

112TH CONGRESS
2^D SESSION

S. 3187

AN ACT

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

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Food and Drug Ad-
3 ministration Safety and Innovation Act”.

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

5 (a) TABLE OF CONTENTS.—The table of contents of
6 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 pro-
cess 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

Subtitle A—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.

Subtitle B—Pharmaceutical Distribution Integrity

Sec. 721. Short title.

Sec. 722. Securing the pharmaceutical distribution supply chain.

Sec. 723. Independent assessment.

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.

Sec. 908. Reporting of inclusion of demographic subgroups in clinical trials and data analysis in applications for drugs, biologics, and devices.

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 testing.
- Sec. 1132. Patient participation in medical product discussions.
- Sec. 1133. Nanotechnology regulatory science program.
- Sec. 1134. Online pharmacy report to Congress.
- Sec. 1135. Medication and device errors.
- Sec. 1136. Compliance provision.
- Sec. 1137. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups.
- Sec. 1138. Report on small businesses.
- Sec. 1139. Protections for the commissioned corps of the public health service act.
- Sec. 1140. Regulations on clinical trial registration; GAO Study of clinical trial registration and reporting requirements.
- Sec. 1141. Hydrocodone amendment.
- Sec. 1142. Compliance date for rule relating to sunscreen drug products for over-the-counter human use.
- Sec. 1143. Recommendations on interoperability standards.

Subtitle D—Synthetic Drugs

- Sec. 1151. Short title.
- Sec. 1152. Addition of synthetic drugs to schedule I of the Controlled Substances Act.
- Sec. 1153. Temporary scheduling to avoid imminent hazards to public safety expansion.
- Sec. 1154. Prohibition on imposing mandatory minimum sentences.

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
 4 provision of the Federal Food, Drug, and Cosmetic Act
 5 (21 U.S.C. 301 et seq.).

6 **TITLE I—FEES RELATING TO** 7 **DRUGS**

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

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

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

14 **SEC. 102. DEFINITIONS.**

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

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

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

20 (1) in subsection (a)—

21 (A) in the matter preceding paragraph (1),
22 by striking “fiscal year 2008” and inserting
23 “fiscal year 2013”;

24 (B) in paragraph (1), in clauses (i) and (ii)
25 of subparagraph (A), by striking “subsection

1 (c)(5)” each place such term appears and in-
2 serting “subsection (c)(4)”;

3 (C) in the matter following clause (ii) in
4 paragraph (2)(A)—

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

7 (ii) by striking “payable on or before
8 October 1 of each year” and inserting
9 “due on the later of the first business day
10 on or after October 1 of each fiscal year or
11 the first business day after the enactment
12 of an appropriations Act providing for the
13 collection and obligation of fees for such
14 fiscal year under this section”;

15 (D) in paragraph (3)—

16 (i) in subparagraph (A)—

17 (I) by striking “subsection
18 (c)(5)” and inserting “subsection
19 (c)(4)”;

20 (II) by striking “payable on or
21 before October 1 of each year.” and
22 inserting “due on the later of the first
23 business day on or after October 1 of
24 each fiscal year or the first business
25 day after the enactment of an appro-

1 priations Act providing for the collec-
2 tion and obligation of fees for such
3 fiscal year under this section.”; and

4 (ii) by amending subparagraph (B) to
5 read as follows:

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

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

12 “(ii) the same product as another
13 product that—

14 “(I) was approved under an ap-
15 plication filed under section 505(b) or
16 505(j); and

17 “(II) is not in the list of discon-
18 tinued products compiled under sec-
19 tion 505(j)(7);

20 “(iii) the same product as another
21 product that was approved under an abbrev-
22 viated application filed under section 507
23 (as in effect on the day before the date of
24 enactment of the Food and Drug Adminis-
25 tration Modernization Act of 1997); or

1 “(iv) the same product as another
2 product that was approved under an abbrevi-
3 ated new drug application pursuant to
4 regulations in effect prior to the implemen-
5 tation of the Drug Price Competition and
6 Patent Term Restoration Act of 1984.”;

7 (2) in subsection (b)—

8 (A) in paragraph (1)—

9 (i) in the matter preceding subpara-
10 graph (A), by striking “fiscal years 2008
11 through 2012” and inserting “fiscal years
12 2013 through 2017”;

13 (ii) in subparagraph (A), by striking
14 “\$392,783,000; and” and inserting
15 “\$693,099,000;”; and

16 (iii) by striking subparagraph (B) and
17 inserting the following:

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

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

24 (B) by striking paragraphs (3) and (4) and
25 inserting the following:

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

6 “(A) INFLATION ADJUSTMENT.—The infla-
7 tion adjustment for fiscal year 2013 shall be
8 the sum of—

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

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

17 “(B) WORKLOAD ADJUSTMENT.—Subject
18 to subparagraph (C), the workload adjustment
19 for fiscal 2013 shall be—

20 “(i) \$652,709,000 plus the amount of
21 the inflation adjustment calculated under
22 subparagraph (A); multiplied by

23 “(ii) the amount (if any) by which a
24 percentage workload adjustment for fiscal
25 year 2013, as determined using the meth-

1 odology described in subsection (c)(2)(A),
2 would exceed the percentage workload ad-
3 justment (as so determined) for fiscal year
4 2012, if both such adjustment percentages
5 were calculated using the 5-year base pe-
6 riod consisting of fiscal years 2003
7 through 2007.

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

14 (3) by striking subsection (c) and inserting the
15 following:

16 “(c) ADJUSTMENTS.—

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

23 “(A) one;

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

1 Food and Drug Administration, of all personnel
2 compensation and benefits paid with respect to
3 such positions for the first 3 years of the pre-
4 ceeding 4 fiscal years, multiplied by the propor-
5 tion of personnel compensation and benefits
6 costs to total costs of the process for the review
7 of human drug applications (as defined in sec-
8 tion 735(6)) for the first 3 years of the pre-
9 ceeding 4 fiscal years; and

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

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

1 “(2) WORKLOAD ADJUSTMENT.—For fiscal
2 year 2014 and subsequent fiscal years, after the fee
3 revenues established in subsection (b) are adjusted
4 for a fiscal year for inflation in accordance with
5 paragraph (1), the fee revenues shall be adjusted
6 further for such fiscal year to reflect changes in the
7 workload of the Secretary for the process for the re-
8 view of human drug applications. With respect to
9 such adjustment:

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

1 the adjustment and the supporting methodolo-
2 gies.

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

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

1 receipt of public comments, the Secretary shall,
2 if warranted, adopt appropriate changes to the
3 methodology. If the Secretary adopts changes to
4 the methodology based on the first report, the
5 changes shall be effective for the first fiscal
6 year for which fees are set after the Secretary
7 adopts such changes and each subsequent fiscal
8 year.

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

1 “(4) ANNUAL FEE SETTING.—The Secretary
2 shall, not later than 60 days before the start of each
3 fiscal year that begins after September 30, 2012, es-
4 tablish, for the next fiscal year, application, product,
5 and establishment fees under subsection (a), based
6 on the revenue amounts established under subsection
7 (b) and the adjustments provided under this sub-
8 section.

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

14 (4) in subsection (g)—

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

18 (B) in paragraph (2)—

19 (i) in subparagraph (A)—

20 (I) in clause (i), by striking
21 “shall be retained” and inserting
22 “subject to subparagraph (C), shall be
23 collected and available”; and

1 (II) in clause (ii), by striking
2 “shall only be collected and available”
3 and inserting “shall be available”; and
4 (ii) by adding at the end the following
5 new subparagraph:

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

12 (C) in paragraph (3), by striking “fiscal
13 years 2008 through 2012” and inserting “fiscal
14 years 2013 through 2017”; and

15 (D) in paragraph (4)—

16 (i) by striking “fiscal years 2008
17 through 2010” and inserting “fiscal years
18 2013 through 2015”;

19 (ii) by striking “fiscal year 2011” and
20 inserting “fiscal year 2016”;

21 (iii) by striking “fiscal years 2008
22 though 2011” and inserting “fiscal years
23 2013 through 2016”; and

24 (iv) by striking “fiscal year 2012”
25 and inserting “fiscal year 2017”.

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

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

3 (1) by amending subsection (a) to read as fol-
4 lows:

5 “(a) PERFORMANCE REPORT.—Beginning with fiscal
6 year 2013, not later than 120 days after the end of each
7 fiscal year for which fees are collected under this part,
8 the Secretary shall prepare and submit to the Committee
9 on Energy and Commerce of the House of Representatives
10 and the Committee on Health, Education, Labor, and
11 Pensions of the Senate a report concerning the progress
12 of the Food and Drug Administration in achieving the
13 goals identified in the letters described in section 101(b)
14 of the Prescription Drug User Fee Amendments of 2012
15 during such fiscal year and the future plans of the Food
16 and Drug Administration for meeting the goals. The re-
17 port under this subsection for a fiscal year shall include
18 information on all previous cohorts for which the Sec-
19 retary has not given a complete response on all human
20 drug applications and supplements in the cohort.”;

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

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

1 **SEC. 105. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 735 and 736 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
4 379h) shall cease to be effective October 1, 2017.

5 (b) REPORTING REQUIREMENTS.—Section 736B of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 379h–2) shall cease to be effective January 31, 2018.

8 (c) PREVIOUS SUNSET PROVISION.—Section 106 of
9 the Prescription Drug User Fee Amendments of 2007
10 (Title I of Public Law 110–85) is repealed.

11 (d) TECHNICAL CLARIFICATIONS.—

12 (1) Effective September 30, 2007, section 509
13 of the Prescription Drug User Fee Amendments Act
14 of 2002 (Title V of Public Law 107–188) is re-
15 pealed.

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

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

22 **SEC. 106. EFFECTIVE DATE.**

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

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

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

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

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

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

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

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

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

8 **SEC. 202. DEFINITIONS.**

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

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

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

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

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

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

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

- 1 (2) in paragraph (2)(A)—
- 2 (A) in the matter preceding clause (i)—
- 3 (i) by striking “subsections (d) and
- 4 (e)” and inserting “subsections (d), (e),
- 5 and (f)”;
- 6 (ii) by striking “October 1, 2002” and
- 7 inserting “October 1, 2012”; and
- 8 (iii) by striking “subsection (c)(1)”
- 9 and inserting “subsection (c)”; and
- 10 (B) in clause (viii), by striking “1.84” and
- 11 inserting “2”; and
- 12 (3) in paragraph (3)—
- 13 (A) in subparagraph (A)—
- 14 (i) by inserting “and subsection (f)”
- 15 after “subparagraph (B)”; and
- 16 (ii) by striking “2008” and inserting
- 17 “2013”; and
- 18 (B) in subparagraph (C), by striking “ini-
- 19 tial registration” and all that follows through
- 20 “section 510.” and inserting “later of—
- 21 “(i) the initial or annual registration
- 22 (as applicable) of the establishment under
- 23 section 510; or
- 24 “(ii) the first business day after the
- 25 date of enactment of an appropriations Act

1 providing for the collection and obligation
2 of fees for such year under this section.”.

3 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.
4 379j(b)) is amended to read as follows:

5 “(b) FEE AMOUNTS.—

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

12 “(2) BASE FEE AMOUNTS.—For purposes of
13 paragraph (1), the base fee amounts specified in this
14 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

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

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

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

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

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

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

1 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
2 738(c) (21 U.S.C. 379j(c)) is amended—

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

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

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

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

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

17 “(2) INFLATION ADJUSTMENTS.—

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

1 “(B) APPLICABLE INFLATION ADJUST-
2 MENT TO TOTAL REVENUE AMOUNTS.—The ap-
3 plicable inflation adjustment for a fiscal year
4 is—

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

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

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

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

18 “(C) BASE INFLATION ADJUSTMENT TO
19 TOTAL REVENUE AMOUNTS.—

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

24 “(I) the average annual percent
25 change in the cost, per full-time equiv-

1 alent position of the Food and Drug
2 Administration, of all personnel com-
3 pensation and benefits paid with re-
4 spect to such positions for the first 3
5 years of the preceding 4 fiscal years,
6 multiplied by 0.60; and

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

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

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

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

1 “(D) ADJUSTMENT TO BASE FEE
2 AMOUNTS.—For each of fiscal years 2014
3 through 2017, the base fee amounts specified in
4 subsection (b)(2) shall be adjusted as needed,
5 on a uniform proportionate basis, to generate
6 the total revenue amounts under subsection
7 (b)(3), as adjusted for inflation under subpara-
8 graph (A).

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

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

21 (1) redesignating subsections (f) through (k) as
22 subsections (g) through (l), respectively; and

23 (2) by inserting after subsection (e) the fol-
24 lowing new subsection:

25 “(f) FEE WAIVER OR REDUCTION.—

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

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

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

13 (e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C.
14 379j(h)(1)(A)), as redesignated by subsection (d)(1), is
15 amended by striking “\$205,720,000” and inserting
16 “\$280,587,000”.

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

20 (1) in paragraph (1), by striking “Fees author-
21 ized” and inserting “Subject to paragraph (2)(C),
22 fees authorized”;

23 (2) in paragraph (2)—

24 (A) in subparagraph (A)—

1 (i) in clause (i), by striking “shall be
2 retained” and inserting “subject to sub-
3 paragraph (C), shall be collected and avail-
4 able”; and

5 (ii) in clause (ii)—

6 (I) by striking “collected and”
7 after “shall only be”; and

8 (II) by striking “fiscal year
9 2002” and inserting “fiscal year
10 2009”; and

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

12 “(C) PROVISION FOR EARLY PAYMENTS.—

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

18 (3) by amending paragraph (3) to read as fol-
19 lows:

20 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—

21 For each of the fiscal years 2013 through 2017,
22 there is authorized to be appropriated for fees under
23 this section an amount equal to the total revenue
24 amount specified under subsection (b)(3) for the fis-
25 cal year, as adjusted under subsection (c) and, for

1 fiscal year 2017 only, as further adjusted under
2 paragraph (4).”; and

3 (4) in paragraph (4)—

4 (A) by striking “fiscal years 2008, 2009,
5 and 2010” and inserting “fiscal years 2013,
6 2014, and 2015”;

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

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

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

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

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

18 (g) CONFORMING AMENDMENT.—Section
19 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by
20 striking “738(g)” and inserting “738(h)”.

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

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

24 (1) in paragraph (1), by striking “2012” and
25 inserting “2017”; and

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

3 (b) REPORTS.—Section 738A(a) (21 U.S.C. 379j–
4 1(a)) is amended—

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

7 (2) by striking “section 201(c) of the Food and
8 Drug Administration Amendments Act of 2007” and
9 inserting “section 201(b) of the Medical Device User
10 Fee Amendments of 2012”.

11 **SEC. 205. SAVINGS CLAUSE.**

12 Notwithstanding the amendments made by this title,
13 part 3 of subchapter C of chapter VII of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
15 effect on the day before the date of the enactment of this
16 title, shall continue to be in effect with respect to submis-
17 sions described in section 738(a)(2)(A) of the Federal
18 Food, Drug, and Cosmetic Act (as in effect as of such
19 day) that on or after October 1, 2007, but before October
20 1, 2012, were accepted by the Food and Drug Administra-
21 tion for filing with respect to assessing and collecting any
22 fee required by such part for a fiscal year prior to fiscal
23 year 2013.

1 **SEC. 206. EFFECTIVE DATE.**

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

10 **SEC. 207. SUNSET DATES.**

11 (a) **AUTHORIZATIONS.**—Sections 737 and 738 (21
12 U.S.C. 739i; 739j) shall cease to be effective October 1,
13 2017.

14 (b) **REPORTING REQUIREMENTS.**—Section 738A (21
15 U.S.C. 739j–1) shall cease to be effective January 31,
16 2018.

17 (c) **PREVIOUS SUNSET PROVISION.**—Section 217 of
18 the Medical Device User Fee Amendments of 2007 (Title
19 II of Public Law 110–85) is repealed.

20 (d) **TECHNICAL CLARIFICATION.**—Effective Sep-
21 tember 30, 2007, section 107 of the Medical Device User
22 Fee and Modernization Act of 2002 (Public Law 107–
23 250) is repealed.

1 **SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT**
2 **ACTIVITIES RELATED TO THE PROCESS FOR**
3 **THE REVIEW OF DEVICE APPLICATIONS.**

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

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

8 “(a) **IN GENERAL.**—In addition to any other per-
9 sonnel authorities under other provisions of law, the Sec-
10 retary may, without regard to the provisions of title 5,
11 United States Code, governing appointments in the com-
12 petitive service, appoint employees to positions in the Food
13 and Drug Administration to perform, administer, or sup-
14 port activities described in subsection (b), if the Secretary
15 determines that such appointments are needed to achieve
16 the objectives specified in subsection (c).

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

21 “(c) **OBJECTIVES SPECIFIED.**—The objectives speci-
22 fied in this subsection are with respect to the activities
23 under subsection (b), the goals referred to in section
24 738A(a)(1).

1 “(d) INTERNAL CONTROLS.—The Secretary shall in-
2 stitute appropriate internal controls for appointments
3 under this section.

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

7 **TITLE III—FEES RELATING TO**
8 **GENERIC DRUGS**

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

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

12 (b) FINDING.—The Congress finds that the fees au-
13 thorized by the amendments made in this title will be dedi-
14 cated to human generic drug activities, as set forth in the
15 goals identified for purposes of part 7 of subchapter C
16 of chapter VII of the Federal Food, Drug, and Cosmetic
17 Act, in the letters from the Secretary of Health and
18 Human Services to the Chairman of the Committee on
19 Health, Education, Labor, and Pensions of the Senate and
20 the Chairman of the Committee on Energy and Commerce
21 of the House of Representatives, as set forth in the Con-
22 gressional Record.

1 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
2 **NERIC DRUG FEES.**

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

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

6 **“SEC. 744A. DEFINITIONS.**

7 “For purposes of this part:

8 “(1) The term ‘abbreviated new drug applica-
9 tion’—

10 “(A) means an application submitted
11 under section 505(j), an abbreviated application
12 submitted under section 507 (as in effect on the
13 day before the date of enactment of the Food
14 and Drug Administration Modernization Act of
15 1997), or an abbreviated new drug application
16 submitted pursuant to regulations in effect
17 prior to the implementation of the Drug Price
18 Competition and Patent Term Restoration Act
19 of 1984; and

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

22 “(2) The term ‘active pharmaceutical ingre-
23 dient’ means—

24 “(A) a substance, or a mixture when the
25 substance is unstable or cannot be transported
26 on its own, intended—

1 “(i) to be used as a component of a
2 drug; and

3 “(ii) to furnish pharmacological activ-
4 ity or other direct effect in the diagnosis,
5 cure, mitigation, treatment, or prevention
6 of disease, or to affect the structure or any
7 function of the human body; or

8 “(B) a substance intended for final crys-
9 tallization, purification, or salt formation, or
10 any combination of those activities, to become a
11 substance or mixture described in subparagraph
12 (A).

13 “(3) The term ‘adjustment factor’ means a fac-
14 tor applicable to a fiscal year that is the Consumer
15 Price Index for all urban consumers (all items;
16 United States city average) for October of the pre-
17 ceding fiscal year divided by such Index for October
18 2011.

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

22 “(A) one business entity controls, or has
23 the power to control, the other business entity;
24 or

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

3 “(5)(A) The term ‘facility’—

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

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

7 “(II) at one geographic location or ad-
8 dress engaged in manufacturing or proc-
9 essing an active pharmaceutical ingredient
10 or a finished dosage form; and

11 “(ii) does not include a business or other
12 entity whose only manufacturing or processing
13 activities are one or more of the following: re-
14 packaging, relabeling, or testing.

15 “(B) For purposes of subparagraph (A), sepa-
16 rate buildings within close proximity are considered
17 to be at one geographic location or address if the ac-
18 tivities in them are—

19 “(i) closely related to the same business
20 enterprise;

21 “(ii) under the supervision of the same
22 local management; and

23 “(iii) capable of being inspected by the
24 Food and Drug Administration during a single
25 inspection.

1 “(C) If a business or other entity would meet
2 the definition of a facility under this paragraph but
3 for being under multiple management, the business
4 or other entity is deemed to constitute multiple fa-
5 cilities, one per management entity, for purposes of
6 this paragraph.

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

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

11 “(B) a drug product in a form in which re-
12 constitution is necessary prior to administration
13 to a patient, such as oral suspensions or
14 lyophilized powders; or

15 “(C) any combination of an active pharma-
16 ceutical ingredient with another component of a
17 drug product for purposes of production of a
18 drug product described in subparagraph (A) or
19 (B).

20 “(7) The term ‘generic drug submission’ means
21 an abbreviated new drug application, an amendment
22 to an abbreviated new drug application, or a prior
23 approval supplement to an abbreviated new drug ap-
24 plication.

1 “(8) The term ‘human generic drug activities’
2 means the following activities of the Secretary asso-
3 ciated with generic drugs and inspection of facilities
4 associated with generic drugs:

5 “(A) The activities necessary for the re-
6 view of generic drug submissions, including re-
7 view of drug master files referenced in such
8 submissions.

9 “(B) The issuance of—

10 “(i) approval letters which approve
11 abbreviated new drug applications or sup-
12 plements to such applications; or

13 “(ii) complete response letters which
14 set forth in detail the specific deficiencies
15 in such applications and, where appro-
16 priate, the actions necessary to place such
17 applications in condition for approval.

18 “(C) The issuance of letters related to
19 Type II active pharmaceutical drug master files
20 which—

21 “(i) set forth in detail the specific de-
22 ficiencies in such submissions, and where
23 appropriate, the actions necessary to re-
24 solve those deficiencies; or

1 “(ii) document that no deficiencies
2 need to be addressed.

3 “(D) Inspections related to generic drugs.

4 “(E) Monitoring of research conducted in
5 connection with the review of generic drug sub-
6 missions and drug master files.

7 “(F) Postmarket safety activities with re-
8 spect to drugs approved under abbreviated new
9 drug applications or supplements, including the
10 following activities:

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

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

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

21 “(iv) Implementing and enforcing sec-
22 tion 505(o) (relating to postapproval stud-
23 ies and clinical trials and labeling changes)
24 and section 505(p) (relating to risk evalua-
25 tion and mitigation strategies) insofar as

1 those activities relate to abbreviated new
2 drug applications.

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

6 “(G) Regulatory science activities related
7 to generic drugs.

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

13 “(10) The term ‘prior approval supplement’
14 means a request to the Secretary to approve a
15 change in the drug substance, drug product, produc-
16 tion process, quality controls, equipment, or facilities
17 covered by an approved abbreviated new drug appli-
18 cation when that change has a substantial potential
19 to have an adverse effect on the identity, strength,
20 quality, purity, or potency of the drug product as
21 these factors may relate to the safety or effective-
22 ness of the drug product.

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

1 “(A) officers and employees of the Food
2 and Drug Administration, contractors of the
3 Food and Drug Administration, advisory com-
4 mittees, and costs related to such officers and
5 employees and to contracts with such contrac-
6 tors;

7 “(B) management of information, and the
8 acquisition, maintenance, and repair of com-
9 puter resources;

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

15 “(D) collecting fees under subsection (a)
16 and accounting for resources allocated for the
17 review of abbreviated new drug applications and
18 supplements and inspection related to generic
19 drugs.

20 “(12) The term ‘Type II active pharmaceutical
21 ingredient drug master file’ means a submission of
22 information to the Secretary by a person that in-
23 tends to authorize the Food and Drug Administra-
24 tion to reference the information to support approval
25 of a generic drug submission without the submitter

1 having to disclose the information to the generic
2 drug submission applicant.

3 **“SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GE-**
4 **NERIC DRUG FEES.**

5 “(a) TYPES OF FEES.—Beginning in fiscal year
6 2013, the Secretary shall assess and collect fees in accord-
7 ance with this section as follows:

8 “(1) ONE-TIME BACKLOG FEE FOR ABBRE-
9 VIATED NEW DRUG APPLICATIONS PENDING ON OC-
10 TOBER 1, 2012.—

11 “(A) IN GENERAL.—Each person that
12 owns an abbreviated new drug application that
13 is pending on October 1, 2012, and that has
14 not received a tentative approval prior to that
15 date, shall be subject to a fee for each such ap-
16 plication, as calculated under subparagraph
17 (B).

18 “(B) METHOD OF FEE AMOUNT CALCULA-
19 TION.—The amount of each one-time backlog
20 fee shall be calculated by dividing \$50,000,000
21 by the total number of abbreviated new drug
22 applications pending on October 1, 2012, that
23 have not received a tentative approval as of that
24 date.

1 “(C) NOTICE.—Not later than October 31,
2 2012, the Secretary shall publish in the Federal
3 Register a notice announcing the amount of the
4 fee required by subparagraph (A).

5 “(D) FEE DUE DATE.—The fee required
6 by subparagraph (A) shall be due no later than
7 30 calendar days after the date of the publica-
8 tion of the notice specified in subparagraph (C).

9 “(2) DRUG MASTER FILE FEE.—

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

16 “(B) ONE-TIME PAYMENT.—If a person
17 has paid a drug master file fee for a Type II
18 active pharmaceutical ingredient drug master
19 file, the person shall not be required to pay a
20 subsequent drug master file fee when that Type
21 II active pharmaceutical ingredient drug master
22 file is subsequently referenced in generic drug
23 submissions.

24 “(C) NOTICE.—

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

6 “(ii) FISCAL YEAR 2014 THROUGH
7 2017.—Not later than 60 days before the
8 start of each of fiscal years 2014 through
9 2017, the Secretary shall publish in the
10 Federal Register the amount of the drug
11 master file fee established by this para-
12 graph for such fiscal year.

13 “(D) AVAILABILITY FOR REFERENCE.—

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

20 “(ii) CONDITIONS.—A drug master
21 file shall be deemed available for reference
22 by the Secretary if—

23 “(I) the person that owns a Type
24 II active pharmaceutical ingredient
25 drug master file has paid the fee re-

1 quired under subparagraph (A) within
2 20 calendar days after the applicable
3 due date under subparagraph (E);
4 and

5 “(II) the drug master file has not
6 failed an initial completeness assess-
7 ment by the Secretary, in accordance
8 with criteria to be published by the
9 Secretary.

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

19 “(E) FEE DUE DATE.—

20 “(i) IN GENERAL.—Subject to clause
21 (ii), a drug master file fee shall be due no
22 later than the date on which the first ge-
23 neric drug submission is submitted that
24 references the associated Type II active
25 pharmaceutical ingredient drug master file.

1 “(ii) LIMITATION.—No fee shall be
2 due under subparagraph (A) for a fiscal
3 year until the later of—

4 “(I) 30 calendar days after publi-
5 cation of the notice provided for in
6 clause (i) or (ii) of subparagraph (C),
7 as applicable; or

8 “(II) 30 calendar days after the
9 date of enactment of an appropria-
10 tions Act providing for the collection
11 and obligation of fees under this sec-
12 tion.

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

15 “(A) IN GENERAL.—Each applicant that
16 submits, on or after October 1, 2012, an abbrevi-
17 ated new drug application or a prior approval
18 supplement to an abbreviated new drug applica-
19 tion shall be subject to a fee for each such sub-
20 mission in the amount established under sub-
21 section (d).

22 “(B) NOTICE.—

23 “(i) FISCAL YEAR 2013.—Not later
24 than October 31, 2012, the Secretary shall
25 publish in the Federal Register a notice

1 announcing the amount of the fees under
2 subparagraph (A) for fiscal year 2013.

3 “(ii) FISCAL YEARS 2014 THROUGH
4 2017.—Not later than 60 days before the
5 start of each of fiscal years 2014 through
6 2017, the Secretary shall publish in the
7 Federal Register the amount of the fees
8 under subparagraph (A) for such fiscal
9 year.

10 “(C) FEE DUE DATE.—

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

18 “(ii) SPECIAL RULE FOR 2013.—For
19 fiscal year 2013, such fees shall be due on
20 the later of—

21 “(I) the date on which the fee is
22 due under clause (i);

23 “(II) 30 calendar days after pub-
24 lication of the notice referred to in
25 subparagraph (B)(i); or

1 “(III) if an appropriations Act is
2 not enacted providing for the collec-
3 tion and obligation of fees under this
4 section by the date of submission of
5 the application or prior approval sup-
6 plement for which the fees under sub-
7 paragraphs (A) and (F) apply, 30 cal-
8 endar days after the date that such an
9 appropriations Act is enacted.

10 “(D) REFUND OF FEE IF ABBREVIATED
11 NEW DRUG APPLICATION IS NOT CONSIDERED
12 TO HAVE BEEN RECEIVED.—The Secretary
13 shall refund 75 percent of the fee paid under
14 subparagraph (A) for any abbreviated new drug
15 application or prior approval supplement to an
16 abbreviated new drug application that the Sec-
17 retary considers not to have been received with-
18 in the meaning of section 505(j)(5)(A) for a
19 cause other than failure to pay fees.

20 “(E) FEE FOR AN APPLICATION THE SEC-
21 RETARY CONSIDERS NOT TO HAVE BEEN RE-
22 CEIVED, OR THAT HAS BEEN WITHDRAWN.—An
23 abbreviated new drug application or prior ap-
24 proval supplement that was submitted on or
25 after October 1, 2012, and that the Secretary

1 considers not to have been received, or that has
2 been withdrawn, shall, upon resubmission of the
3 application or a subsequent new submission fol-
4 lowing the applicant's withdrawal of the appli-
5 cation, be subject to a full fee under subpara-
6 graph (A).

7 “(F) ADDITIONAL FEE FOR ACTIVE PHAR-
8 MACEUTICAL INGREDIENT INFORMATION NOT
9 INCLUDED BY REFERENCE TO TYPE II ACTIVE
10 PHARMACEUTICAL INGREDIENT DRUG MASTER
11 FILE.—An applicant that submits a generic
12 drug submission on or after October 1, 2012,
13 shall pay a fee, in the amount determined under
14 subsection (d)(3), in addition to the fee re-
15 quired under subparagraph (A), if—

16 “(i) such submission contains infor-
17 mation concerning the manufacture of an
18 active pharmaceutical ingredient at a facil-
19 ity by means other than reference by a let-
20 ter of authorization to a Type II active
21 pharmaceutical drug master file; and

22 “(ii) a fee in the amount equal to the
23 drug master file fee established in para-
24 graph (2) has not been previously paid
25 with respect to such information.

1 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
2 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

3 “(A) IN GENERAL.—Facilities identified,
4 or intended to be identified, in at least one ge-
5 neric drug submission that is pending or ap-
6 proved to produce a finished dosage form of a
7 human generic drug or an active pharma-
8 ceutical ingredient contained in a human ge-
9 neric drug shall be subject to fees as follows:

10 “(i) GENERIC DRUG FACILITY.—Each
11 person that owns a facility which is identi-
12 fied or intended to be identified in at least
13 one generic drug submission that is pend-
14 ing or approved to produce one or more
15 finished dosage forms of a human generic
16 drug shall be assessed an annual fee for
17 each such facility.

18 “(ii) ACTIVE PHARMACEUTICAL IN-
19 GREDIENT FACILITY.—Each person that
20 owns a facility which produces, or which is
21 pending review to produce, one or more ac-
22 tive pharmaceutical ingredients identified,
23 or intended to be identified, in at least one
24 generic drug submission that is pending or
25 approved or in a Type II active pharma-

1 ceutical ingredient drug master file ref-
2 erenced in such a generic drug submission,
3 shall be assessed an annual fee for each
4 such facility.

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

17 “(B) AMOUNT.—The amount of fees estab-
18 lished under subparagraph (A) shall be estab-
19 lished under subsection (d).

20 “(C) NOTICE.—

21 “(i) FISCAL YEAR 2013.—For fiscal
22 year 2013, the Secretary shall publish in
23 the Federal Register a notice announcing
24 the amount of the fees provided for in sub-

1 paragraph (A) within the timeframe speci-
2 fied in subsection (d)(1)(B).

3 “(ii) FISCAL YEARS 2014 THROUGH
4 2017.—Within the timeframe specified in
5 subsection (d)(2), the Secretary shall pub-
6 lish in the Federal Register the amount of
7 the fees under subparagraph (A) for such
8 fiscal year.

9 “(D) FEE DUE DATE.—

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

13 “(I) not later than 45 days after
14 the publication of the notice under
15 subparagraph (B); or

16 “(II) if an appropriations Act is
17 not enacted providing for the collec-
18 tion and obligation of fees under this
19 section by the date of the publication
20 of such notice, 30 days after the date
21 that such an appropriations Act is en-
22 acted.

23 “(ii) FISCAL YEARS 2014 THROUGH
24 2017.—For each of fiscal years 2014
25 through 2017, the fees under subpara-

1 graph (A) for such fiscal year shall be due
2 on the later of—

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

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

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

14 “(A) if it is submitted via a Food and
15 Drug Administration electronic gateway, on the
16 day when transmission to that electronic gate-
17 way is completed, except that a submission or
18 master file that arrives on a weekend, Federal
19 holiday, or day when the Food and Drug Ad-
20 ministration office that will review that submis-
21 sion is not otherwise open for business shall be
22 deemed to be submitted on the next day when
23 that office is open for business; or

24 “(B) if it is submitted in physical media
25 form, on the day it arrives at the appropriate

1 designated document room of the Food and
2 Drug Administration.

3 “(b) FEE REVENUE AMOUNTS.—

4 “(1) IN GENERAL.—

5 “(A) FISCAL YEAR 2013.—For fiscal year
6 2013, fees under subsection (a) shall be estab-
7 lished to generate a total estimated revenue
8 amount under such subsection of \$299,000,000.

9 Of that amount—

10 “(i) \$50,000,000 shall be generated
11 by the one-time backlog fee for generic
12 drug applications pending on October 1,
13 2012, established in subsection (a)(1); and

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

17 “(B) FISCAL YEARS 2014 THROUGH 2017.—

18 For each of the fiscal years 2014 through 2017,
19 fees under paragraphs (2) through (4) of sub-
20 section (a) shall be established to generate a
21 total estimated revenue amount under such sub-
22 section that is equal to \$299,000,000, as ad-
23 justed pursuant to subsection (c).

24 “(2) TYPES OF FEES.—In establishing fees
25 under paragraph (1) to generate the revenue

1 amounts specified in paragraph (1)(A)(ii) for fiscal
2 year 2013 and paragraph (1)(B) for each of fiscal
3 years 2014 through 2017, such fees shall be derived
4 from the fees under paragraphs (2) through (4) of
5 subsection (a) as follows:

6 “(A) 6 percent shall be derived from fees
7 under subsection (a)(2) (relating to drug mas-
8 ter files).

9 “(B) 24 percent shall be derived from fees
10 under subsection (a)(3) (relating to abbreviated
11 new drug applications and supplements). The
12 amount of a fee for a prior approval supplement
13 shall be half the amount of the fee for an ab-
14 breviated new drug application.

15 “(C) 56 percent shall be derived from fees
16 under subsection (a)(4)(A)(i) (relating to ge-
17 neric drug facilities). The amount of the fee for
18 a facility located outside the United States and
19 its territories and possessions shall be not less
20 than \$15,000 and not more than \$30,000 high-
21 er than the amount of the fee for a facility lo-
22 cated in the United States and its territories
23 and possessions, as determined by the Secretary
24 on the basis of data concerning the difference
25 in cost between inspections of facilities located

1 in the United States, including its territories
2 and possessions, and those located outside of
3 the United States and its territories and posses-
4 sions.

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

20 “(c) ADJUSTMENTS.—

21 “(1) INFLATION ADJUSTMENT.—For fiscal year
22 2014 and subsequent fiscal years, the revenues es-
23 tablished in subsection (b) shall be adjusted by the
24 Secretary by notice, published in the Federal Reg-

1 ister, for a fiscal year, by an amount equal to the
2 sum of—

3 “(A) one;

4 “(B) the average annual percent change in
5 the cost, per full-time equivalent position of the
6 Food and Drug Administration, of all personnel
7 compensation and benefits paid with respect to
8 such positions for the first 3 years of the pre-
9 ceding 4 fiscal years multiplied by the propor-
10 tion of personnel compensation and benefits
11 costs to total costs of human generic drug ac-
12 tivities for the first 3 years of the preceding 4
13 fiscal years; and

14 “(C) the average annual percent change
15 that occurred in the Consumer Price Index for
16 urban consumers (Washington-Baltimore, DC-
17 MD-VA-WV; Not Seasonally Adjusted; All
18 items; Annual Index) for the first 3 years of the
19 preceding 4 years of available data multiplied
20 by the proportion of all costs other than per-
21 sonnel compensation and benefits costs to total
22 costs of human generic drug activities for the
23 first 3 years of the preceding 4 fiscal years.

24 The adjustment made each fiscal year under this
25 subsection shall be added on a compounded basis to

1 the sum of all adjustments made each fiscal year
2 after fiscal year 2013 under this subsection.

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

19 “(d) ANNUAL FEE SETTING.—

20 “(1) FISCAL YEAR 2013.—For fiscal year
21 2013—

22 “(A) the Secretary shall establish, by Octo-
23 ber 31, 2012, the one-time generic drug backlog
24 fee for generic drug applications pending on Oc-
25 tober 1, 2012, the drug master file fee, the ab-

1 breviated new drug application fee, and the
2 prior approval supplement fee under subsection
3 (a), based on the revenue amounts established
4 under subsection (b); and

5 “(B) the Secretary shall establish, not
6 later than 45 days after the date to comply
7 with the requirement for identification of facili-
8 ties in subsection (f)(2), the generic drug facil-
9 ity fee and active pharmaceutical ingredient fa-
10 cility fee under subsection (a) based on the rev-
11 enue amounts established under subsection (b).

12 “(2) FISCAL YEARS 2014 THROUGH 2017.—Not
13 more than 60 days before the first day of each of
14 fiscal years 2014 through 2017, the Secretary shall
15 establish the drug master file fee, the abbreviated
16 new drug application fee, the prior approval supple-
17 ment fee, the generic drug facility fee, and the active
18 pharmaceutical ingredient facility fee under sub-
19 section (a) for such fiscal year, based on the revenue
20 amounts established under subsection (b) and the
21 adjustments provided under subsection (c).

22 “(3) FEE FOR ACTIVE PHARMACEUTICAL IN-
23 GREDIENT INFORMATION NOT INCLUDED BY REF-
24 ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-
25 GREDIENT DRUG MASTER FILE.—In establishing the

1 fees under paragraphs (1) and (2), the amount of
2 the fee under subsection (a)(3)(F) shall be deter-
3 mined by multiplying—

4 “(A) the sum of—

5 “(i) the total number of such active
6 pharmaceutical ingredients in such submis-
7 sion; and

8 “(ii) for each such ingredient that is
9 manufactured at more than one such facil-
10 ity, the total number of such additional fa-
11 cilities; and

12 “(B) the amount equal to the drug master
13 file fee established in subsection (a)(2) for such
14 submission.

15 “(e) LIMIT.—The total amount of fees charged, as
16 adjusted under subsection (c), for a fiscal year may not
17 exceed the total costs for such fiscal year for the resources
18 allocated for human generic drug activities.

19 “(f) IDENTIFICATION OF FACILITIES.—

20 “(1) PUBLICATION OF NOTICE; DEADLINE FOR
21 COMPLIANCE.—Not later than October 1, 2012, the
22 Secretary shall publish in the Federal Register a no-
23 tice requiring each person that owns a facility de-
24 scribed in subsection (a)(4)(A), or a site or organi-
25 zation required to be identified by paragraph (4), to

1 submit to the Secretary information on the identity
2 of each such facility, site, or organization. The no-
3 tice required by this paragraph shall specify the type
4 of information to be submitted and the means and
5 format for submission of such information.

6 “(2) REQUIRED SUBMISSION OF FACILITY
7 IDENTIFICATION.—Each person that owns a facility
8 described in subsection (a)(4)(A) or a site or organi-
9 zation required to be identified by paragraph (4)
10 shall submit to the Secretary the information re-
11 quired under this subsection each year. Such infor-
12 mation shall—

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

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

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

22 “(A) identification of a facility identified or
23 intended to be identified in an approved or
24 pending generic drug submission;

1 “(B) whether the facility manufactures ac-
2 tive pharmaceutical ingredients or finished dos-
3 age forms, or both;

4 “(C) whether or not the facility is located
5 within the United States and its territories and
6 possessions;

7 “(D) whether the facility manufactures
8 positron emission tomography drugs solely, or
9 in addition to other drugs; and

10 “(E) whether the facility manufactures
11 drugs that are not generic drugs.

12 “(4) CERTAIN SITES AND ORGANIZATIONS.—

13 “(A) IN GENERAL.—Any person that owns
14 or operates a site or organization described in
15 subparagraph (B) shall submit to the Secretary
16 information concerning the ownership, name,
17 and address of the site or organization.

18 “(B) SITES AND ORGANIZATIONS.—A site
19 or organization is described in this subpara-
20 graph if it is identified in a generic drug sub-
21 mission and is—

22 “(i) a site in which a bioanalytical
23 study is conducted;

24 “(ii) a clinical research organization;

1 “(iii) a contract analytical testing site;

2 or

3 “(iv) a contract repackager site.

4 “(C) NOTICE.—The Secretary may, by no-
5 tice published in the Federal Register, specify
6 the means and format for submission of the in-
7 formation under subparagraph (A) and may
8 specify, as necessary for purposes of this sec-
9 tion, any additional information to be sub-
10 mitted.

11 “(D) INSPECTION AUTHORITY.—The Sec-
12 retary’s inspection authority under section
13 704(a)(1) shall extend to all such sites and or-
14 ganizations.

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

16 “(1) GENERIC DRUG BACKLOG FEE.—Failure
17 to pay the fee under subsection (a)(1) shall result in
18 the Secretary placing the person that owns the ab-
19 breviated new drug application subject to that fee on
20 an arrears list, such that no new abbreviated new
21 drug applications or supplement submitted on or
22 after October 1, 2012, from that person, or any af-
23 filiate of that person, will be received within the
24 meaning of section 505(j)(5)(A) until such out-
25 standing fee is paid.

1 “(2) DRUG MASTER FILE FEE.—

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

9 “(B)(i) Any generic drug submission sub-
10 mitted on or after October 1, 2012, that ref-
11 erences, by a letter of authorization, a Type II
12 active pharmaceutical ingredient drug master
13 file that has not been deemed available for ref-
14 erence shall not be received within the meaning
15 of section 505(j)(5)(A) unless the condition
16 specified in clause (ii) is met.

17 “(ii) The condition specified in this clause
18 is that the fee established under subsection
19 (a)(2) has been paid within 20 calendar days of
20 the Secretary providing the notification to the
21 sponsor of the abbreviated new drug application
22 or supplement of the failure of the owner of the
23 Type II active pharmaceutical ingredient drug
24 master file to pay the drug master file fee as
25 specified in subparagraph (C).

1 “(C)(i) If an abbreviated new drug applica-
2 tion or supplement to an abbreviated new drug
3 application references a Type II active pharma-
4 ceutical ingredient drug master file for which a
5 fee under subsection (a)(2)(A) has not been
6 paid by the applicable date under subsection
7 (a)(2)(E), the Secretary shall notify the sponsor
8 of the abbreviated new drug application or sup-
9 plement of the failure of the owner of the Type
10 II active pharmaceutical ingredient drug master
11 file to pay the applicable fee.

12 “(ii) If such fee is not paid within 20 cal-
13 endar days of the Secretary providing the noti-
14 fication, the abbreviated new drug application
15 or supplement to an abbreviated new drug ap-
16 plication shall not be received within the mean-
17 ing of 505(j)(5)(A).

18 “(3) ABBREVIATED NEW DRUG APPLICATION
19 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—
20 Failure to pay a fee under subparagraph (A) or (F)
21 of subsection (a)(3) within 20 calendar days of the
22 applicable due date under subparagraph (C) of such
23 subsection shall result in the abbreviated new drug
24 application or the prior approval supplement to an
25 abbreviated new drug application not being received

1 within the meaning of section 505(j)(5)(A) until
2 such outstanding fee is paid.

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

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

10 “(i) The Secretary shall place the fa-
11 cility on a publicly available arrears list,
12 such that no new abbreviated new drug ap-
13 plication or supplement submitted on or
14 after October 1, 2012, from the person
15 that is responsible for paying such fee, or
16 any affiliate of that person, will be received
17 within the meaning of section 505(j)(5)(A).

18 “(ii) Any new generic drug submission
19 submitted on or after October 1, 2012,
20 that references such a facility shall not be
21 received, within the meaning of section
22 505(j)(5)(A) if the outstanding facility fee
23 is not paid within 20 calendar days of the
24 Secretary providing the notification to the
25 sponsor of the failure of the owner of the

1 facility to pay the facility fee under sub-
2 section (a)(4)(C).

3 “(iii) All drugs or active pharma-
4 ceutical ingredients manufactured in such
5 a facility or containing an ingredient man-
6 ufactured in such a facility shall be deemed
7 misbranded under section 502(aa).

8 “(B) APPLICATION OF PENALTIES.—The
9 penalties under this paragraph shall apply until
10 the fee established by subsection (a)(4) is paid
11 or the facility is removed from all generic drug
12 submissions that refer to the facility.

13 “(C) NONRECEIVAL FOR NONPAYMENT.—

14 “(i) NOTICE.—If an abbreviated new
15 drug application or supplement to an ab-
16 breviated new drug application submitted
17 on or after October 1, 2012, references a
18 facility for which a facility fee has not been
19 paid by the applicable date under sub-
20 section (a)(4)(C), the Secretary shall notify
21 the sponsor of the generic drug submission
22 of the failure of the owner of the facility
23 to pay the facility fee.

24 “(ii) NONRECEIVAL.—If the facility
25 fee is not paid within 20 calendar days of

1 the Secretary providing the notification
2 under clause (i), the abbreviated new drug
3 application or supplement to an abbrevi-
4 ated new drug application shall not be re-
5 ceived within the meaning of section
6 505(j)(5)(A).

7 “(h) LIMITATIONS.—

8 “(1) IN GENERAL.—Fees under subsection (a)
9 shall be refunded for a fiscal year beginning after
10 fiscal year 2012, unless appropriations for salaries
11 and expenses of the Food and Drug Administration
12 for such fiscal year (excluding the amount of fees
13 appropriated for such fiscal year) are equal to or
14 greater than the amount of appropriations for the
15 salaries and expenses of the Food and Drug Admin-
16 istration for the fiscal year 2009 (excluding the
17 amount of fees appropriated for such fiscal year)
18 multiplied by the adjustment factor (as defined in
19 section 744A) applicable to the fiscal year involved.

20 “(2) AUTHORITY.—If the Secretary does not
21 assess fees under subsection (a) during any portion
22 of a fiscal year and if at a later date in such fiscal
23 year the Secretary may assess such fees, the Sec-
24 retary may assess and collect such fees, without any
25 modification in the rate, for Type II active pharma-

1 ceutical ingredient drug master files, abbreviated
2 new drug applications and prior approval supple-
3 ments, and generic drug facilities and active phar-
4 maceutical ingredient facilities at any time in such
5 fiscal year notwithstanding the provisions of sub-
6 section (a) relating to the date fees are to be paid.

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

8 “(1) IN GENERAL.—Fees authorized under sub-
9 section (a) shall be collected and available for obliga-
10 tion only to the extent and in the amount provided
11 in advance in appropriations Acts, subject to para-
12 graph (2). Such fees are authorized to remain avail-
13 able until expended. Such sums as may be necessary
14 may be transferred from the Food and Drug Admin-
15 istration salaries and expenses appropriation account
16 without fiscal year limitation to such appropriation
17 account for salaries and expenses with such fiscal
18 year limitation. The sums transferred shall be avail-
19 able solely for human generic drug activities.

20 “(2) COLLECTIONS AND APPROPRIATION
21 ACTS.—

22 “(A) IN GENERAL.—The fees authorized
23 by this section—

24 “(i) subject to subparagraphs (C) and
25 (D), shall be collected and available in each

1 fiscal year in an amount not to exceed the
2 amount specified in appropriation Acts, or
3 otherwise made available for obligation for
4 such fiscal year; and

5 “(ii) shall be available for a fiscal year
6 beginning after fiscal year 2012 to defray
7 the costs of human generic drug activities
8 (including such costs for an additional
9 number of full-time equivalent positions in
10 the Department of Health and Human
11 Services to be engaged in such activities),
12 only if the Secretary allocates for such
13 purpose an amount for such fiscal year
14 (excluding amounts from fees collected
15 under this section) no less than
16 \$97,000,000 multiplied by the adjustment
17 factor, as defined in section 744A(3), ap-
18 plicable to the fiscal year involved.

19 “(B) COMPLIANCE.—The Secretary shall
20 be considered to have met the requirements of
21 subparagraph (A)(ii) in any fiscal year if the
22 costs funded by appropriations and allocated for
23 human generic activities are not more than 10
24 percent below the level specified in such sub-
25 paragraph.

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

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

17 “(3) AUTHORIZATION OF APPROPRIATIONS.—
18 For each of the fiscal years 2013 through 2017,
19 there is authorized to be appropriated for fees under
20 this section an amount equivalent to the total rev-
21 enue amount determined under subsection (b) for
22 the fiscal year, as adjusted under subsection (c), if
23 applicable, or as otherwise affected under paragraph
24 (2) of this subsection.

1 “(j) 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 calendar days after
4 it is due, such fee shall be treated as a claim of the United
5 States Government subject to subchapter II of chapter 37
6 of title 31, United States Code.

7 “(k) CONSTRUCTION.—This section may not be con-
8 strued to require that the number of full-time equivalent
9 positions in the Department of Health and Human Serv-
10 ices, for officers, employees, and advisory committees not
11 engaged in human generic drug activities, be reduced to
12 offset the number of officers, employees, and advisory
13 committees so engaged.

14 “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

15 “(1) EXEMPTION FROM FEES.—Submission of
16 an application for a positron emission tomography
17 drug or active pharmaceutical ingredient for a
18 positron emission tomography drug shall not require
19 the payment of any fee under this section. Facilities
20 that solely produce positron emission tomography
21 drugs shall not be required to pay a facility fee as
22 established in subsection (a)(4).

23 “(2) IDENTIFICATION REQUIREMENT.—Facili-
24 ties that produce positron emission tomography
25 drugs or active pharmaceutical ingredients of such

1 drugs are required to be identified pursuant to sub-
2 section (f).

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

8 “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—
9 An abbreviated new drug application that is not consid-
10 ered to be received within the meaning of section
11 505(j)(5)(A) because of failure to pay an applicable fee
12 under this provision within the time period specified in
13 subsection (g) shall be deemed not to have been ‘substan-
14 tially complete’ on the date of its submission within the
15 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbrevi-
16 ated new drug application that is not substantially com-
17 plete on the date of its submission solely because of failure
18 to pay an applicable fee under the preceding sentence shall
19 be deemed substantially complete and received within the
20 meaning of section 505(j)(5)(A) as of the date such appli-
21 cable fee is received.”.

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

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

1 **“SEC. 744C. 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 301(b)
12 of the Generic Drug User Fee Amendments of 2012 dur-
13 ing such fiscal year and the future plans of the Food and
14 Drug Administration for meeting the goals.

15 “(b) **FISCAL REPORT.**—Beginning with fiscal year
16 2013, not later than 120 days after the end of each fiscal
17 year for which fees are collected under this part, the Sec-
18 retary shall prepare and submit to the Committee on En-
19 ergy and Commerce of the House of Representatives and
20 the Committee on Health, Education, Labor, and Pen-
21 sions of the Senate a report on the implementation of the
22 authority for such fees during such fiscal year and the
23 use, by the Food and Drug Administration, of the fees
24 collected for such fiscal year.

25 “(c) **PUBLIC AVAILABILITY.**—The Secretary shall
26 make the reports required under subsections (a) and (b)

1 available to the public on the Internet Web site of the
2 Food and Drug Administration.

3 “(d) REAUTHORIZATION.—

4 “(1) CONSULTATION.—In developing rec-
5 ommendations to present to the Congress with re-
6 spect to the goals, and plans for meeting the goals,
7 for human generic drug activities for the first 5 fis-
8 cal years after fiscal year 2017, and for the reau-
9 thorization of this part for such fiscal years, the Sec-
10 retary shall consult with—

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

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

15 “(C) scientific and academic experts;

16 “(D) health care professionals;

17 “(E) representatives of patient and con-
18 sumer advocacy groups; and

19 “(F) the generic drug industry.

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

23 “(A) publish a notice in the Federal Reg-
24 ister requesting public input on the reauthoriza-
25 tion;

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

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

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

10 “(3) PERIODIC CONSULTATION.—Not less fre-
11 quently than once every month during negotiations
12 with the generic drug industry, the Secretary shall
13 hold discussions with representatives of patient and
14 consumer advocacy groups to continue discussions of
15 their views on the reauthorization and their sugges-
16 tions for changes to this part as expressed under
17 paragraph (2).

18 “(4) PUBLIC REVIEW OF RECOMMENDA-
19 TIONS.—After negotiations with the generic drug in-
20 dustry, the Secretary shall—

21 “(A) present the recommendations devel-
22 oped under paragraph (1) to the congressional
23 committees specified in such paragraph;

24 “(B) publish such recommendations in the
25 Federal Register;

1 “(C) provide for a period of 30 days for
2 the public to provide written comments on such
3 recommendations;

4 “(D) hold a meeting at which the public
5 may present its views on such recommenda-
6 tions; and

7 “(E) after consideration of such public
8 views and comments, revise such recommenda-
9 tions as necessary.

10 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
11 Not later than January 15, 2017, the Secretary
12 shall transmit to the Congress the revised rec-
13 ommendations under paragraph (4), a summary of
14 the views and comments received under such para-
15 graph, and any changes made to the recommenda-
16 tions in response to such views and comments.

17 “(6) MINUTES OF NEGOTIATION MEETINGS.—

18 “(A) PUBLIC AVAILABILITY.—Before pre-
19 sented the recommendations developed under
20 paragraphs (1) through (5) to the Congress, the
21 Secretary shall make publicly available, on the
22 Internet Web site of the Food and Drug Ad-
23 ministration, minutes of all negotiation meet-
24 ings conducted under this subsection between

1 the Food and Drug Administration and the ge-
2 neric drug industry.

3 “(B) CONTENT.—The minutes described
4 under subparagraph (A) shall summarize any
5 substantive proposal made by any party to the
6 negotiations as well as significant controversies
7 or differences of opinion during the negotiations
8 and their resolution.”.

9 **SEC. 304. SUNSET DATES.**

10 (a) AUTHORIZATION.—The amendments made by
11 section 302 cease to be effective October 1, 2017.

12 (b) REPORTING REQUIREMENTS.—The amendments
13 made by section 303 cease to be effective January 31,
14 2018.

15 **SEC. 305. EFFECTIVE DATE.**

16 The amendments made by this title shall take effect
17 on October 1, 2012, or the date of the enactment of this
18 title, whichever is later, except that fees under section 302
19 shall be assessed for all human generic drug submissions
20 and Type II active pharmaceutical drug master files re-
21 ceived on or after October 1, 2012, regardless of the date
22 of enactment of this title.

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

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

1 “(aa) If it is a drug, or an active pharmaceutical in-
 2 gredient, and it was manufactured, prepared, propagated,
 3 compounded, or processed in a facility for which fees have
 4 not been paid as required by section 744A(a)(4) or for
 5 which identifying information required by section 744B(f)
 6 has not been submitted, or it contains an active pharma-
 7 ceutical ingredient that was manufactured, prepared,
 8 propagated, compounded, or processed in such a facility.”.

9 **SEC. 307. STREAMLINED HIRING AUTHORITY OF THE FOOD**
 10 **AND DRUG ADMINISTRATION TO SUPPORT**
 11 **ACTIVITIES RELATED TO HUMAN GENERIC**
 12 **DRUGS.**

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

15 (1) in subsection (b)—

16 (A) by striking “are activities” and insert-
 17 ing “are—

18 “(1) activities”;

19 (B) by striking the period at the end and
 20 inserting “; and”; and

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

22 “(2) activities under this Act related to human
 23 generic drug activities (as defined in section
 24 744A).”; and

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

3 “(c) OBJECTIVES SPECIFIED.—The objectives speci-
4 fied in this subsection are—

5 “(1) with respect to the activities under sub-
6 section (b)(1), the goals referred to in section
7 738A(a)(1); and

8 “(2) with respect to the activities under sub-
9 section (b)(2), the performance goals with respect to
10 section 744A (regarding assessment and use of
11 human generic drug fees), as set forth in the letters
12 described in section 301(b) of the Generic Drug
13 User Fee Amendments of 2012.”.

14 **TITLE IV—FEES RELATING TO**
15 **BIOSIMILAR BIOLOGICAL**
16 **PRODUCTS**

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

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

20 (b) FINDING.—The Congress finds that the fees au-
21 thorized by the amendments made in this title will be dedi-
22 cated to expediting the process for the review of biosimilar
23 biological product applications, including postmarket safe-
24 ty activities, as set forth in the goals identified for pur-
25 poses of part 8 of subchapter C of chapter VII of the Fed-

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

7 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
8 **PRODUCTS.**

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

12 **“PART 8—FEES RELATING TO BIOSIMILAR**
13 **BIOLOGICAL PRODUCTS**

14 **“SEC. 744G. DEFINITIONS.**

15 “For purposes of this part:

16 “(1) The term ‘adjustment factor’ applicable to
17 a fiscal year that is the Consumer Price Index for
18 all urban consumers (Washington-Baltimore, DC-
19 MD-VA-WV; Not Seasonally Adjusted; All items) of
20 the preceding fiscal year divided by such Index for
21 September 2011.

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

1 “(A) one business entity controls, or has
2 the power to control, the other business entity;
3 or

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

6 “(3) The term ‘biosimilar biological product’
7 means a product for which a biosimilar biological
8 product application has been approved.

9 “(4)(A) Subject to subparagraph (B), the term
10 ‘biosimilar biological product application’ means an
11 application for licensure of a biological product
12 under section 351(k) of the Public Health Service
13 Act.

14 “(B) Such term does not include—

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

16 “(ii) an application filed under section
17 351(k) of the Public Health Service Act that
18 cites as the reference product a bovine blood
19 product for topical application licensed before
20 September 1, 1992, or a large volume paren-
21 teral drug product approved before such date;

22 “(iii) an application filed under section
23 351(k) of the Public Health Service Act with
24 respect to—

1 “(I) whole blood or a blood component
2 for transfusion;

3 “(II) an allergenic extract product;

4 “(III) an in vitro diagnostic biological
5 product; or

6 “(IV) a biological product for further
7 manufacturing use only; or

8 “(iv) an application for licensure under
9 section 351(k) of the Public Health Service Act
10 that is submitted by a State or Federal Govern-
11 ment entity for a product that is not distributed
12 commercially.

13 “(5) The term ‘biosimilar biological product de-
14 velopment meeting’ means any meeting, other than
15 a biosimilar initial advisory meeting, regarding the
16 content of a development program, including a pro-
17 posed design for, or data from, a study intended to
18 support a biosimilar biological product application.

19 “(6) The term ‘biosimilar biological product de-
20 velopment program’ means the program under this
21 part for expediting the process for the review of sub-
22 missions in connection with biosimilar biological
23 product development.

1 “(7)(A) The term ‘biosimilar biological product
2 establishment’ means a foreign or domestic place of
3 business—

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

7 “(ii) at which one or more biosimilar bio-
8 logical products are manufactured in final dos-
9 age form.

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

12 “(8) The term ‘biosimilar initial advisory meet-
13 ing’—

14 “(A) means a meeting, if requested, that is
15 limited to—

16 “(i) a general discussion regarding
17 whether licensure under section 351(k) of
18 the Public Health Service Act may be fea-
19 sible for a particular product; and

20 “(ii) if so, general advice on the ex-
21 pected content of the development pro-
22 gram; and

23 “(B) does not include any meeting that in-
24 volves substantive review of summary data or
25 full study reports.

1 “(9) The term ‘costs of resources allocated for
2 the process for the review of biosimilar biological
3 product applications’ means the expenses in connec-
4 tion with the process for the review of biosimilar bio-
5 logical product applications for—

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

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

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

20 “(D) collecting fees under section 744H
21 and accounting for resources allocated for the
22 review of submissions in connection with bio-
23 similar biological product development, bio-
24 similar biological product applications, and sup-
25 plements.

1 “(10) The term ‘final dosage form’ means, with
2 respect to a biosimilar biological product, a finished
3 dosage form which is approved for administration to
4 a patient without substantial further manufacturing
5 (such as lyophilized products before reconstitution).

6 “(11) The term ‘financial hold’—

7 “(A) means an order issued by the Sec-
8 retary to prohibit the sponsor of a clinical in-
9 vestigation from continuing the investigation if
10 the Secretary determines that the investigation
11 is intended to support a biosimilar biological
12 product application and the sponsor has failed
13 to pay any fee for the product required under
14 subparagraph (A), (B), or (D) of section
15 744H(a)(1); and

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

20 “(12) The term ‘person’ includes an affiliate of
21 such person.

22 “(13) The term ‘process for the review of bio-
23 similar biological product applications’ means the
24 following activities of the Secretary with respect to
25 the review of submissions in connection with bio-

1 similar biological product development, biosimilar bi-
2 ological product applications, and supplements:

3 “(A) The activities necessary for the re-
4 view of submissions in connection with bio-
5 similar biological product development, bio-
6 similar biological product applications, and sup-
7 plements.

8 “(B) Actions related to submissions in con-
9 nection with biosimilar biological product devel-
10 opment, the issuance of action letters which ap-
11 prove biosimilar biological product applications
12 or which set forth in detail the specific defi-
13 ciencies in such applications, and where appro-
14 priate, the actions necessary to place such ap-
15 plications in condition for approval.

16 “(C) The inspection of biosimilar biological
17 product establishments and other facilities un-
18 dertaken as part of the Secretary’s review of
19 pending biosimilar biological product applica-
20 tions and supplements.

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

1 “(E) Monitoring of research conducted in
2 connection with the review of biosimilar biological
3 product applications.

4 “(F) Postmarket safety activities with re-
5 spect to biologics approved under biosimilar bio-
6 logical product applications or supplements, in-
7 cluding the following activities:

8 “(i) Collecting, developing, and re-
9 viewing safety information on biosimilar bi-
10 ological products, including adverse-event
11 reports.

12 “(ii) Developing and using improved
13 adverse-event data-collection systems, in-
14 cluding information technology systems.

15 “(iii) Developing and using improved
16 analytical tools to assess potential safety
17 problems, including access to external data
18 bases.

19 “(iv) Implementing and enforcing sec-
20 tion 505(o) (relating to postapproval stud-
21 ies and clinical trials and labeling changes)
22 and section 505(p) (relating to risk evalua-
23 tion and mitigation strategies).

1 “(v) Carrying out section 505(k)(5)
2 (relating to adverse-event reports and
3 postmarket safety activities).

4 “(14) The term ‘supplement’ means a request
5 to the Secretary to approve a change in a biosimilar
6 biological product application which has been ap-
7 proved, including a supplement requesting that the
8 Secretary determine that the biosimilar biological
9 product meets the standards for interchangeability
10 described in section 351(k)(4) of the Public Health
11 Service Act.

12 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
13 **BIOLOGICAL PRODUCT FEES.**

14 “(a) TYPES OF FEES.—Beginning in fiscal year
15 2013, the Secretary shall assess and collect fees in accord-
16 ance with this section as follows:

17 “(1) BIOSIMILAR DEVELOPMENT PROGRAM
18 FEES.—

19 “(A) INITIAL BIOSIMILAR BIOLOGICAL
20 PRODUCT DEVELOPMENT FEE.—

21 “(i) IN GENERAL.—Each person that
22 submits to the Secretary a meeting request
23 described under clause (ii) or a clinical
24 protocol for an investigational new drug
25 protocol described under clause (iii) shall

1 pay for the product named in the meeting
2 request or the investigational new drug ap-
3 plication the initial biosimilar biological
4 product development fee established under
5 subsection (b)(1)(A).

6 “(ii) MEETING REQUEST.—The meet-
7 ing request described in this clause is a re-
8 quest for a biosimilar biological product
9 development meeting for a product.

10 “(iii) CLINICAL PROTOCOL FOR IND.—
11 A clinical protocol for an investigational
12 new drug protocol described in this clause
13 is a clinical protocol consistent with the
14 provisions of section 505(i), including any
15 regulations promulgated under section
16 505(i), (referred to in this section as ‘in-
17 vestigational new drug application’) de-
18 scribing an investigation that the Secretary
19 determines is intended to support a bio-
20 similar biological product application for a
21 product.

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

1 “(I) Not later than 5 days after
2 the Secretary grants a request for a
3 biosimilar biological product develop-
4 ment meeting.

5 “(II) The date of submission of
6 an investigational new drug applica-
7 tion describing an investigation that
8 the Secretary determines is intended
9 to support a biosimilar biological
10 product application.

11 “(v) TRANSITION RULE.—Each per-
12 son that has submitted an investigational
13 new drug application prior to the date of
14 enactment of the Biosimilars User Fee Act
15 of 2012 shall pay the initial biosimilar bio-
16 logical product development fee by the ear-
17 lier of the following:

18 “(I) Not later than 60 days after
19 the date of the enactment of the
20 Biosimilars User Fee Act of 2012, if
21 the Secretary determines that the in-
22 vestigational new drug application de-
23 scribes an investigation that is in-
24 tended to support a biosimilar biologi-
25 cal product application.

1 “(II) Not later than 5 days after
2 the Secretary grants a request for a
3 biosimilar biological product develop-
4 ment meeting.

5 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
6 PRODUCT DEVELOPMENT FEE.—

7 “(i) IN GENERAL.—A person that
8 pays an initial biosimilar biological product
9 development fee for a product shall pay for
10 such product, beginning in the fiscal year
11 following the fiscal year in which the initial
12 biosimilar biological product development
13 fee was paid, an annual fee established
14 under subsection (b)(1)(B) for biosimilar
15 biological product development (referred to
16 in this section as ‘annual biosimilar bio-
17 logical product development fee’).

18 “(ii) DUE DATE.—The annual bio-
19 similar biological product development pro-
20 gram fee for each fiscal year will be due on
21 the later of—

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

24 “(II) the first business day after
25 the enactment of an appropriations

1 Act providing for the collection and
2 obligation of fees for such year under
3 this section.

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

8 “(I) submitted a marketing appli-
9 cation for the biological product that
10 was accepted for filing; or

11 “(II) discontinued participation
12 in the biosimilar biological product de-
13 velopment program for the product
14 under subparagraph (C).

15 “(C) DISCONTINUATION OF FEE OBLIGA-
16 TION.—A person may discontinue participation
17 in the biosimilar biological product development
18 program for a product effective October 1 of a
19 fiscal year by, not later than August 1 of the
20 preceding fiscal year—

21 “(i) if no investigational new drug ap-
22 plication concerning the product has been
23 submitted, submitting to the Secretary a
24 written declaration that the person has no
25 present intention of further developing the

1 product as a biosimilar biological product;

2 or

3 “(ii) if an investigational new drug
4 application concerning the product has
5 been submitted, by withdrawing the inves-
6 tigational new drug application in accord-
7 ance with part 312 of title 21, Code of
8 Federal Regulations (or any successor reg-
9 ulations).

10 “(D) REACTIVATION FEE.—

11 “(i) IN GENERAL.—A person that has
12 discontinued participation in the biosimilar
13 biological product development program for
14 a product under subparagraph (C) shall
15 pay a fee (referred to in this section as ‘re-
16 activation fee’) by the earlier of the fol-
17 lowing:

18 “(I) Not later than 5 days after
19 the Secretary grants a request for a
20 biosimilar biological product develop-
21 ment meeting for the product (after
22 the date on which such participation
23 was discontinued).

24 “(II) Upon the date of submis-
25 sion (after the date on which such

1 participation was discontinued) of an
2 investigational new drug application
3 describing an investigation that the
4 Secretary determines is intended to
5 support a biosimilar biological product
6 application for that product.

7 “(ii) APPLICATION OF ANNUAL
8 FEE.—A person that pays a reactivation
9 fee for a product shall pay for such prod-
10 uct, beginning in the next fiscal year, the
11 annual biosimilar biological product devel-
12 opment fee under subparagraph (B).

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

15 “(i) NO BIOSIMILAR BIOLOGICAL
16 PRODUCT DEVELOPMENT MEETINGS.—If a
17 person has failed to pay an initial or an-
18 nual biosimilar biological product develop-
19 ment fee as required under subparagraph
20 (A) or (B), or a reactivation fee as re-
21 quired under subparagraph (D), the Sec-
22 retary shall not provide a biosimilar bio-
23 logical product development meeting relat-
24 ing to the product for which fees are owed.

1 “(ii) NO RECEIPT OF INVESTIGA-
2 TIONAL NEW DRUG APPLICATIONS.—Ex-
3 cept in extraordinary circumstances, the
4 Secretary shall not consider an investiga-
5 tional new drug application to have been
6 received under section 505(i)(2) if—

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

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

18 “(iii) FINANCIAL HOLD.—Notwith-
19 standing section 505(i)(2), except in ex-
20 traordinary circumstances, the Secretary
21 shall prohibit the sponsor of a clinical in-
22 vestigation from continuing the investiga-
23 tion if—

24 “(I) the Secretary determines
25 that the investigation is intended to

1 support a biosimilar biological product
2 application; and

3 “(II) the sponsor has failed to
4 pay an initial or annual biosimilar bio-
5 logical product development fee for
6 the product as required under sub-
7 paragraph (A) or (B), or a reactiva-
8 tion fee for the product as required
9 under subparagraph (D).

10 “(iv) NO ACCEPTANCE OF BIOSIMILAR
11 BIOLOGICAL PRODUCT APPLICATIONS OR
12 SUPPLEMENTS.—If a person has failed to
13 pay an initial or annual biosimilar biologi-
14 cal product development fee as required
15 under subparagraph (A) or (B), or a reac-
16 tivation fee as required under subpara-
17 graph (D), any biosimilar biological prod-
18 uct application or supplement submitted by
19 that person shall be considered incomplete
20 and shall not be accepted for filing by the
21 Secretary until all such fees owed by such
22 person have been paid.

23 “(F) LIMITS REGARDING BIOSIMILAR DE-
24 VELOPMENT PROGRAM FEES.—

1 “(i) NO REFUNDS.—The Secretary
2 shall not refund any initial or annual bio-
3 similar biological product development fee
4 paid under subparagraph (A) or (B), or
5 any reactivation fee paid under subpara-
6 graph (D).

7 “(ii) NO WAIVERS, EXEMPTIONS, OR
8 REDUCTIONS.—The Secretary shall not
9 grant a waiver, exemption, or reduction of
10 any initial or annual biosimilar biological
11 product development fee due or payable
12 under subparagraph (A) or (B), or any re-
13 activation fee due or payable under sub-
14 paragraph (D).

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

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

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

23 “(I) the amount of the fee estab-
24 lished under subsection (b)(1)(D) for

1 a biosimilar biological product applica-
2 tion; minus

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

8 “(ii) A fee for a biosimilar biological
9 product application for which clinical data
10 (other than comparative bioavailability
11 studies) with respect to safety or effective-
12 ness are not required, that is equal to—

13 “(I) half of the amount of the fee
14 established under subsection (b)(1)(D)
15 for a biosimilar biological product ap-
16 plication; minus

17 “(II) the cumulative amount of
18 fees paid, if any, under subparagraphs
19 (A), (B), and (D) of paragraph (1)
20 for that product.

21 “(iii) A fee for a supplement for which
22 clinical data (other than comparative bio-
23 availability studies) with respect to safety
24 or effectiveness are required, that is equal
25 to half of the amount of the fee established

1 under subsection (b)(1)(D) for a biosimilar
2 biological product application.

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

17 “(C) PAYMENT DUE DATE.—Any fee re-
18 quired by subparagraph (A) shall be due upon
19 submission of the application or supplement for
20 which such fee applies.

21 “(D) EXCEPTION FOR PREVIOUSLY FILED
22 APPLICATION OR SUPPLEMENT.—If a biosimilar
23 biological product application or supplement
24 was submitted by a person that paid the fee for
25 such application or supplement, was accepted

1 for filing, and was not approved or was with-
2 drawn (without a waiver), the submission of a
3 biosimilar biological product application or a
4 supplement for the same product by the same
5 person (or the person's licensee, assignee, or
6 successor) shall not be subject to a fee under
7 subparagraph (A).

8 “(E) REFUND OF APPLICATION FEE IF AP-
9 PPLICATION REFUSED FOR FILING OR WITH-
10 DRAWN BEFORE FILING.—The Secretary shall
11 refund 75 percent of the fee paid under this
12 paragraph for any application or supplement
13 which is refused for filing or withdrawn without
14 a waiver before filing.

15 “(F) FEES FOR APPLICATIONS PRE-
16 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
17 BEFORE FILING.—A biosimilar biological prod-
18 uct application or supplement that was sub-
19 mitted but was refused for filing, or was with-
20 drawn before being accepted or refused for fil-
21 ing, shall be subject to the full fee under sub-
22 paragraph (A) upon being resubmitted or filed
23 over protest, unless the fee is waived under sub-
24 section (c).

1 “(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTAB-
2 LISHMENT FEE.—

3 “(A) IN GENERAL.—Except as provided in
4 subparagraph (E), each person that is named
5 as the applicant in a biosimilar biological prod-
6 uct application shall be assessed an annual fee
7 established under subsection (b)(1)(E) for each
8 biosimilar biological product establishment that
9 is listed in the approved biosimilar biological
10 product application as an establishment that
11 manufactures the biosimilar biological product
12 named in such application.

13 “(B) ASSESSMENT IN FISCAL YEARS.—The
14 establishment fee shall be assessed in each fis-
15 cal year for which the biosimilar biological prod-
16 uct named in the application is assessed a fee
17 under paragraph (4) unless the biosimilar bio-
18 logical product establishment listed in the appli-
19 cation does not engage in the manufacture of
20 the biosimilar biological product during such
21 fiscal year.

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

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

1 “(ii) the first business day after the
2 enactment of an appropriations Act pro-
3 viding for the collection and obligation of
4 fees for such fiscal year under this section.

5 “(D) APPLICATION TO ESTABLISHMENT.—

6 “(i) Each biosimilar biological product
7 establishment shall be assessed only one
8 fee per biosimilar biological product estab-
9 lishment, notwithstanding the number of
10 biosimilar biological products manufac-
11 tured at the establishment, subject to
12 clause (ii).

13 “(ii) In the event an establishment is
14 listed in a biosimilar biological product ap-
15 plication by more than one applicant, the
16 establishment fee for the fiscal year shall
17 be divided equally and assessed among the
18 applicants whose biosimilar biological prod-
19 ucts are manufactured by the establish-
20 ment during the fiscal year and assessed
21 biosimilar biological product fees under
22 paragraph (4).

23 “(E) EXCEPTION FOR NEW PRODUCTS.—

24 If, during the fiscal year, an applicant initiates
25 or causes to be initiated the manufacture of a

1 biosimilar biological product at an establish-
2 ment listed in its biosimilar biological product
3 application—

4 “(i) that did not manufacture the bio-
5 similar biological product in the previous
6 fiscal year; and

7 “(ii) for which the full biosimilar bio-
8 logical product establishment fee has been
9 assessed in the fiscal year at a time before
10 manufacture of the biosimilar biological
11 product was begun,

12 the applicant shall not be assessed a share of
13 the biosimilar biological product establishment
14 fee for the fiscal year in which the manufacture
15 of the product began.

16 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

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

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

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

3 “(ii) the first business day after the
4 enactment of an appropriations Act pro-
5 viding for the collection and obligation of
6 fees for such year under this section.

7 “(C) ONE FEE PER PRODUCT PER YEAR.—

8 The biosimilar biological product fee shall be
9 paid only once for each product for each fiscal
10 year.

11 “(b) FEE SETTING AND AMOUNTS.—

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

18 “(A) INITIAL BIOSIMILAR BIOLOGICAL
19 PRODUCT DEVELOPMENT FEE.—The initial bio-
20 similar biological product development fee under
21 subsection (a)(1)(A) for a fiscal year shall be
22 equal to 10 percent of the amount established
23 under section 736(c)(4) for a human drug ap-
24 plication described in section 736(a)(1)(A)(i)
25 for that fiscal year.

1 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
2 PRODUCT DEVELOPMENT FEE.—The annual
3 biosimilar biological product development fee
4 under subsection (a)(1)(B) for a fiscal year
5 shall be equal to 10 percent of the amount es-
6 tablished under section 736(c)(4) for a human
7 drug application described in section
8 736(a)(1)(A)(i) for that fiscal year.

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

15 “(D) BIOSIMILAR BIOLOGICAL PRODUCT
16 APPLICATION FEE.—The biosimilar biological
17 product application fee under subsection (a)(2)
18 for a fiscal year shall be equal to the amount
19 established under section 736(c)(4) for a
20 human drug application described in section
21 736(a)(1)(A)(i) for that fiscal year.

22 “(E) BIOSIMILAR BIOLOGICAL PRODUCT
23 ESTABLISHMENT FEE.—The biosimilar biologi-
24 cal product establishment fee under subsection
25 (a)(3) for a fiscal year shall be equal to the

1 amount established under section 736(c)(4) for
2 a prescription drug establishment for that fiscal
3 year.

4 “(F) BIOSIMILAR BIOLOGICAL PRODUCT
5 FEE.—The biosimilar biological product fee
6 under subsection (a)(4) for a fiscal year shall be
7 equal to the amount established under section
8 736(c)(4) for a prescription drug product for
9 that fiscal year.

10 “(2) LIMIT.—The total amount of fees charged
11 for a fiscal year under this section may not exceed
12 the total amount for such fiscal year of the costs of
13 resources allocated for the process for the review of
14 biosimilar biological product applications.

15 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-
16 NESS.—

17 “(1) WAIVER OF APPLICATION FEE.—The Sec-
18 retary shall grant to a person who is named in a bio-
19 similar biological product application a waiver from
20 the application fee assessed to that person under
21 subsection (a)(2)(A) for the first biosimilar biologi-
22 cal product application that a small business or its
23 affiliate submits to the Secretary for review. After a
24 small business or its affiliate is granted such a waiv-
25 er, the small business or its affiliate shall pay—

1 “(A) application fees for all subsequent
2 biosimilar biological product applications sub-
3 mitted to the Secretary for review in the same
4 manner as an entity that is not a small busi-
5 ness; and

6 “(B) all supplement fees for all supple-
7 ments to biosimilar biological product applica-
8 tions submitted to the Secretary for review in
9 the same manner as an entity that is not a
10 small business.

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

16 “(3) SMALL BUSINESS DEFINED.—In this sub-
17 section, the term ‘small business’ means an entity
18 that has fewer than 500 employees, including em-
19 ployees of affiliates, and does not have a drug prod-
20 uct that has been approved under a human drug ap-
21 plication (as defined in section 735) or a biosimilar
22 biological product application (as defined in section
23 744G(4)) and introduced or delivered for introduc-
24 tion into interstate commerce.

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

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

8 “(1) IN GENERAL.—Subject to paragraph (2),
9 fees authorized under subsection (a) shall be col-
10 lected and available for obligation only to the extent
11 and in the amount provided in advance in appropria-
12 tions Acts. Such fees are authorized to remain avail-
13 able until expended. Such sums as may be necessary
14 may be transferred from the Food and Drug Admin-
15 istration salaries and expenses appropriation account
16 without fiscal year limitation to such appropriation
17 account for salaries and expenses with such fiscal
18 year limitation. The sums transferred shall be avail-
19 able solely for the process for the review of bio-
20 similar biological product applications.

21 “(2) COLLECTIONS AND APPROPRIATION
22 ACTS.—

23 “(A) IN GENERAL.—Subject to subpara-
24 graphs (C) and (D), the fees authorized by this
25 section shall be collected and available in each

1 fiscal year in an amount not to exceed the
2 amount specified in appropriation Acts, or oth-
3 erwise made available for obligation for such
4 fiscal year.

5 “(B) USE OF FEES AND LIMITATION.—

6 The fees authorized by this section shall be
7 available for a fiscal year beginning after fiscal
8 year 2012 to defray the costs of the process for
9 the review of biosimilar biological product appli-
10 cations (including such costs for an additional
11 number of full-time equivalent positions in the
12 Department of Health and Human Services to
13 be engaged in such process), only if the Sec-
14 retary allocates for such purpose an amount for
15 such fiscal year (excluding amounts from fees
16 collected under this section) no less than
17 \$20,000,000, multiplied by the adjustment fac-
18 tor applicable to the fiscal year involved.

19 “(C) FEE COLLECTION DURING FIRST

20 PROGRAM YEAR.—Until the date of enactment
21 of an Act making appropriations through Sep-
22 tember 30, 2013, for the salaries and expenses
23 account of the Food and Drug Administration,
24 fees authorized by this section for fiscal year
25 2013 may be collected and shall be credited to

1 such account and remain available until ex-
2 pended.

3 “(D) PROVISION FOR EARLY PAYMENTS IN
4 SUBSEQUENT YEARS.—Payment of fees author-
5 ized under this section for a fiscal year (after
6 fiscal year 2013), prior to the due date for such
7 fees, may be accepted by the Secretary in ac-
8 cordance with authority provided in advance in
9 a prior year appropriations Act.

10 “(3) AUTHORIZATION OF APPROPRIATIONS.—
11 For each of fiscal years 2013 through 2017, there
12 is authorized to be appropriated for fees under this
13 section an amount equivalent to the total amount of
14 fees assessed for such fiscal year under this section.

15 “(f) COLLECTION OF UNPAID FEES.—In any case
16 where the Secretary does not receive payment of a fee as-
17 sessed under subsection (a) within 30 days after it is due,
18 such fee shall be treated as a claim of the United States
19 Government subject to subchapter II of chapter 37 of title
20 31, United States Code.

21 “(g) WRITTEN REQUESTS FOR WAIVERS AND RE-
22 FUNDS.—To qualify for consideration for a waiver under
23 subsection (e), or for a refund of any fee collected in ac-
24 cordance with subsection (a)(2)(A), a person shall submit

1 to the Secretary a written request for such waiver or re-
2 fund not later than 180 days after such fee is due.

3 “(h) CONSTRUCTION.—This section may not be con-
4 strued to require that the number of full-time equivalent
5 positions in the Department of Health and Human Serv-
6 ices, for officers, employers, and advisory committees not
7 engaged in the process of the review of biosimilar biologi-
8 cal product applications, be reduced to offset the number
9 of officers, employees, and advisory committees so en-
10 gaged.”.

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

12 Part 8 of subchapter C of chapter VII, as added by
13 section 402, is further amended by inserting after section
14 744H the following:

15 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**
16 **MENTS.**

17 “(a) PERFORMANCE REPORT.—Beginning with fiscal
18 year 2013, not later than 120 days after the end of each
19 fiscal year for which fees are collected under this part,
20 the Secretary shall prepare and submit to the Committee
21 on Energy and Commerce of the House of Representatives
22 and the Committee on Health, Education, Labor, and
23 Pensions of the Senate a report concerning the progress
24 of the Food and Drug Administration in achieving the
25 goals identified in the letters described in section 401(b)

1 of the Biosimilar User Fee Act of 2012 during such fiscal
2 year and the future plans of the Food and Drug Adminis-
3 tration for meeting such goals. The report for a fiscal year
4 shall include information on all previous cohorts for which
5 the Secretary has not given a complete response on all
6 biosimilar biological product applications and supplements
7 in the cohort.

8 “(b) FISCAL REPORT.—Not later than 120 days after
9 the end of fiscal year 2013 and each subsequent fiscal year
10 for which fees are collected under this part, the Secretary
11 shall prepare and submit to the Committee on Energy and
12 Commerce of the House of Representatives and the Com-
13 mittee on Health, Education, Labor, and Pensions of the
14 Senate a report on the implementation of the authority
15 for such fees during such fiscal year and the use, by the
16 Food and Drug Administration, of the fees collected for
17 such fiscal year.

18 “(c) PUBLIC AVAILABILITY.—The Secretary shall
19 make the reports required under subsections (a) and (b)
20 available to the public on the Internet Web site of the
21 Food and Drug Administration.

22 “(d) STUDY.—

23 “(1) IN GENERAL.—The Secretary shall con-
24 tract with an independent accounting or consulting
25 firm to study the workload volume and full costs as-

1 sociated with the process for the review of biosimilar
2 biological product applications.

3 “(2) INTERIM RESULTS.—Not later than June
4 1, 2015, the Secretary shall publish, for public com-
5 ment, interim results of the study described under
6 paragraph (1).

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

11 “(e) REAUTHORIZATION.—

12 “(1) CONSULTATION.—In developing rec-
13 ommendations to present to the Congress with re-
14 spect to the goals described in subsection (a), and
15 plans for meeting the goals, for the process for the
16 review of biosimilar biological product applications
17 for the first 5 fiscal years after fiscal year 2017, and
18 for the reauthorization of this part for such fiscal
19 years, the Secretary shall consult with—

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

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

24 “(C) scientific and academic experts;

25 “(D) health care professionals;

1 “(E) representatives of patient and con-
2 sumer advocacy groups; and

3 “(F) the regulated industry.

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

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

10 “(B) publish such recommendations in the
11 Federal Register;

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

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

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

21 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
22 Not later than January 15, 2017, the Secretary
23 shall transmit to the Congress the revised rec-
24 ommendations under paragraph (2), a summary of
25 the views and comments received under such para-

1 graph, and any changes made to the recommenda-
2 tions in response to such views and comments.”.

3 **SEC. 404. SUNSET DATES.**

4 (a) AUTHORIZATION.—The amendment made by sec-
5 tion 402 shall cease to be effective October 1, 2017.

6 (b) REPORTING REQUIREMENTS.—The amendment
7 made by section 403 shall cease to be effective January
8 31, 2018.

9 **SEC. 405. EFFECTIVE DATE.**

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

13 (1) October 1, 2012; or

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

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

21 **SEC. 406. SAVINGS CLAUSE.**

22 Notwithstanding the amendments made by this title,
23 part 2 of subchapter C of chapter VII of the Federal Food,
24 Drug, and Cosmetic Act, as in effect on the day before
25 the date of the enactment of this title, shall continue to

1 be in effect with respect to human drug applications and
2 supplements (as defined in such part as of such day) that
3 were accepted by the Food and Drug Administration for
4 filing on or after October 1, 2007, but before October 1,
5 2012, with respect to assessing and collecting any fee re-
6 quired by such part for a fiscal year prior to fiscal year
7 2013.

8 **SEC. 407. CONFORMING AMENDMENT.**

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

11 **TITLE V—PEDIATRIC DRUGS**
12 **AND DEVICES**

13 **SEC. 501. PERMANENCE.**

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

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

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

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

22 (b) RESEARCH INTO PEDIATRIC USES FOR DRUGS
23 AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C.
24 355c) is amended—

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

1 under section 505C of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355d) of any significant modifica-
3 tions to initial pediatric study plans, agreed initial pedi-
4 atric study plans, and written requests under sections
5 505A and 505B of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355c). Such internal standard operating
7 procedures shall be made publicly available on the Internet
8 website of the Food and Drug Administration.

9 **SEC. 504. ACCESS TO DATA.**

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

1 **SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC**
2 **STUDIES.**

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

5 (1) in subsection (a)(3)—

6 (A) by redesignating subparagraph (B) as
7 subparagraph (C);

8 (B) by inserting after subparagraph (A)
9 the following:

10 “(B) **DEFERRAL EXTENSION.**—

11 “(i) **IN GENERAL.**—On the initiative
12 of the Secretary or at the request of the
13 applicant, the Secretary may grant an ex-
14 tension of a deferral approved under sub-
15 paragraph (A) for submission of some or
16 all assessments required under paragraph
17 (1) if—

18 “(I) the Secretary determines
19 that the conditions described in sub-
20 clause (II) or (III) of subparagraph
21 (A)(i) continue to be met; and

22 “(II) the applicant submits a new
23 timeline under subparagraph
24 (A)(ii)(IV) and any significant up-
25 dates to the information required
26 under subparagraph (A)(ii).

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

1 of enactment of such Act. The Secretary
2 shall respond to any such request as soon
3 as practicable, but not later than 1 year
4 after the date of enactment of such Act.
5 Nothing in this clause shall prevent the
6 Secretary from updating the status of a
7 study or studies publicly if components of
8 such study or studies are late or delayed.”;
9 and

10 (C) in subparagraph (C), as so redesign-
11 nated—

12 (i) in clause (i), by adding at the end
13 the following:

14 “(III) Projected completion date
15 for pediatric studies.

16 “(IV) The reason or reasons why
17 a deferral or deferral extension con-
18 tinues to be necessary.”; and

19 (ii) in clause (ii)—

20 (I) by inserting “, as well as the
21 date of each deferral or deferral ex-
22 tension, as applicable,” after “clause
23 (i)”;

24 (II) by inserting “not later than
25 90 days after submission to the Sec-

1 retary or with the next routine quar-
2 terly update” after “Administration”;
3 and

4 (2) in subsection (f)—

5 (A) in the subsection heading, by inserting
6 “DEFERRAL EXTENSIONS,” after “DEFER-
7 RALS,”;

8 (B) in paragraph (1), by inserting “, defer-
9 ral extension,” after “deferral”; and

10 (C) in paragraph (4)—

11 (i) in the paragraph heading, by in-
12 serting “DEFERRAL EXTENSIONS,” after
13 “DEFERRALS,”; and

14 (ii) by inserting “, deferral exten-
15 sions,” after “deferrals”.

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

19 “(D) aggregated on an annual basis—

20 “(i) the total number of deferrals and
21 deferral extensions requested and granted
22 under this section and, if granted, the rea-
23 sons for each such deferral or deferral ex-
24 tension;

1 “(ii) the timeline for completion of the
2 assessments; and

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

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

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

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

16 “(1) Beginning 270 days after the date of en-
17 actment of the Food and Drug Administration Safe-
18 ty and Innovation Act, the Secretary shall issue a
19 non-compliance letter to such person informing them
20 of such failure to submit or meet the requirements
21 of the applicable subsection. Such letter shall require
22 the person to respond in writing within 45 calendar
23 days of issuance of such letter. Such response may
24 include the person’s request for a deferral extension
25 if applicable. Such letter and the person’s written re-

1 sponse to such letter shall be made publicly available
2 on the Internet Web site of the Food and Drug Ad-
3 ministration 60 calendar days after issuance, with
4 redactions for any trade secrets and confidential
5 commercial information. If the Secretary determines
6 that the letter was issued in error, the requirements
7 of this paragraph shall not apply.

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

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

19 “(B) to revoke the license for a biological
20 product under section 351 of the Public Health
21 Service Act.”.

22 (2) TRACKING OF LETTERS ISSUED.—Subpara-
23 graph (D) of section 505B(f)(6) (21 U.S.C.
24 355c(f)(6)), as amended by subsection (b), is further
25 amended—

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

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

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

6 “(iv) the number of postmarket non-
7 compliance letters issued pursuant to sub-
8 section (d), and the recipients of such let-
9 ters;”.

10 **SEC. 506. PEDIATRIC STUDY PLANS.**

11 (a) IN GENERAL.—Subsection (e) of section 505B
12 (21 U.S.C. 355c) is amended to read as follows:

13 “(e) PEDIATRIC STUDY PLANS.—

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

18 “(2) TIMING; CONTENT; MEETING.—

19 “(A) TIMING.—An applicant shall submit
20 an initial pediatric study plan to the Secretary
21 not later than 60 calendar days after the date
22 of the end of phase II meeting or such other
23 equivalent time agreed upon between the Sec-
24 retary and the applicant. Nothing in this para-
25 graph shall preclude the Secretary from accept-

1 ing the submission of an initial pediatric study
2 plan earlier than the date described under the
3 preceding sentence.

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

6 “(i) an outline of the pediatric study
7 or studies that the applicant plans to con-
8 duct (including, to the extent practicable
9 study objectives and design, age groups,
10 relevant endpoints, and statistical ap-
11 proach);

12 “(ii) any request for a deferral, partial
13 waiver, or waiver under this section, if ap-
14 plicable, along with any supporting infor-
15 mation; and

16 “(iii) other information specified in
17 the regulations promulgated under para-
18 graph (4).

19 “(C) MEETING.—The Secretary—

20 “(i) shall meet with the applicant to
21 discuss the initial pediatric study plan as
22 soon as practicable, but not later than 90
23 calendar days after the receipt of such plan
24 under subparagraph (A);

1 “(ii) may determine that a written re-
2 sponse to the initial pediatric study plan is
3 sufficient to communicate comments on the
4 initial pediatric study plan, and that no
5 meeting is necessary; and

6 “(iii) if the Secretary determines that
7 no meeting is necessary, shall so notify the
8 applicant and provide written comments of
9 the Secretary as soon as practicable, but
10 not later than 90 calendar days after the
11 receipt of the initial pediatric study plan.

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

23 “(4) DEFERRAL AND WAIVER.—If the agreed
24 initial pediatric study plan contains a request from
25 the applicant for a deferral, partial waiver, or waiver

1 under this section, the written confirmation under
2 paragraph (3) shall include a recommendation from
3 the Secretary as to whether such request meets the
4 standards under paragraphs (3) or (4) of subsection
5 (a).

6 “(5) AMENDMENTS TO THE PLAN.—At the ini-
7 tiative of the Secretary or the applicant, the agreed
8 initial pediatric study plan may be amended at any
9 time. The requirements of paragraph (2)(C) shall
10 apply to any such proposed amendment in the same
11 manner and to the same extent as such require-
12 ments apply to an initial pediatric study plan under
13 paragraph (1). The requirements of paragraphs (3)
14 and (4) shall apply to any agreement resulting from
15 such proposed amendment in the same manner and
16 to the same extent as such requirements apply to an
17 agreed initial pediatric study plan.

18 “(6) INTERNAL COMMITTEE.—The Secretary
19 shall consult the internal committee under section
20 505C on the review of the initial pediatric study
21 plan, agreed initial pediatric plan, and any signifi-
22 cant amendments to such plans.

23 “(7) REQUIRED RULEMAKING.—Not later than
24 1 year after the date of enactment of the Food and
25 Drug Administration Safety and Innovation Act, the

1 Secretary shall promulgate proposed regulations and
2 issue proposed guidance to implement the provisions
3 of this subsection.”.

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

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

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

10 (2) in subsection (f)—

11 (A) in the subsection heading, by striking
12 “PEDIATRIC PLANS,” and inserting “PEDI-
13 ATRIC STUDY PLANS,”;

14 (B) in paragraph (1), by striking “all pedi-
15 atric plans” and inserting “initial pediatric
16 study plans, agreed initial pediatric study
17 plans,”; and

18 (C) in paragraph (4)—

19 (i) in the paragraph heading, by strik-
20 ing “PEDIATRIC PLANS,” and inserting
21 “PEDIATRIC STUDY PLANS,”; and

22 (ii) by striking “pediatric plans” and
23 inserting “initial pediatric study plans,
24 agreed initial pediatric study plans,”.

25 (c) EFFECTIVE DATES.—

1 (1) PEDIATRIC STUDY PLANS.—Subsection (e)
2 of section 505B of the Federal Food, Drug, and
3 Cosmetic Act (other than paragraph (4) of such sub-
4 section), as amended by subsection (a), shall take ef-
5 fect 180 days after the date of enactment of this
6 Act, without regard to whether the Secretary has
7 promulgated final regulations under paragraph (4)
8 of such subsection by such date.

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

12 **SEC. 507. REAUTHORIZATIONS.**

13 (a) PEDIATRIC ADVISORY COMMITTEE.—Section
14 14(d) of the Best Pharmaceuticals for Children Act (42
15 U.S.C. 284m note) is amended by striking “Notwith-
16 standing section 14 of the Federal Advisory Committee
17 Act, the advisory committee shall continue to operate dur-
18 ing the five-year period beginning on the date of the enact-
19 ment of the Best Pharmaceuticals for Children Act of
20 2007” and inserting “Section 14 of the Federal Advisory
21 Committee Act shall not apply to the advisory committee”.

22 (b) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
23 DRUGS ADVISORY COMMITTEE.—Section 15(a)(3) of the
24 Best Pharmaceuticals for Children Act (42 U.S.C. 284m
25 note) is amended by striking “during the five-year period

1 beginning on the date of the enactment of the Best Phar-
2 maceuticals for Children Act of 2007” and inserting “for
3 the duration of the operation of the Oncologic Drugs Advi-
4 sory Committee”.

5 (c) HUMANITARIAN DEVICE EXEMPTION EXTEN-
6 SION.—Section 520(m)(6)(A)(iv) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is
8 amended by striking “2012” and inserting “2017”.

9 (d) DEMONSTRATION GRANTS TO IMPROVE PEDI-
10 ATRIC DEVICE AVAILABILITY.—Section 305(e) of Pedi-
11 atric Medical Device Safety and Improvement Act (Public
12 Law 110–85; 42 U.S.C. 282 note)) is amended by striking
13 “\$6,000,000 for each of fiscal years 2008 through 2012”
14 and inserting “\$4,500,000 for each of fiscal years 2013
15 through 2017”.

16 (e) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN
17 PHSA.—Section 409I(e)(1) of the Public Health Service
18 Act (42 U.S.C. 284m(e)(1)) is amended by striking “to
19 carry out this section” and all that follows through the
20 end of paragraph (1) and inserting “to carry out this sec-
21 tion \$25,000,000 for each of fiscal years 2012 through
22 2017.”.

23 **SEC. 508. REPORT.**

24 (a) IN GENERAL.—Not later than October 31, 2016,
25 and at the end of each subsequent 5-year period, the Sec-

1 retary shall submit to Congress a report that evaluates
2 the effectiveness of sections 505A and 505B of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355a,
4 355c) and section 409I of the Public Health Service Act
5 (42 U.S.C. 284m) in ensuring that medicines used by chil-
6 dren are tested in pediatric populations and properly la-
7 beled for use in children.

8 (b) CONTENTS.—The report under subsection (a)
9 shall include—

10 (1) the number and importance of drugs and
11 biological products for children for which studies
12 have been requested or required (as of the date of
13 such report) under 505A and 505B of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 355a,
15 355c) and section 409I of the Public Health Service
16 Act (42 U.S.C. 284m), including—

17 (A) the number of labeling changes made
18 to drugs and biological products pursuant to
19 such sections since the date of enactment of
20 this Act; and

21 (B) the importance of such drugs and bio-
22 logical products in the improvement of the
23 health of children;

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

4 (A) the number of deferrals and deferral
5 extensions granted and the reasons such exten-
6 sions were granted;

7 (B) the number of waivers and partial
8 waivers granted; and

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

11 (3) the number of written requests issued, de-
12 clined, and referred to the National Institutes of
13 Health under such section 505A since the date of
14 enactment of this Act (including the reasons for
15 such declination), and a description and status of re-
16 ferrals made under subsection (n) of such section
17 505A;

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

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

24 (6) the number and current status of pediatric
25 postmarketing requirements;

1 (7) the number and importance of drugs and
2 biological products for children that are not being
3 tested for use in pediatric populations, notwith-
4 standing the existence of the programs under such
5 sections 505A and 505B and section 409I of the
6 Public Health Service Act;

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

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

14 (A) the date labeling changes are made;

15 (B) which labeling changes required the
16 use of the dispute resolution process; and

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

19 (i) the disputes;

20 (ii) the recommendations of the Pedi-
21 atric Advisory Committee; and

22 (iii) the outcomes of such process; and

23 (D) an assessment of the effectiveness in
24 improving information about pediatric uses of
25 drugs and biological products;

1 (10)(A) the efforts made by the Secretary to in-
2 crease the number of studies conducted in the neo-
3 natal population (including efforts made to encour-
4 age the conduct of appropriate studies in neonates
5 by companies with products that have sufficient
6 safety and other information to make the conduct of
7 the studies ethical and safe); and

8 (B) the results of such efforts;

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

13 (B) any recommendations for modifications to
14 such programs that would lead to new and better
15 therapies for children with cancer, including a de-
16 tailed rationale for each recommendation;

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

23 (A) improving public access to information
24 from pediatric studies conducted under such
25 sections 505A and 505B; and

1 (B) improving the timeliness of pediatric
2 studies and pediatric study planning under such
3 sections 505A and 505B;

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

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

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

22 **SEC. 509. TECHNICAL AMENDMENTS.**

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

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

3 (2) in subsection (n)—

4 (A) in the subsection heading, by striking
5 “COMPLETED” and inserting “SUBMITTED”;
6 and

7 (B) in paragraph (1)—

8 (i) in the matter preceding subpara-
9 graph (A), by striking “have not been com-
10 pleted” and inserting “have not been sub-
11 mitted by the date specified in the written
12 request issued or if the applicant or holder
13 does not agree to the request”;

14 (ii) in subparagraph (A)—

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

23 (II) by striking “Prior to” and
24 all that follows through the period at
25 the end; and

1 (iii) in subparagraph (B), by striking
2 “no listed patents or has 1 or more listed
3 patents that have expired,” and inserting
4 “no unexpired listed patents and for which
5 no unexpired periods of exclusivity eligible
6 for extension under subsection (b)(1) or
7 (c)(1) of this section or under subsection
8 (m)(2) or (m)(3) of section 351 of the
9 Public Health Service Act apply,”; and

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

12 “(B) a statement of any appropriate pedi-
13 atric contraindications, warnings, precautions,
14 or other information that the Secretary con-
15 siders necessary to assure safe use.”.

16 (b) RESEARCH INTO PEDIATRIC USES FOR DRUGS
17 AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B
18 (21 U.S.C. 355c) is amended—

19 (1) in subsection (a)—

20 (A) in paragraph (1)—

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

24 (ii) in subparagraph (A), by striking
25 “for a” and inserting “, including, with re-

1 spect to a drug, an application (or supple-
2 ment to an application) for a”;

3 (iii) in subparagraph (B), by striking
4 “for a” and inserting “, including, with re-
5 spect to a drug, an application (or supple-
6 ment to an application) for a”; and

7 (iv) in the matter following subpara-
8 graph (B), by inserting “(or supplement)”
9 after “application”; and

10 (B) in paragraph (4)(C)—

11 (i) in the first sentence, by inserting
12 “partial” before “waiver is granted”; and

13 (ii) in the second sentence, by striking
14 “either a full or” and inserting “such a”;

15 (2) in subsection (b)(1), in the matter pre-
16 ceding subparagraph (A), by striking “After pro-
17 viding notice” and all that follows through “studies),
18 the” and inserting “The”;

19 (3) in subsection (g)—

20 (A) in paragraph (1)(A), by inserting
21 “that receives a priority review or 330 days
22 after the date of the submission of an applica-
23 tion or supplement that receives a standard re-
24 view” after “after the date of the submission of
25 the application or supplement”; and

1 (B) in paragraph (2), by striking “the
2 label of such product” and inserting “the label-
3 ing of such product”; and

4 (4) in subsection (h)(1)—

5 (A) by inserting “an application (or sup-
6 plement to an application) that contains” after
7 “date of submission of”; and

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

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

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

22 (1) in paragraph (1)—

23 (A) in the matter preceding subparagraph
24 (A), by inserting “or section 351(m) of this
25 Act,” after “Cosmetic Act,”;

1 (B) in subparagraph (A)(i), by inserting
2 “or section 351(k) of this Act” after “Cosmetic
3 Act”; and

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

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

19 (2) in paragraph (2)—

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

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

24 (C) by striking “505A of such Act” and
25 inserting “505A of the Federal Food, Drug,

1 and Cosmetic Act or section 351(m) of this
2 Act”.

3 (e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
4 ADVISORY COMMITTEE.—Section 15(a) of the Best Phar-
5 maceuticals for Children Act (Public Law 107–109), as
6 amended by section 502(e) of the Food and Drug Admin-
7 istration Amendments Act of 2007 (Public Law 110–85),
8 is amended in paragraph (1)(D), by striking “section
9 505B(f)” and inserting ““section 505C””.

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

16 (g) APPLICATION.—Notwithstanding any provision of
17 section 505A and 505B of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provi-
19 sion applies beginning on the date of the enactment of the
20 Best Pharmaceuticals for Children Act of 2007 or the date
21 of the enactment of the Pediatric Research Equity Act of
22 2007, any amendment made by this title to such a provi-
23 sion applies beginning on the date of the enactment of this
24 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. 360c(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 ministrative 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
24 website 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 360c(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. 360e(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. 360e(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 **Subtitle A—Drug Supply Chain**

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

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

24 (1) in subsection (b)—

1 (A) in paragraph (1), by striking “On or
2 before” and all that follows through the period
3 at the end and inserting the following: “During
4 the period beginning on October 1 and ending
5 on December 31 of each year, every person who
6 owns or operates any establishment in any
7 State engaged in the manufacture, preparation,
8 propagation, compounding, or processing of a
9 drug or drugs shall register with the Sec-
10 retary—

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

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

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

23 “(3) The Secretary may specify the unique facility
24 identifier system that shall be used by registrants under
25 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), in
23 any State, that is engaged in the manufacture, prop-
24 agation, compounding, or processing of a device or
25 devices classified in class II or III shall be so in-

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

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 tabishment 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 CON-
12 FIDENTIAL INFORMATION OBTAINED FROM FOREIGN
13 GOVERNMENTS.—

14 “(1) IN GENERAL.—The Secretary shall not be
15 required to disclose under section 552 of title 5,
16 United States Code (commonly referred to as the
17 Freedom of Information Act), or any other provision
18 of law, any information described in subsection
19 (c)(3) obtained from a foreign government agency,
20 if—

21 “(A) the information is provided or made
22 available to the United States Government vol-
23 untarily and on the condition that the informa-
24 tion not be released to the public; and

1 “(B) the information is covered by, and
2 subject to, a certification and written agreement
3 under subsections (c)(1) and (c)(2).

4 “(2) TIME LIMITATIONS.—The written agree-
5 ment described in subsection (c)(2) shall specify the
6 time period for which the non-disclosure require-
7 ments under paragraph (1) shall apply to the volun-
8 tarily disclosed information. The non-disclosure re-
9 quirements under paragraph (1) shall not apply
10 after the date specified, but all other applicable legal
11 protections, including section 552 of title 5, United
12 States Code and section 319L(e)(1) of the Public
13 Health Service Act, shall continue to apply to such
14 information, as appropriate. If no date is specified
15 in the written agreement, the non-disclosure protec-
16 tions described in paragraph (1) shall not exceed 3
17 years.

18 “(3) DISCLOSURES NOT AFFECTED.—Nothing
19 in this section authorizes any official to withhold, or
20 to authorize the withholding of, information from
21 Congress or information required to be disclosed
22 pursuant to an order of a court of the United
23 States.

24 “(4) PUBLIC INFORMATION.—For purposes of
25 section 552 of title 5, United States Code, this sub-

1 section shall be considered a statute described in
2 section 552(b)(3)(B).

3 “(c) AUTHORITY TO ENTER INTO MEMORANDA OF
4 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-
5 CHANGE.—The Secretary may enter into written agree-
6 ments regarding the exchange of information referenced
7 in section 301(j) subject to the following criteria:

8 “(1) CERTIFICATION.—The Secretary may only
9 enter into written agreements under this subsection
10 with foreign governments that the Secretary has cer-
11 tified as having the authority and demonstrated abil-
12 ity to protect trade secret information from disclo-
13 sure. Responsibility for this certification shall not be
14 delegated to any officer or employee other than the
15 Commissioner.

16 “(2) WRITTEN AGREEMENT.—The written
17 agreement under this subsection shall include a com-
18 mitment by the foreign government to protect infor-
19 mation exchanged under this subsection from disclo-
20 sure unless and until the sponsor gives written per-
21 mission for disclosure or the Secretary makes a dec-
22 laration of a public health emergency pursuant to
23 section 319 of the Public Health Service Act that is
24 relevant to the information.

1 “(3) INFORMATION EXCHANGE.—The Secretary
2 may provide to a foreign government that has been
3 certified under paragraph (1) and that has executed
4 a written agreement under paragraph (2) informa-
5 tion referenced in section 301(j) in the following cir-
6 cumstances:

7 “(A) Information concerning the inspection
8 of a facility may be provided if—

9 “(i) the Secretary reasonably believes,
10 or that the written agreement described in
11 paragraph (2) establishes, that the govern-
12 ment has authority to otherwise obtain
13 such information; and

14 “(ii) the written agreement executed
15 under paragraph (2) limits the recipient’s
16 use of the information to the recipient’s
17 civil regulatory purposes.

18 “(B) Information not described in sub-
19 paragraph (A) may be provided as part of an
20 investigation, or to alert the foreign government
21 to the potential need for an investigation, if the
22 Secretary has reasonable grounds to believe
23 that a drug has a reasonable probability of
24 causing serious adverse health consequences or
25 death to humans or animals.

1 “(4) EFFECT OF SUBSECTION.—Nothing in this
2 subsection affects the ability of the Secretary to
3 enter into any written agreement authorized by
4 other provisions of law to share confidential informa-
5 tion.”.

6 **SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE**
7 **DRUG SUPPLY.**

8 Section 501 (21 U.S.C. 351) is amended by adding
9 at the end the following flush text:

10 “For purposes of subsection (a)(2)(B), the term ‘current
11 good manufacturing practice’ includes the implementation
12 of oversight and controls over the manufacture of drugs
13 to ensure quality, including managing the risk of and es-
14 tablishing the safety of raw materials, materials used in
15 the manufacturing of drugs, and finished drug products.”.

16 **SEC. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR**
17 **DRUG ESTABLISHMENTS.**

18 (a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et
19 seq.) is amended by adding at the end the following:

20 **“SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS**
21 **FOR DRUG ESTABLISHMENTS.**

22 “(a) DEFINITIONS.—In this section:

23 “(1) ACCREDITATION BODY.—The term ‘ac-
24 creditation body’ means an authority that performs
25 accreditation of third-party auditors.

1 “(2) ACCREDITED THIRD-PARTY AUDITOR.—

2 The term ‘accredited third-party auditor’ means a
3 third-party auditor (which may be an individual) ac-
4 credited by an accreditation body to conduct drug
5 safety and quality audits.

6 “(3) AUDIT AGENT.—The term ‘audit agent’
7 means an individual who is an employee or agent of
8 an accredited third-party auditor and, although not
9 individually accredited, is qualified to conduct drug
10 safety and quality audits on behalf of an accredited
11 third-party auditor.

12 “(4) CONSULTATIVE AUDIT.—The term ‘con-
13 sultative audit’ means an audit of an eligible entity
14 intended for internal purposes only to determine
15 whether an establishment is in compliance with the
16 provisions of this Act and applicable industry prac-
17 tices, or any other such service.

18 “(5) DRUG SAFETY AND QUALITY AUDIT.—The
19 term ‘drug safety and quality audit’—

20 “(A) means an audit of an eligible entity
21 to certify that the eligible entity meets the re-
22 quirements of this Act applicable to drugs, in-
23 cluding the requirements of section 501 with re-
24 spect to drugs; and

25 “(B) is not a consultative audit.

1 “(6) ELIGIBLE ENTITY.—The term ‘eligible en-
2 tity’ means an entity, including a foreign drug estab-
3 lishment registered under section 510(c), in the drug
4 supply chain that chooses to be audited by an ac-
5 credited third-party auditor or the audit agent of
6 such accredited third-party auditor.

7 “(7) THIRD-PARTY AUDITOR.—The term ‘third-
8 party auditor’ means a foreign government, agency
9 of a foreign government or any other third party
10 (which may be an individual), as the Secretary de-
11 termines appropriate in accordance with the criteria
12 described in subsection (c)(1), that is eligible to be
13 considered for accreditation to conduct drug safety
14 and quality audits.

15 “(b) ACCREDITATION SYSTEM.—

16 “(1) RECOGNITION OF ACCREDITATION BOD-
17 IES.—

18 “(A) IN GENERAL.—Not later than 2 years
19 after date of enactment of the Food and Drug
20 Administration Safety and Innovation Act, the
21 Secretary shall establish a system for the rec-
22 ognition of accreditation bodies that accredit
23 third-party auditors to conduct drug safety and
24 quality audits.

25 “(B) DIRECT ACCREDITATION.—

1 “(i) IN GENERAL.—If, by the date
2 that is 2 years after the date of establish-
3 ment of the system described in subpara-
4 graph (A), the Secretary has not identified
5 and recognized an accreditation body to
6 meet the requirements of this section, the
7 Secretary may directly accredit third-party
8 auditors.

9 “(ii) CERTAIN DIRECT ACCREDITA-
10 TIONS.—Notwithstanding subparagraph
11 (A) or clause (i), the Secretary may di-
12 rectly accredit any foreign government or
13 any agency of a foreign government as a
14 third-party auditor at any time after the
15 date of enactment of the Food and Drug
16 Administration Safety and Innovation Act.

17 “(2) NOTIFICATION.—Each accreditation body
18 recognized by the Secretary shall submit to the Sec-
19 retary—

20 “(A) a list of all accredited third-party
21 auditors accredited by such body (including the
22 name, contact information, and scope and dura-
23 tion of accreditation for each such auditor), and
24 the audit agents of such auditors; and

1 “(B) updated lists as needed to ensure the
2 list held by the Secretary is accurate.

3 “(3) REVOCATION OF RECOGNITION AS AN AC-
4 CREDITATION BODY.—The Secretary shall promptly
5 revoke, after the opportunity for an informal hear-
6 ing, the recognition of any accreditation body found
7 not to be in compliance with the requirements of this
8 section.

9 “(4) REINSTATEMENT.—The Secretary shall es-
10 tablish procedures to reinstate recognition of an ac-
11 creditation body if the Secretary determines, based
12 on evidence presented by such accreditation body,
13 that revocation was inappropriate or that the body
14 meets the requirements for recognition under this
15 section.

16 “(5) MODEL ACCREDITATION STANDARDS.—

17 “(A) IN GENERAL.—Not later than 18
18 months after the date of enactment of the Food
19 and Drug Administration Safety and Innova-
20 tion Act, the Secretary shall develop model
21 standards, including standards for drug safety
22 and quality audit results, reports, and certifi-
23 cations, and each recognized accreditation body
24 shall ensure that third-party auditors and audit
25 agents of such auditors meet such standards in

1 order to qualify such third-party auditors as ac-
2 credited third-party auditors under this section.

3 “(B) CONTENT.—The standards developed
4 under subparagraph (A) may—

5 “(i) include a description of required
6 standards relating to the training proce-
7 dures, competency, management respon-
8 sibilities, quality control, and conflict of in-
9 terest requirements of accredited third-
10 party auditors; and

11 “(ii) set forth procedures for the peri-
12 odic renewal of the accreditation of accred-
13 ited third-party auditors.

14 “(C) REQUIREMENT TO PROVIDE RESULTS
15 AND REPORTS TO THE SECRETARY.—An ac-
16 creditation body (or, in the case of direct ac-
17 creditation under subsection (b)(1)(B), the Sec-
18 retary) may not accredit a third-party auditor
19 unless such third-party auditor agrees to pro-
20 vide to the Secretary, upon request, the results
21 and reports of any drug safety and quality
22 audit conducted pursuant to the accreditation
23 provided under this section.

24 “(6) DISCLOSURE.—The Secretary shall main-
25 tain on the Internet Web site of the Food and Drug

1 Administration a list of recognized accreditation
2 bodies and accredited third-party auditors under this
3 section.

4 “(c) ACCREDITED THIRD-PARTY AUDITORS.—

5 “(1) REQUIREMENTS FOR ACCREDITATION AS A
6 THIRD-PARTY AUDITOR.—

7 “(A) FOREIGN GOVERNMENTS.—Prior to
8 accrediting a foreign government or an agency
9 of a foreign government as an accredited third-
10 party auditor, the accreditation body (or, in the
11 case of direct accreditation under subsection
12 (b)(1)(B), the Secretary) shall perform such re-
13 views and audits of drug safety programs, sys-
14 tems, and standards of the government or agen-
15 cy of the government as the Secretary deems
16 necessary, including requirements under the
17 standards developed under subsection (b)(5), to
18 determine that the foreign government or agen-
19 cy of the foreign government is capable of ade-
20 quately ensuring that eligible entities or drugs
21 certified by such government or agency meet
22 the requirements of this Act.

23 “(B) OTHER THIRD PARTIES.—Prior to
24 accrediting any other third party to be an ac-
25 credited third-party auditor, the accreditation

1 body (or, in the case of direct accreditation
2 under subsection (b)(1)(B), the Secretary) shall
3 perform such reviews and audits of the training
4 and qualifications of audit agents used by that
5 party and conduct such reviews of internal sys-
6 tems and such other investigation of the party
7 as the Secretary deems necessary, including re-
8 quirements under the standards developed
9 under subsection (b)(5), to determine that the
10 third-party auditor is capable of adequately en-
11 suring that an eligible entity or drug certified
12 by such third-party auditor meets the require-
13 ments of this Act.

14 “(2) USE OF AUDIT AGENTS.—An accredited
15 third-party auditor may conduct drug safety and
16 quality audits and may employ or use audit agents
17 to conduct drug safety and quality audits, but must
18 ensure that such audit agents comply with all re-
19 quirements the Secretary deems necessary, including
20 requirements under paragraph (1) and subsection
21 (b)(5).

22 “(3) REVOCATION OF ACCREDITATION.—

23 “(A) IN GENERAL.—The Secretary shall
24 promptly revoke, after the opportunity for an

1 informal hearing, the accreditation of an ac-
2 credited third-party auditor—

3 “(i) if, following an evaluation, the
4 Secretary finds that the accredited third-
5 party auditor is not in compliance with the
6 requirements of this section; or

7 “(ii) following a refusal to allow
8 United States officials to conduct such au-
9 dits and investigations as may be necessary
10 to determine compliance with the require-
11 ments set forth in this section.

12 “(B) ADDITIONAL BASIS FOR REVOCATION
13 OF ACCREDITATION.—The Secretary may re-
14 voke accreditation from an accredited third-
15 party auditor in the case that such third-party
16 auditor is accredited by an accreditation body
17 for which recognition as an accreditation body
18 under subsection (b)(3) is revoked, if the Sec-
19 retary determines that there is good cause for
20 the revocation of accreditation.

21 “(4) REACCREDITATION.—The Secretary shall
22 establish procedures to reinstate the accreditation of
23 a third-party auditor for which accreditation has
24 been revoked under paragraph (3)—

1 “(A) if the Secretary determines, based on
2 evidence presented, that—

3 “(i) the third-party auditor satisfies
4 the requirements of this section; and

5 “(ii) adequate grounds for revocation
6 no longer exist; and

7 “(B) in the case of a third-party auditor
8 accredited by an accreditation body for which
9 recognition as an accreditation body is revoked
10 under subsection (b)(3)—

11 “(i) if the third-party auditor becomes
12 accredited not later than 1 year after rev-
13 ocation of accreditation under paragraph
14 (3), through direct accreditation under
15 subsection (b)(1)(B), or by an accredita-
16 tion body in good standing; or

17 “(ii) under such other conditions as
18 the Secretary may require.

19 “(5) REQUIREMENT TO ISSUE CERTIFICATION
20 OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CUR-
21 RENT GOOD MANUFACTURING PRACTICE.—

22 “(A) IN GENERAL.—An accreditation body
23 (or, in the case of direct accreditation under
24 subsection (b)(1)(B), the Secretary) may not
25 accredit a third-party auditor unless such third-

1 party auditor agrees to issue a written and, as
2 appropriate, electronic, document or certifi-
3 cation, as the Secretary may require under this
4 Act, regarding compliance with section 501.
5 The Secretary may consider any such document
6 or certification to satisfy requirements under
7 section 801(r) and to target inspection re-
8 sources under section 510(h).

9 “(B) REQUIREMENTS FOR ISSUING CER-
10 TIFICATION.—

11 “(i) IN GENERAL.—An accredited
12 third-party auditor shall issue a drug cer-
13 tification described in subparagraph (A)
14 only after conducting a drug safety and
15 quality audit and such other activities that
16 may be necessary to establish compliance
17 with the provisions of section 501.

18 “(ii) PROVISION OF CERTIFICATION.—
19 Only an accredited third-party auditor or
20 the Secretary may provide a drug certifi-
21 cation described in subparagraph (A).

22 “(C) RECORDS.—Following any accredita-
23 tion of a third-party auditor, the Secretary
24 may, at any time, require the accredited third-
25 party auditor or any audit agent of such audi-

1 tor to submit to the Secretary a drug safety
2 and quality audit report and such other reports
3 or documents required as part of the drug safe-
4 ty and quality audit process, for any eligible en-
5 tity for which the accredited third-party auditor
6 or audit agent of such auditor performed a
7 drug safety and quality audit. The Secretary
8 may require documentation that the eligible en-
9 tity is in compliance with any applicable reg-
10 istration requirements.

11 “(D) LIMITATION.—The requirement
12 under subparagraph (C) shall not include any
13 report or other documents resulting from a con-
14 sultative audit, except that the Secretary may
15 access the results of a consultative audit in ac-
16 cordance with section 704.

17 “(E) DECLARATION OF AUDIT TYPE.—Be-
18 fore an accredited third-party auditor begins
19 any audit or provides any consultative service to
20 an eligible entity, both the accredited third-
21 party auditor and eligible entity shall establish
22 in writing whether the audit is intended to be
23 a drug safety and quality audit. Any audit, in-
24 spection, or consultative service of any type pro-
25 vided by an accredited third-party auditor on

1 behalf of an eligible entity shall be presumed to
2 be a drug safety and quality audit in the ab-
3 sence of such a written agreement. Once a drug
4 safety and quality audit is initiated, it shall be
5 subject to the requirements of this section, and
6 no person may withhold from the Secretary any
7 document subject to subparagraph (C) on the
8 grounds that the audit was a consultative audit
9 or otherwise not a drug safety and quality
10 audit.

11 “(F) RULE OF CONSTRUCTION.—Nothing
12 in this section shall be construed to limit the
13 authority of the Secretary under section 704.

14 “(6) REQUIREMENTS REGARDING SERIOUS
15 RISKS TO THE PUBLIC HEALTH.—If, at any time
16 during a drug safety and quality audit, an accredited
17 third-party auditor or an audit agent of such auditor
18 discovers a condition that could cause or contribute
19 to a serious risk to the public health, such auditor
20 shall immediately notify the Secretary of—

21 “(A) the identity and location of the eligi-
22 ble entity subject to the drug safety and quality
23 audit; and

24 “(B) such condition.

25 “(7) LIMITATIONS.—

1 “(A) IN GENERAL.—An audit agent of an
2 accredited third-party auditor may not perform
3 a drug safety and quality audit of an eligible
4 entity if such audit agent has performed a drug
5 safety and quality audit or consultative audit of
6 such eligible entity during the previous 13-
7 month period.

8 “(B) WAIVER.—The Secretary may waive
9 the application of subparagraph (A) if the Sec-
10 retary determines that there is insufficient ac-
11 cess to accredited third-party auditors in a
12 country or region or that the use of the same
13 audit agent or accredited third-party auditor is
14 otherwise necessary.

15 “(8) CONFLICTS OF INTEREST.—

16 “(A) ACCREDITATION BODIES.—A recog-
17 nized accreditation body shall—

18 “(i) not be owned, managed, or con-
19 trolled by any person that owns or operates
20 a third-party auditor to be accredited by
21 such body;

22 “(ii) in carrying out accreditation of
23 third-party auditors under this section,
24 have procedures to ensure against the use
25 of any officer or employee of such body

1 that has a financial conflict of interest re-
2 garding a third-party auditor to be accred-
3 ited by such body; and

4 “(iii) annually make available to the
5 Secretary disclosures of the extent to
6 which such body and the officers and em-
7 ployees of such body have maintained com-
8 pliance with clauses (i) and (ii) relating to
9 financial conflicts of interest.

10 “(B) ACCREDITED THIRD-PARTY AUDI-
11 TORS.—An accredited third-party auditor
12 shall—

13 “(i) not be owned, managed, or con-
14 trolled by any person that owns or operates
15 an eligible entity to be certified by such
16 auditor;

17 “(ii) in carrying out drug safety and
18 quality audits of eligible entities under this
19 section, have procedures to ensure against
20 the use of any officer or employee of such
21 auditor that has a financial conflict of in-
22 terest regarding an eligible entity to be
23 certified by such auditor; and

24 “(iii) annually make available to the
25 Secretary disclosures of the extent to

1 which such auditor and the officers and
2 employees of such auditor have maintained
3 compliance with clauses (i) and (ii) relat-
4 ing to financial conflicts of interest.

5 “(C) AUDIT AGENTS.—An audit agent
6 shall—

7 “(i) not own or operate an eligible en-
8 tity to be audited by such agent;

9 “(ii) in carrying out audits of eligible
10 entities under this section, have procedures
11 to ensure that such agent does not have a
12 financial conflict of interest regarding an
13 eligible entity to be audited by such agent;
14 and

15 “(iii) annually make available to the
16 Secretary disclosures of the extent to
17 which such agent has maintained compli-
18 ance with clauses (i) and (ii) relating to fi-
19 nancial conflicts of interest.

20 “(d) FALSE STATEMENTS.—Any statement or rep-
21 resentation made—

22 “(1) by an employee or agent of an eligible enti-
23 ty to an accredited third-party auditor or audit
24 agent; or

1 “(2) by an accreditation body, accredited third-
2 party auditor, or audit agent of such auditor to the
3 Secretary, shall be subject to section 1001 of title
4 18, United States Code.

5 “(e) MONITORING.—To ensure compliance with the
6 requirements of this section, the Secretary—

7 “(1) shall periodically, or at least once every 4
8 years, reevaluate the accreditation bodies described
9 in subsection (b)(1);

10 “(2) shall periodically, or at least once every 4
11 years, evaluate the performance of each accredited
12 third-party auditor, through the review of regulatory
13 audit reports by such auditors, the compliance his-
14 tory as available of eligible entities certified by such
15 auditors, and any other measures deemed necessary
16 by the Secretary;

17 “(3) may at any time, conduct an onsite audit
18 of any eligible entity certified by an accredited third-
19 party auditor, with or without the auditor present;
20 and

21 “(4) shall take any other measures deemed nec-
22 essary by the Secretary.

23 “(f) EFFECT OF AUDIT.—The results of a drug safe-
24 ty and quality audit by an accredited third-party auditor
25 under this section—

1 “(1) may be used by the eligible entity—

2 “(A) as documentation of compliance with
3 section 501(a)(2)(B) or section 801(r); and

4 “(B) for other purposes as determined ap-
5 propriate by the Secretary; and

6 “(2) shall be used by the Secretary in estab-
7 lishing the risk-based inspection schedules under sec-
8 tion 510(h).

9 “(g) COSTS.—

10 “(1) AUTHORIZED FEES OF SECRETARY.—The
11 Secretary may assess fees on accreditation bodies
12 and accredited third-party auditors in such an
13 amount necessary to establish and administer the
14 recognition and accreditation program under this
15 section. The Secretary may require accredited third-
16 party auditors and audit agents to reimburse the
17 Food and Drug Administration for the work per-
18 formed to carry out this section. The Secretary shall
19 not generate surplus revenue from such a reimburse-
20 ment mechanism. Fees authorized under this para-
21 graph shall be collected and available for obligation
22 only to the extent and in the amount provided in ad-
23 vance in appropriation Acts. Such fees are author-
24 ized to remain available until expended.

1 “(2) AUTHORIZED FEES FOR RECOGNIZED AC-
2 CREDITATION BODIES.—An accreditation body rec-
3 ognized by the Secretary under subsection (b) may
4 assess a reasonable fee to accredit third-party audi-
5 tors.

6 “(h) LIMITATIONS.—

7 “(1) NO EFFECT ON SECTION 704 INSPEC-
8 TIONS.—The drug safety and quality audits per-
9 formed under this section shall not be considered in-
10 spections under section 704.

11 “(2) NO EFFECT ON INSPECTION AUTHOR-
12 ITY.—Nothing in this section affects the authority of
13 the Secretary to inspect any eligible entity pursuant
14 to this Act.

15 “(i) REGULATIONS.—

16 “(1) IN GENERAL.—Not later than 18 months
17 after the date of enactment of the Food and Drug
18 Administration Safety and Innovation Act, the Sec-
19 retary shall adopt final regulations implementing
20 this section.

21 “(2) PROCEDURE.—In promulgating the regula-
22 tions implementing this section, the Secretary
23 shall—

24 “(A) issue a notice of proposed rulemaking
25 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 (a) FFDCA.—Section 303(b) (21 U.S.C. 333(b)), as
16 amended by section 713, is further amended by adding
17 at the end the 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 (b) TITLE 18.—Section 2320(b) of title 18, United
23 States Code, is amended—

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

1 (2) by inserting after paragraph (1) the fol-
2 lowing:

3 “(2) COUNTERFEIT DRUGS.—

4 “(A) IN GENERAL.—Whoever commits an
5 offense under subsection (a) with respect to a
6 drug (as defined in section 201 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 321)) shall—

9 “(i) if an individual, be fined not more
10 than \$4,000,000, imprisoned not more
11 than 20 years, or both; and

12 “(ii) if a person other than an indi-
13 vidual, be fined not more than
14 \$10,000,000.

15 “(B) MULTIPLE OFFENSES.—In the case
16 of an offense by a person under this paragraph
17 that occurs after that person is convicted of an-
18 other offense under this paragraph, the person
19 convicted—

20 “(i) if an individual, shall be fined not
21 more than \$8,000,000, imprisoned not
22 more than 20 years, or both; and

23 “(ii) if other than an individual, shall
24 be fined not more than \$20,000,000.”.

25 (c) SENTENCING.—

1 (1) DIRECTIVE TO SENTENCING COMMISSION.—

2 Pursuant to its authority under section 994(p) of
3 title 28, United States Code, and in accordance with
4 this section, the United States Sentencing Commis-
5 sion shall review and amend, if appropriate, its
6 guidelines and its policy statements applicable to
7 persons convicted of an offense described in section
8 2320(b)(2) of title 18, United States Code, as
9 amended by subsection (b), in order to reflect the in-
10 tent of Congress that such penalties be increased in
11 comparison to those currently provided by the guide-
12 lines and policy statements.

13 (2) REQUIREMENTS.—In carrying out this sub-
14 section, the Commission shall—

15 (A) ensure that the sentencing guidelines
16 and policy statements reflect the intent of Con-
17 gress that the guidelines and policy statements
18 reflect the serious nature of the offenses de-
19 scribed in paragraph (1) and the need for an ef-
20 fective deterrent and appropriate punishment to
21 prevent such offenses;

22 (B) consider the extent to which the guide-
23 lines may or may not appropriately account for
24 the potential and actual harm to the public re-
25 sulting from the offense;

1 (C) assure reasonable consistency with
2 other relevant directives and with other sen-
3 tencing guidelines;

4 (D) account for any additional aggravating
5 or mitigating circumstances that might justify
6 exceptions to the generally applicable sentencing
7 ranges;

8 (E) make any necessary conforming
9 changes to the sentencing guidelines; and

10 (F) assure that the guidelines adequately
11 meet the purposes of sentencing as set forth in
12 section 3553(a)(2) of title 18, United States
13 Code.

14 **SEC. 715. EXTRATERRITORIAL JURISDICTION.**

15 Chapter III (21 U.S.C. 331 et seq.) is amended by
16 adding at the end the following:

17 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

18 “There is extraterritorial jurisdiction over any viola-
19 tion of this Act relating to any article regulated under this
20 Act if such article was intended for import into the United
21 States or if any act in furtherance of the violation was
22 committed in the United States.”.

1 **SEC. 716. COMPLIANCE WITH INTERNATIONAL AGREE-**
 2 **MENTS.**

3 Nothing in this title (or an amendment made by this
 4 title) shall be construed in a manner inconsistent with the
 5 obligations of the United States under the Agreement Es-
 6 tablishing the World Trade Organization, or any other
 7 treaty or international agreement to which the United
 8 States is a party.

9 **Subtitle B—Pharmaceutical**
 10 **Distribution Integrity**

11 **SEC. 721. SHORT TITLE.**

12 This subtitle may be referred to as the “Securing
 13 Pharmaceutical Distribution Integrity to Protect the Pub-
 14 lic Health Act of 2012” or the “Securing Pharmaceutical
 15 Distribution Integrity Act of 2012”.

16 **SEC. 722. SECURING THE PHARMACEUTICAL DISTRIBUTION**
 17 **SUPPLY CHAIN.**

18 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.)
 19 is amended by adding at the end the following:

20 **“Subchapter H—Pharmaceutical Distribution**
 21 **Integrity**

22 **“SEC. 581. DEFINITIONS.**

23 “In this subchapter:

24 “(1) DATA CARRIER.—The term ‘data carrier’
 25 means a machine-readable graphic that is intended
 26 to be affixed to, or imprinted upon, an individual

1 saleable unit and a homogeneous case of product.
2 The data carrier shall comply with a form and for-
3 mat developed by a widely recognized international
4 standards development organization to ensure inter-
5 operability among distribution chain participants.

6 “(2) INDIVIDUAL SALEABLE UNIT.—The term
7 ‘individual saleable unit’ means the smallest con-
8 tainer of product put into interstate commerce by
9 the manufacturer that is intended by the manufac-
10 turer for individual sale to a pharmacy or other dis-
11 penser of such product.

12 “(3) PRODUCT.—The term ‘product’ means a
13 finished drug subject to section 503(b)(1).

14 “(4) PRODUCT TRACING.—The term ‘product
15 tracing’ means—

16 “(A) identifying the immediate previous
17 source and immediate subsequent recipient of a
18 product in wholesale distribution at the lot level
19 where a change of ownership of such product
20 has occurred between non-affiliated entities, ex-
21 cept as otherwise described in this subchapter;

22 “(B) identifying the immediate subsequent
23 recipient of the product at the lot level when a
24 manufacturer or repackager introduces such
25 product into interstate commerce;

1 “(C) identifying that manufacturer and
2 dispenser of a product at the lot level when a
3 manufacturer ships a product at the lot level,
4 without regard to the change in ownership in-
5 volving the wholesale distributor; and

6 “(D) identifying the immediate previous
7 source of a product at the lot level for dis-
8 pensers.

9 “(5) RXTEC.—The term ‘RxTEC’ means a data
10 carrier that includes the standardized numerical
11 identifier (SNI), the lot number, and the expiration
12 date of a product. The standard data carrier RxTEC
13 shall be a 2D data matrix barcode affixed to each
14 individual saleable unit of a product and a linear or
15 2D data matrix barcode on a homogenous case of a
16 product. Such information shall be both machine
17 readable and human readable.

18 “(6) SUSPECT PRODUCT.—The term ‘suspect
19 product’ means a product that, based on credible
20 evidence—

21 “(A) is potentially counterfeit, diverted, or
22 stolen;

23 “(B) is reasonably likely to be intentionally
24 adulterated such that the product would result

1 in serious adverse health consequences or death
2 to humans; or

3 “(C) appears otherwise unfit for distribu-
4 tion such that the product would result in seri-
5 ous adverse health consequence or death to hu-
6 mans.

7 “(7) VERIFICATION.—The term ‘verification’
8 means the process of determining whether a product
9 has the standardized numerical identifier or lot
10 number, consistent with section 582, and expiration
11 date assigned by the manufacturer, or the repack-
12 ager as applicable, and identifying whether a prod-
13 uct has the appearance of being a counterfeit, di-
14 verted, or stolen product, or a product otherwise
15 unfit for distribution. Verification of the RxTEC
16 data may occur by using either a human-readable,
17 machine-readable, or other method such as through
18 purchase records or invoices.

19 **“SEC. 582. ENSURING THE SAFETY OF THE PHARMA-
20 CEUTICAL DISTRIBUTION SUPPLY CHAIN
21 THROUGH THE ESTABLISHMENT OF AN
22 RXTEC SYSTEM.**

23 “(a) MANUFACTURER REQUIREMENTS.—

24 “(1) PRODUCT TRACING.—A manufacturer, not
25 later than 4½ years after the date of enactment of

1 the Securing Pharmaceutical Distribution Integrity
2 Act of 2012 and in accordance with this section,
3 shall—

4 “(A) apply RxTEC to the individual sale-
5 able units and homogeneous case of all products
6 intended to be introduced into interstate com-
7 merce;

8 “(B) maintain change of ownership and
9 transaction information, including RxTEC data
10 that associate unit and lot level data for each
11 individual saleable unit of product and homoge-
12 nous case introduced in interstate commerce;
13 and

14 “(C) maintain, where a change of owner-
15 ship has occurred between non-affiliated entities
16 or, in the case of a return from the immediate
17 previous source, change of ownership and trans-
18 action information relating to a product, includ-
19 ing—

20 “(i) RxTEC data;

21 “(ii) the business name and address
22 of the immediate previous source, if appli-
23 cable, and the immediate subsequent re-
24 cipient of the product;

1 “(iii) the proprietary or established
2 name or names of the product;

3 “(iv) the National Drug Code number
4 of the product;

5 “(v) container size;

6 “(vi) number of containers;

7 “(vii) the lot number or numbers of
8 the product; and

9 “(viii) the date of the transaction;

10 “(D) provide the following change of own-
11 ership and trans action information to the im-
12 mediate subsequent recipient of such product—

13 “(i) the proprietary or established
14 name or names of the product;

15 “(ii) the National Drug Code number
16 of the product;

17 “(iii) container size;

18 “(iv) number of containers;

19 “(v) the lot number or numbers of the
20 product; and

21 “(vi) a signed statement that the
22 manufacturer did not knowingly and inten-
23 tionally adulterate or knowingly and inten-
24 tionally counterfeit such product; and

1 “(E) upon request by the Secretary, other
2 appropriate Federal official, or State official, in
3 the event of a recall or as determined necessary
4 by the Secretary, or such other Federal or
5 State official, to investigate a suspect product,
6 provide in a reasonable time and in a reason-
7 able manner—

8 “(i) RxTEC data by lot; and

9 “(ii) change of ownership and trans-
10 action information pursuant to subpara-
11 graphs (C) and (D) necessary to identify
12 the immediate previous source or imme-
13 diate subsequent recipient of such product,
14 as applicable.

15 “(2) VERIFICATION REQUIREMENTS.—A manu-
16 facturer, not later than 4½ years after the date of
17 enactment of the Securing Pharmaceutical Distribu-
18 tion Integrity Act of 2012 and in accordance with
19 this section, shall—

20 “(A) utilize RxTEC data at the lot level,
21 as part of ongoing activities to significantly
22 minimize or prevent the incidences of a suspect
23 product in the pharmaceutical distribution sup-
24 ply chain, as applicable and appropriate,
25 which—

1 “(i) may include responding to an
2 alert regarding a suspect product from a
3 trading partner or the Secretary, routine
4 monitoring of a suspect product at the lot
5 level while such product is in the posses-
6 sion of the manufacturer, and checking in-
7 ventory for a suspect product at the re-
8 quest of a trading partner or the Secretary
9 in case of returns; and

10 “(ii) shall take into consideration—

11 “(I) the likelihood that a par-
12 ticular product has a high potential
13 risk with respect to pharmaceutical
14 distribution supply chain security;

15 “(II) the history and severity of
16 incidences of counterfeit, diversion,
17 and theft of such product;

18 “(III) the point in the pharma-
19 ceutical distribution supply chain
20 where counterfeit, diversion, or theft
21 has occurred or is most likely to
22 occur;

23 “(IV) the likelihood that such ac-
24 tivities will reduce the possibility of

1 the counterfeit, diversion, and theft of
2 such product;

3 “(V) whether the product could
4 mitigate or prevent a drug shortage as
5 defined in section 506C; and

6 “(VI) any guidance the Secretary
7 issues regarding high-risk scenarios
8 that could increase the risk of a sus-
9 pect product entering the pharma-
10 ceutical distribution supply chain; and

11 “(B) conduct unit level verification upon
12 the request of a licensed or registered repack-
13 ager, wholesale distributor, dispenser, or the
14 Secretary, regarding such product.

15 “(3) NOTIFICATION OF PRODUCT REMOVAL.—

16 “(A) IN GENERAL.—Not later than 4½
17 years after the date of enactment of the Secur-
18 ing Pharmaceutical Distribution Integrity Act
19 of 2012 and in accordance with this section, a
20 manufacturer, upon confirming that a product
21 does not have the standardized numerical iden-
22 tifier or lot number, consistent with this sec-
23 tion, and expiration date assigned by the manu-
24 facturer, or has the appearance of being a coun-
25 terfeit, diverted, or stolen product, or a product

1 otherwise unfit for distribution such that the
2 product would result in serious adverse health
3 consequences or death to humans, shall—

4 “(i) promptly notify the Secretary and
5 impacted trading partners, as applicable
6 and appropriate; and

7 “(ii) take steps to remove such prod-
8 uct from the pharmaceutical distribution
9 supply chain.

10 “(B) REDISTRIBUTION.—Any product sub-
11 ject to a notification under this subsection may
12 not be redistributed as a saleable product un-
13 less the manufacturer, in consultation with the
14 Secretary, determines such product may reenter
15 the pharmaceutical distribution supply chain.

16 “(4) LIMITATION.—Nothing in this section
17 shall require a manufacturer to aggregate unit level
18 data to cases or pallets.

19 “(b) REPACKAGER REQUIREMENTS.—

20 “(1) PRODUCT TRACING.—A repackager, not
21 later than 5½ years after the date of enactment of
22 the Securing Pharmaceutical Distribution Integrity
23 Act of 2012 and in accordance with this section,
24 shall—

1 “(A) apply RxTEC to the individual sale-
2 able unit and the homogenous case of all prod-
3 uct intended to be introduced into interstate
4 commerce;

5 “(B) maintain change of ownership and
6 transaction information, including RxTEC data,
7 that associate unit and lot level data for each
8 individual saleable unit of product and each ho-
9 mogenous case of product introduced in inter-
10 state commerce, including RxTEC data received
11 for such products and for which a repackager
12 applies a new RxTEC;

13 “(C) receive only products encoded with
14 RxTEC data from a licensed or registered man-
15 ufacturer or wholesaler;

16 “(D) maintain, where a change of owner-
17 ship has occurred between non-affiliated entities
18 in wholesale distribution, change of ownership
19 and transaction information relating to a prod-
20 uct, including—

21 “(i) RxTEC data;

22 “(ii) the business name and address
23 of the immediate previous source and the
24 immediate subsequent recipient of the
25 product;

1 “(iii) the proprietary or established
2 name or names of the product;

3 “(iv) the National Drug Code number
4 of the product;

5 “(v) container size;

6 “(vi) number of containers;

7 “(vii) the lot number or numbers of
8 the product; and

9 “(viii) the date of the transaction;

10 “(E) provide the following change of own-
11 ership and transaction information to the im-
12 mediate subsequent recipient of such product—

13 “(i) the proprietary or established
14 name or names of the product;

15 “(ii) the National Drug Code number
16 of the product;

17 “(iii) container size;

18 “(iv) number of containers;

19 “(v) the lot number or numbers of the
20 product; and

21 “(vi) a signed statement that the re-
22 packager—

23 “(I) is licensed or registered;

1 “(II) received the product from a
2 manufacturer that is licensed or reg-
3 istered;

4 “(III) received a signed state-
5 ment from the manufacturer of such
6 product consistent with subsection
7 (a)(1)(D)(vi); and

8 “(IV) did not knowingly and in-
9 tentionally adulterate or knowingly
10 and intentionally counterfeit such
11 product; and

12 “(F) upon request by the Secretary, other
13 appropriate Federal official, or State official, in
14 the event of a recall, or as determined necessary
15 by the Secretary or such other Federal or State
16 official to investigate a suspect product, provide
17 in a reasonable time and in a reasonable man-
18 ner—

19 “(i) RxTEC data by lot; and

20 “(ii) change of ownership and trans-
21 action information pursuant to subpara-
22 graph (C) or (E) necessary to identify the
23 immediate previous source or the imme-
24 diate subsequent recipient of such product,
25 as applicable.

1 “(2) VERIFICATION REQUIREMENTS.—A re-
2 packager, not later than 5½ years after the date of
3 enactment of the Securing Pharmaceutical Distribu-
4 tion Integrity Act of 2012 and in accordance with
5 this section, shall—

6 “(A) utilize RxTEC data at the lot level,
7 as part of ongoing activities to significantly
8 minimize or prevent the incidences of suspect
9 product in the pharmaceutical distribution sup-
10 ply chain, as applicable and appropriate,
11 which—

12 “(i) may include—

13 “(I) responding to alerts regard-
14 ing a suspect product from a trading
15 partner or the Secretary, routine mon-
16 itoring of a suspect product at the lot
17 level while such product is in the pos-
18 session of the repackager; and

19 “(II) checking inventory for a
20 suspect product at the request of a
21 trading partner or the Secretary in
22 the case of returns; and

23 “(ii) shall take into consideration—

24 “(I) the likelihood that a par-
25 ticular product has a high potential

1 risk with respect to pharmaceutical
2 distribution supply chain security;

3 “(II) the history and severity of
4 incidences of counterfeit, diversion,
5 and theft of such product;

6 “(III) the point in the pharma-
7 ceutical distribution supply chain
8 where counterfeit, diversion, and theft
9 has occurred or is most likely to
10 occur;

11 “(IV) the likelihood that such ac-
12 tivities will reduce the possibility of
13 counterfeit, diversion, and theft of
14 such product;

15 “(V) whether the product could
16 mitigate or prevent a drug shortage as
17 defined in section 506C; and

18 “(VI) any guidance the Secretary
19 issues regarding high-risk scenarios
20 that could increase the risk of a sus-
21 pect product entering the pharma-
22 ceutical distribution supply chain; and

23 “(B) conduct unit level verification upon
24 the request of a licensed or registered manufac-

1 turer, wholesale distributor, dispenser, or the
2 Secretary, regarding such product.

3 “(3) NOTIFICATION AND PRODUCT REMOVAL.—

4 “(A) IN GENERAL.—Not later than 5½
5 years after the date of enactment of the Secur-
6 ing Pharmaceutical Distribution Integrity Act
7 of 2012 and in accordance with this section, a
8 repackager, upon confirming that a product
9 does not have the standardized numerical iden-
10 tifier or lot number, consistent with this sec-
11 tion, and expiration date assigned by the manu-
12 facturer, or has the appearance of being a coun-
13 terfeit, diverted, or stolen product, or a product
14 otherwise unfit for distribution such that it
15 would result in serious adverse health con-
16 sequences or death to humans, shall—

17 “(i) promptly notify the Secretary and
18 impacted trading partners, as applicable
19 and appropriate; and

20 “(ii) take steps to remove such prod-
21 uct from the pharmaceutical distribution
22 supply chain.

23 “(B) REDISTRIBUTION.—Any product sub-
24 ject to a notification under this subsection may
25 not be redistributed as a saleable product un-

1 less the repackager, in consultation with the
2 Secretary, and manufacturer as applicable, de-
3 termines such product may reenter the pharma-
4 ceutical distribution supply chain.

5 “(4) LIMITATION.—Nothing in this section
6 shall require a repackager to aggregate unit level
7 data to cases or pallets.

8 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

9 “(1) PRODUCT TRACING REQUIREMENTS.—A
10 wholesale distributor engaged in wholesale distribu-
11 tion, not later than 6½ years after the date of en-
12 actment of the Securing Pharmaceutical Distribu-
13 tion Integrity Act of 2012 and in accordance with
14 this section, shall—

15 “(A) receive only products encoded with
16 RxTEC from a licensed or registered manufac-
17 turer, wholesaler, or repackager;

18 “(B) maintain, in wholesale distribution
19 where a change of ownership has occurred be-
20 tween non-affiliated entities, change of owner-
21 ship and transaction information, including—

22 “(i) RxTEC data by lot;

23 “(ii) the business name and address
24 of the immediate previous source and the

1 immediate subsequent recipient of the
2 product;

3 “(iii) the proprietary or established
4 name or names of the product;

5 “(iv) the National Drug Code number
6 of the product;

7 “(v) container size;

8 “(vi) number of containers;

9 “(vii) the lot number or numbers of
10 the product; and

11 “(viii) the date of the transaction;

12 “(C) provide the following change of own-
13 ership and transaction information to the im-
14 mediate subsequent recipient of such product—

15 “(i) the proprietary or established
16 name or names of the product;

17 “(ii) the National Drug Code number
18 of the product;

19 “(iii) container size;

20 “(iv) number of containers;

21 “(v) the lot number or numbers of the
22 product;

23 “(vi) the date of the transaction; and

24 “(vii) a signed statement that the
25 wholesale distributor—

1 “(I) is licensed or registered;

2 “(II) received the product from a
3 registered or licensed manufacturer,
4 repackager, or wholesale distributor,
5 as applicable;

6 “(III) received a signed state-
7 ment from the immediate subsequent
8 recipient of such product that such
9 trading partner did not knowingly and
10 intentionally adulterate or knowingly
11 and intentionally counterfeit such
12 product; and

13 “(IV) did not knowingly and in-
14 tentiously adulterate or knowingly
15 and intentionally counterfeit such
16 product; and

17 “(D) upon request by the Secretary, other
18 appropriate Federal official, or State official, in
19 the event of a recall, return, or as determined
20 necessary by the Secretary, or such other Fed-
21 eral or State official, to investigate a suspect
22 product, provide in a reasonable time and in a
23 reasonable manner—

24 “(i) RxTEC data by lot; and

1 “(ii) change of ownership and trans-
2 action information pursuant to subpara-
3 graphs (B) and (C), as necessary to iden-
4 tify the immediate previous source or the
5 immediate subsequent recipient of such
6 product.

7 “(2) VERIFICATION REQUIREMENTS.—

8 “(A) IN GENERAL.—A wholesale dis-
9 tributor engaged in wholesale distribution, not
10 later than 6½ years after the date of enact-
11 ment of the Securing Pharmaceutical Distribu-
12 tion Integrity Act of 2012 and in accordance
13 with this section, shall—

14 “(i) utilize RxTEC data at the lot
15 level, as part of ongoing activities to sig-
16 nificantly minimize or prevent the inci-
17 dence of suspect product in the pharma-
18 ceutical distribution supply chain, as appli-
19 cable and appropriate, which—

20 “(I) may include responding to
21 an alert regarding a suspect product
22 from a trading partner or the Sec-
23 retary, routine monitoring of a sus-
24 pect product at the lot level while
25 such product is in the possession of

1 the wholesale distributor, and check-
2 ing inventory for a suspect product at
3 the request of a trading partner or
4 the Secretary; and

5 “(II) shall take into consider-
6 ation—

7 “(aa) the likelihood that a
8 particular product has a high po-
9 tential risk with respect to phar-
10 maceutical distribution supply
11 chain security;

12 “(bb) the history and sever-
13 ity of incidences of counterfeit,
14 diversion, and theft of such prod-
15 uct;

16 “(cc) the point in the phar-
17 maceutical distribution supply
18 chain where counterfeit, diver-
19 sion, and theft has occurred or is
20 most likely to occur;

21 “(dd) the likelihood that
22 such activities will reduce the
23 possibility of counterfeit, diver-
24 sion, and theft of such product;

1 “(ee) whether the product
2 could mitigate or prevent a drug
3 shortage as defined in section
4 506C; and

5 “(ff) any guidance the Sec-
6 retary issues regarding high-risk
7 scenarios that could increase the
8 risk of suspect product entering
9 the pharmaceutical distribution
10 supply chain;

11 “(ii) conduct lot-level verification in
12 the event of a recall, including upon the re-
13 quest of a licensed or registered manufac-
14 turer, repackager, dispenser, or the Sec-
15 retary, regarding such product and recall;

16 “(iii) conduct verification of a re-
17 turned product to validate the return at
18 the lot level for a sealed homogenous case
19 of such product or at the individual sale-
20 able unit of such product if the unit is not
21 in a sealed homogenous case; and

22 “(iv) conduct unit level verification of
23 a suspect product—

24 “(I) upon the request of a li-
25 censed or registered manufacturer, re-

1 packager, wholesaler, dispenser, or the
2 Secretary, regarding such product; or

3 “(II) upon the determination
4 that a product is a suspect product.

5 “(B) LIMITATION.—Nothing in this para-
6 graph shall require a wholesale distributor to
7 verify product at the unit level except as re-
8 quired under clauses (iii) and (iv) of subpara-
9 graph (A).

10 “(3) NOTIFICATION AND PRODUCT REMOVAL.—

11 “(A) IN GENERAL.—Not later than 6½
12 years after the date of enactment of the Secur-
13 ing Pharmaceutical Distribution Integrity Act
14 of 2012 and in accordance with this section, a
15 wholesale distributor, upon confirming that a
16 product does not have the standardized numer-
17 ical identifier or lot number, consistent with
18 this section, and expiration date assigned by the
19 manufacturer, or has the appearance of being a
20 counterfeit, diverted, or stolen product, or a
21 product otherwise unfit for distribution such
22 that the product would result in serious adverse
23 health consequences or death to humans,
24 shall—

1 “(i) promptly notify the Secretary and
2 impacted trading partners, as applicable
3 and appropriate; and

4 “(ii) take steps to remove such prod-
5 uct from the pharmaceutical distribution
6 supply chain.

7 “(B) REDISTRIBUTION.—Any product sub-
8 ject to a notification under this subsection may
9 not be redistributed as a saleable product un-
10 less the wholesaler, in consultation with the
11 Secretary, and manufacturer or repackager as
12 applicable, determines such product may reen-
13 ter the pharmaceutical distribution supply
14 chain.

15 “(C) CONFIDENTIAL DATA.—A wholesale
16 distributor may confidentially maintain RxTEC
17 data for a direct trading partner and provide
18 access to such information to such trading part-
19 ner in lieu of data transmission, if mutually
20 agreed upon by such trading partners.

21 “(d) DISPENSER REQUIREMENTS.—

22 “(1) PRODUCT TRACING REQUIREMENTS.—A
23 dispenser, not later than 7½ years after the date of
24 enactment of the Securing Pharmaceutical Distribu-

1 tion Integrity Act of 2012 and in accordance with
2 this section, shall—

3 “(A) receive product only from a licensed
4 or registered manufacturer, repackager, or
5 wholesale distributor;

6 “(B) receive only products encoded with
7 RxTEC lot level data from a manufacturer, re-
8 packager, or wholesale distributor selling the
9 drug product to the dispenser;

10 “(C) maintain RxTEC lot level data or
11 allow the wholesale distributor to confidentially
12 maintain and store the RxTEC lot level data
13 sufficient to identify the product provided to the
14 dispenser from the immediate previous source
15 where a change of ownership has occurred be-
16 tween non-affiliated entities (if such arrange-
17 ment is mutually agreed upon by the dispenser
18 and the wholesale distributor);

19 “(D) use the RxTEC lot level data main-
20 tained by the dispenser or maintained by the
21 wholesale distributor on behalf of the dispenser
22 (if such arrangement is mutually agreed upon
23 by the dispenser and the wholesale distributor),
24 as necessary to respond to a request from the

1 Secretary in the event of a suspect product or
2 recall;

3 “(E) maintain lot level data upon change
4 of ownership between non-affiliated entities and
5 for recalled product; and

6 “(F) for investigation purposes only, and
7 upon request by the Secretary, other appro-
8 priate Federal official, or State official, for the
9 purpose of investigating a suspect or recalled
10 product, provide the RxTEC data by lot and
11 the immediate previous source or immediate
12 subsequent receipt of the suspect or recalled
13 product, as applicable.

14 “(2) VERIFICATION REQUIREMENTS.—Not later
15 than 7½ years after the date of enactment of the
16 Securing Pharmaceutical Distribution Integrity Act
17 of 2012 and in accordance with this section, a dis-
18 penser shall be required to conduct lot level
19 verification of suspect product only.

20 “(3) NOTIFICATION AND PRODUCT REMOVAL.—

21 “(A) IN GENERAL.—Not later than 7½
22 years after the date of enactment of the Secur-
23 ing Pharmaceutical Distribution Integrity Act
24 of 2012 and in accordance with this section, a
25 dispenser, upon confirming that a product is a

1 suspect product or a product otherwise unfit for
2 distribution, shall—

3 “(i) promptly notify the Secretary and
4 impacted trading partners, as applicable
5 and appropriate; and

6 “(ii) take steps to remove such prod-
7 uct from the pharmaceutical distribution
8 supply chain.

9 “(B) REDISTRIBUTION.—Any product sub-
10 ject to a notification under this paragraph may
11 not be redistributed as a saleable product un-
12 less the dispenser, in consultation with the Sec-
13 retary, and manufacturer, repackager, or whole-
14 saler as applicable, determines such product
15 may reenter the pharmaceutical distribution
16 supply chain.

17 “(C) LIMITATIONS.—Nothing in this sec-
18 tion shall—

19 “(i) require a dispenser to verify prod-
20 uct at the unit level; or

21 “(ii) require a dispenser to adopt spe-
22 cific technologies or business systems for
23 compliance with this section.

24 “(e) ENSURING FLEXIBILITY.—The requirements
25 under this section shall—

1 “(1) require the maintenance and transmission
2 only of information that is reasonably available and
3 appropriate;

4 “(2) be based on current scientific and techno-
5 logical capabilities and shall neither require nor re-
6 strict the use of additional data carrier technologies;

7 “(3) not prescribe or proscribe specific tech-
8 nologies or systems for the maintenance and trans-
9 mission of data other than the standard data carrier
10 for RxTEC or specific methods of verification;

11 “(4) not require a record of the complete pre-
12 vious distribution history of the drug from the point
13 of origin of such drug;

14 “(5) take into consideration whether the public
15 health benefits of imposing any additional regula-
16 tions outweigh the cost of compliance with such re-
17 quirements;

18 “(6) be scale-appropriate and practicable for
19 entities of varying sizes and capabilities;

20 “(7) with respect to cost and recordkeeping
21 burdens, not require the creation and maintenance
22 of duplicative records where the information is con-
23 tained in other company records kept in the normal
24 course of business;

1 “(8) to the extent practicable, not require spe-
2 cific business systems for compliance with such re-
3 quirements;

4 “(9) include a process by which the Secretary
5 may issue a waiver of such regulations for an indi-
6 vidual entity if the Secretary determines that such
7 requirements would result in an economic hardship
8 or for emergency medical reasons, including a public
9 health emergency declaration pursuant to section
10 319 of the Public Health Service Act; and

11 “(10) include a process by which the Secretary
12 may determine exceptions to the standard data car-
13 rier RxTEC requirement if a drug is packaged in a
14 container too small or otherwise unable to accommo-
15 date a label with sufficient space to bear the infor-
16 mation required for compliance with this section.

17 “(f) REGULATIONS AND GUIDANCE.—

18 “(1) IN GENERAL.—The Secretary may issue
19 guidance consistent with this section regarding the
20 circumstances surrounding suspect product and
21 verification practices.

22 “(2) PROCEDURE.—The Secretary, in promul-
23 gating any regulation pursuant to this section,
24 shall—

1 “(A) issue a notice of proposed rulemaking
2 that includes a copy of 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).

13 “(g) STANDARDS.—The Secretary shall, in consulta-
14 tion with other appropriate Federal officials, manufactur-
15 ers, repackagers, wholesale distributors, dispensers, and
16 other supply chain stakeholders, prioritize and develop
17 standards for the interoperable exchange of ownership and
18 transaction information for tracking and tracing prescrip-
19 tion drugs.”.

20 (b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
21 as amended by section 712, is further amended by insert-
22 ing at the end the following:

23 “(bbb) The violation of any requirement under sec-
24 tion 582.”.

1 (c) SMALL ENTITY COMPLIANCE GUIDE.—Not later
2 than 180 days after enactment of this Act, the Secretary
3 of Health and Human Services (referred to in this title
4 as the “Secretary”) shall issue a compliance guide setting
5 forth in plain language the requirements under section
6 582 of the Federal Food, Drug, and Cosmetic Act, as
7 added by subsection (a), in order to assist small entities
8 in complying with such section.

9 (d) LIMITATIONS.—

10 (1) SAVINGS CLAUSE.—Nothing in this subtitle
11 or the amendments made by this subtitle shall pre-
12 empt any State or local law or regulation.

13 (2) EFFECT ON CALIFORNIA LAW.—Notwith-
14 standing any other provision of Federal or State
15 law, including any provision of this subtitle or of
16 subchapter H of chapter V of the Federal Food,
17 Drug, and Cosmetic Act, as added by subsection (a),
18 such subchapter H shall not trigger California Busi-
19 ness and Professions Code, section 4034.1.

20 (3) EFFECTIVE DATE.—Subsection (c) and the
21 amendments made by subsections (a) and (b) shall
22 take effect on January 1, 2022, or on the date on
23 which Congress enacts a law providing for express
24 preemption of any State law regulating the distribu-
25 tion of drugs, whichever is later.

1 **SEC. 723. INDEPENDENT ASSESSMENT.**

2 (a) IN GENERAL.—The Secretary shall contract with
3 a private, independent consulting firm capable of per-
4 forming the technical analysis, management assessment,
5 and program evaluation tasks required to conduct a com-
6 prehensive assessment of the process for the review of
7 drug applications under subsections (b) and (j) of section
8 505 of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 355(b), (j)) and subsections (a) and (k) of section
10 351 of the Public Health Service Act (42 U.S.C. 262(a),
11 (k)). The assessment shall address the premarket review
12 process of drugs by the Food and Drug Administration,
13 using an assessment framework that draws from appro-
14 priate quality system standards, including management
15 responsibility, documents controls and records manage-
16 ment, and corrective and preventive action.

17 (b) PARTICIPATION.—Representatives of the Food
18 and Drug Administration and manufacturers of drugs
19 subject to user fees under part 2 of subchapter C of chap-
20 ter VII of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 379g et seq.) shall participate in a comprehensive
22 assessment of the process for the review of drug applica-
23 tions under section 505 of the Federal Food, Drug, and
24 Cosmetic Act and section 351 of the Public Health Service
25 Act. The assessment shall be conducted in phases.

1 (c) FIRST CONTRACT.—The Secretary shall award
2 the contract for the first assessment under this section
3 not later than March 31, 2013. Such contractor shall
4 evaluate the implementation of recommendations and pub-
5 lish a written assessment not later than February 1, 2016.

6 (d) FINDINGS AND RECOMMENDATIONS.—

7 (1) IN GENERAL.—The Secretary shall publish
8 the findings and recommendations under this section
9 that are likely to have a significant impact on review
10 times not later than 6 months after the contract is
11 awarded. Final comprehensive findings and rec-
12 ommendations shall be published not later than 1
13 year after the contract is awarded.

14 (2) IMPLEMENTATION PLAN.—The Food and
15 Drug Administration shall publish an implementa-
16 tion plan not later than 6 months after the date of
17 receipt of each set of recommendation.

18 (e) SCOPE OF ASSESSMENT.—The assessment under
19 this section shall include the following:

20 (1) Identification of process improvements and
21 best practices for conducting predictable, efficient,
22 and consistent premarket reviews that meet regu-
23 latory review standards.

1 (2) Analysis of elements of the review process
2 that consume or save time to facilitate a more effi-
3 cient process. Such analysis shall include—

4 (A) consideration of root causes for ineffi-
5 ciencies that may affect review performance and
6 total time to decision;

7 (B) recommended actions to correct any
8 failures to meet user fee program goals; and

9 (C) consideration of the impact of com-
10 bination products on the review process.

11 (3) Assessment of methods and controls of the
12 Food and Drug Administration for collecting and re-
13 porting information on premarket review process re-
14 source use and performance.

15 (4) Assessment of effectiveness of the reviewer
16 training program of the Food and Drug Administra-
17 tion.

18 (5) Recommendations for ongoing periodic as-
19 sessments and any additional, more detailed or fo-
20 cused assessments.

21 (f) REQUIREMENTS.—The Secretary shall—

22 (1) analyze the recommendations for improve-
23 ment opportunities identified in the assessment, de-
24 velop and implement a corrective action plan, and
25 ensure it effectiveness;

1 (2) incorporate the findings and recommenda-
2 tions of the contractors, as appropriate, into the
3 management of the premarket review program of the
4 Food and Drug Administration; and

5 (3) incorporate the results of the assessment in
6 a Good Review Management Practices guidance doc-
7 ument, which shall include initial and ongoing train-
8 ing of Food and Drug Administration staff, and
9 periodic audits of compliance with the guidance.

10 **TITLE VIII—GENERATING** 11 **ANTIBIOTIC INCENTIVES NOW**

12 **SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

13 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.)
14 is amended by inserting after section 505D the following:

15 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW** 16 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

17 “(a) EXTENSION.—If the Secretary approves an ap-
18 plication pursuant to section 505 for a drug that has been
19 designated as a qualified infectious disease product under
20 subsection (d), the 4- and 5-year periods described in sub-
21 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the
22 3-year periods described in clauses (iii) and (iv) of sub-
23 section (c)(3)(E) and clauses (iii) and (iv) of subsection
24 (j)(5)(F) of section 505, or the 7-year period described
25 in section 527, as applicable, shall be extended by 5 years.

1 “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
2 extension under subsection (a) of a period shall be in addi-
3 tion to any extension of the period under section 505A
4 with respect to the drug.

5 “(c) LIMITATIONS.—Subsection (a) does not apply to
6 the approval of—

7 “(1) a supplement to an application under sec-
8 tion 505(b) for any qualified infectious disease prod-
9 uct for which an extension described in subsection
10 (a) is in effect or has expired;

11 “(2) a subsequent application filed with respect
12 to a product approved under section 505 for a
13 change that results in a new indication, route of ad-
14 ministration, dosing schedule, dosage form, delivery
15 system, delivery device, or strength; or

16 “(3) an application for a product that is not ap-
17 proved for the use for which it received a designa-
18 tion under subsection (d).

19 “(d) DESIGNATION.—

20 “(1) IN GENERAL.—The manufacturer or spon-
21 sor of a drug may request the Secretary to designate
22 a drug as a qualified infectious disease product at
23 any time before the submission of an application
24 under section 505(b) for such drug. The Secretary
25 shall, not later than 60 days after the submission of

1 such a request, determine whether the drug is a
2 qualified infectious disease product.

3 “(2) LIMITATION.—Except as provided in para-
4 graph (3), a designation under this subsection shall
5 not be withdrawn for any reason, including modifica-
6 tions to the list of qualifying pathogens under sub-
7 section (f)(2)(C).

8 “(3) REVOCATION OF DESIGNATION.—The Sec-
9 retary may revoke a designation of a drug as a
10 qualified infectious disease product if the Secretary
11 finds that the request for such designation contained
12 an untrue statement of material fact.

13 “(e) REGULATIONS.—

14 “(1) IN GENERAL.—Not later than 2 years
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 a regula-
20 tion implementing this section, the Secretary shall—

21 “(A) issue a notice of proposed rulemaking
22 that includes the proposed regulation;

23 “(B) provide a period of not less than 60
24 days for comments on the proposed regulation;
25 and

1 “(C) publish the final regulation not less
2 than 30 days before the effective date of the
3 regulation.

4 “(3) RESTRICTIONS.—Notwithstanding any
5 other provision of law, the Secretary shall promul-
6 gate regulations implementing this section only as
7 described in paragraph (2), except that the Sec-
8 retary may issue interim guidance for sponsors seek-
9 ing designation under subsection (d) prior to the
10 promulgation of such regulations.

11 “(4) DESIGNATION PRIOR TO REGULATIONS.—
12 The Secretary may designate drugs as qualified in-
13 fectious disease products under subsection (d) prior
14 to the promulgation of regulations under this sub-
15 section.

16 “(f) QUALIFYING PATHOGEN.—

17 “(1) DEFINITION.—In this section, the term
18 ‘qualifying pathogen’ means a pathogen identified
19 and listed by the Secretary under paragraph (2) that
20 has the potential to pose a serious threat to public
21 health, such as—

22 “(A) resistant gram positive pathogens, in-
23 cluding methicillin-resistant *Staphylococcus*
24 aureus, vancomycin-resistant *Staphylococcus*
25 aureus, and vancomycin-resistant enterococcus;

1 “(B) multi-drug resistant gram negative
2 bacteria, including *Acinetobacter*, *Klebsiella*,
3 *Pseudomonas*, and *E. coli* species;

4 “(C) multi-drug resistant tuberculosis; and

5 “(D) *Clostridium difficile*.

6 “(2) LIST OF QUALIFYING PATHOGENS.—

7 “(A) IN GENERAL.—The Secretary shall
8 establish and maintain a list of qualifying
9 pathogens, and shall make public the method-
10 ology for developing such list.

11 “(B) CONSIDERATIONS.—In establishing
12 and maintaining the list of pathogens described
13 under this section the Secretary shall—

14 “(i) consider—

15 “(I) the impact on the public
16 health due to drug-resistant orga-
17 nisms in humans;

18 “(II) the rate of growth of drug-
19 resistant organisms in humans;

20 “(III) the increase in resistance
21 rates in humans; and

22 “(IV) the morbidity and mor-
23 tality in humans; and

24 “(ii) consult with experts in infectious
25 diseases and antibiotic resistance, includ-

1 ing the Centers for Disease Control and
2 Prevention, the Food and Drug Adminis-
3 tration, medical professionals, and the clin-
4 ical research community.

5 “(C) REVIEW.—Every 5 years, or more
6 often as needed, the Secretary shall review, pro-
7 vide modifications to, and publish the list of
8 qualifying pathogens under subparagraph (A)
9 and shall by regulation revise the list as nec-
10 essary, in accordance with subsection (e).

11 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
12 The term ‘qualified infectious disease product’ means an
13 antibacterial or antifungal drug for human use intended
14 to treat serious or life-threatening infections, including
15 those caused by—

16 “(1) an antibacterial or antifungal resistant
17 pathogen, including novel or emerging infectious
18 pathogens; or

19 “(2) qualifying pathogens listed by the Sec-
20 retary under subsection (f).”.

21 (b) APPLICATION.—Section 505E of the Federal
22 Food, Drug, and Cosmetic Act, as added by subsection
23 (a), applies only with respect to a drug that is first ap-
24 proved under section 505(c) of such Act (21 U.S.C.
25 355(c)) on or after the date of the enactment of this Act.

1 **SEC. 802. PRIORITY REVIEW.**

2 (a) AMENDMENT.—Chapter V (21 U.S.C. 351 et
3 seq.) is amended by inserting after section 524 the fol-
4 lowing:

5 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**
6 **DISEASE PRODUCTS.**

7 “If the Secretary designates a drug under section
8 505E(d) as a qualified infectious disease product, then the
9 Secretary shall give priority review to any application sub-
10 mitted for approval for such drug under section 505(b).”.

11 (b) APPLICATION.—Section 524A of the Federal
12 Food, Drug, and Cosmetic Act, as added by subsection
13 (a), applies only with respect to an application that is sub-
14 mitted under section 505(b) of such Act (21 U.S.C.
15 355(b)) on or after the date of the enactment of this Act.

16 **SEC. 803. FAST TRACK PRODUCT.**

17 Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended
18 by section 901(b), is amended by inserting “, or if the
19 Secretary designates the drug as a qualified infectious dis-
20 ease product under section 505E(d)” before the period at
21 the end of the first sentence.

22 **SEC. 804. GAO STUDY.**

23 (a) IN GENERAL.—The Comptroller General of the
24 United States shall—

25 (1) conduct a study—

1 (A) on the need for, and public health im-
2 pact of, incentives to encourage the research,
3 development, and marketing of qualified infec-
4 tious disease biological products and antifungal
5 products; and

6 (B) consistent with trade and confiden-
7 tiality data protections, assessing, for all anti-
8 bacterial and antifungal drugs, including bio-
9 logical products, the average or aggregate—

10 (i) costs of all clinical trials for each
11 phase;

12 (ii) percentage of success or failure at
13 each phase of clinical trials; and

14 (iii) public versus private funding lev-
15 els of the trials for each phase; and

16 (2) not later than 1 year after the date of en-
17 actment of this Act, submit a report to Congress on
18 the results of such study, including any rec-
19 ommendations of the Comptroller General on appro-
20 priate incentives for addressing such need.

21 (b) CONTENTS.—The part of the study described in
22 subsection (a)(1)(A) shall include—

23 (1) an assessment of any underlying regulatory
24 issues related to qualified infectious disease prod-

1 ucts, including qualified infectious disease biological
2 products;

3 (2) an assessment of the management by the
4 Food and Drug Administration of the review of
5 qualified infectious disease products, including quali-
6 fied infectious disease biological products and the
7 regulatory certainty of related regulatory pathways
8 for such products;

9 (3) a description of any regulatory impediments
10 to the clinical development of new qualified infec-
11 tious disease products, including qualified infectious
12 disease biological products, and the efforts of the
13 Food and Drug Administration to address such im-
14 pediments; and

15 (4) recommendations with respect to—

16 (A) improving the review and predictability
17 of regulatory pathways for such products; and

18 (B) overcoming any regulatory impedi-
19 ments identified in paragraph (3).

20 (c) DEFINITIONS.—In this section:

21 (1) The term “biological product” has the
22 meaning given to such term in section 351 of the
23 Public Health Service Act (42 U.S.C. 262).

24 (2) The term “qualified infectious disease bio-
25 logical product” means a biological product intended

1 to treat a serious or life-threatening infection de-
2 scribed in section 505E(g) of the Federal Food,
3 Drug, and Cosmetic Act, as added by section 801.

4 (3) The term “qualified infectious disease prod-
5 uct” has the meaning given such term in section
6 505E(g) of the Federal Food, Drug, and Cosmetic
7 Act, as added by section 801.

8 **SEC. 805. CLINICAL TRIALS.**

9 (a) REVIEW AND REVISION OF GUIDANCE DOCU-
10 MENTS.—

11 (1) IN GENERAL.—The Secretary of Health and
12 Human Services (referred to in this section as the
13 “Secretary”) shall review and, as appropriate, revise
14 not fewer than 3 guidance documents per year,
15 which shall include—

16 (A) reviewing the guidance documents of
17 the Food and Drug Administration for the con-
18 duct of clinical trials with respect to anti-
19 bacterial and antifungal drugs; and

20 (B) as appropriate, revising such guidance
21 documents to reflect developments in scientific
22 and medical information and technology and to
23 ensure clarity regarding the procedures and re-
24 quirements for approval of antibacterial and
25 antifungal drugs under chapter V of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C.
2 351 et seq.).

3 (2) ISSUES FOR REVIEW.—At a minimum, the
4 review under paragraph (1) shall address the appro-
5 priate animal models of infection, in vitro tech-
6 niques, valid micro-biological surrogate markers, the
7 use of non-inferiority versus superiority trials, trial
8 enrollment, data requirements, and appropriate delta
9 values for non-inferiority trials.

10 (3) RULE OF CONSTRUCTION.—Except to the
11 extent to which the Secretary makes revisions under
12 paragraph (1)(B), nothing in this section shall be
13 construed to repeal or otherwise effect the guidance
14 documents of the Food and Drug Administration.

15 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

16 (1) REQUEST.—The sponsor of a drug intended
17 to be designated as a qualified infectious disease
18 product may request that the Secretary provide writ-
19 ten recommendations for nonclinical and clinical in-
20 vestigations which the Secretary believes may be
21 necessary to be conducted with the drug before such
22 drug may be approved under section 505 of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)
24 for use in treating, detecting, preventing, or identi-

1 fying a qualifying pathogen, as defined in section
2 505E of such Act.

3 (2) RECOMMENDATIONS.—If the Secretary has
4 reason to believe that a drug for which a request is
5 made under this subsection is a qualified infectious
6 disease product, the Secretary shall provide the per-
7 son making the request written recommendations for
8 the nonclinical and clinical investigations which the
9 Secretary believes, on the basis of information avail-
10 able to the Secretary at the time of the request,
11 would be necessary for approval under section 505
12 of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 355) of such drug for the use described in
14 paragraph (1).

15 (c) GAO STUDY.—Not later than January 1, 2016,
16 the Comptroller General of the United States shall submit
17 to Congress a report—

18 (1) regarding the review and revision of the
19 clinical trial guidance documents required under
20 subsection (a) and the impact such review and revi-
21 sion has had on the review and approval of qualified
22 infectious disease products;

23 (2) assessing—

24 (A) the effectiveness of the results-oriented
25 metrics managers employ to ensure that review-

1 ers of such products are familiar with, and con-
2 sistently applying, clinical trial guidance docu-
3 ments; and

4 (B) the predictability of related regulatory
5 pathways and review;

6 (3) identifying any outstanding regulatory im-
7 pediments to the clinical development of qualified in-
8 fectious disease products;

9 (4) reporting on the progress the Food and
10 Drug Administration has made in addressing the im-
11 pediments identified under paragraph (3); and

12 (5) containing recommendations regarding how
13 to improve the review of, and regulatory pathway
14 for, such products.

15 (d) **QUALIFIED INFECTIOUS DISEASE PRODUCT.**—
16 For purposes of this section, the term “qualified infectious
17 disease product” has the meaning given such term in sec-
18 tion 505E(g) of the Federal Food, Drug, and Cosmetic
19 Act, as added by section 801.

20 **SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.**

21 (a) **INITIAL STRATEGY AND IMPLEMENTATION**
22 **PLAN.**—Not later than 1 year after the date of enactment
23 of this Act, the Secretary of Health and Human Services
24 (referred to in this section as the “Secretary”) shall sub-
25 mit to Congress a strategy and implementation plan with

1 respect to the requirements of this Act. The strategy and
2 implementation plan shall include—

3 (1) a description of the regulatory challenges to
4 clinical development, approval, and licensure of
5 qualified infectious disease products;

6 (2) the regulatory and scientific priorities of the
7 Secretary with respect to such challenges; and

8 (3) the steps the Secretary will take to ensure
9 regulatory certainty and predictability with respect
10 to qualified infectious disease products, including
11 steps the Secretary will take to ensure managers and
12 reviewers are familiar with related regulatory path-
13 ways, requirements of the Food and Drug Adminis-
14 tration, guidance documents related to such prod-
15 ucts, and applying such requirements consistently.

16 (b) SUBSEQUENT REPORT.—Not later than 3 years
17 after the date of enactment of this Act, the Secretary shall
18 submit to Congress a report on—

19 (1) the progress made toward the priorities
20 identified under subsection (a)(2);

21 (2) the number of qualified infectious disease
22 products that have been submitted for approval or li-
23 censure on or after the date of enactment of this
24 Act;

1 (3) a list of qualified infectious disease products
2 with information on the types of exclusivity granted
3 for each product, consistent with the information
4 published under section 505(j)(7)(A)(iii) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(j)(7)(A)(iii));

7 (4) the number of such qualified infectious dis-
8 ease products and that have been approved or li-
9 censed on or after the date of enactment of this Act;
10 and

11 (5) the number of calendar days it took for the
12 approval or licensure of the qualified infectious dis-
13 ease products approved or licensed on or after the
14 date of enactment of this Act.

15 (c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
16 For purposes of this section, the term “qualified infectious
17 disease product” has the meaning given such term in sec-
18 tion 505E(g) of the Federal Food, Drug, and Cosmetic
19 Act, as added by section 801.

20 **TITLE IX—DRUG APPROVAL AND** 21 **PATIENT ACCESS**

22 **SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT AC-** 23 **CESS TO NEW MEDICAL TREATMENTS.**

24 (a) FINDINGS; SENSE OF CONGRESS.—

25 (1) FINDINGS.—Congress finds as follows:

1 (A) The Food and Drug Administration
2 (referred to in this section as the “FDA”)
3 serves a critical role in helping to assure that
4 new medicines are safe and effective. Regu-
5 latory innovation is 1 element of the Nation’s
6 strategy to address serious and life-threatening
7 diseases or conditions by promoting investment
8 in and development of innovative treatments for
9 unmet medical needs.

10 (B) During the 2 decades following the es-
11 tablishment of the accelerated approval mecha-
12 nism, advances in medical sciences, including
13 genomics, molecular biology, and bioinformatics,
14 have provided an unprecedented understanding
15 of the underlying biological mechanism and
16 pathogenesis of disease. A new generation of
17 modern, targeted medicines is under develop-
18 ment to treat serious and life-threatening dis-
19 eases, some applying drug development strate-
20 gies based on biomarkers or pharmacogenomics,
21 predictive toxicology, clinical trial enrichment
22 techniques, and novel clinical trial designs, such
23 as adaptive clinical trials.

24 (C) As a result of these remarkable sci-
25 entific and medical advances, the FDA should

1 be encouraged to implement more broadly effective
2 processes for the expedited development
3 and review of innovative new medicines intended
4 to address unmet medical needs for serious
5 or life-threatening diseases or conditions,
6 including those for rare diseases or conditions,
7 using a broad range of surrogate or clinical
8 endpoints and modern scientific tools earlier in
9 the drug development cycle when appropriate.
10 This may result in fewer, smaller, or shorter
11 clinical trials for the intended patient population
12 or targeted subpopulation without compromising
13 or altering the high standards of the
14 FDA for the approval of drugs.

15 (D) Patients benefit from expedited access
16 to safe and effective innovative therapies to
17 treat unmet medical needs for serious or life-
18 threatening diseases or conditions.

19 (E) For these reasons, the statutory authority
20 in effect on the day before the date of
21 enactment of this Act governing expedited approval
22 of drugs for serious or life-threatening
23 diseases or conditions should be amended in
24 order to enhance the authority of the FDA to
25 consider appropriate scientific data, methods,

1 it is intended, whether alone or in combination with
2 one or more other drugs, for the treatment of a seri-
3 ous or life-threatening disease or condition, and it
4 demonstrates the potential to address unmet medical
5 needs for such a disease or condition. (In this sec-
6 tion, such a drug is referred to as a ‘fast track prod-
7 uct’.)

8 “(2) REQUEST FOR DESIGNATION.—The spon-
9 sor of a new drug may request the Secretary to des-
10 ignate the drug as a fast track product. A request
11 for the designation may be made concurrently with,
12 or at any time after, submission of an application
13 for the investigation of the drug under section 505(i)
14 or section 351(a)(3) of the Public Health Service
15 Act.

16 “(3) DESIGNATION.—Within 60 calendar days
17 after the receipt of a request under paragraph (2),
18 the Secretary shall determine whether the drug that
19 is the subject of the request meets the criteria de-
20 scribed in paragraph (1). If the Secretary finds that
21 the drug meets the criteria, the Secretary shall des-
22 ignate the drug as a fast track product and shall
23 take such actions as are appropriate to expedite the
24 development and review of the application for ap-
25 proval of such product.

1 “(b) ACCELERATED APPROVAL OF A DRUG FOR A
2 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
3 TION, INCLUDING A FAST TRACK PRODUCT.—

4 “(1) IN GENERAL.—

5 “(A) ACCELERATED APPROVAL.—The Sec-
6 retary may approve an application for approval
7 of a product for a serious or life-threatening
8 disease or condition, including a fast track
9 product, under section 505(c) or section 351(a)
10 of the Public Health Service Act upon a deter-
11 mination that the product has an effect on a
12 surrogate endpoint that is reasonably likely to
13 predict clinical benefit, or on a clinical endpoint
14 that can be measured earlier than irreversible
15 morbidity or mortality, that is reasonably likely
16 to predict an effect on irreversible morbidity or
17 mortality or other clinical benefit, taking into
18 account the severity, rarity, or prevalence of the
19 condition and the availability or lack of alter-
20 native treatments. The approval described in
21 the preceding sentence is referred to in this sec-
22 tion as ‘accelerated approval’.

23 “(B) EVIDENCE.—The evidence to support
24 that an endpoint is reasonably likely to predict
25 clinical benefit under subparagraph (A) may in-

1 clude epidemiological, pathophysiological, thera-
2 peutic, pharmacologic, or other evidence devel-
3 oped using biomarkers, for example, or other
4 scientific methods or tools.

5 “(2) LIMITATION.—Approval of a product
6 under this subsection may be subject to 1 or both
7 of the following requirements:

8 “(A) That the sponsor conduct appropriate
9 post-approval studies to verify and describe the
10 predicted effect on irreversible morbidity or
11 mortality or other clinical benefit.

12 “(B) That the sponsor submit copies of all
13 promotional materials related to the product
14 during the preapproval review period and, fol-
15 lowing approval and for such period thereafter
16 as the Secretary determines to be appropriate,
17 at least 30 days prior to dissemination of the
18 materials.

19 “(3) EXPEDITED WITHDRAWAL OF AP-
20 PROVAL.—The Secretary may withdraw approval of
21 a product approved under accelerated approval using
22 expedited procedures (as prescribed by the Secretary
23 in regulations which shall include an opportunity for
24 an informal hearing) if—

1 “(A) the sponsor fails to conduct any re-
2 quired post-approval study of the drug with due
3 diligence;

4 “(B) a study required to verify and de-
5 scribe the predicted effect on irreversible mor-
6 bidity or mortality or other clinical benefit of
7 the product fails to verify and describe such ef-
8 fect or benefit;

9 “(C) other evidence demonstrates that the
10 product is not safe or effective under the condi-
11 tions of use; or

12 “(D) the sponsor disseminates false or
13 misleading promotional materials with respect
14 to the product.

15 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR
16 APPROVAL OF A FAST TRACK PRODUCT.—

17 “(1) IN GENERAL.—If the Secretary deter-
18 mines, after preliminary evaluation of clinical data
19 submitted by the sponsor, that a fast track product
20 may be effective, the Secretary shall evaluate for fil-
21 ing, and may commence review of portions of, an ap-
22 plication for the approval of the product before the
23 sponsor submits a complete application. The Sec-
24 retary shall commence such review only if the appli-
25 cant—

1 “(A) provides a schedule for submission of
2 information necessary to make the application
3 complete; and

4 “(B) pays any fee that may be required
5 under section 736.

6 “(2) EXCEPTION.—Any time period for review
7 of human drug applications that has been agreed to
8 by the Secretary and that has been set forth in goals
9 identified in letters of the Secretary (relating to the
10 use of fees collected under section 736 to expedite
11 the drug development process and the review of
12 human drug applications) shall not apply to an ap-
13 plication submitted under paragraph (1) until the
14 date on which the application is complete.

15 “(d) AWARENESS EFFORTS.—The Secretary shall—

16 “(1) develop and disseminate to physicians, pa-
17 tient organizations, pharmaceutical and bio-
18 technology companies, and other appropriate persons
19 a description of the provisions of this section appli-
20 cable to accelerated approval and fast track prod-
21 ucts; and

22 “(2) establish a program to encourage the de-
23 velopment of surrogate and clinical endpoints, in-
24 cluding biomarkers, and other scientific methods and
25 tools that can assist the Secretary in determining

1 whether the evidence submitted in an application is
2 reasonably likely to predict clinical benefit for seri-
3 ous or life-threatening conditions for which signifi-
4 cant unmet medical needs exist.

5 “(e) CONSTRUCTION.—

6 “(1) PURPOSE.—The amendments made by the
7 Food and Drug Administration Safety and Innova-
8 tion Act to this section are intended to encourage
9 the Secretary to utilize innovative and flexible ap-
10 proaches to the assessment of products under accel-
11 erated approval for treatments for patients with seri-
12 ous or life-threatening diseases or conditions and
13 unmet medical needs.

14 “(2) CONSTRUCTION.—Nothing in this section
15 shall be construed to alter the standards of evidence
16 under subsection (c) or (d) of section 505 (including
17 the substantial evidence standard in section 505(d))
18 of this Act or under section 351(a) of the Public
19 Health Service Act. Such sections and standards of
20 evidence apply to the review and approval of prod-
21 ucts under this section, including whether a product
22 is safe and effective. Nothing in this section alters
23 the ability of the Secretary to rely on evidence that
24 does not come from adequate and well-controlled in-
25 vestigations for the purpose of determining whether

1 an endpoint is reasonably likely to predict clinical
2 benefit as described in subsection (b)(1)(B).”.

3 (c) GUIDANCE; AMENDED REGULATIONS.—

4 (1) DRAFT GUIDANCE.—Not later than 1 year
5 after the date of enactment of this Act, the Sec-
6 retary of Health and Human Services (referred to in
7 this section as the “Secretary”) shall issue draft
8 guidance to implement the amendments made by
9 this section. In developing such guidance, the Sec-
10 retary shall specifically consider issues arising under
11 the accelerated approval and fast track processes
12 under section 506 of the Federal Food, Drug, and
13 Cosmetic Act, as amended by subsection (b), for
14 drugs designated for a rare disease or condition
15 under section 526 of such Act (21 U.S.C. 360bb)
16 and shall also consider any unique issues associated
17 with very rare diseases.

18 (2) FINAL GUIDANCE.—Not later than 1 year
19 after the issuance of draft guidance under para-
20 graph (1), and after an opportunity for public com-
21 ment, the Secretary shall issue final guidance.

22 (3) CONFORMING CHANGES.—The Secretary
23 shall issue, as necessary, conforming amendments to
24 the applicable regulations under title 21, Code of
25 Federal Regulations, governing accelerated approval.

1 (4) NO EFFECT OF INACTION ON REQUESTS.—

2 If the Secretary fails to issue final guidance or
3 amended regulations as required by this subsection,
4 such failure shall not preclude the review of, or ac-
5 tion on, a request for designation or an application
6 for approval submitted pursuant to section 506 of
7 the Federal Food, Drug, and Cosmetic Act, as
8 amended by subsection (b).

9 (d) INDEPENDENT REVIEW.—The Secretary may, in
10 conjunction with other planned reviews, contract with an
11 independent entity with expertise in assessing the quality
12 and efficiency of biopharmaceutical development and regu-
13 latory review programs to evaluate the Food and Drug Ad-
14 ministration's application of the processes described in
15 section 506 of the Federal Food, Drug, and Cosmetic Act,
16 as amended by subsection (b), and the impact of such
17 processes on the development and timely availability of in-
18 novative treatments for patients suffering from serious or
19 life-threatening conditions. Any such evaluation shall in-
20 clude consultation with regulated industries, patient advo-
21 cacy and disease research foundations, and relevant aca-
22 demic medical centers.

23 **SEC. 902. BREAKTHROUGH THERAPIES.**

24 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as
25 amended by section 901, is further amended—

1 (1) by redesignating subsections (a) through (c)
2 as subsections (b) through (d), respectively;

3 (2) by redesignating subsection (d) as sub-
4 section (f);

5 (3) by inserting before subsection (b), as so re-
6 designated, the following:

7 “(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH
8 THERAPY.—

9 “(1) IN GENERAL.—The Secretary shall, at the
10 request of the sponsor of a drug, expedite the devel-
11 opment and review of such drug if the drug is in-
12 tended, alone or in combination with 1 or more other
13 drugs, to treat a serious or life-threatening disease
14 or condition and preliminary clinical evidence indi-
15 cates that the drug may demonstrate substantial im-
16 provement over existing therapies on 1 or more clini-
17 cally significant endpoints, such as substantial treat-
18 ment effects observed early in clinical development.
19 (In this section, such a drug is referred to as a
20 ‘breakthrough therapy’.)

21 “(2) REQUEST FOR DESIGNATION.—The spon-
22 sor of a drug may request the Secretary to designate
23 the drug as a breakthrough therapy. A request for
24 the designation may be made concurrently with, or
25 at any time after, the submission of an application

1 for the investigation of the drug under section 505(i)
2 or section 351(a)(3) of the Public Health Service
3 Act.

4 “(3) DESIGNATION.—

5 “(A) IN GENERAL.—Not later than 60 cal-
6 endar days after the receipt of a request under
7 paragraph (2), the Secretary shall determine
8 whether the drug that is the subject of the re-
9 quest meets the criteria described in paragraph
10 (1). If the Secretary finds that the drug meets
11 the criteria, the Secretary shall designate the
12 drug as a breakthrough therapy and shall take
13 such actions as are appropriate to expedite the
14 development and review of the application for
15 approval of such drug.

16 “(B) ACTIONS.—The actions to expedite
17 the development and review of an application
18 under subparagraph (A) may include, as appro-
19 priate—

20 “(i) holding meetings with the sponsor
21 and the review team throughout the devel-
22 opment of the drug;

23 “(ii) providing timely advice to, and
24 interactive communication with, the spon-
25 sor regarding the development of the drug

1 to ensure that the development program to
2 gather the non-clinical and clinical data
3 necessary for approval is as efficient as
4 practicable;

5 “(iii) involving senior managers and
6 experienced review staff, as appropriate, in
7 a collaborative, cross-disciplinary review;

8 “(iv) assigning a cross-disciplinary
9 project lead for the Food and Drug Ad-
10 ministration review team to facilitate an
11 efficient review of the development pro-
12 gram and to serve as a scientific liaison be-
13 tween the review team and the sponsor;
14 and

15 “(v) taking steps to ensure that the
16 design of the clinical trials is as efficient as
17 practicable, when scientifically appropriate,
18 such as by minimizing the number of pa-
19 tients exposed to a potentially less effica-
20 cious treatment.”;

21 (4) in subsection (f)(1), as so redesignated, by
22 striking “applicable to accelerated approval” and in-
23 sserting “applicable to breakthrough therapies, accel-
24 erated approval, and”; and

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

1 “(g) REPORT.—Beginning in fiscal year 2013, the
2 Secretary shall annually prepare and submit to the Com-
3 mittee on Health, Education, Labor, and Pensions of the
4 Senate and the Committee on Energy and Commerce of
5 the House of Representatives, and make publicly available,
6 with respect to this section for the previous fiscal year—

7 “(1) the number of drugs for which a sponsor
8 requested designation as a breakthrough therapy;

9 “(2) the number of products designated as a
10 breakthrough therapy; and

11 “(3) for each product designated as a break-
12 through therapy, a summary of the actions taken
13 under subsection (a)(3).”.

14 (b) GUIDANCE; AMENDED REGULATIONS.—

15 (1) IN GENERAL.—

16 (A) GUIDANCE.—Not later than 18
17 months after the date of enactment of this Act,
18 the Secretary of Health and Human Services
19 (referred to in this section as the “Secretary”)
20 shall issue draft guidance on implementing the
21 requirements with respect to breakthrough
22 therapies, as set forth in section 506(a) of the
23 Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 356(a)), as amended by this section.
25 The Secretary shall issue final guidance not

1 later than 1 year after the close of the comment
2 period for the draft guidance.

3 (B) AMENDED REGULATIONS.—

4 (i) IN GENERAL.—If the Secretary de-
5 termines that it is necessary to amend the
6 regulations under title 21, Code of Federal
7 Regulations in order to implement the
8 amendments made by this section to sec-
9 tion 506(a) of the Federal Food, Drug,
10 and Cosmetic Act, the Secretary shall
11 amend such regulations not later than 2
12 years after the date of enactment of this
13 Act.

14 (ii) PROCEDURE.—In amending regu-
15 lations under clause (i), the Secretary
16 shall—

17 (I) issue a notice of proposed
18 rulemaking that includes the proposed
19 regulation;

20 (II) provide a period of not less
21 than 60 days for comments on the
22 proposed regulation; and

23 (III) publish the final regulation
24 not less than 30 days before the effec-
25 tive date of the regulation.

1 (iii) RESTRICTIONS.—Notwithstanding
2 any other provision of law, the Secretary
3 shall promulgate regulations implementing
4 the amendments made by section only as
5 described in clause (ii).

6 (2) REQUIREMENTS.—Guidance issued under
7 this section shall—

8 (A) specify the process and criteria by
9 which the Secretary makes a designation under
10 section 506(a)(3) of the Federal Food, Drug,
11 and Cosmetic Act; and

12 (B) specify the actions the Secretary shall
13 take to expedite the development and review of
14 a breakthrough therapy pursuant to such des-
15 ignation under such section 506(a)(3), includ-
16 ing updating good review management practices
17 to reflect breakthrough therapies.

18 (c) INDEPENDENT REVIEW.—Not later than 3 years
19 after the date of enactment of this Act, the Comptroller
20 General of the United States, in consultation with appro-
21 priate experts, shall assess the manner by which the Food
22 and Drug Administration has applied the processes de-
23 scribed in section 506(a) of the Federal Food, Drug, and
24 Cosmetic Act, as amended by this section, and the impact
25 of such processes on the development and timely avail-

1 ability of innovative treatments for patients affected by se-
2 rious or life-threatening conditions. Such assessment shall
3 be made publicly available upon completion.

4 (d) CONFORMING AMENDMENTS.—Section 506B(e)
5 (21 U.S.C. 356b) is amended by striking “section
6 506(b)(2)(A)” each place such term appears and inserting
7 “section 506(c)(2)(A)”.

8 **SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON**
9 **RARE DISEASES, TARGETED THERAPIES, AND**
10 **GENETIC TARGETING OF TREATMENTS.**

11 Subchapter E of chapter V (21 U.S.C. 360bbb et
12 seq.), as amended by section 712, is further amended by
13 adding at the end the following:

14 **“SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON**
15 **RARE DISEASES, TARGETED THERAPIES, AND**
16 **GENETIC TARGETING OF TREATMENTS.**

17 “(a) IN GENERAL.—For the purpose of promoting
18 the efficiency of and informing the review by the Food
19 and Drug Administration of new drugs and biological
20 products for rare diseases and drugs and biological prod-
21 ucts that are genetically targeted, the following shall
22 apply:

23 “(1) CONSULTATION WITH STAKEHOLDERS.—
24 Consistent with sections X.C and IX.E.4 of the
25 PDUFA Reauthorization Performance Goals and

1 Procedures Fiscal Years 2013 through 2017, as ref-
2 erenced in the letters described in section 101(b) of
3 the Prescription Drug User Fee Amendments of
4 2012, the Secretary shall ensure that opportunities
5 exist, at a time the Secretary determines appro-
6 priate, for consultations with stakeholders on the
7 topics described in subsection (c).

8 “(2) CONSULTATION WITH EXTERNAL EX-
9 PERTS.—The Secretary shall develop and maintain a
10 list of external experts who, because of their special
11 expertise, are qualified to provide advice on rare dis-
12 ease issues, including topics described in subsection
13 (c). The Secretary may, when appropriate to address
14 a specific regulatory question, consult such external
15 experts on issues related to the review of new drugs
16 and biological products for rare diseases and drugs
17 and biological products that are genetically targeted,
18 including the topics described in subsection (c),
19 when such consultation is necessary because the Sec-
20 retary lacks specific scientific, medical, or technical
21 expertise necessary for the performance of its regu-
22 latory responsibilities and the necessary expertise
23 can be provided by the external experts.

24 “(b) EXTERNAL EXPERTS.—For purposes of sub-
25 section (a)(2), external experts are those who possess sci-

1 entific or medical training that the Secretary lacks with
2 respect to one or more rare diseases.

3 “(c) TOPICS FOR CONSULTATION.—Topics for con-
4 sultation pursuant to this section may include—

5 “(1) rare diseases;

6 “(2) the severity of rare diseases;

7 “(3) the unmet medical need associated with
8 rare diseases;

9 “(4) the willingness and ability of individuals
10 with a rare disease to participate in clinical trials;

11 “(5) an assessment of the benefits and risks of
12 therapies to treat rare diseases;

13 “(6) the general design of clinical trials for rare
14 disease populations and subpopulations; and

15 “(7) demographics and the clinical description
16 of patient populations.

17 “(d) CLASSIFICATION AS SPECIAL GOVERNMENT EM-
18 PLOYEES.—The external experts who are consulted under
19 this section may be considered special government employ-
20 ees, as defined under section 202 of title 18, United States
21 Code.

22 “(e) PROTECTION OF PROPRIETARY INFORMA-
23 TION.—Nothing in this section shall be construed to alter
24 the protections offered by laws, regulations, and policies
25 governing disclosure of confidential commercial or trade

1 secret information, and any other information exempt
2 from disclosure pursuant to section 552(b) of title 5,
3 United States Code, as such provisions would be applied
4 to consultation with individuals and organizations prior to
5 the date of enactment of this section.

6 “(f) OTHER CONSULTATION.—Nothing in this sec-
7 tion shall be construed to limit the ability of the Secretary
8 to consult with individuals and organizations as authorized
9 prior to the date of enactment of this section.

10 “(g) NO RIGHT OR OBLIGATION.—Nothing in this
11 section shall be construed to create a legal right for a con-
12 sultation on any matter or require the Secretary to meet
13 with any particular expert or stakeholder. Nothing in this
14 section shall be construed to alter agreed upon goals and
15 procedures identified in the letters described in section
16 101(b) of the Prescription Drug User Fee Amendments
17 of 2012. Nothing in this section is intended to increase
18 the number of review cycles as in effect before the date
19 of enactment of this section.”.

20 **SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIP-**
21 **TION DRUG CONTAINER LABELS BY VIS-**
22 **UALLY-IMPAIRED AND BLIND CONSUMERS.**

23 (a) ESTABLISHMENT OF WORKING GROUP.—

24 (1) IN GENERAL.—The Architectural and
25 Transportation Barriers Compliance Board (referred

1 to in this section as the “Access Board”) shall con-
2 vene a stakeholder working group (referred to in this
3 section as the “working group”) to develop best
4 practices on access to information on prescription
5 drug container labels for individuals who are blind
6 or visually impaired.

7 (2) MEMBERS.—The working group shall be
8 comprised of representatives of national organiza-
9 tions representing blind and visually-impaired indi-
10 viduals, national organizations representing the el-
11 derly, and industry groups representing stake-
12 holders, including retail, mail order, and independent
13 community pharmacies, who would be impacted by
14 such best practices. Representation within the work-
15 ing group shall be divided equally between consumer
16 and industry advocates.

17 (3) BEST PRACTICES.—

18 (A) IN GENERAL.—The working group
19 shall develop, not later than 1 year after the
20 date of the enactment of this Act, best practices
21 for pharmacies to ensure that blind and vis-
22 ually-impaired individuals have safe, consistent,
23 reliable, and independent access to the informa-
24 tion on prescription drug container labels.

1 (B) PUBLIC AVAILABILITY.—The best
2 practices developed under subparagraph (A)
3 may be made publicly available, including
4 through the Internet websites of the working
5 group participant organizations, and through
6 other means, in a manner that provides access
7 to interested individuals, including individuals
8 with disabilities.

9 (C) LIMITATIONS.—The best practices de-
10 veloped under subparagraph (A) shall not be
11 construed as accessibility guidelines or stand-
12 ards of the Access Board, and shall not confer
13 any rights or impose any obligations on working
14 group participants or other persons. Nothing in
15 this section shall be construed to limit or condi-
16 tion any right, obligation, or remedy available
17 under the Americans with Disabilities Act of
18 1990 (42 U.S.C. 12101 et seq.) or any other
19 Federal or State law requiring effective commu-
20 nication, barrier removal, or nondiscrimination
21 on the basis of disability.

22 (4) CONSIDERATIONS.—In developing and
23 issuing the best practices under paragraph (3)(A),
24 the working group shall consider—

25 (A) the use of—

- 1 (i) Braille;
- 2 (ii) auditory means, such as—
- 3 (I) “talking bottles” that provide
- 4 audible container label information;
- 5 (II) digital voice recorders at-
- 6 tached to the prescription drug con-
- 7 tainer; and
- 8 (III) radio frequency identifica-
- 9 tion tags;
- 10 (iii) enhanced visual means, such as—
- 11 (I) large font labels or large font
- 12 “duplicate” labels that are affixed or
- 13 matched to a prescription drug con-
- 14 tainer;
- 15 (II) high-contrast printing; and
- 16 (III) sans-serif font; and
- 17 (iv) other relevant alternatives as de-
- 18 termined by the working group;
- 19 (B) whether there are technical, financial,
- 20 manpower, or other factors unique to phar-
- 21 macies with 20 or fewer retail locations which
- 22 may pose significant challenges to the adoption
- 23 of the best practices; and
- 24 (C) such other factors as the working
- 25 group determines to be appropriate.

1 (5) INFORMATION CAMPAIGN.—Upon comple-
2 tion of development of the best practices under sub-
3 section (a)(3), the National Council on Disability, in
4 consultation with the working group, shall conduct
5 an informational and educational campaign designed
6 to inform individuals with disabilities, pharmacists,
7 and the public about such best practices.

8 (6) FACA WAIVER.—The Federal Advisory
9 Committee Act (5 U.S.C. App.) shall not apply to
10 the working group.

11 (b) GAO STUDY.—

12 (1) IN GENERAL.—Beginning 18 months after
13 the completion of the development of best practices
14 under subsection (a)(3)(A), the Comptroller General
15 of the United States shall conduct a review of the
16 extent to which pharmacies are utilizing such best
17 practices, and the extent to which barriers to acces-
18 sible information on prescription drug container la-
19 bels for blind and visually-impaired individuals con-
20 tinue.

21 (2) REPORT.—Not later than September 30,
22 2016, the Comptroller General of the United States
23 shall submit to Congress a report on the review con-
24 ducted under paragraph (1). Such report shall in-
25 clude recommendations about how best to reduce the

1 barriers experienced by blind and visually-impaired
2 individuals to independently accessing information
3 on prescription drug container labels.

4 (c) DEFINITIONS.—In this section—

5 (1) the term “pharmacy” includes a pharmacy
6 that receives prescriptions and dispenses prescription
7 drugs through an Internet website or by mail;

8 (2) the term “prescription drug” means a drug
9 subject to section 503(b)(1) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

11 (3) the term “prescription drug container label”
12 means the label with the directions for use that is
13 affixed to the prescription drug container by the
14 pharmacist and dispensed to the consumer.

15 **SEC. 905. RISK-BENEFIT FRAMEWORK.**

16 Section 505(d) (21 U.S.C. 355(d)) is amended by
17 adding at the end the following: “The Secretary shall im-
18 plement a structured risk-benefit assessment framework
19 in the new drug approval process to facilitate the balanced
20 consideration of benefits and risks, a consistent and sys-
21 tematic approach to the discussion and regulatory deci-
22 sionmaking, and the communication of the benefits and
23 risks of new drugs. Nothing in the preceding sentence
24 shall alter the criteria for evaluating an application for
25 premarket approval of a drug.”.

1 **SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION**
2 **INDUCEMENT MODEL.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services shall enter into an agreement with the
5 National Academies to provide expert consultation and
6 conduct a study that evaluates the feasibility and possible
7 consequences of the use of innovation inducement prizes
8 to reward successful medical innovations. Under the
9 agreement, the National Academies shall submit to the
10 Secretary a report on such study not later than 15 months
11 after the date of enactment of this Act.

12 (b) REQUIREMENTS.—

13 (1) IN GENERAL.—The study conducted under
14 subsection (a) shall model at least 3 separate seg-
15 ments on the medical technologies market as can-
16 didate targets for the new incentive system and con-
17 sider different medical innovation inducement prize
18 design issues, including the challenges presented in
19 the implementation of prizes for end products, open
20 source dividend prizes, and prizes for upstream re-
21 search.

22 (2) MARKET SEGMENTS.—The segments on the
23 medical technologies market that shall be considered
24 under paragraph (1) include—

25 (A) all pharmaceutical and biologic drugs
26 and vaccines;

1 (B) drugs and vaccines used solely for the
2 treatment of HIV/AIDS; and

3 (C) antibiotics.

4 (c) ELEMENTS.—The study conducted under sub-
5 section (a) shall include consideration of each of the fol-
6 lowing:

7 (1) Whether a system of large innovation in-
8 ducement prizes could work as a replacement for the
9 existing product monopoly/patent-based system, as
10 in effect on the date of enactment of this Act.

11 (2) How large the innovation prize funds would
12 have to be in order to induce at least as much re-
13 search and development investment in innovation as
14 is induced under the current system of time-limited
15 market exclusivity, as in effect on the date of enact-
16 ment of this Act.

17 (3) Whether a system of large innovation in-
18 ducement prizes would be more or less expensive
19 than the current system of time-limited market ex-
20 clusivity, as in effect on the date of enactment of
21 this Act, calculated over different time periods.

22 (4) Whether a system of large innovation in-
23 ducement prizes would expand access to new prod-
24 ucts and improve health outcomes.

1 (5) The type of information and decisionmaking
2 skills that would be necessary to manage end prod-
3 uct prizes.

4 (6) Whether there would there be major advan-
5 tages in rewarding the incremental impact of innova-
6 tions, as benchmarked against existing products.

7 (7) How open-source dividend prizes could be
8 managed, and whether such prizes would increase
9 access to knowledge, materials, data and tech-
10 nologies.

11 (8) Whether a system of competitive inter-
12 mediaries for interim research prizes would provide
13 an acceptable solution to the valuation challenges for
14 interim prizes.

15 **SEC. 907. ORPHAN PRODUCT GRANTS PROGRAM.**

16 (a) REAUTHORIZATION OF PROGRAM.—Section 5(c)
17 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended
18 by striking “2008 through 2012” and inserting “2013
19 through 2017”.

20 (b) HUMAN CLINICAL TESTING.—Section
21 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.
22 360ee(b)(1)(A)(ii)) is amended by striking “after the date
23 such drug is designated under section 526 of such Act
24 and”.

1 **SEC. 908. REPORTING OF INCLUSION OF DEMOGRAPHIC**
2 **SUBGROUPS IN CLINICAL TRIALS AND DATA**
3 **ANALYSIS IN APPLICATIONS FOR DRUGS, BIO-**
4 **LOGICS, AND DEVICES.**

5 (a) REPORT.—

6 (1) IN GENERAL.—Not later than 1 year after
7 the date of enactment of this Act, the Secretary, act-
8 ing through the Commissioner, shall publish on the
9 Internet website of the Food and Drug Administra-
10 tion a report, consistent with the regulations of the
11 Food and Drug Administration pertaining to the
12 protection of sponsors' confidential commercial infor-
13 mation as of the date of enactment of this Act, ad-
14 dressing the extent to which clinical trial participa-
15 tion and the inclusion of safety and effectiveness
16 data by demographic subgroups including sex, age,
17 race, and ethnicity, is included in applications sub-
18 mitted to the Food and Drug Administration, and
19 shall provide such publication to Congress.

20 (2) CONTENTS OF REPORT.—The report de-
21 scribed in paragraph (1) shall contain the following:

22 (A) A description of existing tools to en-
23 sure that data to support demographic analyses
24 are submitted in applications for drugs, biologi-
25 cal products, and devices, and that these anal-
26 yses are conducted by applicants consistent

1 with applicable Food and Drug Administration
2 requirements and Guidance for Industry. The
3 report shall address how the Food and Drug
4 Administration makes available information
5 about differences in safety and effectiveness of
6 medical products according to demographic sub-
7 groups, such as sex, age, racial, and ethnic sub-
8 groups, to healthcare providers, researchers,
9 and patients.

10 (B) An analysis of the extent to which de-
11 mographic data subset analyses on sex, age,
12 race, and ethnicity is presented in applications
13 for new drug applications for new molecular en-
14 tities under section 505 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 355), in
16 biologics license applications under section 351
17 of the Public Health Service Act (42 U.S.C.
18 262), and in premarket approval applications
19 under section 515 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 360e) for prod-
21 ucts approved or licensed by the Food and
22 Drug Administration, consistent with applicable
23 requirements and Guidance for Industry, and
24 consistent with the regulations of the Food and
25 Drug Administration pertaining to the protec-

1 tion of sponsors' confidential commercial infor-
2 mation as of the date of enactment of this Act.

3 (C) An analysis of the extent to which de-
4 mographic subgroups, including sex, age, racial,
5 and ethnic subgroups, are represented in clin-
6 ical studies to support applications for approved
7 or licensed new molecular entities, biological
8 products, and devices.

9 (D) An analysis of the extent to which a
10 summary of product safety and effectiveness
11 data by demographic subgroups including sex,
12 age, race, and ethnicity is readily available to
13 the public in a timely manner by means of the
14 product labeling or the Food and Drug Admin-
15 istration's Internet website.

16 (b) ACTION PLAN.—

17 (1) IN GENERAL.—Not later than 1 year after
18 the publication of the report described in subsection
19 (a), the Secretary, acting through the Commissioner,
20 shall publish an action plan on the Internet website
21 of the Food and Drug Administration, and provide
22 such publication to Congress.

23 (2) CONTENT OF ACTION PLAN.—The plan de-
24 scribed in paragraph (1) shall include—

1 (A) recommendations, as appropriate, to
2 improve the completeness and quality of anal-
3 yses of data on demographic subgroups in sum-
4 maries of product safety and effectiveness data
5 and in labeling;

6 (B) recommendations, as appropriate, on
7 the inclusion of such data, or the lack of avail-
8 ability of such data in labeling;

9 (C) recommendations, as appropriate, to
10 otherwise improve the public availability of such
11 data to patients, healthcare providers, and re-
12 searchers; and

13 (D) a determination with respect to each
14 recommendation identified in subparagraphs
15 (A) through (C) that distinguishes between
16 product types referenced in subsection
17 (a)(2)(B) insofar as the applicability of each
18 such recommendation to each type of product.

19 (c) DEFINITIONS.—In this section:

20 (1) The term “Commissioner” means the Com-
21 missioner of Food and Drugs.

22 (2) The term “device” has the meaning given
23 such term in section 201(h) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 321(h)).

1 (3) The term “drug” has the meaning given
2 such term in section 201(g) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 321(g)).

4 (4) The term “biological product” has the
5 meaning given such term in section 351(i) of the
6 Public Health Service Act (42 U.S.C. 262(i)).

7 (5) The term “Secretary” means the Secretary
8 of Health and Human Services.

9 **TITLE X—DRUG SHORTAGES**

10 **SEC. 1001. DRUG SHORTAGES.**

11 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)
12 is amended to read as follows:

13 **“SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE** 14 **PRODUCTION OF LIFE-SAVING DRUGS.**

15 “(a) IN GENERAL.—A manufacturer of a drug—

16 “(1) that is—

17 “(A) life-supporting;

18 “(B) life-sustaining;

19 “(C) intended for use in the prevention of
20 a debilitating disease or condition;

21 “(D) a sterile injectable product; or

22 “(E) used in emergency medical care or
23 during surgery; and

24 “(2) that is not a radio pharmaceutical drug
25 product, a human tissue replaced by a recombinant

1 product, a product derived from human plasma pro-
2 tein, or any other product as designated by the Sec-
3 retary,

4 shall notify the Secretary, in accordance with subsection
5 (b), of a permanent discontinuance in the manufacture of
6 the drug or an interruption of the manufacture of the drug
7 that could lead to a meaningful disruption in the supply
8 of that drug in the United States.

9 “(b) TIMING.—A notice required under subsection (a)
10 shall be submitted to the Secretary—

11 “(1) at least 6 months prior to the date of the
12 discontinuance or interruption; or

13 “(2) if compliance with paragraph (1) is not
14 possible, as soon as practicable.

15 “(c) EXPEDITED INSPECTIONS AND REVIEWS.—If,
16 based on notifications described in subsection (a) or any
17 other relevant information, the Secretary concludes that
18 there is, or is likely to be, a drug shortage of a drug de-
19 scribed in subsection (a), the Secretary may—

20 “(1) expedite the review of a supplement to a
21 new drug application submitted under section
22 505(b), an abbreviated new drug application sub-
23 mitted under section 505(j), or a supplement to such
24 an application submitted under section 505(j) that
25 could help mitigate or prevent such shortage; or

1 “(2) expedite an inspection or reinspection of
2 an establishment that could help mitigate or prevent
3 such drug shortage.

4 “(d) COORDINATION.—

5 “(1) TASK FORCE AND STRATEGIC PLAN.—

6 “(A) IN GENERAL.—

7 “(i) TASK FORCE.—As soon as prac-
8 ticable after the date of enactment of the
9 Food and Drug Administration Safety and
10 Innovation Act, the Secretary shall estab-
11 lish a Task Force to develop and imple-
12 ment a strategic plan for enhancing the
13 Secretary’s response to preventing and
14 mitigating drug shortages.

15 “(ii) STRATEGIC PLAN.—The strategic
16 plan described in clause (i) shall include—

17 “(I) plans for enhanced inter-
18 agency and intraagency coordination,
19 communication, and decisionmaking;

20 “(II) plans for ensuring that
21 drug shortages are considered when
22 the Secretary initiates a regulatory
23 action that could precipitate a drug
24 shortage or exacerbate an existing
25 drug shortage;

1 “(III) plans for effective commu-
2 nication with outside stakeholders, in-
3 cluding who the Secretary should alert
4 about potential or actual drug short-
5 ages, how the communication should
6 occur, and what types of information
7 should be shared; and

8 “(IV) plans for considering the
9 impact of drug shortages on research
10 and clinical trials.

11 “(iii) CONSULTATION.—In carrying
12 out this subparagraph, the Task Force
13 shall ensure consultation with the appro-
14 priate offices within the Food and Drug
15 Administration, including the Office of the
16 Commissioner, the Center for Drug Eval-
17 uation and Research, the Office of Regu-
18 latory Affairs, and employees within the
19 Department of Health and Human Serv-
20 ices with expertise regarding drug short-
21 ages. The Secretary shall engage external
22 stakeholders and experts as appropriate.

23 “(B) TIMING.—Not later than 1 year after
24 the date of enactment Food and Drug Adminis-

1 tration Safety and Innovation Act, the Task
2 Force shall—

3 “(i) publish the strategic plan de-
4 scribed in subparagraph (A); and

5 “(ii) submit such plan to Congress.

6 “(2) COMMUNICATION.—The Secretary shall
7 ensure that, prior to any enforcement action or
8 issuance of a warning letter that the Secretary de-
9 termines could reasonably be anticipated to lead to
10 a meaningful disruption in the supply in the United
11 States of a drug described under subsection (a),
12 there is communication with the appropriate office
13 of the Food and Drug Administration with expertise
14 regarding drug shortages regarding whether the ac-
15 tion or letter could cause, or exacerbate, a shortage
16 of the drug.

17 “(3) ACTION.—If the Secretary determines,
18 after the communication described in paragraph (2),
19 that an enforcement action or a warning letter could
20 reasonably cause or exacerbate a shortage of a drug
21 described under subsection (a), then the Secretary
22 shall evaluate the risks associated with the impact of
23 such shortage upon patients and those risks associ-
24 ated with the violation involved before taking such
25 action or issuing such letter, unless there is immi-

1 nent risk of serious adverse health consequences or
2 death to humans.

3 “(4) REPORTING BY OTHER ENTITIES.—The
4 Secretary shall identify or establish a mechanism by
5 which healthcare providers and other third-party or-
6 ganizations may report to the Secretary evidence of
7 a drug shortage.

8 “(5) REVIEW AND CONSTRUCTION.—No deter-
9 mination, finding, action, or omission of the Sec-
10 retary under this subsection shall—

11 “(A) be subject to judicial review; or

12 “(B) be construed to establish a defense to
13 an enforcement action by the Secretary.

14 “(e) RECORDKEEPING AND REPORTING.—

15 “(1) RECORDKEEPING.—The Secretary shall
16 maintain records related to drug shortages, includ-
17 ing with respect to each of the following:

18 “(A) The number of manufacturers that
19 submitted a notification to the Secretary under
20 subsection (a) in each calendar year.

21 “(B) The number of drug shortages that
22 occurred in each calendar year and a list of
23 drug names, drug types, and classes that were
24 the subject of such shortages.

1 “(C) A list of the known factors contrib-
2 uting to the drug shortages described in sub-
3 paragraph (B).

4 “(D)(i) A list of major actions taken by
5 the Secretary to prevent or mitigate the drug
6 shortages described in subparagraph (B).

7 “(ii) The Secretary shall include in the list
8 under clause (i) the following:

9 “(I) The number of applications for
10 which the Secretary expedited review under
11 subsection (c)(1) in each calendar year.

12 “(II) The number of establishment in-
13 spections or reinspections that the Sec-
14 retary expedited under subsection (c)(2) in
15 each calendar year.

16 “(E) The number of notifications sub-
17 mitted to the Secretary under subsection (a) in
18 each calendar year.

19 “(F) The names of manufacturers that the
20 Secretary has learned did not comply with the
21 notification requirement under subsection (a) in
22 each calendar year.

23 “(G) The number of times in each cal-
24 endar year that the Secretary determined under
25 subsection (d)(3) that an enforcement action or

1 a warning letter could reasonably cause or exac-
2 erbate a shortage of a drug described under
3 subsection (a), but did not evaluate the risks
4 associated with the impact of such shortage
5 upon patients and those risks associated with
6 the violation involved before taking such action
7 or issuing such letter on the grounds that there
8 was imminent risk of serious adverse health
9 consequences or death to humans, and a sum-
10 mary of the determinations.

11 “(H) A summary of the communications
12 made and actions taken under subsection (d) in
13 each calendar year.

14 “(I) Any other information the Secretary
15 deems appropriate to better prevent and miti-
16 gate drug shortages.

17 “(2) TREND ANALYSIS.—The Secretary is au-
18 thorized to retain a third party to conduct a study,
19 if the Secretary believes such a study would help
20 clarify the causes, trends, or solutions related to
21 drug shortages.

22 “(3) ANNUAL SUMMARY.—Not later than 18
23 months after the date of enactment of the Food and
24 Drug Administration Safety and Innovation Act, and
25 annually thereafter, the Secretary shall submit to

1 the Committee on Health, Education, Labor, and
2 Pensions of the Senate and the Committee on En-
3 ergy and Commerce of the House of Representatives
4 a report summarizing, with respect to the 1-year pe-
5 riod preceding such report, the information de-
6 scribed in paragraph (1). Such report shall not in-
7 clude any information that is exempt from disclosure
8 under subsection (a) of section 552 of title 5, United
9 States Code, by reason of subsection (b)(4) of such
10 section.

11 “(f) DEFINITIONS.—For purposes of this section—

12 “(1) the term ‘drug’—

13 “(A) means a drug (as defined in section
14 201(g)) that is intended for human use; and

15 “(B) does not include biological products
16 (as defined in section 351 of the Public Health
17 Service Act), unless otherwise provided by the
18 Secretary in the regulations promulgated under
19 subsection (h);

20 “(2) the term ‘drug shortage’ or ‘shortage’,
21 with respect to a drug, means a period of time when
22 the demand or projected demand for the drug within
23 the United States exceeds the supply of the drug;
24 and

25 “(3) the term ‘meaningful disruption’—

1 “(A) means a change in production that is
2 reasonably likely to lead to a reduction in the
3 supply of a drug by a manufacturer that is
4 more than negligible and impacts the ability of
5 the manufacturer to fill orders or meet expected
6 demand for its product; and

7 “(B) does not include interruptions in
8 manufacturing due to matters such as routine
9 maintenance or insignificant changes in manu-
10 facturing so long as the manufacturer expects
11 to resume operations in a short period of time.

12 “(g) DISTRIBUTION.—To the maximum extent prac-
13 ticable, the Secretary may distribute information on drug
14 shortages and on the permanent discontinuation of the
15 drugs described in this section to appropriate provider and
16 patient organizations, except that any such distribution
17 shall not include any information that is exempt from dis-
18 closure under section 552 of title 5, United States Code,
19 by reason of subsection (b)(4) of such section.

20 “(h) REGULATIONS.—

21 “(1) IN GENERAL.—Not later than 18 months
22 after the date of enactment of the Food and Drug
23 Administration Safety and Innovation Act, the Sec-
24 retary shall adopt a final regulation implementing
25 this section.

1 “(2) INCLUSION OF BIOLOGICAL PRODUCTS.—

2 “(A) IN GENERAL.—The Secretary may by
3 regulation apply this section to biological prod-
4 ucts (as defined in section 351 of the Public
5 Health Service Act) if the Secretary determines
6 such inclusion would benefit the public health.

7 “(B) RULE FOR VACCINES.—If the Sec-
8 retary applies this section to vaccines pursuant
9 to subparagraph (A), the Secretary shall—

10 “(i) consider whether the notification
11 requirement under subsection (a) may be
12 satisfied by submitting a notification to the
13 Centers for Disease Control and Preven-
14 tion under the vaccine shortage notification
15 program of such Centers; and

16 “(ii) explain the determination made
17 by the Secretary under clause (i) in the
18 regulation.

19 “(3) PROCEDURE.—In promulgating a regula-
20 tion implementing this section, the Secretary shall—

21 “(A) issue a notice of proposed rulemaking
22 that includes the proposed regulation;

23 “(B) provide a period of not less than 60
24 days for comments on the proposed regulation;
25 and

1 “(C) publish the final regulation not less
2 than 30 days before the regulation’s effective
3 date.

4 “(4) RESTRICTIONS.—Notwithstanding any
5 other provision of Federal law, in implementing this
6 section, the Secretary shall only promulgate regula-
7 tions as described in paragraph (3).”.

8 (b) EFFECT OF NOTIFICATION.—The submission of
9 a notification to the Secretary of Health and Human Serv-
10 ices (referred to in this section as the “Secretary”) for
11 purposes of complying with the requirement in section
12 506C(a) of the Federal Food, Drug, and Cosmetic Act (as
13 amended by subsection (a)) shall not be construed—

14 (1) as an admission that any product that is
15 the subject of such notification violates any provision
16 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 301 et seq.); or

18 (2) as evidence of an intention to promote or
19 market the product for an indication or use for
20 which the product has not been approved by the Sec-
21 retary.

22 (c) INTERNAL REVIEW.—Not later than 2 years after
23 the date of enactment of this Act, the Secretary shall—

24 (1) analyze and review the regulations promul-
25 gated under the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 301 et seq.), the guidances or poli-
2 cies issued under such Act related to drugs intended
3 for human use, and the practices of the Food and
4 Drug Administration regarding enforcing such Act
5 related to manufacturing of such drugs, to identify
6 any such regulations, guidances, policies, or prac-
7 tices that cause, exacerbate, prevent, or mitigate
8 drug shortages (as defined in section 506C of the
9 Federal Food, Drug, and Cosmetic Act (as amended
10 by subsection (a))); and

11 (2) determine how regulations, guidances, poli-
12 cies, or practices identified under paragraph (1)
13 should be modified, streamlined, expanded, or dis-
14 continued in order to reduce or prevent such drug
15 shortages, taking into consideration the effect of any
16 changes on the public health.

17 (d) STUDY ON MARKET FACTORS CONTRIBUTING TO
18 DRUG SHORTAGES AND STOCKPILING.—

19 (1) IN GENERAL.—Not later than 1 year after
20 the date of enactment of this Act, the Comptroller
21 General of the United States, in consultation with
22 the Secretary, the Department of Health and
23 Human Services Office of the Inspector General, the
24 Attorney General, and Chairman of the Federal
25 Trade Commission, shall publish a report reviewing

1 any findings that drug shortages (as so defined)
2 have led market participants to stockpile affected
3 drugs or sell them at significantly increased prices,
4 the impact of such activities on Federal revenue, and
5 any economic factors that have exacerbated or cre-
6 ated a market for such actions.

7 (2) CONTENT.—The report under paragraph
8 (1) shall include—

9 (A) an analysis of the incidence of any of
10 the activities described in paragraph (1) and
11 the effect of such activities on the public health;

12 (B) an evaluation of whether in such cases
13 there is a correlation between drugs in shortage
14 and—

15 (i) the number of manufacturers pro-
16 ducing such drugs;

17 (ii) the pricing structure, including
18 Federal reimbursements, for such drugs
19 before such drugs were in shortage, and to
20 the extent possible, revenue received by
21 each such manufacturer of such drugs;

22 (iii) pricing structure and revenue, to
23 the extent possible, for the same drugs
24 when sold under the conditions described
25 in paragraph (1); and

1 (iv) the impact of contracting prac-
2 tices by market participants (including
3 manufacturers, distributors, group pur-
4 chasing organizations, and providers) on
5 competition, access to drugs, and pricing
6 of drugs;

7 (C) whether the activities described in
8 paragraph (1) are consistent with applicable
9 law; and

10 (D) recommendations to Congress on what,
11 if any, additional reporting or enforcement ac-
12 tions are necessary.

13 (3) TRADE SECRET AND CONFIDENTIAL INFOR-
14 MATION.—Nothing in this subsection alters or
15 amends section 1905 of title 18, United States Code,
16 or section 552(b)(4) of title 5, United States Code.

17 (e) GUIDANCE REGARDING REPACKAGING.—Not
18 later than 1 year after the date of enactment of this Act,
19 the Secretary shall issue guidance that clarifies the policy
20 of the Food and Drug Administration regarding hospital
21 pharmacies repackaging and safely transferring repack-
22 aged drugs among hospitals within a common health sys-
23 tem during a drug shortage, as identified by the Secretary.

1 **TITLE XI—OTHER PROVISIONS**

2 **Subtitle A—Reauthorizations**

3 **SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO**
 4 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
 5 **TAINING SINGLE ENANTIOMERS.**

6 (a) IN GENERAL.—Section 505(u)(4) (21 U.S.C.
 7 355(u)(4)) is amended by striking “2012” and inserting
 8 “2017”.

9 (b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21
 10 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting
 11 “clinical” after “any”.

12 **SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH**
 13 **PUBLIC-PRIVATE PARTNERSHIPS.**

14 Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended
 15 by striking “2012” and inserting “2017”.

16 **Subtitle B—Medical Gas Product**
 17 **Regulation**

18 **SEC. 1111. REGULATION OF MEDICAL GAS PRODUCTS.**

19 (a) REGULATION.—Chapter V (21 U.S.C. 351 et
 20 seq.) is amended by adding at the end the following:

21 **“Subchapter G—Medical Gas Products**

22 **“SEC. 575. DEFINITIONS.**

23 “In this subchapter:

24 “(1) The term ‘designated medical gas product’
 25 means any of the following:

1 “(A) Oxygen, that meets the standards set
2 forth in an official compendium.

3 “(B) Nitrogen, that meets the standards
4 set forth in an official compendium.

5 “(C) Nitrous oxide, that meets the stand-
6 ards set forth in an official compendium.

7 “(D) Carbon dioxide, that meets the stand-
8 ards set forth in an official compendium.

9 “(E) Helium, that meets the standards set
10 forth in an official compendium.

11 “(F) Carbon monoxide, that meets the
12 standards set forth in an official compendium.

13 “(G) Medical air, that meets the standards
14 set forth in an official compendium.

15 “(H) Any other medical gas product
16 deemed appropriate by the Secretary, unless
17 any period of exclusivity under section
18 505(c)(3)(E)(ii) or 505(j)(5)(F)(ii), or the ex-
19 tension of any such period under section 505A,
20 applicable to such medical gas product has not
21 expired.

22 “(2) The term ‘medical gas product’ means a
23 drug that—

24 “(A) is manufactured or stored in a lique-
25 fied, nonliquefied, or cryogenic state; and

1 “(B) is administered as a gas.

2 **“SEC. 576. REGULATION OF MEDICAL GAS PRODUCTS.**

3 “(a) CERTIFICATION OF DESIGNATED MEDICAL GAS
4 PRODUCTS.—

5 “(1) SUBMISSION.—

6 “(A) IN GENERAL.—Beginning on the date
7 of enactment of this section, any person may
8 file with the Secretary a request for a certifi-
9 cation of a designated medical gas product.

10 “(B) CONTENT.—A request under sub-
11 paragraph (A) shall contain—

12 “(i) a description of the medical gas
13 product;

14 “(ii) the name and address of the
15 sponsor;

16 “(iii) the name and address of the fa-
17 cility or facilities where the gas product is
18 or will be manufactured; and

19 “(iv) any other information deemed
20 appropriate by the Secretary to determine
21 whether the medical gas product is a des-
22 ignated medical gas product.

23 “(2) GRANT OF CERTIFICATION.—A certifi-
24 cation described under paragraph (1)(A) shall be de-
25 termined to have been granted unless, not later than

1 60 days after the filing of a request under para-
2 graph (1), the Secretary finds that—

3 “(A) the medical gas product subject to
4 the certification is not a designated medical gas
5 product;

6 “(B) the request does not contain the in-
7 formation required under paragraph (1) or oth-
8 erwise lacks sufficient information to permit the
9 Secretary to determine that the gas product is
10 a designated medical gas product; or

11 “(C) granting the request would be con-
12 trary to public health.

13 “(3) EFFECT OF CERTIFICATION.—

14 “(A) IN GENERAL.—

15 “(i) APPROVED USES.—A designated
16 medical gas product for which a certifi-
17 cation is granted under paragraph (2) is
18 deemed, alone or in combination with an-
19 other designated gas product or products
20 as medically appropriate, to have in effect
21 an approved application under section 505
22 or 512, subject to all applicable post-
23 approval requirements, for the following in-
24 dications for use:

1 “(I) Oxygen for the treatment or
2 prevention of hypoxemia or hypoxia.

3 “(II) Nitrogen for use in hypoxic
4 challenge testing.

5 “(III) Nitrous oxide for analge-
6 sia.

7 “(IV) Carbon dioxide for use in
8 extracorporeal membrane oxygenation
9 therapy or respiratory stimulation.

10 “(V) Helium for the treatment of
11 upper airway obstruction or increased
12 airway resistance.

13 “(VI) Medical air to reduce the
14 risk of hyperoxia.

15 “(VII) Carbon monoxide for use
16 in lung diffusion testing.

17 “(VIII) Any other indication for
18 use for a designated medical gas prod-
19 uct or combination of designated med-
20 ical gas products deemed appropriate
21 by the Secretary, unless any period of
22 exclusivity under clause (iii) or (iv) of
23 section 505(c)(3)(E), under clause
24 (iii) or (iv) of section 505(j)(5)(F), or
25 under section 527, or the extension of

1 any such period under section 505A,
2 applicable to such indication for use
3 for such gas product or combination
4 of products has not expired.

5 “(ii) LABELING.—The requirements
6 established in sections 503(b)(4) and
7 502(f) shall be deemed to have been met
8 for a designated medical gas product if the
9 labeling on final use containers of such gas
10 product bears the information required by
11 section 503(b)(4) and a warning statement
12 concerning the use of the gas product, as
13 determined by the Secretary by regulation,
14 as well as appropriate directions and warn-
15 ings concerning storage and handling.

16 “(B) INAPPLICABILITY OF EXCLUSIVITY
17 PROVISIONS.—

18 “(i) EFFECT ON INELIGIBILITY.—No
19 designated medical gas product deemed
20 under paragraph (3)(A)(i) to have in effect
21 an approved application shall be eligible for
22 any periods of exclusivity under sections
23 505(c), 505(j), or 527, or the extension of
24 any such period under section 505A, on
25 the basis of such deemed approval.

1 “(ii) EFFECT ON CERTIFICATION.—
2 No period of exclusivity under sections
3 505(c), 505(j), or section 527, or the ex-
4 tension of any such period under section
5 505A, with respect to an application for a
6 drug shall prohibit, limit, or otherwise af-
7 fect the submission, grant, or effect of a
8 certification under this section, except as
9 provided in paragraph (3)(A)(i)(VIII).

10 “(4) WITHDRAWAL, SUSPENSION, OR REVOCA-
11 TION OF APPROVAL.—

12 “(A) IN GENERAL.—Nothing in this sub-
13 chapter limits the authority of the Secretary to
14 withdraw or suspend approval of a drug, includ-
15 ing a designated medical gas product deemed
16 under this section to have in effect an approved
17 application, under section 505 or section 512.

18 “(B) REVOCATION.—The Secretary may
19 revoke the grant of a certification under this
20 section if the Secretary determines that the re-
21 quest for certification contains any material
22 omission or falsification.

23 “(b) PRESCRIPTION REQUIREMENT.—

24 “(1) IN GENERAL.—A designated medical gas
25 product shall be subject to section 503(b)(1) unless

1 the Secretary exercises the authority provided in sec-
2 tion 503(b)(3) to remove such gas product from the
3 requirements of section 503(b)(1) or the use in ques-
4 tion is authorized pursuant to another provision of
5 this Act relating to use of medical products in emer-
6 gencies.

7 “(2) EXCEPTION FOR OXYGEN.—

8 “(A) IN GENERAL.—Notwithstanding para-
9 graph (1), oxygen may be provided without a
10 prescription for the following uses:

11 “(i) The use in the event of depres-
12 surization or other environmental oxygen
13 deficiency.

14 “(ii) The use in the event of oxygen
15 deficiency or use in emergency resuscita-
16 tion, when administered by properly
17 trained personnel.

18 “(B) LABELING.—For oxygen provided
19 pursuant to subparagraph (A), the require-
20 ments established in section 503(b)(4) shall be
21 deemed to have been met if the labeling of the
22 oxygen bears a warning that the medical gas
23 product can be used for emergency use only and
24 for all other medical applications a prescription
25 is required.

1 “(c) INAPPLICABILITY OF DRUGS FEES TO DES-
2 IGNATED MEDICAL GAS PRODUCTS.—A designated med-
3 ical gas product deemed under this section to have in ef-
4 fect an approved application shall not be assessed fees
5 under section 736(a) on the basis of such deemed ap-
6 proval.”.

7 **SEC. 1112. REGULATIONS.**

8 (a) REVIEW OF REGULATIONS.—Not later than 18
9 months after the date of enactment of this Act, the Sec-
10 retary of Health and Human Services (referred to in this
11 section as the “Secretary”) shall, after obtaining input
12 from medical gas product manufacturers, and any other
13 interested members of the public, submit a report to the
14 Committee on Health, Education, Labor, and Pensions of
15 the Senate and the Committee on Energy and Commerce
16 of the House of Representatives regarding any changes to
17 the Federal drug regulations in title 21, Code of Federal
18 Regulations that the Secretary determines to be necessary.

19 (b) AMENDED REGULATIONS.—If the Secretary de-
20 termines that changes to the Federal drug regulations in
21 title 21, Code of Federal Regulations are necessary under
22 subsection (a), the Secretary shall issue final regulations
23 implementing such changes not later than 4 years after
24 the date of enactment of this Act.

1 **SEC. 1113. APPLICABILITY.**

2 Nothing in this subtitle or the amendments made by
3 this subtitle shall apply to—

4 (1) a drug that is covered by an application
5 under section 505 or 512 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355, 360b) ap-
7 proved prior to May 1, 2012; or

8 (2) any of the gases listed in subparagraphs (A)
9 through (G) of section 575(1) of such Act (as added
10 by section 1111), or any mixture of any such gases,
11 for an indication that—

12 (A) is not included in, or is different from,
13 those specified in subclauses (I) through (VII)
14 of section 576(a)(3)(i) of such Act (as added by
15 section 1111); and

16 (B) is approved on or after May 1, 2012,
17 pursuant to an application submitted under sec-
18 tion 505 or 512 of such Act.

19 **Subtitle C—Miscellaneous**
20 **Provisions**

21 **SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTER-**
22 **EST.**

23 Section 712 (21 U.S.C. 379d–1) is amended—

24 (1) in subsection (b)—

25 (A) by striking paragraph (2); and

26 (B) in paragraph (1)—

1 (i) by redesignating subparagraph (B)
2 as paragraph (2) and moving such para-
3 graph, as so redesignated, 2 ems to the
4 left;

5 (ii) in subparagraph (A), by redesi-
6 gnating clauses (i) through (iii) as subpara-
7 graphs (A) through (C), respectively, and
8 moving such subparagraphs, as so redesi-
9 gnated, 2 ems to the left;

10 (iii) in subparagraph (A), as so redesi-
11 gnated, by inserting “, including strategies
12 to increase the number of special Govern-
13 ment employees across medical and sci-
14 entific specialties in areas where the Sec-
15 retary would benefit from specific sci-
16 entific, medical, or technical expertise nec-
17 essary for the performance of its regu-
18 latory responsibilities” before the semicolon
19 at the end;

20 (iv) by striking “(1) RECRUITMENT.—
21 ” and inserting “(1) RECRUITMENT IN
22 GENERAL.—The Secretary shall—”;

23 (v) by striking “(A) IN GENERAL.—
24 The Secretary shall—”;

1 (vi) by redesignating clauses (i)
2 through (iii) of paragraph (2) (as so redesi-
3 gnated) as subparagraphs (A) through
4 (C), respectively, and moving such sub-
5 paragraphs, as so redesignated, 2 ems to
6 the left;

7 (vii) in paragraph (2) (as so redesi-
8 gnated), in the matter before subparagraph
9 (A) (as so redesignated), by striking “sub-
10 paragraph (A)” and inserting “paragraph
11 (1)”; and

12 (viii) by adding at the end the fol-
13 lowing:

14 “(3) RECRUITMENT THROUGH REFERRALS.—In
15 carrying out paragraph (1), the Secretary shall, in
16 order to further the goal of including in advisory
17 committees highly qualified and specialized experts
18 in the specific diseases to be considered by such ad-
19 visory committees, at least every 180 days, request
20 referrals from a variety of stakeholders, such as the
21 Institute of Medicine, the National Institutes of
22 Health, product developers, patient groups, disease
23 advocacy organizations, professional societies, med-
24 ical societies, including the American Academy of

1 Medical Colleges, and other governmental organiza-
2 tions.”;

3 (2) by amending subsection (c)(2)(C) to read as
4 follows:

5 “(C) CONSIDERATION BY SECRETARY.—

6 The Secretary shall ensure that each determina-
7 tion made under subparagraph (B) considers
8 the type, nature, and magnitude of the financial
9 interests at issue and the public health interest
10 in having the expertise of the member with re-
11 spect to the particular matter before the advi-
12 sory committee.”;

13 (3) in subsection (e), by inserting “, and shall
14 make publicly available,” after “House of Represent-
15 atives”; and

16 (4) by adding at the end the following:

17 “(g) GUIDANCE ON REPORTED FINANCIAL INTEREST
18 OR INVOLVEMENT.—The Secretary shall issue guidance
19 that describes how the Secretary reviews the financial in-
20 terests and involvement of advisory committee members
21 that are reported under subsection (c)(1) but that the Sec-
22 retary determines not to meet the definition of a disquali-
23 fying interest under section 208 of title 18, United States
24 Code for the purposes of participating in a particular mat-
25 ter.”.

1 **SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT**
2 **PROMOTION USING THE INTERNET.**

3 Not later than 2 years after the date of enactment
4 this Act, the Secretary of Health and Human Services
5 shall issue guidance that describes Food and Drug Admin-
6 istration policy regarding the promotion, using the Inter-
7 net (including social media), of medical products that are
8 regulated by such Administration.

9 **SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.**

10 Subchapter D of chapter VII (21 U.S.C. 379k et
11 seq.) is amended by inserting after section 745 the fol-
12 lowing:

13 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

14 “(a) DRUGS AND BIOLOGICS.—

15 “(1) IN GENERAL.—Beginning no earlier than
16 24 months after the issuance of a final guidance
17 issued after public notice and opportunity for com-
18 ment, submissions under subsection (b), (i), or (j) of
19 section 505 of this Act or subsection (a) or (k) of
20 section 351 of the Public Health Service Act shall
21 be submitted in such electronic format as specified
22 by the Secretary in such guidance.

23 “(2) GUIDANCE CONTENTS.—In the guidance
24 under paragraph (1), the Secretary may—

25 “(A) provide a timetable for establishment
26 by the Secretary of further standards for elec-

1 tronic submission as required by such para-
2 graph; and

3 “(B) set forth criteria for waivers of and
4 exemptions from the requirements of this sub-
5 section.

6 “(3) EXCEPTION.—This subsection shall not
7 apply to submissions described in section 561.

8 “(b) DEVICES.—

9 “(1) IN GENERAL.—Beginning after the
10 issuance of final guidance implementing this para-
11 graph, pre-submissions and submissions for devices
12 under section 510(k), 513(f)(2)(A), 515(c), 515(d),
13 515(f), 520(g), 520(m), or 564 of this Act or section
14 351 of the Public Health Service Act, and any sup-
15 plements to such pre-submissions or submissions,
16 shall include an electronic copy of such pre-submis-
17 sions or submissions.

18 “(2) GUIDANCE CONTENTS.—In the guidance
19 under paragraph (1), the Secretary may—

20 “(A) provide standards for the electronic
21 copy required under such paragraph; and

22 “(B) set forth criteria for waivers of and
23 exemptions from the requirements of this sub-
24 section.”.

1 **SEC. 1124. COMBATING PRESCRIPTION DRUG ABUSE.**

2 (a) IN GENERAL.—To combat the significant rise in
3 prescription drug abuse and the consequences of such
4 abuse, the Secretary of Health and Human Services (re-
5 ferred to in this section as the “Secretary”), acting
6 through the Commissioner of Food and Drugs (referred
7 to in this section as the “Commissioner”) and in coordina-
8 tion with other Federal agencies, as appropriate, shall re-
9 view current Federal initiatives and identify gaps and op-
10 portunities with respect to ensuring the safe use and dis-
11 posal of prescription drugs with the potential for abuse.

12 (b) REPORT.—Not later than 1 year after the date
13 of enactment of this Act, the Secretary shall post a report
14 on the Internet website of the Food and Drug Administra-
15 tion on the findings of the review under subsection (a).
16 Such report shall include findings and recommendations
17 on—

18 (1) how best to leverage and build upon existing
19 Federal and federally funded data sources, such as
20 prescription drug monitoring program data and the
21 sentinel initiative of the Food and Drug Administra-
22 tion under section 505(k)(3) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as
24 it relates to collection of information relevant to ad-
25 verse events, patient safety, and patient outcomes, to

1 create a centralized data clearinghouse and early
2 warning tool;

3 (2) how best to develop and disseminate widely
4 best practices models and suggested standard re-
5 quirements to States for achieving greater interoper-
6 ability and effectiveness of prescription drug moni-
7 toring programs, especially with respect to provider
8 participation, producing standardized data on ad-
9 verse events, patient safety, and patient outcomes;
10 and

11 (3) how best to develop provider, pharmacist,
12 and patient education tools and a strategy to widely
13 disseminate such tools and assess the efficacy of
14 such tools.

15 (c) GUIDANCE ON ABUSE-DETERRENT PRODUCTS.—
16 Not later than 6 months after the date of enactment of
17 this Act, the Secretary, acting through the Commissioner,
18 shall promulgate guidance on the development of abuse-
19 deterrent drug products.

20 (d) STUDY AND REPORT ON PRESCRIPTION DRUG
21 ABUSE.—Not later than 1 year after the date of enact-
22 ment of this Act, the Secretary shall seek to enter into
23 an agreement with the Institute of Medicine to conduct
24 a study and report on prescription drug abuse. Such re-
25 port shall evaluate trends in prescription drug abuse, as-

1 sess opportunities to inform and educate the public, pa-
2 tients, and health care providers on issues related to pre-
3 scription drug abuse and misuse, and identify potential
4 barriers, if any, to prescription drug monitoring program
5 participation and implementation.

6 **SEC. 1125. TANNING BED LABELING.**

7 Not later than 18 months after the date of enactment
8 of this Act, the Secretary of Health and Human Services
9 shall determine whether to amend the warning label re-
10 quirements for sunlamp products to include specific re-
11 quirements to more clearly and effectively convey the risks
12 that such products pose for the development of irreversible
13 damage to the eyes and skin, including skin cancer.

14 **SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.**

15 Subchapter E of chapter V (21 U.S.C. 360bbb et
16 seq.), as amended by section 903, is further amended by
17 adding at the end the following:

18 **“SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.**

19 “(a) IN GENERAL.—The Secretary shall—

20 “(1) work with other regulatory authorities of
21 similar standing, medical research companies, and
22 international organizations to foster and encourage
23 uniform, scientifically-driven clinical trial standards
24 with respect to medical products around the world;
25 and

1 “(2) enhance the commitment to provide con-
2 sistent parallel scientific advice to manufacturers
3 seeking simultaneous global development of new
4 medical products in order to—

5 “(A) enhance medical product develop-
6 ment;

7 “(B) facilitate the use of foreign data; and

8 “(C) minimize the need to conduct duplica-
9 tive clinical studies, preclinical studies, or non-
10 clinical studies.

11 “(b) **MEDICAL PRODUCT.**—In this section, the term
12 ‘medical product’ means a drug, as defined in subsection
13 (g) of section 201, a device, as defined in subsection (h)
14 of such section, or a biological product, as defined in sec-
15 tion 351(i) of the Public Health Service Act.

16 “(c) **SAVINGS CLAUSE.**—Nothing in this section shall
17 alter the criteria for evaluating the safety or effectiveness
18 of a medical product under this Act.

19 **“SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM**
20 **OUTSIDE THE UNITED STATES.**

21 “(a) **IN GENERAL.**—In determining whether to ap-
22 prove, license, or clear a drug or device pursuant to an
23 application submitted under this chapter, the Secretary
24 shall accept data from clinical investigations conducted
25 outside of the United States, including the European

1 Union, if the applicant demonstrates that such data are
2 adequate under applicable standards to support approval,
3 licensure, or clearance of the drug or device in the United
4 States.

5 “(b) NOTICE TO SPONSOR.—If the Secretary finds
6 under subsection (a) that the data from clinical investiga-
7 tions conducted outside the United States, including in the
8 European Union, are inadequate for the purpose of mak-
9 ing a determination on approval, clearance, or licensure
10 of a drug or device pursuant to an application submitted
11 under this chapter, the Secretary shall provide written no-
12 tice to the sponsor of the application of such finding and
13 include the rationale for such finding.”.

14 **SEC. 1127. ADVANCING REGULATORY SCIENCE TO PRO-**
15 **MOTE PUBLIC HEALTH INNOVATION.**

16 (a) IN GENERAL.—Not later than 1 year after the
17 date of enactment of this Act, the Secretary of Health and
18 Human Services (referred to in this section as the “Sec-
19 retary”) shall develop a strategy and implementation plan
20 for advancing regulatory science for medical products in
21 order to promote the public health and advance innovation
22 in regulatory decisionmaking.

23 (b) REQUIREMENTS.—The strategy and implementa-
24 tion plan developed under subsection (a) shall be con-
25 sistent with the user fee performance goals in the Pre-

1 scription Drug User Fee Agreement commitment letter,
2 the Generic Drug User Fee Agreement commitment letter,
3 and the Biosimilar User Fee Agreement commitment let-
4 ter transmitted by the Secretary to Congress on January
5 13, 2012, and the Medical Device User Fee Agreement
6 commitment letter transmitted by the Secretary to Con-
7 gress on April 20, 2012, and shall—

8 (1) identify a clear vision of the fundamental
9 role of efficient, consistent, and predictable, science-
10 based decisions throughout regulatory decision-
11 making of the Food and Drug Administration with
12 respect to medical products;

13 (2) identify the regulatory science priorities of
14 the Food and Drug Administration directly related
15 to fulfilling the mission of the agency with respect
16 to decisionmaking concerning medical products and
17 allocation of resources towards such regulatory
18 science priorities;

19 (3) identify regulatory and scientific gaps that
20 impede the timely development and review of, and
21 regulatory certainty with respect to, the approval, li-
22 censure, or clearance of medical products, including
23 with respect to companion products and new tech-
24 nologies, and facilitating the timely introduction and

1 adoption of new technologies and methodologies in a
2 safe and effective manner;

3 (4) identify clear, measurable metrics by which
4 progress on the priorities identified under paragraph
5 (2) and gaps identified under paragraph (3) will be
6 measured by the Food and Drug Administration, in-
7 cluding metrics specific to the integration and adop-
8 tion of advances in regulatory science described in
9 paragraph (5) and improving medical product deci-
10 sionmaking, in a predictable and science-based man-
11 ner; and

12 (5) set forth how the Food and Drug Adminis-
13 tration will ensure that advances in regulatory
14 science for medical products are adopted, as appro-
15 priate, on an ongoing basis and in an manner inte-
16 grated across centers, divisions, and branches of the
17 Food and Drug Administration, including by senior
18 managers and reviewers, including through the—

19 (A) development, updating, and consistent
20 application of guidance documents that support
21 medical product decisionmaking; and

22 (B) the adoption of the tools, methods, and
23 processes under section 566 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.
25 360bbb-5).

1 (c) ANNUAL PERFORMANCE REPORTS.—As part of
2 the annual performance reports submitted to Congress
3 under sections 736B(a) (as amended by section 104),
4 738A(a) (as amended by section 204), 744C(a) (as added
5 by section 303), and 744I(a) (as added by section 403)
6 of the Federal Food, Drug, and Cosmetic Act for each
7 of fiscal years 2013 through 2017, the Secretary shall an-
8 nually report on the progress made with respect to—

9 (1) advancing the regulatory science priorities
10 identified under paragraph (2) of subsection (b) and
11 resolving the gaps identified under paragraph (3) of
12 such subsection, including reporting on specific
13 metrics identified under paragraph (4) of such sub-
14 section;

15 (2) the integration and adoption of advances in
16 regulatory science as set forth in paragraph (5) of
17 such subsection; and

18 (3) the progress made in advancing the regu-
19 latory science goals outlined in the Prescription
20 Drug User Fee Agreement commitment letter, the
21 Generic Drug User Fee Agreement commitment let-
22 ter, and the Biosimilar User Fee Agreement commit-
23 ment letter transmitted by the Secretary to Congress
24 on January 13, 2012, and the Medical Device User

1 Fee Agreement transmitted by the Secretary to Con-
2 gress on April 20, 2012.

3 (d) INDEPENDENT ASSESSMENT.—Not later than
4 January 1, 2016, the Comptroller General of the United
5 States shall submit to Congress a report—

6 (1) detailing the progress made by the Food
7 and Drug Administration in meeting the priorities
8 and addressing the gaps identified in subsection (b),
9 including any outstanding gaps; and

10 (2) containing recommendations, as appro-
11 priate, on how regulatory science initiatives for med-
12 ical products can be strengthened and improved to
13 promote the public health and advance innovation in
14 regulatory decisionmaking.

15 (e) MEDICAL PRODUCT.—In this section, the term
16 “medical product” means a drug, as defined in subsection
17 (g) of section 201 of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 321), a device, as defined in sub-
19 section (h) of such section, or a biological product, as de-
20 fined in section 351(i) of the Public Health Service Act.

21 **SEC. 1128. INFORMATION TECHNOLOGY.**

22 (a) HHS REPORT.—Not later than 1 year after the
23 date of enactment of this Act, the Secretary of Health and
24 Human Services shall—

25 (1) report to Congress on—

1 (A) the milestones and a completion date
2 for developing and implementing a comprehen-
3 sive information technology strategic plan to
4 align the information technology systems mod-
5 ernization projects with the strategic goals of
6 the Food and Drug Administration, including
7 results-oriented goals, strategies, milestones,
8 performance measures;

9 (B) efforts to finalize and approve a com-
10 prehensive inventory of the information tech-
11 nology systems of the Food and Drug Adminis-
12 tration that includes information describing
13 each system, such as costs, system function or
14 purpose, and status information, and incor-
15 porate use of the system portfolio into the in-
16 formation investment management process of
17 the Food and Drug Administration;

18 (C) the ways in which the Food and Drug
19 Administration uses the plan described in sub-
20 paragraph (A) to guide and coordinate the
21 modernization projects and activities of the
22 Food and Drug Administration, including the
23 interdependencies among projects and activities;
24 and

1 (D) the extent to which the Food and
2 Drug Administration has fulfilled or is imple-
3 menting recommendations of the Government
4 Accountability Office with respect to the Food
5 and Drug Administration and information tech-
6 nology; and

7 (2) develop—

8 (A) a documented enterprise architecture
9 program management plan that includes the
10 tasks, activities, and timeframes associated with
11 developing and using the architecture and ad-
12 dresses how the enterprise architecture program
13 management will be performed in coordination
14 with other management disciplines, such as or-
15 ganizational strategic planning, capital planning
16 and investment control, and performance man-
17 agement; and

18 (B) a skills inventory, needs assessment,
19 gap analysis, and initiatives to address skills
20 gaps as part of a strategic approach to informa-
21 tion technology human capital planning.

22 (b) GAO REPORT.—Not later than January 1, 2016,
23 the Comptroller General of the United States shall issue
24 a report regarding the strategic plan described in sub-
25 section (a)(1)(A) and related actions carried out by the

1 Food and Drug Administration. Such report shall assess
2 the progress the Food and Drug Administration has made
3 on—

4 (1) the development and implementation of a
5 comprehensive information technology strategic plan,
6 including the results-oriented goals, strategies, mile-
7 stones, and performance measures identified in sub-
8 section (a)(1)(A);

9 (2) the effectiveness of the comprehensive infor-
10 mation technology strategic plan described in sub-
11 section (a)(1)(A), including the results-oriented
12 goals and performance measures; and

13 (3) the extent to which the Food and Drug Ad-
14 ministration has fulfilled recommendations of the
15 Government Accountability Office with respect to
16 such agency and information technology.

17 **SEC. 1129. REPORTING REQUIREMENTS.**

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

21 **“SEC. 715. REPORTING REQUIREMENTS.**

22 “(a) NEW DRUGS.—Beginning with fiscal year 2013
23 and ending with fiscal year 2017, not later than 120 days
24 after the end of each fiscal year for which fees are col-
25 lected under part 2 of subchapter C, the Secretary shall

1 prepare and submit to the Committee on Health Edu-
2 cation, Labor, and Pensions of the Senate and the Com-
3 mittee on Energy and Commerce of the House of Rep-
4 resentatives a report concerning, for all applications for
5 approval of a new drug under section 505(b) of this Act
6 or a new biological product under section 351(a) of the
7 Public Health Service Act filed in the previous fiscal
8 year—

9 “(1) the number of such applications that met
10 the goals identified for purposes of part 2 of sub-
11 chapter C in the letters from the Secretary of
12 Health and Human Services to the Chairman of the
13 Committee on Health, Education, Labor, and Pen-
14 sions of the Senate and the Chairman of the Com-
15 mittee on Energy and Commerce of the House of
16 Representatives, as set forth in the Congressional
17 Record;

18 “(2) the percentage of such applications that
19 were approved;

20 “(3) the percentage of such applications that
21 were issued complete response letters;

22 “(4) the percentage of such applications that
23 were subject to a refuse-to-file action;

24 “(5) the percentage of such applications that
25 were withdrawn; and

1 “(6) the average total time to decision by the
2 Secretary for all applications for approval of a new
3 drug under section 505(b) of this Act or a new bio-
4 logical product under section 351(a) of the Public
5 Health Service Act filed in the previous fiscal year,
6 including the number of calendar days spent during
7 the review by the Food and Drug Administration
8 and the number of calendar days spent by the spon-
9 sor responding to a complete response letter.”.

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

22 “(1) the number of such applications that met
23 the goals identified for purposes of part 7 of sub-
24 chapter C, in the letters from the Secretary of
25 Health and Human Services to the Chairman of the

1 Committee on Health, Education, Labor, and Pen-
2 sions of the Senate and the Chairman of the Com-
3 mittee on Energy and Commerce of the House of
4 Representatives, as set forth in the Congressional
5 Record;

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

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

23 “(4) the number of applications described in
24 paragraph (3) on which the Food and Drug Admin-

1 istration took final regulatory action in the previous
2 fiscal year.

3 “(c) BIOSIMILAR BIOLOGICAL PRODUCTS.—

4 “(1) IN GENERAL.—Beginning with fiscal year
5 2014, not later than 120 days after the end of each
6 fiscal year for which fees are collected under part 8
7 of subchapter C, the Secretary shall prepare and
8 submit to the Committee on Health Education,
9 Labor, and Pensions of the Senate and the Com-
10 mittee on Energy and Commerce of the House of
11 Representatives a report concerning—

12 “(A) the number of applications for ap-
13 proval filed under section 351(k) of the Public
14 Health Service Act; and

15 “(B) the percentage of applications de-
16 scribed in subparagraph (A) that were approved
17 by the Secretary.

18 “(2) ADDITIONAL INFORMATION.—As part of
19 the performance report described in paragraph (1),
20 the Secretary shall include an explanation of how the
21 Food and Drug Administration is managing the bio-
22 logical product review program to ensure that the
23 user fees collected under part 2 are not used to re-
24 view an application under section 351(k) of the Pub-
25 lic Health Service Act.”.

1 **SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.**

2 (a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—

3 Not later than 1 year after the date of enactment of this
4 Act, the Secretary of Health and Human Services (re-
5 ferred to in this section as the “Secretary”) shall submit
6 to Congress a strategic integrated management plan for
7 the Center for Drug Evaluation and Research, the Center
8 for Biologics Evaluation and Research, and the Center for
9 Devices and Radiological Health. Such strategic manage-
10 ment plan shall—

11 (1) identify strategic institutional goals and pri-
12 orities for the Center for Drug Evaluation and Re-
13 search, the Center for Biologics Evaluation and Re-
14 search, and the Center for Devices and Radiological
15 Health;

16 (2) describe the actions the Secretary will take
17 to recruit, retain, train, and continue to develop the
18 workforce at the Center for Drug Evaluation and
19 Research, the Center for Biologics Evaluation and
20 Research, and the Center for Devices and Radio-
21 logical Health to fulfill the public health mission of
22 the Food and Drug Administration; and

23 (3) identify results-oriented, outcome-based
24 measures that the Secretary will use to measure the
25 progress of achieving the strategic goals and prior-
26 ities identified under paragraph (1) and the effec-

1 tiveness of the actions identified under paragraph
2 (2), including metrics to ensure that managers and
3 reviewers of the Center for Drug Evaluation and Re-
4 search, the Center for Biologics Evaluation and Re-
5 search, and the Center for Devices and Radiological
6 Health are familiar with and appropriately and con-
7 sistently apply the requirements under the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
9 seq.), including new requirements under parts 2, 3,
10 7, and 8 of subchapter C of title VII of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379f et
12 seq.).

13 (b) REPORT.—Not later than January 1, 2016, the
14 Comptroller General of the United States shall issue a re-
15 port regarding the strategic management plan described
16 in subsection (a) and related actions carried out by the
17 Food and Drug Administration. Such report shall—

18 (1) assess the effectiveness of the actions de-
19 scribed in subsection (a)(2) in recruiting, retaining,
20 training, and developing the workforce at the Center
21 for Drug Evaluation and Research, the Center for
22 Biologics Evaluation and Research, and the Center
23 for Devices and Radiological Health in fulfilling the
24 public health mission of the Food and Drug Admin-
25 istration;

1 (2) assess the effectiveness of the measures
2 identified under subsection (a)(3) in gauging
3 progress against the strategic goals and priorities
4 identified under subsection (a)(1);

5 (3) assess the extent to which the Center for
6 Drug Evaluation and Research, the Center for Bio-
7 logics Evaluation and Research, and the Center for
8 Devices and Radiological Health are using the iden-
9 tified results-oriented set of performance measures
10 in tracking their workload by strategic goals and the
11 effectiveness of such measures;

12 (4) assess the extent to which performance in-
13 formation is collected, analyzed, and acted on by
14 managers; and

15 (5) make recommendations, as appropriate, re-
16 garding how the strategic management plan and re-
17 lated actions of the Center for Drug Evaluation and
18 Research, the Center for Biologics Evaluation and
19 Research, and the Center for Devices and Radio-
20 logical Health could be improved to fulfill the public
21 health mission of the Food and Drug Administration
22 in as efficient and effective manner as possible.

23 **SEC. 1131. DRUG DEVELOPMENT AND TESTING.**

24 (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355–
25 1) is amended by adding at the end the following:

1 “(k) DRUG DEVELOPMENT AND TESTING.—

2 “(1) IN GENERAL.—Notwithstanding any other
3 provision of law, if a drug is a covered drug, no ele-
4 ments to ensure safe use shall prohibit, or be con-
5 strued or applied to prohibit, supply of such drug to
6 any eligible drug developer for the purpose of con-
7 ducting testing necessary to support an application
8 under subsection (b)(2) or (j) of section 505 of this
9 Act or section 351(k) of the Public Health Service
10 Act, if the Secretary has issued a written notice de-
11 scribed in paragraph (2), and the eligible drug devel-
12 oper has agreed to comply with the terms of the no-
13 tice.

14 “(2) WRITTEN NOTICE.—For purposes of this
15 subsection, the Secretary shall, within a reasonable
16 period of time, consider and respond to a request by
17 an eligible drug developer for a written notice au-
18 thORIZING the supply of a covered drug for purposes
19 of testing as described in paragraph (1), and the
20 Secretary shall issue a written notice to such eligible
21 drug developer and the holder of an application for
22 a covered drug authorizing the supply of such drug
23 to such eligible drug developer for purposes of test-
24 ing if—

1 “(A) the eligible drug developer has agreed
2 to comply with any conditions the Secretary
3 considers necessary;

4 “(B) in the event the eligible drug devel-
5 oper is conducting bioequivalence or other clin-
6 ical testing, the eligible drug developer has sub-
7 mitted, and the Secretary has approved, a pro-
8 tocol that includes protections that the Sec-
9 retary finds will provide assurance of safety
10 comparable to the assurance of safety provided
11 by the elements to ensure safe use in the risk
12 evaluation and mitigation strategy for the cov-
13 ered drug as applicable to such testing; and

14 “(C) the eligible drug developer is in com-
15 pliance with applicable laws and regulations re-
16 lated to such testing, including any applicable
17 requirements related to Investigational New
18 Drug Applications or informed consent.

19 “(3) ADDITIONAL REQUIRED ELEMENT.—The
20 Secretary shall require as an element of each risk
21 evaluation and mitigation strategy with elements to
22 ensure safe use approved by the Secretary that the
23 holder of an application for a covered drug shall not
24 restrict the resale of the covered drug to an eligible
25 drug developer that receives a written notice from

1 the Secretary under paragraph (2) unless, at any
2 time, the Secretary provides written notice to the
3 holder of the application directing otherwise based
4 on a shortage of such drug for patients, national se-
5 curity concerns related to access to such drug, or
6 such other reason as the Secretary may specify.

7 “(4) VIOLATION AND PENALTIES.—For pur-
8 poses of subsection (f)(8) and sections 301,
9 303(f)(4), 502(y), and 505(p), it shall be a violation
10 of the risk evaluation and mitigation strategy for the
11 holder of the application for a covered drug to vio-
12 late the element described in paragraph (3), or in
13 the case of a holder of an application that is a sole
14 distributor or supplier of a covered drug, to prevent
15 the sale thereof after receipt of a written notice by
16 the Secretary issued under paragraph (2). The Sec-
17 retary shall provide written notice to the Committee
18 on Health, Education, Labor, and Pensions of the
19 Senate and the Committee on Energy and Com-
20 merce of the House of Representatives within 30
21 days of the Secretary becoming aware that a holder
22 of an application of a covered drug has restricted
23 the sale of such a covered drug to any eligible drug
24 developer after receipt of written notice as provided
25 in paragraph (2).

1 “(5) LIABILITY.—Unless the holder of the ap-
2 plication for a covered drug and the eligible devel-
3 oper are the same entity, the holder of an applica-
4 tion for a covered drug shall not be liable for any
5 claim arising out of the eligible drug developer’s
6 testing necessary to support an application under
7 subsection (b)(2) or (j) of section 505 of this Act or
8 section 351(k) of the Public Health Service Act for
9 a drug obtained under this subsection. Nothing in
10 this subsection shall be construed to expand or limit
11 the liability of the eligible drug developer or the
12 holder of an application for a covered drug for any
13 other claim.

14 “(6) CERTIFICATION.—In any request for sup-
15 ply of a covered drug for purposes of testing as de-
16 scribed in paragraph (1), an eligible drug developer
17 shall certify to the Secretary that—

18 “(A) the eligible drug developer will comply
19 with all conditions the Secretary considers nec-
20 essary, any protocol approved by the Secretary,
21 and all applicable laws and regulations per-
22 taining to such testing; and

23 “(B) the eligible drug developer intends to
24 submit an application under subsection (b)(2)
25 or (j) of section 505 of this Act or section

1 351(k) of the Public Health Service Act for the
2 drug for which it is requesting written notice
3 pursuant to paragraph (2), and will use the
4 covered drug only for the purpose of conducting
5 testing to support such an application.

6 “(7) DEFINITIONS.—

7 “(A) COVERED DRUG.—Notwithstanding
8 subsection (b)(2), for purposes of this sub-
9 section, the term ‘covered drug’ means a drug,
10 including a biological product licensed under
11 section 351(a) of the Public Health Service Act,
12 that is subject to a risk evaluation and mitiga-
13 tion strategy with elements to ensure safe use
14 under subsection (f), or a drug, including a bio-
15 logical product licensed under section 351(a) of
16 the Public Health Service Act, required to have
17 a risk evaluation and mitigation strategy with
18 elements to ensure safe use under section
19 909(b) of the Food and Drug Administration
20 Amendments Act of 2007.

21 “(B) ELIGIBLE DRUG DEVELOPER.—For
22 purposes of this subsection, the term ‘eligible
23 drug developer’ means a sponsor that has sub-
24 mitted, or intends to submit, an application
25 under subsection (b)(2) or (j) of section 505 of

1 this Act or section 351(k) of the Public Health
2 Service Act to market a version of the covered
3 drug in the United States.

4 “(8) EFFECT ON OTHER LAW.—Notwith-
5 standing the provisions of this subsection, the anti-
6 trust statutes enforced by the Federal Trade Com-
7 mission, including the Federal Trade Commission
8 Act (15 U.S.C. 41–58), the Sherman Act (15 U.S.C.
9 1–7), and any other statute properly under such
10 Commission’s jurisdiction, shall apply to the conduct
11 described in this subsection to the same extent as
12 such statutes did on the day before the date of en-
13 actment of this subsection.”.

14 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

15 (1) Section 505–1(c)(2) (21 U.S.C. 355–
16 1(c)(2)) is amended by striking “(e) and (f)” and in-
17 serting “(e), (f), and (k)(3)”.

18 (2) Section 502(y) (21 U.S.C. 352(y)) is
19 amended by striking “”(d), (e), or (f) of section
20 505–1” and inserting “(d), (e), (f), or (k)(3) of sec-
21 tion 505–1”.

1 **SEC. 1132. PATIENT PARTICIPATION IN MEDICAL PRODUCT**
2 **DISCUSSIONS.**

3 Subchapter E of chapter V (21 U.S.C. 360bbb et
4 seq.), as amended by section 1126, is further amended by
5 adding at the end the following:

6 **“SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PROD-**
7 **UCT DISCUSSION.**

8 “(a) IN GENERAL.—The Secretary shall develop and
9 implement strategies to solicit the views of patients during
10 the medical product development process and consider the
11 perspectives of patients during regulatory discussions, in-
12 cluding by—

13 “(1) fostering participation of a patient rep-
14 resentative who may serve as a special government
15 employee in appropriate agency meetings with med-
16 ical product sponsors and investigators; and

17 “(2) exploring means to provide for identifica-
18 tion of patient representatives who do not have any,
19 or have minimal, financial interests in the medical
20 products industry.

21 “(b) FINANCIAL INTEREST.—In this section, the
22 term ‘financial interest’ means a financial interest under
23 section 208(a) of title 18, United States Code.”.

1 **SEC. 1133. NANOTECHNOLOGY REGULATORY SCIENCE PRO-**
2 **GRAM.**

3 (a) IN GENERAL.—Chapter X (21 U.S.C. 391 et
4 seq.) is amended by adding at the end the following:

5 **“SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE**
6 **PROGRAM.**

7 “(a) IN GENERAL.—Not later than 180 days after
8 the date of enactment of the Food and Drug Administra-
9 tion Safety and Innovation Act, the Secretary, in consulta-
10 tion as appropriate with the Secretary of Agriculture, shall
11 establish within the Food and Drug Administration a
12 Nanotechnology Regulatory Science Program (referred to
13 in this section as the ‘program’) to enhance scientific
14 knowledge regarding nanomaterials included or intended
15 for inclusion in products regulated under this Act or other
16 statutes administered by the Food and Drug Administra-
17 tion, to address issues relevant to the regulation of those
18 products, including the potential toxicology of such mate-
19 rials, the effects of such materials on biological systems,
20 and interaction of such materials with biological systems.

21 “(b) PROGRAM PURPOSES.—The purposes of the pro-
22 gram established under subsection (a) may include—

23 “(1) assessing scientific literature and data on
24 general nanomaterials interactions with biological
25 systems and on specific nanomaterials of concern to
26 the Food and Drug Administration;

1 “(2) in cooperation with other Federal agencies,
2 developing and organizing information using data-
3 bases and models that will facilitate the identifica-
4 tion of generalized principles and characteristics re-
5 garding the behavior of classes of nanomaterials
6 with biological systems;

7 “(3) promoting Food and Drug Administration
8 programs and participate in collaborative efforts, to
9 further the understanding of the science of novel
10 properties of nanomaterials that might contribute to
11 toxicity;

12 “(4) promoting and participating in collabo-
13 rative efforts to further the understanding of meas-
14 urement and detection methods for nanomaterials;

15 “(5) collecting, synthesizing, interpreting, and
16 disseminating scientific information and data related
17 to the interactions of nanomaterials with biological
18 systems;

19 “(6) building scientific expertise on nanomate-
20 rials within the Food and Drug Administration, in-
21 cluding field and laboratory expertise, for monitoring
22 the production and presence of nanomaterials in do-
23 mestic and imported products regulated under this
24 Act;

1 “(7) ensuring ongoing training, as well as dis-
2 semination of new information within the centers of
3 the Food and Drug Administration, and more broad-
4 ly across the Food and Drug Administration, to en-
5 sure timely, informed consideration of the most cur-
6 rent science pertaining to nanomaterials;

7 “(8) encouraging the Food and Drug Adminis-
8 tration to participate in international and national
9 consensus standards activities pertaining to nano-
10 materials; and

11 “(9) carrying out other activities that the Sec-
12 retary determines are necessary and consistent with
13 the purposes described in paragraphs (1) through
14 (8).

15 “(c) PROGRAM ADMINISTRATION.—

16 “(1) DESIGNATED INDIVIDUAL.—In carrying
17 out the program under this section, the Secretary,
18 acting through the Commissioner of Food and
19 Drugs, may designate an appropriately qualified in-
20 dividual who shall supervise the planning, manage-
21 ment, and coordination of the program.

22 “(2) DUTIES.—The duties of the individual des-
23 ignated under paragraph (1) may include—

1 “(A) developing a detailed strategic plan
2 for achieving specific short- and long-term tech-
3 nical goals for the program;

4 “(B) coordinating and integrating the stra-
5 tegic plan with activities by the Food and Drug
6 Administration and other departments and
7 agencies participating in the National Nano-
8 technology Initiative; and

9 “(C) developing Food and Drug Adminis-
10 tration programs, contracts, memoranda of
11 agreement, joint funding agreements, and other
12 cooperative arrangements necessary for meeting
13 the long-term challenges and achieving the spe-
14 cific technical goals of the program.

15 “(d) REPORT.—Not later than March 15, 2015, the
16 Secretary shall publish on the Internet Web site of the
17 Food and Drug Administration a report on the program
18 carried out under this section. Such report shall include—

19 “(1) a review of the specific short- and long-
20 term goals of the program;

21 “(2) an assessment of current and proposed
22 funding levels for the program, including an assess-
23 ment of the adequacy of such funding levels to sup-
24 port program activities; and

1 “(3) a review of the coordination of activities
2 under the program with other departments and
3 agencies participating in the National Nanotechnol-
4 ogy Initiative.

5 “(e) EFFECT OF SECTION.—Nothing in this section
6 shall affect the authority of the Secretary under any other
7 provision of this Act or other statutes administered by the
8 Food and Drug Administration.”.

9 (b) EFFECTIVE DATE; SUNSET.—The Nanotechnol-
10 ogy Regulatory Science Program authorized under section
11 1013 of the Federal Food, Drug, and Cosmetic Act (as
12 added by subsection (a)) shall take effect on October 1,
13 2012, or the date of the enactment of this Act, whichever
14 is later. Such Program shall cease to be effective October
15 1, 2017.

16 **SEC. 1134. ONLINE PHARMACY REPORT TO CONGRESS.**

17 Not later than 1 year after the date of enactment
18 of this Act, the Comptroller General of the United States
19 shall submit to the Committee on Health, Education,
20 Labor, and Pensions of the Senate and the Committee on
21 Energy and Commerce of the House of Representatives
22 a report that describes any problems posed by pharmacy
23 Internet websites that violate Federal or State law, includ-
24 ing—

1 (1) the methods by which Internet websites are
2 used to sell prescription drugs in violation of Federal
3 or State law or established industry standards;

4 (2) the harmful health effects that patients ex-
5 perience when they consume prescription drugs pur-
6 chased through such pharmacy Internet websites;

7 (3) efforts by the Federal Government and
8 State and local governments to investigate and pros-
9 ecute the owners or operators of pharmacy Internet
10 websites, to address the threats such websites pose,
11 and to protect patients;

12 (4) the level of success that Federal, State, and
13 local governments have experienced in investigating
14 and prosecuting such cases;

15 (5) whether the law, as in effect on the date of
16 the report, provides sufficient authorities to Federal,
17 State, and local governments to investigate and
18 prosecute the owners and operators of pharmacy
19 Internet websites;

20 (6) additional authorities that could assist Fed-
21 eral, State, and local governments in investigating
22 and prosecuting the owners and operators of phar-
23 macy Internet websites;

24 (7) laws, policies, and activities that would edu-
25 cate consumers about how to distinguish pharmacy

1 Internet websites that comply with Federal and
2 State laws and established industry standards from
3 those pharmacy Internet websites that do not com-
4 ply with such laws and standards; and

5 (8) laws, policies, and activities that would en-
6 courage private sector actors to take steps to ad-
7 dress the prevalence of illegitimate pharmacy Inter-
8 net websites.

9 **SEC. 1135. MEDICATION AND DEVICE ERRORS.**

10 The Secretary of Health and Human Services shall
11 continue and further coordinate activities of the Depart-
12 ment of Health and Human Services related to the preven-
13 tion of medication and device errors, including consider-
14 ation of medication and device errors that affect the pedi-
15 atric patient population. In developing initiatives to ad-
16 dress medication and device errors, the Secretary shall
17 consider the root causes of medication and device errors,
18 including pediatric medication and device errors, in the
19 clinical setting and consult with relevant stakeholders on
20 effective strategies to reduce and prevent medication and
21 device errors in the clinical setting.

22 **SEC. 1136. COMPLIANCE PROVISION.**

23 The budgetary effects of this Act, for the purpose of
24 complying with the Statutory Pay-As-You-Go-Act of 2010,
25 shall be determined by reference to the latest statement

1 titled “Budgetary Effects of PAYGO Legislation” for this
2 Act, submitted for printing in the Congressional Record
3 by the Chairman of the Senate Budget Committee, pro-
4 vided that such statement has been submitted prior to the
5 vote on passage.

6 **SEC. 1137. ENSURING ADEQUATE INFORMATION REGARD-**
7 **ING PHARMACEUTICALS FOR ALL POPU-**
8 **LATIONS, PARTICULARLY UNDERREP-**
9 **RESENTED SUBPOPULATIONS, INCLUDING**
10 **RACIAL SUBGROUPS.**

11 (a) COMMUNICATION PLAN.—The Secretary of
12 Health and Human Services (referred to in this section
13 as the “Secretary”), acting through the Commissioner of
14 Food and Drugs, shall review and modify, as necessary,
15 the Food and Drug Administration’s communication plan
16 to inform and educate health care providers, patients, and
17 payors on the benefits and risks of medical products, with
18 particular focus on underrepresented subpopulations, in-
19 cluding racial subgroups.

20 (b) CONTENT.—The communication plan described
21 under subsection (a)—

22 (1) shall take into account—

23 (A) the goals and principles set forth in
24 the Strategic Action Plan to Reduce Racial and

1 Ethnic Health Disparities issued by the Depart-
2 ment of Health and Human Services;

3 (B) the nature of the medical product; and

4 (C) health and disease information avail-
5 able from other agencies within such Depart-
6 ment, as well as any new means of commu-
7 nicating health and safety benefits and risks re-
8 lated to medical products;

9 (2) taking into account the nature of the med-
10 ical product, shall address the best strategy for com-
11 municating safety alerts, labeled indications for the
12 medical products, changes to the label or labeling of
13 medical products (including black box warnings,
14 health advisories, health and safety benefits and
15 risks), particular actions to be taken by healthcare
16 professionals and patients, any information identi-
17 fying particular subpopulations, and any other rel-
18 evant information as determined appropriate to en-
19 hance communication, including varied means of
20 electronic communication; and

21 (3) shall include a process for implementation
22 of any improvements or other modifications deter-
23 mined to be necessary.

24 (c) ISSUANCE AND POSTING OF COMMUNICATION

25 PLAN.—

1 (1) COMMUNICATION PLAN.—Not later than 1
2 year after the date of enactment of this Act, the
3 Secretary, acting through the Commissioner of Food
4 and Drugs, shall issue the communication plan de-
5 scribed under this section.

6 (2) POSTING OF COMMUNICATION PLAN ON THE
7 OFFICE OF MINORITY HEALTH WEBSITE.—The Sec-
8 retary, acting through the Commissioner of Food
9 and Drugs, shall publicly post the communication
10 plan on the Internet website of the Office of Minor-
11 ity Health of the Food and Drug Administration,
12 and provide links to any other appropriate webpage,
13 and seek public comment on the communication
14 plan.

15 **SEC. 1138. REPORT ON SMALL BUSINESSES.**

16 Not later than 1 year after the date of enactment
17 of this Act, the Commissioner of Food and Drugs shall
18 submit a report to Congress that includes—

19 (1) a listing of and staffing levels of all small
20 business offices at the Food and Drug Administra-
21 tion, including the small business liaison program;

22 (2) the status of partnership efforts between
23 the Food and Drug Administration and the Small
24 Business Administration;

1 (3) a summary of outreach efforts to small
2 businesses and small business associations, including
3 availability of toll-free telephone help lines;

4 (4) with respect to the program under the Or-
5 phan Drug Act (Public Law 97–414), the number of
6 applications made by small businesses and number
7 of applications approved for research grants, the
8 amount of tax credits issued for clinical research,
9 and the number of companies receiving protocol as-
10 sistance for the development of drugs for rare dis-
11 eases and disorders;

12 (5) with respect to waivers and reductions for
13 small business under the Prescription Drug User
14 Fee Act, the number of small businesses applying
15 for and receiving waivers and reductions from drug
16 user fees under subchapter C of chapter VII of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 379f et seq.);

19 (6) the number of small businesses submitting
20 applications and receiving approval for unsolicited
21 grant applications from the Food and Drug Admin-
22 istration;

23 (7) the number of small businesses submitting
24 applications and receiving approval for solicited

1 grant applications from the Food and Drug Admin-
2 istration;

3 (8) barriers small businesses encounter in the
4 drug and medical device approval process; and

5 (9) recommendations for changes in the user
6 fee structure to help alleviate generic drug short-
7 ages.

8 **SEC. 1139. PROTECTIONS FOR THE COMMISSIONED CORPS**
9 **OF THE PUBLIC HEALTH SERVICE ACT.**

10 (a) IN GENERAL.—Section 221(a) of the Public
11 Health Service Act (42 U.S.C. 213a(a)) is amended by
12 adding at the end the following:

13 “(18) Section 1034, Protected Communications;
14 Prohibition of Retaliatory Personnel Actions.”.

15 (b) CONFORMING AMENDMENT.—Section 221(b) of
16 the Public Health Service Act (42 U.S.C. 213a(b)) is
17 amended by adding at the end the following: “For pur-
18 poses of paragraph (18) of subsection (a), the term ‘In-
19 spector General’ in section 1034 of such title 10 shall
20 mean the Inspector General of the Department of Health
21 and Human Services.”.

22 **SEC. 1140. REGULATIONS ON CLINICAL TRIAL REGISTRA-**
23 **TION; GAO STUDY OF CLINICAL TRIAL REG-**
24 **ISTRATION AND REPORTING REQUIREMENTS.**

25 (a) DEFINITIONS.—In this section—

1 (1) the term “applicable clinical trial” has the
2 meaning given such term under section 402(j) of the
3 Public Health Service Act (42 U.S.C. 282(j));

4 (2) the term “Director” means the Director of
5 the National Institutes of Health;

6 (3) the term “responsible party” has the mean-
7 ing given such term under such section 402(j); and

8 (4) the term “Secretary” means the Secretary
9 of Health and Human Services.

10 (b) REQUIRED REGULATIONS.—

11 (1) PROPOSED RULEMAKING.—Not later than
12 180 days after the date of enactment of this Act, the
13 Secretary, acting through the Director, shall issue a
14 notice of proposed rulemaking for a proposed rule on
15 the registration of applicable clinical trials by re-
16 sponsible parties under section 402(j) of the Public
17 Health Service Act (42 U.S.C. 282(j)) (as amended
18 by section 801 of the Food and Drug Administration
19 Amendments Act of 2007).

20 (2) FINAL RULE.—Not later than 180 days
21 after the issuance of the notice of proposed rule-
22 making under paragraph (1), the Secretary, acting
23 through the Director, shall issue the final rule on
24 the registration of applicable clinical trials by re-
25 sponsible parties under such section 402(j).

1 (3) LETTER TO CONGRESS.—If the final rule
2 described in paragraph (2) is not issued by the date
3 required under such paragraph, the Secretary shall
4 submit to Congress a letter that describes the rea-
5 sons why such final rule has not been issued.

6 (c) REPORT BY GAO.—

7 (1) IN GENERAL.—Not later than 2 years after
8 the issuance of the final rule under subsection (b),
9 the Comptroller General of the United States shall
10 submit to the Committee on Health, Education,
11 Labor, and Pensions of the Senate and the Com-
12 mittee on Energy and Commerce of the House of
13 Representatives a report on the implementation of
14 the registration and reporting requirements for ap-
15 plicable drug and device clinical trials under section
16 402(j) the Public Health Service Act (42 U.S.C.
17 282(j)) (as amended by section 801 of the Food and
18 Drug Administration Amendments Act of 2007).

19 (2) CONTENT.—The report under paragraph
20 (1) shall include—

21 (A) information on the rate of compliance
22 and non-compliance (by category of sponsor,
23 category of trial (phase II, III, or IV), whether
24 the applicable clinical trial is conducted domes-
25 tically, in foreign sites, or a combination of

1 sites, and such other categories as the Comp-
2 troller General determines useful) with the re-
3 quirements of—

4 (i) registering applicable clinical trials
5 under such section 402(j);

6 (ii) reporting the results of such trials
7 under such section; and

8 (iii) the completeness of the reporting
9 of the required data under such section;
10 and

11 (B) information on the promulgation of
12 regulations for the registration of applicable
13 clinical trials by the responsible parties under
14 such section 402(j).

15 (3) RECOMMENDATIONS.—If the Comptroller
16 General finds problems with timely compliance or
17 completeness of the data being reported under such
18 section 402(j), or finds that the implementation of
19 registration and reporting requirements under such
20 section 402(j) for applicable drug and device clinical
21 trials could be improved, the Comptroller General
22 shall, after consulting with the Commissioner of
23 Food and Drugs, applicable stakeholders, and ex-
24 perts in the conduct of clinical trials, make rec-
25 ommendations for administrative or legislative ac-

1 tions to increase the compliance with the require-
2 ments of such section 402(j).

3 **SEC. 1141. HYDROCODONE AMENDMENT.**

4 The Controlled Substances Act is amended—

5 (1) in schedule III(d) in section 202(e) (21
6 U.S.C. 812(e)), by—

7 (A) striking paragraphs (3) and (4); and

8 (B) redesignating paragraphs (5), (6), (7),
9 and (8) as paragraphs (3), (4), (5), and (6), re-
10 spectively; and

11 (2) in section 401(b)(1) (21 U.S.C. 841(b)(1)),
12 by adding at the end the following:

13 “(F) In the case of any material, compound,
14 mixture, or preparation containing—

15 “(i) not more than 300 milligrams of
16 dihydrocodeinone per 100 milliliters or not
17 more than 15 milligrams per dosage unit, with
18 a fourfold or greater quantity of an isoquinoline
19 alkaloid of opium; or

20 “(ii) not more than 300 milligrams of
21 dihydrocodeinone per 100 milliliters or not
22 more than 15 milligrams per dosage unit, with
23 one or more active, nonnarcotic ingredients in
24 recognized therapeutic amounts,

1 subparagraph (C) shall not apply and such case
2 shall be subject to subparagraph (E).”.

3 **SEC. 1142. COMPLIANCE DATE FOR RULE RELATING TO**
4 **SUNSCREEN DRUG PRODUCTS FOR OVER-**
5 **THE-COUNTER HUMAN USE.**

6 In accordance with the final rule issued by the Com-
7 missioner of Food and Drug entitled “Labeling and Effec-
8 tiveness Testing; Sunscreen Drug Products for Over-the-
9 Counter Human Use; Delay of Compliance Dates” (77
10 Fed. Reg. 27591 (May 11, 2012)), a product subject to
11 the final rule issued by the Commissioner entitled “Label-
12 ing and Effectiveness Testing; Sunscreen Drug Products
13 for Over-the-Counter Human Use” (76 Fed. Reg. 35620
14 (June 17, 2011)), shall comply with such rule not later
15 than—

16 (1) December 17, 2013, for products subject to
17 such rule with annual sales of less than \$25,000 and

18 (2) December 17, 2012, for all other products
19 subject to such rule.

20 **SEC. 1143. RECOMMENDATIONS ON INTEROPERABILITY**
21 **STANDARDS.**

22 (a) IN GENERAL.—The Attorney General and the
23 Secretary of Health and Human Services may collaborate
24 to facilitate the development of recommendations on inter-
25 operability standards to inform and facilitate the exchange

1 of prescription information across State lines by States re-
2 ceiving grant funds under—

3 (1) the Harold Rogers Prescription Drug Moni-
4 toring Program established under the Departments
5 of Commerce, Justice, and State, the Judiciary, and
6 Related Agencies Appropriations Act, 2002 (Public
7 Law 107–77; 115 Stat. 748); and

8 (2) the Controlled Substance Monitoring Pro-
9 gram established under section 3990 of the Public
10 Health Service Act (42 U.S.C. 280g–3).

11 (b) REQUIREMENTS.—The Attorney General and the
12 Secretary of Health and Human Services shall consider
13 the following in facilitating the development of rec-
14 ommendations on interoperability of prescription drug
15 monitoring programs under subsection (a)—

16 (1) open standards that are freely available,
17 without cost and without restriction, in order to pro-
18 mote broad implementation;

19 (2) the use of exchange intermediaries, or hubs,
20 as necessary to facilitate interstate interoperability
21 by accommodating State-to-hub and direct State-to-
22 State communication;

23 (3) the support of transmissions that are fully
24 secured as required, using industry standard meth-
25 ods of encryption, to ensure that Protected Health

1 Information and Personally Identifiable Information
2 are not compromised at any point during such trans-
3 mission; and

4 (4) access control methodologies to share pro-
5 tected information solely in accordance with State
6 laws and regulations.

7 (c) REPORT.—

8 (1) IN GENERAL.—Not later than 1 year after
9 the date of enactment of this Act, the Attorney Gen-
10 eral, in consultation with the Secretary of Health
11 and Human Services, shall submit to the Committee
12 on the Judiciary and the Committee on Health,
13 Education, Labor, and Pensions of the Senate and
14 the Committee on the Judiciary and the Committee
15 on Energy and Commerce of the House of Rep-
16 resentatives a report on enhancing the interoper-
17 ability of State prescription monitoring programs
18 with other technologies and databases used for de-
19 tecting and reducing fraud, diversion, and abuse of
20 prescription drugs.

21 (2) CONTENTS.—The report required under
22 paragraph (1) shall include—

23 (A) an assessment of legal, technical, fis-
24 cal, privacy, or security challenges that have an
25 impact on interoperability;

1 (B) a discussion of how State prescription
2 monitoring programs could increase the produc-
3 tion and distribution of unsolicited reports to
4 prescribers and dispensers of prescription
5 drugs, law enforcement officials, and health
6 professional licensing agencies, including the
7 enhancement of such reporting through inter-
8 operability with other States and relevant tech-
9 nology and databases; and

10 (C) any recommendations for addressing
11 challenges that impact interoperability of State
12 prescription monitoring programs in order to
13 reduce fraud, diversion, and abuse of prescrip-
14 tion drugs.

15 **Subtitle D—Synthetic Drugs**

16 **SEC. 1151. SHORT TITLE.**

17 This subtitle may be cited as the “Synthetic Drug
18 Abuse Prevention Act of 2012”.

19 **SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE** 20 **I OF THE CONTROLLED SUBSTANCES ACT.**

21 (a) CANNABIMIMETIC AGENTS.—Schedule I, as set
22 forth in section 202(c) of the Controlled Substances Act
23 (21 U.S.C. 812(c)) is amended by adding at the end the
24 following:

1 “(d)(1) Unless specifically exempted or unless listed
2 in another schedule, any material, compound, mixture, or
3 preparation which contains any quantity of
4 cannabimimetic agents, or which contains their salts, iso-
5 mers, and salts of isomers whenever the existence of such
6 salts, isomers, and salts of isomers is possible within the
7 specific chemical designation.

8 “(2) In paragraph (1):

9 “(A) The term ‘cannabimimetic agents’ means
10 any substance that is a cannabinoid receptor type 1
11 (CB1 receptor) agonist as demonstrated by binding
12 studies and functional assays within any of the fol-
13 lowing structural classes:

14 “(i) 2-(3-hydroxycyclohexyl)phenol with
15 substitution at the 5-position of the phenolic
16 ring by alkyl or alkenyl, whether or not sub-
17 stituted on the cyclohexyl ring to any extent.

18 “(ii) 3-(1-naphthoyl)indole or 3-(1-
19 naphthylmethane)indole by substitution at the
20 nitrogen atom of the indole ring, whether or not
21 further substituted on the indole ring to any ex-
22 tent, whether or not substituted on the naph-
23 thoyl or naphthyl ring to any extent.

24 “(iii) 3-(1-naphthoyl)pyrrole by substi-
25 tution at the nitrogen atom of the pyrrole ring,

1 whether or not further substituted in the
2 pyrrole ring to any extent, whether or not sub-
3 stituted on the naphthoyl ring to any extent.

4 “(iv) 1-(1-naphthylmethylene)indene by
5 substitution of the 3-position of the indene ring,
6 whether or not further substituted in the indene
7 ring to any extent, whether or not substituted
8 on the naphthyl ring to any extent.

9 “(v) 3-phenylacetylindole or 3-
10 benzoylindole by substitution at the nitrogen
11 atom of the indole ring, whether or not further
12 substituted in the indole ring to any extent,
13 whether or not substituted on the phenyl ring
14 to any extent.

15 “(B) Such term includes—

16 “(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-
17 hydroxycyclohexyl]-phenol (CP-47,497);

18 “(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-
19 hydroxycyclohexyl]-phenol (cannabicyclohexanol
20 or CP-47,497 C8-homolog);

21 “(iii) 1-pentyl-3-(1-naphthoyl)indole
22 (JWH-018 and AM678);

23 “(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-
24 073);

1 “(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–
2 019);

3 “(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naph-
4 thoyl)indole (JWH–200);

5 “(vii) 1-pentyl-3-(2-
6 methoxyphenylacetyl)indole (JWH–250);

7 “(viii) 1-pentyl-3-[1-(4-
8 methoxynaphthoyl)]indole (JWH–081);

9 “(ix) 1-pentyl-3-(4-methyl-1-naph-
10 thoyl)indole (JWH–122);

11 “(x) 1-pentyl-3-(4-chloro-1-naph-
12 thoyl)indole (JWH–398);

13 “(xi) 1-(5-fluoropentyl)-3-(1-naph-
14 thoyl)indole (AM2201);

15 “(xii) 1-(5-fluoropentyl)-3-(2-
16 iodobenzoyl)indole (AM694);

17 “(xiii) 1-pentyl-3-[(4-methoxy)-ben-
18 zoyl]indole (SR–19 and RCS–4);

19 “(xiv) 1-cyclohexylethyl-3-(2-
20 methoxyphenylacetyl)indole (SR–18 and RCS–
21 8); and

22 “(xv) 1-pentyl-3-(2-
23 chlorophenylacetyl)indole (JWH–203).”.

24 (b) OTHER DRUGS.—Schedule I of section 202(c) of
25 the Controlled Substances Act (21 U.S.C. 812(c)) is

1 amended in subsection (c) by adding at the end the fol-
2 lowing:

3 “(18) 4-methylmethcathinone (Mephedrone).

4 “(19) 3,4-methylenedioxypropylvalerone (MDPV).

5 “(20) 2-(2,5-Dimethoxy-4-
6 ethylphenyl)ethanamine (2C-E).

7 “(21) 2-(2,5-Dimethoxy-4-
8 methylphenyl)ethanamine (2C-D).

9 “(22) 2-(4-Chloro-2,5-
10 dimethoxyphenyl)ethanamine (2C-C).

11 “(23) 2-(4-Iodo-2,5-
12 dimethoxyphenyl)ethanamine (2C-I).

13 “(24) 2-[4-(Ethylthio)-2,5-
14 dimethoxyphenyl]ethanamine (2C-T-2).

15 “(25) 2-[4-(Isopropylthio)-2,5-
16 dimethoxyphenyl]ethanamine (2C-T-4).

17 “(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-
18 H).

19 “(27) 2-(2,5-Dimethoxy-4-nitro-
20 phenyl)ethanamine (2C-N).

21 “(28) 2-(2,5-Dimethoxy-4-(n)-
22 propylphenyl)ethanamine (2C-P).”

1 **SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT**
2 **HAZARDS TO PUBLIC SAFETY EXPANSION.**

3 Section 201(h)(2) of the Controlled Substances Act
4 (21 U.S.C. 811(h)(2)) is amended—

5 (1) by striking “one year” and inserting “2
6 years”; and

7 (2) by striking “six months” and inserting “1
8 year”.

9 **SEC. 1154. PROHIBITION ON IMPOSING MANDATORY MIN-**
10 **IMUM SENTENCES.**

11 Section 401(b)(1)(C) of the Controlled Substances
12 Act (21 U.S.C. 841(b)(1)(C)) is amended by adding at
13 the end the following: “Any mandatory minimum term of
14 imprisonment required to be imposed under this subpara-
15 graph shall not apply with respect to any controlled sub-
16 stance added to schedule I by the Synthetic Drug Abuse
17 Prevention Act of 2012.”.

Passed the Senate May 24, 2012.

Attest:

Secretary.

112TH CONGRESS
2^D SESSION

S. 3187

AN ACT

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