

112TH CONGRESS
2D SESSION

S. _____

To promote accountability, transparency, innovation, efficiency, and timeliness
at the Food and Drug Administration for America’s patients.

IN THE SENATE OF THE UNITED STATES

Mr. BURR (for himself and Mr. COBURN) introduced the following bill; which
was read twice and referred to the Committee on _____

A BILL

To promote accountability, transparency, innovation, effi-
ciency, and timeliness at the Food and Drug Administra-
tion for America’s patients.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Promoting Account-
5 ability, Transparency, Innovation, Efficiency, and Timeli-
6 ness at FDA Act of 2012” or the “PATIENTS’ FDA
7 Act”.

8 **SEC. 2. TABLE OF CONTENTS.**

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

Sec. 1. Short title.

2

Sec. 2. Table of contents.

TITLE I—ENSURING GREATER TRANSPARENCY AND
ACCOUNTABILITY IN FDA REGULATORY DECISIONMAKING

- Sec. 101. Advancing regulatory science to promote public health and innovation.
Sec. 102. Reporting with respect to prescription drugs.
Sec. 103. Reporting with respect to generic drugs.
Sec. 104. Reporting with respect to biosimilars.
Sec. 105. Documentation of regulatory decisions.
Sec. 106. Review of regulations and guidance.
Sec. 107. Leveraging information technology to fulfill FDA's public health mission.

TITLE II—RECALIBRATING RISK-BENEFIT CONSIDERATIONS

- Sec. 201. Devices.
Sec. 202. Drugs.

TITLE III—REDUCING UNNECESSARY DELAYS AND REGULATORY
BURDENS

- Sec. 301. Optimizing global clinical trials.
Sec. 302. Advancing American patients' timely access to innovative devices.
Sec. 303. Ensuring legal sufficiency and consistency of FDA enforcement policies.

TITLE IV—STRENGTHENING ADVISORY COMMITTEES FOR
PATIENTS

- Sec. 401. Strengthening advisory committees for patients.

TITLE V—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

- Sec. 501. Tracking and review of applications for investigational device exemptions.
Sec. 502. Investigational Device Exemptions.
Sec. 503. Device submission acceptance criteria.
Sec. 504. Transparency in clearance process.
Sec. 505. Restoring regulatory certainty with respect to 510(k) reports required for certain modifications.
Sec. 506. Meeting the device needs of individual patients.

Subtitle B—FDA Renewing Efficiency From Outside Reviewer Management

- Sec. 511. Persons accredited to review reports under section 510(k) and make recommendations for initial classification.
Sec. 512. Persons accredited to conduct inspections.

TITLE VI—STRENGTHENING MANAGEMENT TO SUPPORT FDA'S
PUBLIC HEALTH MISSION

- Sec. 601. Integrated strategy and management plan.
Sec. 602. Independent assessment.

1 **TITLE I—ENSURING GREATER**
2 **TRANSPARENCY AND AC-**
3 **COUNTABILITY IN FDA REGU-**
4 **LATORY DECISIONMAKING**

5 **SEC. 101. ADVANCING REGULATORY SCIENCE TO PROMOTE**
6 **PUBLIC HEALTH AND INNOVATION.**

7 (a) IN GENERAL.—Not later than 1 year after the
8 date of enactment of this Act, the Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”) shall develop a strategy and implementation plan
11 for advancing regulatory science for medical products in
12 order to promote the public health and advance innovation
13 in regulatory decisionmaking.

14 (b) REQUIREMENTS.—The strategy and implementa-
15 tion plan developed under subsection (a) shall be con-
16 sistent with the user fee performance goals in the Pre-
17 scription Drug User Fee Agreement commitment letter,
18 the Generic Drug User Fee Agreement commitment letter,
19 and the Biosimilar User Fee Agreement commitment let-
20 ter transmitted by the Secretary to Congress on January
21 13, 2012, and the Medical Device User Fee Agreement
22 published in the Federal Register on March 20, 2012, and
23 shall—

24 (1) identify a clear vision of the fundamental
25 role of efficient, consistent, and predictable, science-

1 based decisions throughout regulatory decision-
2 making of the Food and Drug Administration with
3 respect to medical products;

4 (2) identify the regulatory science priorities of
5 the Food and Drug Administration directly related
6 to fulfilling the mission of the agency with respect
7 to decisionmaking concerning medical products and
8 allocation of resources towards these regulatory
9 science priorities;

10 (3) identify regulatory and scientific gaps that
11 impede the timely development and review of, and
12 regulatory certainty with respect to, the approval, li-
13 censure, or clearance of medical products, including
14 with respect to companion products and new tech-
15 nologies, and facilitating the timely introduction and
16 adoption of new technologies and methodologies in a
17 safe and effective manner;

18 (4) identify clear, measurable metrics by which
19 progress on the priorities identified under paragraph
20 (2) and gaps identified under paragraph (3) will be
21 measured by the Food and Drug Administration, in-
22 cluding metrics specific to the integration and adop-
23 tion of advances in regulatory science described in
24 paragraph (5) and improving medical product deci-

1 sionmaking, in a predictable and science-based man-
2 ner; and

3 (5) set forth how the Food and Drug Adminis-
4 tration will ensure that advances in regulatory
5 science for medical products are adopted, as appro-
6 priate, on an ongoing basis and in a manner inte-
7 grated across centers, divisions, and branches of the
8 Food and Drug Administration, including by senior
9 managers and reviewers, including through the—

10 (A) development, updating, and consistent
11 application of guidance documents that support
12 medical product decisionmaking; and

13 (B) the adoption of the tools, methods, and
14 processes under section 566 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 360bbb–5).

17 (c) ANNUAL PERFORMANCE REPORTS.—As part of
18 the annual performance reports by the Food and Drug
19 Administration to Congress, the Secretary shall annually
20 report on the progress made with respect to—

21 (1) advancing the regulatory science priorities
22 and resolving the gaps identified under paragraph
23 (3) of subsection (b), including reporting on specific
24 metrics identified under paragraph (4) of such sub-
25 section;

1 (2) the integration and adoption of advances in
2 regulatory science as set forth in paragraph (5) of
3 such subsection; and

4 (3) the progress made in advancing the regu-
5 latory science goals outlined in the Prescription
6 Drug User Fee Agreement commitment letter, the
7 Generic Drug User Fee Agreement commitment let-
8 ter, and the Biosimilar User Fee Agreement commit-
9 ment letter transmitted by the Secretary to Congress
10 on January 13, 2012, and the Medical Device User
11 Fee Agreement published in the Federal Register on
12 March 20, 2012.

13 (d) INDEPENDENT ASSESSMENT.—Not later than
14 January 1, 2016, the Comptroller General of the United
15 States shall submit to Congress a report—

16 (1) detailing the progress made by the Food
17 and Drug Administration in meeting the priorities
18 and addressing the gaps identified in subsection (b),
19 including any outstanding gaps; and

20 (2) containing recommendations, as appro-
21 priate, on how regulatory science initiatives for med-
22 ical products can be strengthened and improved to
23 promote the public health and advance innovation in
24 regulatory decisionmaking.

1 (e) MEDICAL PRODUCT.—In this section, the term
2 “medical product” means a drug, as defined in subsection
3 (g) of section 201 of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 321), a device, as defined in sub-
5 section (h) of such section, or a biological product, as de-
6 fined in section 351(i) of the Public Health Service Act
7 (42 U.S.C. 262(i)).

8 **SEC. 102. REPORTING WITH RESPECT TO PRESCRIPTION**
9 **DRUGS.**

10 Section 736B of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 379h–2) is amended—

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

14 “(a) PERFORMANCE REPORT.—Beginning with fiscal
15 year 2013, not later than 120 days after the end of each
16 fiscal year for which fees are collected under this part,
17 the Secretary shall prepare and submit to the Committee
18 on Health Education, Labor, and Pensions of the Senate
19 and the Committee on Energy and Commerce of the
20 House of Representatives a report concerning—

21 “(1) the progress of the Food and Drug Admin-
22 istration in achieving the goals identified in the doc-
23 ument entitled, ‘PDUFA Reauthorization Perform-
24 ance Goals and Procedures Fiscal Years 2013
25 through 2017’, and included in the Prescription

1 Drug User Fee Agreement commitment letter trans-
2 mitted by the Secretary to Congress on January 13,
3 2012, during such fiscal year and the future plans
4 of the Food and Drug Administration for meeting
5 the goals; and

6 “(2) the progress of each review division and
7 branch within the Center for Drug Evaluation and
8 Research and the Center for Biologics Evaluation
9 and Research in achieving such goals, and the plans
10 of each such division and branch for meeting the
11 goals, including—

12 “(A) the number of applications for ap-
13 proval of a new drug under section 505(b) of
14 this Act or a new biological product under sec-
15 tion 351(a) of the Public Health Service Act
16 filed per fiscal year by each review division and
17 branch;

18 “(B) the number of such applications that
19 did not meet the goals described in paragraph
20 (1);

21 “(C) the percentage of such applications
22 approved by each review division and branch;

23 “(D) the percentage of such applications
24 found to be approvable by each review division
25 and branch;

1 “(E) the percentage of such applications
2 that were issued complete response letters by
3 each review division and branch;

4 “(F) the percentage of such applications
5 that were subject to a refuse-to-file action by
6 each review division and branch;

7 “(G) the percentage of such applications
8 withdrawn by each review division and branch;

9 “(H) the total number of review cycles per
10 such approval and the average, mean, and me-
11 dian number of review cycles per such applica-
12 tion by each review division and branch;

13 “(I) the mean and median time to final de-
14 cision, including approval, per such application
15 by each review division and branch;

16 “(J) the average total time to decision by
17 each review division and branch, including the
18 number of days spent during the review by the
19 Food and Drug Administration and days spent
20 by the sponsor responding to a complete re-
21 sponse letter;

22 “(K) the percentage of applications that
23 are considered as fast track products under sec-
24 tion 506 and through accelerated approval by
25 each review division and branch; and

1 “(L) the number of full-time equivalent po-
2 sitions and overall budget assigned to each re-
3 view division and branch.

4 “(b) INCLUSION.—The report under this section for
5 a fiscal year shall include information on all previous co-
6 horts for which the Secretary has not given a complete
7 response on all human drug applications and supplements
8 in the cohort.”; and

9 (2) in subsection (b), by inserting “, including
10 a qualitative and quantitative report with respect to
11 how user fees and appropriated funds are used for
12 the drug review process, including the percentage of
13 review time devoted to activities related to the review
14 of applications under subsections (b) and (j) of sec-
15 tion 505 and subsections (a) and (k) of section 351
16 of the Public Health Service Act” before the period
17 at the end.

18 **SEC. 103. REPORTING WITH RESPECT TO GENERIC DRUGS.**

19 Part 2 of subchapter C of chapter VII of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.)
21 is amended by adding at the end the following:

22 **“SEC. 736C. REPORTING WITH RESPECT TO GENERIC**
23 **DRUGS.**

24 “(a) IN GENERAL.—Beginning with fiscal year 2013,
25 not later than 120 days after the end of each fiscal year

1 for which fees are collected under this part, the Secretary
2 shall prepare and submit to the Committee on Health
3 Education, Labor, and Pensions of the Senate and the
4 Committee on Energy and Commerce of the House of
5 Representatives a report concerning—

6 “(1) the progress of the Food and Drug Admin-
7 istration in achieving the goals identified in the Ge-
8 neric Drug User Fee Act (GDUFA) proposal of the
9 Food and Drug Administration, as set forth in the
10 Generic Drug User Fee Agreement commitment let-
11 ter dated January 13, 2012, during such fiscal year
12 and the future plans of the Food and Drug Adminis-
13 tration for meeting the goals; and

14 “(2) the progress of the Office of Generic
15 Drugs within the Center for Drug Evaluation and
16 Research and the Office of Regulatory Affairs in
17 achieving such goals, and the plans of the Office of
18 Generic Drugs, the Center for Drug Evaluation and
19 the Office of Regulatory Affairs in meeting the
20 goals, including—

21 “(A)(i) the progress in completing review
22 of applications under section 505(j) of the Fed-
23 eral Food, Drug, and Cosmetic Act, amend-
24 ments to such applications, and prior approval
25 supplements with respect to such applications

1 that have been pending for more than 10
2 months, including applications under section
3 505(j) that have been pending for more than 10
4 months as of October 1, 2012, and prior ap-
5 proval supplements to such applications that
6 have been pending for more than 180 days as
7 of October 1, 2012;

8 “(ii) the total number of applications
9 under section 505(j), amendments to such ap-
10 plications, and prior approval supplements with
11 respect to such applications that have been
12 pending for more than 10 months; and

13 “(iii) the average total time it takes to re-
14 view and reach a final decision on—

15 “(I) applications under section 505(j);

16 “(II) major and minor amendments to
17 applications under section 505(j); and

18 “(III) prior approval supplements
19 with respect to applications under section
20 505(j);

21 “(B) the number of such applications that
22 did not meet the goals described in paragraph
23 (1);

24 “(C) the total number of review cycles per
25 approval of an application described in sub-

1 clause (I), (II), or (III) of subparagraph (A)(iii)
2 and the average, mean, and median number of
3 review cycles per such application by each re-
4 view division and branch;

5 “(D) the number of meetings granted to
6 industry and the number of meeting requests
7 submitted by industry;

8 “(E) the mean and median time to final
9 decision, including approval, per such applica-
10 tion by the Office of Generic Drugs;

11 “(F) the median time frames and ranges
12 for reporting decisions with respect to good
13 manufacturing practices to the Office of Ge-
14 neric Drugs following completion of inspections;

15 “(G) the median time frames for com-
16 pleting requested foreign and domestic inspec-
17 tions;

18 “(H) the total number of review cycles per
19 such approval and the average, mean, and me-
20 dian number of review cycles per such applica-
21 tion;

22 “(I) the average total time to decision by
23 the Office of Generic Drugs, including the num-
24 ber of days spent during the review by the Food

1 and Drug Administration and days spent by the
2 sponsor responding to a complete response; and
3 “(J) the number of full-time equivalent po-
4 sitions and overall budget assigned to the Office
5 of Generic Drugs and each unit of the Food
6 and Drug Administration.

7 “(b) INCLUSION.—The report under this section for
8 a fiscal year shall include information on all previous co-
9 horts for which the Secretary has not given a complete
10 response on all human drug applications and supplements
11 in the cohort.

12 “(c) FISCAL REPORT.—Beginning not later than fis-
13 cal year 2013, not later than 120 days after the end of
14 each fiscal year, the Secretary shall prepare and submit
15 to the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Committee on Energy and
17 Commerce of the House of Representatives a report on
18 the implementation of the authority for any user fees with
19 respect to generic drugs during such fiscal year, and the
20 use, by the Food and Drug Administration, of any such
21 fees collected for such fiscal year, including a qualitative
22 and quantitative report with respect to how user fees and
23 appropriated funds are used for the drug review process,
24 including the percentage of review time devoted to direct
25 review of applications under section (j) of section 505.”.

1 **SEC. 104. REPORTING WITH RESPECT TO BIOSIMILARS.**

2 Part 2 of subchapter C of chapter VII of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.),
4 as amended by section 103, is further amended by adding
5 at the end the following:

6 **“SEC. 736D. REPORTING WITH RESPECT TO BIOSIMILARS.**

7 “(a) PERFORMANCE REPORT.—Beginning with fiscal
8 year 2013, not later than 120 days after the end of each
9 fiscal year for which fees are collected under this part,
10 the Secretary shall prepare and submit to the Committee
11 on Energy and Commerce of the House of Representatives
12 and the Committee on Health, Education, Labor, and
13 Pensions of the Senate a report concerning—

14 “(1) the progress of the Food and Drug Admin-
15 istration in achieving the goals identified in the
16 Biosimilars User Fee Act (BSUFA) proposal of the
17 Food and Drug Administration, as set forth in the
18 Biosimilar User Fee Agreement commitment letter
19 dated January 13, 2012, during such fiscal year and
20 the future plans of the Food and Drug Administra-
21 tion for meeting the goals; and

22 “(2) the progress of each review division and
23 branch within the Center for Drug Evaluation and
24 Research and the Center for Biologics Evaluation
25 and Research in achieving the goals, and the plans

1 of each such division and branch for meeting the
2 goals, including—

3 “(A) the number of applications for ap-
4 proval under section 351(k) of the Public
5 Health Service Act filed per fiscal year by each
6 review division and branch;

7 “(B) the number of such applications that
8 did not meet the goals described in paragraph
9 (1) and the total time elapsed since such appli-
10 cations were submitted, including the time such
11 application was with the Food and Drug Ad-
12 ministration and the time such application was
13 with the sponsor;

14 “(C) the percentage of such applications
15 approved by each review division and branch;

16 “(D) the percentage of such applications
17 that were issued complete response letters by
18 each review division and branch;

19 “(E) the percentage of such applications
20 that were subject to a refuse-to-file action by
21 each review division and branch;

22 “(F) the percentage of such applications
23 withdrawn by the sponsor by each review divi-
24 sion and branch;

1 “(G) the total number of review cycles per
2 each approval and the average, mean, and me-
3 dian review cycles per such application (or for
4 all approvals) by each review division and
5 branch;

6 “(H) the mean and median time to final
7 decision, including approval, per such applica-
8 tion by each review division and branch; and

9 “(I) the number of full-time equivalent po-
10 sitions and overall budget assigned to each re-
11 view division and branch.

12 “(b) INCLUSION.—The report under this subsection
13 for a fiscal year shall include information on all previous
14 cohorts for which the Secretary has not given a complete
15 response on all applications under section 351(k) of the
16 Public Health Service Act in the cohort.

17 “(c) FISCAL REPORT.—Beginning not later than fis-
18 cal year 2013, not later than 120 days after the end of
19 each fiscal year, the Secretary shall prepare and submit
20 to the Committee on Health, Education, Labor, and Pen-
21 sions of the Senate and the Committee on Energy and
22 Commerce of the House a report on the implementation
23 of the authority for any user fees with respect to biological
24 products approved under section 351(k) of the Public
25 Health Service Act during such fiscal year, and the use,

1 by the Food and Drug Administration, of any such fees
2 collected for such fiscal year, including a qualitative and
3 quantitative report with respect to how user fees and ap-
4 propriated funds are used for the drug review process, in-
5 cluding the percentage of review time devoted to direct re-
6 view of applications under subsections (a) and (k) of Sec-
7 tion 351 of the Public Health Service Act.”.

8 **SEC. 105. DOCUMENTATION OF REGULATORY DECISIONS.**

9 Chapter V of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 351 et seq.) is amended by adding at the
11 end the following:

12 **“SEC. 524A. AGENCY DOCUMENTATION OF SIGNIFICANT DE-**
13 **CISIONS REGARDING DRUGS AND DEVICES.**

14 “(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-
15 CANT DECISIONS.—The Secretary shall document the sci-
16 entific and regulatory rationale for any significant deci-
17 sion—

18 “(1) of the Center for Drug Evaluation and Re-
19 search regarding an application under subsection (b)
20 or (j) of section 505;

21 “(2) of the Center for Biologics Evaluation and
22 Research regarding an application under subsection
23 (a) or (k) of section 351 of the Public Health Serv-
24 ice Act; and

1 “(3) of the Center for Devices and Radiological
2 Health regarding submission or review of a report
3 under section 510(k), an application under section
4 515, or an application for an exemption under sec-
5 tion 520(g).

6 “(b) PROVISION OF DOCUMENTATION.—Upon re-
7 quest, the Secretary shall furnish such documentation to
8 the person who is seeking to submit, or who has sub-
9 mitted, such report or application.”.

10 **SEC. 106. REVIEW OF REGULATIONS AND GUIDANCE.**

11 Not later than 1 year after the date of enactment
12 of this Act, the Secretary of Health and Human Services
13 shall review all regulations and guidance of the Food and
14 Drug Administration with respect to human medical prod-
15 ucts (as defined in section 101) to ensure consistency
16 with—

17 (a) the requirements of the Federal, Food, Drug, and
18 Cosmetic Act (21 U.S.C. 301 et seq.); and

19 (b) the regulatory principles of the benefits of such
20 regulations and guidance justifying the costs and adoption
21 of the least burdensome approaches to such regulation and
22 guidance as outlined in Executive Order 13563, dated
23 January 18, 2011.

1 **SEC. 107. LEVERAGING INFORMATION TECHNOLOGY TO**
2 **FULFILL FDA'S PUBLIC HEALTH MISSION.**

3 (a) HHS REPORT.—Not later than 1 year after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services shall—

6 (1) report to Congress on—

7 (A) the milestones and a completion date
8 for developing and implementing a comprehen-
9 sive information technology strategic plan to
10 align the information technology systems mod-
11 ernization projects with the strategic goals of
12 the Food and Drug Administration, including
13 results-oriented goals, strategies, milestones,
14 performance measures;

15 (B) efforts to finalize and approve a com-
16 prehensive inventory of the information tech-
17 nology systems of the Food and Drug Adminis-
18 tration that includes information describing
19 each system, such as costs, system function or
20 purpose, and status information, and incor-
21 porate use of the system portfolio into the in-
22 formation investment management process of
23 the Food and Drug Administration;

24 (C) the ways in which the Food and Drug
25 Administration uses the plan described in sub-
26 paragraph (A) to guide and coordinate the

1 modernization projects and activities of the
2 Food and Drug Administration, including the
3 interdependencies among projects and activities;
4 and

5 (D) the extent to which the Food and
6 Drug Administration has fulfilled or is imple-
7 menting recommendations of the Government
8 Accountability Office with respect to the Food
9 and Drug Administration and information tech-
10 nology; and

11 (2) develop—

12 (A) a documented enterprise architecture
13 program management plan that includes the
14 tasks, activities, and timeframes associated with
15 developing and using the architecture and ad-
16 dresses how the enterprise architecture program
17 management will be performed in coordination
18 with other management disciplines, such as or-
19 ganizational strategic planning, capital planning
20 and investment control, and performance man-
21 agement; and

22 (B) a skills inventory, needs assessment,
23 gap analysis, and initiatives to address skills
24 gaps as part of a strategic approach to informa-
25 tion technology human capital planning.

1 (b) GAO REPORT.—Not later than January 1, 2016,
2 the Comptroller General of the United States shall issue
3 a report regarding the strategic plan described in sub-
4 section (a) and related actions carried out by the Food
5 and Drug Administration. Such report shall assess the
6 progress the Food and Drug Administration has made
7 on—

8 (1) the development and implementation of a
9 comprehensive information technology strategic plan,
10 including the results-oriented goals, strategies, mile-
11 stones, and performance measures identified in sub-
12 paragraph (a);

13 (2) the effectiveness of the comprehensive infor-
14 mation technology strategic plan in subparagraph
15 (a), including the results-oriented goals and perform-
16 ance measures; and

17 (3) the extent to which the Food and Drug Ad-
18 ministration has fulfilled recommendations of the
19 Government Accountability Office with respect to
20 such agency and information technology.

21 **TITLE II—RECALIBRATING RISK-**
22 **BENEFIT CONSIDERATIONS**

23 **SEC. 201. DEVICES.**

24 Section 513(a) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 360(a)) is amended—

1 (1) in paragraph (2)—

2 (A) by redesignating subparagraphs (A)
3 through (C) as clauses (i) through (iii), respec-
4 tively,

5 (B) by striking “(2) For” and inserting
6 “(2)(A) For”; and

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

8 “(B) The Secretary shall assess the safety and
9 effectiveness of a device as required under subpara-
10 graph (A) from the perspective of a reasonable pa-
11 tient in the intended use population who would as-
12 sign the most value to the effect the device purports
13 to have or is represented to have under the condi-
14 tions of use prescribed, recommended, or suggested
15 in the labeling or proposed labeling, and who would
16 be willing to accept the probable risks that may be
17 associated with the use of the device as prescribed,
18 recommended, or suggested in the labeling or pro-
19 posed labeling.”;

20 (2) by redesignating paragraph (3) as para-
21 graph (4); and

22 (3) by inserting after paragraph (2) the fol-
23 lowing:

24 “(3)(A) The safety of a device is, for purposes
25 of this section and sections 514 and 515, to be de-

1 terminated in accordance with regulations promul-
2 gated by the Secretary, on the basis of information
3 contained in the application and valid scientific evi-
4 dence derived from well-controlled investigations.
5 The Secretary shall not find a lack of reasonable as-
6 surance of safety unless information contained in the
7 application or valid scientific evidence demonstrates
8 that there is a reasonable probability of a risk of in-
9 jury or illness from the proposed use of the device
10 that is not outweighed by the probable benefit to
11 health from the device.

12 “(B) The Secretary may determine there is not
13 reasonable assurance of safety with respect to a de-
14 vice only after identifying in writing—

15 “(i) the probable risk of injury or illness;

16 “(ii) the scientific evidence that reasonably
17 supports the Secretary’s determination; and

18 “(iii) the type of data or information, con-
19 sistent with the least burdensome provisions of
20 this Act, that would demonstrate a benefit that
21 would exceed the probable risk.”.

22 **SEC. 202. DRUGS.**

23 Section 505(d) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 355(d)) is amended by adding at
25 the end the following:

1 “In assessing the safety and effectiveness of a drug under
2 this subsection, the Secretary shall implement a struc-
3 tured benefit-risk assessment framework in the new drug
4 approval process to facilitate the balanced consideration
5 of benefits and risks, a consistent and systematic approach
6 to the discussion and regulatory decisionmaking, and the
7 communication of the benefits and risks of new drugs.”.

8 **TITLE III—REDUCING UNNECES-**
9 **SARY DELAYS AND REGU-**
10 **LATORY BURDENS**

11 **SEC. 301. OPTIMIZING GLOBAL CLINICAL TRIALS.**

12 Subchapter E of chapter V of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
14 amended by adding at the end the following:

15 **“SEC. 568. OPTIMIZING GLOBAL CLINICAL TRIALS.**

16 “For purposes of eliminating costly and scientifically
17 unnecessary clinical trials, enhancing the efficiency of
18 medical products development, and facilitating the Food
19 and Drug Administration and the acceptance of foreign
20 clinical data of other health authorities, the Food and
21 Drug Administration shall—

22 “(1) work with other regulatory authorities of
23 similar standing, medical research companies, and
24 international organizations to foster and encourage

1 uniform, scientifically-driven clinical trial standards
2 around the world; and

3 “(2) enhance the commitment to provide the
4 least burdensome, consistent parallel scientific advice
5 to manufacturers seeking simultaneous global devel-
6 opment of new medical products in order to mini-
7 mize the need for conduct and duplication of clinical
8 studies, preclinical studies, or non-clinical studies.”.

9 **SEC. 302. ADVANCING AMERICAN PATIENTS’ TIMELY AC-**
10 **CESS TO INNOVATIVE DEVICES.**

11 Section 520(g) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 360j(g)) is amended by adding at
13 the end the following:

14 “(8) In the case of a person intending to inves-
15 tigate the safety or effectiveness of a class II or a
16 class III device that—

17 “(A) has a valid marketing authorization
18 by the appropriate authority in Australia, Can-
19 ada, Israel, Japan, New Zealand, Switzerland,
20 or South Africa or in the European Union or
21 a country in the European Economic Area (the
22 countries in the European Union and the Euro-
23 pean Free Trade Association), or such other
24 authority recognized by the Secretary; and

1 “(B) has a history of use pursuant to its
2 marketing authorization with no device-related
3 serious unanticipated adverse event reports,
4 the Secretary shall permit an exemption for clinical
5 testing of such device for the purpose of developing
6 data to obtain clearance or approval for the commer-
7 cial distribution of such device.”.

8 **SEC. 303. ENSURING LEGAL SUFFICIENCY AND CONSIST-**
9 **ENCY OF FDA ENFORCEMENT POLICIES.**

10 Subchapter E of chapter V of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as
12 amended by section 301, is further amended by adding
13 at the end the following:

14 **“SEC. 569. WARNING LETTERS.**

15 “(a) IN GENERAL.—Before a warning letter with re-
16 spect to a drug or device is issued, the Office of the Chief
17 Counsel shall review such warning letter to ensure that
18 such warning letter is legally sufficient and consistent with
19 all policies of the Food and Drug Administration.

20 “(b) WARNING LETTER.—For purposes of this sec-
21 tion, the term ‘warning letter’ shall include all notices of
22 alleged violations, including untitled letters.”.

1 **TITLE IV—STRENGTHENING AD-**
2 **VISORY COMMITTEES FOR PA-**
3 **TIENTS**

4 **SEC. 401. STRENGTHENING ADVISORY COMMITTEES FOR**
5 **PATIENTS.**

6 (a) FINDING.—Congress finds that—

7 (1) as science becomes more specialized, it be-
8 comes more difficult for general scientists to keep up
9 with the scientific advances in the many areas that
10 the Food and Drug Administration regulates;

11 (2) it is necessary for the Food and Drug Ad-
12 ministration to be able to draw upon essential med-
13 ical and scientific expertise across specialized areas
14 in order to fulfill its public health mission;

15 (3) the programs with respect to advisory com-
16 mittees under the Food and Drug Administration
17 should be strengthened and improved to ensure that
18 the Food and Drug Administration is able to be ad-
19 vised by the most qualified medical and scientific
20 subject experts; and

21 (4) an appropriate balance should be restored
22 with respect to conflict of interest considerations for
23 advisory committees and experts advising the Food
24 and Drug Administration to ensure that the Food

1 and Drug Administration is able to draw upon the
2 most qualified medical and scientific experts.

3 (b) ADVISORY COMMITTEES AND SPECIAL GOVERN-
4 MENT EMPLOYEES.—Subchapter A of chapter VII of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
6 et seq.) is amended by adding at the end the following:

7 **“SEC. 714. STRENGTHENING ADVISORY COMMITTEES.**

8 “(a) INCREASING NUMBERS OF MEDICAL AND SCI-
9 ENTIFIC SPECIALISTS PROVIDING EXPERTISE AND AN-
10 NUAL REPORT.—

11 “(1) SPECIAL GOVERNMENT EMPLOYEES.—In
12 this section, the term ‘special Government employee’
13 has the meaning given the term in section 202 of
14 title 18, United States Code.

15 “(2) INCREASING NUMBERS.—The Secretary,
16 acting through the Commissioner of Food and
17 Drugs, shall collaborate with stakeholders, including
18 consumer groups, patient groups, academia, and in-
19 dustry representatives, to increase the number of
20 special Government employees across medical and
21 scientific specialties in areas where the Secretary
22 lacks specific scientific, medical, or technical exper-
23 tise necessary for the performance of its regulatory
24 responsibilities.

1 “(3) ANNUAL REPORTS.—The Secretary, acting
2 through the Commissioner of Food and Drugs, shall
3 submit an annual report, as part of the annual user
4 fee agreement performance report, on the manage-
5 ment of the pool of special Government employees of
6 the Food and Drug Administration by citing—

7 “(A) the total number of such employees;

8 “(B) the employees’ specific areas of ex-
9 pertise;

10 “(C) the turnover by resignation of such
11 employees;

12 “(D) new special Government employee ap-
13 pointments;

14 “(E) the frequency of participation by spe-
15 cial Government employees in decisions by the
16 Food and Drug Administration or advice pro-
17 vided to the Food and Drug Administration;
18 and

19 “(F) the total number of applicants not se-
20 lected to serve as special government employees.

21 “(b) TEMPLATE FOR ADVISORY COMMITTEE BY-
22 LAWS.—The Secretary, acting through the Commissioner
23 of Food and Drugs, shall—

1 “(1) publish a standardized template for the by-
2 laws of advisory committees established under this
3 Act; and

4 “(2) require each of such advisory committees
5 to compile and publish online an annual report con-
6 taining, at a minimum—

7 “(A) a list of the members of the advisory
8 committee, the business address of each mem-
9 ber, and the dates of each member’s term;

10 “(B) a list of the Chair and any other des-
11 ignated leaders of the Advisory Committee;

12 “(C) a list of any vacancies on the advisory
13 committee and the length of any vacancy;

14 “(D) the advisory committee’s functions,
15 expenditures, the dates and places of meetings,
16 and the attendance of members present at such
17 meetings; and

18 “(E) a summary of the advisory commit-
19 tee’s activities and recommendations made dur-
20 ing the fiscal year.

21 “(c) TEMPLATE FOR PUBLICATION OF CVs.—

22 “(1) IN GENERAL.—The Secretary, acting
23 through the Commissioner of Food and Drugs, shall
24 collaborate with stakeholders, including consumer
25 groups, patient groups, academia, and industry rep-

1 representatives, to publish a standardized template as
2 guidance for special Government employees of the
3 Food and Drug Administration and members of ad-
4 visory committees established under this Act to use
5 in publicizing their curriculum vitae.

6 “(2) CONTENT OF TEMPLATE.—The standard-
7 ized template described in paragraph (1) shall be
8 consistent with the following:

9 “(A) Peer-reviewed research shall be sepa-
10 rated from non-peer-reviewed research.

11 “(B) The template shall include a separate
12 list of research that has been submitted for re-
13 view but not yet published.

14 “(C) The template shall include a separate
15 list of non-research publications.

16 “(D) The template shall include general in-
17 formation about the topic and date in cases
18 where the research or grant subject matter has
19 been redacted.

20 “(E) All items shall be listed in chrono-
21 logical order beginning with the most recent.

22 “(d) AFFIDAVITS.—The Secretary may require mem-
23 bers of advisory committees established under this Act to
24 sign an affidavit stating that the member has read the
25 majority of the briefing materials pertinent to the decision

1 or advice and agrees to the code of conduct to serve as
2 a special government employee.

3 “(e) REPORT.—

4 “(1) IN GENERAL.—Not later than January 1,
5 2017, the Secretary, acting through the Commis-
6 sioner of Food and Drugs, shall report to Congress
7 on the issue of temporary members serving on advi-
8 sory committees established under this Act.

9 “(2) CONTENT OF REPORT.—The report de-
10 scribed in paragraph (1) shall include the following
11 information:

12 “(A) How many temporary members have
13 served on advisory committees established
14 under this Act and how many temporary mem-
15 bers served on each advisory committee.

16 “(B) What percentage of such temporary
17 members were called upon to offer subject mat-
18 ter expertise in voting or to reach a quorum.

19 “(C) Whether temporary members offer
20 expertise on an issue being decided.

21 “(D) Whether temporary members being
22 called upon merely to reach a quorum.

23 “(E) How temporary members are se-
24 lected.”.

1 **TITLE V—MEDICAL DEVICE**
2 **REGULATORY IMPROVEMENTS**
3 **Subtitle A—Premarket**
4 **Predictability**

5 **SEC. 501. TRACKING AND REVIEW OF APPLICATIONS FOR**
6 **INVESTIGATIONAL DEVICE EXEMPTIONS.**

7 Section 520(g) (21 U.S.C. 360j(g)) is amended by
8 adding at the end the following:

9 “(8)(A) Upon the submission of an application for
10 an exemption for a device under this subsection, the sub-
11 mission of a request to classify a device under section 513,
12 or the submission of a report for a device under section
13 510(k), whichever occurs first, the Secretary shall assign
14 a tracking number to the device.

15 “(B) The Secretary shall use such tracking number
16 to record the following interactions between the Secretary
17 and applicant with respect to the device:

18 “(i) Submission or approval of an application
19 for an exemption under this subsection.

20 “(ii) Submission of a request to classify the de-
21 vice under section 513.

22 “(iii) Submission or clearance of a report under
23 section 510(k).

1 “(iv) Any meeting or meeting request, including
2 in anticipation of the submission of such an applica-
3 tion or report.

4 “(v) Submission or approval of an application
5 under section 515(c).

6 “(vi) Any formal or informal request by the
7 Secretary for additional information.

8 “(vii) Any deficiency letter.

9 “(viii) Any response by the applicant to a re-
10 quest described in clause (v) or a deficiency letter.

11 “(ix) Any written submission by the applicant
12 to the Food and Drug Administration.

13 “(x) Any other matter, as determined appro-
14 priate by the Secretary.

15 “(9) Upon the submission of an application for an
16 exemption under this subsection for a device, the Sec-
17 retary shall assign, to review the application, a reviewer
18 with prior review experience with that type of device or
19 technology or other relevant expertise.”.

20 **SEC. 502. INVESTIGATIONAL DEVICE EXEMPTIONS.**

21 Section 520(g) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360j(g)) is amended—

23 (1) in paragraph (2)(B)(ii), by inserting “safety
24 and effectiveness” after “Secretary of”; and

1 (2) in paragraph (4), by adding at the end the
2 following:

3 “(C) Consistent with paragraph (1), the
4 Secretary shall not disapprove an application
5 under this subsection because the Secretary de-
6 termines—

7 “(i) that the investigation may not
8 support a substantial equivalence or de
9 novo classification determination or ap-
10 proval of the device;

11 “(ii) that the investigation may not
12 meet a requirement, including a data re-
13 quirement, relating to the approval or
14 clearance of a device; or

15 “(iii) that an additional or different
16 investigation may be necessary to support
17 clearance or approval of the device.”.

18 **SEC. 503. DEVICE SUBMISSION ACCEPTANCE CRITERIA.**

19 (a) IN GENERAL.—To ensure more efficient and
20 timely evaluation of devices, the Secretary of Health and
21 Human Services (referred to in this section as the “Sec-
22 retary”) shall revise the device submission acceptance cri-
23 teria utilized by the Secretary under chapter V of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 et

1 seq.) as in effect on the date of enactment of this Act
2 and implement such revised criteria.

3 (b) DESCRIPTION; CONTENT.—

4 (1) DESCRIPTION.—The revised acceptance cri-
5 teria described under subsection (a) shall be objec-
6 tive and consistent with the Federal Food, Drug,
7 and Cosmetic Act and regulations issued under such
8 Act (as in effect on the date of enactment of this
9 Act).

10 (2) CONTENT.—Under such revised criteria, the
11 Secretary's decision to refuse to accept or file a de-
12 vice submission shall be consistent with the require-
13 ments for such submission as set forth in the Fed-
14 eral Food, Drug, and Cosmetic Act and the regula-
15 tions issued under such Act (as in effect on the date
16 of enactment of this Act), and shall not be based on
17 criteria inconsistent with the Federal Food, Drug,
18 and Cosmetic Act or such regulations.

19 (c) REPORT.—Not later than 2 years after the date
20 of enactment of this Act, the Comptroller General of the
21 United States shall issue a report regarding the device
22 submission acceptance criteria. The Comptroller General
23 shall, in consultation with persons accredited under sec-
24 tion 523 of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 360m), assess and report on the clarity of the

1 revised device submission acceptance criteria under this
2 section, and the effectiveness of the outcome measures
3 adopted by the Center for Device and Radiological Health
4 to ensure the consistent, appropriate, and predictable ap-
5 plication of such device submission acceptance criteria
6 consistent with the Federal Food, Drug, and Cosmetic Act
7 and regulations issued under such Act (as in effect on the
8 date of enactment of this Act).

9 **SEC. 504. TRANSPARENCY IN CLEARANCE PROCESS.**

10 (a) PUBLICATION OF DETAILED DECISION SUM-
11 MARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended
12 by adding at the end the following:

13 “(5) Subject to subsection (c) and section 301(j), the
14 Secretary shall regularly publish detailed decision sum-
15 maries for each clearance of a device under section
16 510(k).”.

17 (b) APPLICATION.—The requirement of section
18 520(h)(5) of the Federal Food, Drug, and Cosmetic Act,
19 as added by subsection (a), applies only with respect to
20 clearance of a device occurring after the date of the enact-
21 ment of this Act.

1 **SEC. 505. RESTORING REGULATORY CERTAINTY WITH RE-**
2 **SPECT TO 510(K) REPORTS REQUIRED FOR**
3 **CERTAIN MODIFICATIONS.**

4 (a) IN GENERAL.—Section 510(n) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 360(n)) is
6 amended—

7 (1) by striking “(n) The Secretary” and insert-
8 ing “(n)(1) The Secretary”; and

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

10 “(2) A report under subsection (k) is not required
11 for a modification to a device that has been classified into
12 class I or II under subsection (f)(1) or (i) of section 513
13 if—

14 “(A) the change is—

15 “(i) validated by same method applied to
16 the classified device undergoing modification, or
17 a current validation method that is equivalent
18 to the validation method applied to the device
19 undergoing modification;

20 “(ii) the validation identified under clause
21 (i) includes all changes to the last version of the
22 device that the Secretary found substantially
23 equivalent to a predicate device, within the
24 meaning of subsections (f)(1) and (i) of section
25 513; and

1 “(iii) the validation of the modified device
2 reveals that the safety and effectiveness results
3 are consistent with the validation results of the
4 unmodified device;

5 “(B) the device’s intended use remains the
6 same; and

7 “(C) the information identified under subpara-
8 graphs (A) and (B) is documented and maintained
9 as part of the design file subject to inspection by the
10 Secretary under section 704(a) for a period of time
11 equal to the design life of the device, or 2 years from
12 the date of the first commercial distribution of the
13 modified device, whichever occurs later.”.

14 (b) REGULATIONS.—Not later than 1 year after the
15 date of the enactment of this Act, the Secretary shall pro-
16 mulgate a final regulation to implement section 510(n)(2)
17 of the Federal Food, Drug, and Cosmetic Act, as added
18 by subsection (a), including to define the phrase “signifi-
19 cantly affect the safety or effectiveness of the device” con-
20 sistent with the substantive criteria of clauses (i) through
21 (iii) of section 510(n)(2)(A).

22 (c) ANNUAL REPORT.—The Secretary shall annually
23 submit to the Committee on Health, Education, Labor,
24 and Pensions of the Senate and the Committee on Energy
25 and Commerce of the House of Representatives, a report

1 that specifies, with respect to the preceding 2-year pe-
2 riod—

3 (1) the number of reports submitted under sub-
4 section 510(k) for a modification or change to a de-
5 vice that was cleared under such subsection prior to
6 such modification or change; and

7 (2) the number of such reports submitted in re-
8 sponse to—

9 (A) a request from the Secretary,

10 (B) an observation made by the Secretary
11 during an inspection of an applicant's facility;
12 or

13 (C) any other enforcement action initiated
14 by the Secretary.

15 **SEC. 506. MEETING THE DEVICE NEEDS OF INDIVIDUAL PA-**
16 **TIENTS.**

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

20 **“SEC. 515B. MEETING THE DEVICE NEEDS OF INDIVIDUAL**
21 **PATIENTS.**

22 “(a) CUSTOM DEVICES.—Sections 514 and 515 shall
23 not apply to any device modified to meet the individual
24 needs of a specific patient if such device—

1 “(1) in order to comply with the order of an in-
2 dividual physician or dentist (or any other specially
3 qualified person designated under regulations pro-
4 mulgated by the Secretary after an opportunity for
5 an oral hearing), necessarily deviates from an other-
6 wise applicable performance standard or requirement
7 prescribed by or under section 515;

8 “(2) is not generally available in the United
9 States in finished form and no other devices are do-
10 mestically available to treat the unique pathology or
11 physiological condition of the specific patient;

12 “(3) is intended to meet the special needs of
13 such physician or dentist (or other specially qualified
14 person so designated)—

15 “(A) in the course of the professional prac-
16 tice of such physician or dentist (or other spe-
17 cially qualified person so designated);

18 “(B) the need for which has been docu-
19 mented in the patient’s medical record by such
20 physician or dentist (or other specially qualified
21 person so designated); and

22 “(C) is for use by the individual patient
23 described in subparagraph (B); and

24 “(4) is—

1 “(A) assembled from components or manu-
2 factured on a case-by-case basis;

3 “(B) premanufactured and finished on a
4 case-by-case basis; or

5 “(C) a modification to an existing, legally
6 marketed device.

7 “(b) LIMITATIONS.—Subsection (a) shall apply to a
8 device only if—

9 “(1) such device includes particular features to
10 accommodate a specific patient’s unique anatomical,
11 physiological, or clinical needs;

12 “(2) such device is for the purpose of treating
13 sufficiently rare patient conditions, such that con-
14 ducting clinical investigations would be impractical;
15 and

16 “(3) production of such device is limited to no
17 more than 10 units per year of a particular device
18 meeting a specific patient need or exhibiting a spe-
19 cific feature.”.

1 **Subtitle B—FDA Renewing Effi-**
2 **ciency From Outside Reviewer**
3 **Management**

4 **SEC. 511. PERSONS ACCREDITED TO REVIEW REPORTS**
5 **UNDER SECTION 510(k) AND MAKE REC-**
6 **OMMENDATIONS FOR INITIAL CLASSIFICA-**
7 **TION.**

8 (a) TIME PERIOD FOR REVIEW OF RECOMMENDA-
9 TIONS OF ACCREDITED PERSONS.—Section 523(a) (21
10 U.S.C. 360m(a)) is amended—

11 (1) in paragraph (1), by striking “reviewing re-
12 ports” and inserting “reviewing, and making rec-
13 ommendations to the Secretary regarding, reports”;
14 and

15 (2) in paragraph (2), by amending subpara-
16 graph (B) to read as follows:

17 “(B) TIME PERIOD FOR REVIEW.—Not
18 later than 30 days after the date on which the
19 Secretary is notified under subparagraph (A) by
20 an accredited person with respect to a rec-
21 ommendation regarding a report submitted
22 under section 510(k) or an initial classification
23 of a device, the Secretary shall make a deter-
24 mination with respect to the recommendation.”.

1 (b) ACCESS TO DEVICE INFORMATION.—Section
2 523(a)(2) (21 U.S.C. 360m(a)(2)), as amended by sub-
3 section (a)(2), is amended by adding at the end the fol-
4 lowing:

5 “(D) ACCESS TO DEVICE INFORMATION.—

6 “(i) IN GENERAL.—Subject to section
7 301(j), for the purpose of providing accred-
8 ited persons with additional information to
9 review reports submitted under section
10 510(k) and make recommendations regard-
11 ing the initial classification of devices, the
12 Secretary shall regularly publish—

13 “(I) detailed decision summaries
14 for each substantial equivalence deter-
15 mination under section 513(f)(1) and
16 each initial classification under section
17 513(f)(2); and

18 “(II) total product life cycles in-
19 formation for each device classified
20 under section 513(f).

21 “(ii) REQUIREMENT.—Any informa-
22 tion published under this subparagraph
23 shall be consistent with the requirements
24 of part 20 of title 21, Code of Federal

1 Regulations (or any successor regula-
2 tions).”.

3 (c) ACCREDITATION.—Section 523(b) (21 U.S.C.
4 360m(b)) is amended—

5 (1) in paragraph (2)—

6 (A) in the heading of subparagraph (C), by
7 inserting “AND TRAINING” after “AUDITING”;

8 (B) in subparagraph (C)—

9 (i) in clause (i), by striking “and” at
10 the end;

11 (ii) by redesignating clause (ii) as
12 clause (iii); and

13 (iii) by inserting after clause (i) the
14 following:

15 “(ii) provide for the initial training
16 and periodic updating of training of such
17 person; and”; and

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

19 “(E) PERIODIC REACCREDITATION.—

20 “(i) PERIOD.—Subject to suspension
21 or withdrawal under subparagraph (B),
22 any accreditation under this section shall
23 be valid for a period of 3 years after its
24 issuance.

1 “(ii) RESPONSE TO REACCREDITATION
2 REQUEST.—Upon the submission of a re-
3 quest by an accredited person for re-
4 accreditation under this section, the Sec-
5 retary shall approve or deny such request
6 not later than 60 days after receipt of the
7 request.

8 “(iii) CRITERIA.—Not later than 120
9 days after the date of the enactment of
10 this subparagraph, the Secretary shall es-
11 tablish and publish in the Federal Register
12 criteria to reaccredit or deny reaccredita-
13 tion to persons under this section. The re-
14 accreditation of persons under this section
15 shall specify the particular activities under
16 subsection (a) for which such persons are
17 reaccredited.”;

18 (2) in paragraph (3)—

19 (A) in subparagraph (A), by inserting “a
20 sole practitioner or” after “may not be”;

21 (B) in subparagraph (B), by striking
22 “such a manufacturer, supplier, or vendor” and
23 inserting “a manufacturer, supplier, or vendor
24 of devices of the type for which such person is
25 accredited”; and

1 (C) in subparagraph (D), by striking “de-
2 vices” and inserting “devices of the type for
3 which such person is accredited”;

4 (3) by striking paragraph (4) (relating to selec-
5 tion of accredited persons); and

6 (4) by redesignating paragraph (5) as para-
7 graph (4).

8 (d) DURATION OF AUTHORITY.—Section 523(c) (21
9 U.S.C. 360m(c)) is amended by striking “October 1,
10 2012” and inserting “October 1, 2017”.

11 (e) REPORT.—Section 523(d) (21 U.S.C. 360m(d))
12 is amended by striking “January 10, 2007” and inserting
13 “January 15, 2015”.

14 **SEC. 512. PERSONS ACCREDITED TO CONDUCT INSPEC-**
15 **TIONS.**

16 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-
17 ed by striking “October 1, 2012” and inserting “October
18 1, 2017”.

1 **TITLE VI—STRENGTHENING**
2 **MANAGEMENT TO SUPPORT**
3 **FDA’S PUBLIC HEALTH MIS-**
4 **SION**

5 **SEC. 601. INTEGRATED STRATEGY AND MANAGEMENT**
6 **PLAN.**

7 (a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—

8 Not later than 1 year after the date of enactment of this
9 Act, the Secretary shall submit to Congress a strategic
10 integrated management plan for the Center for Drug
11 Evaluation and Research, the Center for Biologics Evalua-
12 tion and Research, and the Center for Devices and Radio-
13 logical Health. Such strategic management plan shall—

14 (1) identify strategic institutional goals and pri-
15 orities for the Center for Drug Evaluation and Re-
16 search, the Center for Biologics Evaluation and Re-
17 search, and the Center for Devices and Radiological
18 Health;

19 (2) describe the actions the Secretary will take
20 to recruit, retain, train, and continue to develop the
21 workforce at the Center for Drug Evaluation and
22 Research, the Center for Biologics Evaluation and
23 Research, and the Center for Devices and Radio-
24 logical Health to fulfill the public health mission of
25 the Food and Drug Administration;

1 (3) identify results-oriented, outcome-based
2 measures that the Secretary will use to measure the
3 progress of achieving the strategic goals and prior-
4 ities identified under paragraph (1) and the effec-
5 tiveness of the actions identified under paragraph
6 (2), including metrics to ensure that managers and
7 reviewers of the Center for Drug Evaluation and Re-
8 search, the Center for Biologics Evaluation and Re-
9 search, and the Center for Devices and Radiological
10 Health are familiar with and appropriately and con-
11 sistently apply the requirements under the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
13 seq.), including new requirements under the 2012
14 user fee agreements.

15 (b) REPORT.—Not later than January 1, 2016, the
16 Comptroller General of the United States shall issue a re-
17 port regarding the strategic management plan described
18 in subsection (a) and related actions carried out by the
19 Food and Drug Administration. Such report shall—

20 (1) assess the effectiveness of the actions de-
21 scribed in paragraph (2) in recruiting, retaining,
22 training, and developing the workforce at the Center
23 for Drug Evaluation and Research, the Center for
24 Biologics Evaluation and Research, and the Center
25 for Devices and Radiological Health in fulfilling the

1 public health mission of the Food and Drug Admin-
2 istration;

3 (2) assess the effectiveness of the measures
4 identified under paragraph (2) in gauging progress
5 against the strategic goals and priorities identified
6 under paragraph (1);

7 (3) assess the extent to which the Center for
8 Drug Evaluation and Research, the Center for Bio-
9 logics Evaluation and Research, and the Center for
10 Devices and Radiological Health are using the iden-
11 tified results-oriented set of performance measures
12 in tracking their workload by strategic goals and the
13 effectiveness of such measures;

14 (4) assess the extent to which performance in-
15 formation is collected, analyzed, and acted on by
16 managers; and

17 (5) make recommendations, as appropriate, re-
18 garding how the strategic management plan and re-
19 lated actions of the Center for Drug Evaluation and
20 Research, the Center for Biologics Evaluation and
21 Research, and the Center for Devices and Radio-
22 logical Health could be improved to fulfill the public
23 health mission of the Food and Drug Administration
24 in as efficient and effective manner as possible.

1 **SEC. 602. 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.