drug application pursuant to
13 regulations in effect prior to the implemen-
14 tation of the Drug Price Competition and
15 Patent Term Restoration Act of 1984.”;

16 (2) in subsection (b)—

17 (A) in paragraph (1)—

18 (i) in the matter preceding subpara-
19 graph (A), by striking “fiscal years 2008
20 through 2012” and inserting “fiscal years
21 2013 through 2017”;

22 (ii) in subparagraph (A), by striking
23 “\$392,783,000; and” and inserting
24 “\$693,099,000;”; and

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

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

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

9 (B) by striking paragraphs (3) and (4) and
10 inserting the following:

11 “(3) FISCAL YEAR 2013 INFLATION AND WORK-
12 LOAD ADJUSTMENTS.—For purposes of paragraph
13 (1), the dollar amount of the inflation and workload
14 adjustments for fiscal year 2013 shall be determined
15 as follows:

16 “(A) INFLATION ADJUSTMENT.—The infla-
17 tion adjustment for fiscal year 2013 shall be
18 the sum of—

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

23 “(ii) \$652,709,000 multiplied by the
24 result of an inflation adjustment calcula-

1 tion determined using the methodology de-
2 scribed in subsection (c)(1)(C).

3 “(B) WORKLOAD ADJUSTMENT.—Subject
4 to subparagraph (C), the workload adjustment
5 for fiscal 2013 shall be—

6 “(i) \$652,709,000 plus the amount of
7 the inflation adjustment calculated under
8 subparagraph (A); multiplied by

9 “(ii) the amount (if any) by which a
10 percentage workload adjustment for fiscal
11 year 2013, as determined using the meth-
12 odology described in subsection (c)(2)(A),
13 would exceed the percentage workload ad-
14 justment (as so determined) for fiscal year
15 2012, if both such adjustment percentages
16 were calculated using the 5-year base pe-
17 riod consisting of fiscal years 2003
18 through 2007.

19 “(C) LIMITATION.—Under no cir-
20 cumstances shall the adjustment under sub-
21 paragraph (B) result in fee revenues for fiscal
22 year 2013 that are less than the sum of the
23 amount under paragraph (1)(A) and the
24 amount under paragraph (1)(B).”;

1 (3) by striking subsection (c) and inserting the
2 following:

3 “(c) ADJUSTMENTS.—

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

10 “(A) one;

11 “(B) the average annual percent change in
12 the cost, per full-time equivalent position of the
13 Food and Drug Administration, of all personnel
14 compensation and benefits paid with respect to
15 such positions for the first 3 years of the pre-
16 ceeding 4 fiscal years, multiplied by the propor-
17 tion of personnel compensation and benefits
18 costs to total costs of the process for the review
19 of human drug applications (as defined in sec-
20 tion 735(6)) for the first 3 years of the pre-
21 ceeding 4 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 the process for the review of human
6 drug applications (as defined in section 735(6))
7 for the first 3 years of the preceding 4 fiscal
8 years.

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

13 “(2) WORKLOAD ADJUSTMENT.—For fiscal
14 year 2014 and subsequent fiscal years, after the fee
15 revenues established in subsection (b) are adjusted
16 for a fiscal year for inflation in accordance with
17 paragraph (1), the fee revenues shall be adjusted
18 further for such fiscal year to reflect changes in the
19 workload of the Secretary for the process for the re-
20 view of human drug applications. With respect to
21 such adjustment:

22 “(A) The adjustment shall be determined
23 by the Secretary based on a weighted average
24 of the change in the total number of human
25 drug applications (adjusted for changes in re-

1 view activities, as described in the notice that
2 the Secretary is required to publish in the Fed-
3 eral Register under this subparagraph), efficacy
4 supplements, and manufacturing supplements
5 submitted to the Secretary, and the change in
6 the total number of active commercial investiga-
7 tional new drug applications (adjusted for
8 changes in review activities, as so described)
9 during the most recent 12-month period for
10 which data on such submissions is available.
11 The Secretary shall publish in the Federal Reg-
12 ister the fee revenues and fees resulting from
13 the adjustment and the supporting methodolo-
14 gies.

15 “(B) Under no circumstances shall the ad-
16 justment result in fee revenues for a fiscal year
17 that are less than the sum of the amount under
18 subsection (b)(1)(A) and the amount under
19 subsection (b)(1)(B), as adjusted for inflation
20 under paragraph (1).

21 “(C) The Secretary shall contract with an
22 independent accounting or consulting firm to
23 periodically review the adequacy of the adjust-
24 ment and publish the results of those reviews.
25 The first review shall be conducted and pub-

1 lished by the end of fiscal year 2013 (to exam-
2 ine the performance of the adjustment since fis-
3 cal year 2009), and the second review shall be
4 conducted and published by the end of fiscal
5 year 2015 (to examine the continued perform-
6 ance of the adjustment). The reports shall
7 evaluate whether the adjustment reasonably
8 represents actual changes in workload volume
9 and complexity and present options to dis-
10 continue, retain, or modify any elements of the
11 adjustment. The reports shall be published for
12 public comment. After review of the reports and
13 receipt of public comments, the Secretary shall,
14 if warranted, adopt appropriate changes to the
15 methodology. If the Secretary adopts changes to
16 the methodology based on the first report, the
17 changes shall be effective for the first fiscal
18 year for which fees are set after the Secretary
19 adopts such changes and each subsequent fiscal
20 year.

21 “(3) FINAL YEAR ADJUSTMENT.—For fiscal
22 year 2017, the Secretary may, in addition to adjust-
23 ments under this paragraph and paragraphs (1) and
24 (2), further increase the fee revenues and fees estab-
25 lished in subsection (b) if such an adjustment is nec-

1 essary to provide for not more than 3 months of op-
2 erating reserves of carryover user fees for the proc-
3 ess for the review of human drug applications for
4 the first 3 months of fiscal year 2018. If such an
5 adjustment is necessary, the rationale for the
6 amount of the increase shall be contained in the an-
7 nual notice establishing fee revenues and fees for fis-
8 cal year 2017. If the Secretary has carryover bal-
9 ances for such process in excess of 3 months of such
10 operating reserves, the adjustment under this para-
11 graph shall not be made.

12 “(4) ANNUAL FEE SETTING.—The Secretary
13 shall, not later than 60 days before the start of each
14 fiscal year that begins after September 30, 2012, es-
15 tablish, for the next fiscal year, application, product,
16 and establishment fees under subsection (a), based
17 on the revenue amounts established under subsection
18 (b) and the adjustments provided under this sub-
19 section.

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

25 (4) in subsection (g)—

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

4 (B) in paragraph (2)—

5 (i) in subparagraph (A)—

6 (I) in clause (i), by striking
7 “shall be retained” and inserting
8 “subject to subparagraph (C), shall be
9 collected and available”; and

10 (II) in clause (ii), by striking
11 “shall only be collected and available”
12 and inserting “shall be available”; and

13 (ii) by adding at the end the following
14 new subparagraph:

15 “(C) PROVISION FOR EARLY PAYMENTS.—

16 Payment of fees authorized under this section
17 for a fiscal year, prior to the due date for such
18 fees, may be accepted by the Secretary in ac-
19 cordance with authority provided in advance in
20 a prior year appropriations Act.”;

21 (C) in paragraph (3), by striking “fiscal
22 years 2008 through 2012” and inserting “fiscal
23 years 2013 through 2017”; and

24 (D) in paragraph (4)—

1 (i) by striking “fiscal years 2008
2 through 2010” and inserting “fiscal years
3 2013 through 2015”;

4 (ii) by striking “fiscal year 2011” and
5 inserting “fiscal year 2016”;

6 (iii) by striking “fiscal years 2008
7 though 2011” and inserting “fiscal years
8 2013 through 2016”; and

9 (iv) by striking “fiscal year 2012”
10 and inserting “fiscal year 2017”.

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

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

13 (1) by amending subsection (a) to read as fol-
14 lows:

15 “(a) PERFORMANCE REPORT.—Beginning with fiscal
16 year 2013, not later than 120 days after the end of each
17 fiscal year for which fees are collected under this part,
18 the Secretary shall prepare and submit to the Committee
19 on Energy and Commerce of the House of Representatives
20 and the Committee on Health, Education, Labor, and
21 Pensions of the Senate a report concerning the progress
22 of the Food and Drug Administration in achieving the
23 goals identified in the letters described in section 101(b)
24 of the Prescription Drug User Fee Amendments of 2012
25 during such fiscal year and the future plans of the Food

1 and Drug Administration for meeting the goals. The re-
2 port under this subsection for a fiscal year shall include
3 information on all previous cohorts for which the Sec-
4 retary has not given a complete response on all human
5 drug applications 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.—Section 106 of
18 the Prescription Drug User Fee Amendments of 2007
19 (Title I of Public Law 110–85) is repealed.

20 (d) TECHNICAL CLARIFICATIONS.—

21 (1) Effective September 30, 2007, section 509
22 of the Prescription Drug User Fee Amendments Act
23 of 2002 (Title V of Public Law 107–188) is re-
24 pealed.

1 (2) Effective September 30, 2002, section 107
2 of the Food and Drug Administration Modernization
3 Act of 1997 (Public Law 105–115) is repealed.

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

7 **SEC. 106. EFFECTIVE DATE.**

8 The amendments made by this title shall take effect
9 on October 1, 2012, or the date of the enactment of this
10 Act, whichever is later, except that fees under part 2 of
11 subchapter C of chapter VII of the Federal Food, Drug,
12 and Cosmetic Act shall be assessed for all human drug
13 applications received on or after October 1, 2012, regard-
14 less of the date of the enactment of this Act.

15 **SEC. 107. SAVINGS CLAUSE.**

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

1 quired by such part for a fiscal year prior to fiscal year
2 2012.

3 **TITLE II—FEES RELATING TO** 4 **DEVICES**

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

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

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

20 **SEC. 202. DEFINITIONS.**

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

22 (1) in paragraph (9), by striking “incurred”
23 after “expenses”;

24 (2) in paragraph (10), by striking “October
25 2001” and inserting “October 2011”; and

1 (3) in paragraph (13), by striking “is required
2 to register” and all that follows through the end of
3 paragraph (13) and inserting the following: “is reg-
4 istered (or is required to register) with the Secretary
5 under section 510 because such establishment is en-
6 gaged in the manufacture, preparation, propagation,
7 compounding, or processing of a device.”.

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

9 (a) TYPES OF FEES.—Section 738(a) (21 U.S.C.
10 379j(a)) is amended—

11 (1) in paragraph (1), by striking “fiscal year
12 2008” and inserting “fiscal year 2013”;

13 (2) in paragraph (2)(A)—

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

15 (i) by striking “subsections (d) and
16 (e)” and inserting “subsections (d), (e),
17 and (f)”;

18 (ii) by striking “October 1, 2002” and
19 inserting “October 1, 2012”; and

20 (iii) by striking “subsection (c)(1)”
21 and inserting “subsection (c)”;

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

24 (3) in paragraph (3)—

25 (A) in subparagraph (A)—

1 (i) by inserting “and subsection (f)”
2 after “subparagraph (B)”; and

3 (ii) by striking “2008” and inserting
4 “2013”; and

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

8 “(i) the initial or annual registration
9 (as applicable) of the establishment under
10 section 510; or

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

15 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.
16 379j(b)) is amended to read as follows:

17 “(b) FEE AMOUNTS.—

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

1 “(2) BASE FEE AMOUNTS.—For purposes of
 2 paragraph (1), the base fee amounts specified in this
 3 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

4 “(3) TOTAL REVENUE AMOUNTS.—For pur-
 5 poses of paragraph (1), the total revenue amounts
 6 specified in this paragraph are as follows:

- 7 “(A) \$97,722,301 for fiscal year 2013.
 8 “(B) \$112,580,497 for fiscal year 2014.
 9 “(C) \$125,767,107 for fiscal year 2015.
 10 “(D) \$129,339,949 for fiscal year 2016.
 11 “(E) \$130,184,348 for fiscal year 2017.”.

12 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
 13 738(c) (21 U.S.C. 379j(c)) is amended—

- 14 (1) in the subsection heading, by inserting “;
 15 ADJUSTMENTS” after “SETTING”;
 16 (2) by striking paragraphs (1) and (2);
 17 (3) by redesignating paragraphs (3) and (4) as
 18 paragraphs (4) and (5), respectively; and
 19 (4) by inserting before paragraph (4), as so re-
 20 designated, the following:

21 “(1) IN GENERAL.—The Secretary shall, 60
 22 days before the start of each fiscal year after Sep-
 23 tember 30, 2012, establish fees under subsection (a),

1 based on amounts specified under subsection (b) and
2 the adjustments provided under this subsection, and
3 publish such fees, and the rationale for any adjust-
4 ments to such fees, in the Federal Register.

5 “(2) INFLATION ADJUSTMENTS.—

6 “(A) ADJUSTMENT TO TOTAL REVENUE
7 AMOUNTS.—For fiscal year 2014 and each sub-
8 sequent fiscal year, the Secretary shall adjust
9 the total revenue amount specified in subsection
10 (b)(3) for such fiscal year by multiplying such
11 amount by the applicable inflation adjustment
12 under subparagraph (B) for such year.

13 “(B) APPLICABLE INFLATION ADJUST-
14 MENT TO TOTAL REVENUE AMOUNTS.—The ap-
15 plicable inflation adjustment for a fiscal year
16 is—

17 “(i) for fiscal year 2014, the base in-
18 flation adjustment under subparagraph (C)
19 for such fiscal year; and

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

22 “(I) the base inflation adjust-
23 ment under subparagraph (C) for
24 such fiscal year; and

1 “(II) the product of the base in-
2 flation adjustment under subpara-
3 graph (C) for each of the fiscal years
4 preceding such fiscal year, beginning
5 with fiscal year 2014.

6 “(C) BASE INFLATION ADJUSTMENT TO
7 TOTAL REVENUE AMOUNTS.—

8 “(i) IN GENERAL.—Subject to further
9 adjustment under clause (ii), the base in-
10 flation adjustment for a fiscal year is the
11 sum of one plus—

12 “(I) the average annual percent
13 change in the cost, per full-time equiv-
14 alent position of the Food and Drug
15 Administration, of all personnel com-
16 pensation and benefits paid with re-
17 spect to such positions for the first 3
18 years of the preceding 4 fiscal years,
19 multiplied by 0.60; and

20 “(II) the average annual percent
21 change that occurred in the Consumer
22 Price Index for urban consumers
23 (Washington-Baltimore, DC–MD–VA–
24 WV; Not Seasonally Adjusted; All
25 items; Annual Index) for the first 3

1 years of the preceding 4 years of
2 available data multiplied by 0.40.

3 “(ii) LIMITATIONS.—For purposes of
4 subparagraph (B), if the base inflation ad-
5 justment for a fiscal year under clause
6 (i)—

7 “(I) is less than 1, such adjust-
8 ment shall be considered to be equal
9 to 1; or

10 “(II) is greater than 1.04, such
11 adjustment shall be considered to be
12 equal to 1.04.

13 “(D) ADJUSTMENT TO BASE FEE
14 AMOUNTS.—For each of fiscal years 2014
15 through 2017, the base fee amounts specified in
16 subsection (b)(2) shall be adjusted as needed,
17 on a uniform proportionate basis, to generate
18 the total revenue amounts under subsection
19 (b)(3), as adjusted for inflation under subpara-
20 graph (A).

21 “(3) VOLUME-BASED ADJUSTMENTS TO ESTAB-
22 LISHMENT REGISTRATION BASE FEES.—For each of
23 fiscal years 2014 through 2017, after the base fee
24 amounts specified in subsection (b)(2) are adjusted
25 under paragraph (2)(D), the base establishment reg-

1 istration fee amounts specified in such subsection
2 shall be further adjusted, as the Secretary estimates
3 is necessary in order for total fee collections for such
4 fiscal year to generate the total revenue amounts, as
5 adjusted under paragraph (2).”.

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

8 (1) redesignating subsections (f) through (k) as
9 subsections (g) through (l), respectively; and

10 (2) by inserting after subsection (e) the fol-
11 lowing new subsection:

12 “(f) FEE WAIVER OR REDUCTION.—

13 “(1) IN GENERAL.—The Secretary may, at the
14 Secretary’s sole discretion, grant a waiver or reduc-
15 tion of fees under subsection (a)(2) or (a)(3) if the
16 Secretary finds that such waiver or reduction is in
17 the interest of public health.

18 “(2) LIMITATION.—The sum of all fee waivers
19 or reductions granted by the Secretary in any fiscal
20 year under paragraph (1) shall not exceed 2 percent
21 of the total fee revenue amounts established for such
22 year under subsection (c).

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

1 (e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C.
 2 379j(h)(1)(A)), as redesignated by subsection (d)(1), is
 3 amended by striking “\$205,720,000” and inserting
 4 “\$280,587,000”.

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

8 (1) in paragraph (1), by striking “Fees author-
 9 ized” and inserting “Subject to paragraph (2)(C),
 10 fees authorized”;

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in clause (i), by striking “shall be
 14 retained” and inserting “subject to sub-
 15 paragraph (C), shall be collected and avail-
 16 able”; and

17 (ii) in clause (ii)—

18 (I) by striking “collected and”
 19 after “shall only be”; and

20 (II) by striking “fiscal year
 21 2002” and inserting “fiscal year
 22 2009”; and

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

24 “(C) PROVISION FOR EARLY PAYMENTS.—

25 Payment of fees authorized under this section

1 for a fiscal year, prior to the due date for such
2 fees, may be accepted by the Secretary in ac-
3 cordance with authority provided in advance in
4 a prior year appropriations Act.”;

5 (3) by amending paragraph (3) to read as fol-
6 lows:

7 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—
8 For each of the fiscal years 2013 through 2017,
9 there is authorized to be appropriated for fees under
10 this section an amount equal to the total revenue
11 amount specified under subsection (b)(3) for the fis-
12 cal year, as adjusted under subsection (c) and, for
13 fiscal year 2017 only, as further adjusted under
14 paragraph (4).”; and

15 (4) in paragraph (4)—

16 (A) by striking “fiscal years 2008, 2009,
17 and 2010” and inserting “fiscal years 2013,
18 2014, and 2015”;

19 (B) by striking “fiscal year 2011” and in-
20 sserting “fiscal year 2016”;

21 (C) by striking “June 30, 2011” and in-
22 sserting “June 30, 2016”;

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

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

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

5 (g) CONFORMING AMENDMENT.—Section
6 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by
7 striking “738(g)” and inserting “738(h)”.

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

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

11 (1) in paragraph (1), by striking “2012” and
12 inserting “2017”; and

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

15 (b) REPORTS.—Section 738A(a) (21 U.S.C. 379j–
16 1(a)) is amended—

17 (1) by striking “2008 through 2012” each place
18 it appears and inserting “2013 through 2017”; and

19 (2) by striking “section 201(c) of the Food and
20 Drug Administration Amendments Act of 2007” and
21 inserting “section 201(b) of the Medical Device User
22 Fee Amendments of 2012”.

23 **SEC. 205. SAVINGS CLAUSE.**

24 Notwithstanding the amendments made by this title,
25 part 3 of subchapter C of chapter VII of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
2 effect on the day before the date of the enactment of this
3 title, shall continue to be in effect with respect to submis-
4 sions described in section 738(a)(2)(A) of the Federal
5 Food, Drug, and Cosmetic Act (as in effect as of such
6 day) that on or after October 1, 2007, but before October
7 1, 2012, were accepted by the Food and Drug Administra-
8 tion for filing with respect to assessing and collecting any
9 fee required by such part for a fiscal year prior to fiscal
10 year 2013.

11 **SEC. 206. EFFECTIVE DATE.**

12 The amendments made by this title shall take effect
13 on October 1, 2012, or the date of the enactment of this
14 Act, whichever is later, except that fees under part 3 of
15 subchapter C of chapter VII of the Federal Food, Drug,
16 and Cosmetic Act shall be assessed for submissions de-
17 scribed in section 738(a)(2)(A) of the Federal Food,
18 Drug, and Cosmetic Act received on or after October 1,
19 2012, regardless of the date of the enactment of this Act.

20 **SEC. 207. SUNSET DATES.**

21 (a) **AUTHORIZATIONS.**—Sections 737 and 738 (21
22 U.S.C. 739i; 739j) shall cease to be effective October 1,
23 2017.

1 (b) REPORTING REQUIREMENTS.—Section 738A (21
2 U.S.C. 739j–1) shall cease to be effective January 31,
3 2018.

4 (c) PREVIOUS SUNSET PROVISION.—Section 217 of
5 the Medical Device User Fee Amendments of 2007 (Title
6 II of Public Law 110–85) is repealed.

7 (d) TECHNICAL CLARIFICATION.—Effective Sep-
8 tember 30, 2007, section 107 of the Medical Device User
9 Fee and Modernization Act of 2002 (Public Law 107–
10 250) is repealed.

11 **SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT**
12 **ACTIVITIES RELATED TO THE PROCESS FOR**
13 **THE REVIEW OF DEVICE APPLICATIONS.**

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

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

18 “(a) IN GENERAL.—In addition to any other per-
19 sonnel authorities under other provisions of law, the Sec-
20 retary may, without regard to the provisions of title 5,
21 United States Code, governing appointments in the com-
22 petitive service, appoint employees to positions in the Food
23 and Drug Administration to perform, administer, or sup-
24 port activities described in subsection (b), if the Secretary

1 determines that such appointments are needed to achieve
2 the objectives specified in subsection (c).

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

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

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

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

17 **TITLE III—FEES RELATING TO** 18 **GENERIC DRUGS**

19 **SEC. 301. SHORT TITLE.**

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

22 (b) FINDING.—The Congress finds that the fees au-
23 thorized by the amendments made in this title will be dedi-
24 cated to human generic drug activities, as set forth in the
25 goals identified for purposes of part 7 of subchapter C

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

8 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
9 **NERIC DRUG FEES.**

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

12 **“PART 7—FEES RELATING TO GENERIC DRUGS**

13 **“SEC. 744A. DEFINITIONS.**

14 “For purposes of this part:

15 “(1) The term ‘abbreviated new drug applica-
16 tion’—

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

1 Competition and Patent Term Restoration Act
2 of 1984; and

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

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

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

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

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

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

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

1 ceding fiscal year divided by such Index for October
2 2011.

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

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

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

11 “(5)(A) The term ‘facility’—

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

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

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

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

23 “(B) For purposes of subparagraph (A), sepa-
24 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) 6 percent shall be derived from fees
16 under subsection (a)(2) (relating to drug mas-
17 ter files).

18 “(B) 24 percent shall be derived from fees
19 under subsection (a)(3) (relating to abbreviated
20 new drug applications and supplements). The
21 amount of a fee for a prior approval supplement
22 shall be half the amount of the fee for an ab-
23 breviated new drug application.

24 “(C) 56 percent shall be derived from fees
25 under subsection (a)(4)(A)(i) (relating to ge-

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

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

1 States and its territories and possessions and
2 those located outside of the United States and
3 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 an arrears list, such that no new abbreviated new
6 drug applications or supplement submitted on or
7 after October 1, 2012, from that person, or any af-
8 filiate of that person, will be received within the
9 meaning of section 505(j)(5)(A) until such out-
10 standing 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 breviated 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 the fiscal year 2009 (excluding the
4 amount of fees appropriated for such fiscal year)
5 multiplied by the adjustment factor (as defined in
6 section 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, as defined in section 744A(3), ap-
5 plicable 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 abbrevi-
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.—The amendments made by
23 section 302 cease to be effective October 1, 2017.

1 (b) REPORTING REQUIREMENTS.—The amendments
2 made by section 303 cease to be effective January 31,
3 2018.

4 **SEC. 305. EFFECTIVE DATE.**

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

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

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

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

1 **SEC. 307. STREAMLINED HIRING AUTHORITY OF THE FOOD**
2 **AND DRUG ADMINISTRATION TO SUPPORT**
3 **ACTIVITIES RELATED TO HUMAN GENERIC**
4 **DRUGS.**

5 Section 714 of the Federal Food, Drug, and Cosmetic
6 Act, as added by section 208, is amended—

7 (1) in subsection (b)—

8 (A) by striking “are activities” and insert-
9 ing “are—

10 “(1) activities”;

11 (B) by striking the period at the end and
12 inserting “; and”; and

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

14 “(2) activities under this Act related to human
15 generic drug activities (as defined in section
16 744A).”; and

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

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

21 “(1) with respect to the activities under sub-
22 section (b)(1), the goals referred to in section
23 738A(a)(1); and

24 “(2) with respect to the activities under sub-
25 section (b)(2), the performance goals with respect to
26 section 744A (regarding assessment and use of

1 human generic drug fees), as set forth in the letters
2 described in section 301(b) of the Generic Drug
3 User Fee Amendments of 2012.”.

4 **TITLE IV—FEES RELATING TO**
5 **BIOSIMILAR BIOLOGICAL**
6 **PRODUCTS**

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

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

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

1 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
2 **PRODUCTS.**

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

6 **“PART 8—FEES RELATING TO BIOSIMILAR**
7 **BIOLOGICAL PRODUCTS**

8 **“SEC. 744G. DEFINITIONS.**

9 “For purposes of this part:

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

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

19 “(A) one business entity controls, or has
20 the power to control, the other business entity;
21 or

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

24 “(3) The term ‘biosimilar biological product’
25 means a product for which a biosimilar biological
26 product application has been approved.

1 “(4)(A) Subject to subparagraph (B), the term
2 ‘biosimilar biological product application’ means an
3 application for licensure of a biological product
4 under section 351(k) of the Public Health Service
5 Act.

6 “(B) Such term does not include—

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

8 “(ii) an application filed under section
9 351(k) of the Public Health Service Act that
10 cites as the reference product a bovine blood
11 product for topical application licensed before
12 September 1, 1992, or a large volume paren-
13 teral drug product approved before such date;

14 “(iii) an application filed under section
15 351(k) of the Public Health Service Act with
16 respect to—

17 “(I) whole blood or a blood component
18 for transfusion;

19 “(II) an allergenic extract product;

20 “(III) an in vitro diagnostic biological
21 product; or

22 “(IV) a biological product for further
23 manufacturing use only; or

24 “(iv) an application for licensure under
25 section 351(k) of the Public Health Service Act

1 that is submitted by a State or Federal Govern-
2 ment entity for a product that is not distributed
3 commercially.

4 “(5) The term ‘biosimilar biological product de-
5 velopment meeting’ means any meeting, other than
6 a biosimilar initial advisory meeting, regarding the
7 content of a development program, including a pro-
8 posed design for, or data from, a study intended to
9 support a biosimilar biological product application.

10 “(6) The term ‘biosimilar biological product de-
11 velopment program’ means the program under this
12 part for expediting the process for the review of sub-
13 missions in connection with biosimilar biological
14 product development.

15 “(7)(A) The term ‘biosimilar biological product
16 establishment’ means a foreign or domestic place of
17 business—

18 “(i) that is at one general physical location
19 consisting of one or more buildings, all of which
20 are within five miles of each other; and

21 “(ii) at which one or more biosimilar bio-
22 logical products are manufactured in final dos-
23 age form.

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

1 “(8) The term ‘biosimilar initial advisory meet-
2 ing’—

3 “(A) means a meeting, if requested, that is
4 limited to—

5 “(i) a general discussion regarding
6 whether licensure under section 351(k) of
7 the Public Health Service Act may be fea-
8 sible for a particular product; and

9 “(ii) if so, general advice on the ex-
10 pected content of the development pro-
11 gram; and

12 “(B) does not include any meeting that in-
13 volves substantive review of summary data or
14 full study reports.

15 “(9) The term ‘costs of resources allocated for
16 the process for the review of biosimilar biological
17 product applications’ means the expenses in connec-
18 tion with the process for the review of biosimilar bio-
19 logical product applications for—

20 “(A) officers and employees of the Food
21 and Drug Administration, contractors of the
22 Food and Drug Administration, advisory com-
23 mittees, and costs related to such officers em-
24 ployees and committees and to contracts with
25 such contractors;

1 “(B) management of information, and the
2 acquisition, maintenance, and repair of com-
3 puter resources;

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

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

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

20 “(11) The term ‘financial hold’—

21 “(A) means an order issued by the Sec-
22 retary to prohibit the sponsor of a clinical in-
23 vestigation from continuing the investigation if
24 the Secretary determines that the investigation
25 is intended to support a biosimilar biological

1 product application and the sponsor has failed
2 to pay any fee for the product required under
3 subparagraph (A), (B), or (D) of section
4 744H(a)(1); and

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

9 “(12) The term ‘person’ includes an affiliate of
10 such person.

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

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

22 “(B) Actions related to submissions in con-
23 nection with biosimilar biological product devel-
24 opment, the issuance of action letters which ap-
25 prove biosimilar biological product applications

1 or which set forth in detail the specific defi-
2 ciencies in such applications, and where appro-
3 priate, the actions necessary to place such ap-
4 plications in condition for approval.

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

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

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

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

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

1 “(ii) Developing and using improved
2 adverse-event data-collection systems, in-
3 cluding information technology systems.

4 “(iii) Developing and using improved
5 analytical tools to assess potential safety
6 problems, including access to external data
7 bases.

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

13 “(v) Carrying out section 505(k)(5)
14 (relating to adverse-event reports and
15 postmarket safety activities).

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

1 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
2 **BIOLOGICAL PRODUCT FEES.**

3 “(a) TYPES OF FEES.—Beginning in fiscal year
4 2013, the Secretary shall assess and collect fees in accord-
5 ance with this section as follows:

6 “(1) BIOSIMILAR DEVELOPMENT PROGRAM
7 FEES.—

8 “(A) INITIAL BIOSIMILAR BIOLOGICAL
9 PRODUCT DEVELOPMENT FEE.—

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

20 “(ii) MEETING REQUEST.—The meet-
21 ing request described in this clause is a re-
22 quest for a biosimilar biological product
23 development meeting for a product.

24 “(iii) CLINICAL PROTOCOL FOR IND.—
25 A clinical protocol for an investigational
26 new drug protocol described in this clause

1 is a clinical protocol consistent with the
2 provisions of section 505(i), including any
3 regulations promulgated under section
4 505(i), (referred to in this section as ‘in-
5 vestigational new drug application’) de-
6 scribing an investigation that the Secretary
7 determines is intended to support a bio-
8 similar biological product application for a
9 product.

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

13 “(I) Not later than 5 days after
14 the Secretary grants a request for a
15 biosimilar biological product develop-
16 ment meeting.

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

23 “(v) TRANSITION RULE.—Each per-
24 son that has submitted an investigational
25 new drug application prior to the date of

1 enactment of the Biosimilars User Fee Act
2 of 2012 shall pay the initial biosimilar bio-
3 logical product development fee by the ear-
4 lier of the following:

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

13 “(II) Not later than 5 days after
14 the Secretary grants a request for a
15 biosimilar biological product develop-
16 ment meeting.

17 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
18 PRODUCT DEVELOPMENT FEE.—

19 “(i) IN GENERAL.—A person that
20 pays an initial biosimilar biological product
21 development fee for a product shall pay for
22 such product, beginning in the fiscal year
23 following the fiscal year in which the initial
24 biosimilar biological product development
25 fee was paid, an annual fee established

1 under subsection (b)(1)(B) for biosimilar
2 biological product development (referred to
3 in this section as ‘annual biosimilar bio-
4 logical product development fee’).

5 “(ii) DUE DATE.—The annual bio-
6 similar biological product development pro-
7 gram fee for each fiscal year will be due on
8 the later of—

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

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

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

20 “(I) submitted a marketing appli-
21 cation for the biological product that
22 was accepted for filing; or

23 “(II) discontinued participation
24 in the biosimilar biological product de-

1 development program for the product
2 under subparagraph (C).

3 “(C) DISCONTINUATION OF FEE OBLIGA-
4 TION.—A person may discontinue participation
5 in the biosimilar biological product development
6 program for a product effective October 1 of a
7 fiscal year by, not later than August 1 of the
8 preceding fiscal year—

9 “(i) if no investigational new drug ap-
10 plication concerning the product has been
11 submitted, submitting to the Secretary a
12 written declaration that the person has no
13 present intention of further developing the
14 product as a biosimilar biological product;
15 or

16 “(ii) if an investigational new drug
17 application concerning the product has
18 been submitted, by withdrawing the inves-
19 tigational new drug application in accord-
20 ance with part 312 of title 21, Code of
21 Federal Regulations (or any successor reg-
22 ulations).

23 “(D) REACTIVATION FEE.—

24 “(i) IN GENERAL.—A person that has
25 discontinued participation in the biosimilar

1 biological product development program for
2 a product under subparagraph (C) shall
3 pay a fee (referred to in this section as ‘re-
4 activation fee’) by the earlier of the fol-
5 lowing:

6 “(I) Not later than 5 days after
7 the Secretary grants a request for a
8 biosimilar biological product develop-
9 ment meeting for the product (after
10 the date on which such participation
11 was discontinued).

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

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

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

3 “(i) NO BIOSIMILAR BIOLOGICAL
4 PRODUCT DEVELOPMENT MEETINGS.—If a
5 person has failed to pay an initial or an-
6 nual biosimilar biological product develop-
7 ment fee as required under subparagraph
8 (A) or (B), or a reactivation fee as re-
9 quired under subparagraph (D), the Sec-
10 retary shall not provide a biosimilar bio-
11 logical product development meeting relat-
12 ing to the product for which fees are owed.

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

19 “(I) the Secretary determines
20 that the investigation is intended to
21 support a biosimilar biological product
22 application; and

23 “(II) the sponsor has failed to
24 pay an initial or annual biosimilar bio-
25 logical product development fee for

1 the product as required under sub-
2 paragraph (A) or (B), or a reactiva-
3 tion fee as required under subpara-
4 graph (D).

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

11 “(I) the Secretary determines
12 that the investigation is intended to
13 support a biosimilar biological product
14 application; and

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

22 “(iv) NO ACCEPTANCE OF BIOSIMILAR
23 BIOLOGICAL PRODUCT APPLICATIONS OR
24 SUPPLEMENTS.—If a person has failed to
25 pay an initial or annual biosimilar biologi-

1 cal product development fee as required
2 under subparagraph (A) or (B), or a reac-
3 tivation fee as required under subpara-
4 graph (D), any biosimilar biological prod-
5 uct application or supplement submitted by
6 that person shall be considered incomplete
7 and shall not be accepted for filing by the
8 Secretary until all such fees owed by such
9 person have been paid.

10 “(F) LIMITS REGARDING BIOSIMILAR DE-
11 VELOPMENT PROGRAM FEES.—

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

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

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

3 “(A) IN GENERAL.—Each person that sub-
4 mits, on or after October 1, 2012, a biosimilar
5 biological product application or a supplement
6 shall be subject to the following fees:

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

9 “(I) the amount of the fee estab-
10 lished under subsection (b)(1)(D) for
11 a biosimilar biological product applica-
12 tion; minus

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

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

23 “(I) half of the amount of the fee
24 established under subsection (b)(1)(D)

1 for a biosimilar biological product ap-
2 plication; minus

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

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

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

1 graphs (A), (B), and (D) of paragraph (1) for
2 that product.

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

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

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

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

11 “(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTAB-
12 LISHMENT FEE.—

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

23 “(B) ASSESSMENT IN FISCAL YEARS.—The
24 establishment fee shall be assessed in each fis-
25 cal year for which the biosimilar biological prod-

1 uct named in the application is assessed a fee
2 under paragraph (4) unless the biosimilar bio-
3 logical product establishment listed in the appli-
4 cation does not engage in the manufacture of
5 the biosimilar biological product during such
6 fiscal year.

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

9 “(i) the first business day on or after
10 October 1 of such fiscal 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 fiscal year under this section.

15 “(D) APPLICATION TO ESTABLISHMENT.—

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

23 “(ii) In the event an establishment is
24 listed in a biosimilar biological product ap-
25 plication by more than one applicant, the

1 establishment fee for the fiscal year shall
2 be divided equally and assessed among the
3 applicants whose biosimilar biological prod-
4 ucts are manufactured by the establish-
5 ment during the fiscal year and assessed
6 biosimilar biological product fees under
7 paragraph (4).

8 “(E) EXCEPTION FOR NEW PRODUCTS.—

9 If, during the fiscal year, an applicant initiates
10 or causes to be initiated the manufacture of a
11 biosimilar biological product at an establish-
12 ment listed in its biosimilar biological product
13 application—

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

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

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

1 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

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

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

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

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

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

20 “(b) FEE SETTING AND AMOUNTS.—

21 “(1) IN GENERAL.—Subject to paragraph (2),
22 the Secretary shall, 60 days before the start of each
23 fiscal year that begins after September 30, 2012, es-
24 tablish, for the next fiscal year, the fees under sub-

1 section (a). Except as provided in subsection (c),
2 such fees shall be in the following amounts:

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

11 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
12 PRODUCT DEVELOPMENT FEE.—The annual
13 biosimilar biological product development fee
14 under subsection (a)(1)(B) for a fiscal year
15 shall be equal to 10 percent of the amount es-
16 tablished under section 736(c)(4) for a human
17 drug application described in section
18 736(a)(1)(A)(i) for that fiscal year.

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

1 “(D) BIOSIMILAR BIOLOGICAL PRODUCT
2 APPLICATION FEE.—The biosimilar biological
3 product application fee under subsection (a)(2)
4 for a fiscal year shall be equal to the amount
5 established under section 736(c)(4) for a
6 human drug application described in section
7 736(a)(1)(A)(i) for that fiscal year.

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

15 “(F) BIOSIMILAR BIOLOGICAL PRODUCT
16 FEE.—The biosimilar biological product fee
17 under subsection (a)(4) for a fiscal year shall be
18 equal to the amount established under section
19 736(c)(4) for a prescription drug product for
20 that fiscal year.

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

1 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-
2 NESS.—

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

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

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

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

1 and assets of the applicant involved and any affiliate
2 of the applicant.

3 “(3) SMALL BUSINESS DEFINED.—In this sub-
4 section, the term ‘small business’ means an entity
5 that has fewer than 500 employees, including em-
6 ployees of affiliates, and does not have a drug prod-
7 uct that has been approved under a human drug ap-
8 plication (as defined in section 735) or a biosimilar
9 biological product application (as defined in section
10 744G(4)) and introduced or delivered for introduc-
11 tion into interstate commerce.

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

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

19 “(1) IN GENERAL.—Subject to paragraph (2),
20 fees authorized under subsection (a) shall be col-
21 lected and available for obligation only to the extent
22 and in the amount provided in advance in appropria-
23 tions Acts. Such fees are authorized to remain avail-
24 able until expended. Such sums as may be necessary
25 may be transferred from the Food and Drug Admin-

1 istration salaries and expenses appropriation account
2 without fiscal year limitation to such appropriation
3 account for salaries and expenses with such fiscal
4 year limitation. The sums transferred shall be avail-
5 able solely for the process for the review of bio-
6 similar biological product applications.

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

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

16 “(B) USE OF FEES AND LIMITATION.—
17 The fees authorized by this section shall be
18 available for a fiscal year beginning after fiscal
19 year 2012 to defray the costs of the process for
20 the review of biosimilar biological product appli-
21 cations (including such costs for an additional
22 number of full-time equivalent positions in the
23 Department of Health and Human Services to
24 be engaged in such process), only if the Sec-
25 retary allocates for such purpose an amount for

1 such fiscal year (excluding amounts from fees
2 collected under this section) no less than
3 \$20,000,000, multiplied by the adjustment fac-
4 tor applicable to the fiscal year involved.

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

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

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

1 “(f) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a) within 30 days after it is due,
4 such fee shall be treated as a claim of the United States
5 Government subject to subchapter II of chapter 37 of title
6 31, United States Code.

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

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

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

22 Part 8 of subchapter C of chapter VII, as added by
23 section 402, is further amended by inserting after section
24 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.—The amendment made by sec-
16 tion 402 shall cease to be effective October 1, 2017.

17 (b) REPORTING REQUIREMENTS.—The amendment
18 made by section 403 shall cease to be effective January
19 31, 2018.

20 **SEC. 405. EFFECTIVE DATE.**

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

24 (1) October 1, 2012; or

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

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

7 **SEC. 406. SAVINGS CLAUSE.**

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

19 **SEC. 407. CONFORMING AMENDMENT.**

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

1 **TITLE V—PEDIATRIC DRUGS**
2 **AND DEVICES**

3 **SEC. 501. PERMANENCE.**

4 (a) PEDIATRIC STUDIES OF DRUGS.—Subsection (q)
5 of section 505A (21 U.S.C. 355a) is amended—

6 (1) in the subsection heading, by striking
7 “SUNSET” and inserting “PERMANENCE”;

8 (2) in paragraph (1), by striking “on or before
9 October 1, 2012,”; and

10 (3) in paragraph (2), by striking “on or before
11 October 1, 2012,”.

12 (b) RESEARCH INTO PEDIATRIC USES FOR DRUGS
13 AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C.
14 355c) is amended—

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

16 (2) by redesignating subsection (n) as sub-
17 section (m).

18 **SEC. 502. WRITTEN REQUESTS.**

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

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

1 submitted and accepted in accordance with subsection
2 (d)(3). Written requests under this section may consist of
3 a study or studies required under section 505B.”

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

9 **SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COM-**
10 **MITTEE.**

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

1 **SEC. 504. ACCESS TO DATA.**

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

18 **SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC**
19 **STUDIES.**

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

22 (1) in subsection (a)(3)—

23 (A) by redesignating subparagraph (B) as
24 subparagraph (C);

25 (B) by inserting after subparagraph (A)
26 the following:

1 “(B) DEFERRAL EXTENSION.—

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

9 “(I) the Secretary determines
10 that the conditions described in sub-
11 clause (II) or (III) of subparagraph
12 (A)(i) continue to be met; and

13 “(II) the applicant submits a new
14 timeline under subparagraph
15 (A)(ii)(IV) and any significant up-
16 dates to the information required
17 under subparagraph (A)(ii).

18 “(ii) TIMING AND INFORMATION.—If
19 the deferral extension under this subpara-
20 graph is requested by the applicant, the
21 applicant shall submit the deferral exten-
22 sion request containing the information de-
23 scribed in this subparagraph not less than
24 90 days prior to the date that the deferral
25 would expire. The Secretary shall respond

1 to such request not later than 45 days
2 after the receipt of such letter. If the Sec-
3 retary grants such an extension, the speci-
4 fied date shall be the extended date. The
5 sponsor of the required assessment under
6 paragraph (1) shall not be issued a letter
7 described in subsection (d) unless the spec-
8 ified or extended date of submission for
9 such required studies has passed or if the
10 request for an extension is pending. For a
11 deferral that has expired prior to the date
12 of enactment of the Food and Drug Ad-
13 ministration Safety and Innovation Act or
14 that will expire prior to 270 days after the
15 date of enactment of such Act, a deferral
16 extension shall be requested by an appli-
17 cant not later than 180 days after the date
18 of enactment of such Act. The Secretary
19 shall respond to any such request as soon
20 as practicable, but not later than 1 year
21 after the date of enactment of such Act.
22 Nothing in this clause shall prevent the
23 Secretary from updating the status of a
24 study or studies publicly if components of

1 such study or studies are late or delayed.”;

2 and

3 (C) in subparagraph (C), as so redesign-

4 nated—

5 (i) in clause (i), by adding at the end

6 the following:

7 “(III) Projected completion date
8 for pediatric studies.

9 “(IV) The reason or reasons why
10 a deferral or deferral extension con-
11 tinues to be necessary.”; and

12 (ii) in clause (ii)—

13 (I) by inserting “, as well as the
14 date of each deferral or deferral ex-
15 tension, as applicable,” after “clause
16 (i)”;

17 (II) by inserting “not later than
18 90 days after submission to the Sec-
19 retary or with the next routine quar-
20 terly update” after “Administration”;
21 and

22 (2) in subsection (f)—

23 (A) in the subsection heading, by inserting
24 “DEFERRAL EXTENSIONS,” after “DEFER-
25 RALS,”;

1 (B) in paragraph (1), by inserting “, deferral
2 extension,” after “deferral”; and

3 (C) in paragraph (4)—

4 (i) in the paragraph heading, by inserting
5 “DEFERRAL EXTENSIONS,” after
6 “DEFERRALS;” and

7 (ii) by inserting “, deferral extensions,”
8 after “deferrals”.

9 (b) TRACKING OF EXTENSIONS; ANNUAL INFORMATION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D))
10 TION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D))
11 is amended to read as follows:

12 “(D) aggregated on an annual basis—

13 “(i) the total number of deferrals and
14 deferral extensions requested and granted
15 under this section and, if granted, the reasons
16 for each such deferral or deferral extension;
17

18 “(ii) the timeline for completion of the
19 assessments; and

20 “(iii) the number of assessments completed
21 and pending;”.

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

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

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

8 “(1) Beginning 270 days after the date of en-
9 actment of the Food and Drug Administration Safe-
10 ty and Innovation Act, the Secretary shall issue a
11 non-compliance letter to such person informing them
12 of such failure to submit or meet the requirements
13 of the applicable subsection. Such letter shall require
14 the person to respond in writing within 45 calendar
15 days of issuance of such letter. Such response may
16 include the person’s request for a deferral extension
17 if applicable. Such letter and the person’s written re-
18 sponse to such letter shall be made publicly available
19 on the Internet Web site of the Food and Drug Ad-
20 ministration 45 calendar days after issuance, with
21 redactions for any trade secrets and confidential
22 commercial information. If the Secretary determines
23 that the letter was issued in error, the requirements
24 of this paragraph shall not apply.

1 “(2) The drug or biological product that is the
2 subject of an assessment described in subsection
3 (a)(2), applicable requirements in subsection (a)(3),
4 or request for approval of a pediatric formulation,
5 may be considered misbranded solely because of that
6 failure and subject to relevant enforcement action
7 (except that the drug or biological product shall not
8 be subject to action under section 303), but such
9 failure shall not be the basis for a proceeding—

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

12 “(B) to revoke the license for a biological
13 product under section 351 of the Public Health
14 Service Act.”.

15 (2) TRACKING OF LETTERS ISSUED.—Subpara-
16 graph (D) of section 505B(f)(6) (21 U.S.C.
17 355c(f)(6)), as amended by subsection (b), is further
18 amended—

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

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

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

24 “(iv) the number of postmarket non-
25 compliance letters issued pursuant to sub-

1 section (d), and the recipients of such let-
2 ters;”.

3 **SEC. 506. PEDIATRIC STUDY PLANS.**

4 (a) IN GENERAL.—Subsection (e) of section 505B
5 (21 U.S.C. 355c) is amended to read as follows:

6 “(e) PEDIATRIC STUDY PLANS.—

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

11 “(2) TIMING; CONTENT; MEETING.—

12 “(A) TIMING.—An applicant shall submit
13 an initial pediatric study plan to the Secretary
14 not later than 60 calendar days after the date
15 of the end of phase II meeting or such other
16 equivalent time agreed upon between the Sec-
17 retary and the applicant. Nothing in this para-
18 graph shall preclude the Secretary from accept-
19 ing the submission of an initial pediatric study
20 plan earlier than the date described under the
21 preceding sentence.

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

24 “(i) an outline of the pediatric study
25 or studies that the applicant plans to con-

1 duct (including, to the extent practicable
2 study objectives and design, age groups,
3 relevant endpoints, and statistical ap-
4 proach);

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

9 “(iii) other information specified in
10 the regulations promulgated under para-
11 graph (4).

12 “(C) MEETING.—The Secretary—

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

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

23 “(iii) if the Secretary determines that
24 no meeting is necessary, shall so notify the
25 applicant and provide written comments of

1 the Secretary as soon as practicable, but
2 not later than 90 calendar days after the
3 receipt of the initial pediatric study plan.

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

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

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

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

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

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

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

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

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

3 (2) in subsection (f)—

4 (A) in the subsection heading, by striking
5 “PEDIATRIC PLANS,” and inserting “PEDIATRIC
6 STUDY PLANS,”;

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

11 (C) in paragraph (4)—

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

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

18 (c) EFFECTIVE DATES.—

19 (1) PEDIATRIC STUDY PLANS.—Subsection (e)
20 of section 505B of the Federal Food, Drug, and
21 Cosmetic Act (other than paragraph (4) of such sub-
22 section), as amended by subsection (a), shall take ef-
23 fect 180 days after the date of enactment of this
24 Act, without regard to whether the Secretary has

1 promulgated final regulations under paragraph (4)
2 of such subsection by such date.

3 (2) CONFORMING AMENDMENTS.—The amend-
4 ments made by subsection (b) shall take effect 180
5 days after the date of enactment of this Act.

6 **SEC. 507. REAUTHORIZATIONS.**

7 (a) PEDIATRIC ADVISORY COMMITTEE.—Section
8 14(d) of the Best Pharmaceuticals for Children Act (42
9 U.S.C. 284m note) is amended by striking “Notwith-
10 standing section 14 of the Federal Advisory Committee
11 Act, the advisory committee shall continue to operate dur-
12 ing the five-year period beginning on the date of the enact-
13 ment of the Best Pharmaceuticals for Children Act of
14 2007” and inserting “Section 14 of the Federal Advisory
15 Committee Act shall not apply to the advisory committee”.

16 (b) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
17 DRUGS ADVISORY COMMITTEE.—Section 15(a)(3) of the
18 Best Pharmaceuticals for Children Act (42 U.S.C. 284m
19 note) is amended by striking “during the five-year period
20 beginning on the date of the enactment of the Best Phar-
21 maceuticals for Children Act of 2007” and inserting “for
22 the duration of the operation of the Oncologic Drugs Advi-
23 sory Committee”.

24 (c) HUMANITARIAN DEVICE EXEMPTION EXTEN-
25 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) DEMONSTRATION GRANTS TO IMPROVE PEDI-
4 ATRIC DEVICE AVAILABILITY.—Section 305(e) of Pedi-
5 atric Medical Device Safety and Improvement Act (Public
6 Law 110–85; 42 U.S.C. 282 note)) is amended by striking
7 “\$6,000,000 for each of fiscal years 2008 through 2012”
8 and inserting “\$4,500,000 for each of fiscal years 2013
9 through 2017”.

10 (e) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN
11 PHSA.—Section 409I(e)(1) of the Public Health Service
12 Act (42 U.S.C. 284m(e)(1)) is amended by striking “to
13 carry out this section” and all that follows through the
14 end of paragraph (1) and inserting “to carry out this sec-
15 tion \$25,000,000 for each of fiscal years 2012 through
16 2017.”.

17 **SEC. 508. REPORT.**

18 (a) IN GENERAL.—Not later than October 31, 2016,
19 and at the end of each subsequent 5-year period, the Sec-
20 retary shall submit to Congress a report that evaluates
21 the effectiveness of sections 505A and 505B of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355a,
23 355c) and section 409I of the Public Health Service Act
24 (42 U.S.C. 284m) in ensuring that medicines used by chil-

1 dren are tested in pediatric populations and properly la-
2 beled for use in children.

3 (b) CONTENTS.—The report under subsection (a)
4 shall include—

5 (1) the number and importance of drugs and
6 biological products for children for which studies
7 have been requested or required (as of the date of
8 such report) under 505A and 505B of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 355a,
10 355c) and section 409I of the Public Health Service
11 Act (42 U.S.C. 284m), including—

12 (A) the number of labeling changes made
13 to drugs and biological products pursuant to
14 such sections since the date of enactment of
15 this Act; and

16 (B) the importance of such drugs and bio-
17 logical products in the improvement of the
18 health of children;

19 (2) the number of required studies under such
20 section 505B that have not met the initial deadline
21 provided under such section, including—

22 (A) the number of deferrals and deferral
23 extensions granted and the reasons such exten-
24 sions were granted;

1 (B) the number of waivers and partial
2 waivers granted; and

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

5 (3) the number of written requests issued, de-
6 clined, and referred to the National Institutes of
7 Health under such section 505A since the date of
8 enactment of this Act (including the reasons for
9 such declination), and a description and status of re-
10 ferrals made under subsection (n) of such section
11 505A;

12 (4) the number of proposed pediatric study
13 plans submitted and agreed to as identified in the
14 marketing application under such section 505B;

15 (5) any labeling changes recommended by the
16 Pediatric Advisory Committee as a result of the re-
17 view by such Committee of adverse events reports;

18 (6) the number and current status of pediatric
19 postmarketing requirements;

20 (7) the number and importance of drugs and
21 biological products for children that are not being
22 tested for use in pediatric populations, notwith-
23 standing the existence of the programs under such
24 sections 505A and 505B and section 409I of the
25 Public Health Service Act;

1 (8) the possible reasons for the lack of testing
2 reported under paragraph (7);

3 (9) the number of drugs and biological products
4 for which testing is being done (as of the date of the
5 report) and for which a labeling change is required
6 under the programs described in paragraph (7), in-
7 cluding—

8 (A) the date labeling changes are made;

9 (B) which labeling changes required the
10 use of the dispute resolution process; and

11 (C) for labeling changes that required such
12 dispute resolution process, a description of—

13 (i) the disputes;

14 (ii) the recommendations of the Pedi-
15 atric Advisory Committee; and

16 (iii) the outcomes of such process; and

17 (D) an assessment of the effectiveness in
18 improving information about pediatric uses of
19 drugs and biological products;

20 (10)(A) the efforts made by the Secretary to in-
21 crease the number of studies conducted in the neo-
22 natal population (including efforts made to encour-
23 age the conduct of appropriate studies in neonates
24 by companies with products that have sufficient

1 safety and other information to make the conduct of
2 the studies ethical and safe); and

3 (B) the results of such efforts;

4 (11)(A) the number and importance of drugs
5 and biological products for children with cancer that
6 are being tested as a result of the programs de-
7 scribed in paragraph (7); and

8 (B) any recommendations for modifications to
9 such programs that would lead to new and better
10 therapies for children with cancer, including a de-
11 tailed rationale for each recommendation;

12 (12) an assessment of progress made in ad-
13 dressing the recommendations and findings of any
14 prior report issued by the Comptroller General, the
15 Institute of Medicine, or the Secretary regarding the
16 topics addressed in the report under this section, in-
17 cluding with respect to—

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

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

24 (13) any recommendations for modification to
25 the programs that would improve pediatric drug re-

1 search and increase pediatric labeling of drugs and
2 biological products; and

3 (14) an assessment of the successes of and limi-
4 tations to studying drugs for rare diseases under
5 such sections 505A and 505B.

6 (c) CONSULTATION ON RECOMMENDATIONS.—At
7 least 180 days before the report is due under subsection
8 (a), and no sooner than 4 years after the date of enact-
9 ment of this Act, the Secretary shall consult with rep-
10 resentatives of patient groups, including pediatric patient
11 groups, consumer groups, regulated industry, scientific
12 and medical communities, academia, and other interested
13 parties to obtain any recommendations or information rel-
14 evant to the effectiveness of the programs described in
15 subsection (b)(7), including suggestions for modifications
16 to such programs.

17 **SEC. 509. TECHNICAL AMENDMENTS.**

18 (a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—
19 Section 505A (21 U.S.C. 355a) is amended—

20 (1) in subsection (k)(2), by striking “subsection
21 (f)(3)(F)” and inserting “subsection (f)(6)(F)”;

22 (2) in subsection (n)—

23 (A) in the subsection heading, by striking
24 “COMPLETED” and inserting “SUBMITTED”;

25 and

1 (B) in paragraph (1)—

2 (i) in the matter preceding subpara-
3 graph (A), by striking “have not been com-
4 pleted” and inserting “have not been sub-
5 mitted by the date specified in the written
6 request issued or if the applicant or holder
7 does not agree to the request”;

8 (ii) in subparagraph (A)—

9 (I) in the first sentence, by in-
10 sserting “, or for which a period of ex-
11 clusivity eligible for extension under
12 subsection (b)(1) or (c)(1) of this sec-
13 tion or under subsection (m)(2) or
14 (m)(3) of section 351 of the Public
15 Health Service Act has not ended”
16 after “expired”; and

17 (II) by striking “Prior to” and
18 all that follows through the period at
19 the end; and

20 (iii) in subparagraph (B), by striking
21 “no listed patents or has 1 or more listed
22 patents that have expired,” and inserting
23 “no unexpired listed patents and for which
24 no unexpired periods of exclusivity eligible
25 for extension under subsection (b)(1) or

1 (c)(1) of this section or under subsection
2 (m)(2) or (m)(3) of section 351 of the
3 Public Health Service Act apply,”; and

4 (3) in subsection (o)(2), by amendment sub-
5 paragraph (B) to read as follows:

6 “(B) a statement of any appropriate pedi-
7 atric contraindications, warnings, precautions,
8 or other information that the Secretary con-
9 siders necessary to assure safe use.”.

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

13 (1) in subsection (a)—

14 (A) in paragraph (1)—

15 (i) in the matter preceding subpara-
16 graph (A), by inserting “for a drug” after
17 “(or supplement to an application)”;

18 (ii) in subparagraph (A), by striking
19 “for a” and inserting “, including, with re-
20 spect to a drug, an application (or supple-
21 ment to an application) for a”;

22 (iii) in subparagraph (B), by striking
23 “for a” and inserting “, including, with re-
24 spect to a drug, an application (or supple-
25 ment to an application) for a”; and

- 1 (iv) in the matter following subpara-
2 graph (B), by inserting “(or supplement)”
3 after “application”; and
4 (B) in paragraph (4)(C)—
5 (i) in the first sentence, by inserting
6 “partial” before “waiver is granted”; and
7 (ii) in the second sentence, by striking
8 “either a full or” and inserting “such a”;
9 (2) in subsection (b)(1), in the matter pre-
10 ceding subparagraph (A), by striking “After pro-
11 viding notice” and all that follows through “studies),
12 the” and inserting “The”;
13 (3) in subsection (g)—
14 (A) in paragraph (1)(A), by inserting
15 “that receives a priority review or 330 days
16 after the date of the submission of an applica-
17 tion or supplement that receives a standard re-
18 view” after “after the date of the submission of
19 the application or supplement”; and
20 (B) in paragraph (2), by striking “the
21 label of such product” and inserting “the label-
22 ing of such product”; and
23 (4) in subsection (h)(1)—

1 (A) by inserting “an application (or sup-
2 plement to an application) that contains” after
3 “date of submission of”; and

4 (B) by inserting “, if the application (or
5 supplement) receives a priority review, or not
6 later than 330 days after the date of submis-
7 sion of an application (or supplement to an ap-
8 plication) that contains a pediatric assessment
9 under this section, if the application (or supple-
10 ment) receives a standard review,” after “under
11 this section,”.

12 (c) INTERNAL REVIEW COMMITTEE.—The heading of
13 section 505C (21 U.S.C. 355d) is amended by inserting
14 “**AND DEFERRAL EXTENSIONS**” after “**DEFERRALS**”.

15 (d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—
16 Section 409I(c) of the Public Health Service Act (42
17 U.S.C. 284m(e)) is amended—

18 (1) in paragraph (1)—

19 (A) in the matter preceding subparagraph
20 (A), by inserting “or section 351(m) of this
21 Act,” after “Cosmetic Act,”;

22 (B) in subparagraph (A)(i), by inserting
23 “or section 351(k) of this Act” after “Cosmetic
24 Act”; and

1 (C) by amending subparagraph (B) to read
2 as follows:

3 “(B) there remains no patent listed pursu-
4 ant to section 505(b)(1) of the Federal Food,
5 Drug, and Cosmetic Act, and every three-year
6 and five-year period referred to in subsection
7 (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv),
8 (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of
9 section 505 of the Federal Food, Drug, and
10 Cosmetic Act, or applicable twelve-year period
11 referred to in section 351(k)(7) of this Act, and
12 any seven-year period referred to in section 527
13 of the Federal Food, Drug, and Cosmetic Act
14 has ended for at least one form of the drug;
15 and”;

16 (2) in paragraph (2)—

17 (A) in the paragraph heading, by striking
18 “FOR DRUGS LACKING EXCLUSIVITY”; and

19 (B) by striking “under section 505 of the
20 Federal Food, Drug, and Cosmetic Act”; and

21 (C) by striking “505A of such Act” and
22 inserting “505A of the Federal Food, Drug,
23 and Cosmetic Act or section 351(m) of this
24 Act”.

1 (e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
2 ADVISORY COMMITTEE.—Section 15(a) of the Best Phar-
3 maceuticals for Children Act (Public Law 107–109), as
4 amended by section 502(e) of the Food and Drug Admin-
5 istration Amendments Act of 2007 (Public Law 110–85),
6 is amended in paragraph (1)(D), by striking “section
7 505B(f)” and inserting “‘section 505C’”.

8 (f) FOUNDATION OF NATIONAL INSTITUTES OF
9 HEALTH.—Section 499(c)(1)(C) of the Public Health
10 Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by
11 striking “for which the Secretary issues a certification in
12 the affirmative under section 505A(n)(1)(A) of the Fed-
13 eral Food, Drug, and Cosmetic Act”.

14 (g) APPLICATION.—Notwithstanding any provision of
15 section 505A and 505B of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provi-
17 sion applies beginning on the date of the enactment of the
18 Best Pharmaceuticals for Children Act of 2007 or the date
19 of the enactment of the Pediatric Research Equity Act of
20 2007, any amendment made by this title to such a provi-
21 sion applies beginning on the date of the enactment of this
22 Act.

1 **SEC. 510. RELATIONSHIP BETWEEN PEDIATRIC LABELING**
2 **AND NEW CLINICAL INVESTIGATION EXCLU-**
3 **SIVITY.**

4 (a) IN GENERAL.—Section 505 (21 U.S.C. 351) is
5 amended by adding at the end the following:

6 “(w) RELATIONSHIP BETWEEN PEDIATRIC LABEL-
7 ING AND NEW CLINICAL INVESTIGATION EXCLUSIVITY.—
8 The period of market exclusivity described in clauses (iii)
9 and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv)
10 of subsection (j)(5)(F) shall not apply to a pediatric study
11 conducted under section 505A or 505B that results, pur-
12 suant to section 505B(g)(2), in the inclusion in the label-
13 ing of the product a determination that the product is not
14 indicated for use in pediatric populations or subpopula-
15 tions or information indicating that the results of a study
16 were inconclusive or did not demonstrate that the product
17 is safe or effective in pediatric populations or subpopula-
18 tions.”.

19 (b) PEDIATRIC STUDIES OF DRUGS.—Section
20 505A(m) (21 U.S.C. 355a(m)) is amended—

21 (1) by striking “(m) CLARIFICATION OF INTER-
22 ACTION OF MARKET EXCLUSIVITY UNDER THIS
23 SECTION AND MARKET EXCLUSIVITY AWARDED TO
24 AN APPLICANT FOR APPROVAL OF A DRUG UNDER
25 SECTION 505(j).—If a” and all that follows through

1 the end of the matter that precedes paragraph (1)
2 and inserting the following:

3 “(m) CLARIFICATION OF INTERACTION OF MARKET
4 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-
5 CLUSIVITY AWARDED TO AN APPLICATION OR SUPPLE-
6 MENT UNDER SUBSECTION (C) OR (J) OF SECTION 505.—

7 “(1) 180-DAY EXCLUSIVITY PERIOD.—If a 180-
8 day period under section 505(j)(5)(B)(iv) overlaps
9 with a 6-month exclusivity period under this section,
10 so that the applicant for approval of a drug under
11 section 505(j) entitled to the 180-day period under
12 that section loses a portion of the 180-day period to
13 which the applicant is entitled for the drug, the 180-
14 day period shall be extended from—”;

15 (2) by redesignating paragraphs (1) and (2) as
16 subparagraphs (A) and (B) and moving such sub-
17 paragraphs, as so redesignated, 2 ems to the right;
18 and

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

20 “(2) 3-YEAR EXCLUSIVITY PERIOD.—The 3-year
21 period of exclusivity under clauses (iii) and (iv) of
22 subsection 505(c)(3)(E) and clauses (iii) and (iv) of
23 subsection 505(j)(5)(F) are not available for ap-
24 proval of applications or supplements to applications
25 based on reports of pediatric studies conducted

1 under sections 505A or 505B that resulted, pursu-
2 ant to section 505A(j) or 505B(g)(2), in the inclu-
3 sion in the labeling of the product a determination
4 that the product is not indicated for use in pediatric
5 populations or subpopulations or information indi-
6 cating that the results of an assessment were incon-
7 clusive or did not demonstrate that the product is
8 safe or effective in pediatric populations or sub-
9 population.”.

10 (c) PROMPT APPROVAL OF DRUGS.—Section 505A(o)
11 (21 U.S.C. 355a(o)) is amended—

12 (1) in the heading, by striking “SECTION
13 505(J)” and inserting “SUBSECTIONS (C) AND (J)
14 OF SECTION 505”;

15 (2) in paragraph (1), by striking “under section
16 505(j)” and inserting “under subsection (b)(2), (c),
17 or (j) of section 505”;

18 (3) in paragraph (2), in the matter preceding
19 subparagraph (A), by inserting “clauses (iii) and (iv)
20 of section 505(c)(3)(E) or” after “Notwith-
21 standing”; and

22 (4) in paragraph (3)—

23 (A) in subparagraph (B), by inserting
24 “that differ from adult formulations” before the
25 semicolon at the end; and

1 (B) in subparagraph (C)—

2 (i) by striking “under section 505(j)”
 3 and inserting “under subsection (c) or (j)
 4 of section 505”; and

5 (ii) by inserting “clauses (iii) or (iv)
 6 of section 505(c)(3)(E) or” after “exclu-
 7 sivity under”.

8 **SEC. 511. PEDIATRIC RARE DISEASES.**

9 (a) PUBLIC MEETING.—Not later than 18 months
 10 after the date of enactment of this Act, the Secretary shall
 11 hold a public meeting to discuss ways to encourage and
 12 accelerate the development of new therapies for pediatric
 13 rare diseases.

14 (b) REPORT.—Not later than 180 days after the date
 15 of the public meeting under subsection (a), the Secretary
 16 shall issue a report that includes a strategic plan for en-
 17 couraging and accelerating the development of new thera-
 18 pies for treating pediatric rare diseases.

19 **TITLE VI—MEDICAL DEVICE**
 20 **REGULATORY IMPROVEMENTS**

21 **SEC. 601. RECLASSIFICATION PROCEDURES.**

22 (a) CLASSIFICATION CHANGES.—

23 (1) IN GENERAL.—Section 513(e)(1) (21
 24 U.S.C. 360e(e)(1)) is amended to read as follows:

1 “(e)(1)(A) Based on new information respecting a de-
2 vice, the Secretary may, upon the initiative of the Sec-
3 retary or upon petition of an interested person, change
4 the classification of such device, and revoke, on account
5 of the change in classification, any regulation or require-
6 ment in effect under section 514 or 515 with respect to
7 such device, by administrative order published in the Fed-
8 eral Register following publication of a proposed reclassi-
9 fication order in the Federal Register, a meeting of a de-
10 vice classification panel described in subsection (b), and
11 consideration of comments to a public docket, notwith-
12 standing subchapter II of Chapter 5 of title 5 of the
13 United States Code. An order under this subsection
14 changing the classification of a device from class III to
15 class II may provide that such classification shall not take
16 effect until the effective date of a performance standard
17 established under section 514 for such device.

18 “(B) Authority to issue such administrative order
19 shall not be delegated below the Commissioner. The Com-
20 missioner shall issue such an order as proposed by the Di-
21 rector of the Center for Devices and Radiological Health
22 unless the Commissioner, in consultation with the Office
23 of the Secretary of Health and Human Services, concludes
24 that the order exceeds the legal authority of the Food and

1 Drug Administration or that the order would be lawful,
2 but unlikely to advance the public health.”.

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:

1 “Authority to issue such administrative order shall not be
2 delegated below the Commissioner. Before publishing such
3 administrative order, the Commissioner shall consult with
4 the Office of the Secretary. The Commissioner shall issue
5 such an order as proposed by the Director of the Center
6 for Devices and Radiological Health unless the Commis-
7 sioner, in consultation with the Office of the Secretary,
8 concludes that the order exceeds the legal authority of the
9 Food and Drug Administration or that the order would
10 be lawful, but unlikely to advance the public health.”;

11

12 (ii) in paragraph (2)—

13 (I) by striking subparagraph (B);

14 and

15 (II) in subparagraph (A)—

16 (aa) by striking “(2)(A) A
17 proceeding for the promulgation
18 of a regulation under paragraph
19 (1) respecting a device shall be
20 initiated by the publication in the
21 Federal Register of a notice of
22 proposed rulemaking. Such notice
23 shall contain—” and inserting
24 “(2) A proposed order required

1 under paragraph (1) shall con-
2 tain—”;

3 (bb) by redesignating
4 clauses (i) through (iv) as sub-
5 paragraphs (A) through (D), re-
6 spectively;

7 (cc) in subparagraph (A), as
8 so redesignated, by striking “reg-
9 ulation” and inserting “order”;
10 and

11 (dd) in subparagraph (C), as
12 so redesignated, by striking “reg-
13 ulation” and inserting “order”;

14 (iii) in paragraph (3)—

15 (I) by striking “proposed regula-
16 tion” each place such term appears
17 and inserting “proposed order”;

18 (II) by striking “paragraph (2)
19 and after” and inserting “paragraph
20 (2),”;

21 (III) by inserting “and a meeting
22 of a device classification panel de-
23 scribed in section 513(b),” after “such
24 proposed regulation and findings,”;

1 (IV) by striking “(A) promulgate
2 such regulation” and inserting “(A)
3 issue an administrative order under
4 paragraph (1)”;

5 (V) by striking “paragraph
6 (2)(A)(ii)” and inserting “paragraph
7 (2)(B)”;

8 (VI) by striking “promulgation of
9 the regulation” and inserting
10 “issuance of the administrative
11 order”;

12 (iv) by striking paragraph (4); and

13 (C) in subsection (i)—

14 (i) in paragraph (2)—

15 (I) in the matter preceding sub-
16 paragraph (A)—

17 (aa) by striking “December
18 1, 1995” and inserting “the date
19 that is 2 years after the date of
20 enactment of the Food and Drug
21 Administration Safety and Inno-
22 vation Act”;

23 (bb) by striking “publish a
24 regulation in the Federal Reg-
25 ister” and inserting “issue an ad-

1 administrative order following pub-
2 lication of a proposed order in
3 the Federal Register, a meeting
4 of a device classification panel
5 described in section 513(b), and
6 consideration of comments from
7 all affected stakeholders, includ-
8 ing patients, payors, and pro-
9 viders, notwithstanding sub-
10 chapter II of chapter 5 of title 5,
11 United States Code,”;

12 (II) in subparagraph (B), by
13 striking “final regulation has been
14 promulgated under section 515(b)”
15 and inserting “administrative order
16 has been issued under subsection (b)
17 (or no regulation has been promul-
18 gated under such subsection prior to
19 the date of enactment of the Food
20 and Drug Administration Safety and
21 Innovation Act)”;

22 (III) in the matter following sub-
23 paragraph (B), by striking “regula-
24 tion requires” and inserting “adminis-

1 trative order issued under this para-
2 graph requires”; and

3 (IV) by striking the third and
4 fourth sentences; and

5 (ii) in paragraph (3)—

6 (I) by striking “regulation requir-
7 ing” each place such term appears
8 and inserting “order requiring”; and

9 (II) by striking “promulgation of
10 a section 515(b) regulation” and in-
11 serting “issuance of an administrative
12 order under subsection (b)”.

13 (2) TECHNICAL AND CONFORMING AMEND-
14 MENTS.—Section 501(f) (21 U.S.C. 351(f)) is
15 amended—

16 (A) in subparagraph (1)(A)—

17 (i) in subclause (i), by striking “a reg-
18 ulation promulgated” and inserting “an
19 order issued”; and

20 (ii) in subclause (ii), by striking “pro-
21 mulgation of such regulation” and insert-
22 ing “issuance of such order”;

23 (B) in subparagraph (2)(B)—

1 (i) by striking “a regulation promul-
2 gated” and inserting “an order issued”;
3 and

4 (ii) by striking “promulgation of such
5 regulation” and inserting “issuance of
6 such order”; and

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

8 “(3) In the case of a device with respect to which
9 a regulation was promulgated under section 515(b) prior
10 to the date of enactment of the Food and Drug Adminis-
11 tration Safety and Innovation Act, a reference in this sub-
12 section to an order issued under section 515(b) shall be
13 deemed to include such regulation.”.

14 (3) APPROVAL BY REGULATION PRIOR TO THE
15 DATE OF ENACTMENT OF THIS ACT.—The amend-
16 ments made by this subsection shall have no effect
17 on a regulation that was promulgated prior to the
18 date of enactment of this Act requiring that a device
19 have an approval under section 515 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of
21 an application for premarket approval.

22 (c) REPORTING.—The Secretary of Health and
23 Human Services shall annually post on the Internet web
24 site of the Food and Drug Administration—

1 (1) the number and type of class I and class II
2 devices reclassified as class II or class III in the pre-
3 vious calendar year under section 513(e)(1) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 360e(e)(1));

6 (2) the number and type of class II and class
7 III devices reclassified as class I or class II in the
8 previous calendar year under such section 513(e)(1);
9 and

10 (3) the number and type of devices reclassified
11 in the previous calendar year under section 515 of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360e).

14 **SEC. 602. CONDITION OF APPROVAL STUDIES.**

15 Section 515(d)(1)(B)(ii) (21 U.S.C.
16 360e(d)(1)(B)(ii)) is amended—

17 (1) by striking “(ii)” and inserting “(ii)(I)”;
18 and

19 (2) by adding at the end the following:

20 “(II) An order approving an application for a device
21 may require as a condition to such approval that the appli-
22 cant conduct a postmarket study regarding the device.”.

23 **SEC. 603. POSTMARKET SURVEILLANCE.**

24 Section 522 (21 U.S.C. 360l) is amended—

1 (1) in subsection (a)(1)(A), in the matter pre-
2 ceding clause (i), by inserting “, at the time of ap-
3 proval or clearance of a device or at any time there-
4 after,” after “by order”; and

5 (2) in subsection (b)(1), by inserting “The
6 manufacturer shall commence surveillance under this
7 section not later than 15 months after the day on
8 which the Secretary issues an order under this sec-
9 tion.” after the second sentence.

10 **SEC. 604. SENTINEL.**

11 Section 519 (21 U.S.C. 360i) is amended by adding
12 at the end the following:

13 “(h) INCLUSION OF DEVICES IN THE POSTMARKET
14 RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

15 “(1) IN GENERAL.—

16 “(A) APPLICATION TO DEVICES.—The Sec-
17 retary shall amend the procedures established
18 and maintained under clauses (i), (ii), (iii), and
19 (v) of section 505(k)(3)(C) in order to expand
20 the postmarket risk identification and analysis
21 system established under such section to include
22 and apply to devices.

23 “(B) EXCEPTION.—Subclause (II) of
24 clause (i) of section 505(k)(3)(C) shall not
25 apply to devices.

1 “(C) CLARIFICATION.—With respect to de-
2 vices, the private sector health-related electronic
3 data provided under section
4 505(k)(3)(C)(i)(III)(bb) may include medical
5 device utilization data, health insurance claims
6 data, and procedure and device registries.

7 “(2) DATA.—In expanding the system as de-
8 scribed in paragraph (1)(A), the Secretary shall use
9 relevant data with respect to devices cleared under
10 section 510(k) or approved under section 515, in-
11 cluding claims data, patient survey data, and any
12 other data deemed appropriate by the Secretary.

13 “(3) STAKEHOLDER INPUT.—To help ensure ef-
14 fective implementation of the system described in
15 paragraph (1)(A), the Secretary shall engage outside
16 stakeholders in development of the system through a
17 public hearing, advisory committee meeting, public
18 docket, or other like public measures, as appro-
19 priate.

20 “(4) VOLUNTARY SURVEYS.—Chapter 35 of
21 title 44, United States Code, shall not apply to the
22 collection of voluntary information from health care
23 providers, such as voluntary surveys or question-
24 naires, initiated by the Secretary for purposes of
25 postmarket risk identification for devices.”.

1 **SEC. 605. RECALLS.**

2 (a) ASSESSMENT OF DEVICE RECALL INFORMA-
3 TION.—

4 (1) IN GENERAL.—

5 (A) ASSESSMENT PROGRAM.—The Sec-
6 retary of Health and Human Services (referred
7 to in this section as the “Secretary”) shall en-
8 hance the Food and Drug Administration’s re-
9 call program to routinely and systematically as-
10 sess—

11 (i) information submitted to the Sec-
12 retary pursuant to a device recall order
13 under section 518(e) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C.
15 360h(e)); and

16 (ii) information required to be re-
17 ported to the Secretary regarding a correc-
18 tion or removal of a device under section
19 519(g) of such Act (21 U.S.C. 360i(g)).

20 (B) USE.—The Secretary shall use the as-
21 sessment of information described under sub-
22 paragraph (A) to proactively identify strategies
23 for mitigating health risks presented by defec-
24 tive or unsafe devices.

25 (2) DESIGN.—The program under paragraph
26 (1) shall, at a minimum, identify—

1 (A) trends in the numbers and types of de-
2 vice recalls;

3 (B) the types of devices in each device
4 class that are most frequently recalled;

5 (C) the causes of device recalls; and

6 (D) any other information as the Secretary
7 determines appropriate.

8 (b) AUDIT CHECK PROCEDURES.—The Secretary
9 shall clarify procedures for conducting device recall audit
10 checks to improve the ability of investigators to perform
11 these checks in a consistent manner.

12 (c) ASSESSMENT CRITERIA.—The Secretary shall de-
13 velop explicit criteria for assessing whether a person sub-
14 ject to a recall order under section 518(e) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to
16 a requirement under section 519(g) of such Act (21
17 U.S.C. 360i(g)) has performed an effective recall under
18 such section 518(e) or an effective correction or removal
19 action under such section 519(g), respectively.

20 (d) TERMINATION OF RECALLS.—The Secretary shall
21 document the basis for the termination by the Food and
22 Drug Administration of—

23 (1) an individual device recall ordered under
24 section 518(e) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 360h(e)); and

1 is to be investigated, and the health status of the
2 subjects involved; or

3 “(ii) the clinical hold should be issued for such
4 other reasons as the Secretary may by regulation es-
5 tablish.

6 “(C) Any written request to the Secretary from the
7 sponsor of an investigation that a clinical hold be removed
8 shall receive a decision, in writing and specifying the rea-
9 sons therefor, within 30 days after receipt of such request.
10 Any such request shall include sufficient information to
11 support the removal of such clinical hold.”.

12 **SEC. 607. UNIQUE DEVICE IDENTIFIER.**

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

14 (1) by striking “The Secretary shall promul-
15 gate” and inserting “Not later than December 31,
16 2012, the Secretary shall issue proposed”; and

17 (2) by adding at the end the following: “The
18 Secretary shall finalize the proposed regulations not
19 later than 6 months after the close of the comment
20 period and shall implement the final regulations with
21 respect to devices that are implantable, life-saving,
22 and life sustaining not later than 2 years after the
23 regulations are finalized.”.

1 **SEC. 608. CLARIFICATION OF LEAST BURDENSOME STAND-**
2 **ARD.**

3 (a) **PREMARKET APPROVAL.**—Section 513(a)(3)(D)
4 (21 U.S.C. 360c(a)(3)(D)) is amended—

5 (1) by redesignating clause (iii) as clause (v);

6 and

7 (2) by inserting after clause (ii) the following:

8 “(iii) For purposes of clause (ii), the term ‘necessary’
9 means the minimum required information that would sup-
10 port a determination by the Secretary that an application
11 provides reasonable assurance of the effectiveness of the
12 device.

13 “(iv) Nothing in this subparagraph shall alter the cri-
14 teria for evaluating an application for premarket approval
15 of a device.”.

16 (b) **PREMARKET NOTIFICATION UNDER SECTION**
17 **510(K).**—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D))
18 is amended—

19 (1) by striking “(D) Whenever” and inserting

20 “(D)(i) Whenever”; and

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

22 “(ii) For purposes of clause (i), the term ‘necessary’
23 means the minimum required information that would sup-
24 port a determination of substantial equivalence between
25 a new device and a predicate device.

1 “(iii) Nothing in this subparagraph shall alter the
2 standard for determining substantial equivalence between
3 a new device and a predicate device.”.

4 **SEC. 609. CUSTOM DEVICES.**

5 Section 520(b) (21 U.S.C. 360j(b)) is amended to
6 read as follows:

7 “(b) CUSTOM DEVICES.—

8 “(1) IN GENERAL.—The requirements of sec-
9 tions 514 and 515 shall not apply to a device that—

10 “(A) is created or modified in order to
11 comply with the order of an individual physician
12 or dentist (or any other specially qualified per-
13 son designated under regulations promulgated
14 by the Secretary after an opportunity for an
15 oral hearing);

16 “(B) in order to comply with an order de-
17 scribed in subparagraph (A), necessarily devi-
18 ates from an otherwise applicable performance
19 standard under section 514 or requirement
20 under section 515;

21 “(C) is not generally available in the
22 United States in finished form through labeling
23 or advertising by the manufacturer, importer,
24 or distributor for commercial distribution;

1 “(D) is designed to treat a unique pathol-
2 ogy or physiological condition that no other de-
3 vice is domestically available to treat;

4 “(E)(i) is intended to meet the special
5 needs of such physician or dentist (or other spe-
6 cially qualified person so designated) in the
7 course of the professional practice of such phy-
8 sician or dentist (or other specially qualified
9 person so designated); or

10 “(ii) is intended for use by an individual
11 patient named in such order of such physician
12 or dentist (or other specially qualified person so
13 designated);

14 “(F) is assembled from components or
15 manufactured and finished on a case-by-case
16 basis to accommodate the unique needs de-
17 scribed in clause (i) or (ii) of subparagraph (E);
18 and

19 “(G) may have common, standardized de-
20 sign characteristics, chemical and material com-
21 positions, and manufacturing processes as com-
22 mercially distributed devices.

23 “(2) LIMITATIONS.—Paragraph (1) shall apply
24 to a device only if—

1 “(A) such device is for the purpose of
2 treating a sufficiently rare condition, such that
3 conducting clinical investigations on such device
4 would be impractical;

5 “(B) production of such device under para-
6 graph (1) is limited to no more than 5 units per
7 year of a particular device type, provided that
8 such replication otherwise complies with this
9 section; and

10 “(C) the manufacturer of such device cre-
11 ated or modified as described in paragraph (1)
12 notifies the Secretary on an annual basis, in a
13 manner prescribed by the Secretary, of the
14 manufacture of such device.

15 “(3) EXCEPTION.—Paragraph (1) shall not
16 apply to oral facial devices.

17 “(4) GUIDANCE.—Not later than 2 years after
18 the date of enactment of this section, the Secretary
19 shall issue final guidance on replication of multiple
20 devices described in paragraph (2)(B).”.

21 **SEC. 610. AGENCY DOCUMENTATION AND REVIEW OF CER-**
22 **TAIN DECISIONS REGARDING DEVICES.**

23 Chapter V (21 U.S.C. 351 et seq.) is amended by
24 inserting after section 517 the following:

1 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**
2 **CERTAIN DECISIONS REGARDING DEVICES.**

3 “(a) DOCUMENTATION OF RATIONALE FOR DE-
4 NIAL.—If the Secretary renders a final decision to deny
5 clearance of a premarket notification under section 510(k)
6 or approval of a premarket application under section 515,
7 or when the Secretary disapproves an application for an
8 investigational exemption under 520(g), the written cor-
9 respondence to the applicant communicating that decision
10 shall provide a substantive summary of the scientific and
11 regulatory rationale for the decision.

12 “(b) REVIEW OF DENIAL.—

13 “(1) IN GENERAL.—A person who has sub-
14 mitted a report under section 510(k), an application
15 under section 515, or an application for an exemp-
16 tion under section 520(g) and for whom clearance of
17 the report or approval of the application is denied
18 may request a supervisory review of the decision to
19 deny such clearance or approval. Such review shall
20 be conducted by an individual at the organizational
21 level above the organization level at which the deci-
22 sion to deny the clearance of the report or approval
23 of the application is made.

24 “(2) SUBMISSION OF REQUEST.—A person re-
25 questing a supervisory review under paragraph (1)
26 shall submit such request to the Secretary not later

1 than 30 days after such denial and shall indicate in
2 the request whether such person seeks an in-person
3 meeting or a teleconference review.

4 “(3) TIMEFRAME.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B), the Secretary shall schedule
7 an in-person or teleconference review, if so re-
8 quested, not later than 30 days after such re-
9 quest is made. The Secretary shall issue a deci-
10 sion to the person requesting a review under
11 this subsection not later than 45 days after the
12 request is made under paragraph (1), or, in the
13 case of a person who requests an in-person
14 meeting or teleconference, 30 days after such
15 meeting or teleconference.

16 “(B) EXCEPTION.—Subparagraph (A)
17 shall not apply in cases that involve consulta-
18 tion with experts outside of the Food and Drug
19 Administration, or in cases in which the spon-
20 sor seeks to introduce evidence not already in
21 the administrative record at the time the denial
22 decision was made.”.

1 **SEC. 611. GOOD GUIDANCE PRACTICES RELATING TO DE-**
2 **VICES.**

3 Subparagraph (C) of section 701(h)(1) (21 U.S.C.
4 371(h)(1)) is amended—

5 (1) by striking “(C) For guidance documents”
6 and inserting “(C)(i) For guidance documents”; and

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

8 “(ii) With respect to devices, if a notice to in-
9 dustry guidance letter, a notice to industry advisory
10 letter, or any similar notice sets forth initial inter-
11 pretations of a regulation or policy or sets forth
12 changes in interpretation or policy, such notice shall
13 be treated as a guidance document for purposes of
14 this subparagraph.”.

15 **SEC. 612. MODIFICATION OF DE NOVO APPLICATION PROC-**
16 **ESS.**

17 (a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.
18 360c(f)(2)) is amended—

19 (1) by redesignating subparagraphs (B) and
20 (C) as subparagraphs (C) and (D), respectively;

21 (2) by amending subparagraph (A) to read as
22 follows:

23 “(A) In the case of a type of device that has not pre-
24 viously been classified under this Act, a person may do
25 one of the following:

1 “(i) Submit a report under section 510(k), and,
2 if the device is classified into class III under para-
3 graph (1), such person may request, not later than
4 30 days after receiving written notice of such a clas-
5 sification, the Secretary to classify the device under
6 the criteria set forth in subparagraphs (A) through
7 (C) of subsection (a)(1). The person may, in the re-
8 quest, recommend to the Secretary a classification
9 for the device. Any such request shall describe the
10 device and provide detailed information and reasons
11 for the recommended classification.

12 “(ii) Submit a request for initial classification
13 of the device under this subparagraph, if the person
14 declares that there is no legally marketed device
15 upon which to base a substantial equivalence deter-
16 mination as that term is defined in subsection (i).
17 Subject to subparagraph (B), the Secretary shall
18 classify the device under the criteria set forth in sub-
19 paragraphs (A) through (C) of subsection (a)(1).
20 The person submitting the request for classification
21 under this subparagraph may recommend to the
22 Secretary a classification for the device and shall, if
23 recommending classification in class II, include in
24 the request an initial draft proposal for applicable
25 special controls, as described in subsection

1 (a)(1)(B), that are necessary, in conjunction with
2 general controls, to provide reasonable assurance of
3 safety and effectiveness and a description of how the
4 special controls provide such assurance. Requests
5 under this clause shall be subject to the electronic
6 copy requirements of section 745A(b).”;

7 (3) by inserting after subparagraph (A) the fol-
8 lowing:

9 “(B) The Secretary may decline to undertake a clas-
10 sification request submitted under clause (2)(A)(ii) if the
11 Secretary identifies a legally marketed device that could
12 provide a reasonable basis for review of substantial equiva-
13 lence under paragraph (1), or when the Secretary deter-
14 mines that the device submitted is not of low-moderate
15 risk or that general controls would be inadequate to con-
16 trol the risks and special controls to mitigate the risks
17 cannot be developed.”; and

18 (4) in subparagraph (C), as so redesignated—

19 (A) in clause (i), by striking “Not later
20 than 60 days after the date of the submission
21 of the request under subparagraph (A),” and
22 inserting “Not later than 120 days after the
23 date of the submission of the request under
24 subparagraph (A)(i) or 150 days after the date

1 of the submission of the request under subpara-
2 graph (A)(ii),”; and

3 (B) in clause (ii), by inserting “or is classi-
4 fied in” after “remains in”.

5 (b) GAO REPORT.—Not later than 2 years after the
6 date of enactment of this Act, the Comptroller General
7 of the United States shall complete a study and submit
8 to Congress a report on the effectiveness of the review
9 pathway under section 513(f)(2)(A) of the Federal Food,
10 Drug, and Cosmetic Act, as amended by this Act.

11 (c) CONFORMING AMENDMENT.—Section
12 513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by in-
13 serting “a request under paragraph (2) or” after “re-
14 sponse to”.

15 **SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.**

16 (a) IN GENERAL.—Section 520(m) (21 U.S.C.
17 360j(m)) is amended—

18 (1) in paragraph (6)—

19 (A) in subparagraph (A)—

20 (i) by striking clause (i) and inserting
21 the following:

22 “(i) The device with respect to which the ex-
23 emption is granted—

24 “(I) is intended for the treatment or diag-
25 nosis of a disease or condition that occurs in

1 pediatric patients or in a pediatric subpopula-
2 tion, and such device is labeled for use in pedi-
3 atric patients or in a pediatric subpopulation in
4 which the disease or condition occurs; or

5 “(II) is intended for the treatment or diag-
6 nosis of a disease or condition that does not
7 occur in pediatric patients or that occurs in pe-
8 diatric patients in such numbers that the devel-
9 opment of the device for such patients is impos-
10 sible, highly impracticable, or unsafe.”; and

11 (ii) by striking clause (ii) and insert-
12 ing the following:

13 “(ii) During any calendar year, the number of
14 such devices distributed during that year under each
15 exemption granted under this subsection does not
16 exceed the annual distribution number for such de-
17 vice. In this paragraph, the term ‘annual distribu-
18 tion number’ means the number of such devices rea-
19 sonably needed to treat, diagnose, or cure a popu-
20 lation of 4,000 individuals in the United States. The
21 Secretary shall determine the annual distribution
22 number when the Secretary grants such exemp-
23 tion.”; and

24 (B) by amending subparagraph (C) to read
25 as follows:

1 “(C) A person may petition the Secretary to modify
2 the annual distribution number determined by the Sec-
3 retary under subparagraph (A)(ii) with respect to a device
4 if additional information arises, and the Secretary may
5 modify such annual distribution number.”;

6 (2) in paragraph (7), by striking “regarding a
7 device” and inserting “regarding a device described
8 in paragraph (6)(A)(i)(I)”; and

9 (3) in paragraph (8), by striking “of all devices
10 described in paragraph (6)” and inserting “of all de-
11 vices described in paragraph (6)(A)(i)(I)”.

12 (b) **APPLICABILITY TO EXISTING DEVICES.**—A spon-
13 sor of a device for which an exemption was approved under
14 paragraph (2) of section 520(m) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the
16 date of enactment of this Act may seek a determination
17 under subclause (I) or (II) of section 520(m)(6)(A)(i) (as
18 amended by subsection (a)). If the Secretary of Health
19 and Human Services determines that such subclause (I)
20 or (II) applies with respect to a device, clauses (ii), (iii),
21 and (iv) of subparagraph (A) and subparagraphs (B), (C),
22 (D), and (E) of paragraph (6) of such section 520(m)
23 shall apply to such device, and the Secretary shall deter-
24 mine the annual distribution number for purposes of

1 clause (ii) of such subparagraph (A) when making the de-
2 termination under this subsection.

3 (c) REPORT.—Not later than January 1, 2017, the
4 Comptroller General of the United States shall submit to
5 Congress a report that evaluates and describes—

6 (1) the effectiveness of the amendments made
7 by subsection (a) in stimulating innovation with re-
8 spect to medical devices, including any favorable or
9 adverse impact on pediatric device development;

10 (2) the impact of such amendments on pediatric
11 device approvals for devices that received a humani-
12 tarian use designation under section 520(m) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 360j(m)) prior to the date of enactment of this Act;

15 (3) the status of public and private insurance
16 coverage of devices granted an exemption under
17 paragraph (2) of such section 520(m) (as amended
18 by subsection (a)) and costs to patients of such de-
19 vices;

20 (4) the impact that paragraph (4) of such sec-
21 tion 520(m) has had on access to and insurance cov-
22 erage of devices granted an exemption under para-
23 graph (2) of such section 520(m); and

1 (5) the effect of the amendments made by sub-
2 section (a) on patients described in such section
3 520(m).

4 **SEC. 614. REAUTHORIZATION OF THIRD-PARTY REVIEW**
5 **AND INSPECTIONS.**

6 (a) **THIRD PARTY REVIEW.**—Section 523(c) (21
7 U.S.C. 360m(c)) is amended by striking “2012” and in-
8 serting “2017”.

9 (b) **THIRD PARTY INSPECTIONS.**—Section
10 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking
11 “2012” and inserting “2017”.

12 **SEC. 615. 510(K) DEVICE MODIFICATIONS.**

13 Having acknowledged to Congress potential unin-
14 tended consequences that may result from the implemen-
15 tation of the Food and Drug Administration guidance en-
16 titled “Guidance for Industry and FDA Staff—510(k) De-
17 vice Modifications: Deciding When to Submit a 510(k) for
18 a Change to an Existing Device”, the Secretary of Health
19 and Human Services shall withdraw such guidance
20 promptly and ensure that, before any future guidance doc-
21 ument on this issue is made final, affected stakeholders
22 are provided with an opportunity to comment.

23 **SEC. 616. HEALTH INFORMATION TECHNOLOGY.**

24 (a) **LIMITATION.**—Notwithstanding any other provi-
25 sion of law, the Secretary of Health and Human Services

1 (referred to in this section as the “Secretary”) may issue
2 final guidance on medical mobile applications only after
3 the requirements under subsections (b) and (c) are met.

4 (b) REPORT.—Not later than 18 months after the
5 date of enactment of this Act, the Secretary, in consulta-
6 tion with the Commissioner of Food and Drugs, the Na-
7 tional Coordinator for Health Information Technology,
8 and the Chairman of the Federal Communications Com-
9 mission, shall submit to the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate and the Com-
11 mittee on Energy and Commerce of the House of Rep-
12 resentatives a report that contains a proposed strategy
13 and recommendations on an appropriate, risk-based regu-
14 latory framework pertaining to medical device regulation
15 and health information technology software, including mo-
16 bile applications, that promotes innovation and protects
17 patient safety.

18 (c) WORKING GROUP.—

19 (1) IN GENERAL.—In carrying out subsection
20 (b), the Secretary shall convene a working group of
21 external stakeholders and experts to provide appro-
22 priate input on the strategy and recommendations
23 required for the report under subsection (b).

24 (2) REPRESENTATIVES.—The Secretary shall
25 determine the number of representatives partici-

1 pating in the working group, and shall ensure that
 2 the working group is geographically diverse and in-
 3 cludes representatives of patients, consumers, health
 4 care providers, startup companies, health plans or
 5 other third-party payers, venture capital investors,
 6 information technology vendors, small businesses,
 7 purchasers, employers, and other stakeholders with
 8 relevant expertise, as determined by the Secretary.

9 (3) OTHER REQUIREMENTS.—

10 (A) FACA.—The Federal Advisory Com-
 11 mittee Act (5 U.S.C. App.) shall apply to the
 12 working group under this section.

13 (B) FFDCA ADVISORY COMMITTEES.—
 14 The requirements for advisory committees
 15 under section 712 of the Federal Food, Drug,
 16 and Cosmetic Act (21 U.S.C. 379d–1), as
 17 amended by section 1121, shall not apply to the
 18 working group under this section.

19 **TITLE VII—DRUG SUPPLY CHAIN**

20 **SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISH-**
 21 **MENTS.**

22 Section 510 (21 U.S.C. 360) is amended—

23 (1) in subsection (b)—

24 (A) in paragraph (1), by striking “On or
 25 before” and all that follows through the period

1 at the end and inserting the following: “During
2 the period beginning on October 1 and ending
3 on December 31 of each year, every person who
4 owns or operates any establishment in any
5 State engaged in the manufacture, preparation,
6 propagation, compounding, or processing of a
7 drug or drugs shall register with the Sec-
8 retary—

9 “(A) the name of such person, places of busi-
10 ness of such person, all such establishments, the
11 unique facility identifier of each such establishment,
12 and a point of contact e-mail address; and

13 “(B) the name and place of business of each
14 importer that takes physical possession of and sup-
15 plies a drug (other than an excipient) to such per-
16 son, including all establishments of each such drug
17 importer, the unique facility identifier of each such
18 drug importer establishment, and a point of contact
19 e-mail address for each such drug importer.”; and

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

21 “(3) The Secretary may specify the unique facility
22 identifier system that shall be used by registrants under
23 paragraph (1).”; and

1 (2) in subsection (c), by striking “with the Sec-
2 retary his name, place of business, and such estab-
3 lishment” and inserting “with the Secretary—

4 “(1) with respect to drugs, the information de-
5 scribed under subsection (b)(1); and

6 “(2) with respect to devices, the information de-
7 scribed under subsection (b)(2).”.

8 **SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

9 (a) ENFORCEMENT OF REGISTRATION OF FOREIGN
10 ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is
11 amended by striking “in any State”.

12 (b) REGISTRATION OF FOREIGN DRUG ESTABLISH-
13 MENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

14 (1) in paragraph (1)—

15 (A) by amending the matter preceding sub-
16 paragraph (A) to read as follows: “Every per-
17 son who owns or operates any establishment
18 within any foreign country engaged in the man-
19 ufacture, preparation, propagation,
20 compounding, or processing of a drug or device
21 that is imported or offered for import into the
22 United States shall, through electronic means
23 in accordance with the criteria of the Sec-
24 retary—”;

1 (B) by amending subparagraph (A) to read
2 as follows:

3 “(A) upon first engaging in any such activity,
4 immediately submit a registration to the Secretary
5 that includes—

6 “(i) with respect to drugs, the name and
7 place of business of such person, all such estab-
8 lishments, the unique facility identifier of each
9 such establishment, a point of contact e-mail
10 address, the name of the United States agent of
11 each such establishment, the name and place of
12 business of each drug importer with which such
13 person conducts business to import or offer to
14 import drugs into the United States, including
15 all establishments of each such drug importer,
16 the unique facility identifier of each such estab-
17 lishment, and a point of contact e-mail address
18 for each such drug importer; and

19 “(ii) with respect to devices, the name and
20 place of business of the establishment, the name
21 of the United States agent for the establish-
22 ment, the name of each importer of such device
23 in the United States that is known to the estab-
24 lishment, and the name of each person who im-
25 ports or offers for import such device to the

1 United States for purposes of importation;
2 and”; and

3 (C) by amending subparagraph (B) to read
4 as follows:

5 “(B) each establishment subject to the require-
6 ments of subparagraph (A) shall thereafter register
7 with the Secretary during the period beginning on
8 October 1 and ending on December 31 of each
9 year.”; and

10 (2) by adding at the end the following:

11 “(4) The Secretary may specify the unique facility
12 identifier system that shall be used by registrants under
13 paragraph (1) with respect to drugs.”.

14 **SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMA-**
15 **TION WITH PRODUCT LISTING.**

16 Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amend-
17 ed—

18 (1) in subparagraph (C), by striking “; and”
19 and inserting a semicolon;

20 (2) in subparagraph (D), by striking the period
21 at the end and inserting “; and”; and

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

23 “(E) in the case of a drug contained in the ap-
24 plicable list, the name and place of business of each
25 manufacturer of an excipient of the listed drug with

1 which the person listing the drug conducts business,
2 including all establishments used in the production
3 of such excipient, the unique facility identifier of
4 each such establishment, and a point of contact e-
5 mail address for each such excipient manufacturer.”.

6 **SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND**
7 **LISTING.**

8 Section 510(p) (21 U.S.C. 360(p)) is amended—

9 (1) by striking “(p) Registrations and listings”
10 and inserting the following:

11 “(p) **ELECTRONIC REGISTRATION AND LISTING.**—

12 “(1) **IN GENERAL.**—Registration and listing”;

13 and

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

15 “(2) **ELECTRONIC DATABASE.**—Not later than
16 2 years after the Secretary specifies a unique facility
17 identifier system under subsections (b) and (i), the
18 Secretary shall maintain an electronic database,
19 which shall not be subject to inspection under sub-
20 section (f), populated with the information submitted
21 as described under paragraph (1) that—

22 “(A) enables personnel of the Food and
23 Drug Administration to search the database by
24 any field of information submitted in a registra-

1 tion described under paragraph (1), or com-
2 bination of such fields; and

3 “(B) uses the unique facility identifier sys-
4 tem to link with other relevant databases within
5 the Food and Drug Administration, including
6 the database for submission of information
7 under section 801(r).

8 “(3) RISK-BASED INFORMATION AND COORDI-
9 NATION.—The Secretary shall ensure the accuracy
10 and coordination of relevant Food and Drug Admin-
11 istration databases in order to identify and inform
12 risk-based inspections under section 510(h).”.

13 **SEC. 705. RISK-BASED INSPECTION FREQUENCY.**

14 Section 510(h) (21 U.S.C. 360(h)) is amended to
15 read as follows:

16 “(h) INSPECTIONS.—

17 “(1) IN GENERAL.—Every establishment that is
18 required to be registered with the Secretary under
19 this section shall be subject to inspection pursuant
20 to section 704.

21 “(2) BIENNIAL INSPECTIONS FOR DEVICES.—
22 Every establishment described in paragraph (1) that
23 is engaged in the manufacture, propagation,
24 compounding, or processing of a device or devices
25 classified in class II or III shall be so inspected by

1 one or more officers or employees duly designated by
2 the Secretary, or by persons accredited to conduct
3 inspections under section 704(g), at least once in the
4 2-year period beginning with the date of registration
5 of such establishment pursuant to this section and
6 at least once in every successive 2-year period there-
7 after.

8 “(3) RISK-BASED SCHEDULE FOR DRUGS.—The
9 Secretary, acting through one or more officers or
10 employees duly designated by the Secretary, shall in-
11 spect establishments described in paragraph (1) that
12 are engaged in the manufacture, preparation, propa-
13 gation, compounding, or processing of a drug or
14 drugs (referred to in this subsection as ‘drug estab-
15 lishments’) in accordance with a risk-based schedule
16 established by the Secretary.

17 “(4) RISK FACTORS.—In establishing the risk-
18 based scheduled under paragraph (3), the Secretary
19 shall inspect establishments according to the known
20 safety risks of such establishments, which shall be
21 based on the following factors:

22 “(A) The compliance history of the estab-
23 lishment.

24 “(B) The record, history, and nature of re-
25 calls linked to the establishment.

1 “(C) The inherent risk of the drug manu-
2 factured, prepared, propagated, compounded, or
3 processed at the establishment.

4 “(D) The certifications described under
5 sections 801(r) and 809 for the establishment.

6 “(E) Whether the establishment has been
7 inspected in the preceding 4-year period.

8 “(F) Any other criteria deemed necessary
9 and appropriate by the Secretary for purposes
10 of allocating inspection resources.

11 “(5) EFFECT OF STATUS.—In determining the
12 risk associated with an establishment for purposes of
13 establishing a risk-based schedule under paragraph
14 (3), the Secretary shall not consider whether the
15 drugs manufactured, prepared, propagated, com-
16 pounded, or processed by such establishment are
17 drugs described in section 503(b).

18 “(6) ANNUAL REPORT ON INSPECTIONS OF ES-
19 TABLISHMENTS.—Not later than February 1 of each
20 year, the Secretary shall submit a report to Con-
21 gress regarding—

22 “(A)(i) the number of domestic and foreign
23 establishments registered pursuant to this sec-
24 tion in the previous fiscal year; and

1 “(ii) the number of such domestic estab-
2 lishments and the number of such foreign es-
3 tablishments that the Secretary inspected in the
4 previous fiscal year;

5 “(B) with respect to establishments that
6 manufacture, prepare, propagate, compound, or
7 process an active ingredient of a drug, a fin-
8 ished drug product, or an excipient of a drug,
9 the number of each such type of establishment;
10 and

11 “(C) the percentage of the budget of the
12 Food and Drug Administration used to fund
13 the inspections described under subparagraph
14 (A).

15 “(7) PUBLIC AVAILABILITY OF ANNUAL RE-
16 PORTS.—The Secretary shall make the report re-
17 quired under paragraph (6) available to the public
18 on the Internet Web site of the Food and Drug Ad-
19 ministration.”.

20 **SEC. 706. RECORDS FOR INSPECTION.**

21 Section 704(a) (21 U.S.C. 374(a)) is amended by
22 adding at the end the following:

23 “(4)(A) Any records or other information that the
24 Secretary is entitled to inspect under this section from a
25 person that owns or operates an establishment that is en-

1 gaged in the manufacture, preparation, propagation,
2 compounding, or processing of a drug shall, upon the re-
3 quest of the Secretary, be provided to the Secretary by
4 such person within a reasonable time frame, within rea-
5 sonable limits and in a reasonable manner, and in elec-
6 tronic form, at the expense of such person. The Sec-
7 retary's request shall include a clear description of the
8 records requested.

9 “(B) Upon receipt of the records requested under
10 subparagraph (A), the Secretary shall provide to the per-
11 son confirmation of the receipt of such records.

12 “(C) Nothing in this paragraph supplants the author-
13 ity of the Secretary to conduct inspections otherwise per-
14 mitted under this Act in order to ensure compliance by
15 an establishment with this Act.”.

16 **SEC. 707. FAILURE TO ALLOW FOREIGN INSPECTION.**

17 Section 801(a) (21 U.S.C. 381(a)) is amended by
18 adding at the end the following: “Notwithstanding any
19 other provision of this subsection, the Secretary of Home-
20 land Security shall, upon request from the Secretary of
21 Health and Human Services refuse to admit into the
22 United States any article if the article was manufactured,
23 prepared, propagated, compounded, processed, or held at
24 an establishment that has refused to permit the Secretary
25 of Health and Human Services to enter or inspect the es-

1 tablishment in the same manner and to the same extent
2 as the Secretary may inspect establishments under section
3 704.”.

4 **SEC. 708. EXCHANGE OF INFORMATION.**

5 Section 708 (21 U.S.C. 379) is amended—

6 (1) by striking “CONFIDENTIAL INFORMATION”
7 and all that follows through “The Secretary” and in-
8 serting “**CONFIDENTIAL INFORMATION.**

9 “(a) CONTRACTORS.—The Secretary”; and

10 (2) by adding at the end the following:

11 “(b) ABILITY TO RECEIVE AND PROTECT CONFIDEN-
12 TIAL INFORMATION.—The Secretary shall not be required
13 to disclose under section 552 of title 5, United States
14 Code, or any other provision of law, any information relat-
15 ing to drugs obtained from a Federal, State or local gov-
16 ernment agency, or from a foreign government agency, if
17 the agency has requested that the information be kept con-
18 fidential, except pursuant to an order of a court of the
19 United States. For purposes of section 552 of title 5,
20 United States Code, this subsection shall be considered a
21 statute described in section 552(b)(3)(B).

22 “(c) AUTHORITY TO ENTER INTO MEMORANDA OF
23 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-
24 CHANGE.—The Secretary may enter into written agree-

1 ments regarding the exchange of information referenced
2 in section 301(j) subject to the following criteria:

3 “(1) CERTIFICATION.—The Secretary may only
4 enter into written agreements under this subsection
5 with foreign governments that the Secretary has cer-
6 tified as having the authority and demonstrated abil-
7 ity to protect trade secret information from disclo-
8 sure. Responsibility for this certification shall not be
9 delegated to any officer or employee other than the
10 Commissioner.

11 “(2) WRITTEN AGREEMENT.—The written
12 agreement under this subsection shall include a com-
13 mitment by the foreign government to protect infor-
14 mation exchanged under this subsection from disclo-
15 sure unless and until the sponsor gives written per-
16 mission for disclosure or the Secretary makes a dec-
17 laration of a public health emergency pursuant to
18 section 319 of the Public Health Service Act that is
19 relevant to the information.

20 “(3) INFORMATION EXCHANGE.—The Secretary
21 may provide to a foreign government that has been
22 certified under paragraph (1) and that has executed
23 a written agreement under paragraph (2) informa-
24 tion referenced in section 301(j) in the following cir-
25 cumstances:

1 “(A) Information concerning the inspection
2 of a facility may be provided if—

3 “(i) the Secretary reasonably believes,
4 or that the written agreement described in
5 paragraph (2) establishes, that the govern-
6 ment has authority to otherwise obtain
7 such information; and

8 “(ii) the written agreement executed
9 under paragraph (2) limits the recipient’s
10 use of the information to the recipient’s
11 civil regulatory purposes.

12 “(B) Information not described in sub-
13 paragraph (A) may be provided as part of an
14 investigation, or to alert the foreign government
15 to the potential need for an investigation, if the
16 Secretary has reasonable grounds to believe
17 that a drug has a reasonable probability of
18 causing serious adverse health consequences or
19 death to humans or animals.

20 “(4) EFFECT OF SUBSECTION.—Nothing in this
21 subsection affects the ability of the Secretary to
22 enter into any written agreement authorized by
23 other provisions of law to share confidential informa-
24 tion.”.

1 **SEC. 709. 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 subsection (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. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR**
 12 **DRUG ESTABLISHMENTS.**

13 (a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et
 14 seq.) is amended by adding at the end the following:

15 **“SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS**
 16 **FOR DRUG ESTABLISHMENTS.**

17 “(a) DEFINITIONS.—In this section:

18 “(1) ACCREDITATION BODY.—The term ‘ac-
 19 creditation body’ means an authority that performs
 20 accreditation of third-party auditors.

21 “(2) ACCREDITED THIRD-PARTY AUDITOR.—
 22 The term ‘accredited third-party auditor’ means a
 23 third-party auditor (which may be an individual) ac-
 24 credited by an accreditation body to conduct drug
 25 safety and quality audits.

1 “(3) AUDIT AGENT.—The term ‘audit agent’
2 means an individual who is an employee or agent of
3 an accredited third-party auditor and, although not
4 individually accredited, is qualified to conduct drug
5 safety and quality audits on behalf of an accredited
6 third-party auditor.

7 “(4) CONSULTATIVE AUDIT.—The term ‘con-
8 sultative audit’ means an audit of an eligible entity
9 intended for internal purposes only to determine
10 whether an establishment is in compliance with the
11 provisions of this Act and applicable industry prac-
12 tices, or any other such service.

13 “(5) DRUG SAFETY AND QUALITY AUDIT.—The
14 term ‘drug safety and quality audit’—

15 “(A) means an audit of an eligible entity
16 to certify that the eligible entity meets the re-
17 quirements of this Act applicable to drugs, in-
18 cluding the requirements of section 501 with re-
19 spect to drugs; and

20 “(B) is not a consultative audit.

21 “(6) ELIGIBLE ENTITY.—The term ‘eligible en-
22 tity’ means an entity, including a foreign drug estab-
23 lishment registered under section 510(c), in the drug
24 supply chain that chooses to be audited by an ac-

1 credited third-party auditor or the audit agent of
2 such accredited third-party auditor.

3 “(7) THIRD-PARTY AUDITOR.—The term ‘third-
4 party auditor’ means a foreign government, agency
5 of a foreign government or any other third party
6 (which may be an individual), as the Secretary de-
7 termines appropriate in accordance with the criteria
8 described in subsection (c)(1), that is eligible to be
9 considered for accreditation to conduct drug safety
10 and quality audits.

11 “(b) ACCREDITATION SYSTEM.—

12 “(1) RECOGNITION OF ACCREDITATION BOD-
13 IES.—

14 “(A) IN GENERAL.—Not later than 2 years
15 after date of enactment of the Food and Drug
16 Administration Safety and Innovation Act, the
17 Secretary shall establish a system for the rec-
18 ognition of accreditation bodies that accredit
19 third-party auditors to conduct drug safety and
20 quality audits.

21 “(B) DIRECT ACCREDITATION.—

22 “(i) IN GENERAL.—If, by the date
23 that is 2 years after the date of establish-
24 ment of the system described in subpara-
25 graph (A), the Secretary has not identified

1 and recognized an accreditation body to
2 meet the requirements of this section, the
3 Secretary may directly accredit third-party
4 auditors.

5 “(ii) CERTAIN DIRECT ACCREDITA-
6 TIONS.—Notwithstanding subparagraph
7 (A) or clause (i), the Secretary may di-
8 rectly accredit any foreign government or
9 any agency of a foreign government as a
10 third-party auditor at any time after the
11 date of enactment of the Food and Drug
12 Administration Safety and Innovation Act.

13 “(2) NOTIFICATION.—Each accreditation body
14 recognized by the Secretary shall submit to the Sec-
15 retary—

16 “(A) a list of all accredited third-party
17 auditors accredited by such body (including the
18 name, contact information, and scope and dura-
19 tion of accreditation for each such auditor), and
20 the audit agents of such auditors; and

21 “(B) updated lists as needed to ensure the
22 list held by the Secretary is accurate.

23 “(3) REVOCATION OF RECOGNITION AS AN AC-
24 CREDITATION BODY.—The Secretary shall promptly
25 revoke, after the opportunity for an informal hear-

1 ing, the recognition of any accreditation body found
2 not to be in compliance with the requirements of this
3 section.

4 “(4) REINSTATEMENT.—The Secretary shall es-
5 tablish procedures to reinstate recognition of an ac-
6 creditation body if the Secretary determines, based
7 on evidence presented by such accreditation body,
8 that revocation was inappropriate or that the body
9 meets the requirements for recognition under this
10 section.

11 “(5) MODEL ACCREDITATION STANDARDS.—

12 “(A) IN GENERAL.—Not later than 18
13 months after the date of enactment of the Food
14 and Drug Administration Safety and Innova-
15 tion Act, the Secretary shall develop model
16 standards, including standards for drug safety
17 and quality audit results, reports, and certifi-
18 cations, and each recognized accreditation body
19 shall ensure that third-party auditors and audit
20 agents of such auditors meet such standards in
21 order to qualify such third-party auditors as ac-
22 credited third-party auditors under this section.

23 “(B) CONTENT.—The standards developed
24 under subparagraph (A) may—

1 “(i) include a description of required
2 standards relating to the training proce-
3 dures, competency, management respon-
4 sibilities, quality control, and conflict of in-
5 terest requirements of accredited third-
6 party auditors; and

7 “(ii) set forth procedures for the peri-
8 odic renewal of the accreditation of accred-
9 ited third-party auditors.

10 “(C) REQUIREMENT TO PROVIDE RESULTS
11 AND REPORTS TO THE SECRETARY.—An ac-
12 creditation body (or, in the case of direct ac-
13 creditation under subsection (b)(1)(B), the Sec-
14 retary) may not accredit a third-party auditor
15 unless such third-party auditor agrees to pro-
16 vide to the Secretary, upon request, the results
17 and reports of any drug safety and quality
18 audit conducted pursuant to the accreditation
19 provided under this section.

20 “(6) DISCLOSURE.—The Secretary shall main-
21 tain on the Internet Web site of the Food and Drug
22 Administration a list of recognized accreditation
23 bodies and accredited third-party auditors under this
24 section.

25 “(c) ACCREDITED THIRD-PARTY AUDITORS.—

1 “(1) REQUIREMENTS FOR ACCREDITATION AS A
2 THIRD-PARTY AUDITOR.—

3 “(A) FOREIGN GOVERNMENTS.—Prior to
4 accrediting a foreign government or an agency
5 of a foreign government as an accredited third-
6 party auditor, the accreditation body (or, in the
7 case of direct accreditation under subsection
8 (b)(1)(B), the Secretary) shall perform such re-
9 views and audits of drug safety programs, sys-
10 tems, and standards of the government or agen-
11 cy of the government as the Secretary deems
12 necessary, including requirements under the
13 standards developed under subsection (b)(5), to
14 determine that the foreign government or agen-
15 cy of the foreign government is capable of ade-
16 quately ensuring that eligible entities or drugs
17 certified by such government or agency meet
18 the requirements of this Act.

19 “(B) OTHER THIRD PARTIES.—Prior to
20 accrediting any other third party to be an ac-
21 credited third-party auditor, the accreditation
22 body (or, in the case of direct accreditation
23 under subsection (b)(1)(B), the Secretary) shall
24 perform such reviews and audits of the training
25 and qualifications of audit agents used by that

1 party and conduct such reviews of internal sys-
2 tems and such other investigation of the party
3 as the Secretary deems necessary, including re-
4 quirements under the standards developed
5 under subsection (b)(5), to determine that the
6 third-party auditor is capable of adequately en-
7 suring that an eligible entity or drug certified
8 by such third-party auditor meets the require-
9 ments of this Act.

10 “(2) USE OF AUDIT AGENTS.—An accredited
11 third-party auditor may conduct drug safety and
12 quality audits and may employ or use audit agents
13 to conduct drug safety and quality audits, but must
14 ensure that such audit agents comply with all re-
15 quirements the Secretary deems necessary, including
16 requirements under paragraph (1) and subsection
17 (b)(5).

18 “(3) REVOCATION OF ACCREDITATION.—

19 “(A) IN GENERAL.—The Secretary shall
20 promptly revoke, after the opportunity for an
21 informal hearing, the accreditation of an ac-
22 credited third-party auditor—

23 “(i) if, following an evaluation, the
24 Secretary finds that the accredited third-

1 party auditor is not in compliance with the
2 requirements of this section; or

3 “(ii) following a refusal to allow
4 United States officials to conduct such au-
5 dits and investigations as may be necessary
6 to determine compliance with the require-
7 ments set forth in this section.

8 “(B) ADDITIONAL BASIS FOR REVOCATION
9 OF ACCREDITATION.—The Secretary may re-
10 voke accreditation from an accredited third-
11 party auditor in the case that such third-party
12 auditor is accredited by an accreditation body
13 for which recognition as an accreditation body
14 under subsection (b)(3) is revoked, if the Sec-
15 retary determines that there is good cause for
16 the revocation of accreditation.

17 “(4) REACCREDITATION.—The Secretary shall
18 establish procedures to reinstate the accreditation of
19 a third-party auditor for which accreditation has
20 been revoked under paragraph (3)—

21 “(A) if the Secretary determines, based on
22 evidence presented, that—

23 “(i) the third-party auditor satisfies
24 the requirements of this section; and

1 “(ii) adequate grounds for revocation
2 no longer exist; and

3 “(B) in the case of a third-party auditor
4 accredited by an accreditation body for which
5 recognition as an accreditation body is revoked
6 under subsection (b)(3)—

7 “(i) if the third-party auditor becomes
8 accredited not later than 1 year after rev-
9 ocation of accreditation under paragraph
10 (3), through direct accreditation under
11 subsection (b)(1)(B), or by an accredita-
12 tion body in good standing; or

13 “(ii) under such other conditions as
14 the Secretary may require.

15 “(5) REQUIREMENT TO ISSUE CERTIFICATION
16 OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CUR-
17 RENT GOOD MANUFACTURING PRACTICE.—

18 “(A) IN GENERAL.—An accreditation body
19 (or, in the case of direct accreditation under
20 subsection (b)(1)(B), the Secretary) may not
21 accredit a third-party auditor unless such third-
22 party auditor agrees to issue a written and, as
23 appropriate, electronic, document or certifi-
24 cation, as the Secretary may require under this
25 Act, regarding compliance with section 501.

1 The Secretary may consider any such document
2 or certification to satisfy requirements under
3 section 801(r) and to target inspection re-
4 sources under section 510(h).

5 “(B) REQUIREMENTS FOR ISSUING CER-
6 TIFICATION.—

7 “(i) IN GENERAL.—An accredited
8 third-party auditor shall issue a drug cer-
9 tification described in subparagraph (A)
10 only after conducting a drug safety and
11 quality audit and such other activities that
12 may be necessary to establish compliance
13 with the provisions of section 501.

14 “(ii) PROVISION OF CERTIFICATION.—
15 Only an accredited third-party auditor or
16 the Secretary may provide a drug certifi-
17 cation described in subparagraph (A).

18 “(C) RECORDS.—Following any accredita-
19 tion of a third-party auditor, the Secretary
20 may, at any time, require the accredited third-
21 party auditor or any audit agent of such audi-
22 tor to submit to the Secretary a drug safety
23 and quality audit report and such other reports
24 or documents required as part of the drug safe-
25 ty and quality audit process, for any eligible en-

1 tity for which the accredited third-party auditor
2 or audit agent of such auditor performed a
3 drug safety and quality audit. The Secretary
4 may require documentation that the eligible en-
5 tity is in compliance with any applicable reg-
6 istration requirements.

7 “(D) LIMITATION.—The requirement
8 under subparagraph (C) shall not include any
9 report or other documents resulting from a con-
10 sultative audit, except that the Secretary may
11 access the results of a consultative audit in ac-
12 cordance with section 704.

13 “(E) DECLARATION OF AUDIT TYPE.—Be-
14 fore an accredited third-party auditor begins
15 any audit or provides any consultative service to
16 an eligible entity, both the accredited third-
17 party auditor and eligible entity shall establish
18 in writing whether the audit is intended to be
19 a drug safety and quality audit. Any audit, in-
20 spection, or consultative service of any type pro-
21 vided by an accredited third-party auditor on
22 behalf of an eligible entity shall be presumed to
23 be a drug safety and quality audit in the ab-
24 sence of such a written agreement. Once a drug
25 safety and quality audit is initiated, it shall be

1 subject to the requirements of this section, and
2 no person may withhold from the Secretary any
3 document subject to subparagraph (C) on the
4 grounds that the audit was a consultative audit
5 or otherwise not a drug safety and quality
6 audit.

7 “(F) RULE OF CONSTRUCTION.—Nothing
8 in this section shall be construed to limit the
9 authority of the Secretary under section 704.

10 “(6) REQUIREMENTS REGARDING SERIOUS
11 RISKS TO THE PUBLIC HEALTH.—If, at any time
12 during a drug safety and quality audit, an accredited
13 third-party auditor or an audit agent of such auditor
14 discovers a condition that could cause or contribute
15 to a serious risk to the public health, such auditor
16 shall immediately notify the Secretary of—

17 “(A) the identity and location of the eligi-
18 ble entity subject to the drug safety and quality
19 audit; and

20 “(B) such condition.

21 “(7) LIMITATIONS.—

22 “(A) IN GENERAL.—An audit agent of an
23 accredited third-party auditor may not perform
24 a drug safety and quality audit of an eligible
25 entity if such audit agent has performed a drug

1 safety and quality audit or consultative audit of
2 such eligible entity during the previous 13-
3 month period.

4 “(B) WAIVER.—The Secretary may waive
5 the application of subparagraph (A) if the Sec-
6 retary determines that there is insufficient ac-
7 cess to accredited third-party auditors in a
8 country or region or that the use of the same
9 audit agent or accredited third-party auditor is
10 otherwise necessary.

11 “(8) CONFLICTS OF INTEREST.—

12 “(A) ACCREDITATION BODIES.—A recog-
13 nized accreditation body shall—

14 “(i) not be owned, managed, or con-
15 trolled by any person that owns or operates
16 a third-party auditor to be accredited by
17 such body;

18 “(ii) in carrying out accreditation of
19 third-party auditors under this section,
20 have procedures to ensure against the use
21 of any officer or employee of such body
22 that has a financial conflict of interest re-
23 garding a third-party auditor to be accred-
24 ited by such body; and

1 “(iii) annually make available to the
2 Secretary disclosures of the extent to
3 which such body and the officers and em-
4 ployees of such body have maintained com-
5 pliance with clauses (i) and (ii) relating to
6 financial conflicts of interest.

7 “(B) ACCREDITED THIRD-PARTY AUDI-
8 TORS.—An accredited third-party auditor
9 shall—

10 “(i) not be owned, managed, or con-
11 trolled by any person that owns or operates
12 an eligible entity to be certified by such
13 auditor;

14 “(ii) in carrying out drug safety and
15 quality audits of eligible entities under this
16 section, have procedures to ensure against
17 the use of any officer or employee of such
18 auditor that has a financial conflict of in-
19 terest regarding an eligible entity to be
20 certified by such auditor; and

21 “(iii) annually make available to the
22 Secretary disclosures of the extent to
23 which such auditor and the officers and
24 employees of such auditor have maintained

1 compliance with clauses (i) and (ii) relat-
2 ing to financial conflicts of interest.

3 “(C) AUDIT AGENTS.—An audit agent
4 shall—

5 “(i) not own or operate an eligible en-
6 tity to be audited by such agent;

7 “(ii) in carrying out audits of eligible
8 entities under this section, have procedures
9 to ensure that such agent does not have a
10 financial conflict of interest regarding an
11 eligible entity to be audited by such agent;
12 and

13 “(iii) annually make available to the
14 Secretary disclosures of the extent to
15 which such agent has maintained compli-
16 ance with clauses (i) and (ii) relating to fi-
17 nancial conflicts of interest.

18 “(d) FALSE STATEMENTS.—Any statement or rep-
19 resentation made—

20 “(1) by an employee or agent of an eligible enti-
21 ty to an accredited third-party auditor or audit
22 agent; or

23 “(2) by an accreditation body, accredited third-
24 party auditor, or audit agent of such auditor to the

1 Secretary, shall be subject to section 1001 of title
2 18, United States Code.

3 “(e) MONITORING.—To ensure compliance with the
4 requirements of this section, the Secretary—

5 “(1) shall periodically, or at least once every 4
6 years, reevaluate the accreditation bodies described
7 in subsection (b)(1);

8 “(2) shall periodically, or at least once every 4
9 years, evaluate the performance of each accredited
10 third-party auditor, through the review of regulatory
11 audit reports by such auditors, the compliance his-
12 tory as available of eligible entities certified by such
13 auditors, and any other measures deemed necessary
14 by the Secretary;

15 “(3) may at any time, conduct an onsite audit
16 of any eligible entity certified by an accredited third-
17 party auditor, with or without the auditor present;
18 and

19 “(4) shall take any other measures deemed nec-
20 essary by the Secretary.

21 “(f) EFFECT OF AUDIT.—The results of a drug safe-
22 ty and quality audit by an accredited third-party auditor
23 under this section—

24 “(1) may be used by the eligible entity—

1 “(A) as documentation of compliance with
2 section 501(a)(2)(B) or section 801(r); and

3 “(B) for other purposes as determined ap-
4 propriate by the Secretary; and

5 “(2) shall be used by the Secretary in estab-
6 lishing the risk-based inspection schedules under sec-
7 tion 510(h).

8 “(g) COSTS.—

9 “(1) AUTHORIZED FEES OF SECRETARY.—The
10 Secretary may assess fees on accreditation bodies
11 and accredited third-party auditors in such an
12 amount necessary to establish and administer the
13 recognition and accreditation program under this
14 section. The Secretary may require accredited third-
15 party auditors and audit agents to reimburse the
16 Food and Drug Administration for the work per-
17 formed to carry out this section. The Secretary shall
18 not generate surplus revenue from such a reimburse-
19 ment mechanism. Fees authorized under this para-
20 graph shall be collected and available for obligation
21 only to the extent and in the amount provided in ad-
22 vance in appropriation Acts. Such fees are author-
23 ized to remain available until expended.

24 “(2) AUTHORIZED FEES FOR RECOGNIZED AC-
25 CREDITATION BODIES.—An accreditation body rec-

1 ognized by the Secretary under subsection (b) may
2 assess a reasonable fee to accredit third-party audi-
3 tors.

4 “(h) LIMITATIONS.—

5 “(1) NO EFFECT ON SECTION 704 INSPEC-
6 TIONS.—The drug safety and quality audits per-
7 formed under this section shall not be considered in-
8 spections under section 704.

9 “(2) NO EFFECT ON INSPECTION AUTHOR-
10 ITY.—Nothing in this section affects the authority of
11 the Secretary to inspect any eligible entity pursuant
12 to this Act.

13 “(i) REGULATIONS.—

14 “(1) IN GENERAL.—Not later than 18 months
15 after the date of enactment of the Food and Drug
16 Administration Safety and Innovation Act, the Sec-
17 retary shall adopt final regulations implementing
18 this section.

19 “(2) PROCEDURE.—In promulgating the regula-
20 tions implementing this section, the Secretary
21 shall—

22 “(A) issue a notice of proposed rulemaking
23 that includes the proposed regulation;

1 “(B) provide a period of not less than 60
2 days for comments on the proposed regulation;
3 and

4 “(C) publish the final regulation not less
5 than 30 days before the effective date of the
6 regulation.

7 “(3) CONTENT.—Such regulations shall in-
8 clude—

9 “(A) requirements that, to the extent prac-
10 ticable, drug safety and quality audits per-
11 formed under this section be unannounced;

12 “(B) a structure to decrease the potential
13 for conflicts of interest, including timing and
14 public disclosure, for fees paid by eligible enti-
15 ties to accredited third-party auditors; and

16 “(C) appropriate limits on financial affili-
17 ations between an accredited third-party audi-
18 tor or audit agents of such auditor and any per-
19 son that owns or operates an eligible entity to
20 be audited by such auditor, as described in sub-
21 paragraphs (A) and (B).

22 “(4) RESTRICTIONS.—Notwithstanding any
23 other provision of law, the Secretary shall promul-
24 gate regulations implementing this section only as
25 described in paragraph (2).”.

1 (b) REPORT ON ACCREDITED THIRD-PARTY AUDI-
2 TORS.—Not later than January 20, 2017, the Comptroller
3 General of the United States shall submit to Congress a
4 report that addresses the following, with respect to the pe-
5 riod beginning on the date of implementation of section
6 809 of the Federal Food, Drug, and Cosmetic Act (as
7 added by subsection (a)) and ending on the date of such
8 report:

9 (1) The extent to which drug safety and quality
10 audits completed by accredited third-party auditors
11 under such section 809 are being used by the Sec-
12 retary of Health and Human Services (referred to in
13 this subsection as the “Secretary”) in establishing or
14 applying the risk-based inspection schedules under
15 section 510(h) of such Act (as amended by section
16 705).

17 (2) The extent to which drug safety and quality
18 audits completed by accredited third-party auditors
19 or agents are assisting the Food and Drug Adminis-
20 tration in evaluating compliance with sections
21 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B))
22 and 801(r) of such Act (as added by section 711).

23 (3) Whether the Secretary has been able to ac-
24 cess drug safety and quality audit reports completed

1 by accredited third-party auditors under such section
2 809.

3 (4) Whether accredited third-party auditors ac-
4 credited under such section 809 have adhered to the
5 conflict of interest provisions set forth in such sec-
6 tion.

7 (5) The extent to which the Secretary has au-
8 dited recognized accreditation bodies or accredited
9 third-party auditors to ensure compliance with the
10 requirements of such section 809.

11 (6) The number of waivers under subsection
12 (c)(7)(B) of such section 809 issued during the most
13 recent 12-month period and the official justification
14 by the Secretary for each determination that there
15 was insufficient access to an accredited third-party
16 auditor.

17 (7) The number of times a manufacturer has
18 used the same accredited third-party auditor for 2 or
19 more consecutive drug safety and quality audits
20 under such section 809.

21 (8) Recommendations to Congress regarding
22 the accreditation program under such section 809,
23 including whether Congress should continue, modify,
24 or terminate the program.

1 **SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED**
2 **DRUGS.**

3 Section 801 (21 U.S.C. 381) is amended—

4 (1) in subsection (o), by striking “drug or”;
5 and

6 (2) by adding at the end the following:

7 “(r)(1) The Secretary may require, as a condition of
8 granting admission to a drug imported or offered for im-
9 port into the United States, that the importer electroni-
10 cally submit information demonstrating that the drug
11 complies with applicable requirements of this Act.

12 “(2) The information described under paragraph (1)
13 may include—

14 “(A) information demonstrating the regulatory
15 status of the drug, such as the new drug application,
16 abbreviated new drug application, or investigational
17 new drug or drug master file number;

18 “(B) facility information, such as proof of reg-
19 istration and the unique facility identifier;

20 “(C) indication of compliance with current good
21 manufacturing practice, testing results, certifications
22 relating to satisfactory inspections, and compliance
23 with the country of export regulations; and

24 “(D) any other information deemed necessary
25 and appropriate by the Secretary to assess compli-
26 ance of the article being offered for import.

1 “(3) Information requirements referred to in para-
2 graph (2)(C) may, at the discretion of the Secretary, be
3 satisfied—

4 “(A) by certifications from accredited third par-
5 ties, as described under section 809;

6 “(B) through representation by a foreign gov-
7 ernment, if such inspection is conducted using
8 standards and practices as determined appropriate
9 by the Secretary; or

10 “(C) other appropriate documentation or evi-
11 dence as described by the Secretary.

12 “(4)(A) Not later than 18 months after the date of
13 enactment of the Food and Drug Administration Safety
14 and Innovation Act, the Secretary shall adopt final regula-
15 tions implementing this subsection. Such requirements
16 shall be appropriate for the type of import, such as wheth-
17 er the drug is for import into the United States for use
18 in preclinical research or in a clinical investigation under
19 an investigational new drug exemption under 505(i).

20 “(B) In promulgating the regulations implementing
21 this subsection, the Secretary shall—

22 “(i) issue a notice of proposed rulemaking that
23 includes the proposed regulation;

24 “(ii) provide a period of not less than 60 days
25 for comments on the proposed regulation; and

1 “(iii) publish the final regulation not less than
2 30 days before the effective date of the regulation.

3 “(C) Notwithstanding any other provision of law, the
4 Secretary shall promulgate regulations implementing this
5 subsection only as described in subparagraph (B).”.

6 **SEC. 712. NOTIFICATION.**

7 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
8 331) is amended by adding at the end the following:

9 “(aaa) The failure to notify the Secretary in violation
10 of section 568.”.

11 (b) NOTIFICATION.—

12 (1) IN GENERAL.—Subchapter E of chapter V
13 (21 U.S.C. 360bbb et seq.) is amended by adding at
14 the end the following:

15 **“SEC. 568. NOTIFICATION.**

16 “(a) NOTIFICATION TO SECRETARY.—With respect
17 to a drug, the Secretary may require notification to the
18 Secretary by a covered person if the covered person
19 knows—

20 “(1) of a substantial loss or theft of such drug;

21 or

22 “(2) that such drug—

23 “(A) has been or is being counterfeited;

24 and

1 “(B)(i) is a counterfeit product in com-
2 merce in the United States; or

3 “(ii) is offered for import into the United
4 States.

5 “(b) MANNER OF NOTIFICATION.—Notification
6 under this section shall be made in a reasonable time, in
7 such reasonable manner, and by such reasonable means
8 as the Secretary may require by regulation or specify in
9 guidance.

10 “(c) DEFINITION.—In this section, the term ‘covered
11 person’ means—

12 “(1) a person who is required to register under
13 section 510 with respect to an establishment en-
14 gaged in the manufacture, preparation, propagation,
15 compounding, or processing of a drug; or

16 “(2) a person engaged in the wholesale distribu-
17 tion (as defined in section 503(e)(3)(B)) of a drug.”.

18 “(2) APPLICABILITY.—Notifications under sec-
19 tion 568 of the Federal Food, Drug, and Cosmetic
20 Act (as added by paragraph (1)) apply to losses,
21 thefts, or counterfeiting, as described in subsection
22 (a) of such section 568, that occur on or after the
23 date of enactment of this Act.

1 **SEC. 713. 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. 714. ENHANCED CRIMINAL PENALTY FOR COUNTER-**
14 **FEITING DRUGS.**

15 Section 303(b) (21 U.S.C. 333(b)), as amended by
16 section 713, is further amended by adding at the end the
17 following:

18 “(8) Notwithstanding subsection (a)(2), any person
19 who knowingly and intentionally violates section 301(i)
20 shall be imprisoned for not more than 20 years or fined
21 not more than \$4,000,000 or both.”.

22 **SEC. 715. EXTRATERRITORIAL JURISDICTION.**

23 Chapter III (21 U.S.C. 331 et seq.) is amended by
24 adding at the end the following:

1 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

2 “There is extraterritorial jurisdiction over any viola-
3 tion of this Act relating to any article regulated under this
4 Act if such article was intended for import into the United
5 States or if any act in furtherance of the violation was
6 committed in the United States.”.

7 **SEC. 716. COMPLIANCE WITH INTERNATIONAL AGREE-**
8 **MENTS.**

9 Nothing in this title (or an amendment made by this
10 title) shall be construed in a manner inconsistent with the
11 obligations of the United States under the Agreement Es-
12 tablishing the World Trade Organization, or any other
13 treaty or international agreement to which the United
14 States is a party.

15 **TITLE VIII—GENERATING**
16 **ANTIBIOTIC INCENTIVES NOW**

17 **SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

18 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.)
19 is amended by inserting after section 505D the following:

20 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**
21 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

22 “(a) EXTENSION.—If the Secretary approves an ap-
23 plication pursuant to section 505 for a drug that has been
24 designated as a qualified infectious disease product under
25 subsection (d), the 4- and 5-year periods described in sub-
26 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the

1 3-year periods described in clauses (iii) and (iv) of sub-
2 section (c)(3)(E) and clauses (iii) and (iv) of subsection
3 (j)(5)(F) of section 505, or the 7-year period described
4 in section 527, as applicable, shall be extended by 5 years.

5 “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
6 extension under subsection (a) of a period shall be in addi-
7 tion to any extension of the period under section 505A
8 with respect to the drug.

9 “(c) LIMITATIONS.—Subsection (a) does not apply to
10 the approval of—

11 “(1) a supplement to an application under sec-
12 tion 505(b) for any qualified infectious disease prod-
13 uct for which an extension described in subsection
14 (a) is in effect or has expired;

15 “(2) a subsequent application filed with respect
16 to a product approved under section 505 for a
17 change that results in a new indication, route of ad-
18 ministration, dosing schedule, dosage form, delivery
19 system, delivery device, or strength; or

20 “(3) an application for a product that is not ap-
21 proved for the use for which it received a designa-
22 tion under subsection (d).

23 “(d) DESIGNATION.—

24 “(1) IN GENERAL.—The manufacturer or spon-
25 sor of a drug may request the Secretary to designate

1 a drug as a qualified infectious disease product at
2 any time before the submission of an application
3 under section 505(b) for such drug. The Secretary
4 shall, not later than 60 days after the submission of
5 such a request, determine whether the drug is a
6 qualified infectious disease product.

7 “(2) LIMITATION.—Except as provided in para-
8 graph (3), a designation under this subsection shall
9 not be withdrawn for any reason, including modifica-
10 tions to the list of qualifying pathogens under sub-
11 section (f)(2)(C).

12 “(3) REVOCATION OF DESIGNATION.—The Sec-
13 retary may revoke a designation of a drug as a
14 qualified infectious disease product if the Secretary
15 finds that the request for such designation contained
16 an untrue statement of material fact.

17 “(e) REGULATIONS.—

18 “(1) IN GENERAL.—Not later than 2 years
19 after the date of enactment of the Food and Drug
20 Administration Safety and Innovation Act, the Sec-
21 retary shall adopt final regulations implementing
22 this section.

23 “(2) PROCEDURE.—In promulgating a regula-
24 tion implementing this section, the Secretary shall—

1 “(A) issue a notice of proposed rulemaking
2 that includes the proposed regulation;

3 “(B) provide a period of not less than 60
4 days for comments on the proposed regulation;
5 and

6 “(C) publish the final regulation not less
7 than 30 days before the effective date of the
8 regulation.

9 “(3) RESTRICTIONS.—Notwithstanding any
10 other provision of law, the Secretary shall promul-
11 gate regulations implementing this section only as
12 described in paragraph (2), except that the Sec-
13 retary may issue interim guidance for sponsors seek-
14 ing designation under subsection (d) prior to the
15 promulgation of such regulations.

16 “(4) DESIGNATION PRIOR TO REGULATIONS.—
17 The Secretary may designate drugs as qualified in-
18 fectious disease products under subsection (d) prior
19 to the promulgation of regulations under this sub-
20 section.

21 “(f) QUALIFYING PATHOGEN.—

22 “(1) DEFINITION.—In this section, the term
23 ‘qualifying pathogen’ means a pathogen identified
24 and listed by the Secretary under paragraph (2) that

1 has the potential to pose a serious threat to public
2 health, such as—

3 “(A) resistant gram positive pathogens, in-
4 cluding methicillin-resistant *Staphylococcus*
5 *aureus*, vancomycin-resistant *Staphylococcus*
6 *aureus*, and vancomycin-resistant enterococcus;

7 “(B) multi-drug resistant gram negative
8 bacteria, including *Acinetobacter*, *Klebsiella*,
9 *Pseudomonas*, and *E. coli* species;

10 “(C) multi-drug resistant tuberculosis; and

11 “(D) *Clostridium difficile*.

12 “(2) LIST OF QUALIFYING PATHOGENS.—

13 “(A) IN GENERAL.—The Secretary shall
14 establish and maintain a list of qualifying
15 pathogens, and shall make public the method-
16 ology for developing such list.

17 “(B) CONSIDERATIONS.—In establishing
18 and maintaining the list of pathogens described
19 under this section the Secretary shall—

20 “(i) consider—

21 “(I) the impact on the public
22 health due to drug-resistant orga-
23 nisms in humans;

24 “(II) the rate of growth of drug-
25 resistant organisms in humans;

1 “(III) the increase in resistance
2 rates in humans; and

3 “(IV) the morbidity and mor-
4 tality in humans; and

5 “(ii) consult with experts in infectious
6 diseases and antibiotic resistance, includ-
7 ing the Centers for Disease Control and
8 Prevention, the Food and Drug Adminis-
9 tration, medical professionals, and the clin-
10 ical research community.

11 “(C) REVIEW.—Every 5 years, or more
12 often as needed, the Secretary shall review, pro-
13 vide modifications to, and publish the list of
14 qualifying pathogens under subparagraph (A)
15 and shall by regulation revise the list as nec-
16 essary, in accordance with subsection (e).

17 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
18 The term ‘qualified infectious disease product’ means an
19 antibacterial or antifungal drug for human use intended
20 to treat serious or life-threatening infections, including
21 those caused by—

22 “(1) an antibacterial or antifungal resistant
23 pathogen, including novel or emerging infectious
24 pathogens; or

1 “(2) qualifying pathogens listed by the Sec-
2 retary under subsection (f).”.

3 (b) APPLICATION.—Section 505E of the Federal
4 Food, Drug, and Cosmetic Act, as added by subsection
5 (a), applies only with respect to a drug that is first ap-
6 proved under section 505(c) of such Act (21 U.S.C.
7 355(c)) on or after the date of the enactment of this Act.

8 **SEC. 802. PRIORITY REVIEW.**

9 (a) AMENDMENT.—Chapter V (21 U.S.C. 351 et
10 seq.) is amended by inserting after section 524 the fol-
11 lowing:

12 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**
13 **DISEASE PRODUCTS.**

14 “If the Secretary designates a drug under section
15 505E(d) as a qualified infectious disease product, then the
16 Secretary shall give priority review to any application sub-
17 mitted for approval for such drug under section 505(b).”.

18 (b) APPLICATION.—Section 524A of the Federal
19 Food, Drug, and Cosmetic Act, as added by subsection
20 (a), applies only with respect to an application that is sub-
21 mitted under section 505(b) of such Act (21 U.S.C.
22 355(b)) on or after the date of the enactment of this Act.

23 **SEC. 803. FAST TRACK PRODUCT.**

24 Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended
25 by section 901(b), is amended by inserting “, or if the

1 Secretary designates the drug as a qualified infectious dis-
2 ease product under section 505E(d)” before the period at
3 the end of the first sentence.

4 **SEC. 804. GAO STUDY.**

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

7 (1) conduct a study—

8 (A) on the need for, and public health im-
9 pact of, incentives to encourage the research,
10 development, and marketing of qualified infec-
11 tious disease biological products and antifungal
12 products; and

13 (B) consistent with trade and confiden-
14 tiality data protections, assessing, for all anti-
15 bacterial and antifungal drugs, including bio-
16 logical products, the average or aggregate—

17 (i) costs of all clinical trials for each
18 phase;

19 (ii) percentage of success or failure at
20 each phase of clinical trials; and

21 (iii) public versus private funding lev-
22 els of the trials for each phase; and

23 (2) not later than 1 year after the date of en-
24 actment of this Act, submit a report to Congress on
25 the results of such study, including any rec-

1 ommendations of the Comptroller General on appro-
2 priate incentives for addressing such need.

3 (b) CONTENTS.—The part of the study described in
4 subsection (a)(1)(A) shall include—

5 (1) an assessment of any underlying regulatory
6 issues related to qualified infectious disease prod-
7 ucts, including qualified infectious disease biological
8 products;

9 (2) an assessment of the management by the
10 Food and Drug Administration of the review of
11 qualified infectious disease products, including quali-
12 fied infectious disease biological products and the
13 regulatory certainty of related regulatory pathways
14 for such products;

15 (3) a description of any regulatory impediments
16 to the clinical development of new qualified infec-
17 tious disease products, including qualified infectious
18 disease biological products, and the efforts of the
19 Food and Drug Administration to address such im-
20 pediments; and

21 (4) recommendations with respect to—

22 (A) improving the review and predictability
23 of regulatory pathways for such products; and

24 (B) overcoming any regulatory impedi-
25 ments identified in paragraph (3).

1 (c) DEFINITIONS.—In this section:

2 (1) The term “biological product” has the
3 meaning given to such term in section 351 of the
4 Public Health Service Act (42 U.S.C. 262).

5 (2) The term “qualified infectious disease bio-
6 logical product” means a biological product intended
7 to treat a serious or life-threatening infection de-
8 scribed in section 505E(g) of the Federal Food,
9 Drug, and Cosmetic Act, as added by section 801.

10 (3) The term “qualified infectious disease prod-
11 uct” has the meaning given such term in section
12 505E(g) of the Federal Food, Drug, and Cosmetic
13 Act, as added by section 801.

14 **SEC. 805. CLINICAL TRIALS.**

15 (a) REVIEW AND REVISION OF GUIDANCE DOCU-
16 MENTS.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services (referred to in this section as the
19 “Secretary”) shall review and, as appropriate, revise
20 not fewer than 3 guidance documents per year,
21 which shall include—

22 (A) reviewing the guidance documents of
23 the Food and Drug Administration for the con-
24 duct of clinical trials with respect to anti-
25 bacterial and antifungal drugs; and

1 (B) as appropriate, revising such guidance
2 documents to reflect developments in scientific
3 and medical information and technology and to
4 ensure clarity regarding the procedures and re-
5 quirements for approval of antibacterial and
6 antifungal drugs under chapter V of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 351 et seq.).

9 (2) ISSUES FOR REVIEW.—At a minimum, the
10 review under paragraph (1) shall address the appro-
11 priate animal models of infection, in vitro tech-
12 niques, valid micro-biological surrogate markers, the
13 use of non-inferiority versus superiority trials, trial
14 enrollment, data requirements, and appropriate delta
15 values for non-inferiority trials.

16 (3) RULE OF CONSTRUCTION.—Except to the
17 extent to which the Secretary makes revisions under
18 paragraph (1)(B), nothing in this section shall be
19 construed to repeal or otherwise effect the guidance
20 documents of the Food and Drug Administration.

21 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

22 (1) REQUEST.—The sponsor of a drug intended
23 to be designated as a qualified infectious disease
24 product may request that the Secretary provide writ-
25 ten recommendations for nonclinical and clinical in-

1 investigations which the Secretary believes may be
2 necessary to be conducted with the drug before such
3 drug may be approved under section 505 of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)
5 for use in treating, detecting, preventing, or identi-
6 fying a qualifying pathogen, as defined in section
7 505E of such Act.

8 (2) RECOMMENDATIONS.—If the Secretary has
9 reason to believe that a drug for which a request is
10 made under this subsection is a qualified infectious
11 disease product, the Secretary shall provide the per-
12 son making the request written recommendations for
13 the nonclinical and clinical investigations which the
14 Secretary believes, on the basis of information avail-
15 able to the Secretary at the time of the request,
16 would be necessary for approval under section 505
17 of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 355) of such drug for the use described in
19 paragraph (1).

20 (c) GAO STUDY.—Not later than January 1, 2016,
21 the Comptroller General of the United States shall submit
22 to Congress a report—

23 (1) regarding the review and revision of the
24 clinical trial guidance documents required under
25 subsection (a) and the impact such review and revi-

1 sion has had on the review and approval of qualified
2 infectious disease products;

3 (2) assessing—

4 (A) the effectiveness of the results-oriented
5 metrics managers employ to ensure that review-
6 ers of such products are familiar with, and con-
7 sistently applying, clinical trial guidance docu-
8 ments; and

9 (B) the predictability of related regulatory
10 pathways and review;

11 (3) identifying any outstanding regulatory im-
12 pediments to the clinical development of qualified in-
13 fectionous disease products;

14 (4) reporting on the progress the Food and
15 Drug Administration has made in addressing the im-
16 pediments identified under paragraph (3); and

17 (5) containing recommendations regarding how
18 to improve the review of, and regulatory pathway
19 for, such products.

20 (d) QUALIFIED INFECTIOUS DISEASE PRODUCT.—

21 For purposes of this section, the term “qualified infectious
22 disease product” has the meaning given such term in sec-
23 tion 505E(g) of the Federal Food, Drug, and Cosmetic
24 Act, as added by section 801.

1 **SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.**

2 (a) INITIAL STRATEGY AND IMPLEMENTATION
3 PLAN.—Not later than 1 year after the date of enactment
4 of this Act, the Secretary of Health and Human Services
5 (referred to in this section as the “Secretary”) shall sub-
6 mit to Congress a strategy and implementation plan with
7 respect to the requirements of this Act. The strategy and
8 implementation plan shall include—

9 (1) a description of the regulatory challenges to
10 clinical development, approval, and licensure of
11 qualified infectious disease products;

12 (2) the regulatory and scientific priorities of the
13 Secretary with respect to such challenges; and

14 (3) the steps the Secretary will take to ensure
15 regulatory certainty and predictability with respect
16 to qualified infectious disease products, including
17 steps the Secretary will take to ensure managers and
18 reviewers are familiar with related regulatory path-
19 ways, requirements of the Food and Drug Adminis-
20 tration, guidance documents related to such prod-
21 ucts, and applying such requirements consistently.

22 (b) SUBSEQUENT REPORT.—Not later than 3 years
23 after the date of enactment of this Act, the Secretary shall
24 submit to Congress a report on—

25 (1) the progress made toward the priorities
26 identified under subsection (a)(2);

1 (2) the number of qualified infectious disease
2 products that have been submitted for approval or li-
3 censure on or after the date of enactment of this
4 Act;

5 (3) a list of qualified infectious disease products
6 with information on the types of exclusivity granted
7 for each product, consistent with the information
8 published under section 505(j)(7)(A)(iii) of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 355(j)(7)(A)(iii));

11 (4) the number of such qualified infectious dis-
12 ease products and that have been approved or li-
13 censed on or after the date of enactment of this Act;
14 and

15 (5) the number of calendar days it took for the
16 approval or licensure of the qualified infectious dis-
17 ease products approved or licensed on or after the
18 date of enactment of this Act.

19 (c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
20 For purposes of this section, the term “qualified infectious
21 disease product” has the meaning given such term in sec-
22 tion 505E(g) of the Federal Food, Drug, and Cosmetic
23 Act, as added by section 801.

1 **TITLE IX—DRUG APPROVAL AND**
2 **PATIENT ACCESS**

3 **SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT AC-**
4 **CESS TO NEW MEDICAL TREATMENTS.**

5 (a) FINDINGS; SENSE OF CONGRESS.—

6 (1) FINDINGS.—Congress finds as follows:

7 (A) The Food and Drug Administration
8 (referred to in this section as the “FDA”)
9 serves a critical role in helping to assure that
10 new medicines are safe and effective. Regu-
11 latory innovation is 1 element of the Nation’s
12 strategy to address serious and life-threatening
13 diseases or conditions by promoting investment
14 in and development of innovative treatments for
15 unmet medical needs.

16 (B) During the 2 decades following the es-
17 tablishment of the accelerated approval mecha-
18 nism, advances in medical sciences, including
19 genomics, molecular biology, and bioinformatics,
20 have provided an unprecedented understanding
21 of the underlying biological mechanism and
22 pathogenesis of disease. A new generation of
23 modern, targeted medicines is under develop-
24 ment to treat serious and life-threatening dis-
25 eases, some applying drug development strate-

1 gies based on biomarkers or pharmacogenomics,
2 predictive toxicology, clinical trial enrichment
3 techniques, and novel clinical trial designs, such
4 as adaptive clinical trials.

5 (C) As a result of these remarkable sci-
6 entific and medical advances, the FDA should
7 be encouraged to implement more broadly effec-
8 tive processes for the expedited development
9 and review of innovative new medicines in-
10 tended to address unmet medical needs for seri-
11 ous or life-threatening diseases or conditions,
12 including those for rare diseases or conditions,
13 using a broad range of surrogate or clinical
14 endpoints and modern scientific tools earlier in
15 the drug development cycle when appropriate.
16 This may result in fewer, smaller, or shorter
17 clinical trials for the intended patient popu-
18 lation or targeted subpopulation without com-
19 promising or altering the high standards of the
20 FDA for the approval of drugs.

21 (D) Patients benefit from expedited access
22 to safe and effective innovative therapies to
23 treat unmet medical needs for serious or life-
24 threatening diseases or conditions.

1 (E) For these reasons, the statutory au-
2 thority in effect on the day before the date of
3 enactment of this Act governing expedited ap-
4 proval of drugs for serious or life-threatening
5 diseases or conditions should be amended in
6 order to enhance the authority of the FDA to
7 consider appropriate scientific data, methods,
8 and tools, and to expedite development and ac-
9 cess to novel treatments for patients with a
10 broad range of serious or life-threatening dis-
11 eases or conditions.

12 (2) SENSE OF CONGRESS.—It is the sense of
13 Congress that the Food and Drug Administration
14 should apply the accelerated approval and fast track
15 provisions set forth in section 506 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 356), as
17 amended by this section, to help expedite the devel-
18 opment and availability to patients of treatments for
19 serious or life-threatening diseases or conditions
20 while maintaining safety and effectiveness standards
21 for such treatments.

22 (b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS
23 OR LIFE-THREATENING DISEASES OR CONDITIONS.—Sec-
24 tion 506 (21 U.S.C. 356) is amended to read as follows:

1 **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**
2 **OR LIFE-THREATENING DISEASES OR CONDI-**
3 **TIONS.**

4 “(a) DESIGNATION OF DRUG AS FAST TRACK PROD-
5 UCT.—

6 “(1) IN GENERAL.—The Secretary shall, at the
7 request of the sponsor of a new drug, facilitate the
8 development and expedite the review of such drug if
9 it is intended, whether alone or in combination with
10 one or more other drugs, for the treatment of a seri-
11 ous or life-threatening disease or condition, and it
12 demonstrates the potential to address unmet medical
13 needs for such a disease or condition. (In this sec-
14 tion, such a drug is referred to as a ‘fast track prod-
15 uct’.)

16 “(2) REQUEST FOR DESIGNATION.—The spon-
17 sor of a new drug may request the Secretary to des-
18 ignate the drug as a fast track product. A request
19 for the designation may be made concurrently with,
20 or at any time after, submission of an application
21 for the investigation of the drug under section 505(i)
22 or section 351(a)(3) of the Public Health Service
23 Act.

24 “(3) DESIGNATION.—Within 60 calendar days
25 after the receipt of a request under paragraph (2),
26 the Secretary shall determine whether the drug that

1 is the subject of the request meets the criteria de-
2 scribed in paragraph (1). If the Secretary finds that
3 the drug meets the criteria, the Secretary shall des-
4 ignate the drug as a fast track product and shall
5 take such actions as are appropriate to expedite the
6 development and review of the application for ap-
7 proval of such product.

8 “(b) ACCELERATED APPROVAL OF A DRUG FOR A
9 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
10 TION, INCLUDING A FAST TRACK PRODUCT.—

11 “(1) IN GENERAL.—

12 “(A) ACCELERATED APPROVAL.—The Sec-
13 retary may approve an application for approval
14 of a product for a serious or life-threatening
15 disease or condition, including a fast track
16 product, under section 505(c) or section 351(a)
17 of the Public Health Service Act upon a deter-
18 mination that the product has an effect on a
19 surrogate endpoint that is reasonably likely to
20 predict clinical benefit, or on a clinical endpoint
21 that can be measured earlier than irreversible
22 morbidity or mortality, that is reasonably likely
23 to predict an effect on irreversible morbidity or
24 mortality or other clinical benefit, taking into
25 account the severity, rarity, or prevalence of the

1 condition and the availability or lack of alter-
2 native treatments. The approval described in
3 the preceding sentence is referred to in this sec-
4 tion as ‘accelerated approval’.

5 “(B) EVIDENCE.—The evidence to support
6 that an endpoint is reasonably likely to predict
7 clinical benefit under subparagraph (A) may in-
8 clude epidemiological, pathophysiological, thera-
9 peutic, pharmacologic, or other evidence devel-
10 oped using biomarkers, for example, or other
11 scientific methods or tools.

12 “(2) LIMITATION.—Approval of a product
13 under this subsection may be subject to 1 or both
14 of the following requirements:

15 “(A) That the sponsor conduct appropriate
16 post-approval studies to verify and describe the
17 predicted effect on irreversible morbidity or
18 mortality or other clinical benefit.

19 “(B) That the sponsor submit copies of all
20 promotional materials related to the product
21 during the preapproval review period and, fol-
22 lowing approval and for such period thereafter
23 as the Secretary determines to be appropriate,
24 at least 30 days prior to dissemination of the
25 materials.

1 “(3) EXPEDITED WITHDRAWAL OF AP-
2 PROVAL.—The Secretary may withdraw approval of
3 a product approved under accelerated approval using
4 expedited procedures (as prescribed by the Secretary
5 in regulations which shall include an opportunity for
6 an informal hearing) if—

7 “(A) the sponsor fails to conduct any re-
8 quired post-approval study of the drug with due
9 diligence;

10 “(B) a study required to verify and de-
11 scribe the predicted effect on irreversible mor-
12 bidity or mortality or other clinical benefit of
13 the product fails to verify and describe such ef-
14 fect or benefit;

15 “(C) other evidence demonstrates that the
16 product is not safe or effective under the condi-
17 tions of use; or

18 “(D) the sponsor disseminates false or
19 misleading promotional materials with respect
20 to the product.

21 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR
22 APPROVAL OF A FAST TRACK PRODUCT.—

23 “(1) IN GENERAL.—If the Secretary deter-
24 mines, after preliminary evaluation of clinical data
25 submitted by the sponsor, that a fast track product

1 may be effective, the Secretary shall evaluate for fil-
2 ing, and may commence review of portions of, an ap-
3 plication for the approval of the product before the
4 sponsor submits a complete application. The Sec-
5 retary shall commence such review only if the appli-
6 cant—

7 “(A) provides a schedule for submission of
8 information necessary to make the application
9 complete; and

10 “(B) pays any fee that may be required
11 under section 736.

12 “(2) EXCEPTION.—Any time period for review
13 of human drug applications that has been agreed to
14 by the Secretary and that has been set forth in goals
15 identified in letters of the Secretary (relating to the
16 use of fees collected under section 736 to expedite
17 the drug development process and the review of
18 human drug applications) shall not apply to an ap-
19 plication submitted under paragraph (1) until the
20 date on which the application is complete.

21 “(d) AWARENESS EFFORTS.—The Secretary shall—

22 “(1) develop and disseminate to physicians, pa-
23 tient organizations, pharmaceutical and bio-
24 technology companies, and other appropriate persons
25 a description of the provisions of this section appli-

1 cable to accelerated approval and fast track prod-
2 ucts; and

3 “(2) establish a program to encourage the de-
4 velopment of surrogate and clinical endpoints, in-
5 cluding biomarkers, and other scientific methods and
6 tools that can assist the Secretary in determining
7 whether the evidence submitted in an application is
8 reasonably likely to predict clinical benefit for seri-
9 ous or life-threatening conditions for which signifi-
10 cant unmet medical needs exist.

11 “(e) CONSTRUCTION.—

12 “(1) PURPOSE.—The amendments made by the
13 Food and Drug Administration Safety and Innova-
14 tion Act to this section are intended to encourage
15 the Secretary to utilize innovative and flexible ap-
16 proaches to the assessment of products under accel-
17 erated approval for treatments for patients with seri-
18 ous or life-threatening diseases or conditions and
19 unmet medical needs.

20 “(2) CONSTRUCTION.—Nothing in this section
21 shall be construed to alter the standards of evidence
22 under subsection (c) or (d) of section 505 (including
23 the substantial evidence standard in section 505(d))
24 of this Act or under section 351(a) of the Public
25 Health Service Act. Such sections and standards of

1 evidence apply to the review and approval of prod-
2 ucts under this section, including whether a product
3 is safe and effective. Nothing in this section alters
4 the ability of the Secretary to rely on evidence that
5 does not come from adequate and well-controlled in-
6 vestigations for the purpose of determining whether
7 an endpoint is reasonably likely to predict clinical
8 benefit as described in subsection (b)(1)(B).”.

9 (c) GUIDANCE; AMENDED REGULATIONS.—

10 (1) DRAFT GUIDANCE.—Not later than 1 year
11 after the date of enactment of this Act, the Sec-
12 retary of Health and Human Services (referred to in
13 this section as the “Secretary”) shall issue draft
14 guidance to implement the amendments made by
15 this section. In developing such guidance, the Sec-
16 retary shall specifically consider issues arising under
17 the accelerated approval and fast track processes
18 under section 506 of the Federal Food, Drug, and
19 Cosmetic Act, as amended by subsection (b), for
20 drugs designated for a rare disease or condition
21 under section 526 of such Act (21 U.S.C. 360bb)
22 and shall also consider any unique issues associated
23 with very rare diseases.

24 (2) FINAL GUIDANCE.—Not later than 1 year
25 after the issuance of draft guidance under para-

1 graph (1), and after an opportunity for public com-
2 ment, the Secretary shall issue final guidance.

3 (3) CONFORMING CHANGES.—The Secretary
4 shall issue, as necessary, conforming amendments to
5 the applicable regulations under title 21, Code of
6 Federal Regulations, governing accelerated approval.

7 (4) NO EFFECT OF INACTION ON REQUESTS.—
8 If the Secretary fails to issue final guidance or
9 amended regulations as required by this subsection,
10 such failure shall not preclude the review of, or ac-
11 tion on, a request for designation or an application
12 for approval submitted pursuant to section 506 of
13 the Federal Food, Drug, and Cosmetic Act, as
14 amended by subsection (b).

15 (d) INDEPENDENT REVIEW.—The Secretary may, in
16 conjunction with other planned reviews, contract with an
17 independent entity with expertise in assessing the quality
18 and efficiency of biopharmaceutical development and regu-
19 latory review programs to evaluate the Food and Drug Ad-
20 ministration's application of the processes described in
21 section 506 of the Federal Food, Drug, and Cosmetic Act,
22 as amended by subsection (b), and the impact of such
23 processes on the development and timely availability of in-
24 novative treatments for patients suffering from serious or
25 life-threatening conditions. Any such evaluation shall in-

1 clude consultation with regulated industries, patient advo-
2 cacy and disease research foundations, and relevant aca-
3 demic medical centers.

4 **SEC. 902. BREAKTHROUGH THERAPIES.**

5 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as
6 amended by section 901, is further amended—

7 (1) by redesignating subsections (a) through (c)
8 as subsections (b) through (d), respectively;

9 (2) by redesignating subsection (d) as sub-
10 section (f);

11 (3) by inserting before subsection (b), as so re-
12 designated, the following:

13 “(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH
14 THERAPY.—

15 “(1) IN GENERAL.—The Secretary shall, at the
16 request of the sponsor of a drug, expedite the devel-
17 opment and review of such drug if the drug is in-
18 tended, alone or in combination with 1 or more other
19 drugs, to treat a serious or life-threatening disease
20 or condition and preliminary clinical evidence indi-
21 cates that the drug may demonstrate substantial im-
22 provement over existing therapies on 1 or more clini-
23 cally significant endpoints, such as substantial treat-
24 ment effects observed early in clinical development.

1 (In this section, such a drug is referred to as a
2 ‘breakthrough therapy’.)

3 “(2) REQUEST FOR DESIGNATION.—The spon-
4 sor of a drug may request the Secretary to designate
5 the drug as a breakthrough therapy. A request for
6 the designation may be made concurrently with, or
7 at any time after, the submission of an application
8 for the investigation of the drug under section 505(i)
9 or section 351(a)(3) of the Public Health Service
10 Act.

11 “(3) DESIGNATION.—

12 “(A) IN GENERAL.—Not later than 60 cal-
13 endar days after the receipt of a request under
14 paragraph (2), the Secretary shall determine
15 whether the drug that is the subject of the re-
16 quest meets the criteria described in paragraph
17 (1). If the Secretary finds that the drug meets
18 the criteria, the Secretary shall designate the
19 drug as a breakthrough therapy and shall take
20 such actions as are appropriate to expedite the
21 development and review of the application for
22 approval of such drug.

23 “(B) ACTIONS.—The actions to expedite
24 the development and review of an application

1 under subparagraph (A) may include, as appro-
2 priate—

3 “(i) holding meetings with the sponsor
4 and the review team throughout the devel-
5 opment of the drug;

6 “(ii) providing timely advice to, and
7 interactive communication with, the spon-
8 sor regarding the development of the drug
9 to ensure that the development program to
10 gather the non-clinical and clinical data
11 necessary for approval is as efficient as
12 practicable;

13 “(iii) involving senior managers and
14 experienced review staff, as appropriate, in
15 a collaborative, cross-disciplinary review;

16 “(iv) assigning a cross-disciplinary
17 project lead for the Food and Drug Ad-
18 ministration review team to facilitate an
19 efficient review of the development pro-
20 gram and to serve as a scientific liaison be-
21 tween the review team and the sponsor;
22 and

23 “(v) taking steps to ensure that the
24 design of the clinical trials is as efficient as
25 practicable, when scientifically appropriate,

1 such as by minimizing the number of pa-
2 tients exposed to a potentially less effica-
3 cious treatment.”;

4 (4) in subsection (f)(1), as so redesignated, by
5 striking “applicable to accelerated approval” and in-
6 serting “applicable to breakthrough therapies, accel-
7 erated approval, and”; and

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

9 “(g) REPORT.—Beginning in fiscal year 2013, the
10 Secretary shall annually prepare and submit to the Com-
11 mittee on Health, Education, Labor, and Pensions of the
12 Senate and the Committee on Energy and Commerce of
13 the House of Representatives, and make publicly available,
14 with respect to this section for the previous fiscal year—

15 “(1) the number of drugs for which a sponsor
16 requested designation as a breakthrough therapy;

17 “(2) the number of products designated as a
18 breakthrough therapy; and

19 “(3) for each product designated as a break-
20 through therapy, a summary of the actions taken
21 under subsection (a)(3).”.

22 (b) GUIDANCE; AMENDED REGULATIONS.—

23 (1) IN GENERAL.—

24 (A) GUIDANCE.—Not later than 18
25 months after the date of enactment of this Act,

1 the Secretary of Health and Human Services
2 (referred to in this section as the “Secretary”)
3 shall issue draft guidance on implementing the
4 requirements with respect to breakthrough
5 therapies, as set forth in section 506(a) of the
6 Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 356(a)), as amended by this section.
8 The Secretary shall issue final guidance not
9 later than 1 year after the close of the comment
10 period for the draft guidance.

11 (B) AMENDED REGULATIONS.—

12 (i) IN GENERAL.—If the Secretary de-
13 termines that it is necessary to amend the
14 regulations under title 21, Code of Federal
15 Regulations in order to implement the
16 amendments made by this section to sec-
17 tion 506(a) of the Federal Food, Drug,
18 and Cosmetic Act, the Secretary shall
19 amend such regulations not later than 2
20 years after the date of enactment of this
21 Act.

22 (ii) PROCEDURE.—In amending regu-
23 lations under clause (i), the Secretary
24 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 section only as
14 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) INDEPENDENT REVIEW.—Not later than 3 years
4 after the date of enactment of this Act, the Comptroller
5 General of the United States, in consultation with appro-
6 priate experts, shall assess the manner by which the Food
7 and Drug Administration has applied the processes de-
8 scribed in section 506(a) of the Federal Food, Drug, and
9 Cosmetic Act, as amended by this section, and the impact
10 of such processes on the development and timely avail-
11 ability of innovative treatments for patients affected by se-
12 rious or life-threatening conditions. Such assessment shall
13 be made publicly available upon completion.

14 (d) CONFORMING AMENDMENTS.—Section 506B(e)
15 (21 U.S.C. 356b) is amended by striking “section
16 506(b)(2)(A)” each place such term appears and inserting
17 “section 506(c)(2)(A)”.

18 **SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON**
19 **RARE DISEASES, TARGETED THERAPIES, AND**
20 **GENETIC TARGETING OF TREATMENTS.**

21 Subchapter E of chapter V (21 U.S.C. 360bbb et
22 seq.), as amended by section 712, is further amended by
23 adding at the end the following:

1 **“SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON**
2 **RARE DISEASES, TARGETED THERAPIES, AND**
3 **GENETIC TARGETING OF TREATMENTS.**

4 “(a) IN GENERAL.—For the purpose of promoting
5 the efficiency of and informing the review by the Food
6 and Drug Administration of new drugs and biological
7 products for rare diseases and drugs and biological prod-
8 ucts that are genetically targeted, the following shall
9 apply:

10 “(1) CONSULTATION WITH STAKEHOLDERS.—
11 Consistent with sections X.C and IX.E.4 of the
12 PDUFA Reauthorization Performance Goals and
13 Procedures Fiscal Years 2013 through 2017, as ref-
14 erenced in the letters described in section 101(b) of
15 the Prescription Drug User Fee Amendments of
16 2012, the Secretary shall ensure that opportunities
17 exist, at a time the Secretary determines appro-
18 priate, for consultations with stakeholders on the
19 topics described in subsection (c).

20 “(2) CONSULTATION WITH EXTERNAL EX-
21 PERTS.—The Secretary shall develop and maintain a
22 list of external experts who, because of their special
23 expertise, are qualified to provide advice on rare dis-
24 ease issues, including topics described in subsection
25 (c). The Secretary may, when appropriate to address
26 a specific regulatory question, consult such external

1 experts on issues related to the review of new drugs
2 and biological products for rare diseases and drugs
3 and biological products that are genetically targeted,
4 including the topics described in subsection (c),
5 when such consultation is necessary because the Sec-
6 retary lacks specific scientific, medical, or technical
7 expertise necessary for the performance of its regu-
8 latory responsibilities and the necessary expertise
9 can be provided by the external experts.

10 “(b) EXTERNAL EXPERTS.—For purposes of sub-
11 section (a)(2), external experts are those who possess sci-
12 entific or medical training that the Secretary lacks with
13 respect to one or more rare diseases.

14 “(c) TOPICS FOR CONSULTATION.—Topics for con-
15 sultation pursuant to this section may include—

16 “(1) rare diseases;

17 “(2) the severity of rare diseases;

18 “(3) the unmet medical need associated with
19 rare diseases;

20 “(4) the willingness and ability of individuals
21 with a rare disease to participate in clinical trials;

22 “(5) an assessment of the benefits and risks of
23 therapies to treat rare diseases;

24 “(6) the general design of clinical trials for rare
25 disease populations and subpopulations; and

1 “(7) demographics and the clinical description
2 of patient populations.

3 “(d) CLASSIFICATION AS SPECIAL GOVERNMENT EM-
4 PLOYEES.—The external experts who are consulted under
5 this section may be considered special government employ-
6 ees, as defined under section 202 of title 18, United States
7 Code.

8 “(e) PROTECTION OF PROPRIETARY INFORMA-
9 TION.—Nothing in this section shall be construed to alter
10 the protections offered by laws, regulations, and policies
11 governing disclosure of confidential commercial or trade
12 secret information, and any other information exempt
13 from disclosure pursuant to section 552(b) of title 5,
14 United States Code, as such provisions would be applied
15 to consultation with individuals and organizations prior to
16 the date of enactment of this section.

17 “(f) OTHER CONSULTATION.—Nothing in this sec-
18 tion shall be construed to limit the ability of the Secretary
19 to consult with individuals and organizations as authorized
20 prior to the date of enactment of this section.

21 “(g) NO RIGHT OR OBLIGATION.—Nothing in this
22 section shall be construed to create a legal right for a con-
23 sultation on any matter or require the Secretary to meet
24 with any particular expert or stakeholder. Nothing in this
25 section shall be construed to alter agreed upon goals and

1 procedures identified in the letters described in section
2 101(b) of the Prescription Drug User Fee Amendments
3 of 2012. Nothing in this section is intended to increase
4 the number of review cycles as in effect before the date
5 of enactment of this section.”.

6 **SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIP-**
7 **TION DRUG CONTAINER LABELS BY VIS-**
8 **UALLY-IMPAIRED AND BLIND CONSUMERS.**

9 (a) ESTABLISHMENT OF WORKING GROUP.—

10 (1) IN GENERAL.—The Architectural and
11 Transportation Barriers Compliance Board (referred
12 to in this section as the “Access Board”) shall con-
13 vene a stakeholder working group (referred to in this
14 section as the “working group”) to develop best
15 practices on access to information on prescription
16 drug container labels for individuals who are blind
17 or visually impaired.

18 (2) MEMBERS.—The working group shall be
19 comprised of representatives of national organiza-
20 tions representing blind and visually-impaired indi-
21 viduals, national organizations representing the el-
22 derly, and industry groups representing stake-
23 holders, including retail, mail order, and independent
24 community pharmacies, who would be impacted by
25 such best practices. Representation within the work-

1 ing group shall be divided equally between consumer
2 and industry advocates.

3 (3) BEST PRACTICES.—

4 (A) IN GENERAL.—The working group
5 shall develop, not later than 1 year after the
6 date of the enactment of this Act, best practices
7 for pharmacies to ensure that blind and vis-
8 ually-impaired individuals have safe, consistent,
9 reliable, and independent access to the informa-
10 tion on prescription drug container labels.

11 (B) PUBLIC AVAILABILITY.—The best
12 practices developed under subparagraph (A)
13 may be made publicly available, including
14 through the Internet Web sites of the working
15 group participant organizations, and through
16 other means, in a manner that provides access
17 to interested individuals, including individuals
18 with disabilities.

19 (C) LIMITATIONS.—The best practices de-
20 veloped under subparagraph (A) shall not be
21 construed as accessibility guidelines or stand-
22 ards of the Access Board, and shall not confer
23 any rights or impose any obligations on working
24 group participants or other persons. Nothing in
25 this section shall be construed to limit or condi-

1 tion any right, obligation, or remedy available
2 under the Americans with Disabilities Act of
3 1990 (42 U.S.C. 12101 et seq.) or any other
4 Federal or State law requiring effective commu-
5 nication, barrier removal, or nondiscrimination
6 on the basis of disability.

7 (4) CONSIDERATIONS.—In developing and
8 issuing the best practices under paragraph (3)(A),
9 the working group shall consider—

10 (A) the use of—

11 (i) Braille;

12 (ii) auditory means, such as—

13 (I) “talking bottles” that provide
14 audible container label information;

15 (II) digital voice recorders at-
16 tached to the prescription drug con-
17 tainer; and

18 (III) radio frequency identifica-
19 tion tags;

20 (iii) enhanced visual means, such as—

21 (I) large font labels or large font
22 “duplicate” labels that are affixed or
23 matched to a prescription drug con-
24 tainer;

25 (II) high-contrast printing; and

1 (III) sans-serif font; and

2 (iv) other relevant alternatives as de-
3 termined by the working group;

4 (B) whether there are technical, financial,
5 manpower, or other factors unique to phar-
6 macies with 20 or fewer retail locations which
7 may pose significant challenges to the adoption
8 of the best practices; and

9 (C) such other factors as the working
10 group determines to be appropriate.

11 (5) INFORMATION CAMPAIGN.—Upon comple-
12 tion of development of the best practices under sub-
13 section (a)(3), the National Council on Disability, in
14 consultation with the working group, shall conduct
15 an informational and educational campaign designed
16 to inform individuals with disabilities, pharmacists,
17 and the public about such best practices.

18 (6) FACA WAIVER.—The Federal Advisory
19 Committee Act (5 U.S.C. App.) shall not apply to
20 the working group.

21 (b) GAO STUDY.—

22 (1) IN GENERAL.—Beginning 18 months after
23 the completion of the development of best practices
24 under subsection (a)(3)(A), the Comptroller General
25 of the United States shall conduct a review of the

1 extent to which pharmacies are utilizing such best
2 practices, and the extent to which barriers to acces-
3 sible information on prescription drug container la-
4 bels for blind and visually-impaired individuals con-
5 tinue.

6 (2) REPORT.—Not later than September 30,
7 2016, the Comptroller General of the United States
8 shall submit to Congress a report on the review con-
9 ducted under paragraph (1). Such report shall in-
10 clude recommendations about how best to reduce the
11 barriers experienced by blind and visually-impaired
12 individuals to independently accessing information
13 on prescription drug container labels.

14 (c) DEFINITIONS.—In this section—

15 (1) the term “pharmacy” includes a pharmacy
16 that receives prescriptions and dispenses prescription
17 drugs through an Internet Web site or by mail;

18 (2) the term “prescription drug” means a drug
19 subject to section 503(b)(1) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

21 (3) the term “prescription drug container label”
22 means the label with the directions for use that is
23 affixed to the prescription drug container by the
24 pharmacist and dispensed to the consumer.

1 **SEC. 905. RISK-BENEFIT FRAMEWORK.**

2 Section 505(d) (21 U.S.C. 355(d)) is amended by
3 adding at the end the following: “The Secretary shall im-
4 plement a structured risk-benefit assessment framework
5 in the new drug approval process to facilitate the balanced
6 consideration of benefits and risks, a consistent and sys-
7 tematic approach to the discussion and regulatory deci-
8 sionmaking, and the communication of the benefits and
9 risks of new drugs. Nothing in the preceding sentence
10 shall alter the criteria for evaluating an application for
11 premarket approval of a drug.”.

12 **SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION**
13 **INDUCEMENT MODEL.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services shall enter into an agreement with the
16 National Academies to provide expert consultation and
17 conduct a study that evaluates the feasibility and possible
18 consequences of the use of innovation inducement prizes
19 to reward successful medical innovations. Under the
20 agreement, the National Academies shall submit to the
21 Secretary a report on such study not later than 15 months
22 after the date of enactment of this Act.

23 (b) REQUIREMENTS.—

24 (1) IN GENERAL.—The study conducted under
25 subsection (a) shall model at least 3 separate seg-
26 ments on the medical technologies market as can-

1 didate targets for the new incentive system and con-
2 sider different medical innovation inducement prize
3 design issues, including the challenges presented in
4 the implementation of prizes for end products, open
5 source dividend prizes, and prizes for upstream re-
6 search.

7 (2) MARKET SEGMENTS.—The segments on the
8 medical technologies market that shall be considered
9 under paragraph (1) include—

10 (A) all pharmaceutical and biologic drugs
11 and vaccines;

12 (B) drugs and vaccines used solely for the
13 treatment of HIV/AIDS; and

14 (C) antibiotics.

15 (c) ELEMENTS.—The study conducted under sub-
16 section (a) shall include consideration of each of the fol-
17 lowing:

18 (1) Whether a system of large innovation in-
19 ducement prizes could work as a replacement for the
20 existing product monopoly/patent-based system, as
21 in effect on the date of enactment of this Act.

22 (2) How large the innovation prize funds would
23 have to be in order to induce at least as much re-
24 search and development investment in innovation as
25 is induced under the current system of time-limited

1 market exclusivity, as in effect on the date of enact-
2 ment of this Act.

3 (3) Whether a system of large innovation in-
4 ducement prizes would be more or less expensive
5 than the current system of time-limited market ex-
6 clusivity, as in effect on the date of enactment of
7 this Act, calculated over different time periods.

8 (4) Whether a system of large innovation in-
9 ducement prizes would expand access to new prod-
10 ucts and improve health outcomes.

11 (5) The type of information and decisionmaking
12 skills that would be necessary to manage end prod-
13 uct prizes.

14 (6) Whether there would there be major advan-
15 tages in rewarding the incremental impact of innova-
16 tions, as benchmarked against existing products.

17 (7) How open-source dividend prizes could be
18 managed, and whether such prizes would increase
19 access to knowledge, materials, data and tech-
20 nologies.

21 (8) Whether a system of competitive inter-
22 mediaries for interim research prizes would provide
23 an acceptable solution to the valuation challenges for
24 interim prizes.

1 **SEC. 907. ORPHAN PRODUCT GRANTS PROGRAM.**

2 (a) REAUTHORIZATION OF PROGRAM.—Section 5(c)
3 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended
4 by striking “2008 through 2012” and inserting “2013
5 through 2017”.

6 (b) HUMAN CLINICAL TESTING.—Section
7 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.
8 360ee(b)(1)(A)(ii)) is amended by striking “after the date
9 such drug is designated under section 526 of such Act
10 and”.

11 **TITLE X—DRUG SHORTAGES**

12 **SEC. 1001. DRUG SHORTAGES.**

13 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)
14 is amended to read as follows:

15 **“SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE**
16 **PRODUCTION OF LIFE-SAVING DRUGS.**

17 “(a) IN GENERAL.—A manufacturer of a drug—

18 “(1) that is—

19 “(A) life-supporting;

20 “(B) life-sustaining;

21 “(C) intended for use in the prevention of
22 a debilitating disease or condition;

23 “(D) a sterile injectable product; or

24 “(E) used in emergency medical care or
25 during surgery; and

1 “(2) that is not a radio pharmaceutical drug
2 product, a human tissue replaced by a recombinant
3 product, a product derived from human plasma pro-
4 tein, or any other product as designated by the Sec-
5 retary,

6 shall notify the Secretary, in accordance with subsection
7 (b), of a permanent discontinuance in the manufacture of
8 the drug or an interruption of the manufacture of the drug
9 that could lead to a meaningful disruption in the supply
10 of that drug in the United States.

11 “(b) TIMING.—A notice required under subsection (a)
12 shall be submitted to the Secretary—

13 “(1) at least 6 months prior to the date of the
14 discontinuance or interruption; or

15 “(2) if compliance with paragraph (1) is not
16 possible, as soon as practicable.

17 “(c) EXPEDITED INSPECTIONS AND REVIEWS.—If,
18 based on notifications described in subsection (a) or any
19 other relevant information, the Secretary concludes that
20 there is, or is likely to be, a drug shortage of a drug de-
21 scribed in subsection (a), the Secretary may—

22 “(1) expedite the review of a supplement to a
23 new drug application submitted under section
24 505(b), an abbreviated new drug application sub-
25 mitted under section 505(j), or a supplement to such

1 an application submitted under section 505(j) that
2 could help mitigate or prevent such shortage; or

3 “(2) expedite an inspection or reinspection of
4 an establishment that could help mitigate or prevent
5 such drug shortage.

6 “(d) COORDINATION.—

7 “(1) TASK FORCE AND STRATEGIC PLAN.—

8 “(A) IN GENERAL.—

9 “(i) TASK FORCE.—As soon as prac-
10 ticable after the date of enactment of the
11 Food and Drug Administration Safety and
12 Innovation Act, the Secretary shall estab-
13 lish a Task Force to develop and imple-
14 ment a strategic plan for enhancing the
15 Secretary’s response to preventing and
16 mitigating drug shortages.

17 “(ii) STRATEGIC PLAN.—The strategic
18 plan described in clause (i) shall include—

19 “(I) plans for enhanced inter-
20 agency and intraagency coordination,
21 communication, and decisionmaking;

22 “(II) plans for ensuring that
23 drug shortages are considered when
24 the Secretary initiates a regulatory
25 action that could precipitate a drug

1 shortage or exacerbate an existing
2 drug shortage;

3 “(III) plans for effective commu-
4 nication with outside stakeholders, in-
5 cluding who the Secretary should alert
6 about potential or actual drug short-
7 ages, how the communication should
8 occur, and what types of information
9 should be shared; and

10 “(IV) plans for considering the
11 impact of drug shortages on research
12 and clinical trials.

13 “(iii) CONSULTATION.—In carrying
14 out this subparagraph, the Task Force
15 shall ensure consultation with the appro-
16 priate offices within the Food and Drug
17 Administration, including the Office of the
18 Commissioner, the Center for Drug Eval-
19 uation and Research, the Office of Regu-
20 latory Affairs, and employees within the
21 Department of Health and Human Serv-
22 ices with expertise regarding drug short-
23 ages. The Secretary shall engage external
24 stakeholders and experts as appropriate.

1 “(B) TIMING.—Not later than 1 year after
2 the date of enactment Food and Drug Adminis-
3 tration Safety and Innovation Act, the Task
4 Force shall—

5 “(i) publish the strategic plan de-
6 scribed in subparagraph (A); and

7 “(ii) submit such plan to Congress.

8 “(2) COMMUNICATION.—The Secretary shall
9 ensure that, prior to any enforcement action or
10 issuance of a warning letter that the Secretary de-
11 termines could reasonably be anticipated to lead to
12 a meaningful disruption in the supply in the United
13 States of a drug described under subsection (a),
14 there is communication with the appropriate office
15 of the Food and Drug Administration with expertise
16 regarding drug shortages regarding whether the ac-
17 tion or letter could cause, or exacerbate, a shortage
18 of the drug.

19 “(3) ACTION.—If the Secretary determines,
20 after the communication described in paragraph (2),
21 that an enforcement action or a warning letter could
22 reasonably cause or exacerbate a shortage of a drug
23 described under subsection (a), then the Secretary
24 shall evaluate the risks associated with the impact of
25 such shortage upon patients and those risks associ-

1 ated with the violation involved before taking such
2 action or issuing such letter, unless there is immi-
3 nent risk of serious adverse health consequences or
4 death to humans.

5 “(4) REPORTING BY OTHER ENTITIES.—The
6 Secretary shall identify or establish a mechanism by
7 which healthcare providers and other third-party or-
8 ganizations may report to the Secretary evidence of
9 a drug shortage.

10 “(5) REVIEW AND CONSTRUCTION.—No deter-
11 mination, finding, action, or omission of the Sec-
12 retary under this subsection shall—

13 “(A) be subject to judicial review; or

14 “(B) be construed to establish a defense to
15 an enforcement action by the Secretary.

16 “(e) RECORDKEEPING AND REPORTING.—

17 “(1) RECORDKEEPING.—The Secretary shall
18 maintain records related to drug shortages, includ-
19 ing with respect to each of the following:

20 “(A) The number of manufacturers that
21 submitted a notification to the Secretary under
22 subsection (a) in each calendar year.

23 “(B) The number of drug shortages that
24 occurred in each calendar year and a list of

1 drug names, drug types, and classes that were
2 the subject of such shortages.

3 “(C) A list of the known factors contrib-
4 uting to the drug shortages described in sub-
5 paragraph (B).

6 “(D)(i) A list of major actions taken by
7 the Secretary to prevent or mitigate the drug
8 shortages described in subparagraph (B).

9 “(ii) The Secretary shall include in the list
10 under clause (i) the following:

11 “(I) The number of applications for
12 which the Secretary expedited review under
13 subsection (c)(1) in each calendar year.

14 “(II) The number of establishment in-
15 spections or reinspections that the Sec-
16 retary expedited under subsection (c)(2) in
17 each calendar year.

18 “(E) The number of notifications sub-
19 mitted to the Secretary under subsection (a) in
20 each calendar year.

21 “(F) The names of manufacturers that the
22 Secretary has learned did not comply with the
23 notification requirement under subsection (a) in
24 each calendar year.

1 “(G) The number of times in each cal-
2 endar year that the Secretary determined under
3 subsection (d)(3) that an enforcement action or
4 a warning letter could reasonably cause or exac-
5 erbate a shortage of a drug described under
6 subsection (a), but did not evaluate the risks
7 associated with the impact of such shortage
8 upon patients and those risks associated with
9 the violation involved before taking such action
10 or issuing such letter on the grounds that there
11 was imminent risk of serious adverse health
12 consequences or death to humans, and a sum-
13 mary of the determinations.

14 “(H) A summary of the communications
15 made and actions taken under subsection (d) in
16 each calendar year.

17 “(I) Any other information the Secretary
18 deems appropriate to better prevent and miti-
19 gate drug shortages.

20 “(2) TREND ANALYSIS.—The Secretary is au-
21 thorized to retain a third party to conduct a study,
22 if the Secretary believes such a study would help
23 clarify the causes, trends, or solutions related to
24 drug shortages.

1 “(3) ANNUAL SUMMARY.—Not later than 18
2 months after the date of enactment of the Food and
3 Drug Administration Safety and Innovation Act, and
4 annually thereafter, the Secretary shall submit to
5 the Committee on Health, Education, Labor, and
6 Pensions of the Senate and the Committee on En-
7 ergy and Commerce of the House of Representatives
8 a report summarizing, with respect to the 1-year pe-
9 riod preceding such report, the information de-
10 scribed in paragraph (1). Such report shall not in-
11 clude any information that is exempt from disclosure
12 under subsection (a) of section 552 of title 5, United
13 States Code, by reason of subsection (b)(4) of such
14 section.

15 “(f) 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 “(B) does not include biological products
20 (as defined in section 351 of the Public Health
21 Service Act), unless otherwise provided by the
22 Secretary in the regulations promulgated under
23 subsection (h);

24 “(2) the term ‘drug shortage’ or ‘shortage’,
25 with respect to a drug, means a period of time when

1 the demand or projected demand for the drug within
2 the United States exceeds the supply of the drug;
3 and

4 “(3) the term ‘meaningful disruption’—

5 “(A) means a change in production that is
6 reasonably likely to lead to a reduction in the
7 supply of a drug by a manufacturer that is
8 more than negligible and impacts the ability of
9 the manufacturer to fill orders or meet expected
10 demand for its product; and

11 “(B) does not include interruptions in
12 manufacturing due to matters such as routine
13 maintenance or insignificant changes in manu-
14 facturing so long as the manufacturer expects
15 to resume operations in a short period of time.

16 “(g) DISTRIBUTION.—To the maximum extent prac-
17 ticable, the Secretary may distribute information on drug
18 shortages and on the permanent discontinuation of the
19 drugs described in this section to appropriate provider and
20 patient organizations, except that any such distribution
21 shall not include any information that is exempt from dis-
22 closure under section 552 of title 5, United States Code,
23 by reason of subsection (b)(4) of such section.

24 “(h) REGULATIONS.—

1 “(1) IN GENERAL.—Not later than 18 months
2 after the date of enactment of the Food and Drug
3 Administration Safety and Innovation Act, the Sec-
4 retary shall adopt a final regulation implementing
5 this section.

6 “(2) INCLUSION OF BIOLOGICAL PRODUCTS.—

7 “(A) IN GENERAL.—The Secretary may by
8 regulation apply this section to biological prod-
9 ucts (as defined in section 351 of the Public
10 Health Service Act) if the Secretary determines
11 such inclusion would benefit the public health.

12 “(B) RULE FOR VACCINES.—If the Sec-
13 retary applies this section to vaccines pursuant
14 to subparagraph (A), the Secretary shall—

15 “(i) consider whether the notification
16 requirement under subsection (a) may be
17 satisfied by submitting a notification to the
18 Centers for Disease Control and Preven-
19 tion under the vaccine shortage notification
20 program of such Centers; and

21 “(ii) explain the determination made
22 by the Secretary under clause (i) in the
23 regulation.

24 “(3) PROCEDURE.—In promulgating a regula-
25 tion implementing this section, the Secretary shall—

1 “(A) issue a notice of proposed rulemaking
2 that includes the proposed regulation;

3 “(B) provide a period of not less than 60
4 days for comments on the proposed regulation;
5 and

6 “(C) publish the final regulation not less
7 than 30 days before the regulation’s effective
8 date.

9 “(4) RESTRICTIONS.—Notwithstanding any
10 other provision of Federal law, in implementing this
11 section, the Secretary shall only promulgate regula-
12 tions as described in paragraph (3).”.

13 (b) EFFECT OF NOTIFICATION.—The submission of
14 a notification to the Secretary of Health and Human Serv-
15 ices (referred to in this section as the “Secretary”) for
16 purposes of complying with the requirement in section
17 506C(a) of the Federal Food, Drug, and Cosmetic Act (as
18 amended by subsection (a)) shall not be construed—

19 (1) as an admission that any product that is
20 the subject of such notification violates any provision
21 of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 301 et seq.); or

23 (2) as evidence of an intention to promote or
24 market the product for an indication or use for

1 which the product has not been approved by the Sec-
2 retary.

3 (c) INTERNAL REVIEW.—Not later than 2 years after
4 the date of enactment of this Act, the Secretary shall—

5 (1) analyze and review the regulations promul-
6 gated under the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 301 et seq.), the guidances or poli-
8 cies issued under such Act related to drugs intended
9 for human use, and the practices of the Food and
10 Drug Administration regarding enforcing such Act
11 related to manufacturing of such drugs, to identify
12 any such regulations, guidances, policies, or prac-
13 tices that cause, exacerbate, prevent, or mitigate
14 drug shortages (as defined in section 506C of the
15 Federal Food, Drug, and Cosmetic Act (as amended
16 by subsection (a)); and

17 (2) determine how regulations, guidances, poli-
18 cies, or practices identified under paragraph (1)
19 should be modified, streamlined, expanded, or dis-
20 continued in order to reduce or prevent such drug
21 shortages, taking into consideration the effect of any
22 changes on the public health.

23 (d) STUDY ON MARKET FACTORS CONTRIBUTING TO
24 DRUG SHORTAGES AND STOCKPILING.—

1 (1) IN GENERAL.—Not later than 1 year after
2 the date of enactment of this Act, the Comptroller
3 General of the United States, in consultation with
4 the Secretary, the Department of Health and
5 Human Services Office of the Inspector General, the
6 Attorney General, and Chairman of the Federal
7 Trade Commission, shall publish a report reviewing
8 any findings that drug shortages (as so defined)
9 have led market participants to stockpile affected
10 drugs or sell them at significantly increased prices,
11 the impact of such activities on Federal revenue, and
12 any economic factors that have exacerbated or cre-
13 ated a market for such actions.

14 (2) CONTENT.—The report under paragraph
15 (1) shall include—

16 (A) an analysis of the incidence of any of
17 the activities described in paragraph (1) and
18 the effect of such activities on the public health;

19 (B) an evaluation of whether in such cases
20 there is a correlation between drugs in shortage
21 and—

22 (i) the number of manufacturers pro-
23 ducing such drugs;

24 (ii) the pricing structure, including
25 Federal reimbursements, for such drugs

1 before such drugs were in shortage, and to
2 the extent possible, revenue received by
3 each such manufacturer of such drugs;

4 (iii) pricing structure and revenue, to
5 the extent possible, for the same drugs
6 when sold under the conditions described
7 in paragraph (1); and

8 (iv) the impact of contracting prac-
9 tices by market participants (including
10 manufacturers, distributors, group pur-
11 chasing organizations, and providers) on
12 competition, access to drugs, and pricing
13 of drugs;

14 (C) whether the activities described in
15 paragraph (1) are consistent with applicable
16 law; and

17 (D) recommendations to Congress on what,
18 if any, additional reporting or enforcement ac-
19 tions are necessary.

20 (3) TRADE SECRET AND CONFIDENTIAL INFOR-
21 MATION.—Nothing in this subsection alters or
22 amends section 1905 of title 18, United States Code,
23 or section 552(b)(4) of title 5, United States Code.

24 (e) GUIDANCE REGARDING REPACKAGING.—Not
25 later than 1 year after the date of enactment of this Act,

1 the Secretary shall issue guidance that clarifies the policy
2 of the Food and Drug Administration regarding hospital
3 pharmacies repackaging and safely transferring repack-
4 aged drugs among hospitals within a common health sys-
5 tem during a drug shortage, as identified by the Secretary.

6 **TITLE XI—OTHER PROVISIONS**

7 **Subtitle A—Reauthorizations**

8 **SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO** 9 **EXCLUSIVITY OF CERTAIN DRUGS CON-** 10 **TAINING SINGLE ENANTIOMERS.**

11 (a) IN GENERAL.—Section 505(u)(4) (21 U.S.C.
12 355(u)(4)) is amended by striking “2012” and inserting
13 “2017”.

14 (b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21
15 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting
16 “clinical” after “any”.

17 **SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH** 18 **PUBLIC-PRIVATE PARTNERSHIPS.**

19 Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended
20 by striking “2012” and inserting “2017”.

21 **Subtitle B—Medical Gas Product** 22 **Regulation**

23 **SEC. 1111. REGULATION OF MEDICAL GAS PRODUCTS.**

24 (a) REGULATION.—Chapter V (21 U.S.C. 351 et
25 seq.) is amended by adding at the end the following:

1 **“Subchapter G—Medical Gas Products**

2 **“SEC. 575. DEFINITIONS.**

3 “In this subchapter:

4 “(1) The term ‘designated medical gas product’
5 means 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 product
21 deemed appropriate by the Secretary, unless
22 any period of exclusivity under section
23 505(c)(3)(E)(ii) or 505(j)(5)(F)(ii), or the ex-
24 tension of any such period under section 505A,

1 applicable to such medical gas product has not
2 expired.

3 “(2) The term ‘medical gas product’ means a
4 drug that—

5 “(A) is manufactured or stored in a lique-
6 fied, nonliquefied, or cryogenic state; and

7 “(B) is administered as a gas.

8 **“SEC. 576. REGULATION OF MEDICAL GAS PRODUCTS.**

9 “(a) CERTIFICATION OF DESIGNATED MEDICAL GAS
10 PRODUCTS.—

11 “(1) SUBMISSION.—

12 “(A) IN GENERAL.—Beginning on the date
13 of enactment of this section, any person may
14 file with the Secretary a request for a certifi-
15 cation of a designated medical gas product.

16 “(B) CONTENT.—A request under sub-
17 paragraph (A) shall contain—

18 “(i) a description of the medical gas
19 product;

20 “(ii) the name and address of the
21 sponsor;

22 “(iii) the name and address of the fa-
23 cility or facilities where the gas product is
24 or will be manufactured; and

1 “(iv) any other information deemed
2 appropriate by the Secretary to determine
3 whether the medical gas product is a des-
4 ignated medical gas product.

5 “(2) GRANT OF CERTIFICATION.—A certifi-
6 cation described under paragraph (1)(A) shall be de-
7 termined to have been granted unless, not later than
8 60 days after the filing of a request under para-
9 graph (1), the Secretary finds that—

10 “(A) the medical gas product subject to
11 the certification is not a designated medical gas
12 product;

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 gas product is
17 a designated medical gas product; or

18 “(C) granting the request would be con-
19 trary to public health.

20 “(3) EFFECT OF CERTIFICATION.—

21 “(A) IN GENERAL.—

22 “(i) APPROVED USES.—A designated
23 medical gas product for which a certifi-
24 cation is granted under paragraph (2) is
25 deemed, alone or in combination with an-

1 other designated gas product or products
2 as medically appropriate, to have in effect
3 an approved application under section 505
4 or 512, subject to all applicable post-
5 approval requirements, for the following in-
6 dications for use:

7 “(I) Oxygen for the treatment or
8 prevention of hypoxemia or hypoxia.

9 “(II) Nitrogen for use in hypoxic
10 challenge testing.

11 “(III) Nitrous oxide for analge-
12 sia.

13 “(IV) Carbon dioxide for use in
14 extracorporeal membrane oxygenation
15 therapy or respiratory stimulation.

16 “(V) Helium for the treatment of
17 upper airway obstruction or increased
18 airway resistance.

19 “(VI) Medical air to reduce the
20 risk of hyperoxia.

21 “(VII) Carbon monoxide for use
22 in lung diffusion testing.

23 “(VIII) Any other indication for
24 use for a designated medical gas prod-
25 uct or combination of designated med-

1 ical gas products deemed appropriate
2 by the Secretary, unless any period of
3 exclusivity under clause (iii) or (iv) of
4 section 505(c)(3)(E), under clause
5 (iii) or (iv) of section 505(j)(5)(F), or
6 under section 527, or the extension of
7 any such period under section 505A,
8 applicable to such indication for use
9 for such gas product or combination
10 of products has not expired.

11 “(ii) LABELING.—The requirements
12 established in sections 503(b)(4) and
13 502(f) shall be deemed to have been met
14 for a designated medical gas product if the
15 labeling on final use containers of such gas
16 product bears the information required by
17 section 503(b)(4) and a warning statement
18 concerning the use of the gas product, as
19 determined by the Secretary by regulation,
20 as well as appropriate directions and warn-
21 ings concerning storage and handling.

22 “(B) INAPPLICABILITY OF EXCLUSIVITY
23 PROVISIONS.—

24 “(i) EFFECT ON INELIGIBILITY.—No
25 designated medical gas product deemed

1 under paragraph (3)(A)(i) to have in effect
2 an approved application shall be eligible for
3 any periods of exclusivity under sections
4 505(c), 505(j), or 527, or the extension of
5 any such period under section 505A, on
6 the basis of such deemed approval.

7 “(ii) EFFECT ON CERTIFICATION.—

8 No period of exclusivity under sections
9 505(c), 505(j), or section 527, or the ex-
10 tension of any such period under section
11 505A, with respect to an application for a
12 drug shall prohibit, limit, or otherwise af-
13 fect the submission, grant, or effect of a
14 certification under this section, except as
15 provided in paragraph (3)(A)(i)(VIII).

16 “(4) WITHDRAWAL, SUSPENSION, OR REVOCA-
17 TION OF APPROVAL.—

18 “(A) IN GENERAL.—Nothing in this sub-
19 chapter limits the authority of the Secretary to
20 withdraw or suspend approval of a drug, includ-
21 ing a designated medical gas product deemed
22 under this section to have in effect an approved
23 application, under section 505 or section 512.

24 “(B) REVOCATION.—The Secretary may
25 revoke the grant of a certification under this

1 section if the Secretary determines that the re-
2 quest for certification contains any material
3 omission or falsification.

4 “(b) PRESCRIPTION REQUIREMENT.—

5 “(1) IN GENERAL.—A designated medical gas
6 product shall be subject to section 503(b)(1) unless
7 the Secretary exercises the authority provided in sec-
8 tion 503(b)(3) to remove such gas product from the
9 requirements of section 503(b)(1) or the use in ques-
10 tion is authorized pursuant to another provision of
11 this Act relating to use of medical products in emer-
12 gencies.

13 “(2) EXCEPTION FOR OXYGEN.—

14 “(A) IN GENERAL.—Notwithstanding para-
15 graph (1), oxygen may be provided without a
16 prescription for the following uses:

17 “(i) The use in the event of depres-
18 surization or other environmental oxygen
19 deficiency.

20 “(ii) The use in the event of oxygen
21 deficiency or use in emergency resuscita-
22 tion, when administered by properly
23 trained personnel.

24 “(B) LABELING.—For oxygen provided
25 pursuant to subparagraph (A), the require-

1 ments established in section 503(b)(4) shall be
2 deemed to have been met if the labeling of the
3 oxygen bears a warning that the medical gas
4 product can be used for emergency use only and
5 for all other medical applications a prescription
6 is required.

7 “(c) **INAPPLICABILITY OF DRUGS FEES TO DES-**
8 **IGNATED MEDICAL GAS PRODUCTS.**—A designated med-
9 ical gas product deemed under this section to have in ef-
10 fect an approved application shall not be assessed fees
11 under section 736(a) on the basis of such deemed ap-
12 proval.”.

13 **SEC. 1112. REGULATIONS.**

14 (a) **REVIEW OF REGULATIONS.**—Not later than 18
15 months after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services (referred to in this
17 section as the “Secretary”) shall, after obtaining input
18 from medical gas product manufacturers, and any other
19 interested members of the public, submit a report to the
20 Committee on Health, Education, Labor, and Pensions of
21 the Senate and the Committee on Energy and Commerce
22 of the House of Representatives regarding any changes to
23 the Federal drug regulations in title 21, Code of Federal
24 Regulations that the Secretary determines to be necessary.

1 (b) AMENDED REGULATIONS.—If the Secretary de-
2 termines that changes to the Federal drug regulations in
3 title 21, Code of Federal Regulations are necessary under
4 subsection (a), the Secretary shall issue final regulations
5 implementing such changes not later than 4 years after
6 the date of enactment of this Act.

7 **SEC. 1113. APPLICABILITY.**

8 Nothing in this subtitle or the amendments made by
9 this subtitle shall apply to—

10 (1) a drug that is covered by an application
11 under section 505 or 512 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355, 360b) ap-
13 proved prior to May 1, 2012; or

14 (2) any of the gases listed in subparagraphs (A)
15 through (G) of section 575(1) of such Act (as added
16 by section 1111), or any mixture of any such gases,
17 for an indication that—

18 (A) is not included in, or is different from,
19 those specified in subclauses (I) through (VII)
20 of section 576(a)(3)(i) of such Act (as added by
21 section 1111); and

22 (B) is approved on or after May 1, 2012,
23 pursuant to an application submitted under sec-
24 tion 505 or 512 of such Act.

1 **Subtitle C—Miscellaneous**
2 **Provisions**

3 **SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTER-**
4 **EST.**

5 Section 712 (21 U.S.C. 379d–1) is amended—

6 (1) in subsection (b)—

7 (A) by striking paragraph (2); and

8 (B) in paragraph (1)—

9 (i) by redesignating subparagraph (B)
10 as paragraph (2) and moving such para-
11 graph, as so redesignated, 2 ems to the
12 left;

13 (ii) in subparagraph (A), by redesi-
14 gnating clauses (i) through (iii) as subpara-
15 graphs (A) through (C), respectively, and
16 moving such subparagraphs, as so redesi-
17 gnated, 2 ems to the left;

18 (iii) in subparagraph (A), as so redesi-
19 gnated, by inserting “, including strategies
20 to increase the number of special Govern-
21 ment employees across medical and sci-
22 entific specialties in areas where the Sec-
23 retary would benefit from specific sci-
24 entific, medical, or technical expertise nec-
25 essary for the performance of its regu-

1 latory responsibilities” before the semicolon
2 at the end;

3 (iv) by striking “(1) RECRUITMENT.—
4 ” and inserting “(1) RECRUITMENT IN
5 GENERAL.—The Secretary shall—”;

6 (v) by striking “(A) IN GENERAL.—
7 The Secretary shall—”;

8 (vi) by redesignating clauses (i)
9 through (iii) of paragraph (2) (as so redesi-
10 gnated) as subparagraphs (A) through
11 (C), respectively, and moving such sub-
12 paragraphs, as so redesignated, 2 ems to
13 the left;

14 (vii) in paragraph (2) (as so redesign-
15 nated), in the matter before subparagraph
16 (A) (as so redesignated), by striking “sub-
17 paragraph (A)” and inserting “paragraph
18 (1)”;

19 (viii) by adding at the end the fol-
20 lowing:

21 “(3) RECRUITMENT THROUGH REFERRALS.—In
22 carrying out paragraph (1), the Secretary shall, in
23 order to further the goal of including in advisory
24 committees highly qualified and specialized experts
25 in the specific diseases to be considered by such ad-

1 visory committees, at least every 180 days, request
2 referrals from a variety of stakeholders, such as the
3 Institute of Medicine, the National Institutes of
4 Health, product developers, patient groups, disease
5 advocacy organizations, professional societies, med-
6 ical societies, including the American Academy of
7 Medical Colleges, and other governmental organiza-
8 tions.”;

9 (2) by amending subsection (e)(2)(C) to read as
10 follows:

11 “(C) CONSIDERATION BY SECRETARY.—

12 The Secretary shall ensure that each determina-
13 tion made under subparagraph (B) considers
14 the type, nature, and magnitude of the financial
15 interests at issue and the public health interest
16 in having the expertise of the member with re-
17 spect to the particular matter before the advi-
18 sory committee.”;

19 (3) in subsection (e), by inserting “, and shall
20 make publicly available,” after “House of Represent-
21 atives”; and

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

23 “(g) GUIDANCE ON REPORTED FINANCIAL INTEREST
24 OR INVOLVEMENT.—The Secretary shall issue guidance
25 that describes how the Secretary reviews the financial in-

1 terests and involvement of advisory committee members
 2 that are reported under subsection (c)(1) but that the Sec-
 3 retary determines not to meet the definition of a disquali-
 4 fying interest under section 208 of title 18, United States
 5 Code for the purposes of participating in a particular mat-
 6 ter.”.

7 **SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT**
 8 **PROMOTION USING THE INTERNET.**

9 Not later than 2 years after the date of enactment
 10 this Act, the Secretary of Health and Human Services
 11 shall issue guidance that describes Food and Drug Admin-
 12 istration policy regarding the promotion, using the Inter-
 13 net (including social media), of medical products that are
 14 regulated by such Administration.

15 **SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.**

16 Subchapter D of chapter VII (21 U.S.C. 379k et
 17 seq.) is amended by inserting after section 745 the fol-
 18 lowing:

19 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

20 **“(a) DRUGS AND BIOLOGICS.—**

21 **“(1) IN GENERAL.—**Beginning no earlier than
 22 24 months after the issuance of a final guidance
 23 issued after public notice and opportunity for com-
 24 ment, submissions under subsection (b), (i), or (j) of
 25 section 505 of this Act or subsection (a) or (k) of

1 section 351 of the Public Health Service Act shall
2 be submitted in such electronic format as specified
3 by the Secretary in such guidance.

4 “(2) GUIDANCE CONTENTS.—In the guidance
5 under paragraph (1), the Secretary may—

6 “(A) provide a timetable for establishment
7 by the Secretary of further standards for elec-
8 tronic submission as required by such para-
9 graph; and

10 “(B) set forth criteria for waivers of and
11 exemptions from the requirements of this sub-
12 section.

13 “(3) EXCEPTION.—This subsection shall not
14 apply to submissions described in section 561.

15 “(b) DEVICES.—

16 “(1) IN GENERAL.—Beginning after the
17 issuance of final guidance implementing this para-
18 graph, pre-submissions and submissions for devices
19 under section 510(k), 513(f)(2)(A), 515(c), 515(d),
20 515(f), 520(g), 520(m), or 564 of this Act or section
21 351 of the Public Health Service Act, and any sup-
22 plements to such pre-submissions or submissions,
23 shall include an electronic copy of such pre-submis-
24 sions or submissions.

1 “(2) GUIDANCE CONTENTS.—In the guidance
2 under paragraph (1), the Secretary may—

3 “(A) provide standards for the electronic
4 copy required under such paragraph; and

5 “(B) set forth criteria for waivers of and
6 exemptions from the requirements of this sub-
7 section.”.

8 **SEC. 1124. COMBATING PRESCRIPTION DRUG ABUSE.**

9 (a) IN GENERAL.—To combat the significant rise in
10 prescription drug abuse and the consequences of such
11 abuse, the Secretary of Health and Human Services (re-
12 ferred to in this section as the “Secretary”), acting
13 through the Commissioner of Food and Drugs (referred
14 to in this section as the “Commissioner”) and in coordina-
15 tion with other Federal agencies, as appropriate, shall re-
16 view current Federal initiatives and identify gaps and op-
17 portunities with respect to ensuring the safe use of pre-
18 scription drugs with the potential for abuse.

19 (b) REPORT.—Not later than 1 year after the date
20 of enactment of this Act, the Secretary shall issue a report
21 to Congress on the findings of the review under subsection

22 (a). Such report shall include recommendations on—

23 (1) how best to leverage and build upon existing
24 Federal and federally funded data sources, such as
25 prescription drug monitoring program data and the

1 sentinel initiative of the Food and Drug Administra-
2 tion under section 505(k)(3) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as
4 it relates to collection of information relevant to ad-
5 verse events, patient safety, and patient outcomes, to
6 create a centralized data clearinghouse and early
7 warning tool;

8 (2) how best to develop and disseminate widely
9 best practices models and suggested standard re-
10 quirements to States for achieving greater interoper-
11 ability and effectiveness of prescription drug moni-
12 toring programs, especially with respect to producing
13 standardized data on adverse events, patient safety,
14 and patient outcomes; and

15 (3) how best to develop provider and patient
16 education tools and a strategy to widely disseminate
17 such tools and assess the efficacy of such tools.

18 (c) GUIDANCE ON TAMPER-DETERRENT PROD-
19 UCTS.—Not later than 6 months after the date of enact-
20 ment of this Act, the Secretary, acting through the Com-
21 missioner, shall promulgate guidance on the development
22 of tamper-deterrent drug products.

23 **SEC. 1125. TANNING BED LABELING.**

24 Not later than 18 months after the date of enactment
25 of this Act, the Secretary of Health and Human Services

1 shall determine whether to amend the warning label re-
2 quirements for sunlamp products to include specific re-
3 quirements to more clearly and effectively convey the risks
4 that such products pose for the development of irreversible
5 damage to the eyes and skin, including skin cancer.

6 **SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.**

7 Subchapter E of chapter V (21 U.S.C. 360bbb et
8 seq.), as amended by section 903, is further amended by
9 adding at the end the following:

10 **“SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.**

11 “(a) IN GENERAL.—The Secretary shall—

12 “(1) work with other regulatory authorities of
13 similar standing, medical research companies, and
14 international organizations to foster and encourage
15 uniform, scientifically-driven clinical trial standards
16 with respect to medical products around the world;
17 and

18 “(2) enhance the commitment to provide con-
19 sistent parallel scientific advice to manufacturers
20 seeking simultaneous global development of new
21 medical products in order to—

22 “(A) enhance medical product develop-
23 ment;

24 “(B) facilitate the use of foreign data; and

1 “(C) minimize the need to conduct duplica-
2 tive clinical studies, preclinical studies, or non-
3 clinical studies.

4 “(b) MEDICAL PRODUCT.—In this section, the term
5 ‘medical product’ means a drug, as defined in subsection
6 (g) of section 201, a device, as defined in subsection (h)
7 of such section, or a biological product, as defined in sec-
8 tion 351(i) of the Public Health Service Act.

9 “(c) SAVINGS CLAUSE.—Nothing in this section shall
10 alter the criteria for evaluating the safety or effectiveness
11 of a medical product under this Act.

12 **“SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM**
13 **OUTSIDE THE UNITED STATES.**

14 “(a) IN GENERAL.—In determining whether to ap-
15 prove, license, or clear a drug or device pursuant to an
16 application submitted under this chapter, the Secretary
17 shall accept data from clinical investigations conducted
18 outside of the United States, including the European
19 Union, if the applicant demonstrates that such data are
20 adequate under applicable standards to support approval,
21 licensure, or clearance of the drug or device in the United
22 States.

23 “(b) NOTICE TO SPONSOR.—If the Secretary finds
24 under subsection (a) that the data from clinical investiga-
25 tions conducted outside the United States, including in the

1 European Union, are inadequate for the purpose of mak-
2 ing a determination on approval, clearance, or licensure
3 of a drug or device pursuant to an application submitted
4 under this chapter, the Secretary shall provide written no-
5 tice to the sponsor of the application of such finding and
6 include the rationale for such finding.”.

7 **SEC. 1127. ADVANCING REGULATORY SCIENCE TO PRO-**
8 **MOTE PUBLIC HEALTH INNOVATION.**

9 (a) IN GENERAL.—Not later than 1 year after the
10 date of enactment of this Act, the Secretary of Health and
11 Human Services (referred to in this section as the “Sec-
12 retary”) shall develop a strategy and implementation plan
13 for advancing regulatory science for medical products in
14 order to promote the public health and advance innovation
15 in regulatory decisionmaking.

16 (b) REQUIREMENTS.—The strategy and implementa-
17 tion plan developed under subsection (a) shall be con-
18 sistent with the user fee performance goals in the Pre-
19 scription Drug User Fee Agreement commitment letter,
20 the Generic Drug User Fee Agreement commitment letter,
21 and the Biosimilar User Fee Agreement commitment let-
22 ter transmitted by the Secretary to Congress on January
23 13, 2012, and the Medical Device User Fee Agreement
24 commitment letter transmitted by the Secretary to Con-
25 gress on April 20, 2012, and shall—

1 (1) identify a clear vision of the fundamental
2 role of efficient, consistent, and predictable, science-
3 based decisions throughout regulatory decision-
4 making of the Food and Drug Administration with
5 respect to medical products;

6 (2) identify the regulatory science priorities of
7 the Food and Drug Administration directly related
8 to fulfilling the mission of the agency with respect
9 to decisionmaking concerning medical products and
10 allocation of resources towards such regulatory
11 science priorities;

12 (3) identify regulatory and scientific gaps that
13 impede the timely development and review of, and
14 regulatory certainty with respect to, the approval, li-
15 censure, or clearance of medical products, including
16 with respect to companion products and new tech-
17 nologies, and facilitating the timely introduction and
18 adoption of new technologies and methodologies in a
19 safe and effective manner;

20 (4) identify clear, measurable metrics by which
21 progress on the priorities identified under paragraph
22 (2) and gaps identified under paragraph (3) will be
23 measured by the Food and Drug Administration, in-
24 cluding metrics specific to the integration and adop-
25 tion of advances in regulatory science described in

1 paragraph (5) and improving medical product deci-
2 sionmaking, in a predictable and science-based man-
3 ner; and

4 (5) set forth how the Food and Drug Adminis-
5 tration will ensure that advances in regulatory
6 science for medical products are adopted, as appro-
7 priate, on an ongoing basis and in an manner inte-
8 grated across centers, divisions, and branches of the
9 Food and Drug Administration, including by senior
10 managers and reviewers, including through the—

11 (A) development, updating, and consistent
12 application of guidance documents that support
13 medical product decisionmaking; and

14 (B) the adoption of the tools, methods, and
15 processes under section 566 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C.
17 360bbb-5).

18 (c) ANNUAL PERFORMANCE REPORTS.—As part of
19 the annual performance reports submitted to Congress
20 under sections 736B(a) (as amended by section 104),
21 738A(a) (as amended by section 204), 744C(a) (as added
22 by section 303), and 744I(a) (as added by section 403)
23 of the Federal Food, Drug, and Cosmetic Act for each
24 of fiscal years 2013 through 2017, the Secretary shall an-
25 nually report on the progress made with respect to—

1 (1) advancing the regulatory science priorities
2 identified under paragraph (2) of subsection (b) and
3 resolving the gaps identified under paragraph (3) of
4 such subsection, including reporting on specific
5 metrics identified under paragraph (4) of such sub-
6 section;

7 (2) the integration and adoption of advances in
8 regulatory science as set forth in paragraph (5) of
9 such subsection; and

10 (3) the progress made in advancing the regu-
11 latory science goals outlined in the Prescription
12 Drug User Fee Agreement commitment letter, the
13 Generic Drug User Fee Agreement commitment let-
14 ter, and the Biosimilar User Fee Agreement commit-
15 ment letter transmitted by the Secretary to Congress
16 on January 13, 2012, and the Medical Device User
17 Fee Agreement transmitted by the Secretary to Con-
18 gress on April 20, 2012.

19 (d) INDEPENDENT ASSESSMENT.—Not later than
20 January 1, 2016, the Comptroller General of the United
21 States shall submit to Congress a report—

22 (1) detailing the progress made by the Food
23 and Drug Administration in meeting the priorities
24 and addressing the gaps identified in subsection (b),
25 including any outstanding gaps; and

1 (2) containing recommendations, as appro-
2 priate, on how regulatory science initiatives for med-
3 ical products can be strengthened and improved to
4 promote the public health and advance innovation in
5 regulatory decisionmaking.

6 (e) **MEDICAL PRODUCT.**—In this section, the term
7 “medical product” means a drug, as defined in subsection
8 (g) of section 201 of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 321), a device, as defined in sub-
10 section (h) of such section, or a biological product, as de-
11 fined in section 351(i) of the Public Health Service Act.

12 **SEC. 1128. INFORMATION TECHNOLOGY.**

13 (a) **HHS REPORT.**—Not later than 1 year after the
14 date of enactment of this Act, the Secretary of Health and
15 Human Services shall—

16 (1) report to Congress on—

17 (A) the milestones and a completion date
18 for developing and implementing a comprehen-
19 sive information technology strategic plan to
20 align the information technology systems mod-
21 ernization projects with the strategic goals of
22 the Food and Drug Administration, including
23 results-oriented goals, strategies, milestones,
24 performance measures;

1 (B) efforts to finalize and approve a com-
2 prehensive inventory of the information tech-
3 nology systems of the Food and Drug Adminis-
4 tration that includes information describing
5 each system, such as costs, system function or
6 purpose, and status information, and incor-
7 porate use of the system portfolio into the in-
8 formation investment management process of
9 the Food and Drug Administration;

10 (C) the ways in which the Food and Drug
11 Administration uses the plan described in sub-
12 paragraph (A) to guide and coordinate the
13 modernization projects and activities of the
14 Food and Drug Administration, including the
15 interdependencies among projects and activities;
16 and

17 (D) the extent to which the Food and
18 Drug Administration has fulfilled or is imple-
19 menting recommendations of the Government
20 Accountability Office with respect to the Food
21 and Drug Administration and information tech-
22 nology; and

23 (2) develop—

24 (A) a documented enterprise architecture
25 program management plan that includes the

1 tasks, activities, and timeframes associated with
2 developing and using the architecture and ad-
3 dresses how the enterprise architecture program
4 management will be performed in coordination
5 with other management disciplines, such as or-
6 ganizational strategic planning, capital planning
7 and investment control, and performance man-
8 agement; and

9 (B) a skills inventory, needs assessment,
10 gap analysis, and initiatives to address skills
11 gaps as part of a strategic approach to informa-
12 tion technology human capital planning.

13 (b) GAO REPORT.—Not later than January 1, 2016,
14 the Comptroller General of the United States shall issue
15 a report regarding the strategic plan described in sub-
16 section (a)(1)(A) and related actions carried out by the
17 Food and Drug Administration. Such report shall assess
18 the progress the Food and Drug Administration has made
19 on—

20 (1) the development and implementation of a
21 comprehensive information technology strategic plan,
22 including the results-oriented goals, strategies, mile-
23 stones, and performance measures identified in sub-
24 section (a)(1)(A);

1 (2) the effectiveness of the comprehensive infor-
2 mation technology strategic plan described in sub-
3 section (a)(1)(A), including the results-oriented
4 goals and performance measures; and

5 (3) the extent to which the Food and Drug Ad-
6 ministration has fulfilled recommendations of the
7 Government Accountability Office with respect to
8 such agency and information technology.

9 **SEC. 1129. REPORTING REQUIREMENTS.**

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

13 **“SEC. 715. REPORTING REQUIREMENTS.**

14 “(a) NEW DRUGS.—Beginning with fiscal year 2013
15 and ending with fiscal year 2017, not later than 120 days
16 after the end of each fiscal year for which fees are col-
17 lected under part 2 of subchapter C, the Secretary shall
18 prepare and submit to the Committee on Health Edu-
19 cation, Labor, and Pensions of the Senate and the Com-
20 mittee on Energy and Commerce of the House of Rep-
21 resentatives a report concerning, for all applications for
22 approval of a new drug under section 505(b) of this Act
23 or a new biological product under section 351(a) of the
24 Public Health Service Act filed in the previous fiscal
25 year—

1 “(1) the number of such applications that met
2 the goals identified for purposes of part 2 of sub-
3 chapter C in the letters from the Secretary of
4 Health and Human Services to the Chairman of the
5 Committee on Health, Education, Labor, and Pen-
6 sions of the Senate and the Chairman of the Com-
7 mittee on Energy and Commerce of the House of
8 Representatives, as set forth in the Congressional
9 Record;

10 “(2) the percentage of such applications that
11 were approved;

12 “(3) the percentage of such applications that
13 were issued complete response letters;

14 “(4) the percentage of such applications that
15 were subject to a refuse-to-file action;

16 “(5) the percentage of such applications that
17 were withdrawn; and

18 “(6) the average total time to decision by the
19 Secretary for all applications for approval of a new
20 drug under section 505(b) of this Act or a new bio-
21 logical product under section 351(a) of the Public
22 Health Service Act filed in the previous fiscal year,
23 including the number of calendar days spent during
24 the review by the Food and Drug Administration

1 and the number of calendar days spent by the spon-
2 sor responding to a complete response letter.”.

3 “(b) GENERIC DRUGS.—Beginning with fiscal year
4 2013 and ending after fiscal year 2017, not later than
5 120 days after the end of each fiscal year for which fees
6 are collected under part 7 of subchapter C, the Secretary
7 shall prepare and submit to the Committee on Health
8 Education, Labor, and Pensions of the Senate and the
9 Committee on Energy and Commerce of the House of
10 Representatives a report concerning, for all applications
11 for approval of a generic drug under section 505(j),
12 amendments to such applications, and prior approval sup-
13 plements with respect to such applications filed in the pre-
14 vious fiscal year—

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

24 “(2) the average total time to decision by the
25 Secretary for applications for approval of a generic

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

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

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

20 “(c) BIOSIMILAR BIOLOGICAL PRODUCTS.—

21 “(1) IN GENERAL.—Beginning with fiscal year
22 2014, not later than 120 days after the end of each
23 fiscal year for which fees are collected under part 8
24 of subchapter C, the Secretary shall prepare and
25 submit to the Committee on Health Education,

1 Labor, and Pensions of the Senate and the Com-
2 mittee on Energy and Commerce of the House of
3 Representatives a report concerning—

4 “(A) the number of applications for ap-
5 proval filed under section 351(k) of the Public
6 Health Service Act; and

7 “(B) the percentage of applications de-
8 scribed in subparagraph (A) that were approved
9 by the Secretary.

10 “(2) ADDITIONAL INFORMATION.—As part of
11 the performance report described in paragraph (1),
12 the Secretary shall include an explanation of how the
13 Food and Drug Administration is managing the bio-
14 logical product review program to ensure that the
15 user fees collected under part 2 are not used to re-
16 view an application under section 351(k) of the Pub-
17 lic Health Service Act.”.

18 **SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.**

19 (a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—
20 Not later than 1 year after the date of enactment of this
21 Act, the Secretary of Health and Human Services (re-
22 ferred to in this section as the “Secretary”) shall submit
23 to Congress a strategic integrated management plan for
24 the Center for Drug Evaluation and Research, the Center
25 for Biologics Evaluation and Research, and the Center for

1 Devices and Radiological Health. Such strategic manage-
2 ment plan shall—

3 (1) identify strategic institutional goals and pri-
4 orities for the Center for Drug Evaluation and Re-
5 search, the Center for Biologics Evaluation and Re-
6 search, and the Center for Devices and Radiological
7 Health;

8 (2) describe the actions the Secretary will take
9 to recruit, retain, train, and continue to develop the
10 workforce at the Center for Drug Evaluation and
11 Research, the Center for Biologics Evaluation and
12 Research, and the Center for Devices and Radio-
13 logical Health to fulfill the public health mission of
14 the Food and Drug Administration; and

15 (3) identify results-oriented, outcome-based
16 measures that the Secretary will use to measure the
17 progress of achieving the strategic goals and prior-
18 ities identified under paragraph (1) and the effec-
19 tiveness of the actions identified under paragraph
20 (2), including metrics to ensure that managers and
21 reviewers of the Center for Drug Evaluation and Re-
22 search, the Center for Biologics Evaluation and Re-
23 search, and the Center for Devices and Radiological
24 Health are familiar with and appropriately and con-
25 sistently apply the requirements under the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
2 seq.), including new requirements under parts 2, 3,
3 7, and 8 of subchapter C of title VII of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379f et
5 seq.).

6 (b) REPORT.—Not later than January 1, 2016, the
7 Comptroller General of the United States shall issue a re-
8 port regarding the strategic management plan described
9 in subsection (a) and related actions carried out by the
10 Food and Drug Administration. Such report shall—

11 (1) assess the effectiveness of the actions de-
12 scribed in subsection (a)(2) in recruiting, retaining,
13 training, and developing the workforce at the Center
14 for Drug Evaluation and Research, the Center for
15 Biologics Evaluation and Research, and the Center
16 for Devices and Radiological Health in fulfilling the
17 public health mission of the Food and Drug Admin-
18 istration;

19 (2) assess the effectiveness of the measures
20 identified under subsection (a)(3) in gauging
21 progress against the strategic goals and priorities
22 identified under subsection (a)(1);

23 (3) assess the extent to which the Center for
24 Drug Evaluation and Research, the Center for Bio-
25 logics Evaluation and Research, and the Center for

1 Devices and Radiological Health are using the iden-
2 tified results-oriented set of performance measures
3 in tracking their workload by strategic goals and the
4 effectiveness of such measures;

5 (4) assess the extent to which performance in-
6 formation is collected, analyzed, and acted on by
7 managers; and

8 (5) make recommendations, as appropriate, re-
9 garding how the strategic management plan and re-
10 lated actions of the Center for Drug Evaluation and
11 Research, the Center for Biologics Evaluation and
12 Research, and the Center for Devices and Radio-
13 logical Health could be improved to fulfill the public
14 health mission of the Food and Drug Administration
15 in as efficient and effective manner as possible.

16 **SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE**
17 **TESTING.**

18 (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355–
19 1) is amended by adding at the end the following:

20 “(k) DRUG DEVELOPMENT AND BIOEQUIVALENCE
21 TESTING.—

22 “(1) IN GENERAL.—Notwithstanding any other
23 provision of law, if a drug is a covered drug, no ele-
24 ments to ensure safe use shall prohibit, or be con-
25 strued or applied to prohibit, supply of such drug to

1 any eligible drug developer for the purpose of devel-
2 oping, or conducting bioequivalence testing necessary
3 to support, an application under subsection (b)(2) or
4 (j) of section 505 of this Act or section 351(k) of
5 the Public Health Service Act, if the Secretary has
6 issued a written notice described in paragraph (2),
7 and the eligible drug developer has agreed to comply
8 with the terms of the notice.

9 “(2) WRITTEN NOTICE.—For purposes of this
10 subsection, the Secretary shall issue a written notice
11 to an eligible drug developer and the holder of an
12 application for a covered drug authorizing the supply
13 of a drug to such eligible drug developer for pur-
14 poses of bioequivalence testing if—

15 “(A) the eligible drug developer has agreed
16 to comply with any conditions the Secretary
17 considers necessary; and

18 “(B) the eligible drug developer has sub-
19 mitted and the Secretary has approved a pro-
20 tocol for bioequivalence testing that includes
21 protections that the Secretary finds will provide
22 assurance of safety comparable to the assurance
23 of safety provided by the elements to ensure
24 safe use in the risk evaluation and mitigation
25 strategy for the covered drug.

1 “(3) ADDITIONAL REQUIRED ELEMENT.—The
2 Secretary shall require as an element of each risk
3 evaluation and mitigation strategy approved by the
4 Secretary that the holder of an application for a cov-
5 ered drug shall not restrict the resale of the covered
6 drug to an eligible drug developer that receives a
7 written notice from the Secretary under paragraph
8 (2).

9 “(4) PENALTIES.—For purposes of subsection
10 (f)(8) and sections 301, 303(f)(4), 502(y), and
11 505(p), it shall be a violation of the risk evaluation
12 and mitigation strategy for the holder of the applica-
13 tion for a covered drug to restrict the sale of the
14 drug to an eligible drug developer. The Secretary
15 shall provide written notice to the Committee on
16 Health, Education, Labor, and Pensions of the Sen-
17 ate and the Committee on Energy and Commerce of
18 the House of Representatives of any penalty as-
19 sessed under this subsection within 7 days of such
20 assessment.

21 “(5) LIABILITY.—Unless the holder of the ap-
22 plication for a covered drug and the eligible devel-
23 oper are the same entity, the holder of an applica-
24 tion for a covered drug shall not be liable for any
25 claim arising out of the eligible drug developer’s

1 testing necessary to support an application under
2 subsection (b)(2) or (j) of section 505 of this Act or
3 section 351(k) of the Public Health Service Act for
4 a drug obtained under this subsection. Nothing in
5 this subsection shall be construed to expand or limit
6 the liability of the eligible drug developer or the
7 holder of an application for a covered drug for any
8 other claim.

9 “(6) DEFINITIONS.—

10 “(A) COVERED DRUG.—Notwithstanding
11 subsection (b)(2), for purposes of this sub-
12 section, the term ‘covered drug’ means a drug,
13 including a biological product licensed under
14 section 351(a) of the Public Health Service Act,
15 that is subject to a risk evaluation and mitiga-
16 tion strategy with elements to ensure safe use
17 under subsection (f), or a drug, including a bio-
18 logical product licensed under section 351(a) of
19 the Public Health Service Act, required to have
20 a risk evaluation and mitigation strategy with
21 elements to ensure safe use under section
22 909(b) of the Food and Drug Administration
23 Amendments Act of 2007.

24 “(B) ELIGIBLE DRUG DEVELOPER.—For
25 purposes of this subsection, the term ‘eligible

1 drug developer’ means a sponsor seeking to de-
2 velop an application for submission under sub-
3 section (b)(2) or (j) of section 505 of this Act
4 or section 351(k) of the Public Health Service
5 Act.

6 “(7) EFFECT ON OTHER LAW.—Nothing in this
7 subsection shall affect the authority of the Federal
8 Trade Commission to enforce the Federal Trade
9 Commission Act (15 U.S.C. 41–58), the Sherman
10 Act (15 U.S.C. 1–7)), or any other statute properly
11 under such Commission’s jurisdiction.”.

12 (b) TECHNICAL AND CONFORMING AMENDMENT.—
13 Section 505–1(c)(2) (21 U.S.C. 355–1(c)(2)) is amended
14 by striking “(e) and (f)” and inserting “(e), (f), and
15 (k)(3)”.

16 **SEC. 1132. PATIENT PARTICIPATION IN MEDICAL PRODUCT**
17 **DISCUSSIONS.**

18 Subchapter E of chapter V (21 U.S.C. 360bbb et
19 seq.), as amended by section 1126, is further amended by
20 adding at the end the following:

21 **“SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PROD-**
22 **UCT DISCUSSION.**

23 “(a) IN GENERAL.—The Secretary shall develop and
24 implement strategies to solicit the views of patients during
25 the medical product development process and consider the

1 perspectives of patients during regulatory discussions, in-
2 cluding by—

3 “(1) fostering participation of a patient rep-
4 resentative who may serve as a special government
5 employee in appropriate agency meetings with med-
6 ical product sponsors and investigators; and

7 “(2) exploring means to provide for identifica-
8 tion of patient representatives who do not have any,
9 or have minimal, financial interests in the medical
10 products industry.

11 “(b) FINANCIAL INTEREST.—In this section, the
12 term ‘financial interest’ means a financial interest under
13 section 208(a) of title 18, United States Code.”.

Calendar No. 400

112TH CONGRESS
2^D SESSION

S. 3187

A BILL

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.

MAY 16, 2012

Read the second time and placed on the calendar