

[DISCUSSION DRAFT]

114TH CONGRESS
1ST SESSION

H. R. _____

To accelerate the discovery, development, and delivery of 21st century cures,
and for other purposes

IN THE HOUSE OF REPRESENTATIVES

Mr. UPTON (for himself, Ms. DEGETTE, Mr. PITTS, Mr. PALLONE, and Mr.
GENE GREEN of Texas) introduced the following bill; which was referred
to the Committee on _____

A BILL

To accelerate the discovery, development, and delivery of
21st century cures, and for other purposes

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “21st Century Cures Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

- Sec. 1001. National Institutes of Health reauthorization.
- Sec. 1002. NIH Innovation Fund.

Subtitle B—National Institutes of Health Planning and Administration

- Sec. 1021. NIH research strategic plan.
- Sec. 1022. Increasing accountability at the National Institutes of Health.
- Sec. 1023. Biomedical research working group.
- Sec. 1024. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
- Sec. 1025. NIH travel.
- Sec. 1026. Other Transactions Authority.
- Sec. 1027. NCATS Phase IIB Restriction.
- Sec. 1028. High-risk, high-reward research.

Subtitle C—Supporting Young Emerging Scientists

- Sec. 1041. Funding research by emerging scientists.
- Sec. 1042. Improvement of loan repayment programs of National Institutes of Health.
- Sec. 1043. Report.

Subtitle D—Capstone Grant Program

- Sec. 1061. Capstone award.

Subtitle E—Promoting Pediatric Research Through the National Institutes of Health

- Sec. 1081. National Pediatric Research Network.
- Sec. 1082. Global Pediatric Clinical Trial Network Sense of Congress.

Subtitle F—Advancement of National Institutes of Health Research and Data Access

- Sec. 1101. Sharing of data generated through NIH-funded research.
- Sec. 1102. Standardization of data in Clinical Trial Registry Data Bank on eligibility for clinical trials.

Subtitle G—Facilitating Collaborative Research

- Sec. 1121. Clinical Trial Data System.
- Sec. 1122. National neurological diseases surveillance system.
- Sec. 1123. Public-private partnership for information technology system on data on natural history of diseases.
- Sec. 1124. Accessing, sharing, and using health data for research purposes.

Subtitle H—Council for 21st Century Cures

- Sec. 1141. Council for 21st Century Cures.

TITLE II—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

- Sec. 2001. Development and use of patient experience data To enhance structured risk-Benefit assessment framework.

Subtitle B—Qualification and Use of Drug Development Tools

- Sec. 2021. Biomarkers, surrogate endpoints, and other drug development tools.
- Sec. 2022. Accelerated approval development plans.

Subtitle C—FDA Advancement of Precision Medicine

- Sec. 2041. Precision medicine guidance and other programs of food and drug administration.

Subtitle D—Modern Trial Design and Evidence Development

- Sec. 2061. Broader Application of Bayesian Statistics and Adaptive Trial Designs.
- Sec. 2062. Utilizing evidence from clinical experience.
- Sec. 2063. Streamlined data review program.

Subtitle E—Expediting Patient Access

- Sec. 2081. Sense of Congress.
- Sec. 2082. Expanded access policy.
- Sec. 2083. Finalizing draft guidance on expanded access.

Subtitle F—Facilitating Dissemination of Health Care Economic Information

- Sec. 2101. Facilitating dissemination of health care economic information.

Subtitle G—Antibiotic Drug Development

- Sec. 2121. Approval of certain drugs for use in a limited population of patients.
- Sec. 2122. Susceptibility test interpretive criteria for microorganisms.
- Sec. 2123. Encouraging the development and responsible use of new antimicrobial drugs.

Subtitle H—Vaccine Access, Certainty, and Innovation

- Sec. 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices.
- Sec. 2142. Review of processes and consistency of ACIP recommendations.
- Sec. 2143. Meetings between CDC and vaccine developers.

Subtitle I—Repurposing Drugs for Serious and Life-Threatening Diseases and Conditions

- Sec. 2151. [to be supplied].

Subtitle J—Domestic Manufacturing and Export Efficiencies

- Sec. 2161. Grants for studying the process of continuous drug manufacturing.
- Sec. 2162. Re-exportation among members of the European Economic Area.

Subtitle K—Priority Review for Breakthrough Devices

- Sec. 2181. Priority review for breakthrough devices.

Subtitle L—Medical Device Regulatory Process Improvements

- Sec. 2201. Third-party quality system assessment.
- Sec. 2202. Valid scientific evidence.

- Sec. 2203. Training and oversight in least burdensome appropriate means concept.
- Sec. 2204. Recognition of standards.
- Sec. 2205. Notification of marketing of certain class I devices.
- Sec. 2206. Advisory committee process.
- Sec. 2207. Humanitarian device exemption application.
- Sec. 2208. CLIA waiver study design guidance for in vitro diagnostics.

Subtitle M—Sensible Oversight for Technology Which Advances Regulatory Efficiency

- Sec. 2221. Health software.
- Sec. 2222. Applicability and inapplicability of regulation.
- Sec. 2223. Exclusion from definition of device.

Subtitle N—Streamlining Clinical Trials

- Sec. 2241. Protection of human subjects in research; applicability of rules.
- Sec. 2242. Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions.
- Sec. 2243. Alteration or waiver of informed consent for clinical investigations.

Subtitle O—Improving Scientific Expertise and Outreach at FDA

- Sec. 2261. Silvio O. Conte Senior Biomedical Research Service.
- Sec. 2262. Enabling FDA scientific engagement.
- Sec. 2263. Reagan-Udall Foundation for the Food and Drug Administration.
- Sec. 2264. Collection of certain voluntary information exempted from Paperwork Reduction Act.

TITLE III—DELIVERY

Subtitle A—Interoperability

- Sec. 3001. Interoperability.

Subtitle B—Telemedicine

- Sec. 3021. Telemedicine.

Subtitle C—Encouraging Continuing Medical Education for Physicians

- Sec. 3041. Exempting from manufacturer transparency reporting certain transfers used for educational purposes.

Subtitle D—Disposable Medical Technologies

- Sec. 3061. Disposable Medical technologies.

Subtitle E—Local Coverage Decision Reforms

- Sec. 3081. Improvements in the Medicare local coverage determination (LCD) process.

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

- Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-service Price Transparency

Sec. 3131. Medicare site-of-service price transparency.

Subtitle H—Medicare Part D Patient Safety and Drug Abuse Prevention

Sec. 3151. Establishing PDP safety program to prevent fraud and abuse in Medicare prescription drug plans.

1 **TITLE I—DISCOVERY**
2 **Subtitle A—National Institutes of**
3 **Health Funding**

4 **SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**
5 **IZATION.**

6 Section 402A(a)(1) of the Public Health Service Act
7 (42 U.S.C. 282a(a)(1)) is amended—

8 (1) in subparagraph (B), by striking at the end
9 “and”;

10 (2) in subparagraph (C), by striking at the end
11 the period and inserting “; and”; and

12 (3) by adding at the end the following new sub-
13 paragraphs:

14 “(D) \$31,811,000,000 for fiscal year
15 2016;

16 “(E) \$33,331,000,000 for fiscal year 2017;
17 and

18 “(F) \$34,851,000,000 for fiscal year
19 2018.”.

20 **【SEC. 1002. NIH INNOVATION FUND.**

21 **【(a) USE OF INNOVATION FUND.—Section 402(b) of**
22 **the Public Health Service Act is amended—】**

1 【(1) in paragraph (23), by striking at the end
2 “and”；】

3 【(2) in paragraph (24), by striking at the end
4 the period and inserting “; and”; and】

5 【(3) by inserting after paragraph (24), the fol-
6 lowing new paragraph:】

7 【“(25) shall, with respect to funds appropriated
8 under section 402A(e) to the NIH Innovation Fund,
9 allocate such funds to the national research insti-
10 tutes and national centers for conducting and sup-
11 porting innovation fund initiatives identified under
12 paragraph (3) of such section.”.】

13 【(b) ESTABLISHMENT OF INNOVATION FUND.—Sec-
14 tion 402A of the Public Health Service Act is amended—
15 】

16 【(1) by redesignating subsection (e) as sub-
17 section (f); and】

18 【(2) by inserting after subsection (d) the fol-
19 lowing new subsection:】

20 【“(e) NIH INNOVATION FUND.—】

21 【“(1) ESTABLISHMENT.—For the purpose of
22 allocations under section 402(b)(25), there is estab-
23 lished a fund to be known as the NIH Innovation
24 Fund.】

1 【“(2) AMOUNTS MADE AVAILABLE TO FUND.—
2 】

3 【“(A) IN GENERAL.—Subject to subpara-
4 graph (B), there is authorized to be appro-
5 priated, and appropriated, to the NIH Innova-
6 tion Fund out of any funds in the Treasury not
7 otherwise appropriated, \$2,000,000,000 for
8 each of fiscal years 2016 through 2020. The
9 amounts appropriated to the Fund by the pre-
10 ceding sentence shall be in addition to any
11 amounts otherwise made available to the Na-
12 tional Institutes of Health.】

13 【“(B) MAINTAINING BASE APPROPRIA-
14 TIONS LEVEL.—The amounts appropriated by
15 subparagraph (A) for a fiscal year shall not be
16 available for obligation or expenditure unless
17 and until the 【total amount of funds made
18 available to the National Institutes of Health】
19 for such fiscal year【, without regard to this
20 subsection,】 are not less than the total amount
21 of funds made available to the National Insti-
22 tutes of Health for fiscal year 【____】.】

23 【“(3) AUTHORIZED USES.—Amounts made
24 available to the NIH Innovation Fund established

1 under paragraph (1) may be used for only the fol-
2 lowing innovation fund initiatives:】

3 【“(A) PRECISION MEDICINE.—【To be sup-
4 plied】.】

5 【“(B) YOUNG EMERGING SCIENTISTS.—
6 【To be supplied】.】

7 【“(C) OTHER.—【To be supplied】.”.】

8 **Subtitle B—National Institutes of**
9 **Health Planning and Adminis-**
10 **tration**

11 **SEC. 1021. NIH RESEARCH STRATEGIC PLAN.**

12 Section 402 of the Public Health Service Act (42
13 U.S.C. 282) is amended—

14 (1) in subsection (b), by amending paragraph
15 (5) to read as follows:

16 “(5) shall ensure that scientifically based stra-
17 tegic planning is implemented in support of research
18 priorities as determined by the agencies of the Na-
19 tional Institutes of Health, including through devel-
20 opment, use, and updating of the research strategic
21 plan under subsection (m);”; and

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

23 “(m) RESEARCH STRATEGIC PLAN.—

24 “(1) IN GENERAL.—Beginning in fiscal year
25 2016, and every 5 years thereafter, the Director of

1 NIH, in consultation with the directors of the na-
2 tional research institutes and national centers, re-
3 searchers, patient advocacy groups, and industry
4 leaders, shall develop and maintain a 5-year bio-
5 medical research strategic plan (in this subsection
6 referred to as the ‘strategic plan’) that—

7 “(A) is designed to increase the efficient
8 and effective focus of biomedical research in a
9 manner that leverages the best scientific oppor-
10 tunities through a deliberative planning process;

11 “(B) identifies areas, to be known as stra-
12 tegic focus areas, in which the resources of the
13 National Institutes of Health can best con-
14 tribute to the goal of expanding knowledge on
15 human health in the United States through bio-
16 medical research; and

17 “(C) includes objectives for each such stra-
18 tegic focus area.

19 “(2) USE OF PLAN.—The Director of NIH and
20 the directors of the national research institutes and
21 national centers shall use the strategic plan—

22 “(A) to identify research opportunities;
23 and

24 “(B) to develop individual strategic plans
25 for the research activities of each of the na-

1 tional research institutes and national centers
2 that—

3 “(i) have a common format; and

4 “(ii) identify strategic focus areas in
5 which the resources of the national re-
6 search institutes and national centers can
7 best contribute to the goal described in
8 paragraph (1)(B).

9 “(3) CONTENTS OF PLANS.—

10 “(A) STRATEGIC FOCUS AREAS.—The stra-
11 tegic focus areas identified pursuant to para-
12 graphs (1)(B) and (2)(B) shall—

13 “(i) be identified in a manner that—

14 “(I) considers the return on in-
15 vestment to the United States public
16 through the investments of the Na-
17 tional Institutes of Health in bio-
18 medical research; and

19 “(II) contributes to expanding
20 knowledge to improve the United
21 States public’s health through bio-
22 medical research; and

23 “(ii) [include overarching, multicenter
24 strategic focus areas, to be known as Mis-
25 sion Priority Focus Areas, which best serve

1 the goals of preventing or eliminating the
2 burden of a disease or condition and sci-
3 entifically merit enhanced and focused re-
4 search over the next 5 years.】

5 “(B) RARE AND PEDIATRIC DISEASES AND
6 CONDITIONS.—In developing and maintaining a
7 strategic plan under this subsection, the Direc-
8 tor of NIH shall ensure that rare and pediatric
9 diseases and conditions remain a priority.

10 “(4) INITIAL PLAN.—Not later than 270 days
11 after the date of enactment of this subsection, the
12 Director of NIH and the directors of the national re-
13 search institutes and national centers shall—

14 “(A) complete the initial strategic plans re-
15 quired by paragraphs (1) and (2); and

16 “(B) make such initial strategic plans pub-
17 licly available on the website of the National In-
18 stitutes of Health.

19 “(5) REVIEW; UPDATES.—

20 “(A) PROGRESS REVIEWS.—Not less than
21 annually, the Director of the NIH, in consulta-
22 tion with the directors of the national research
23 institutes and national centers, shall conduct
24 progress reviews for each strategic focus area
25 identified under paragraph (1)(B).

1 “(B) UPDATES.—Not later than the end of
2 the 5-year period covered by the initial strategic
3 plan under this subsection, and every 5 years
4 thereafter, the Director of NIH, in consultation
5 with the directors of the national research insti-
6 tutes and national centers, stakeholders in the
7 scientific field, advocates, and the public at
8 large, shall—

9 “(i) conduct a review of the plan, in-
10 cluding each strategic focus area identified
11 under paragraph (1)(B); and

12 “(ii) update such plan in accordance
13 with this section.”.

14 **SEC. 1022. INCREASING ACCOUNTABILITY AT THE NA-**
15 **TIONAL INSTITUTES OF HEALTH.**

16 (a) APPOINTMENT AND TERMS OF DIRECTORS OF
17 NATIONAL RESEARCH INSTITUTES AND NATIONAL CEN-
18 TERS.—Subsection (a) of section 405 of the Public Health
19 Service Act (42 U.S.C. 284) is amended to read as follows:

20 “(a) APPOINTMENT; TERMS.—

21 “(1) APPOINTMENT.—The Director of the Na-
22 tional Cancer Institute shall be appointed by the
23 President and the directors of the other national re-
24 search institutes, as well as the directors of the na-
25 tional centers, shall be appointed by the Director of

1 NIH. The directors of the national research insti-
2 tutes, as well as national centers, shall report di-
3 rectly to the Director of NIH.

4 “(2) TERMS.—

5 “(A) IN GENERAL.—The term of office of
6 a director of a national research institute or na-
7 tional center shall be 5 years.

8 “(B) REMOVAL.—The director of a na-
9 tional research institute or national center may
10 be removed from office by the Director of NIH
11 prior to the expiration of such director’s 5-year
12 term.

13 “(C) REAPPOINTMENT.—At the end of the
14 term of a director of a national research insti-
15 tute or national center, the director may be re-
16 appointed. There is no limit on the number of
17 terms a director may serve.

18 “(D) VACANCIES.—If the office of a direc-
19 tor of a national research institute or national
20 center becomes vacant before the end of such
21 director’s term, the director appointed to fill the
22 vacancy shall be appointed for a 5-year term
23 starting on the date of such appointment.

24 “(E) TRANSITIONAL PROVISION.—Each di-
25 rector of a national research institute or na-

1 tional center serving on the date of enactment
2 of the 21st Century Cures Act is deemed to be
3 appointed for a 5-year term under this sub-
4 section starting on such date of enactment.”.

5 (b) COMPENSATION TO CONSULTANTS OR INDI-
6 VIDUAL SCIENTISTS.—Section 202 of the Departments of
7 Labor, Health and Human Services, and Education, and
8 Related Agencies Appropriations Act, 1993 (Public Law
9 102–394; 42 U.S.C. 238f note) is amended by striking
10 “portable structures;” and all that follows and inserting
11 “portable structures.”.

12 (c) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—
13 Section 405(b) of the Public Health Service Act (42
14 U.S.C. 284(b)) is amended by adding at the end the fol-
15 lowing:

16 “(3) Before an award is made by a national research
17 institute or by a national center for a grant for a research
18 program or project (commonly referred to as an ‘R-series
19 grant’), other than an award constituting a noncompeting
20 renewal of such grant, or a noncompeting administrative
21 supplement to such grant, the director of such national
22 research institute or national center—

23 “(A) shall review and approve the award; and

24 “(B) shall take into consideration—

1 “(i) the mission of the national research
2 institute or national center and the scientific
3 priorities identified in the strategic plan under
4 section 402(m); and

5 “(ii) whether other agencies are funding
6 programs or projects to accomplish the same
7 goal.”.

8 (d) IOM STUDY ON DUPLICATION IN FEDERAL BIO-
9 MEDICAL RESEARCH.—The Secretary of Health and
10 Human Services shall enter into an arrangement with the
11 Institute of Medicine of the National Academies (or, if the
12 Institute declines, another appropriate entity) under which
13 the Institute (or other appropriate entity) not later than
14 2 years after the date of enactment of this Act will—

15 (1) complete a study on the extent to which bio-
16 medical research conducted or supported by Federal
17 agencies is duplicative; and

18 (2) submit a report to the Congress on the re-
19 sults of such study, including recommendations on
20 how to prevent such duplication.

21 **[SEC. 1023. BIOMEDICAL RESEARCH WORKING GROUP.**

22 **[(a) ESTABLISHMENT.—**There is established a work-
23 ing group to be known as the “Biomedical Research Work-
24 ing Group”.**]**

1 **[(b) DUTIES.—The Biomedical Research Working**
2 **Group shall—]**

3 **[(1) provide recommendations to the Director**
4 **of the National Institutes of Health to reduce ad-**
5 **ministrative burdens of researchers funded by the**
6 **National Institutes of Health, including with respect**
7 **to the extent to which (and how) grant proposals,**
8 **grant review, and management should be restruc-**
9 **ured, streamlined, and simplified;]**

10 **[(2) evaluate and provide recommendations on**
11 **the extent to which it is required for Congress to**
12 **provide any statutory authority to implement any**
13 **recommendation proposed pursuant to paragraph**
14 **(1); and]**

15 **[(3) prepare a plan, including timeframes, for**
16 **implementing recommendations proposed pursuant**
17 **to paragraph (1) for which congressional action is**
18 **not required.]**

19 **[(c) MEMBERSHIP.—The Secretary shall appoint the**
20 **members of the Biomedical Research Working Group. The**
21 **Biomedical Research Working Group shall be composed**
22 **of—]**

23 **[(1) non-Federal members from the extramural**
24 **community;]**

1 【(2) representatives of the Office of the Direc-
2 tor; and】

3 【(3) representatives of other national research
4 institutes and national centers of the National Insti-
5 tutes of Health, as determined necessary.】

6 【(d) IMPLEMENTATION OF MEASURES TO REDUCE
7 ADMINISTRATIVE BURDENS.—The Director of the Na-
8 tional Institutes of Health, taking into account the rec-
9 ommendations, evaluations, and plan described in sub-
10 section (b), shall implement measures to reduce the ad-
11 ministrative burdens of researchers funded by the Na-
12 tional Institutes of Health.】

13 【(e) REPORTS.—】

14 【(1) REPORT BY WORKING GROUP ON REC-
15 COMMENDATIONS AND PLAN.—Not later than one
16 year after the date of the enactment of this Act, the
17 Biomedical Research Working Group shall submit to
18 Congress a report including the recommendations,
19 evaluations, and plan described in subsection (b).】

20 【(2) REPORT BY DIRECTOR OF NIH ON IMPLE-
21 MENTATION OF MEASURES TO REDUCE ADMINISTRA-
22 TIVE BURDENS.—The Director of the National Insti-
23 tutes of Health shall submit to Congress a report on
24 the extent to which the Director has implemented
25 measures pursuant to subsection (d).】

1 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
2 **HEALTH FROM THE PAPERWORK REDUCTION**
3 **ACT REQUIREMENTS.**

4 Section 3518(c)(1) of title 44, United States Code,
5 is amended—

6 (1) in subparagraph (C), by striking “; or” and
7 inserting a semicolon;

8 (2) in subparagraph (D), by striking the period
9 at the end and inserting “; or”; and

10 (3) by inserting at the end the following new
11 subparagraph:

12 “(E) during the conduct of research by the
13 National Institutes of Health or contractors on
14 behalf of the Institutes.”.

15 **SEC. 1025. NIH TRAVEL.**

16 It is the sense of Congress that participation in or
17 sponsorship of scientific conferences and meetings is es-
18 sential to the mission of the National Institutes of Health.

19 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

20 Section 480 of the Public Health Service Act (42
21 U.S.C. 287a) is amended—

22 (1) in subsection (b), by striking “the appro-
23 priation of funds as described in subsection (g)” and
24 inserting “the availability of funds as described in
25 subsection (f)”;

1 (2) in subsection (e)(3), by amending subpara-
2 graph (C) to read as follows:

3 “(C) OTHER TRANSACTIONS AUTHORITY.—

4 The Director of the Center shall have other
5 transactions authority in entering into trans-
6 actions to fund projects in accordance with the
7 terms and conditions of this section.”;

8 (3) by striking subsection (f); and

9 (4) by redesignating subsection (g) as sub-
10 section (f).

11 **SEC. 1027. NCATS PHASE IIB RESTRICTION.**

12 Section 479 of the Public Health Service Act (42
13 U.S.C. 287) is amended—

14 (1) prior to making the amendments under
15 paragraph (2), by striking “IIB” each place it ap-
16 pears and inserting “III”; and

17 (2) by striking “IIA” each place it appears and
18 inserting “IIB”.

19 **SEC. 1028. HIGH-RISK, HIGH-REWARD RESEARCH.**

20 Part B of title IV of the Public Health Service Act
21 (42 U.S.C. 284 et seq.) is amended by adding at the end
22 the following:

1 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**
2 **GRAM.**

3 “The director of each national research institute
4 shall, as appropriate—

5 “(1) establish programs to conduct or support
6 research projects that pursue innovative approaches
7 to major contemporary challenges in biomedical re-
8 search that involve inherent high risk, but have the
9 potential to lead to breakthroughs; and

10 “(2) set aside a specific percentage of funding,
11 to be determined by the Director of NIH for each
12 national research institute, for such projects.”.

13 **Subtitle C—Supporting Young**
14 **Emerging Scientists**

15 **[SEC. 1041. FUNDING RESEARCH BY EMERGING SCI-**
16 **ENTISTS.**

17 **[(a) USE OF FUNDS.—Section 402(b)(7)(B) of the**
18 **Public Health Service Act (42 U.S.C. 282) is amended—**
19 **]**

20 **[(1) in clause (i), by striking “and” at the**
21 **end;]**

22 **[(2) by redesignating clause (ii) as clause (iii);**
23 **and]**

24 **[(3) by inserting after clause (i) the following:]**

25 **[“(ii) shall, with respect to funds reserved**
26 **under section 402A(c)(1)(C) for the Common Fund,**

1 allocate such funds to the national research insti-
2 tutes and national centers for conducting and sup-
3 porting research that is identified under subpara-
4 graph (A) and is carried out by one or more emerg-
5 ing scientists (as defined in section
6 402A(e)(1)(C)(iv)); and”.]

7 **[(b) RESERVATION OF FUNDS.—Section 402A(e)(1)**
8 **of the Public Health Service Act (42 U.S.C. 282a(e)(1))**
9 **is amended—]**

10 **[(1) by redesignating subparagraphs (C) and**
11 **(D) as subparagraphs (D) and (E), respectively;**
12 **and]**

13 **[(2) by inserting after subparagraph (B) the**
14 **following:]**

15 **[[“(C) ADDITIONAL RESERVATION FOR RE-**
16 **SEARCH BY EMERGING SCIENTISTS.—]**

17 **[[“(i) INAPPLICABILITY OF TAP FOR**
18 **EVALUATION ACTIVITIES.—Beginning with**
19 **fiscal year 2015, funds appropriated to the**
20 **National Institutes of Health shall not be**
21 **subject to section 241.]**

22 **[[“(ii) RESERVATION.—In addition to**
23 **the amounts reserved for the Common**
24 **Fund under subparagraph (B) and**
25 **amounts appropriated to the Common**

1 Fund under subsection (a)(2), the Director
2 of NIH shall reserve an amount for the
3 Common Fund for fiscal year 2015 and
4 each subsequent fiscal year that is equal to
5 the amount that, but for clause (i), would
6 be made available under section 241 for
7 evaluation activities for such fiscal year.】

8 【“(iii) PURPOSE OF RESERVATION.—
9 Amounts reserved under clause (ii) shall be
10 used for the purpose of carrying out sec-
11 tion 402(b)(7)(B)(ii) (relating to the con-
12 duct and support of research that is identi-
13 fied under section 402A(b)(7)(A) and is
14 carried out by one or more emerging sci-
15 entists).】

16 【“(iv) DEFINITION.—In this subpara-
17 graph, the term ‘emerging scientist’ means
18 an investigator who—】

19 【“(I) will be the principal investi-
20 gator or the program director of the
21 proposed research;】

22 【“(II) has never been awarded,
23 or has been awarded only once, a sub-
24 stantial, competing grant by the Na-

1 tional Institutes of Health for inde-
2 pendent research; and】

3 【“(III) is within 15 years of hav-
4 ing completed—】

5 【“(aa) the investigator’s ter-
6 minal degree; or】

7 【“(bb) a medical residency
8 (or the equivalent).”】

9 【(c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION
10 AGAINST TRANSFER.—Funds reserved pursuant to sec-
11 tion 402A(c)(1)(C) of the Public Health Service Act, as
12 added by subsection (b)—】

13 【(1) shall be used to supplement, not supplant,
14 the funds otherwise allocated by the National Insti-
15 tutes of Health for young investigators; and】

16 【(2) notwithstanding any transfer authority in
17 any appropriation Act, shall not be used for any
18 purpose other than allocating funds as described in
19 section 402(b)(7)(B)(ii) of the Public Health Service
20 Act, as added by subsection (a).】

21 【(d) CONFORMING AMENDMENTS.—】

22 【(1) Section 241(a) of the Public Health Serv-
23 ice Act (42 U.S.C. 238j(a)) is amended by striking
24 “Such portion” and inserting “Subject to section
25 402A(c)(1)(C)(i), such portion”.】

1 【(2) Section 402A(a)(2) of the Public Health
2 Service Act is amended—】

3 【(A) by striking “402(b)(7)(B)(ii)” and
4 inserting “402(b)(7)(B)(iii)”]; and】

5 【(B) by striking “reserved under sub-
6 section (c)(1)(B)(i)” and inserting “reserved
7 under subparagraph (B)(i) or (C)(ii) of sub-
8 section (c)(1)”】.

9 【(3) Section 3(c)(2) of the Gabriella Miller
10 Kids First Research Act (Public Law 113–94) is
11 amended by striking “402(b)(7)(B)(ii) of the Public
12 Health Service Act, as added by subsection (a)” and
13 inserting “402(b)(7)(B)(iii) of the Public Health
14 Service Act, as added by subsection (a) and redesign-
15 nated by section 1041(a) of the 21st Century Cures
16 Act”】.

17 【(e) RULE OF CONSTRUCTION.—Nothing in this Act
18 (and the amendments made by this Act) is intended to
19 affect the amount of funds authorized to be appropriated
20 to the Agency for Healthcare Research and Quality.】

21 **SEC. 1042. IMPROVEMENT OF LOAN REPAYMENT PRO-**
22 **GRAMS OF NATIONAL INSTITUTES OF**
23 **HEALTH.**

24 Part G of title IV of the Public Health Service (42
25 U.S.C. 288 et seq.) is amended—

1 (1) by redesignating the second section 487F
2 (42 U.S.C. 288–6; pediatric research loan repayment
3 program) as section 487G; and

4 (2) by inserting after section 487G, as so redesi-
5 gnated, the following:

6 **“SEC. 487H. LOAN REPAYMENT PROGRAM.**

7 “(a) IN GENERAL.—The Secretary shall establish a
8 program, based on workforce and scientific needs, of en-
9 tering into contracts with qualified health professionals
10 under which such health professionals agree to engage in
11 research in consideration of the Federal Government
12 agreeing to pay, for each year of engaging in such re-
13 search, not more than \$50,000 of the principal and inter-
14 est of the educational loans of such health professionals.

15 “(b) ADJUSTMENT FOR INFLATION.—Beginning with
16 respect to fiscal year 2017, the Secretary may increase
17 the maximum amount specified in subsection (a) by an
18 amount that is determined by the Secretary, on an annual
19 basis, to reflect inflation.

20 “(c) LIMITATION.—The Secretary may not enter into
21 a contract with a health professional pursuant to sub-
22 section (a) unless such professional has a substantial
23 amount of educational loans relative to income.

24 “(d) APPLICABILITY OF CERTAIN PROVISIONS RE-
25 GARDING OBLIGATED SERVICE.—Except to the extent in-

1 consistent with this section, the provisions of sections
2 338B, 338C, and 338E shall apply to the program estab-
3 lished under this section to the same extent and in the
4 same manner as such provisions apply to the National
5 Health Service Corps Loan Repayment Program estab-
6 lished under section 338B.

7 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts
8 appropriated for a fiscal year for contracts under sub-
9 section (a) are authorized to remain available until the ex-
10 piration of the second fiscal year beginning after the fiscal
11 year for which the amounts were appropriated.”

12 **SEC. 1043. REPORT.**

13 Not later than 18 months after the date of the enact-
14 ment of this Act, the Director of the National Institutes
15 of Health shall submit to Congress a report on efforts of
16 the National Institutes of Health to attract, retain, and
17 develop emerging scientists (as defined in section
18 402A(c)(1)(C)(iv) of the Public Health Service Act, as
19 amended by section 1041).

20 **Subtitle D—Capstone Grant**
21 **Program**

22 **SEC. 1061. CAPSTONE AWARD.**

23 Part G of title IV of the Public Health Service Act
24 (42 U.S.C. 288 et seq.) is amended by adding at the end
25 the following:

1 **“SEC. 490. CAPSTONE AWARD.**

2 “(a) IN GENERAL.—The Secretary may make awards
3 (each of which, hereafter in this section, referred to as
4 a ‘Capstone Award’) to support outstanding scientists who
5 have been funded by the National Institutes of Health.

6 “(b) PURPOSE.—Capstone Awards shall be made to
7 facilitate the successful transition or conclusion of re-
8 search programs, or for other purposes, as determined by
9 the Director of NIH, in consultation with the directors
10 of the national research institutes and national centers.

11 “(c) DURATION AND AMOUNT.—The duration and
12 amount of each Capstone Award shall be determined by
13 the Director of NIH in consultation with the directors of
14 the national research institutes and national centers.

15 “(d) LIMITATION.—Individuals who have received a
16 Capstone Award shall not be eligible to have principle in-
17 vestigator status on subsequent awards from the National
18 Institutes of Health.”

19 **Subtitle E—Promoting Pediatric**
20 **Research Through the National**
21 **Institutes of Health**

22 **SEC. 1081. NATIONAL PEDIATRIC RESEARCH NETWORK.**

23 Section 409D(d) of the Public Health Service Act (42
24 U.S.C. 284h(d)) is amended—

25 (1) in paragraph (1)—

1 (A) by striking “in consultation with the
2 Director of the Eunice Kennedy Shriver Na-
3 tional Institute of Child Health and Human
4 Development and in collaboration with other
5 appropriate national research institutes and na-
6 tional centers that carry out activities involving
7 pediatric research” and inserting “in collabora-
8 tion with the national research institutes and
9 national centers that carry out activities involv-
10 ing pediatric research”;

11 (B) by striking subparagraph (B);

12 (C) by striking “may be comprised of, as
13 appropriate” and all that follows through “the
14 pediatric research consortia” and inserting
15 “may be comprised of, as appropriate, the pedi-
16 atric research consortia”; and

17 (D) by striking “; or” at the end and in-
18 serting a period; and

19 (2) in paragraph (1), paragraph (2)(A), the
20 first sentence of paragraph (2)(E), and paragraph
21 (4), by striking “may” each place it appears and in-
22 serting “shall”.

23 **SEC. 1082. GLOBAL PEDIATRIC CLINICAL TRIAL NETWORK**
24 **SENSE OF CONGRESS.**

25 It is the sense of Congress that—

1 (1) the National Institutes of Health should en-
2 courage a global pediatric clinical trial network
3 through the allocation of grants, contracts, or coop-
4 erative agreements to supplement the salaries of new
5 and early investigators who participate in the global
6 pediatric clinical trial network;

7 (2) National Institutes of Health grants, con-
8 tracts, or cooperative agreements should be awarded,
9 solely for the purpose of supplementing the salaries
10 of new and early investigators, to entities that par-
11 ticipate in the global pediatric clinical trial network;

12 (3) the Food and Drug Administration should
13 engage the European Medicines Agency and other
14 foreign regulatory entities during the formation of
15 the global pediatric clinical trials network to encour-
16 age their participation; and

17 (4) once a global pediatric clinical trial network
18 is established and becomes operational, the Food
19 and Drug Administration should continue to engage
20 the European Medicines Agency and other foreign
21 regulatory entities to encourage and facilitate their
22 participation in the network with the goal of enhanc-
23 ing the global reach of the network.

1 **Subtitle F—Advancement of Na-**
2 **tional Institutes of Health Re-**
3 **search and Data Access**

4 **SEC. 1101. SHARING OF DATA GENERATED THROUGH NIH-**
5 **FUNDED RESEARCH.**

6 Part H of title IV of the Public Health Service Act
7 (42 U.S.C. 282b et seq.) is amended by adding at the end
8 the following:

9 **“SEC. 498E. SHARING OF DATA GENERATED THROUGH NIH-**
10 **FUNDED RESEARCH.**

11 “(a) **AUTHORITY.**—As a condition on the award of
12 a grant or the provision of other financial support for re-
13 search, irrespective of whether the research is fully or only
14 partially funded through such grant or other support, the
15 Director of NIH may require the recipients of such grant
16 or other support to share scientific data generated from
17 research funded by the National Institutes of Health.

18 **【“(b) LIMITATION.**—Subsection (a) does not author-
19 ize the Director of NIH to require the sharing of—**】**

20 **【“(1) any individually identifiable information**
21 **with respect to a human subject participating in the**
22 **research; or**】****

23 **【“(2) any trade secret or commercial or finan-**
24 **cial information that is privileged or confidential.”**】****

1 **SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL**
2 **REGISTRY DATA BANK ON ELIGIBILITY FOR**
3 **CLINICAL TRIALS.**

4 (a) STANDARDIZATION.—

5 (1) IN GENERAL.—Section 402(j) of the Public
6 Health Service Act (42 U.S.C. 282(j)) is amended—

7 (A) by redesignating paragraph (7) as
8 paragraph (8); and

9 (B) by inserting after paragraph (6) the
10 following:

11 “(7) STANDARDIZATION.—The Director of NIH
12 shall ensure that—

13 “(A) the registry and results data bank is
14 easily used by the public;

15 “(B) entries in the registry and results
16 data bank are easily compared; and

17 [“(C) information required to be sub-
18 mitted to the registry and results data bank, in-
19 cluding recruitment information under para-
20 graph (2)(A)(ii)(II), is submitted by persons
21 and posted by the Director of NIH in a stand-
22 ardized format and shall include at least the
23 following:]

24 [“(i) the disease or indication being
25 studied;]

1 【“(ii) inclusion criteria such as age,
2 gender, diagnosis or diagnoses, lab values,
3 and imaging results; and】

4 【“(iii) exclusion criteria such as spe-
5 cific diagnosis or diagnoses, lab values, and
6 prohibited medications.】

7 【To the extent feasible, in applying this paragraph,
8 the National Institutes of Health shall give consider-
9 ation to health care terminology and eligibility cri-
10 teria that are for electronic matching to diagnosis or
11 procedure coding systems, such as the International
12 Classification of Diseases or the Current Procedural
13 Terminology, and integration into electronic health
14 records.】”】

15 (2) CONFORMING AMENDMENT.—Clause (iv) of
16 section 402(j)(2)(B) of the Public Health Service
17 Act (42 U.S.C. 282(j)(2)(B)) is hereby stricken.

18 (b) CONSULTATION.—Not later than 90 days after
19 the date of enactment of this Act, the Secretary of Health
20 and Human Services shall consult with stakeholders (in-
21 cluding patients, researchers, physicians, industry rep-
22 resentatives, health information technology providers, and
23 the Food and Drug Administration) to receive advice on
24 enhancements to the clinical trial registry data bank under
25 section 402(j) of the Public Health Service Act (42 U.S.C.

1 282(j)) (including enhancements to usability,
2 functionality, and search capability) that are necessary to
3 implement paragraph (7) of section 402(j) of such Act,
4 as added by subsection (a).

5 (c) APPLICABILITY.—Not later than [_____]]
6 after the date of enactment of this Act, the Secretary of
7 Health and Human Services shall begin implementation
8 of paragraph (7) of section 402(j) of the Public Health
9 Service Act, as added by subsection (a).

10 **Subtitle G—Facilitating** 11 **Collaborative Research**

12 **[SEC. 1121. CLINICAL TRIAL DATA SYSTEM.**

13 [(a) ESTABLISHMENT.—The Secretary, acting
14 through the Commissioner of Food and Drugs and the Di-
15 rector of the National Institutes of Health, shall enter into
16 a collaborative agreement, to be known as the Clinical
17 Trial Data System Agreement, with one or more eligible
18 entities to implement a system to make de-identified clin-
19 ical trial data from qualified clinical trials available for
20 purposes of conducting further research.]

21 [(b) APPLICATION.—Eligible entities seeking to enter
22 into a cooperative agreement with the Secretary under this
23 section shall submit to the Secretary an application in
24 such time and manner, and containing such information,

1 as the Secretary may require. Any such application shall
2 include the following:】

3 【(1) A certification that each applicant is not
4 currently and does not plan to be involved in spon-
5 soring, operating, or participating in a clinical trial
6 nor collaborating with another entity for the pur-
7 poses of sponsoring, operating, or participating in a
8 clinical trial.】

9 【(2) A description of how each applicant will
10 compile clinical trial data in standardized formats
11 using terminologies and standards that have been
12 developed by recognized standards developing orga-
13 nizations with input from diverse stakeholder
14 groups, and a description of the methodologies to be
15 used to de-identify clinical trial data consistent with
16 the requirements of section 164.514 of title 45, Code
17 of Federal Regulations (or successor regulations).】

18 【(3) Documentation establishing that each ap-
19 plicant has a plan in place to allow registered users
20 to access and use de-identified clinical trial data,
21 gathered from qualified clinical trials, available
22 under carefully controlled contractual terms as de-
23 fined by the Secretary.】

24 【(4) Evidence demonstrating the ability to en-
25 sure dissemination of the results of the research to

1 interested parties to serve as a guide to future med-
2 ical product development or scientific research.】

3 【(5) The plan of each applicant for securing
4 funding for the partnership described in paragraph
5 (2) from governmental sources and private founda-
6 tions, entities, and individuals.】

7 【(6) Evidence demonstrating a proven track
8 record of—】

9 【(A) being a neutral third party in work-
10 ing with medical product manufacturers, aca-
11 demic institutions, and the Food and Drug Ad-
12 ministration; and】

13 【(B) having the ability to protect confiden-
14 tial data.】

15 【(c) DEFINITIONS.—In this section:】

16 【(1) The term “eligible entity” means an entity
17 that has experienced personnel with clinical and
18 other technical expertise in the biomedical sciences
19 and biomedical ethics and that is—】

20 【(A) an institution of higher education (as
21 such term is defined in section 1001 of the
22 Higher Education Act of 1965 (20 U.S.C.
23 1001)) or a consortium of such institutions; or】

24 【(B) an organization described in section
25 501(c)(3) of title 26 of the Internal Revenue

1 Code of 1986 and exempt from tax under sec-
2 tion 501(a) of such title.】

3 【(2) The term “medical product” means a drug
4 (as defined in subsection (g) of section 201 of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 331), a device (as defined in subsection (h) of such
7 section), a biological product (as defined in section
8 351 of the Public Health Service Act (42 U.S.C.
9 262), or any combination thereof.】

10 【(3) The term “qualified clinical trial” means
11 a clinical trial sponsored solely by an agency of the
12 Department of Health and Human Services with re-
13 spect to a medical product—】

14 【(A) that was—】

15 【(i) approved or cleared under section
16 505, 510(k), or 515, or has an exemption
17 for investigational use in effect under sec-
18 tion 505 or 520(m), of the Federal Food,
19 Drug, and Cosmetic Act (42 U.S.C. 301 et
20 seq.); or】

21 【(ii) licensed under section 351 of the
22 Public Health Service Act (42 U.S.C. 262)
23 or has an exemption for investigational use
24 in effect under such section 351; or】

1 【(B) that is an investigational product for
2 which the original development was discon-
3 tinued and with respect to which—】

4 【(i) no additional work to support ap-
5 proval, licensure, or clearance of such med-
6 ical product is being or is planned to be
7 undertaken by the sponsor of the original
8 development program, its successors, as-
9 signs, or collaborators; and】

10 【(ii) the sponsor of the original inves-
11 tigational development program has pro-
12 vided its consent to the Secretary for inclu-
13 sion of data regarding such product in the
14 system established under this section.】

15 **SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**
16 **LANCE SYSTEM.**

17 Part P of title III of the Public Health Service Act
18 (42 U.S.C. 280g et seq.) is amended by adding at the end
19 the following:

20 **“SEC. 399V-6 SURVEILLANCE OF NEUROLOGICAL DISEASES.**

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Director of the Centers for Disease Control and Pre-
23 vention and in coordination with other agencies as deter-
24 mined appropriate by the Secretary, shall—

1 “(1) enhance and expand infrastructure and ac-
2 tivities to track the epidemiology of neurological dis-
3 eases, including multiple sclerosis and Parkinson’s
4 disease; and

5 “(2) incorporate information obtained through
6 such activities into a statistically sound, scientifically
7 credible, integrated surveillance system, to be known
8 as the National Neurological Diseases Surveillance
9 System.

10 “(b) RESEARCH.—The Secretary shall ensure that
11 the National Neurological Diseases Surveillance System is
12 designed in a manner that facilitates further research on
13 neurological diseases.

14 “(c) CONTENT.—In carrying out subsection (a), the
15 Secretary—

16 “(1) shall provide for the collection and storage
17 of information on the incidence and prevalence of
18 neurological diseases in the United States;

19 “(2) to the extent practicable, shall provide for
20 the collection and storage of other available informa-
21 tion on neurological diseases, such as information
22 concerning—

23 “(A) demographics and other information
24 associated or possibly associated with neuro-

1 logical diseases, such as age, race, ethnicity,
2 sex, geographic location, and family history;

3 “(B) risk factors associated or possibly as-
4 sociated with neurological diseases, including
5 genetic and environmental risk factors; and

6 “(C) diagnosis and progression markers;

7 “(3) may provide for the collection and storage
8 of information relevant to analysis on neurological
9 diseases, such as information concerning—

10 “(A) the epidemiology of the diseases;

11 “(B) the natural history of the diseases;

12 “(C) the prevention of the diseases;

13 “(D) the detection, management, and
14 treatment approaches for the diseases; and

15 “(E) the development of outcomes meas-
16 ures; and

17 “(4) may address issues identified during the
18 consultation process under subsection (d).

19 “(d) CONSULTATION.—In carrying out this section,
20 the Secretary shall consult with individuals with appro-
21 priate expertise, including—

22 “(1) epidemiologists with experience in disease
23 surveillance or registries;

24 “(2) representatives of national voluntary
25 health associations that—

1 “(A) focus on neurological diseases, includ-
2 ing multiple sclerosis and Parkinson’s disease;
3 and

4 “(B) have demonstrated experience in re-
5 search, care, or patient services;

6 “(3) health information technology experts or
7 other information management specialists;

8 “(4) clinicians with expertise in neurological
9 diseases; and

10 “(5) research scientists with experience con-
11 ducting translational research or utilizing surveil-
12 lance systems for scientific research purposes.

13 “(e) GRANTS.—The Secretary may award grants to,
14 or enter into contracts or cooperative agreements with,
15 public or private nonprofit entities to carry out activities
16 under this section.

17 “(f) COORDINATION WITH OTHER FEDERAL, STATE,
18 AND LOCAL AGENCIES.—Subject to subsection (h), the
19 Secretary shall make information and analysis in the Na-
20 tional Neurological Diseases Surveillance System avail-
21 able, as appropriate—

22 “(1) to Federal departments and agencies, such
23 as the National Institutes of Health, the Food and
24 Drug Administration, the Centers for Medicare &
25 Medicaid Services, the Agency for Healthcare Re-

1 search and Quality, the Department of Veterans Af-
2 fairs, and the Department of Defense; and

3 “(2) to State and local agencies.

4 “(g) PUBLIC ACCESS.—Subject to subsection (h), the
5 Secretary shall make information and analysis in the Na-
6 tional Neurological Diseases Surveillance System avail-
7 able, as appropriate, to the public, including researchers.

8 “(h) PRIVACY.—The Secretary shall ensure that pri-
9 vacy and security protections applicable to the National
10 Neurological Diseases Surveillance System are at least as
11 stringent as the privacy and security protections under
12 HIPAA privacy and security law (as defined in section
13 3009(a)(2)).

14 “(i) REPORT.—Not later than 4 years after the date
15 of the enactment of this section, the Secretary shall sub-
16 mit a report to the Congress concerning the implementa-
17 tion of this section. Such report shall include information
18 on—

19 “(1) the development and maintenance of the
20 National Neurological Diseases Surveillance System;

21 “(2) the type of information collected and
22 stored in the System;

23 “(3) the use and availability of such informa-
24 tion, including guidelines for such use; and

1 “(4) the use and coordination of databases that
2 collect or maintain information on neurological dis-
3 eases.

4 “(j) DEFINITION.—In this section, the term ‘national
5 voluntary health association’ means a national nonprofit
6 organization with chapters, other affiliated organizations,
7 or networks in States throughout the United States.

8 “(k) AUTHORIZATION OF APPROPRIATIONS.—To
9 carry out this section, there is authorized to be appro-
10 priated [\$_____] for each of fiscal years 2015 through
11 2019.”.

12 **SEC. 1123. PUBLIC-PRIVATE PARTNERSHIP FOR INFORMA-**
13 **TION TECHNOLOGY SYSTEM ON DATA ON**
14 **NATURAL HISTORY OF DISEASES.**

15 Part A of title II of the Public Health Service Act
16 (42 U.S.C. 202 et seq.) is amended by adding at the end
17 the following:

18 **“SEC. 229A. PUBLIC-PRIVATE PARTNERSHIP FOR INFORMA-**
19 **TION TECHNOLOGY SYSTEM ON DATA ON**
20 **NATURAL HISTORY OF DISEASES.**

21 “(a) IN GENERAL.—The Secretary shall enter into
22 a public-private partnership to establish or enhance and
23 support an information technology system, including staff-
24 ing, to collect, maintain, analyze, and interpret data on

1 the natural history of diseases, with a particular focus on
2 rare diseases. Such partnership shall—

3 “(1) build on and cooperate with other disease
4 registries, including disease registries and disease
5 registry platforms for rare diseases;

6 “(2) develop or enhance a secure information
7 technology system that—

8 “(A) has the capacity to support data
9 needs across a wide range of diseases;

10 “(B) is easily modified as knowledge is
11 gained during studies; and

12 “(C) is capable of handling increasing
13 amounts of data as more studies are carried
14 out;

15 “(3) hire professional staff, including biostat-
16 isticians, study coordinators, and individuals with
17 experience and knowledge of medical product devel-
18 opment—

19 “(A) to maintain and oversee operation of
20 the information technology system;

21 “(B) to collect, manage, analyze, update,
22 and interpret data from studies on the natural
23 history of diseases;

1 “(C) to provide advice to clinical research-
2 ers on the appropriate design of such studies;
3 and

4 “(D) to advise patient groups in—
5 “(i) how to design and conduct such
6 studies; and

7 “(ii) how to modify any such ongoing
8 studies;

9 “(4) obtain professional advice to address pri-
10 vacy issues associated with the operation of the part-
11 nership’s information technology system; and

12 “(5) award grants to patient and other organi-
13 zations for studies on the natural history of diseases
14 through registries and information technology struc-
15 tures that complement, but are separate from, the
16 system established by such public-private partner-
17 ship.

18 “(b) AVAILABILITY OF DATA.—The data aggregated
19 in the system maintained under subsection (a) shall be
20 available, consistent with otherwise applicable Federal and
21 State privacy laws, to the public (including patient advo-
22 cacy groups, researchers, and drug developers) to help re-
23 duce the time and size of drug development programs.

1 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 **[\$_____]** for each of fiscal years 2016 through 2020.”.

4 **SEC. 1124. ACCESSING, SHARING, AND USING HEALTH DATA**
5 **FOR RESEARCH PURPOSES.**

6 (a) IN GENERAL.—The HITECH Act (title XIII of
7 division A of Public Law 111–5) is amended by adding
8 at the end of subtitle D of such Act (42 U.S.C. 17921
9 et seq.) the following:

10 **“PART 4—ACCESSING, SHARING, AND USING**
11 **HEALTH DATA FOR RESEARCH PURPOSES**

12 **“SEC. 13441. REFERENCES.**

13 “In this part:

14 “(a) THE RULE.—References to ‘the Rule’ refer to
15 part 160 or part 164, as appropriate, of title 45, Code
16 of Federal Regulations (or any successor regulation).

17 “(b) PART 164.—References to a specified section of
18 ‘part 164’, refer to such specified section of part 164 of
19 title 45, Code of Federal Regulations (or any successor
20 section).

21 **“SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART**
22 **OF HEALTH CARE OPERATIONS.**

23 “(a) IN GENERAL.—Subject to subsection (b), the
24 Secretary shall revise or clarify the Rule to allow the use
25 and disclosure of protected health information by a cov-

1 ered entity for research purposes, including studies whose
2 purpose is to obtain generalizable knowledge, to be treated
3 as the use and disclosure of such information for health
4 care operations described in subparagraph (1) of the defi-
5 nition of health care operations in section 164.501 of part
6 164.

7 “(b) MODIFICATIONS TO RULES FOR DISCLOSURES
8 FOR HEALTH CARE OPERATIONS.—In applying section
9 164.506 of part 164 to the disclosure of protected health
10 information described in subsection (a)—

11 “(1) the Secretary shall revise or clarify the
12 Rule so that the disclosure may be made by the cov-
13 ered entity to only—

14 “(A) another covered entity for health care
15 operations (as defined in such section 164.501
16 of part 164);

17 “(B) a business associate that has entered
18 into a contract under section 164.504(e) of part
19 164 with a disclosing covered entity to perform
20 health care operations; or

21 “(C) a business associate that has entered
22 into a contract under section 164.504(e) of part
23 164 for the purpose of data aggregation (as de-
24 fined in such section 164.501 of part 164); and

1 “(2) the Secretary shall further revise or clarify
2 the Rule so that the limitation specified by section
3 164.506(c)(4) of part 164 does not apply to disclo-
4 sures that are described by subsection (a).

5 “(c) RULE OF CONSTRUCTION.—This section shall
6 not be construed as prohibiting or restricting a use or dis-
7 closure of protected health information for research pur-
8 poses that is otherwise permitted under part 164.

9 **“SEC. 13443. TREATING DISCLOSURES OF PROTECTED**
10 **HEALTH INFORMATION FOR RESEARCH SIMI-**
11 **LARLY TO DISCLOSURES OF SUCH INFORMA-**
12 **TION FOR PUBLIC HEALTH PURPOSES.**

13 “(a) REMUNERATION.—The Secretary shall revise or
14 clarify the Rule so that disclosures of protected health in-
15 formation for research purposes are not subject to the lim-
16 itation on remuneration described in section
17 164.502(a)(5)(ii)(B)(2)(i) of part 164.

18 “(b) PERMITTED USES AND DISCLOSURES.—The
19 Secretary shall revise or clarify the Rule so that research
20 activities, including comparative research activities, re-
21 lated to the quality, safety, or effectiveness of a product
22 or activity that is regulated by the Food and Drug Admin-
23 istration are included as public health activities for pur-
24 poses of which a covered entity may disclose protected

1 health information to a person described in section
2 164.512(b)(1)(iii) of part 164.

3 **“SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED**
4 **HEALTH INFORMATION BY RESEARCHERS.**

5 “The Secretary shall revise or clarify the Rule so that
6 subparagraph (B) of section 164.512(i)(1)(ii) of part 164
7 (prohibiting the removal of protected health information
8 by a researcher) shall not prohibit remote access to health
9 information by a researcher so long as—

10 “(1) appropriate security and privacy safe-
11 guards are maintained by the covered entity and the
12 researcher; and

13 “(2) the protected health information is not
14 copied or otherwise retained by the researcher.

15 **“SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE**
16 **AND DISCLOSURE OF PROTECTED HEALTH**
17 **INFORMATION FOR RESEARCH PURPOSES.**

18 “(a) IN GENERAL.—The Secretary shall revise or
19 clarify the Rule to specify that an authorization for the
20 use or disclosure of protected health information, with re-
21 spect to an individual, for future research purposes shall
22 be deemed to contain a sufficient description of the pur-
23 pose of the use or disclosure if the authorization—

24 “(1) sufficiently describes the purposes such
25 that it would be reasonable for the individual to ex-

1 pect that the protected health information could be
2 used or disclosed for such future research;

3 “(2) either—

4 “(A) states that the authorization will ex-
5 pire on a particular date or on the occurrence
6 of a particular event; or

7 “(B) states that the authorization will re-
8 main valid unless and until it is revoked by the
9 individual; and

10 “(3) provides instruction to the individual on
11 how to revoke such authorization at any time.

12 “(b) REVOCATION OF AUTHORIZATION.—The Sec-
13 retary shall revise or clarify the Rule to specify that, if
14 an individual revokes an authorization for future research
15 purposes such as is described by subsection (a), the cov-
16 ered entity may not make any further uses or disclosures
17 based on that authorization, except, as provided in para-
18 graph (b)(5) of section 164.508 of part 164, to the extent
19 that the covered entity has taken action in reliance on the
20 authorization.”.

21 (b) REVISION OF REGULATIONS.—Not later than 12
22 months after the date of the enactment of this Act, the
23 Secretary of Health and Human Services shall revise and
24 clarify the provisions of title 45, Code of Federal Regula-

1 tions, for consistency with part 4 of subtitle D of the
2 HITECH Act, as added by subsection (a).

3 **Subtitle H—Council for 21st**
4 **Century Cures**

5 **SEC. 1141. COUNCIL FOR 21ST CENTURY CURES.**

6 Title II of the Public Health Service Act (42 U.S.C.
7 202 et seq.) is amended by adding at the end the fol-
8 lowing:

9 **“PART E—COUNCIL FOR 21ST CENTURY CURES**

10 **“SEC. 281. ESTABLISHMENT.**

11 “A nonprofit corporation to be known as Council for
12 21st Century Cures (referred to in this part as the ‘Coun-
13 cil’) shall be established in accordance with this section.
14 The Council shall be a public-private partnership headed
15 by an Executive Director (referred to in this part as the
16 ‘Executive Director’), appointed by the members of the
17 Board of Directors. The Council shall not be an agency
18 or instrumentality of the United States Government.

19 **“SEC. 281A. PURPOSE.**

20 “The purpose of the Council is to accelerate the dis-
21 covery, development, and delivery in the United States of
22 innovative cures, treatments, and preventive measures for
23 patients.

1 **“SEC. 281B. DUTIES.**

2 “For the purpose described in section 281A, the
3 Council shall—

4 “(1) foster collaboration and coordination
5 among the entities that comprise the Council, includ-
6 ing academia, government agencies, industry, health
7 care payors and providers, patient advocates, and
8 others engaged in the cycle of discovery, develop-
9 ment, and delivery of life-saving and health-enhanc-
10 ing innovative interventions;

11 “(2) undertake communication and dissemina-
12 tion activities;

13 “(3) publish information on the activities fund-
14 ed under section 281D;

15 “(4) establish a strategic agenda for accel-
16 erating the discovery, development, and delivery in
17 the United States of innovative cures, treatments,
18 and preventive measures for patients;

19 “(5) identify gaps and opportunities within and
20 across the discovery, development, and delivery cycle;

21 “(6) develop and propose recommendations
22 based on the gaps and opportunities so identified;

23 “(7) facilitate the interoperability of the compo-
24 nents of the discovery, development, and delivery
25 cycle;

1 “(8) propose recommendations that will facili-
2 tate precompetitive collaboration;

3 “(9) identify opportunities to work with, but
4 not duplicate the efforts of, non-profits and other
5 public-private partnerships; and

6 “(10) identify opportunities for collaboration
7 with organizations operating outside of the United
8 States, such as the Innovative Medicines Initiative of
9 the European Union.

10 **“SEC. 281C. ORGANIZATION; ADMINISTRATION.**

11 “(a) BOARD OF DIRECTORS.—

12 “(1) ESTABLISHMENT.—

13 “(A) IN GENERAL.—The Council shall
14 have a Board of Directors (in this part referred
15 to as the ‘Board of Directors’), which shall be
16 composed of the ex officio members under sub-
17 paragraph (B) and the appointed members
18 under subparagraph (C). All members of the
19 Board shall be voting members.

20 “(B) EX OFFICIO MEMBERS.—The ex offi-
21 cio members of the Board shall be the following
22 individuals or their designees:

23 “(i) The Director of the National In-
24 stitutes of Health.

1 “(ii) The Commissioner of Food and
2 Drugs.

3 “(iii) The Administrator of the Cen-
4 ters for Medicare & Medicaid Services.

5 “(iv) The heads of five other Federal
6 agencies deemed to be engaged in bio-
7 medical research and development.

8 “(C) APPOINTED MEMBERS.—The ap-
9 pointed members of the Board shall consist of
10 17 individuals, of whom—

11 “(i) 8 shall be by the Comptroller
12 General of the United States from a list of
13 nominations submitted by leading trade as-
14 sociations—

15 “(I) 4 of whom shall be rep-
16 resentatives of the biopharmaceutical
17 industry;

18 “(II) 2 of whom shall be rep-
19 resentatives of the medical device in-
20 dustry; and

21 “(III) 2 of whom shall be rep-
22 resentatives of the information and
23 digital technology industry; and

1 “(ii) 7 shall be appointed by the
2 Comptroller General of the United States,
3 after soliciting nominations—

4 “(I) 2 of whom shall be rep-
5 resentatives of academic researchers;

6 “(II) 3 of whom shall be rep-
7 resentative of patients;

8 “(III) 2 of whom shall be rep-
9 resentatives of health care providers;
10 and

11 “(IV) 2 of whom shall be rep-
12 resentatives of health care plans and
13 insurers.

14 “(D) CHAIR.—The Chair of the Board
15 shall be selected by the members of the Board
16 by majority vote from among the members of
17 the Board.

18 “(2) TERMS AND VACANCIES.—

19 “(A) IN GENERAL.—The term of office of
20 each member of the Board appointed under
21 paragraph (1)(C) shall be 5 years.

22 “(B) VACANCY.—Any vacancy in the mem-
23 bership of the Board—

1 “(i) shall not affect the power of the
2 remaining members to execute the duties
3 of the Board; and

4 “(ii) shall be filled by appointment by
5 the appointed members described in para-
6 graph (1)(C) by majority vote.

7 “(C) PARTIAL TERM.—If a member of the
8 Board does not serve the full term applicable
9 under subparagraph (A), the individual ap-
10 pointed under subparagraph (B) to fill the re-
11 sulting vacancy shall be appointed for the re-
12 mainder of the term of the predecessor of the
13 individual.

14 “(3) RESPONSIBILITIES.—Not later than 90
15 days after the date of the enactment of the 21st
16 Century Cures Act, the Board of Directors shall es-
17 tablish bylaws and policies for the Council that—

18 “(A) are published in the Federal Register
19 and available for public comment;

20 “(B) establish policies for the selection
21 and, as applicable, appointment of—

22 “(i) the officers, employees, agents,
23 and contractors of the Council; and

24 “(ii) the members of any committees
25 of the Council;

1 “(C) establish policies, including ethical
2 standards, for the conduct of programs and
3 other activities under section 281D; and

4 “(D) establish specific duties of the Execu-
5 tive Director.

6 “(4) MEETINGS.—

7 “(A) IN GENERAL.—the Board of Direc-
8 tors shall—

9 “(i) meet on a quarterly basis; and

10 “(ii) submit to Congress, and make
11 publicly available, the minutes of such
12 meetings.

13 “(B) AGENDA.—The Board of Directors
14 shall, not later than 3 months after the incorpo-
15 ration of the Council—

16 “(i) issue an agenda (in this part re-
17 ferred to as the ‘agenda’) outlining how
18 the Council will achieve the purpose de-
19 scribed in section 281A; and

20 “(ii) annually thereafter, in consulta-
21 tion with the Executive Director, review
22 and update such agenda.

23 “(b) INCORPORATION.—The ex officio members of
24 the Board of Directors shall serve as incorporators and

1 shall take whatever actions necessary to incorporate the
2 Council by not later than January 1, 2016.

3 “(c) NONPROFIT STATUS.—In carrying out this part,
4 the Board of Directors shall establish such policies and
5 bylaws, and the Executive Director shall carry out such
6 activities, as may be necessary to ensure that the Council
7 maintains status as an organization that—

8 “(1) is described in subsection (c)(3) of section
9 501 of the Internal Revenue Code of 1986; and

10 “(2) is, under subsection (a) of such section, ex-
11 empt from taxation.

12 “(d) EXECUTIVE DIRECTOR.—The Executive Direc-
13 tor shall—

14 “(1) be the chief executive officer of the Coun-
15 cil; and

16 “(2) subject to the oversight of the Board of
17 Directors, be responsible for the day-to-day manage-
18 ment of the Council.

19 **“SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.**

20 “(a) IN GENERAL.—The Council shall establish a
21 sufficient operational infrastructure to fulfill the duties
22 specified in section 281B.

23 “(b) PRIVATE SECTOR MATCHING FUNDS.—The
24 Council may accept financial or in-kind support from par-

1 participating entities or private foundations or organizations
2 when such support is deemed appropriate.

3 **“SEC. 281E. TERMINATION; REPORT.**

4 “(a) IN GENERAL.—The Council shall terminate on
5 September 30, 2023.

6 “(b) REPORT.—Not later than one year after the
7 date on which the Council is established and each year
8 thereafter, the Executive Director shall submit to the ap-
9 propriate congressional committees a report on the per-
10 formance of the Council. In preparing such report, the
11 Council shall consult with a nongovernmental consultant
12 with appropriate expertise.

13 **“SEC. 281F. FUNDING.**

14 “For the period of fiscal years 2016 through 2023,
15 the Secretary shall make a payment to the Council for
16 purposes of carrying out the duties of the Council under
17 this part in an amount of not less than
18 **【\$_____】.**”.

1 **TITLE II—DEVELOPMENT**
2 **Subtitle A—Patient-Focused Drug**
3 **Development**

4 **SEC. 2001. DEVELOPMENT AND USE OF PATIENT EXPERI-**
5 **ENCE DATA TO ENHANCE STRUCTURED RISK-**
6 **BENEFIT ASSESSMENT FRAMEWORK.**

7 (a) IN GENERAL.—Section 505 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

9 (1) in subsection (d), by striking “The Sec-
10 retary shall implement” and all that follows through
11 “premarket approval of a drug.”; and

12 (2) by adding at the end the following new sub-
13 sections:

14 “(x) STRUCTURED RISK-BENEFIT ASSESSMENT
15 FRAMEWORK.—

16 “(1) IN GENERAL.—The Secretary shall imple-
17 ment a structured risk-benefit assessment frame-
18 work in the new drug approval process—

19 “(A) to facilitate the balanced consider-
20 ation of benefits and risks; and

21 “(B) to develop and implement a con-
22 sistent and systematic approach to the discus-
23 sion of, regulatory decisionmaking with respect
24 to, and the communication of, the benefits and
25 risks of new drugs.

1 “(2) RULE OF CONSTRUCTION.—Nothing in
2 paragraph (1) shall alter the criteria for evaluating
3 an application for premarket approval of a drug.

4 “(y) DEVELOPMENT AND USE OF PATIENT EXPERI-
5 ENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT
6 ASSESSMENT FRAMEWORK.—

7 “(1) IN GENERAL.—Not later than two years
8 after the date of the enactment of this subsection,
9 the Secretary shall establish and implement proc-
10 esses under which—

11 “(A) an entity seeking to develop patient
12 experience data may submit to the Secretary—

13 “(i) initial research concepts for feed-
14 back from the Secretary; and

15 “(ii) with respect to patient experience
16 data collected by the entity, draft guidance
17 documents, completed data, and sum-
18 maries and analyses of such data;

19 “(B) the Secretary may request such an
20 entity to submit such documents, data, and
21 summaries and analyses; and

22 “(C) patient experience data may be devel-
23 oped and used to enhance the structured risk-
24 benefit assessment framework under subsection
25 (x).

1 “(2) PATIENT EXPERIENCE DATA.—In this sub-
2 section, the term ‘patient experience data’ means
3 data collected by patients, parents, caregivers, pa-
4 tient advocacy organizations, disease research foun-
5 dations, medical researchers, research sponsors or
6 other parties determined appropriate by the Sec-
7 retary that is intended to facilitate or enhance the
8 Secretary’s risk-benefit assessments, including infor-
9 mation about the impact of a disease or a therapy
10 on patients’ lives.”.

11 (b) GUIDANCE.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services shall publish guidance on the imple-
14 mentation of subsection (y) of section 505 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355), as added by subsection (a). Such guidance
17 shall include—

18 (A) with respect to draft guidance docu-
19 ments, data, or summaries and analyses sub-
20 mitted to the Secretary under paragraph (1)(A)
21 of such subsection, guidance—

22 (i) specifying the timelines for the re-
23 view of such documents, data, or sum-
24 maries and analyses by the Secretary; and

1 (ii) on how the Secretary will use such
2 documents, data, or summaries and anal-
3 yses to update any guidance documents
4 published under this subsection or publish
5 new guidance;

6 (B) with respect to the collection and anal-
7 ysis of patient experience data (as defined in
8 paragraph (2) of such subsection (y)), guidance
9 on—

10 (i) methodological considerations for
11 the collection of patient experience data,
12 which may include structured approaches
13 to gathering information on—

14 (I) the experience of a patient liv-
15 ing with a particular disease;

16 (II) the burden of living with or
17 managing the disease;

18 (III) the impact of the disease on
19 daily life and long-term functioning;
20 and

21 (IV) the effect of current thera-
22 peutic options on different aspects of
23 the disease; and

24 (ii) the establishment and mainte-
25 nance of registries designed to increase un-

1 derstanding of the natural history of a dis-
2 ease;

3 (C) methodological approaches that may be
4 used to assess patients' beliefs with respect to
5 the benefits and risks in the management of the
6 patient's disease; and

7 (D) methodologies, standards, and poten-
8 tial experimental designs for patient-reported
9 outcomes.

10 (2) TIMING.—Not later than three years after
11 the date of the enactment of this Act, the Secretary
12 of Health and Human Services shall issue draft
13 guidance on the implementation of subsection (y) of
14 section 505 of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 355), as added by subsection
16 (a). The Secretary shall issue final guidance on the
17 implementation of such subsection not later than one
18 year after the date on which the comment period for
19 the draft guidance closes.

20 (3) WORKSHOPS.—

21 (A) IN GENERAL.—Not later than 6
22 months after the date of the enactment of this
23 Act and once every 6 months during the fol-
24 lowing 12-month period, the Secretary of
25 Health and Human Services shall convene a

1 workshop to obtain input regarding methodolo-
2 gies for developing the guidance under para-
3 graph (1), including the collection of patient ex-
4 perience data.

5 (B) ATTENDEES.—A workshop convened
6 under this paragraph shall include—

7 (i) patients;

8 (ii) representatives from patient advo-
9 cacy organizations, biopharmaceutical com-
10 panies, and disease research foundations;

11 (iii) representatives of the reviewing
12 divisions of the Food and Drug Adminis-
13 tration; and

14 (iv) methodological experts with sig-
15 nificant expertise in patient experience
16 data.

17 (4) PUBLIC MEETING.—Not later than 90 days
18 after the date on which the draft guidance is pub-
19 lished under this subsection, the Secretary of Health
20 and Human Services shall convene a public meeting
21 to solicit input on the guidance.

1 **[Subtitle B—Qualification and Use**
2 **of Drug Development Tools]**

3 **[SEC. 2021. BIOMARKERS, SURROGATE ENDPOINTS, AND**
4 **OTHER DRUG DEVELOPMENT TOOLS.**

5 **[(a) FINDINGS.—Congress finds the following:]**

6 **[(1) development of new drugs has become in-**
7 **creasingly challenging and resource intensive;]**

8 **[(2) the development of biomarkers and other**
9 **drug development tools can benefit the availability of**
10 **new medical therapies by helping translate scientific**
11 **discoveries into clinical applications;]**

12 **[(3) medical research consortia, consisting of**
13 **public-private partnerships of government agencies,**
14 **institutions of higher education, patient advocacy**
15 **groups, industry representatives, clinical and sci-**
16 **entific experts, and other relevant entities and indi-**
17 **viduals can play a valuable role in helping develop**
18 **and qualify biomarkers and other drug development**
19 **tools; and]**

20 **[(4) it is the intent of Congress to promote and**
21 **facilitate a collaborative effort among such medical**
22 **research consortia to—]**

23 **[(A) develop, through a transparent public**
24 **process, data standards and scientific ap-**
25 **proaches to data collection accepted by the**

1 medical and clinical research community for
2 purposes of qualifying biomarkers and other
3 drug development tools;]

4 [(B) coordinate efforts toward developing
5 and qualifying biomarkers and other drug de-
6 velopment tools in key therapeutic areas; and]

7 [(C) encourage development of accessible
8 databases for collecting relevant biomarker data
9 for such purposes.]

10 [(b) QUALIFICATION OF BIOMARKERS, SURROGATE
11 ENDPOINTS, AND OTHER DRUG DEVELOPMENT TOOLS.—
12 Chapter V of the Federal Food, Drug, and Cosmetic Act,
13 as amended under this Act, is further amended by insert-
14 ing after section 506F the following new section:]

15 [“SEC. 507. QUALIFICATION OF BIOMARKERS, SURROGATE
16 ENDPOINTS, AND OTHER DRUG DEVELOP-
17 MENT TOOLS.

18 [“(a) IN GENERAL.—The Secretary shall, to facili-
19 tate the availability of qualified biomarkers, including sur-
20 rogate endpoints, and other drug development tools—]

21 [“(1) issue guidance in accordance with sub-
22 section (b) with respect to standards for the quali-
23 fication of biomarkers; and]

1 【“(2) establish a process for qualification of
2 biomarkers and other drug development tools in ac-
3 cordance with subsection (c).】

4 【“(b) GUIDANCE ON BIOMARKERS.—】

5 【“(1) IN GENERAL.—For purposes of this sec-
6 tion, the Secretary shall issue guidance which—】

7 【“(A) provides a conceptual framework de-
8 scribing appropriate standards and scientific
9 approaches to support the development of spe-
10 cific classes of biomarkers delineated under the
11 taxonomy established under paragraph (2);】

12 【“(B) makes recommendations for dem-
13 onstrating that a surrogate endpoint, as defined
14 in subsection (e), is reasonably likely to predict
15 clinical benefit for the purpose of supporting ac-
16 celerated approval of a drug in accordance with
17 section 506(c); and】

18 【“(C) includes such other information as
19 the Secretary determines appropriate.】

20 【“(2) GUIDANCE DEVELOPMENT TIMING AND
21 PROCESS.—Not later than 24 months after the date
22 of enactment of this Act, the Secretary shall issue
23 draft guidance on the implementation of this section.
24 The Secretary shall issue final guidance on the im-
25 plementation of this section not later than 6 months

1 after the date on which the comment period for the
2 draft guidance closes. Such guidance shall be devel-
3 oped in consultation with medical research consortia
4 and other interested parties through a collaborative
5 public process.】

6 【“(3) TAXONOMY.—For purposes of informing
7 guidance under this subsection, the Secretary shall
8 establish a taxonomy for the classification of bio-
9 markers (and related scientific concepts) for use in
10 drug development. Not later than 18 months after
11 the date of enactment of the 21st Century Cures
12 Act, the Secretary shall make such taxonomy pub-
13 licly available.】

14 【“(c) PROCESS FOR QUALIFICATION OF DRUG DE-
15 VELOPMENT TOOLS.—】

16 【“(1) IN GENERAL; ACCEPTANCE OF SUBMIS-
17 SIONS.—The Secretary shall establish a process for
18 the qualification of drug development tools for a pro-
19 posed context of use, which shall—】

20 【“(A) be initiated upon the submission, by
21 a requestor defined in subsection (e), of a letter
22 of intent to the Secretary;】

23 【“(B) if such letter is accepted by the Sec-
24 retary, be followed by the requestor’s submis-
25 sion, and the Secretary’s consideration, of a

1 qualification plan, including preliminary data
2 supporting the drug development tool for its
3 proposed context of use;】

4 【“(C) if such qualification plan is accepted
5 by the Secretary, be followed by the requestor’s
6 submission of a full qualification package; and】

7 【“(D) if the Secretary determines that
8 such full qualification package warrants com-
9 prehensive review on its merits, result in the
10 Secretary’s acceptance of such package.】

11 【“(2) REVIEW OF FULL QUALIFICATION PACK-
12 AGE.—The Secretary shall—】

13 【“(A) conduct a comprehensive review of a
14 full qualification package accepted under para-
15 graph (1)(D); and】

16 【“(B) make a determination whether the
17 drug development tool at issue is qualified for
18 its proposed context of use under this section.】

19 【“(3) DETERMINATION FACTORS.—】

20 【“(A) ACCEPTANCE OF SUBMISSIONS.—
21 The Secretary shall determine whether to ac-
22 cept submissions under paragraph (1) based on
23 factors that may include—】

24 【“(i) the scientific merit of the sub-
25 mission;】

1 【“(ii) as applicable, the severity, rar-
2 ity, or prevalence of the disease or condi-
3 tion targeted by the drug development tool
4 and the availability or lack of alternative
5 treatments for such disease or condition;】

6 【“(iii) the identification, by the Sec-
7 retary or by medical research consortia
8 and other expert stakeholders, of such a
9 drug development tool and proposed con-
10 text of use as a public health priority;】

11 【“(iv) the availability of Food and
12 Drug Administration resources for review
13 of the drug development tool and proposed
14 context of use; and】

15 【“(v) such other factors as deter-
16 mined appropriate by the Secretary.】

17 【“(B) QUALIFICATION.—The Secretary
18 shall determine whether a drug development
19 tool is qualified for a proposed context of use
20 based on the scientific merit of a full qualifica-
21 tion package reviewed under paragraph (2).】

22 【“(4) SENSE OF THE CONGRESS REGARDING
23 COLLABORATION.—It is the sense of the Congress
24 that a requestor seeking qualification of a drug de-
25 velopment tool may, in addition to consultation with

1 the Secretary, consult with medical research con-
2 sortia and other individuals and entities with expert
3 knowledge and insights that may assist the re-
4 questor and benefit the process under this sub-
5 section.】

6 【“(5) GUIDANCE.—The Secretary shall issue
7 guidance with respect to the requirements that re-
8 questors shall observe when engaging in the quali-
9 fication process under this subsection.】

10 【“(d) EFFECT OF QUALIFICATION DETERMINA-
11 TIONS; RESCISSION.—】

12 【“(1) IN GENERAL.—A drug development tool
13 determined to be qualified under subsection (c) for
14 a specified context of use may be utilized by any
15 person in such context for purposes described in
16 paragraph (2), subject to paragraph (3).】

17 【“(2) UTILIZATION OF QUALIFIED DRUG DE-
18 VELOPMENT TOOL.—A drug development tool quali-
19 fied under this section may be utilized for—】

20 【“(A) supporting or obtaining approval or
21 licensure (as applicable) of a drug or biological
22 product (including in accordance with section
23 506(c)) under—】

24 【“(i) section 505 of this Act; or】

1 【“(ii) section 351 of the Public
2 Health Service Act; or】

3 【“(B) supporting investigational use of a
4 drug or biological product under section 505(i)
5 of this Act or section 351(a)(3) of the Public
6 Health Service Act.】

7 【“(3) RESCISSION OF QUALIFICATION.—The
8 Secretary may rescind a qualification determination
9 under this section if the Secretary determines that
10 the drug development tool is not appropriate for the
11 specified context of use, including based on new in-
12 formation that calls into question the basis for such
13 qualification.】

14 【“(e) DEFINITIONS.—In this section:】

15 【“(1) REQUESTOR.—The term ‘requestor’
16 means an entity or entities seeking to qualify a drug
17 development tool for a proposed context of use under
18 this section.】

19 【“(2) QUALIFICATION.—The terms ‘qualifica-
20 tion’ and ‘qualified’ mean a determination by the
21 Secretary that a drug development tool and its speci-
22 fied context of use can be relied on to have a specific
23 interpretation and application in drug development
24 and regulatory review under this Act.】

1 【“(3) CONTEXT OF USE.—The term ‘context of
2 use’ means a statement that describes the cir-
3 cumstances under which the drug development tool
4 is to be used in drug development and regulatory re-
5 view.】

6 【“(4) DRUG DEVELOPMENT TOOL.—The term
7 ‘drug development tool’ means—】

8 【“(A) biomarkers, including surrogate
9 endpoints;】

10 【“(B) clinical outcome assessments, in-
11 cluding patient-reported outcomes; and】

12 【“(C) any other methods, materials, or
13 measures that the Secretary determines aid
14 drug development and regulatory review for
15 purposes of this section.】

16 【“(5) BIOMARKER.—The term ‘biomarker’—】

17 【“(A) means a characteristic (such as a
18 physiologic, pathologic, or anatomic char-
19 acteristic or measurement) that is objectively
20 measured and evaluated as an indicator of nor-
21 mal biologic processes, pathologic processes, or
22 biological responses to a therapeutic interven-
23 tion; and】

24 【“(B) includes surrogate endpoints.】

1 【“(6) SURROGATE ENDPOINT.—The term ‘sur-
2 rogate endpoint’ means a marker, such as a labora-
3 tory measurement, radiographic image, physical
4 sign, or other measure, that is known to predict clin-
5 ical benefit or is reasonably likely to predict clinical
6 benefit, but is not itself a direct measurement of
7 clinical benefit.】

8 【“(7) CLINICAL OUTCOME ASSESSMENT.—The
9 term ‘clinical outcome assessment’—】

10 【“(A) means a measurement of a patient’s
11 symptoms, overall mental state, or the effects of
12 a disease or condition on how the patient func-
13 tions; and】

14 【“(B) includes patient reported out-
15 comes.】

16 【“(8) PATIENT REPORTED OUTCOME.—The
17 term ‘patient reported outcome’ means a measure-
18 ment based on a report from a patient regarding the
19 status of the patient’s health condition without
20 amendment or interpretation of the patient’s report
21 by a clinician or anyone else.】

22 【“(9) MEDICAL RESEARCH CONSORTIA.—The
23 term ‘medical research consortia’ means public-pri-
24 vate partnerships of government agencies, institu-
25 tions of higher education, patient advocacy groups,

1 industry representatives, clinical and scientific ex-
2 perts, and other relevant entities and individuals.】

3 【“(f) TRANSPARENCY.—】

4 【“(1) PUBLIC AVAILABILITY OF INFORMA-
5 TION.—For purposes of this section, the following
6 information shall be made publicly available by the
7 Secretary:】

8 【“(A) submissions from requestors under
9 the qualification process under subsection (c),
10 including any data and evidence contained in
11 such submissions, and any updates to such sub-
12 missions;】

13 【“(B) the Secretary’s formal written deter-
14 minations in response to submissions under
15 subsection (c);】

16 【“(C) any rescissions of qualification
17 under subsection (d)(3); and】

18 【“(D) summary reviews that document
19 conclusions and recommendations for qualifica-
20 tion determinations under subsection (c).】

21 【“(2) RELATION TO TRADE SECRETS ACT.—In-
22 formation made publicly available by the Secretary
23 under paragraph (1) shall be considered a disclosure
24 authorized by law for purposes of the Trade Secrets
25 Act, 18 U.S.C. 1905.】

1 【“(3) APPLICABILITY.—The provisions of this
2 subsection shall—】

3 【“(A) apply only with respect to requests
4 for qualification of a drug development tool for
5 a proposed context of use which are initiated on
6 or after the date of enactment of the 21st Cen-
7 tury Cures Act;】

8 【“(B) apply to information which is sub-
9 mitted to the Secretary for purposes of both—
10 】

11 【“(i) a request for qualification under
12 this section; and】

13 【“(ii) an application under section
14 505 of this Act or section 351 of the Pub-
15 lic Health Service Act; and】

16 【“(C) not apply to information which is—
17 】

18 【“(i) submitted to the Secretary solely
19 for purposes of an application under sec-
20 tion 505 of this Act or section 351 of the
21 Public Health Service Act; and】

22 【“(ii) not submitted for purposes of a
23 request for qualification under this sec-
24 tion.】

1 **[(g) RULE OF CONSTRUCTION.—Nothing in this**
2 section shall be construed to—]

3 **[(1) alter the standards of evidence under**
4 subsection (c) or (d) of section 505, including the
5 substantial evidence standard in such subsection (d),
6 or under section 351 of the Public Health Service
7 Act (as applicable); or]

8 **[(2) limit the authority of the Secretary to ap-**
9 prove or license products pursuant to this Act or the
10 Public Health Service Act (as applicable) as author-
11 ized under such Acts as in effect prior to the date
12 of enactment of this section.”.]

13 **[(c) MEETING AND REPORT.—]**

14 **[(1) PUBLIC MEETING.—Not later than 18**
15 months after the enactment of the this Act, the Sec-
16 retary shall hold a public meeting to discuss the
17 qualification process under section 507 of the Fed-
18 eral Food, Drug, and Cosmetic Act (as added by
19 this section).]

20 **[(2) REPORT.—Not later than 5 years after the**
21 date of the enactment of this Act, the Secretary
22 shall make publicly available a report on the Inter-
23 net website of the Food and Drug Administration,
24 which shall include, with respect to the qualification
25 process under section 507 of the Federal Food,

1 Drug, and Cosmetic Act (as added by this section)—

2 **]**

3 **[(A) the number of requests, submitted as**
4 **letters of intent, for qualification of a bio-**
5 **marker (including a surrogate endpoint), clin-**
6 **ical outcome assessment, or other drug develop-**
7 **ment tool;]**

8 **[(B) the number of—]**

9 **[(i) such requests accepted and deter-**
10 **mined to be eligible for submission of a**
11 **qualification plan and full qualification**
12 **package, respectively; and]**

13 **[(ii) the number of qualification plans**
14 **and full qualification packages, respec-**
15 **tively, submitted to the Secretary; and]**

16 **[(C) the number of biomarkers (including**
17 **surrogate endpoints), clinical outcome assess-**
18 **ments, or other drug development tools quali-**
19 **fied under such section.]**

20 **[SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT**
21 **PLANS.**

22 Chapter V of the Federal Food, Drug, and Cosmetic
23 Act, as amended by section 2021, is further amended by
24 inserting after section 507 the following new section: **]**

1 **["SEC. 507A. ACCELERATED APPROVAL DEVELOPMENT**
2 **PLAN.**

3 **["(a) IN GENERAL.—**For purposes of facilitating
4 early interactions with the Secretary for planning studies
5 intended to be conducted for purposes of the accelerated
6 approval of a drug under section 506(c), the Secretary
7 shall establish processes for a sponsor to voluntarily sub-
8 mit, and for the Secretary to agree to, an accelerated ap-
9 proval development plan. Such a plan may be used but
10 is not required to be submitted for such accelerated ap-
11 proval.]

12 **["(b) CONTENTS.—**An accelerated approval develop-
13 ment plan under subsection (a) shall include—]

14 **["(1) a determination that unmet medical need**
15 **exists in the patient population being studied; and]**

16 **["(2) the agreement between the sponsor sub-**
17 **mitting the plan and the Secretary—]**

18 **["(A) on the design of the study, includ-**
19 **ing—]**

20 **["(i) planned interim analyses if ap-**
21 **plicable, that will utilize the surrogate end-**
22 **point; and]**

23 **["(ii) the minimum magnitude of the**
24 **effect of the drug involved on the surrogate**
25 **endpoint that would be reasonably likely to**
26 **predict clinical benefit;]**

1 【“(B) on any post-market commitments of
2 the sponsor with respect to the drug; and】

3 【“(C) on what surrogate endpoint will be
4 assessed in the study.】

5 【“(c) TIMING.—In consultation with the Secretary,
6 an accelerated approval development plan submitted under
7 subsection (a) may be agreed upon at any time after the
8 submission of an application for the investigation of a
9 drug under section 505(i) or a biological product under
10 section 351(a)(3).】

11 【“(d) MODIFICATION OR TERMINATION.—An accel-
12 erated approval development plan may be modified or ter-
13 minated if new evidence indicates that—】

14 【“(1) the plan as originally agreed upon is no
15 longer sufficient to demonstrate safety and effective-
16 ness of the drug involved; or】

17 【“(2) the drug is no longer eligible for accel-
18 erated approval under section 506(c).】

19 【“(e) DEFINITION.—In this section, the term ‘accel-
20 erated approval development plan’ refers to a development
21 plan agreed upon by the Secretary and the sponsor sub-
22 mitting the plan that contains study parameters for the
23 use of a surrogate endpoint intended to be the basis of
24 the accelerated approval of a drug under section
25 506(c).”】

1 **[Subtitle C—FDA Advancement of**
2 **Precision Medicine]**

3 **[SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER**
4 **PROGRAMS OF FOOD AND DRUG ADMINIS-**
5 **TRATION.**

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

9 **[“Subchapter J—Precision Medicine]**

10 **[“SEC. 591. DEFINITIONS.**

11 **[“(a) PRECISION MEDICINE.—**For purposes of this
12 subchapter, the term ‘precision medicine’ or ‘precision
13 drug’ means a drug that, either alone or in combination
14 with other therapies, targets a subset of individuals with
15 a disease, which subset—]

16 **[“(1) can be used to address the underlying**
17 **cause of the disease in order to modify the progres-**
18 **sion of the disease, prevent the disease, or cure the**
19 **disease; and]**

20 **[“(2) is identified by—]**

21 **[“(A) genotype, or genotype in combina-**
22 **tion with other biological characteristics; or]**

23 **[“(B) any other biological characteristic,**
24 **or means of identifying such a characteristic,**

1 designated by the Secretary as an advanced an-
2 alytical subset approach.】

3 【“(b) SERIOUS DISEASE.—For purposes of this sub-
4 chapter, the term ‘serious disease’ has the meaning that
5 applies in guidance issued pursuant to section 506 to the
6 term ‘serious condition’.”】

7 **【“SEC. 592. GENERAL AGENCY GUIDANCE ON PRECISION**
8 **MEDICINE.**

9 【“(a) IN GENERAL.—The Secretary shall issue and
10 periodically update guidance on—】

11 【“(1) the requirements to meet the definition of
12 a precision drug under section 591(a); and】

13 【“(2) information to assist sponsors in the de-
14 velopment of such a drug, including clinical studies,
15 in accordance with the requirements referred to in
16 paragraph (1) and other relevant guidance issued by
17 the Secretary.”】

18 【“(b) CERTAIN ISSUES.—The topics addressed by
19 guidance under subsection (a) may include the following:】

20 【“(1) Maximizing the use of scientific tools or
21 methods to incorporate biomarkers into non-clinical
22 and clinical development of a precision drug to
23 evaluate how such drug modifies the progression of
24 disease beyond well-established primary clinical
25 endpoints.”】

1 【“(2) Identifying surrogate endpoints that can
2 reasonably be predicted to demonstrate preliminary
3 evidence of clinical benefit for a precision drug for
4 purposes of section 506(c) (relating to accelerated
5 approval).】

6 【“(3) Recommendations on the appropriate evi-
7 dence needed to demonstrate a clinical benefit by ex-
8 trapolating from the approaches described in para-
9 graphs (1) and (2).】

10 【“(c) FIXED-COMBINATION DRUGS.—Guidance
11 under subsection (a) shall address the manner in which
12 section 300.50 of title 21, Code of Federal Regulations
13 (or successor regulations), applies to precision drugs.】

14 【“(d) DATE CERTAIN FOR INITIAL GUIDANCE.—The
15 Secretary shall issue guidance under subsection (a) not
16 later than one year after the date of the enactment of the
17 21st Century Cures Act.】

18 【“SEC. 593. PRECISION MEDICINE REGARDING ORPHAN-
19 DRUG AND EXPEDITED-APPROVAL PRO-
20 GRAMS.

21 【“(a) IN GENERAL.—Guidance under section 592
22 shall address the manner in which sections 526 and 527
23 (relating to orphan drugs), section 506 (relating to expe-
24 dited approval programs), and other programs under this

1 Act for expedited or priority review will be applied to preci-
2 sion drugs.】

3 【“(b) RELIANCE ON PREVIOUSLY-SUBMITTED INVES-
4 TIGATIONS BY A SPONSOR.—In the case of an application
5 for a precision drug under section 505(b)(1), or section
6 351(a) of the Public Health Service Act, that has been
7 designated under section 526 as a drug for a rare disease
8 for a serious condition, the Secretary may—】

9 【“(1) consistent with applicable standards for
10 approval, rely upon data or information previously
11 developed by the sponsor of a prior approved drug
12 or indication (or another sponsor that has provided
13 the sponsor with a contractual right of reference to
14 such data and information) for such drug or indica-
15 tion in order to expedite clinical development for a
16 precision drug or indication that is using the same
17 or similar precision medicine approach as that of the
18 prior approved drug or indication; and】

19 【“(2) as appropriate under section 506, con-
20 sider the application for approval of such precision
21 drug to be eligible for expedited review, including
22 under section 506(e) (relating to accelerated ap-
23 proval).】

1 **["SEC. 594. AGENCY GUIDANCE ON INTERPRETING EVI-**
2 **DENCE ON SERIOUS-DISEASES POPULATION**
3 **SUBSETS.**

4 **["(a) IN GENERAL.—**To advance clinical develop-
5 ment of precision drugs for serious diseases, the Secretary
6 shall issue and periodically update guidance on identifying
7 population subsets within the meaning of section 591(a)
8 (relating to gene-related and other biological characteris-
9 tics).**"]**

10 **["(b) APPROACHES TO IDENTIFYING POPULATION**
11 **SUBSETS.—**Guidance under subsection (a) may address—
12 **"]**

13 **["(1) whether the population of individuals**
14 **with one or more genetic risk factors for the disease**
15 **involved can be divided into subsets for the purpose**
16 **of identifying the subsets that may have favorable**
17 **clinical responses to particular types of drugs; and¹"]**

18 **["(2) for such purpose—"]**

19 **["(A) whether, when there are multiple ge-**
20 **netic risk factors, a separate subset should be**
21 **identified for each such risk factor;"]**

22 **["(B) whether, in lieu of the approach de-**
23 **scribed in subparagraph (A), subsets can be**
24 **created by grouping or separating individuals**
25 **with genetic risk factors on the basis of addi-**
26 **tional biological characteristics (such as**

1 genotypes or particular molecular mecha-
2 nisms);】

3 【“(C) whether, with respect to two or
4 more serious diseases, subsets can be identified
5 on the basis of genetic risk factors and other bi-
6 ological characteristics that are common to such
7 diseases, notwithstanding the apparent dif-
8 ferences in the diseases;】

9 【“(D) whether, with any of the approaches
10 described in subparagraphs (A) through (C), a
11 subset can be identified by extrapolating from
12 scientific data concerning one or more other
13 subsets, taking into account the issue of deter-
14 mining whether a proposed extrapolation-based
15 subset has characteristics in common with the
16 other subset or subsets that are scientifically
17 sufficient to justify extrapolation;】

18 【“(E) what particular methodologies (such
19 as biomarkers and in vitro assays) should be
20 used to identify subsets as described in sub-
21 paragraphs (A) through (D); and】

22 【“(F) the manner in which clinical trials
23 should be designed on the basis of such subsets,
24 including with respect to statistical methodolo-
25 gies, the number of subjects, the duration of

1 the trials, and standards for determining the
2 trials have demonstrated a clinical benefit (or
3 an effect on a surrogate endpoint or an inter-
4 mediate clinical endpoint, as the case may be).】

5 【“(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The
6 Secretary shall issue guidance under subsection (a) not
7 later than 18 months after the date of the enactment of
8 the 21st Century Cures Act.”.】

9 **Subtitle D—Modern Trial Design** 10 **and Evidence Development**

11 **[SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-** 12 **TICS AND ADAPTIVE TRIAL DESIGNS.**

13 【(a) PROPOSALS FOR USE OF INNOVATIVE STATIS-
14 TICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS
15 AND BIOLOGICAL PRODUCTS.—For purposes of assisting
16 sponsors in incorporating adaptive trial design and
17 Bayesian methods into proposed clinical protocols and ap-
18 plications for new drugs under section 505 of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 355) and bio-
20 logical products under section 351 of the Public Health
21 Service Act (42 U.S.C. 262), the Secretary shall conduct
22 a public meeting and issue guidance in accordance with
23 subsection (b).】

24 【(b) GUIDANCE ADDRESSING USE OF ADAPTIVE
25 TRIAL DESIGNS AND BAYESIAN METHODS.—】

1 **[(1) IN GENERAL.—**The Secretary of Health
2 and Human Services, acting through the Commis-
3 sioner of Food and Drugs (in this subsection re-
4 ferred to as the “Secretary”), shall—**]**

5 **[(A)** update and finalize the draft guid-
6 ance addressing the use of adaptive trial design
7 for drugs and biological products; and**]**

8 **[(B)** issue draft guidance on the use of
9 Bayesian methods in the development and regu-
10 latory review and approval or licensure of drugs
11 and biological products.**]**

12 **[(2) CONTENTS.—**The guidances under para-
13 graph (1) shall address—**]**

14 **[(A)** the use of adaptive trial designs and
15 Bayesian methods in clinical trials, including
16 clinical trials proposed or submitted to help sat-
17 isfy the substantial evidence standard under
18 section 505(d) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 355(d));**]**

20 **[(B)** how sponsors may obtain feedback
21 from the Secretary on technical issues related
22 to modeling and simulations prior to—**]**

23 **[(i)** completion of such modeling or
24 simulations; or**]**

1 【(ii) the submission of resulting infor-
2 mation to the Secretary;】

3 【(C) the types of quantitative and quali-
4 tative information that should be submitted for
5 review; and】

6 【(D) recommended analysis methodolo-
7 gies.】

8 【(3) PUBLIC MEETING.—Prior to updating or
9 developing the guidances required by paragraph (1),
10 the Secretary shall consult with stakeholders includ-
11 ing representatives of regulated industry, academia,
12 patient advocacy organizations, and disease research
13 foundations, through a public meeting to be held no
14 later than 1 year after the date of enactment of this
15 Act.】

16 【(4) SCHEDULE.—The Secretary shall pub-
17 lish—】

18 【(A) the final guidance required by para-
19 graph (1)(A) not later than 18 months after the
20 date of the public meeting required by para-
21 graph (3); and】

22 【(B) the guidance required by paragraph
23 (1)(B) not later than 48 months after the date
24 of the public meeting required by paragraph
25 (3).】

1 **[SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
2 **ENCE.]**

3 Chapter V of the Federal Food, Drug, and Cosmetic
4 Act, as amended by section 1261, is further amended by
5 inserting after section 505G of such Act the following:】

6 **[“SEC. 505H. UTILIZING EVIDENCE FROM CLINICAL EXPE-**
7 **RIENCE.]**

8 **[“(a) IN GENERAL.—**The Secretary shall establish a
9 program to evaluate the potential use of evidence from
10 clinical experience—】

11 **[“(1) to help support the approval of a new in-**
12 **dications for a drug approved under section 505(b);**
13 **and】**

14 **[“(2) to help support or satisfy post-approval**
15 **study requirements.】**

16 **[“(b) EVIDENCE FROM CLINICAL EXPERIENCE DE-**
17 **FINED.—**In this section, the term ‘evidence from clinical
18 experience’ means data regarding the usage, or potential
19 benefits or risks, of a drug derived from sources other
20 than randomized clinical trials, including from observa-
21 tional trials, registries, and therapeutic use.】

22 **[“(c) PROGRAM FRAMEWORK.—】**

23 **[“(1) IN GENERAL.—**The Secretary shall—】

24 **[“(A) engage a public-private entity or**
25 **independent research organization in fact-find-**
26 **ing, stakeholder engagement, and drafting nec-**

1 essary to produce a framework for the program
2 under this section; and】

3 【“(B) not later than 【12 months】 after
4 the date of enactment of this section, establish
5 a draft framework for implementation of the
6 program under this section.】

7 【“(2) CONTENTS OF FRAMEWORK.—The frame-
8 work shall include information describing—】

9 【“(A) the current sources of data devel-
10 oped through clinical experience, including on-
11 going safety surveillance, registry, claims, and
12 patient-centered outcomes research activities;】

13 【“(B) the gaps in current data collection
14 activities;】

15 【“(C) the current standards and meth-
16 odologies for collection and analysis of data
17 generated through clinical experience; and】

18 【“(D) the priority areas, remaining chal-
19 lenges, and potential pilot opportunities that
20 the program established under this section will
21 address.】

22 【“(3) CONSULTATION.—In developing the pro-
23 gram framework under 【this subsection】, the Sec-
24 retary, through the public-private partner or inde-
25 pendent research organization, shall consult with

1 regulated industry, academia, organized medicine,
2 representatives of patient advocacy organizations,
3 disease research foundations, and other interested
4 parties through a public process.】

5 【“(d) PROGRAM IMPLEMENTATION.—The Secretary
6 shall, not later than 【12 months】 after the date of enact-
7 ment of this section and in accordance with the framework
8 established under subsection (c), implement the program
9 to evaluate the potential use of evidence from clinical expe-
10 rience.】

11 【“(e) GUIDANCE FOR INDUSTRY.—The Secretary
12 shall—】

13 【“(1) utilize the program established in sub-
14 section (d), its activities, and any subsequent pilots
15 or written reports, to inform a guidance for industry
16 on—】

17 【“(A) the circumstances under which
18 sponsors of drugs and the Secretary may rely
19 on evidence from clinical experience for the pur-
20 poses described in subsections (a)(1) or (a)(2);】

21 【“(B) the appropriate standards and
22 methodologies for collection and analysis of evi-
23 dence from clinical experience submitted for
24 such purposes.】

1 【“(2) not later than 【36 months】 after the
2 date of enactment of this section, issue draft guid-
3 ance for industry as described in subparagraph (A);
4 and】

5 【“(3) not later than 【40 months】 after the
6 date of enactment of this section, after providing an
7 opportunity for public comment on the draft guid-
8 ance, issue final guidance.】

9 【“(f) RULE OF CONSTRUCTION.—】

10 【“(1) Subject to paragraph (2), nothing in this
11 section prohibits the Secretary from using evidence
12 from clinical experience for purposes not specified in
13 this section, provided the Secretary determines that
14 sufficient basis exists for any such non-specified
15 use.】

16 【“(2) This section shall not be construed to
17 alter—】

18 【“(A) the standards of evidence under—】

19 【“(i) subsection (c) or (d) of section
20 505, including the substantial evidence
21 standard in such subsection (d); or】

22 【“(ii) section 351(a) of the Public
23 Health Services Act; or】

24 【“(B) the Secretary’s authority to require
25 post-approval studies or clinical trials, or the

1 standards of evidence under which studies or
2 trials are evaluated.]

3 **["SEC. 505I. COLLECTING EVIDENCE FROM CLINICAL EXPE-**
4 **RIENCE THROUGH TARGETED EXTENSIONS**
5 **OF THE SENTINEL SYSTEM.**

6 **["(a) IN GENERAL.—**The Secretary shall, in parallel
7 to implementing the program established in section 505H
8 and in order to build capacity for utilizing the evidence
9 from clinical experience described in that section, identify
10 and execute pilot demonstrations to extend existing use
11 of the Sentinel System surveillance infrastructure author-
12 ized under section 505(k).]

13 **["(b) PILOT DEMONSTRATIONS.—**]

14 **["(1) IN GENERAL.—**The Secretary shall de-
15 sign and implement pilot demonstrations to—]

16 **["(A)** make strategic linkages between
17 such data captured through the Sentinel Sys-
18 tem surveillance infrastructure and sources of
19 complementary public health data and infra-
20 structure the Secretary deems appropriate and
21 necessary; and]

22 **["(B)** develop a governance mechanism
23 and operational guidelines for the collection,
24 analysis and use of such data intended to gen-
25 erate evidence from real world clinical experi-

1 ence to improve assessment of benefit-risk, pro-
2 tect public health, and advance patient-centered
3 care.】

4 【“(2) CONTRACTING.—In developing the pilot
5 demonstrations under this subsection, the Secretary
6 may enter into contract only with qualified entities
7 as determined by the Secretary through guidance
8 and consultation with diverse stakeholders including
9 public, academic, non-profit, and private entities.】

10 【“(3) CONSULTATION.—In developing the pilot
11 demonstrations under this subsection, the Secretary
12 shall consult with regulated industry, academia, or-
13 ganized medicine, representatives of patient advoca-
14 cacy organizations, disease research foundations,
15 and other interested parties through a public proc-
16 ess.】

17 【“(4) PUBLIC HEALTH EXEMPTION.—The Sec-
18 retary may—】

19 【“(A) deem such pilot demonstrations pub-
20 lic health activities, permitting the use and dis-
21 closure of protected health information as de-
22 scribed in 164.512(b)(1)(iii) of title 45, Code of
23 Federal Regulations (or any successor regula-
24 tion) and exempted as a public health activity
25 as described in 46.101(b)(5) of title 46, Code of

1 Federal Regulations (or any successor regula-
2 tion); and】

3 【“(B) deem safety surveillance performed
4 at the request of the Food and Drug Adminis-
5 tration or under such jurisdiction by a sponsor
6 with responsibility for a drug approved under
7 this section or section 351 of the Public Health
8 Services Act using the infrastructure authorized
9 at section 505(k) of the Food, Drug, and Cos-
10 metic Act, including use of analytic tools and
11 querying capabilities developed to implement
12 the active post market surveillance system de-
13 scribed in this section, public health activities
14 as described in 164.512(b)(1)(iii) of title 45,
15 Code of Federal Regulations (or any successor
16 regulation) and exempted as a public health ac-
17 tivity as described in 46.101(b)(5) of title 46,
18 Code of Federal Regulations (or any successor
19 regulation).】

20 【“(c) AUTHORIZATION OF APPROPRIATIONS.—To
21 carry out activities under the amendment made by this
22 section there are authorized to be appropriated 【____】
23 for fiscal years 2015 through 2018.”.】

1 **SEC. 2063. STREAMLINED DATA REVIEW PROGRAM.**

2 (a) IN GENERAL.—Chapter V of the Federal Food,
3 Drug, and Cosmetic Act is further amended by inserting
4 after section 505E of such Act (21 U.S.C. 355f) the fol-
5 lowing:

6 **“SEC. 505F. STREAMLINED DATA REVIEW PROGRAM.**

7 “(a) IN GENERAL.—The Secretary shall establish a
8 streamlined data review program under which a holder of
9 an approved application submitted under section
10 505(b)(1) or under section 351(a) of the Public Health
11 Service Act may, to support the approval or licensure (as
12 applicable) of the use of the drug that is the subject of
13 such approved application for a new qualified indication,
14 submit qualified data summaries.

15 “(b) ELIGIBILITY.—In carrying out the streamlined
16 data review program under subsection (a), the Secretary
17 may authorize the holder of the approved application to
18 include one or more qualified data summaries described
19 in subsection (a) in a supplemental application if—

20 “(1) the drug has been approved under section
21 505(c) of this Act or licensed under section 351(a)
22 of the Public Health Service Act for one or more in-
23 dications, and such approval or licensure remains in
24 effect;

25 “(2) the supplemental application is for ap-
26 proval or licensure (as applicable) under such section

1 505(c) or 351(a) of the use of the drug for a new
2 qualified indication under such section 505(c) or
3 351(a);

4 “(3) there is an existing database acceptable to
5 the Secretary regarding the safety of the drug devel-
6 oped for one or more indications of the drug ap-
7 proved under such section 505(c) or licensed under
8 such section 351(a);

9 “(4) the supplemental application incorporates
10 or supplements the data submitted in the application
11 for approval or licensure referred to in paragraph
12 (1); and

13 “(5) the full data sets used to develop the quali-
14 fied data summaries are submitted, unless the Sec-
15 retary determines that the full data sets are not re-
16 quired.

17 “(c) DEFINITIONS.—In this section:

18 “(1) The term ‘qualified indication’ means—

19 “(A) an indication for the treatment of
20 cancer, as determined appropriate by the Sec-
21 retary; or

22 “(B) such other types of indications as the
23 Secretary determines to be subject to the
24 streamlined data review program under this
25 section.

1 “(2) The term ‘qualified data summary’ means
2 a summary of clinical data intended to demonstrate
3 safety and effectiveness with respect to a qualified
4 indication for use of a drug.”.

5 (b) GUIDANCE; REGULATIONS.—The Commissioner
6 of Food and Drugs—

7 (1) shall—

8 (A) issue final guidance for implementation
9 of the streamlined data review program estab-
10 lished under section 505F of the Federal Food,
11 Drug, and Cosmetic Act, as added by sub-
12 section (a), not later than 24 months after the
13 date of enactment of this Act; and

14 (B) include in such guidance the process
15 for expanding the types of indications to be
16 subject to the streamlined data review program,
17 as authorized by section 505F(c)(1)(B) of such
18 Act; and

19 (2) in addition to issuing guidance under sub-
20 paragraph (A), may issue such regulations as may
21 be necessary for implementation of the program.

1 **Subtitle E—Expediting Patient**
2 **Access**

3 **SEC. 2081. SENSE OF CONGRESS.**

4 It is the sense of Congress that the Food and Drug
5 Administration should continue to expedite the approval
6 of drugs designated as breakthrough therapies pursuant
7 to section 506(a) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 356(a)) by approving drugs so des-
9 ignated as early as possible in the clinical development
10 process, regardless of the phase of development, provided
11 that the Secretary of Health and Human Services deter-
12 mines that an application for such a drug meets the stand-
13 ards of evidence of safety and effectiveness under section
14 505 of such Act (21 U.S.C. 355), including the substantial
15 evidence standard under subsection (d) of such section or
16 under section 351(a) of the Public Health Service Act (42
17 U.S.C. 262(a)).

18 **[SEC. 2082. EXPANDED ACCESS POLICY.]**

19 Section 561 of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 360bbb) is amended—**]**

21 **[(1) by redesignating subsections (d) and (e) as**
22 **subsections (e) and (f), respectively; and]**

23 **[(2) by inserting after subsection (c) the fol-**
24 **lowing new subsection:]**

1 **【“(d) EXPANDED ACCESS POLICY REQUIRED FOR**
2 **INVESTIGATIONAL DRUGS.—】**

3 **【“(1) IN GENERAL.—**Not later than 60 days
4 after the initiation of any phase 2 or phase 3 human
5 safety studies with respect to an investigational new
6 drug, the sponsor of such studies shall make publicly
7 available the policy of the sponsor with respect to re-
8 quests submitted under subsection (b) for provision
9 of such drug.**】**

10 **【“(2) CONTENT OF POLICY.—**A policy de-
11 scribed in paragraph (1) shall include—**】**

12 **【“(A) points of contact regarding the re-**
13 **ceipt and processing of such requests;】**

14 **【“(B) procedures for making such re-**
15 **quests;】**

16 **【“(C) the general criteria for the sponsor’s**
17 **consideration or approval of such requests;**
18 **and】**

19 **【“(D) the length of time the sponsor an-**
20 **tipates will be necessary to acknowledge re-**
21 **ceipt of such requests.】**

22 **【“(3) NO GUARANTEE OF ACCESS.—**The post-
23 ing of policies by sponsors under paragraph (1) shall
24 not serve as a guarantee of access to any specific in-
25 vestigational drug to any individual patient.”**】**

1 **[SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED**
2 **ACCESS.**

3 **[(a) IN GENERAL.—**Not later than 12 months after
4 the date of enactment of this Act, the Secretary of Health
5 and Human Services shall finalize the draft guidance enti-
6 tled “Expanded Access to Investigational Drugs for Treat-
7 ment Use—Qs & As” and dated May 2013.]

8 **[(b) CONTENTS.—**The final guidance referred to in
9 subsection (a) shall clearly define how the Secretary of
10 Health and Human Services interprets and uses adverse
11 drug event data reported by investigators in the case of
12 data reported from use under a request submitted under
13 section 561(b) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 360bbb(b)).]

15 **Subtitle F—Facilitating Dissemina-**
16 **tion of Health Care Economic**
17 **Information**

18 **[SEC. 2101. FACILITATING DISSEMINATION OF HEALTH**
19 **CARE ECONOMIC INFORMATION.**

20 Section 502(a) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 352(a)) is amended—]

22 **[(1) by striking “(a) If its” and inserting**
23 **“(a)(1) If its”];]**

24 **[(2) by striking “a formulary committee, or**
25 **other similar entity, in the course of the committee**
26 **or the entity carrying out its responsibilities for the**

1 selection of drugs for managed care or other similar
2 organizations” and inserting “a payor, formulary
3 committee, or other similar entity, in the course of
4 the payor, committee, or other similar entity car-
5 rying out its responsibilities for the selection of
6 drugs for managed care or other similar organiza-
7 tions”;

8 [(3) by striking “directly relates” and inserting
9 “relates”];

10 [(4) by striking “and is based on competent
11 and reliable scientific evidence. The requirements set
12 forth in section 505(a) or in section 351(a) of the
13 Public Health Service Act shall not apply to health
14 care economic information provided to such a com-
15 mittee or entity in accordance with this paragraph”
16 and inserting “, is based on competent and reliable
17 scientific evidence, and includes, where applicable, a
18 conspicuous and prominent statement describing any
19 differences between the information and the indica-
20 tion approved under section 505 or under section
21 351 of the Public Health Service Act. The require-
22 ments set forth in section 505(a) or in section 351
23 of the Public Health Service Act shall not apply to
24 health care economic information provided to such a

1 payor, committee, or entity in accordance with this
2 paragraph”];

3 [(5) by striking “In this paragraph, the term”
4 and all that follows and inserting the following:]

5 [“(2) For purposes of this paragraph, the term
6 ‘health care economic information’ means any analysis (in-
7 cluding the data, inputs, clinical or other assumptions,
8 methods, results, and other components comprising the
9 analysis) that identifies, measures, or describes the con-
10 sequences, including the separate or aggregated clinical
11 consequences and costs of the represented health out-
12 comes, of the use of a drug. Such analyses may be com-
13 parative to the use of another drug, to another health care
14 intervention, or to no intervention.”.]

15 **Subtitle G—Antibiotic Drug** 16 **Development**

17 **[SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A**
18 **LIMITED POPULATION OF PATIENTS.**

19 **[(a) APPROVAL OF CERTAIN ANTIBACTERIAL AND**
20 **ANTIFUNGAL DRUGS.—]**

21 **[(1) IN GENERAL.—**Section 505 of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355), as
23 amended by section 1001, is further amended by
24 adding at the end the following:]

1 【“(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND
2 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-
3 LATION OF PATIENTS.—】

4 【“(1) PROCESS.—At the request of the sponsor
5 of an antibacterial or antifungal drug that is in-
6 tended to treat a serious or life-threatening disease
7 or condition, the Secretary—】

8 【“(A) shall provide the sponsor with an
9 opportunity to request meetings under para-
10 graph (2); and】

11 【“(B) may, consistent with an agreement
12 between the sponsor and the Secretary, if any
13 such agreement is reached, approve the drug
14 under subsection (c) for such treatment in a
15 limited population of patients for which there is
16 an unmet medical need.】

17 【“(2) FORMAL MEETINGS.—】

18 【“(A) IN GENERAL.—In the case of any
19 drug subject to an agreement under paragraph
20 (1) for approval for use in a limited population,
21 the sponsor of the drug may request, and the
22 Secretary shall agree to conduct, any or all of
23 the following types of meetings:】

24 【“(i) A clinical development planning
25 meeting.】

1 【“(ii) An assessment meeting.”】

2 【“(iii) A postapproval meeting.”】

3 【“(B) RELATION TO COMPARABLE FOR-

4 MAL MEETINGS.—A meeting conducted pursu-

5 ant to a request described in subparagraph (A)

6 shall not replace any meeting with the Sec-

7 retary to which the sponsor of the drug is oth-

8 erwise entitled, but may be conducted as part

9 of a comparable formal meeting.”】

10 【“(C) TIMING.—The Secretary shall meet

11 with the sponsor of a drug pursuant to a re-

12 quest described in subparagraph (A) not later

13 than 60 days after the date of the Secretary’s

14 receipt of the request.”】

15 【“(D) DEFINITIONS.—In this paragraph:】

16 【“(i) The term ‘assessment meeting’

17 means a meeting, other than a clinical de-

18 velopment planning meeting, held prior to

19 submission of an application for a drug

20 under section 505(b) of this Act of section

21 351(a) of the Public Health Service Act, at

22 which the sponsor of the drug and the Sec-

23 retary meet—】

1 【“(I) to assess progress in imple-
2 menting the clinical development pro-
3 gram agreed to under paragraph (1);】

4 【“(II) to discuss the necessity of,
5 and reach agreement with respect to,
6 any postapproval commitments; and】

7 【“(III) to reach agreement on
8 the efficacy or safety data necessary
9 to support expansion of the approval
10 or licensure of the drug beyond use in
11 the limited population.】

12 【“(ii) The term ‘clinical development
13 planning meeting’ means a meeting, other
14 than an assessment meeting, at which the
15 sponsor of the drug and the Secretary
16 meet to discuss and reach an initial agree-
17 ment with respect to the content of the
18 clinical development program (including
19 the matters described in paragraph (1)(B))
20 that is necessary to support approval or li-
21 censure of the drug for use in a limited
22 population.】

23 【“(iii) The term ‘comparable formal
24 meeting’—】

1 【“(I) means a formal meeting
2 that is typically held during the drug
3 development or approval process;
4 and】

5 【“(II) includes any such meeting
6 that is described in applicable guid-
7 ance documents of the Food and Drug
8 Administration that are in effect.】

9 【“(iv) The term ‘postapproval meet-
10 ing’ means a meeting, held following initial
11 approval or licensure of the drug for use in
12 a limited population, to discuss any issues
13 regarding postapproval commitments or ex-
14 pansion of approved uses agreed to under
15 paragraph (1).】

16 【“(3) AGREEMENTS.—】

17 【“(A) FORM.—Any agreement that is
18 reached between the Secretary and a sponsor of
19 a drug under paragraph (1), including an
20 agreement with respect to the design or size of
21 clinical trials, shall be reduced to writing and
22 made part of the administrative record by the
23 Secretary.】

24 【“(B) EVIDENCE.—An agreement under
25 paragraph (1) may provide for reliance on—】

1 【“(i) traditional endpoints, alternative
2 endpoints, or a combination of traditional
3 and alternative endpoints;】

4 【“(ii) datasets of limited size;】

5 【“(iii) pharmacologic or patho-
6 physiologic data;】

7 【“(iv) data from phase 2 clinical stud-
8 ies;】

9 【“(v) data obtained in real-world set-
10 tings; and】

11 【“(vi) such other confirmatory evi-
12 dence as the Secretary deems necessary to
13 approve the drug, as described in para-
14 graph (1).】

15 【“(C) LABELING STATEMENT.—An agree-
16 ment under paragraph (1) shall require the
17 drug’s labeling, upon approval pursuant to the
18 agreement, to prominently include in the pre-
19 scribing information required by section 201.57
20 of title 21, Code of Federal Regulations (or any
21 successor regulation) the following statement:
22 ‘This drug is indicated for use in a limited and
23 specific population of patients.’.】

24 【“(D) CHANGES.—An agreement de-
25 scribed in subparagraph (A) shall not be

1 changed after the development of such data be-
2 gins, except—】

3 【“(i) with the written agreement of
4 the sponsor of the drug; or】

5 【“(ii) pursuant to a decision by the
6 director of the division responsible for re-
7 viewing the drug that a substantial sci-
8 entific issue essential to determining the
9 safety or effectiveness of the drug was
10 identified after data development began.】

11 【“(E) DECISION BY DIRECTOR.—A deci-
12 sion under subparagraph (D)(ii) shall be in
13 writing. Before any such decision is made final,
14 the Secretary shall provide to the sponsor of the
15 drug an opportunity for a meeting at which—
16 】

17 【“(i) the director of the division re-
18 sponsible for reviewing the drug and the
19 sponsor will be present; and】

20 【“(ii) the director will document the
21 scientific issues involved.】

22 【“(4) PROMOTIONAL MATERIALS.—The provi-
23 sions of section 506(e)(2)(B) shall apply with re-
24 spect to approval under this subsection to the same
25 extent and in the same manner as such provisions

1 apply with respect to accelerated approval under sec-
2 tion 506(c)(1).】

3 【“(5) WITHDRAWAL OF LIMITED POPULATION
4 APPROVAL REQUIREMENTS.—If a drug is approved
5 pursuant to this subsection for treatment in a lim-
6 ited population of patients and is subsequently ap-
7 proved or licensed under this section or section 351
8 of the Public Health Service Act, respectively, with-
9 out such a limitation, the Secretary shall remove any
10 labeling requirements or postmarketing conditions
11 that were made applicable to the drug on the basis
12 of such limitation.】

13 【“(6) RELATION TO OTHER PROVISIONS.—
14 Nothing in this subsection shall be construed to pro-
15 hibit designation and expedited review of a drug as
16 a breakthrough therapy under section 506(a), ap-
17 proval of such a drug under section 506(g), designa-
18 tion and treatment of a drug as a fast track product
19 under section 506(b), or accelerated approval of a
20 drug under section 506(c), in combination with ap-
21 proval of the drug for use in a limited population of
22 patients under this subsection.】

23 【“(7) RULE OF CONSTRUCTION.—Nothing in
24 this subsection shall be construed to alter the stand-
25 ards of evidence under subsection (c) or (d) (includ-

1 ing the substantial evidence standard in subsection
2 (d)). Subsections (c) and (d) and such standards of
3 evidence apply to the review and approval of drugs
4 under this subsection, including whether a drug is
5 safe and effective. Nothing in this subsection shall
6 be construed to limit the authority of the Secretary
7 to approve products pursuant to this Act and the
8 Public Health Service Act as authorized prior to the
9 date of enactment of this subsection.】

10 【“(8) EFFECTIVE IMMEDIATELY.—The Sec-
11 retary shall have the authorities vested in the Sec-
12 retary by this subsection beginning on the date of
13 enactment of this subsection, irrespective of when
14 and whether the Secretary promulgates final regula-
15 tions or guidance.”.】

16 【(2) GUIDANCE.—Not later than 12 months
17 after the date of enactment of this Act, the Sec-
18 retary of Health and Human Services, acting
19 through the Commissioner of Food and Drugs, shall
20 issue draft guidance describing criteria, processes,
21 and other general considerations for demonstrating
22 the safety and effectiveness of antibacterial and
23 antifungal drugs to be approved for use in a limited
24 population under section 505(z) of the Federal

1 Food, Drug, and Cosmetic Act, as added by para-
2 graph (1).】

3 【(b) LICENSURE OF CERTAIN BIOLOGICAL PROD-
4 UCTS.—Section 351(j) of the Public Health Service Act
5 (42 U.S.C. 262(j)) is amended—】

6 【(1) by striking “(j)” and inserting “(j)(1)”；】

7 【(2) by inserting “505(z),” after “505(p),”；
8 and】

9 【(3) by adding at the end the following:】

10 【“(2) In applying section 505(z) of the Federal
11 Food, Drug, and Cosmetic Act to the licensure of bi-
12 ological products under this section—】

13 【“(A) references to an antibacterial or
14 antifungal drug that is intended to treat a seri-
15 ous or life-threatening disease or condition shall
16 be construed to refer to biological products in-
17 tended to treat a bacterial or fungal infection
18 associated with a serious or life-threatening dis-
19 ease; and】

20 【“(B) references to approval of a drug
21 under section 505(c) of such Act shall be con-
22 strued to refer to licensure of a biological prod-
23 uct under subsection (a) of this section.”.】

1 **[(c) MONITORING.—**Title III of the Public Health
2 Service Act is amended by inserting after section 317T
3 (42 U.S.C. 247b–22) the following:**]**

4 **["SEC. 317U. MONITORING ANTIBACTERIAL AND**
5 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

6 **["(a) MONITORING.—**The Secretary, acting through
7 the Director of the Centers for Disease Control and Pre-
8 vention, shall use the National Healthcare Safety Network
9 or another appropriate monitoring system to monitor**—]**

10 **["(1) the use of antibacterial and antifungal**
11 drugs, including those receiving approval or licensure
12 for a limited population pursuant to section 505(z)
13 of the Federal Food, Drug, and Cosmetic Act; and**]**

14 **["(2) changes in bacterial and fungal resistance**
15 to drugs.**]**

16 **["(b) PUBLIC AVAILABILITY OF DATA.—**The Sec-
17 retary, acting through the Director of the Centers for Dis-
18 ease Control and Prevention, shall make the data derived
19 from monitoring under this section publicly available for
20 the purposes of**—]**

21 **["(1) improving the monitoring of important**
22 trends in antibacterial and antifungal resistance;
23 and**]**

24 **["(2) ensuring appropriate stewardship of anti-**
25 bacterial and antifungal drugs, including those re-

1 ceiving approval or licensure for a limited population
2 pursuant to section 505(z) of the Federal Food,
3 Drug, and Cosmetic Act.”.]

4 **SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
5 **FOR MICROORGANISMS.**

6 (a) IN GENERAL.—Section 511 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to
8 read as follows:

9 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**
10 **TEST INTERPRETIVE CRITERIA FOR MICRO-**
11 **ORGANISMS.**

12 “(a) IDENTIFICATION OF CRITERIA PURPOSE.—

13 “(1) PURPOSE.—The purpose of this section is
14 to provide the Secretary with an expedited, flexible
15 method for—

16 “(A) clearance or premarket approval of
17 antimicrobial susceptibility testing devices uti-
18 lizing updated, recognized susceptibility test in-
19 terpretive criteria to characterize the in vitro
20 susceptibility of particular bacteria, fungi, or
21 other microorganisms to antimicrobial drugs;
22 and

23 “(B) providing public notice of the avail-
24 ability of recognized interpretive criteria to
25 meet premarket submission requirements or

1 other requirements under this Act for anti-
2 microbial susceptibility testing devices.

3 “(2) IN GENERAL.—The Secretary shall iden-
4 tify appropriate susceptibility test interpretive cri-
5 teria with respect to antimicrobial drugs—

6 “(A) if such criteria are available on the
7 date of approval of the drug under section 505
8 of this Act or licensure of the drug under sec-
9 tion 351 of the Public Health Service Act (as
10 applicable), upon such approval or licensure; or

11 “(B) if such criteria are unavailable on
12 such date, on the date on which such criteria
13 are available for such drug.

14 “(3) BASES FOR INITIAL IDENTIFICATION.—
15 The Secretary shall identify appropriate suscepti-
16 bility test interpretive criteria under paragraph (1),
17 based on the Secretary’s review of, to the extent
18 available and relevant—

19 “(A) preclinical and clinical data, including
20 pharmacokinetic, pharmacodynamic, and epide-
21 miological data;

22 “(B) Bayesian and pharmacometric statis-
23 tical methodologies; and

24 “(C) such other evidence and information
25 as the Secretary considers appropriate.

1 “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA
2 WEBSITE.—

3 “(1) IN GENERAL.—Not later than one year
4 after the date of the enactment of the 21st Century
5 Cures Act, the Secretary shall establish, and main-
6 tain thereafter, on the website of the Food and Drug
7 Administration, a dedicated website that contains a
8 list of any appropriate new or updated susceptibility
9 test interpretive criteria standards in accordance
10 with paragraph (2) (referred to in this section as the
11 ‘Interpretive Criteria Website’).

12 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-
13 PRETIVE CRITERIA STANDARDS.—

14 “(A) IN GENERAL.—The list described in
15 paragraph (1) shall consist of any new or up-
16 dated susceptibility test interpretive criteria
17 standards that are—

18 “(i) established by a nationally or
19 internationally recognized standard devel-
20 opment organization that—

21 “(I) establishes and maintains
22 procedures to address potential con-
23 flicts of interest and ensure trans-
24 parent decisionmaking;

1 “(II) holds open meetings to en-
2 sure that there is an opportunity for
3 public input by interested parties, and
4 establishes and maintains processes to
5 ensure that such input is considered
6 in decisionmaking; and

7 “(III) permits its standards to be
8 made publicly available, through the
9 National Library of Medicine or an-
10 other similar source acceptable to the
11 Secretary; and

12 “(ii) recognized in whole, or in part,
13 by the Secretary under subsection (c).

14 “(B) OTHER LISTS.—The Interpretive Cri-
15 teria Website shall, in addition to the list de-
16 scribed in subparagraph (A), include a list of
17 interpretive criteria, if any, that the Secretary
18 has determined to be appropriate with respect
19 to legally marketed antimicrobial drugs,
20 where—

21 “(i) the Secretary does not recognize,
22 in whole or in part, an interpretive criteria
23 standard described under subparagraph
24 (A) otherwise applicable to such a drug;

1 “(ii) the Secretary withdraws under
2 subsection (c)(1)(B) recognition of a
3 standard, in whole or in part, otherwise
4 applicable to such a drug;

5 “(iii) the Secretary approves an appli-
6 cation under section 505 of this Act or sec-
7 tion 351 of the Public Health Service Act,
8 as applicable, with respect to marketing of
9 such a drug for which there are no rel-
10 evant interpretive criteria included in a
11 standard recognized by the Secretary
12 under subsection (c); or

13 “(iv) because the characteristics of
14 such a drug product differ from other drug
15 products with the same active ingredient,
16 the interpretive criteria with respect to
17 such drug—

18 “(I) differ from otherwise appli-
19 cable interpretive criteria included in
20 a standard listed under subparagraph
21 (A) or interpretive criteria otherwise
22 listed under this subparagraph; and

23 “(II) are determined to be appro-
24 priate for the drug.

1 “(C) REQUIRED STATEMENTS ON LIMITA-
2 TIONS OF INFORMATION.—The Interpretive Cri-
3 teria Website shall include the following:

4 “(i) A statement that—

5 “(I) the Website provides infor-
6 mation about the susceptibility of bac-
7 teria, fungi, or other microorganisms
8 to a certain drug (or drugs); and

9 “(II) the safety and efficacy of
10 the drug in treating clinical infections
11 due to such bacteria, fungi, or other
12 microorganisms may not have been es-
13 tablished in adequate and well-con-
14 trolled clinical trials and the clinical
15 significance of such susceptibility in-
16 formation in such trials is unknown.

17 “(ii) A statement that directs health
18 care practitioners to consult the approved
19 product labeling for specific drugs to deter-
20 mine the uses for which the Food and
21 Drug Administration has approved the
22 product.

23 “(iii) Any other statement that the
24 Secretary determines appropriate to ade-
25 quately convey the limitations of the data

1 supporting susceptibility test interpretive
2 criteria standard listed on the Website.

3 “(3) NOTICE.—Not later than the date on
4 which the Interpretive Criteria Website is estab-
5 lished, the Secretary shall publish a notice of that
6 establishment in the Federal Register.

7 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
8 SION.—The inclusion in the approved labeling of an
9 antimicrobial drug of a reference or hyperlink to the
10 Interpretive Criteria Website, in and of itself, shall
11 not cause the drug to be misbranded in violation of
12 section 502, or the regulations promulgated there-
13 under.

14 “(5) TRADE SECRETS AND CONFIDENTIAL IN-
15 FORMATION.—Nothing in this section shall be con-
16 strued as authorizing the Secretary to disclose any
17 information that is a trade secret or confidential in-
18 formation subject to section 552(b)(4) of title 5,
19 United States Code.

20 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
21 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-
22 GANIZATIONS.—

23 “(1) IN GENERAL.—Beginning on the date of
24 the establishment of the Interpretive Criteria

1 Website, and at least every 6 months thereafter, the
2 Secretary shall—

3 “(A) evaluate any appropriate new or up-
4 dated susceptibility test interpretive criteria
5 standards established by a nationally or inter-
6 nationally recognized standard development or-
7 ganization described in subsection (b)(2)(A)(i);
8 and

9 “(B) publish on the public website of the
10 Food and Drug Administration a notice—

11 “(i) withdrawing recognition of any
12 different susceptibility test interpretive cri-
13 teria standard, in whole or in part;

14 “(ii) recognizing the new or updated
15 standards;

16 “(iii) recognizing one or more parts of
17 the new or updated interpretive criteria
18 specified in such a standard and declining
19 to recognize the remainder of such stand-
20 ard; and

21 “(iv) making any necessary updates to
22 the lists under subsection (b)(2).

23 “(2) BASES FOR UPDATING INTERPRETIVE CRI-
24 TERIA STANDARDS.—In evaluating new or updated
25 susceptibility test interpretive criteria standards

1 under paragraph (1)(A), the Secretary may con-
2 sider—

3 “(A) the Secretary’s determination that
4 such a standard is not applicable to a particular
5 drug because the characteristics of the drug dif-
6 fer from other drugs with the same active in-
7 gredient;

8 “(B) information provided by interested
9 third parties, including public comment on the
10 annual compilation of notices published under
11 paragraph (3);

12 “(C) any bases used to identify suscepti-
13 bility test interpretive criteria under subsection
14 (a)(2); and

15 “(D) such other information or factors as
16 the Secretary determines appropriate.

17 “(3) ANNUAL COMPILATION OF NOTICES.—
18 Each year, the Secretary shall compile the notices
19 published under paragraph (1)(B) and publish such
20 compilation in the Federal Register and provide for
21 public comment. If the Secretary receives comments,
22 the Secretary will review such comments and, if the
23 Secretary determines appropriate, update pursuant
24 to this subsection susceptibility test interpretive cri-
25 teria standards—

1 “(A) recognized by the Secretary under
2 this subsection; or

3 “(B) otherwise listed on the Interpretive
4 Criteria Website under subsection (b)(2).

5 “(4) RELATION TO SECTION 514(c).—Any sus-
6 ceptibility test interpretive standard recognized
7 under this subsection or any criteria otherwise listed
8 under subsection (b)(2)(B) shall be deemed to be
9 recognized as a standard by the Secretary under sec-
10 tion 514(c)(1).

11 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-
12 TERIA.—Nothing in this section prohibits a person
13 from seeking approval or clearance of a drug or de-
14 vice, or changes to the drug or the device, on the
15 basis of susceptibility test interpretive criteria stand-
16 ards which differ from those recognized pursuant to
17 paragraph (1).

18 “(d) ANTIMICROBIAL DRUG LABELING.—

19 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-
20 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With
21 respect to an antimicrobial drug lawfully introduced
22 or delivered for introduction into interstate com-
23 merce for commercial distribution before the estab-
24 lishment of the Interpretive Criteria Website, a hold-
25 er of an approved application under section 505 or

1 section 351 of the Public Health Service Act, as ap-
2 plicable, for each such drug—

3 “(A) not later than 1 year after establish-
4 ment of the Interpretive Criteria Website, shall
5 submit to the Secretary a supplemental applica-
6 tion for purposes of changing the drug’s label-
7 ing to substitute a reference or hyperlink to
8 such Website for any susceptibility test inter-
9 pretive criteria and related information; and

10 “(B) may begin distribution of the drug in-
11 volved upon receipt by the Secretary of the sup-
12 plemental application for such change.

13 “(2) DRUGS MARKETED SUBSEQUENT TO ES-
14 TABLISHMENT OF INTERPRETIVE CRITERIA
15 WEBSITE.—With respect to antimicrobial drugs law-
16 fully introduced or delivered for introduction into
17 interstate commerce for commercial distribution on
18 or after the date of the establishment of the Inter-
19 pretive Criteria Website, the labeling for such a drug
20 shall include, in lieu of susceptibility test interpretive
21 criteria and related information, a reference to such
22 Website.

23 “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-
24 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

1 “(1) IN GENERAL.—Notwithstanding sections
2 501, 502, 510, 513, and 515, if the conditions speci-
3 fied in paragraph (2) are met (in addition to other
4 applicable provisions under this chapter) with re-
5 spect to an antimicrobial susceptibility testing device
6 described in subsection (f)(1), the Secretary may au-
7 thorize the marketing of such device for a use de-
8 scribed in such subsection.

9 “(2) CONDITIONS APPLICABLE TO ANTI-
10 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—
11 The conditions specified in this paragraph are the
12 following:

13 “(A) The device is used to make a deter-
14 mination of susceptibility using susceptibility
15 test interpretive criteria that are—

16 “(i) included in a standard recognized
17 by the Secretary under subsection (e); or

18 “(ii) otherwise listed on the Interpre-
19 tive Criteria Website under subsection
20 (b)(2).

21 “(B) The labeling of such device promi-
22 nently and conspicuously—

23 “(i) includes a statement that—

1 “(I) the device provides informa-
2 tion about the susceptibility of bac-
3 teria and fungi to certain drugs; and

4 “(II) the safety and efficacy of
5 such drugs in treating clinical infec-
6 tions due to such bacteria or fungi
7 may not have been established in ade-
8 quate and well-controlled clinical trials
9 and the clinical significance of such
10 susceptibility information in those in-
11 stances is unknown;

12 “(ii) includes a statement directing
13 health care practitioners to consult the ap-
14 proved labeling for drugs tested using such
15 a device, to determine the uses for which
16 the Food and Drug Administration has ap-
17 proved such drugs; and

18 “(iii) includes any other statement the
19 Secretary determines appropriate to ade-
20 quately convey the limitations of the data
21 supporting the interpretive criteria de-
22 scribed in subparagraph (A).

23 “(f) DEFINITIONS.—In this section:

24 “(1) The term ‘antimicrobial susceptibility test-
25 ing device’ means a device that utilizes susceptibility

1 test interpretive criteria to determine and report the
2 in vitro susceptibility of certain microorganisms to a
3 drug (or drugs).

4 “(2) The term ‘qualified infectious disease
5 product’ means a qualified infectious disease product
6 designated under section 505E(d).

7 “(3) The term ‘susceptibility test interpretive
8 criteria’ means—

9 “(A) one or more specific numerical values
10 which characterize the susceptibility of bacteria
11 or other microorganisms to the drug tested; and

12 “(B) related categorizations of such sus-
13 ceptibility, including categorization of the drug
14 as susceptible, intermediate, resistant, or such
15 other term as the Secretary determines appro-
16 priate.

17 “(4)(A) The term ‘antimicrobial drug’ means,
18 subject to subparagraph (B), a systemic anti-
19 bacterial or antifungal drug that—

20 “(i) is intended for human use in the treat-
21 ment of a disease or condition caused by a bac-
22 terium or fungus;

23 “(ii) may include a qualified infectious dis-
24 ease product designated under section 505E(d);
25 and

1 “(iii) is subject to section 503(b)(1).

2 “(B) If provided by the Secretary through regula-
3 tions, such term may include—

4 “(i) drugs other than systemic anti-
5 bacterial and antifungal drugs; and

6 “(ii) biological products (as such term is
7 defined in section 351 of the Public Health
8 Service Act) to the extent such products exhibit
9 antimicrobial activity.

10 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to—

12 “(1) alter the standards of evidence—

13 “(A) under subsection (c) or (d) of section
14 505, including the substantial evidence stand-
15 ard in section 505(d), or under section 351 of
16 the Public Health Service Act (as applicable);
17 or

18 “(B) with respect to marketing authoriza-
19 tion for devices, under sections 510, 513, or
20 515; or

21 “(2) apply with respect to any drug, device, or
22 biological product, in any context other than—

23 “(A) the use of such drug or product as an
24 antimicrobial drug; or

1 “(B) the use of an antimicrobial suscepti-
2 bility testing device to characterize and report
3 the in vitro susceptibility of certain bacteria,
4 fungi, or other microorganisms to antimicrobial
5 drugs in accordance with this section; and

6 “(3) unless specifically stated, have any effect
7 on authorities provided under other sections of this
8 Act, including any regulations issued under such
9 sections.”.

10 (b) CONFORMING AMENDMENTS.—

11 (1) REPEAL OF RELATED AUTHORITY.—Section
12 1111 of the Food and Drug Administration Amend-
13 ments Act of 2007 (42 U.S.C. 247d–5a; relating to
14 identification of clinically susceptible concentrations
15 of antimicrobials) is repealed.

16 (2) MISBRANDING.—Section 502 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
18 amended by adding at the end the following:

19 “(dd) If it is an antimicrobial drug and its labeling
20 fails to conform with the requirements under section
21 511(d).”.

22 (3) RECOGNITION OF INTERPRETIVE CRITERIA
23 AS DEVICE STANDARD.—Section 514(e)(1)(A) of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 360d(e)(1)(A)) is amended by inserting after “the

1 Secretary shall, by publication in the Federal Reg-
2 ister” the following: “(or, with respect to suscepti-
3 bility test interpretive criteria or standards recog-
4 nized or otherwise listed under section 511, by post-
5 ing on the Interpretive Criteria website in accord-
6 ance with such section)”.

7 (c) REPORT TO CONGRESS.—Not later than two
8 years after the date of enactment of this Act, the Sec-
9 retary of Health and Human Services shall submit to the
10 Committee on Energy and Commerce of the House of
11 Representatives and the Committee on Health, Education,
12 Labor, and Pensions of the Senate a report on the
13 progress made in implementing section 511 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as
15 amended by this section.

16 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-
17 TERIA WEBSITE.—Chapter 35 of title 44, United States
18 Code, shall not apply to the collection of information from
19 interested parties regarding the updating of lists under
20 paragraph (2) of subsection (b) section 511 of the Federal
21 Food, Drug, and Cosmetic Act, as amended by subsection
22 (a), and posted on the Interpretive Criteria Website estab-
23 lished under paragraph (1) of such subsection (b).

24 (e) NO EFFECT ON HEALTH CARE PRACTICE.—
25 Nothing in this subtitle (including the amendments made

1 by this subtitle) shall be construed to restrict, in any man-
2 ner, the prescribing or administering of antibiotics or
3 other products by health care practitioners, or to limit the
4 practice of health care.

5 **[SEC. 2123. ENCOURAGING THE DEVELOPMENT AND RE-**
6 **SPONSIBLE USE OF NEW ANTIMICROBIAL**
7 **DRUGS.**

8 **[(a) ADDITIONAL PAYMENT FOR NEW ANTI-**
9 **MICROBIAL DRUGS UNDER MEDICARE.—**Section
10 1886(d)(5) of the Social Security Act (42 U.S.C.
11 1395ww(d)(5)) is amended by adding at the end the fol-
12 lowing new subparagraph:]

13 **["(M)(i) Effective for discharges beginning**
14 **on or after October 1, 2015, the Secretary**
15 **shall, after notice and opportunity for public**
16 **comment (in the publications required by sub-**
17 **section (e)(5) for a fiscal year or otherwise),**
18 **recognize the costs of new antimicrobial drugs**
19 **under the payment system established under**
20 **this subparagraph.]**

21 **["(ii) Pursuant to clause (i), the Secretary**
22 **shall provide for additional payment to be made**
23 **under this subsection with respect to discharges**
24 **involving new antimicrobial drugs in the**
25 **amount provided for under section A for drugs**

1 and biological products that are described in
2 section 1842(o)(1)(C).】

3 【“(iii) For purposes of this subparagraph,
4 the term ‘new antimicrobial drug’ means a
5 product that is approved for use, or a product
6 for which an indication is first approved for
7 use, by the Food and Drug Administration on
8 or after January 1, 2015, and—】

9 【“(I)(aa) is intended to treat an in-
10 fection caused by, or likely to be caused by,
11 a qualifying pathogen (as defined under
12 section 505E(f) of the Federal Food,
13 Drug, and Cosmetic Act); or】

14 【“(bb) meets the definition of a quali-
15 fied infectious disease product under sec-
16 tion 505E(g) of the Federal Food, Drug,
17 and Cosmetic Act;】

18 【“(II) for which there is an ‘unmet
19 medical need’ as determined by the Food
20 and Drug Administration;】

21 【“(III) which is associated with high
22 rates of mortality or significant patient
23 morbidity, as determined by the Secretary,
24 in consultation with the Director of the
25 Centers for Disease Control and Preven-

1 tion and the infectious disease professional
2 community; and】

3 【“(IV) is used in facilities that par-
4 ticipate in the National Healthcare Safety
5 Network of the Centers for Disease Con-
6 trol and Prevention (or, to the extent a
7 similar reporting program relating to anti-
8 microbial drugs is determined by the Sec-
9 retary to be available to such facilities,
10 such similar reporting program as the Sec-
11 retary may specify).】

12 【“(iv)(I) The manufacturer or sponsor of a
13 drug may request the Secretary to designate a
14 drug as a new antimicrobial drug at any time
15 before or after the submission of an application
16 under section 505(b) of the Federal Food,
17 Drug, and Cosmetic Act or section 351(a) of
18 the Public Health Service Act for such drug.
19 The Secretary shall, not later than 60 days
20 after the submission of such a request, deter-
21 mine whether the drug is a new antimicrobial
22 drug.】

23 【“(II) Except as provided in subclause
24 (III), a designation under this subsection shall
25 not be withdrawn for any reason.】

1 【“(III) The Secretary may revoke a des-
2 ignation of a drug as a new antimicrobial drug
3 product if the Secretary finds that the request
4 for such designation contained an untrue state-
5 ment of material fact.”】

6 【“(v) Not later than July 1, 2015, the
7 Secretary shall first publish in the Federal Reg-
8 ister a list of the new antimicrobial drugs.”】

9 【(b) STUDY AND REPORT ON REMOVING BARRIERS
10 TO DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—】

11 【(1) STUDY.—The Comptroller General of the
12 United States shall, in consultation with the Direc-
13 tor of the National Institutes of Health, the Com-
14 missioner of Food and Drugs, and the Director of
15 the Centers for Disease Control and Prevention, con-
16 duct a study to—】

17 【(A) identify and examine the barriers
18 that prevent the development of new anti-
19 microbial drugs, as defined in section
20 1886(d)(5)(M)(iii) of the Social Security Act
21 (42 U.S.C. 1395ww(d)(5)(M)(iii)); and】

22 【(B) develop recommendations for actions
23 to be taken in order to overcome any barriers
24 identified under subparagraph (A).】

1 [(2) REPORT.—Not later than 1 year after the
2 date of the enactment of this Act, the Comptroller
3 General shall submit to Congress a report on the
4 study conducted under paragraph (1).]

5 **[Subtitle H— Vaccine Access,**
6 **Certainty, and Innovation]**

7 **[SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVI-**
8 **SORY COMMITTEE ON IMMUNIZATION PRAC-**
9 **TICES.**

10 Section 2102(a) of the Public Health Service Act (42
11 U.S.C. 300aa–2(a)) is amended by adding at the end the
12 following:]

13 [“(10) ADVISORY COMMITTEE ON IMMUNIZA-

14 TION PRACTICES.—]

15 [“(A) STANDARD PERIODS OF TIME FOR

16 MAKING RECOMMENDATIONS.—Upon the licen-

17 sure of any vaccine or any new indication for a

18 vaccine, the Director of the Program shall di-

19 rect the Advisory Committee on Immunization

20 Practices, at its next regularly scheduled meet-

21 ing, to consider the use of the vaccine.]

22 [“(B) EXPEDITED REVIEW PURSUANT TO

23 REQUEST BY SPONSOR OR MANUFACTURER.—If

24 the Advisory Committee does not make rec-

25 ommendations with respect to the use of a vac-

1 vaccine at the Advisory Committee’s first regularly
2 scheduled meeting after the licensure of the
3 vaccine or any new indication for the vaccine,
4 the Advisory Committee, at the request of the
5 sponsor of the vaccine, shall make such rec-
6 ommendations on an expedited basis.】

7 【“(C) EXPEDITED REVIEW FOR BREAK-
8 THROUGH THERAPIES AND FOR USE DURING
9 PUBLIC HEALTH EMERGENCIES.—If a vaccine
10 is designated as a breakthrough therapy under
11 section 506 of the Federal Food, Drug, and
12 Cosmetic Act and is licensed under section 351
13 of this Act, the Advisory Committee shall make
14 recommendations with respect to the use of the
15 vaccine on an expedited basis.】

16 【“(D) DEFINITION.—In this paragraph,
17 the terms ‘Advisory Committee on Immuniza-
18 tion Practices’ and ‘Advisory Committee’ mean
19 the advisory committee on immunization prac-
20 tices established by the Secretary pursuant to
21 section 222, acting through the Director of the
22 Centers for Disease Control and Prevention.”.】

1 **[SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**
2 **ACIP RECOMMENDATIONS.**

3 **[(a) REVIEW.—**The Director of the Centers for Dis-
4 ease Control and Prevention shall conduct a review of the
5 process used by the Advisory Committee on Immunization
6 Practices to evaluate the consistency of the Advisory Com-
7 mittee in formulating and issuing recommendations per-
8 taining to vaccines.]

9 **[(b) CONSIDERATIONS.—**The review under sub-
10 section (a) shall include assessment of—]

11 **[(1) the criteria used to evaluate new and exist-**
12 **ing vaccines;]**

13 **[(2) the Grading of Recommendations, Assess-**
14 **ment, Development, and Evaluation (GRADE) ap-**
15 **proach to the review and analysis of scientific and**
16 **economic data, including the scientific basis for such**
17 **approach; and]**

18 **[(3) the extent to which the processes used by**
19 **the working groups of the Advisory Committee on**
20 **Immunization Practices are consistent among**
21 **groups.]**

22 **[(c) STAKEHOLDERS.—**In carrying out the review
23 under subsection (a), the Director of the Centers for Dis-
24 ease Control and Prevention shall solicit input from vac-
25 cine stakeholders.]

1 [(d) REPORT.—Not later than 18 months after the
2 date of enactment of this Act, the Director of the Centers
3 for Disease Control and Prevention shall submit to the
4 appropriate committees of the Congress and make publicly
5 available a report on the results of the review under sub-
6 section (a), including recommendations on improving the
7 transparency and consistency of the process described in
8 such subsection.]

9 [(e) DEFINITION.—In this section, the term “Advi-
10 sory Committee on Immunization Practices” means the
11 advisory committee on immunization practices established
12 by the Secretary of Health and Human Services pursuant
13 to section 222 of the Public Health Service Act (42 U.S.C.
14 217a), acting through the Director of the Centers for Dis-
15 ease Control and Prevention.]

16 **[SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**
17 **OPERS.**

18 Section 310 of the Public Health Service Act (42
19 U.S.C. 242o) is amended by adding at the end the fol-
20 lowing:]

21 [“(c)(1) In this subsection, the term ‘vaccine devel-
22 oper’ means a nongovernmental entity engaged in—]

23 [“(A)(i) the development of a vaccine with the
24 intent to pursue licensing of the vaccine by the Food
25 and Drug Administration; or]

1 【“(ii) the production of a vaccine licensed by
2 the Food and Drug Administration; and】

3 【“(B) vaccine research.】

4 【“(2)(A) Upon the submission of a written request
5 for a meeting by a vaccine developer, that includes a jus-
6 tification for the meeting, the Secretary, acting through
7 the Director of the Centers for Disease Control and Pre-
8 vention, shall convene a meeting of representatives of the
9 vaccine developer and experts from the Centers for Dis-
10 ease Control and Prevention in immunization programs,
11 epidemiology, and other relevant areas at which the Direc-
12 tor (or the Director’s designee), for the purpose of inform-
13 ing the vaccine developer’s understanding of public health
14 needs and priorities, shall provide the perspectives of the
15 Centers for Disease Control and Prevention and other rel-
16 evant Federal agencies regarding—】

17 【“(i) public health needs, epidemiology, and im-
18 plementation considerations with regard to a vaccine
19 developer’s potential vaccine profile; and】

20 【“(ii) potential implications of such perspec-
21 tives for the vaccine developer’s vaccine research and
22 development planning.】

23 【“(B) In addition to the representatives specified in
24 subparagraph (A), the Secretary may include in a meeting
25 convened under such subparagraph representatives of—】

1 【“(i) the Food and Drug Administration; and】

2 【“(ii) the National Vaccine Program.】

3 【“(C) The Secretary shall convene a meeting re-
4 requested under subparagraph (A) not later than 120 days
5 after receipt of the request for the meeting.】

6 【“(3)(A) Upon the submission of a written request
7 by a vaccine developer, the Secretary, acting through the
8 Director of the Centers for Disease Control and Preven-
9 tion, shall provide to the vaccine developer any age-based
10 or other demographically assessed disease epidemiological
11 analyses or data that—】

12 【“(i) are specified in the request;】

13 【“(ii) have been published;】

14 【“(iii) have been performed by or are in the
15 possession of the Centers;】

16 【“(iv) are not a trade secret or otherwise con-
17 fidential information subject to section 552(b)(4) of
18 title 5, United States Code, or section 1905 of title
19 18, United States Code; and】

20 【“(v) do not contain individually identifiable in-
21 formation.】

22 【“(B) The Secretary shall provide analyses requested
23 by a vaccine manufacturer under subparagraph (A) not
24 later than 90 calendar days after receipt of the request
25 for the analyses.】

1 【“(4) The Secretary shall promptly notify a vaccine
2 developer if—】

3 【“(A) the Secretary becomes aware of any
4 change to information that was—】

5 【“(i) shared by the Secretary with the vac-
6 cine developer during a meeting under para-
7 graph (2); or】

8 【“(ii) provided by the Secretary to the vac-
9 cine developer in one or more analyses under
10 paragraph (3); and】

11 【“(B) the change may have implications for the
12 vaccine developer’s vaccine research and develop-
13 ment.”.】

14 **【Subtitle I—Repurposing Drugs for**
15 **Serious and Life-Threatening**
16 **Diseases and Conditions】**

17 [SEC. 2151. [TO BE SUPPLIED].

18 **Subtitle J—Domestic Manufac-**
19 **turing and Export Efficiencies**

20 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**
21 **TINUOUS DRUG MANUFACTURING.**

22 (a) IN GENERAL.—The Commissioner of Food and
23 Drugs may award grants to institutions of higher edu-
24 cation and nonprofit organizations for the purpose of
25 studying and recommending improvements to the process

1 of continuous manufacturing of drugs and biological prod-
2 ucts and similar innovative monitoring and control tech-
3 niques.

4 (b) DEFINITIONS.—In this section:

5 (1) The term “drug” has the meaning given to
6 such term in section 201 of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 321).

8 (2) The term “biological product” has the
9 meaning given to such term in section 351(i) of the
10 Public Health Service Act (42 U.S.C. 262(i)).

11 (3) The term “institution of higher education”
12 has the meaning given to such term in section 101
13 of the Higher Education Act of 1965 (20 U.S.C.
14 1001).

15 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
16 authorized to be appropriated \$_____ for each of fiscal
17 years 2016 through 2019 to carry out this section.

18 **[SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE**
19 **EUROPEAN ECONOMIC AREA.**

20 Section 1003(f) of the Controlled Substances Import
21 and Export Act (21 U.S.C. 953(f)) is amended—**]**

22 **[(1) in paragraph (5)—]**

23 **[(A) by striking “(5)” and inserting**
24 **“(5)(A)”;**]

1 [(B) by inserting “, except that the con-
2 trolled substance may be exported from the sec-
3 ond country to another country that is a mem-
4 ber of the European Economic Area” before the
5 period at the end; and]

6 [(C) by adding at the end the following:]

7 [“(B) Subsequent to any re-exportation de-
8 scribed in subparagraph (A), a controlled substance
9 may continue to be exported from any country that
10 is a member of the European Economic Area to any
11 other such country, provided that—]

12 [“(i) the conditions applicable with respect
13 to the first country under paragraphs (1), (2),
14 (3), (4), (6), and (7) are met by each subse-
15 quent country from which the controlled sub-
16 stances is exported pursuant to this paragraph;
17 and]

18 [“(ii) the conditions applicable with re-
19 spect to the second country under such para-
20 graphs are met by each subsequent country to
21 which the controlled substance is exported pur-
22 suant to this paragraph.”; and]

23 [(2) by adding at the end the following:]

24 [“(g) LIMITATION.—The Attorney General shall not
25 promulgate nor enforce any regulation, subregulatory

1 guidance, or enforcement policy which impedes re-exportation among European Economic Area countries (as provided in subsection (f)(5)), including by promulgating or enforcing any requirement that—】

2 【“(1) re-exportation from the first country to the second country or re-exportation from the second country to another country (as such terms are used in subsection (f)) occur within a specified period of time; or】

3 【“(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States.”.】

14 **Subtitle K—Priority Review for** 15 **Breakthrough Devices**

16 **SEC. 2181. PRIORITY REVIEW FOR BREAKTHROUGH DE-** 17 **VICES.**

18 (a) IN GENERAL.—Chapter V of the Federal Food,
19 Drug, and Cosmetic Act is amended—

20 (1) in section 515(d)—

21 (A) by striking paragraph (5); and

22 (B) by redesignating paragraph (6) as
23 paragraph (5); and

24 (2) by inserting after section 515A (21 U.S.C.
25 360e–1) the following:

1 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
2 **VICES.**

3 “(a) IN GENERAL.—In order to provide for more ef-
4 fective treatment or diagnosis of life-threatening or irre-
5 versibly debilitating human diseases or conditions, the
6 Secretary shall establish a program to provide priority re-
7 view for devices—

8 “(1) representing breakthrough technologies;

9 “(2) for which no approved alternatives exist;

10 “(3) offering significant advantages over exist-
11 ing approved or cleared alternatives, including the
12 potential to, compared to existing approved or
13 cleared alternatives, reduce or eliminate the need for
14 hospitalization, improve patient quality of life, facili-
15 tate patients’ ability to manage their own care (such
16 as through self-directed personal assistance), or es-
17 tablish long-term clinical efficiencies; or

18 “(4) the availability of which is in the best in-
19 terest of patients.

20 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
21 device may request that the Secretary designate the device
22 for priority review under this section. Any such request
23 for designation may be made at any time prior to the sub-
24 mission of an application under section 515(c), a petition
25 for classification under section 513(f)(2), or a notification
26 under section 510(k).

1 “(c) DESIGNATION PROCESS.—

2 “(1) IN GENERAL.—Not later than 60 calendar
3 days after the receipt of a request under subsection
4 (b), the Secretary shall determine whether the device
5 that is the subject of the request meets the criteria
6 described in subsection (a). If the Secretary deter-
7 mines that the device meets the criteria, the Sec-
8 retary shall designate the device for priority review.

9 “(2) REVIEW.—Review of a request under sub-
10 section (b) shall be undertaken by a team that is
11 composed of experienced staff and managers of the
12 Food and Drug Administration and is chaired by a
13 senior manager.

14 “(3) DESIGNATION DETERMINATION.—A deter-
15 mination approving or denying a request under sub-
16 section (b) shall be considered a significant decision
17 under section 517A and the Secretary shall provide
18 a written, substantive summary of the basis for the
19 determination in accordance with section 517A(a).

20 “(4) RECONSIDERATION.—

21 “(A) REQUEST FOR RECONSIDERATION.—
22 Any person whose request under subsection (b)
23 is denied may, within 30 days of the denial, re-
24 quest reconsideration of the denial in accord-
25 ance with section 517A(b)—

1 “(i) based upon the submission of
2 documents by such person; or

3 “(ii) based upon such documents and
4 a meeting or teleconference.

5 “(B) RESPONSE.—Reconsideration of a
6 designation determination under this paragraph
7 shall be conducted in accordance with section
8 517A(b).

9 “(5) WITHDRAWAL.—If the Secretary approves
10 a priority review designation for a device under this
11 section, the Secretary may not withdraw the des-
12 ignation based on the fact that the criteria specified
13 in subsection (a) are no longer met because of the
14 subsequent clearance or approval of another device
15 that was designated under—

16 “(A) this section; or

17 “(B) section 515(d)(5) (as in effect imme-
18 diately prior to the enactment of the 21st Cen-
19 tury Cures Act).

20 “(d) PRIORITY REVIEW.—

21 “(1) ACTIONS.—For purposes of expediting the
22 development and review of devices designated under
23 subsection (c), the Secretary shall—

24 “(A) assign a team of staff, including a
25 team leader with appropriate subject matter ex-

1 pertise and experience, for each device for
2 which a request is submitted under subsection
3 (b);

4 “(B) provide for oversight of the team by
5 senior agency personnel to facilitate the effi-
6 cient development of the device and the efficient
7 review of any submission described in sub-
8 section (b) for the device;

9 “(C) adopt an efficient process for timely
10 dispute resolution;

11 “(D) provide for interactive communication
12 with the sponsor of the device during the review
13 process;

14 “(E) expedite the Secretary’s review of
15 manufacturing and quality systems compliance,
16 as applicable;

17 “(F) disclose to the sponsor in advance the
18 topics of any consultation concerning the spon-
19 sor’s device that the Secretary intends to under-
20 take with external experts or an advisory com-
21 mittee and provide the sponsor an opportunity
22 to recommend such external experts;

23 “(G) for applications submitted under sec-
24 tion 515(c), provide for advisory committee
25 input, as the Secretary determines appropriate

1 (including in response to the request of the
2 sponsor); and

3 “(H) assign staff to be available within a
4 reasonable time to address questions by institu-
5 tional review committees concerning the condi-
6 tions and clinical testing requirements applica-
7 ble to the investigational use of the device pur-
8 suant to an exemption under section 520(g).

9 “(2) ADDITIONAL ACTIONS.—In addition to the
10 actions described in paragraph (1), for purposes of
11 expediting the development and review of devices
12 designated under subsection (c), the Secretary, in
13 collaboration with the device sponsor, may, as appro-
14 priate—

15 “(A) coordinate with the sponsor regarding
16 early agreement on a data development plan;

17 “(B) take steps to ensure that the design
18 of clinical trials is as efficient as practicable,
19 such as through adoption of shorter or smaller
20 clinical trials, application of surrogate
21 endpoints, and use of adaptive trial designs and
22 Bayesian statistics, to the extent scientifically
23 appropriate;

24 “(C) facilitate, to the extent scientifically
25 appropriate, expedited and efficient develop-

1 ment and review of the device through utiliza-
2 tion of timely postmarket data collection, with
3 regard to applications for approval under sec-
4 tion 515(e); and

5 “(D) agree to clinical protocols that the
6 Secretary will consider binding on the Secretary
7 and the sponsor, subject to—

8 “(i) changes agreed to by the sponsor
9 and the Secretary;

10 “(ii) changes that the Secretary deter-
11 mines are required to prevent an unreason-
12 able risk to the public health; or

13 “(iii) the identification of a substan-
14 tial scientific issue determined by the Sec-
15 retary to be essential to the safety or effec-
16 tiveness of the device involved.

17 “(e) PRIORITY REVIEW GUIDANCE.—

18 “(1) CONTENT.—The Secretary shall issue
19 guidance on the implementation of this section. Such
20 guidance shall include the following:

21 “(A) The process for a person to seek a
22 priority review designation.

23 “(B) A template for requests under sub-
24 section (b).

1 “(C) The criteria the Secretary will use in
2 evaluating a request for priority review.

3 “(D) The standards the Secretary will use
4 in assigning a team of staff, including team
5 leaders, to review devices designated for priority
6 review, including any training required for such
7 personnel on effective and efficient review.

8 “(2) PROCESS.—Prior to finalizing the guid-
9 ance under paragraph (1), the Secretary shall pro-
10 pose such guidance for public comment.

11 “(f) CONSTRUCTION.—

12 “(1) PURPOSE.—This section is intended to en-
13 courage the Secretary and provide the Secretary suf-
14 ficient authorities to apply efficient and flexible ap-
15 proaches to expedite the development of, and
16 prioritize the agency’s review of, devices that rep-
17 resent breakthrough technologies.

18 “(2) CONSTRUCTION.—Nothing in this section
19 shall be construed to alter the criteria and standards
20 for evaluating an application pursuant to section
21 515(c), a report and request for classification under
22 section 513(f)(2), or a report under section 510(k),
23 including the recognition of valid scientific evidence
24 as described in section 513(a)(3)(B), and consider-
25 ation of the least burdensome means of evaluating

1 device effectiveness or demonstrating substantial
2 equivalence between devices with differing techno-
3 logical characteristics, as applicable. Nothing in this
4 section alters the authority of the Secretary to act
5 on an application pursuant to section 515(d) before
6 completion of an establishment inspection, as the
7 Secretary deems appropriate.”.

8 (b) CONFORMING AMENDMENT RELATED TO DES-
9 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g-
11 1(a)(1)) is amended by inserting “a request for designa-
12 tion under section 515B,” after “an application under sec-
13 tion 515,”.

14 **Subtitle L—Medical Device**

15 **Regulatory Process Improvements**

16 **SEC. 2201. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

17 **【To be provided.】**

18 **SEC. 2202. VALID SCIENTIFIC EVIDENCE.**

19 Section 513(a)(3)(B) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

21 (1) by redesignating clauses (i) and (ii) as sub-
22 clauses (I) and (II), respectively;

23 (2) by striking “(B) If the Secretary” and in-
24 serting “(B)(i) If the Secretary”; and

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

1 “(ii) Valid scientific evidence for purposes
2 of clause (i) may include:

3 “(I) evidence described in well-docu-
4 mented case histories, including registry
5 data, that are collected and monitored
6 under an acceptable protocol;

7 “(II) studies published in peer-re-
8 viewed journals; and

9 “(III) data collected in countries other
10 than the United States so long as such
11 data otherwise meets the criteria specified
12 in this subparagraph.

13 “(iii) In the case of a study published in
14 a peer-reviewed journal that is offered as valid
15 scientific evidence for purposes of clause (i), the
16 Secretary may request data underlying the
17 study if—

18 “(I) the Secretary, in making such re-
19 quest, complies with the requirement of
20 subparagraph (D)(ii) to consider the least
21 burdensome appropriate means of evalu-
22 ating device effectiveness or subsection
23 (i)(1)(D) to consider the least burdensome
24 means of determining substantial equiva-
25 lence, as applicable;

1 “(II) the Secretary furnishes a written
2 rationale for so requesting the underlying
3 data accompanies such request; and

4 “(III) if the requested underlying data
5 for such a study are unavailable, the Sec-
6 retary shall consider such study to be part
7 of the totality of the evidence with respect
8 to the device, as the Secretary determines
9 appropriate.”.

10 **SEC. 2203. TRAINING AND OVERSIGHT IN LEAST BURDEN-**
11 **SOME APPROPRIATE MEANS CONCEPT.**

12 (a) IN GENERAL.— Section 513 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by
14 inserting after subsection (i) the following:

15 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-
16 SOME APPROPRIATE MEANS CONCEPT.—

17 “(1) TRAINING.—Each employee of the Food
18 and Drug Administration who is involved in the re-
19 view of premarket submissions under section 515 or
20 section 510(k), including supervisors, shall receive
21 training regarding the meaning and implementation
22 of the least burdensome appropriate means concept
23 in the context of the use of that term in subsections
24 (a)(3)(D) and (i)(1)(D) of this section and in section
25 515(c)(5).

1 “(2) GUIDANCE DOCUMENTS.—

2 “(A) DRAFT UPDATED GUIDANCE.—Not
3 later than 12 months after the date of enact-
4 ment of the 21st Century Cures Act, the Sec-
5 retary shall issue a draft guidance document
6 updating the October 4, 2002, guidance docu-
7 ment entitled ‘The Least Burdensome provision
8 of the FDA Modernization Act of 1997: Con-
9 cept and Principles; Final 11 Guidance for
10 FDA and Industry’.

11 “(B) MEETING OF STAKEHOLDERS.—In
12 developing such draft guidance document, the
13 Secretary shall convene a meeting of stake-
14 holders to ensure a full record to support the
15 publication of such document.

16 “(3) OMBUDSMAN AUDIT.—Not later than 18
17 months after the date of issuance of final version of
18 the draft guidance under paragraph (2), the om-
19 budsman for the organizational unit of the Food and
20 Drug Administration responsible for the premarket
21 review of devices shall—

22 “(A) conduct, or have conducted, an audit
23 of the training described in paragraph (1); and

24 “(B) include in such audit interviews with
25 a representative sample of persons from indus-

1 try regarding their experience in the device pre-
2 market review process.”.

3 (b) **ADDITIONAL INFORMATION REGARDING PRE-**
4 **MARKET APPLICATIONS.**—Subsection (c) of section 515 of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S. C.
6 29 360e) is amended by adding at the end the follows:

7 “(5)(A) Whenever the Secretary requests additional
8 information from an applicant regarding an application
9 under paragraph (1), the Secretary shall consider the least
10 burdensome appropriate means necessary to demonstrate
11 device safety and effectiveness, and request information
12 accordingly.

13 “(B) For purposes of subparagraph (A), the term
14 ‘necessary’ means the minimum required information that
15 would support a determination by the Secretary that an
16 application provides a reasonable assurance of the safety
17 and effectiveness of the device.

18 “(C) Nothing in this paragraph alters the standards
19 for premarket approval of a device.”.

20 **SEC. 2204. RECOGNITION OF STANDARDS.**

21 Section 514(c) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360d(e)) is amended—

23 (1) in paragraph (1), by inserting after sub-
24 paragraph (B) the following new subparagraphs:

1 “(C)(i) Any person may submit a request
2 for recognition under subparagraph (A) of all
3 or part of an appropriate standard established
4 by a nationally or internationally recognized
5 standard organization.

6 “(ii) Not later than 60 days after the Sec-
7 retary receives such a request, the Secretary
8 shall—

9 “(I) make a determination to recog-
10 nize all, part, or none of the standard that
11 is the subject of the request; and

12 “(II) issue to the person who sub-
13 mitted such request a respond in writing
14 that states the Secretary’s rationale for
15 that determination, including the scientific,
16 technical, regulatory, or other basis for
17 such determination;

18 “(iii) The Secretary make a response
19 issued under clause (ii)(II) publicly available, in
20 such manner as the Secretary determines ap-
21 propriate.

22 “(iv) The Secretary shall take such actions
23 as may be necessary to implement all or part of
24 a standard recognized under subclause (I), in
25 accordance with subparagraph (A).

1 “(D) The Secretary shall make publicly
2 available, in such manner as the Secretary de-
3 termines appropriate, the rationale for recogni-
4 tion under subparagraph (A) of part of a stand-
5 ard, including the scientific, technical, regu-
6 latory, or other basis for such recognition. ”;
7 and

8 (2) by adding at the end the following new
9 paragraphs:

10 “(4) TRAINING ON USE OF STANDARDS.—The
11 Secretary shall provide to all employees of the Food
12 and Drug Administration who review premarket sub-
13 missions for devices periodic training on the concept
14 and use of recognized standards for purposes of
15 meeting a premarket submission requirement or
16 other applicable requirement under this Act, includ-
17 ing standards relevant to an employee’s area of de-
18 vice review.

19 “(5) GUIDANCE.—

20 “(A) DRAFT GUIDANCE.—The Secretary
21 shall publish guidance identifying the principles
22 for recognizing standards under this section. In
23 publishing such guidance, the Secretary shall
24 consider the experience with, and reliance on, a
25 standard by other Federal regulatory authori-

1 ties and the device industry, and whether rec-
2 ognition of a standard will promote harmoni-
3 zation among regulatory authorities in the regu-
4 lation of devices.

5 “(B) TIMING.—The Secretary shall pub-
6 lish—

7 “(i) draft guidance under subpara-
8 graph (A) not later than 12 months after
9 the date of the enactment of the 21st Cen-
10 tury Cures Act; and

11 “(ii) final guidance not later than 12
12 months of the close of the public comment
13 period for the draft guidance under clause
14 (i).”.

15 **SEC. 2205. NOTIFICATION OF MARKETING OF CERTAIN**
16 **CLASS I DEVICES.**

17 **【To be provided.】**

18 **SEC. 2206. ADVISORY COMMITTEE PROCESS.**

19 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-
20 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 360e(b)) is amended—

22 (1) by striking “(5)” and inserting “(5)(A)”;

23 and

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

1 “(B) For review by a classification panel of
2 a premarket submission for a device, the Sec-
3 retary shall—

4 “(i) provide an opportunity for the
5 person whose premarket submission is sub-
6 ject to panel review to provide rec-
7 ommendations on the expertise needed
8 among the voting members of the panel;
9 and

10 “(ii) give due consideration to such
11 recommendations and ensure that adequate
12 expertise is represented on advisory panels
13 to assess—

14 “(I) the disease or condition for
15 which the device is intended to cure,
16 treat, mitigate, prevent, or diagnose;
17 and

18 “(II) the technology of the de-
19 vice.

20 “(C) For purposes of subparagraph (B)(ii),
21 the term ‘adequate expertise’ means that the
22 membership of the classification panel reviewing
23 a premarket submission includes—

1 “(i) two or more voting members, with
2 a specialty or other expertise clinically rel-
3 evant to the device under review; and

4 “(ii) at least one voting member who
5 is knowledgeable about the technology of
6 the device.”.

7 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 360e(b)(6)) is amended—

10 (1) in subparagraph (A)(iii), by inserting before
11 the period at the end “, including by designating a
12 representative who will be provided a time during
13 the panel meeting to address the panel individually
14 (or accompanied by experts selected by such rep-
15 resentative) for the purpose of correcting
16 misstatements of fact or providing clarifying infor-
17 mation, subject to the discretion of panel chair-
18 person.”.

19 (2) by striking subparagraph (B) and inserting
20 the following new subparagraph:

21 “(B)(i) Any meeting of a classification
22 panel with respect to the review of a device
23 shall—

24 “(I) provide adequate time for initial
25 presentations by the person whose device is

1 specifically the subject of such review and
2 by the Secretary; and

3 “(II) encourage free and open partici-
4 pation by all interested persons.

5 “(ii) Following the initial presentations de-
6 scribed in clause (i), the panel may—

7 “(I) pose questions to a designated
8 representative described in subparagraph
9 (A)(iii); and

10 “(II) consider the responses to such
11 questions in the panel’s review of the de-
12 vice.”.

13 **SEC. 2207. HUMANITARIAN DEVICE EXEMPTION APPLICA-**
14 **TION.**

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

18 (1) in paragraph (1) by striking “fewer than
19 4,000” and inserting “not more than 8,000”;

20 (2) in paragraph (2)(A) by striking “fewer than
21 4,000” and inserting “not more than 8,000”; and

22 (3) in paragraph (6)(A)(ii), by striking “4,000”
23 and inserting “8,000”

24 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-
25 EFIT.—Not later than 18 months after the date of enact-

1 ment of this Act, the Secretary of Health and Human
2 Services, acting through the Commissioner of Food and
3 Drugs, shall publish a draft guidance document that de-
4 fines the criteria for establishing “probable benefit” as
5 that term is used in section 520(m)(2)(C) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

7 **SEC. 2208. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**
8 **VITRO DIAGNOSTICS.**

9 (a) **DRAFT REVISED GUIDANCE.**—Not later than 12
10 months after the date of the enactment of this Act, the
11 Secretary of Health and Human Services shall publish a
12 draft guidance that—

13 (1) revises section “V. Demonstrating Insignifi-
14 cant Risk of an Erroneous Result” – “Accuracy” of
15 the guidance entitled “Recommendations for Clinical
16 Laboratory Improvement Amendments of 1988
17 (CLIA) Waiver Applications for Manufacturers of In
18 Vitro Diagnostic Devices” and dated January 30,
19 2008; and

20 (2) includes guidance on the appropriate use of
21 comparable performance between a waived user and
22 a moderately complex laboratory user to dem-
23 onstrate accuracy.

24 (b) **FINAL REVISED GUIDANCE.**—The Secretary of
25 Health and Human Services shall finalize the draft guid-

1 ance published under subsection (a) not later than 12
2 months after the comment period for such draft guidance
3 closes.

4 **[Subtitle M—Sensible Oversight**
5 **for Technology Which Advances**
6 **Regulatory Efficiency]**

7 **[SEC. 2221. HEALTH SOFTWARE.**

8 Section 201 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 321) is amended by adding at the end the
10 following:】

11 **【“(ss)(1) The term ‘health software’ means software**
12 **that does not, through use of an in vitro diagnostic device**
13 **or signal acquisition system, acquire, process, or analyze**
14 **an image or physiological signal, is not an accessory, is**
15 **not an integral part of a device necessary to support the**
16 **use of the device, and—】**

17 **【“(A) is intended for use for administra-**
18 **tive or operational support or the processing**
19 **and maintenance of financial records;】**

20 **【“(B) is intended for use in clinical, lab-**
21 **oratory, or administrative workflow and related**
22 **recordkeeping;】**

23 **【“(C)(i) is intended for use solely in the**
24 **transfer, aggregation, conversion (in accordance**
25 **with a present specification), storage, manage-**

1 ment, retrieval, or transmission of data or in-
2 formation;】

3 【“(ii) utilizes a connectivity software plat-
4 form, electronic or electrical hardware, or a
5 physical communications infrastructure; and】

6 【“(iii) is not intended for use—】

7 【“(I) in active patient monitoring; or】

8 【“(II) in controlling or altering the
9 functions or parameters of a device that is
10 connected to such software;】

11 【“(D) is intended for use to organize and
12 present information for health or wellness edu-
13 cation or for use in maintaining a healthy life-
14 style, including medication reminders and
15 health management tools;】

16 【“(E) to provide general health informa-
17 tion that does not include a patient-specific di-
18 agnosis, treatment, or course of action; or】

19 【“(F) is intended to analyze information
20 to provide patient-specific recommended options
21 to consider in the prevention, diagnosis, treat-
22 ment, cure or mitigation of a particular disease
23 or condition.】

24 【“(2) The term ‘accessory’ means a product that—
25 】

1 【“(A) is intended for use with one or more par-
2 ent devices;】

3 【“(B) is intended to support, supplement, or
4 augment the performance of one or more parent de-
5 vices; and】

6 【“(C) shall be classified by the Secretary—】

7 【“(i) according to its intended use; and】

8 【“(ii) independently of any classification of
9 any parent device with which it is used.”.】

10 **【SEC. 2222. APPLICABILITY AND INAPPLICABILITY OF REG-**
11 **ULATION.**

12 Subchapter A of chapter V of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
14 ed by adding at the end the following:】

15 **【“SEC. 524B. HEALTH SOFTWARE.**

16 【“(a) INAPPLICABILITY OF REGULATION TO HEALTH
17 SOFTWARE.—Subject to subsection (b), health software
18 shall not be subject to regulation under this Act.】

19 【“(b) EXCEPTION.—Subsection (a) shall not apply in
20 the case of a software product of a type described in sub-
21 paragraph (F) of section 201(ss)(1) that the Secretary de-
22 termines poses a significant risk to patient safety. In mak-
23 ing such a determination, the Secretary shall consider the
24 following:】

1 【“(1) The likelihood and severity of patient
2 harm if the product were to function improperly.】

3 【“(2) The clinical significance of the informa-
4 tion or recommendations supplied by the product.】

5 【“(3) The extent to which the product is in-
6 tended to replace the clinical judgment of a medical
7 professional.】

8 【“(4) Whether a review of the means by which
9 the analysis was performed by the product with re-
10 spect to a particular disease or condition could be
11 reasonably performed by a medical professional.】

12 【“(5) Whether there exists a means to inde-
13 pendently evaluate and verify the accuracy of the
14 analysis so performed.】

15 【“(6) The intended use of the product, includ-
16 ing the intended user and user environment, such as
17 whether a health care provider will use a software
18 product of a type described in subparagraph (F) of
19 section 201(ss)(1).】

20 【“(c) DELEGATION.—The Secretary shall delegate
21 primary jurisdiction for regulating a software product of
22 a type described in subparagraph (F) of section 201(ss)(1)
23 to the center at the Food and Drug Administration
24 charged with regulating devices. 】

25 【“(d) REGULATION OF SOFTWARE.—】

1 【“(1) IN GENERAL.—Not later than 24 months
2 after the date of the enactment of this section, the
3 Secretary shall promulgate final regulations for the
4 regulation of software under this Act. The Secretary
5 shall include in such regulations a review of the ex-
6 tent to which the existing standards for the classi-
7 fication, review, and regulation of devices under the
8 Federal Food, Drug, and Cosmetic Act should be
9 modified with respect to software, including each of
10 the following areas:】

11 【“(A) The classification of software.】

12 【“(B) Standards for the development of
13 software.】

14 【“(C) Standards for the validation and
15 verification of software.】

16 【“(D) The review of software.】

17 【“(E) Modifications to software.】

18 【“(F) Manufacturing of software.】

19 【“(G) Quality systems for software.】

20 【“(H) Labeling requirements for soft-
21 ware.】

22 【“(I) Postmarketing requirements for re-
23 porting networks and the reporting of adverse
24 events.】

1 【“(2) PROCESS FOR ISSUING PROPOSED REGU-
2 LATIONS.—Not later than 18 months after the date
3 of enactment of this section, the Secretary shall, in
4 consultation with stakeholders (including patients,
5 industry, health care providers, academia, and gov-
6 ernment) issue proposed regulations under para-
7 graph (1).”】

8 **【SEC. 2223. EXCLUSION FROM DEFINITION OF DEVICE.**

9 Section 201(h) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 321) is amended—】

11 【(1) in subparagraph (2), by striking “or” after
12 “or other animals,”;】

13 【(2) in subparagraph (3), by striking “and”
14 and inserting “or”; and】

15 【(3) by inserting after subparagraph (3) the
16 following:】

17 【“(4) is not health software (other than soft-
18 ware determined to be a risk to patient safety under
19 section 524B(b)), and”】.

1 **Subtitle N—Streamlining Clinical**
2 **Trials**

3 **[SEC. 2241. PROTECTION OF HUMAN SUBJECTS IN RE-**
4 **SEARCH; APPLICABILITY OF RULES.**

5 Part H of title IV of the Public Health Service Act
6 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
7 tion 491 the following section:】

8 **[“SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RE-**
9 **SEARCH; APPLICABILITY OF RULES.**

10 **[“(a) PROTECTION OF HUMAN SUBJECTS.—”]**

11 **[“(1) IN GENERAL.—**All human subject re-
12 search described in paragraph (2)(A) shall be con-
13 ducted in accordance with the HHS Human Subject
14 Regulations, and as applicable to the human sub-
15 jects involved in such research, with the vulnerable-
16 populations rules.】

17 **[“(2) APPLICABILITY.—”]**

18 **[“(A) IN GENERAL.—**This section applies
19 to human subject research that is—】

20 **[“(i) conducted or supported by the**
21 Department of Health and Human Serv-
22 ices; or】

23 **[“(ii) otherwise subject to regulation**
24 by the Department under a provision of
25 Federal law (other than this section).】

1 **【“(B) OTHER FEDERAL DEPARTMENTS**
2 **AND AGENCIES.—The Secretary shall make**
3 **available assistance to any Federal department**
4 **or agency seeking—】**

5 **【“(i) to improve the regulation or**
6 **oversight of human subject research; or】**

7 **【“(ii) to apply the HHS Human Sub-**
8 **ject Regulations or the vulnerable-popu-**
9 **lations rules to human subject research**
10 **that is conducted, supported, or regulated**
11 **by such department or agency.】**

12 **【“(b) HHS HUMAN SUBJECT REGULATIONS; OTHER**
13 **DEFINITIONS.—】**

14 **【“(1) HHS HUMAN SUBJECT REGULATIONS;**
15 **VULNERABLE-POPULATIONS RULES.—For purposes**
16 **of this section:】**

17 **【“(A) The term ‘HHS Human Subject**
18 **Regulations’—】**

19 **【“(i) subject to clause (ii), means the**
20 **provisions of subpart A of part 46 of title**
21 **45, Code of Federal Regulations (or any**
22 **successor regulations); or】**

23 **【“(ii) in the case of human subject re-**
24 **search that is subject to the Federal Food,**
25 **Drug, and Cosmetic Act or to section 351**

1 of this Act, means the provisions of parts
2 50, 56, 312, and 812 of title 21, Code of
3 Federal Regulations (or any successor reg-
4 ulations).】

5 【“(B) The term ‘vulnerable-populations
6 rules’—】

7 【“(i) subject to clause (ii), means the
8 provisions of subparts B through D of
9 such part 46 (or any successor regula-
10 tions); or】

11 【“(ii) as applicable to the human sub-
12 jects involved in research described in sub-
13 paragraph (A), means the provisions appli-
14 cable to vulnerable populations under part
15 56 of such title 21 (or any successor regu-
16 lations) and subpart D of part 50 of such
17 title 21 (or any successor regulations).】

18 【“(2) HUMAN SUBJECT RESEARCH.—For pur-
19 poses of this section:】

20 【“(A) Except as provided in subparagraph
21 (B), the term ‘human subject research’ means
22 research, as defined in subpart A of part 46 of
23 title 45, Code of Federal Regulations (or any
24 successor regulations), that involves a human

1 subject, as defined in such subpart A (or any
2 successor regulations).】

3 【“(B) In the case of an investigation that
4 is subject to the provisions of part 50 of title
5 21, Code of Federal Regulations (or any suc-
6 cessor regulations), the term ‘human subject’
7 has the meaning given such term in such part
8 50, and the term ‘human subject research’
9 means a clinical investigation as defined in such
10 part 50.】

11 【“(3) OTHER DEFINITIONS.—For purposes of
12 this section:】

13 【“(A) The term ‘institutional review
14 board’ has the meaning that applies to the term
15 ‘institutional review board’ under the HHS
16 Human Subject Regulations.】

17 【“(B) The term ‘lead institutional review
18 board’ means an institutional review board that
19 otherwise meets the requirements of the HHS
20 Human Subject Regulations and enters into a
21 written agreement with an institution, another
22 institutional review board, a sponsor, or a prin-
23 cipal investigator to approve and oversee human
24 subject research that is conducted at multiple
25 locations. References to an institutional review

1 board include an institutional review board that
2 serves a single institution as well as a lead in-
3 stitutional review board.】

4 【“(c) SCOPE OF AUTHORITY OF SECRETARY.—】

5 【“(1) IN GENERAL.—The HHS Human Subject
6 Regulations (including provisions regarding exemp-
7 tions) and the vulnerable-populations rules, as in ef-
8 fect on the day before the date of the enactment of
9 the 21st Century Cures Act, continue to be in effect
10 on and after such date, subject to paragraph (2).】

11 【“(2) MODIFICATIONS.—】

12 【“(A) COMPLIANCE WITH LAW.—Promptly
13 after the date of the enactment of the Act re-
14 ferred to in paragraph (1), the Secretary shall
15 promulgate regulations to make such modifica-
16 tions to the provisions of the HHS Human
17 Subject Regulations as may be necessary to en-
18 sure that such provisions implement, and do not
19 conflict with, this section.】

20 【“(B) OTHER MODIFICATIONS.—This sec-
21 tion may not be construed as affecting the au-
22 thority of the Secretary to modify the provisions
23 of the HHS Human Subject Regulations or the
24 vulnerable-populations rules, except to the ex-
25 tent that any such modification is in conflict

1 with this section. Any such modification shall
2 be made by regulation or guidance, as applica-
3 ble.】

4 【“(d) AVOIDING REGULATORY DUPLICATION AND
5 UNNECESSARY DELAYS.—】

6 【“(1) IN GENERAL.—The Secretary shall—】

7 【“(A) make such modifications to the pro-
8 visions of the HHS Human Subject Regulations
9 and the vulnerable-populations rules as may be
10 necessary—】

11 【“(i) to reduce regulatory duplication
12 and unnecessary delays;】

13 【“(ii) to modernize such provisions in
14 the context of multisite and cooperative re-
15 search projects;】

16 【“(iii) to incorporate local consider-
17 ations, community values, and mechanisms
18 to protect vulnerable populations; and】

19 【“(iv) to ensure that human subject
20 research that is subject to the Federal
21 Food, Drug, and Cosmetic Act or to sec-
22 tion 351 of this Act, and is therefore sub-
23 ject to parts 50, 56, 312, and 812 of title
24 21, Code of Federal Regulations (or any
25 successor regulations), is not subject to

1 subpart A of part 46 of title 45, Code of
2 Federal Regulations (or any successor reg-
3 ulations); and】

4 【“(B) ensure that human subject research
5 that is described in subparagraph (A)(iv), or is
6 cooperative research as such term is defined in
7 section 46.114 of title 45, Code of Federal Reg-
8 ulations (or any successor regulations), may—
9 】

10 【“(i) use joint or shared review;】

11 【“(ii) rely upon the review of—】

12 【“(I) an independent institu-
13 tional review board; or】

14 【“(II) an institutional review
15 board of an entity other than the
16 sponsor of the research; or】

17 【“(iii) use similar arrangements to
18 avoid duplication of effort.】

19 【“(2) REGULATIONS AND GUIDANCE.—Not
20 later than 12 months after the date of enactment of
21 the 21st Century Cures Act, the Secretary, acting
22 through the relevant agencies and offices of the De-
23 partment of Health and Human Services, including
24 the Office for Human Research Protections and rel-
25 evant agencies and offices of the Food and Drug Ad-

1 ministration, shall issue such regulations and guid-
2 ance and take such other actions as may be nec-
3 essary to implement this subsection. Such regula-
4 tions and guidance shall include clarification of re-
5 quirements and policies relating to the following:】

6 【“(A) Arrangements to avoid duplication
7 described in paragraph (1)(C), including—】

8 【“(i) delineating the roles of institu-
9 tional review boards in multisite or cooper-
10 ative, multisite studies where one or more
11 local institutional review boards are relied
12 upon, or similar arrangements are used;】

13 【“(ii) the risks and benefits to human
14 subjects;】

15 【“(iii) standardization of informed
16 consent and other processes and legal doc-
17 uments; and】

18 【“(iv) incorporating community values
19 through the use of local institutional re-
20 view boards while continuing to use central
21 or lead institutional review boards.】

22 【“(B) Concerns about regulatory and legal
23 liability contributing to decisions by the spon-
24 sors of research to rely on local institutional re-
25 view boards for multisite research.】

1 【“(3) CONSULTATION.—In issuing regulations
2 or guidance pursuant to paragraph (2), the Sec-
3 retary shall consult with stakeholders (including re-
4 searchers, academic organizations, hospitals, institu-
5 tional research boards, pharmaceutical, bio-
6 technology and medical device developers, clinical re-
7 search organizations, patient groups, and others).”】

8 **SEC. 2242. USE OF NON-LOCAL INSTITUTIONAL REVIEW**
9 **BOARDS FOR REVIEW OF INVESTIGATIONAL**
10 **DEVICE EXEMPTIONS AND HUMAN DEVICE**
11 **EXEMPTIONS.**

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

14 (1) in subsection (g)(3)—

15 (A) by striking “local” each place it ap-
16 pears; and

17 (B) in subparagraph (A)(i), by striking
18 “which has been”; and

19 (2) in subsection (m)(4)—

20 (A) by striking “local” each place it ap-
21 pears; and

22 (B) by striking subparagraph (A) and in-
23 serting the following new subparagraph:

24 “(A) in facilities in which clinical testing of de-
25 vices is supervised by an institutional review com-

1 mittee established in accordance with the regulations
2 of the Secretary, and”.

3 (b) REGULATIONS.—Not later than 12 months after
4 the date of the enactment of this Act, the Secretary of
5 Health and Human Services shall revise or issue such reg-
6 ulations or guidance as may be necessary to carry out the
7 amendments made by subsection (a).

8 **SEC. 2243. ALTERATION OR WAIVER OF INFORMED CON-**
9 **SENT FOR CLINICAL INVESTIGATIONS.**

10 (a) DEVICES.—Section 520(g)(3) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is
12 amended—

13 (1) in subparagraph (D), by striking “except
14 where subject to such conditions as the Secretary
15 may prescribe, the investigator” and inserting the
16 following: “except where, subject to such conditions
17 as the Secretary may prescribe—

18 “(i) the proposed clinical testing poses
19 no more than minimal risk to the human
20 subject and includes appropriate safe-
21 guards to protect the rights, safety, and
22 welfare of the human subject; or

23 “(ii) the investigator”; and

1 (2) in the matter following subparagraph (D),
2 by striking “subparagraph (D)” and inserting “sub-
3 paragraph (D)(ii)”.

4 (b) DRUGS.—Section 505(i)(4) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended
6 by striking “except where it is not feasible or it is contrary
7 to the best interests of such human beings” and inserting
8 “except where it is not feasible, it is contrary to the best
9 interests of such human beings, or the proposed clinical
10 testing poses no more than minimal risk to such human
11 beings and includes appropriate safeguards as prescribed
12 to protect the rights, safety, and welfare of such human
13 beings”.

14 **Subtitle O—Improving Scientific**
15 **Expertise and Outreach at FDA**

16 **SEC. 2261. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**
17 **SEARCH SERVICE.**

18 (a) HIRING AND RETENTION AUTHORITY.—Section
19 228 of the Public Health Service Act (42 U.S.C. 237) is
20 amended—

21 (1) in the section heading, by inserting “AND
22 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-
23 SEARCH”;

24 (2) in subsection (a)(1), by striking “Silvio O.
25 Conte Senior Biomedical Research Service, not to

1 exceed 500 members” and inserting “Silvio O. Conte
2 Senior Biomedical Research and Biomedical Product
3 Assessment Service (in this section referred to as the
4 ‘Service’), the purpose of which is to recruit and re-
5 tain competitive and qualified scientific and tech-
6 nical experts outstanding in the field of biomedical
7 research, clinical research evaluation, and biomedical
8 product assessment”;

9 (3) by amending subsection (a)(2) to read as
10 follows:

11 “(2) The authority established in paragraph (1) may
12 not be construed to require the Secretary to reduce the
13 number of employees serving under any other employment
14 system in order to offset the number of members serving
15 in the Service.”;

16 (4) in subsection (b)—

17 (A) in the matter preceding paragraph (1),
18 by striking “or clinical research evaluation” and
19 inserting “, clinical research evaluation or bio-
20 medical product assessment” after “evalua-
21 tion”; and

22 (B) in paragraph (1), by inserting “or a
23 masters level degree in engineering,
24 bioinformatics, or a related or emerging field,”
25 after the comma;

1 (5) in subsection (d), by striking “and shall not
2 exceed the rate payable for level I of the Executive
3 Schedule unless approved by the President under
4 section 5377(d)(2) of title 5, United States Code”
5 and inserting “and shall not exceed the rate payable
6 for the President”;

7 (6) by striking subsection (e); and

8 (7) by redesignating subsections (f) and (g) as
9 subsections (e) and (f), respectively.

10 (b) REPORT.—Not later than three years after the
11 date of the enactment of this Act, the Secretary of Health
12 and Human Services shall submit, and publish on the
13 Website of the Department of Health and Human Services
14 a report on the implementation of the amendments made
15 by subsection (a), including whether the amendments have
16 improved the ability of the Food and Drug Administration
17 to hire and retain qualified experts to fulfill obligations
18 specified under user fee agreements.

19 **SEC. 2262. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

20 It is the sense of Congress that participation in or
21 sponsorship of scientific conferences and meetings is es-
22 sential to the mission of the Food and Drug Administra-
23 tion.

1 **SEC. 2263. REAGAN-UDALL FOUNDATION FOR THE FOOD**
2 **AND DRUG ADMINISTRATION.**

3 (a) BOARD OF DIRECTORS.—

4 (1) COMPOSITION AND SIZE.—Section
5 770(d)(1)(C) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

7 (A) by redesignating clause (ii) as clause
8 (iii);

9 (B) by inserting after clause (i) the fol-
10 lowing:

11 “(ii) ADDITIONAL MEMBERS.—The
12 Board, through amendments to the bylaws
13 of the Foundation, may provide that the
14 number of voting members of the Board
15 shall be a number (to be specified in such
16 amendment) greater than 14. Any Board
17 positions that are established by any such
18 amendment shall be appointed (by majority
19 vote) by the individuals who, as of the date
20 of such amendment, are voting members of
21 the Board and persons so appointed may
22 represent any of the categories specified in
23 subclauses (I) through (V) of clause (i), so
24 long as no more than 30 percent of the
25 total voting members of the Board (includ-
26 ing members whose positions are estab-

1 lished by such amendment) are representa-
2 tives of the general pharmaceutical, device,
3 food, cosmetic, and biotechnology indus-
4 tries.”; and

5 (C) in clause (iii)(I), as redesignated by
6 subparagraph (A), by striking “The ex officio
7 members shall ensure” and inserting “The ex
8 officio members, acting pursuant to clause (i),
9 and the Board, acting pursuant to clause (ii),
10 shall ensure”.

11 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE
12 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)
13 of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 379dd(d)(1)(C)), as redesignated by para-
15 graph (1)(A), is amended by adding at the end the
16 following: “For purposes of this section, the term
17 ‘employee of the Federal Government’ does not in-
18 clude a ‘special Government employee’, as that term
19 is defined in section 202(a) of title 18, United
20 States Code.”.

21 (3) STAGGERED TERMS.—Subparagraph (A) of
22 section 770(d)(3) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended
24 to read as follows:

1 “(A) TERM.—The term of office of each
2 member of the Board appointed under para-
3 graph (1)(C)(i), and the term of office of any
4 member of the Board whose position is estab-
5 lished pursuant to paragraph (1)(C)(ii), shall be
6 4 years, except that—

7 “(i) the terms of offices for the mem-
8 bers of the Board initially appointed under
9 paragraph (1)(C)(i) shall expire on a stag-
10 gered basis as determined by the ex officio
11 members; and

12 “(ii) the terms of office for the per-
13 sons initially appointed to positions estab-
14 lished pursuant to paragraph (1)(C)(ii)
15 may be made to expire on a staggered
16 basis, as determined by the individuals
17 who, as of the date of the amendment es-
18 tablishing such positions, are members of
19 the Board.”.

20 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section
21 770(g)(2) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall
23 not be greater than the compensation of the Commis-
24 sioner”.

1 (c) SEPARATION OF FUNDS.—Section 770(m) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379dd(m)) is amended by striking “are held in separate
4 accounts from funds received from entities under sub-
5 section (i)” and inserting “are managed as individual pro-
6 grammatic funds under subsection (i), according to best
7 accounting practices”.

8 **SEC. 2264. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
9 **MATION EXEMPTED FROM PAPERWORK RE-**
10 **DUCTION ACT.**

11 Chapter VII of the Federal Food, Drug, and Cos-
12 metic Act is amended by inserting after section 708 of
13 such Act (21 U.S.C. 379) the following:

14 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
15 **MATION EXEMPTED FROM PAPERWORK RE-**
16 **DUCTION ACT.**

17 “Chapter 35 of title 44, United States Code, shall
18 not apply to the collection from patients, industry, aca-
19 demia, and other stakeholders, of voluntary information
20 such as through voluntary surveys or questionnaires, initi-
21 ated by the Secretary.”.

22 **TITLE III—DELIVERY**
23 **Subtitle A—Interoperability**

24 **SEC. 3001. INTEROPERABILITY.**

25 **【To be provided.】**

1 **Subtitle B—Telemedicine**

2 **SEC. 3021. TELEMEDICINE.**

3 **【To be provided by the Energy and Commerce Bipar-**
4 **tisan Telemedicine Working Group】**

5 **Subtitle C—Encouraging Con-**
6 **tinuing Medical Education for**
7 **Physicians**

8 **【SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**
9 **PARENCY REPORTING CERTAIN TRANSFERS**
10 **USED FOR EDUCATIONAL PURPOSES.**

11 **【(a) IN GENERAL.—Section 1128G(e)(10)(B) of the**
12 **Social Security Act (42 U.S.C. 1320a-7h(e)(10)(B)) is**
13 **amended—】**

14 **【(1) in clause (iii), by inserting “, including**
15 **peer-reviewed journals, journal reprints, journal sup-**
16 **plements, medical conference reports, and medical**
17 **textbooks” after “patient use”; and】**

18 **【(2) by adding at the end the following new**
19 **clause:】**

20 **【“(xiii) In the case of a covered re-**
21 **cipient who is a physician, an indirect pay-**
22 **ment or transfer of value to the covered re-**
23 **cipient—】**

24 **【“(I) for speaking at, or pre-**
25 **paring educational materials for, an**

1 educational event for physicians or
2 other health care professionals that
3 does not commercially promote a cov-
4 ered drug, device, biological, or med-
5 ical supply; or】

6 【“(II) that serves the sole pur-
7 pose of providing the covered recipient
8 with medical education, such as by
9 providing the covered recipient with
10 the tuition required to attend an edu-
11 cational event or with materials pro-
12 vided to physicians at an educational
13 event.”.】

14 【(b) EFFECTIVE DATE.—The amendments made by
15 this section shall apply with respect to transfers of value
16 made on or after the date of the enactment of this Act.】

17 **Subtitle D—Disposable Medical**
18 **Technologies**

19 **SEC. 3061. DISPOSABLE MEDICAL TECHNOLOGIES.**

20 【To be provided.】

1 **Subtitle E—Local Coverage**
2 **Decision Reforms**

3 **[SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-**
4 **ERAGE DETERMINATION (LCD) PROCESS.]**

5 **[(a) IN GENERAL.—Section 1874A(g) of the Social**
6 **Security Act (42 U.S.C. 1395kk–1(g)) is amended—]**

7 **[(1) in paragraph (5), by inserting “paragraphs**
8 **(1) through (4) of” before “this subsection”];]**

9 **[(2) by redesignating paragraph (5), as so**
10 **amended, as paragraph (6)];]**

11 **[(3) by inserting after paragraph (4) the fol-**
12 **lowing new paragraph:]**

13 **[(“(5) LOCAL COVERAGE DETERMINATIONS.—]**

14 **[(“(A) IN GENERAL.—Each medicare ad-**
15 **ministrative contractor that develops a local**
16 **coverage determination shall, with respect to**
17 **such determination, make available on the**
18 **website of such contractor on or before the date**
19 **described in subparagraph (B) the following in-**
20 **formation:]**

21 **[(“(i) Such determination in its en-**
22 **tirety.]**

23 **[(“(ii) A response to any comments**
24 **submitted to the contractor with respect to**

1 any proposed versions of such determina-
2 tion that the contractor made available.】

3 【“(iii) A summary of any evidence
4 that was considered by the contractor dur-
5 ing the development of such determination
6 and a list of the sources of such evidence.】

7 【“(iv) An explanation of the rationale
8 that supports such determination.】

9 【“(B) DATE DESCRIBED.—The date de-
10 scribed in this subparagraph is, with respect to
11 a determination described in subparagraph (A),
12 the date that is 45 days before the date on
13 which the determination takes effect.”.】

14 【(b) EFFECTIVE DATE.—The amendment made by
15 subsection (a)(3) shall apply with respect to local coverage
16 determinations that are proposed or revised on or after
17 the date that is 180 days after the date of the enactment
18 of this Act.】

1 **Subtitle F—Medicare Pharma-**
2 **ceutical and Technology Om-**
3 **budsman**

4 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**
5 **NOLOGY OMBUDSMAN.**

6 Section 1808(c) of the Social Security Act (42 U.S.C.
7 1395b–9(c)) is amended by adding at the end the fol-
8 lowing new paragraph:

9 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-
10 BUDSMAN.—Not later than 12 months after the date
11 of the enactment of this paragraph, the Secretary
12 shall provide for a pharmaceutical and technology
13 ombudsman within the Centers for Medicare & Med-
14 icaid Services who shall receive and respond to com-
15 plaints, grievances, and requests that—

16 “(A) are from entities that manufacture
17 pharmaceutical, biotechnology, medical device,
18 or diagnostic products that are covered or for
19 which coverage is being sought under this title;
20 and

21 “(B) regard coverage, coding, or payment
22 under this title for such products.”.

1 **【Subtitle G—Medicare Site-of-**
2 **service Price Transparency】**

3 **【SEC. 3131. MEDICARE SITE-OF-SERVICE PRICE TRANS-**
4 **PARENCY.**

5 **【(a) IN GENERAL.—**In order to facilitate price trans-
6 parency with respect to items and services for which pay-
7 ment may be made either to a hospital outpatient depart-
8 ment or to an ambulatory surgery center under the Medi-
9 care program under title XVIII of the Social Security Act
10 (42 U.S.C. 1395 et seq.), the Secretary of Health and
11 Human Services shall, for 2017 and each year thereafter,
12 make available to the public via a searchable website, with
13 respect to an appropriate number of such items and serv-
14 ices, the anticipated cost of each such item or service to
15 the Federal Government and to the individual who is fur-
16 nished such item or service during such year when such
17 item or service is furnished in each of the following:】

18 **【(1) Such a hospital outpatient department.】**

19 **【(2) Such an ambulatory surgical center.】**

20 **【(b) PERMISSIBLE CALCULATION OF ANTICIPATED**
21 **COST TO THE INDIVIDUAL.—**For purposes of subsection
22 (a), the Secretary may calculate the anticipated cost of
23 an item or service to the individual who is furnished such
24 item or service by calculating the anticipated cost of such
25 item or service, through cost sharing, to an individual who

1 does not receive coverage under a medicare supplemental
2 policy certified under section 1882 of the Social Security
3 Act (42 U.S.C. 1395ss) or any other supplemental insur-
4 ance coverage.】

5 【(c) IMPLEMENTATION.—In carrying out this sec-
6 tion, the Secretary—】

7 【(1) shall include in the notice described in sec-
8 tion 1804(a) of the Social Security Act (42 U.S.C.
9 1395b–2(a)) a notification of the availability of the
10 anticipated costs made available under subsection
11 (a); and】

12 【(2) may utilize existing mechanisms, such as
13 the portion of the website of the Centers for Medi-
14 care & Medicaid Services on which information com-
15 paring physician performance is posted (commonly
16 referred to as the Physician Compare website), to
17 make available such anticipated costs under such
18 subsection.】

19 【(d) FUNDING.—For purposes of implementing this
20 section, the Secretary shall provide for the transfer, from
21 the Supplemental Medical Insurance Trust Fund under
22 section 1841 of the Social Security Act (42 U.S.C. 1395t)
23 to the Centers for Medicare & Medicaid Services Program
24 Management Account, of \$6,000,000 for fiscal year 2015,
25 to remain available until expended.】

1 **[Subtitle H—Medicare Part D Pa-**
2 **tient Safety and Drug Abuse**
3 **Prevention]**

4 **[SEC. 3151. ESTABLISHING PDP SAFETY PROGRAM TO PRE-**
5 **VENT FRAUD AND ABUSE IN MEDICARE PRE-**
6 **SCRIPTION DRUG PLANS.**

7 **[(a) PDP SAFETY PROGRAM.—Section 1860D–4(c)**
8 **of the Social Security Act (42 U.S.C. 1395w–104(c)) is**
9 **amended—]**

10 **[(1) in paragraph (1)(D)—]**

11 **[(A) by inserting “, designed to” after**
12 **“program”; and]**

13 **[(B) by inserting “, that includes the pro-**
14 **cedures described in paragraph (4)” after**
15 **“waste”; and]**

16 **[(2) by adding at the end the following:]**

17 **[“(4) SAFE PHARMACY ACCESS PROGRAM.—]**

18 **[“(A) PDP SPONSOR PROCEDURES.—A**
19 **PDP sponsor (or an MA organization offering**
20 **an MA–PD plan) shall have in place procedures**
21 **designed—]**

22 **[“(i) to identify an individual who has**
23 **obtained coverage for a covered part D**
24 **drug that is a frequently abused schedule**
25 **II, III, IV, or V controlled substance, as**

1 determined in accordance with utilization
2 guidelines established by the Secretary and
3 the sponsor (or MA organization), and to
4 notify such individuals that they have been
5 so identified;】

6 【“(ii) to contract with pharmacies au-
7 thorized to dispense such controlled sub-
8 stances to create a safe pharmacy network
9 that meets the criteria specified in sub-
10 paragraph (C);】

11 【“(iii) taking into account the loca-
12 tion of the individual’s residence (or resi-
13 dences), work site, mobility, and other rel-
14 evant factors, to limit coverage to schedule
15 II, III, IV, or V controlled substances for
16 some or all classes of covered part D drugs
17 for an individual identified under clause (i)
18 (or under subparagraph (B)) to drugs dis-
19 pensed by one or more pharmacies con-
20 tracted with under clause (ii);】

21 【“(iv) to provide to the Secretary the
22 name, and other information that the Sec-
23 retary may require, of individuals so iden-
24 tified and of the fact of such individual’s
25 disenrollment (if any) from the plan of the

1 sponsor (or the MA–PD plan offered by
2 the MA organization);】

3 【“(v) to provide for an appeals proc-
4 ess whereby an individual so identified may
5 appeal such identification on the basis that
6 the identification was not appropriate;】

7 【“(vi) to provide for a process where-
8 by an individual so identified may petition
9 for the termination of such identification
10 on the basis that the limitation on coverage
11 is no longer necessary to prevent fraud and
12 abuse by the individual; and】

13 【“(vii) to provide that coverage shall
14 be provided for a schedule II, III, IV, or
15 V controlled substance only if it is pre-
16 scribed in accordance with an electronic
17 prescribing program under subsection (e),
18 except in such exceptional circumstances as
19 the Secretary may permit.】

20 【“(B) SHARING INFORMATION FOR SUBSE-
21 QUENT PLAN ENROLLMENTS.—The Secretary
22 shall share information, with respect to the
23 identity of an individual identified under sub-
24 paragraph (A)(i) who disenrolls from a plan
25 under subparagraph (A)(iv), with a PDP spon-

1 sor (or MA organization) that subsequently en-
2 rolls such individual under another plan in
3 order that the provisions of subparagraph
4 (A)(iii) would apply under such subsequent en-
5 rollment.】

6 【“(C) SAFE PHARMACY NETWORK CRI-
7 TERIA.—The criteria specified in this subpara-
8 graph for a safe pharmacy network are the fol-
9 lowing:】

10 【“(i) The pharmacies in the network
11 are able to properly monitor the usage of
12 schedule II, III, IV, and V controlled sub-
13 stances.】

14 【“(ii) Such pharmacies and network
15 meet such other drug safety criteria as the
16 Secretary or the PDP sponsor (or MA or-
17 ganization) determines to be appropriate,
18 such as use of a State prescription drug
19 monitoring program, if such a program is
20 available in the State.”.】

21 【(b) DUAL ELIGIBLES.—Section 1860D–1(b)(3)(D)
22 of the Social Security Act (42 U.S.C. 1395w–
23 101(b)(3)(D)) is amended by inserting “, subject to such
24 limits as the Secretary may establish for individuals iden-

1 tified pursuant to section 1860D–4(c)(4)(A)(i)” after “the
2 Secretary”.]

3 [(c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply with respect to plan years begin-
5 ning after the date that is 8 months after the date of the
6 enactment of this Act.]