[DISCUSSION DRAFT]

114TH CONGRESS
1ST SESSION

H. R. _____

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

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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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''21st Century Cures Act''.

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

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION.

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

(1) in subparagraph (B), by striking at the end ''and'';

(2) in subparagraph (C), by striking at the end the period and inserting ''; and''; and

(3) by adding at the end the following new subparagraphs:

''(D) $31,811,000,000 for fiscal year 2016;

''(E) $33,331,000,000 for fiscal year 2017; and

''(F) $34,851,000,000 for fiscal year 2018.''.

[SEC. 1002. NIH INNOVATION FUND.

[(a) USE OF INNOVATION FUND.—Section 402(b) of the Public Health Service Act is amended—]

[(1) in paragraph (23), by striking at the end ''and'';]

[(2) in paragraph (24), by striking at the end the period and inserting ''; and''; and]

[(3) by inserting after paragraph (24), the following new paragraph:]

[''(25) shall, with respect to funds appropriated under section 402A(e) to the NIH Innovation Fund, allocate such funds to the national research institutes and national centers for conducting and supporting innovation fund initiatives identified under paragraph (3) of such section.''.]

[(b) ESTABLISHMENT OF INNOVATION FUND.—Section 402A of the Public Health Service Act is amended—]

[(1) by redesignating subsection (e) as subsection (f); and]

[(2) by inserting after subsection (d) the following new subsection:]

[''(e) NIH INNOVATION FUND.—]

[''(1) ESTABLISHMENT.—For the purpose of allocations under section 402(b)(25), there is established a fund to be known as the NIH Innovation Fund.]

[“(2) AMOUNTS MADE AVAILABLE TO FUND.—]

[“(A) IN GENERAL.—Subject to subparagraph (B), there is authorized to be appropriated, and appropriated, to the NIH Innovation Fund out of any funds in the Treasury not otherwise appropriated, $2,000,000,000 for each of fiscal years 2016 through 2020. The amounts appropriated to the Fund by the preceding sentence shall be in addition to any amounts otherwise made available to the National Institutes of Health.]

[“(B) MAINTAINING BASE APPROPRIATIONS LEVEL.—The amounts appropriated by subparagraph (A) for a fiscal year shall not be available for obligation or expenditure unless and until the [total amount of funds made available to the National Institutes of Health] for such fiscal year[, without regard to this subsection,] are not less than the total amount of funds made available to the National Institutes of Health for fiscal year [____].]

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

under paragraph (1) may be used for only the following innovation fund initiatives:]

[''(A) PRECISION MEDICINE.—[To be supplied].]

[''(B) YOUNG EMERGING SCIENTISTS.—[To be supplied].]

[''(C) OTHER.—[To be supplied].''.]

Subtitle B—National Institutes of Health Planning and Administration

SEC. 1021. NIH RESEARCH STRATEGIC PLAN.

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

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

''(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, including through development, use, and updating of the research strategic plan under subsection (m);''; and

(2) by adding at the end the following:

''(m) RESEARCH STRATEGIC PLAN.—

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

NIH, in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders, shall develop and maintain a 5-year biomedical research strategic plan (in this subsection referred to as the 'strategic plan') that—

''(A) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

''(B) identifies areas, to be known as strategic focus areas, in which the resources of the National Institutes of Health can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research; and

''(C) includes objectives for each such strategic focus area.

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

''(A) to identify research opportunities; and

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

tional research institutes and national centers that—

"(i) have a common format; and

"(ii) identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal described in paragraph (1)(B).

"(3) CONTENTS OF PLANS.—

"(A) STRATEGIC FOCUS AREAS.—The strategic focus areas identified pursuant to paragraphs (1)(B) and (2)(B) shall—

"(i) be identified in a manner that—

"(I) considers the return on investment to the United States public through the investments of the National Institutes of Health in biomedical research; and

"(II) contributes to expanding knowledge to improve the United States public's health through biomedical research; and

"(ii) [include overarching, multicenter strategic focus areas, to be known as Mission Priority Focus Areas, which best serve

the goals of preventing or eliminating the burden of a disease or condition and scientifically merit enhanced and focused research over the next 5 years.]

''(B) RARE AND PEDIATRIC DISEASES AND CONDITIONS.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that rare and pediatric diseases and conditions remain a priority.

''(4) INITIAL PLAN.—Not later than 270 days after the date of enactment of this subsection, the Director of NIH and the directors of the national research institutes and national centers shall—

''(A) complete the initial strategic plans required by paragraphs (1) and (2); and

''(B) make such initial strategic plans publicly available on the website of the National Institutes of Health.

''(5) REVIEW; UPDATES.—

''(A) PROGRESS REVIEWS.—Not less than annually, the Director of the NIH, in consultation with the directors of the national research institutes and national centers, shall conduct progress reviews for each strategic focus area identified under paragraph (1)(B).

''(B) UPDATES.—Not later than the end of the 5-year period covered by the initial strategic plan under this subsection, and every 5 years thereafter, the Director of NIH, in consultation with the directors of the national research institutes and national centers, stakeholders in the scientific field, advocates, and the public at large, shall—

''(i) conduct a review of the plan, including each strategic focus area identified under paragraph (1)(B); and

''(ii) update such plan in accordance with this section.''.

SEC. 1022. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

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

''(a) APPOINTMENT; TERMS.—

''(1) APPOINTMENT.—The Director of the National Cancer Institute shall be appointed by the President and the directors of the other national research institutes, as well as the directors of the national centers, shall be appointed by the Director of

NIH. The directors of the national research institutes, as well as national centers, shall report directly to the Director of NIH.

''(2) TERMS.—

''(A) IN GENERAL.—The term of office of a director of a national research institute or national center shall be 5 years.

''(B) REMOVAL.—The director of a national research institute or national center may be removed from office by the Director of NIH prior to the expiration of such director's 5-year term.

''(C) REAPPOINTMENT.—At the end of the term of a director of a national research institute or national center, the director may be reappointed. There is no limit on the number of terms a director may serve.

''(D) VACANCIES.—If the office of a director of a national research institute or national center becomes vacant before the end of such director's term, the director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

''(E) TRANSITIONAL PROVISION.—Each director of a national research institute or na-

tional center serving on the date of enactment of the 21st Century Cures Act is deemed to be appointed for a 5-year term under this subsection starting on such date of enactment.''.

(b) COMPENSATION TO CONSULTANTS OR INDIVIDUAL SCIENTISTS.—Section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) is amended by striking ''portable structures;'' and all that follows and inserting ''portable structures.''.

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

''(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an 'R-series grant'), other than an award constituting a noncompeting renewal of such grant, or a noncompeting administrative supplement to such grant, the director of such national research institute or national center—

''(A) shall review and approve the award; and

''(B) shall take into consideration—

''(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m); and

''(ii) whether other agencies are funding programs or projects to accomplish the same goal.''.

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

(1) complete a study on the extent to which biomedical research conducted or supported by Federal agencies is duplicative; and

(2) submit a report to the Congress on the results of such study, including recommendations on how to prevent such duplication.

[SEC. 1023. BIOMEDICAL RESEARCH WORKING GROUP.

[(a) ESTABLISHMENT.—There is established a working group to be known as the ''Biomedical Research Working Group''.]

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

[(1) provide recommendations to the Director of the National Institutes of Health to reduce administrative burdens of researchers funded by the National Institutes of Health, including with respect to the extent to which (and how) grant proposals, grant review, and management should be restructured, streamlined, and simplified;]

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

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

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

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

[(2) representatives of the Office of the Director; and]

[(3) representatives of other national research institutes and national centers of the National Institutes of Health, as determined necessary.]

[(d) IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health, taking into account the recommendations, evaluations, and plan described in subsection (b), shall implement measures to reduce the administrative burdens of researchers funded by the National Institutes of Health.]

[(e) REPORTS.—]

[(1) REPORT BY WORKING GROUP ON RECOMMENDATIONS AND PLAN.—Not later than one year after the date of the enactment of this Act, the Biomedical Research Working Group shall submit to Congress a report including the recommendations, evaluations, and plan described in subsection (b).]

[(2) REPORT BY DIRECTOR OF NIH ON IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health shall submit to Congress a report on the extent to which the Director has implemented measures pursuant to subsection (d).]

SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

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

(1) in subparagraph (C), by striking ''; or'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting ''; or''; and

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

''(E) during the conduct of research by the National Institutes of Health or contractors on behalf of the Institutes.''.

SEC. 1025. NIH TRAVEL.

It is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the National Institutes of Health.

SEC. 1026. OTHER TRANSACTIONS AUTHORITY.

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

(1) in subsection (b), by striking ''the appropriation of funds as described in subsection (g)'' and inserting ''the availability of funds as described in subsection (f)'';

(2) in subsection (e)(3), by amending subparagraph (C) to read as follows:

"(C) OTHER TRANSACTIONS AUTHORITY.—The Director of the Center shall have other transactions authority in entering into transactions to fund projects in accordance with the terms and conditions of this section.";

(3) by striking subsection (f); and

(4) by redesignating subsection (g) as subsection (f).

SEC. 1027. NCATS PHASE IIB RESTRICTION.

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

(1) prior to making the amendments under paragraph (2), by striking "IIB" each place it appears and inserting "III"; and

(2) by striking "IIA" each place it appears and inserting "IIB".

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

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

"SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM.

''The director of each national research institute shall, as appropriate—

''(1) establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs; and

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

Subtitle C—Supporting Young Emerging Scientists

[SEC. 1041. FUNDING RESEARCH BY EMERGING SCIENTISTS.

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

[(1) in clause (i), by striking ''and'' at the end;]

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

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

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

allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A) and is carried out by one or more emerging scientists (as defined in section 402A(c)(1)(C)(iv)); and''.]

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

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

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

[''(C) ADDITIONAL RESERVATION FOR RESEARCH BY EMERGING SCIENTISTS.—]

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

[''(ii) RESERVATION.—In addition to the amounts reserved for the Common Fund under subparagraph (B) and amounts appropriated to the Common

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

[''(iii) PURPOSE OF RESERVATION.—Amounts reserved under clause (ii) shall be used for the purpose of carrying out section 402(b)(7)(B)(ii) (relating to the conduct and support of research that is identified under section 402A(b)(7)(A) and is carried out by one or more emerging scientists).]

[''(iv) DEFINITION.—In this subparagraph, the term 'emerging scientist' means an investigator who—]

[''(I) will be the principal investigator or the program director of the proposed research;]

[''(II) has never been awarded, or has been awarded only once, a substantial, competing grant by the Na-

tional Institutes of Health for independent research; and]

[“(III) is within 15 years of having completed—]

[“(aa) the investigator’s terminal degree; or]

[“(bb) a medical residency (or the equivalent).”.]

[(c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER.—Funds reserved pursuant to section 402A(c)(1)(C) of the Public Health Service Act, as added by subsection (b)—]

[(1) shall be used to supplement, not supplant, the funds otherwise allocated by the National Institutes of Health for young investigators; and]

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

[(d) CONFORMING AMENDMENTS.—]

[(1) Section 241(a) of the Public Health Service Act (42 U.S.C. 238j(a)) is amended by striking “Such portion” and inserting “Subject to section 402A(c)(1)(C)(i), such portion”.]

[(2) Section 402A(a)(2) of the Public Health Service Act is amended—]

[(A) by striking ''402(b)(7)(B)(ii)'' and inserting ''402(b)(7)(B)(iii)''; and]

[(B) by striking ''reserved under subsection (c)(1)(B)(i)'' and inserting ''reserved under subparagraph (B)(i) or (C)(ii) of subsection (c)(1)''.]

[(3) Section 3(c)(2) of the Gabriella Miller Kids First Research Act (Public Law 113–94) is amended by striking ''402(b)(7)(B)(ii) of the Public Health Service Act, as added by subsection (a)'' and inserting ''402(b)(7)(B)(iii) of the Public Health Service Act, as added by subsection (a) and redesignated by section 1041(a) of the 21st Century Cures Act''.]

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

SEC. 1042. IMPROVEMENT OF LOAN REPAYMENT PROGRAMS OF NATIONAL INSTITUTES OF HEALTH.

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

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

(2) by inserting after section 487G, as so redesignated, the following:

"SEC. 487H. LOAN REPAYMENT PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a program, based on workforce and scientific needs, of entering into contracts with qualified health professionals under which such health professionals agree to engage in research in consideration of the Federal Government agreeing to pay, for each year of engaging in such research, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

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

''(c) LIMITATION.—The Secretary may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of educational loans relative to income.

''(d) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent in-

consistent with this section, the provisions of sections 338B, 338C, and 338E shall apply to the program established under this section to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

''(e) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) are authorized to remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.''.

SEC. 1043. REPORT.

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

Subtitle D—Capstone Grant Program

SEC. 1061. CAPSTONE AWARD.

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

"SEC. 490. CAPSTONE AWARD.

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

''(b) PURPOSE.—Capstone Awards shall be made to facilitate the successful transition or conclusion of research programs, or for other purposes, as determined by the Director of NIH, in consultation with the directors of the national research institutes and national centers.

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

''(d) LIMITATION.—Individuals who have received a Capstone Award shall not be eligible to have principle investigator status on subsequent awards from the National Institutes of Health.''.

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

SEC. 1081. NATIONAL PEDIATRIC RESEARCH NETWORK.

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

(1) in paragraph (1)—

(A) by striking ''in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research'' and inserting ''in collaboration with the national research institutes and national centers that carry out activities involving pediatric research'';

(B) by striking subparagraph (B);

(C) by striking ''may be comprised of, as appropriate'' and all that follows through ''the pediatric research consortia'' and inserting ''may be comprised of, as appropriate, the pediatric research consortia''; and

(D) by striking ''; or'' at the end and inserting a period; and

(2) in paragraph (1), paragraph (2)(A), the first sentence of paragraph (2)(E), and paragraph (4), by striking ''may'' each place it appears and inserting ''shall''.

SEC. 1082. GLOBAL PEDIATRIC CLINICAL TRIAL NETWORK SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical trial network through the allocation of grants, contracts, or cooperative agreements to supplement the salaries of new and early investigators who participate in the global pediatric clinical trial network;

(2) National Institutes of Health grants, contracts, or cooperative agreements should be awarded, solely for the purpose of supplementing the salaries of new and early investigators, to entities that participate in the global pediatric clinical trial network;

(3) the Food and Drug Administration should engage the European Medicines Agency and other foreign regulatory entities during the formation of the global pediatric clinical trials network to encourage their participation; and

(4) once a global pediatric clinical trial network is established and becomes operational, the Food and Drug Administration should continue to engage the European Medicines Agency and other foreign regulatory entities to encourage and facilitate their participation in the network with the goal of enhancing the global reach of the network.

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

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

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

"SEC. 498E. SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.

''(a) AUTHORITY.—As a condition on the award of a grant or the provision of other financial support for research, irrespective of whether the research is fully or only partially funded through such grant or other support, the Director of NIH may require the recipients of such grant or other support to share scientific data generated from research funded by the National Institutes of Health.

[''(b) LIMITATION.—Subsection (a) does not authorize the Director of NIH to require the sharing of—]

[''(1) any individually identifiable information with respect to a human subject participating in the research; or]

[''(2) any trade secret or commercial or financial information that is privileged or confidential.''.]

SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS.

(a) STANDARDIZATION.—

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

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

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

''(7) STANDARDIZATION.—The Director of NIH shall ensure that—

''(A) the registry and results data bank is easily used by the public;

''(B) entries in the registry and results data bank are easily compared; and

[''(C) information required to be submitted to the registry and results data bank, including recruitment information under paragraph (2)(A)(ii)(II), is submitted by persons and posted by the Director of NIH in a standardized format and shall include at least the following:**]**

[''(i) the disease or indication being studied;**]**

[“(ii) inclusion criteria such as age, gender, diagnosis or diagnoses, lab values, and imaging results; and]

[“(iii) exclusion criteria such as specific diagnosis or diagnoses, lab values, and prohibited medications.]

[To the extent feasible, in applying this paragraph, the National Institutes of Health shall give consideration to health care terminology and eligibility criteria that are for electronic matching to diagnosis or procedure coding systems, such as the International Classification of Diseases or the Current Procedural Terminology, and integration into electronic health records.]”.]

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

(b) CONSULTATION.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with stakeholders (including patients, researchers, physicians, industry representatives, health information technology providers, and the Food and Drug Administration) to receive advice on enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C.

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

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

Subtitle G—Facilitating Collaborative Research

[SEC. 1121. CLINICAL TRIAL DATA SYSTEM.

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

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

as the Secretary may require. Any such application shall include the following:]

[(1) A certification that each applicant is not currently and does not plan to be involved in sponsoring, operating, or participating in a clinical trial nor collaborating with another entity for the purposes of sponsoring, operating, or participating in a clinical trial.]

[(2) A description of how each applicant will compile clinical trial data in standardized formats using terminologies and standards that have been developed by recognized standards developing organizations with input from diverse stakeholder groups, and a description of the methodologies to be used to de-identify clinical trial data consistent with the requirements of section 164.514 of title 45, Code of Federal Regulations (or successor regulations).]

[(3) Documentation establishing that each applicant has a plan in place to allow registered users to access and use de-identified clinical trial data, gathered from qualified clinical trials, available under carefully controlled contractual terms as defined by the Secretary.]

[(4) Evidence demonstrating the ability to ensure dissemination of the results of the research to

interested parties to serve as a guide to future medical product development or scientific research.]

[(5) The plan of each applicant for securing funding for the partnership described in paragraph (2) from governmental sources and private foundations, entities, and individuals.]

[(6) Evidence demonstrating a proven track record of—]

[(A) being a neutral third party in working with medical product manufacturers, academic institutions, and the Food and Drug Administration; and]

[(B) having the ability to protect confidential data.]

[(c) DEFINITIONS.—In this section:]

[(1) The term ''eligible entity'' means an entity that has experienced personnel with clinical and other technical expertise in the biomedical sciences and biomedical ethics and that is—]

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

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

Code of 1986 and exempt from tax under section 501(a) of such title.]

[(2) The term ''medical product'' means a drug (as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), a device (as defined in subsection (h) of such section), a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), or any combination thereof.]

[(3) The term ''qualified clinical trial'' means a clinical trial sponsored solely by an agency of the Department of Health and Human Services with respect to a medical product—]

[(A) that was—]

[(i) approved or cleared under section 505, 510(k), or 515, or has an exemption for investigational use in effect under section 505 or 520(m), of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 301 et seq.); or]

[(ii) licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or has an exemption for investigational use in effect under such section 351; or]

[(B) that is an investigational product for which the original development was discontinued and with respect to which—]

[(i) no additional work to support approval, licensure, or clearance of such medical product is being or is planned to be undertaken by the sponsor of the original development program, its successors, assigns, or collaborators; and]

[(ii) the sponsor of the original investigational development program has provided its consent to the Secretary for inclusion of data regarding such product in the system established under this section.]

SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE SYSTEM.

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

"SEC. 399V–6 SURVEILLANCE OF NEUROLOGICAL DISEASES.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as determined appropriate by the Secretary, shall—

''(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson's disease; and

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

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

''(c) CONTENT.—In carrying out subsection (a), the Secretary—

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

''(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, such as information concerning—

''(A) demographics and other information associated or possibly associated with neuro-

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

''(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

''(C) diagnosis and progression markers;

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

''(A) the epidemiology of the diseases;

''(B) the natural history of the diseases;

''(C) the prevention of the diseases;

''(D) the detection, management, and treatment approaches for the diseases; and

''(E) the development of outcomes measures; and

''(4) may address issues identified during the consultation process under subsection (d).

''(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

''(1) epidemiologists with experience in disease surveillance or registries;

''(2) representatives of national voluntary health associations that—

"(A) focus on neurological diseases, including multiple sclerosis and Parkinson's disease; and

"(B) have demonstrated experience in research, care, or patient services;

"(3) health information technology experts or other information management specialists;

"(4) clinicians with expertise in neurological diseases; and

"(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

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

"(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate—

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

search and Quality, the Department of Veterans Affairs, and the Department of Defense; and

''(2) to State and local agencies.

''(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.

''(h) PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).

''(i) REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

''(1) the development and maintenance of the National Neurological Diseases Surveillance System;

''(2) the type of information collected and stored in the System;

''(3) the use and availability of such information, including guidelines for such use; and

''(4) the use and coordination of databases that collect or maintain information on neurological diseases.

''(j) DEFINITION.—In this section, the term 'national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

''(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated [$_____] for each of fiscal years 2015 through 2019.''.

SEC. 1123. PUBLIC-PRIVATE PARTNERSHIP FOR INFORMATION TECHNOLOGY SYSTEM ON DATA ON NATURAL HISTORY OF DISEASES.

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

''SEC. 229A. PUBLIC-PRIVATE PARTNERSHIP FOR INFORMATION TECHNOLOGY SYSTEM ON DATA ON NATURAL HISTORY OF DISEASES.

''(a) IN GENERAL.—The Secretary shall enter into a public-private partnership to establish or enhance and support an information technology system, including staffing, to collect, maintain, analyze, and interpret data on

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

"(1) build on and cooperate with other disease registries, including disease registries and disease registry platforms for rare diseases;

"(2) develop or enhance a secure information technology system that—

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

"(B) is easily modified as knowledge is gained during studies; and

"(C) is capable of handling increasing amounts of data as more studies are carried out;

"(3) hire professional staff, including biostatisticians, study coordinators, and individuals with experience and knowledge of medical product development—

"(A) to maintain and oversee operation of the information technology system;

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

"(C) to provide advice to clinical researchers on the appropriate design of such studies; and

"(D) to advise patient groups in—

"(i) how to design and conduct such studies; and

"(ii) how to modify any such ongoing studies;

"(4) obtain professional advice to address privacy issues associated with the operation of the partnership's information technology system; and

"(5) award grants to patient and other organizations for studies on the natural history of diseases through registries and information technology structures that complement, but are separate from, the system established by such public-private partnership.

"(b) AVAILABILITY OF DATA.—The data aggregated in the system maintained under subsection (a) shall be available, consistent with otherwise applicable Federal and State privacy laws, to the public (including patient advocacy groups, researchers, and drug developers) to help reduce the time and size of drug development programs.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$_____] for each of fiscal years 2016 through 2020.''.

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

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

''PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

''SEC. 13441. REFERENCES.

''In this part:

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

''(b) PART 164.—References to a specified section of 'part 164', refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

''SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART OF HEALTH CARE OPERATIONS.

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

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

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

''(1) the Secretary shall revise or clarify the Rule so that the disclosure may be made by the covered entity to only—

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

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

''(C) a business associate that has entered into a contract under section 164.504(e) of part 164 for the purpose of data aggregation (as defined in such section 164.501 of part 164); and

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

''(c) RULE OF CONSTRUCTION.—This section shall not be construed as prohibiting or restricting a use or disclosure of protected health information for research purposes that is otherwise permitted under part 164.

''SEC. 13443. TREATING DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH SIMILARLY TO DISCLOSURES OF SUCH INFORMATION FOR PUBLIC HEALTH PURPOSES.

''(a) REMUNERATION.—The Secretary shall revise or clarify the Rule so that disclosures of protected health information for research purposes are not subject to the limitation on remuneration described in section 164.502(a)(5)(ii)(B)(*2*)(*ii*) of part 164.

''(b) PERMITTED USES AND DISCLOSURES.—The Secretary shall revise or clarify the Rule so that research activities, including comparative research activities, related to the quality, safety, or effectiveness of a product or activity that is regulated by the Food and Drug Administration are included as public health activities for purposes of which a covered entity may disclose protected

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

"SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED HEALTH INFORMATION BY RESEARCHERS.

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

''(1) appropriate security and privacy safeguards are maintained by the covered entity and the researcher; and

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

"SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES.

''(a) IN GENERAL.—The Secretary shall revise or clarify the Rule to specify that an authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes shall be deemed to contain a sufficient description of the purpose of the use or disclosure if the authorization—

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

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

''(2) either—

''(A) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

''(B) states that the authorization will remain valid unless and until it is revoked by the individual; and

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

''(b) REVOCATION OF AUTHORIZATION.—The Secretary shall revise or clarify the Rule to specify that, if an individual revokes an authorization for future research purposes such as is described by subsection (a), the covered entity may not make any further uses or disclosures based on that authorization, except, as provided in paragraph (b)(5) of section 164.508 of part 164, to the extent that the covered entity has taken action in reliance on the authorization.''.

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

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

Subtitle H—Council for 21st Century Cures

SEC. 1141. COUNCIL FOR 21ST CENTURY CURES.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"PART E—COUNCIL FOR 21ST CENTURY CURES

"SEC. 281. ESTABLISHMENT.

''A nonprofit corporation to be known as Council for 21st Century Cures (referred to in this part as the 'Council') shall be established in accordance with this section. The Council shall be a public-private partnership headed by an Executive Director (referred to in this part as the 'Executive Director'), appointed by the members of the Board of Directors. The Council shall not be an agency or instrumentality of the United States Government.

"SEC. 281A. PURPOSE.

''The purpose of the Council is to accelerate the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients.

"SEC. 281B. DUTIES.

"For the purpose described in section 281A, the Council shall—

"(1) foster collaboration and coordination among the entities that comprise the Council, including academia, government agencies, industry, health care payors and providers, patient advocates, and others engaged in the cycle of discovery, development, and delivery of life-saving and health-enhancing innovative interventions;

"(2) undertake communication and dissemination activities;

"(3) publish information on the activities funded under section 281D;

"(4) establish a strategic agenda for accelerating the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients;

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

"(6) develop and propose recommendations based on the gaps and opportunities so identified;

"(7) facilitate the interoperability of the components of the discovery, development, and delivery cycle;

''(8) propose recommendations that will facilitate precompetitive collaboration;

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

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

''SEC. 281C. ORGANIZATION; ADMINISTRATION.

''(a) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Council shall have a Board of Directors (in this part referred to as the 'Board of Directors'), which shall be composed of the ex officio members under subparagraph (B) and the appointed members under subparagraph (C). All members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Director of the National Institutes of Health.

"(ii) The Commissioner of Food and Drugs.

"(iii) The Administrator of the Centers for Medicare & Medicaid Services.

"(iv) The heads of five other Federal agencies deemed to be engaged in biomedical research and development.

"(C) APPOINTED MEMBERS.—The appointed members of the Board shall consist of 17 individuals, of whom—

"(i) 8 shall be by the Comptroller General of the United States from a list of nominations submitted by leading trade associations—

"(I) 4 of whom shall be representatives of the biopharmaceutical industry;

"(II) 2 of whom shall be representatives of the medical device industry; and

"(III) 2 of whom shall be representatives of the information and digital technology industry; and

"(ii) 7 shall be appointed by the Comptroller General of the United States, after soliciting nominations—

"(I) 2 of whom shall be representatives of academic researchers;

"(II) 3 of whom shall be representative of patients;

"(III) 2 of whom shall be representatives of health care providers; and

"(IV) 2 of whom shall be representatives of health care plans and insurers.

"(D) CHAIR.—The Chair of the Board shall be selected by the members of the Board by majority vote from among the members of the Board.

"(2) TERMS AND VACANCIES.—

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

"(B) VACANCY.—Any vacancy in the membership of the Board—

"(i) shall not affect the power of the remaining members to execute the duties of the Board; and

"(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

"(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

"(3) RESPONSIBILITIES.—Not later than 90 days after the date of the enactment of the 21st Century Cures Act, the Board of Directors shall establish bylaws and policies for the Council that—

"(A) are published in the Federal Register and available for public comment;

"(B) establish policies for the selection and, as applicable, appointment of—

"(i) the officers, employees, agents, and contractors of the Council; and

"(ii) the members of any committees of the Council;

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

"(D) establish specific duties of the Executive Director.

"(4) MEETINGS.—

"(A) IN GENERAL.—the Board of Directors shall—

"(i) meet on a quarterly basis; and

"(ii) submit to Congress, and make publicly available, the minutes of such meetings.

"(B) AGENDA.—The Board of Directors shall, not later than 3 months after the incorporation of the Council—

"(i) issue an agenda (in this part referred to as the 'agenda') outlining how the Council will achieve the purpose described in section 281A; and

"(ii) annually thereafter, in consultation with the Executive Director, review and update such agenda.

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

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

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

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

''(2) is, under subsection (a) of such section, exempt from taxation.

''(d) EXECUTIVE DIRECTOR.—The Executive Director shall—

''(1) be the chief executive officer of the Council; and

''(2) subject to the oversight of the Board of Directors, be responsible for the day-to-day management of the Council.

''SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.

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

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

ticipating entities or private foundations or organizations when such support is deemed appropriate.

"SEC. 281E. TERMINATION; REPORT.

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

"(b) REPORT.—Not later than one year after the date on which the Council is established and each year thereafter, the Executive Director shall submit to the appropriate congressional committees a report on the performance of the Council. In preparing such report, the Council shall consult with a nongovernmental consultant with appropriate expertise.

"SEC. 281F. FUNDING.

"For the period of fiscal years 2016 through 2023, the Secretary shall make a payment to the Council for purposes of carrying out the duties of the Council under this part in an amount of not less than **[**$_____**]**.".

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.

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

(1) in subsection (d), by striking ''The Secretary shall implement'' and all that follows through ''premarket approval of a drug.''; and

(2) by adding at the end the following new subsections:

''(x) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

''(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process—

''(A) to facilitate the balanced consideration of benefits and risks; and

''(B) to develop and implement a consistent and systematic approach to the discussion of, regulatory decisionmaking with respect to, and the communication of, the benefits and risks of new drugs.

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

"(y) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

"(1) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall establish and implement processes under which—

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

"(i) initial research concepts for feedback from the Secretary; and

"(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;

"(B) the Secretary may request such an entity to submit such documents, data, and summaries and analyses; and

"(C) patient experience data may be developed and used to enhance the structured risk-benefit assessment framework under subsection (x).

''(2) PATIENT EXPERIENCE DATA.—In this subsection, the term 'patient experience data' means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, medical researchers, research sponsors or other parties determined appropriate by the Secretary that is intended to facilitate or enhance the Secretary's risk-benefit assessments, including information about the impact of a disease or a therapy on patients' lives.''.

(b) GUIDANCE.—

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

(A) with respect to draft guidance documents, data, or summaries and analyses submitted to the Secretary under paragraph (1)(A) of such subsection, guidance—

(i) specifying the timelines for the review of such documents, data, or summaries and analyses by the Secretary; and

(ii) on how the Secretary will use such documents, data, or summaries and analyses to update any guidance documents published under this subsection or publish new guidance;

(B) with respect to the collection and analysis of patient experience data (as defined in paragraph (2) of such subsection (y)), guidance on—

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

(I) the experience of a patient living with a particular disease;

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

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

(IV) the effect of current therapeutic options on different aspects of the disease; and

(ii) the establishment and maintenance of registries designed to increase un-

derstanding of the natural history of a disease;

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

(D) methodologies, standards, and potential experimental designs for patient-reported outcomes.

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

(3) WORKSHOPS.—

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

workshop to obtain input regarding methodologies for developing the guidance under paragraph (1), including the collection of patient experience data.

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

(i) patients;

(ii) representatives from patient advocacy organizations, biopharmaceutical companies, and disease research foundations;

(iii) representatives of the reviewing divisions of the Food and Drug Administration; and

(iv) methodological experts with significant expertise in patient experience data.

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

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

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

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

[(1) development of new drugs has become increasingly challenging and resource intensive;]

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

[(3) medical research consortia, consisting of public-private partnerships of government agencies, institutions of higher education, patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals can play a valuable role in helping develop and qualify biomarkers and other drug development tools; and]

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

[(A) develop, through a transparent public process, data standards and scientific approaches to data collection accepted by the

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

[(B) coordinate efforts toward developing and qualifying biomarkers and other drug development tools in key therapeutic areas; and]

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

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

["SEC. 507. QUALIFICATION OF BIOMARKERS, SURROGATE ENDPOINTS, AND OTHER DRUG DEVELOPMENT TOOLS.

[''(a) IN GENERAL.—The Secretary shall, to facilitate the availability of qualified biomarkers, including surrogate endpoints, and other drug development tools—]

[''(1) issue guidance in accordance with subsection (b) with respect to standards for the qualification of biomarkers; and]

[“(2) establish a process for qualification of biomarkers and other drug development tools in accordance with subsection (c).]

[“(b) GUIDANCE ON BIOMARKERS.—]

[“(1) IN GENERAL.—For purposes of this section, the Secretary shall issue guidance which—]

[“(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of specific classes of biomarkers delineated under the taxonomy established under paragraph (2);]

[“(B) makes recommendations for demonstrating that a surrogate endpoint, as defined in subsection (e), is reasonably likely to predict clinical benefit for the purpose of supporting accelerated approval of a drug in accordance with section 506(c); and]

[“(C) includes such other information as the Secretary determines appropriate.]

[“(2) GUIDANCE DEVELOPMENT TIMING AND PROCESS.—Not later than 24 months after the date of enactment of this Act, the Secretary shall issue draft guidance on the implementation of this section. The Secretary shall issue final guidance on the implementation of this section not later than 6 months

after the date on which the comment period for the draft guidance closes. Such guidance shall be developed in consultation with medical research consortia and other interested parties through a collaborative public process.]

[''(3) TAXONOMY.—For purposes of informing guidance under this subsection, the Secretary shall establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development. Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall make such taxonomy publicly available.]

[''(c) PROCESS FOR QUALIFICATION OF DRUG DEVELOPMENT TOOLS.—]

[''(1) IN GENERAL; ACCEPTANCE OF SUBMISSIONS.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use, which shall—]

[''(A) be initiated upon the submission, by a requestor defined in subsection (e), of a letter of intent to the Secretary;]

[''(B) if such letter is accepted by the Secretary, be followed by the requestor's submission, and the Secretary's consideration, of a

qualification plan, including preliminary data supporting the drug development tool for its proposed context of use;]

[“(C) if such qualification plan is accepted by the Secretary, be followed by the requestor’s submission of a full qualification package; and]

[“(D) if the Secretary determines that such full qualification package warrants comprehensive review on its merits, result in the Secretary’s acceptance of such package.]

[“(2) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—]

[“(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(D); and]

[“(B) make a determination whether the drug development tool at issue is qualified for its proposed context of use under this section.]

[“(3) DETERMINATION FACTORS.—]

[“(A) ACCEPTANCE OF SUBMISSIONS.—The Secretary shall determine whether to accept submissions under paragraph (1) based on factors that may include—]

[“(i) the scientific merit of the submission;]

[“(ii) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition;]

[“(iii) the identification, by the Secretary or by medical research consortia and other expert stakeholders, of such a drug development tool and proposed context of use as a public health priority;]

[“(iv) the availability of Food and Drug Administration resources for review of the drug development tool and proposed context of use; and]

[“(v) such other factors as determined appropriate by the Secretary.]

[“(B) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (2).]

[“(4) SENSE OF THE CONGRESS REGARDING COLLABORATION.—It is the sense of the Congress that a requestor seeking qualification of a drug development tool may, in addition to consultation with

the Secretary, consult with medical research consortia and other individuals and entities with expert knowledge and insights that may assist the requestor and benefit the process under this subsection.]

[''(5) GUIDANCE.—The Secretary shall issue guidance with respect to the requirements that requestors shall observe when engaging in the qualification process under this subsection.]

[''(d) EFFECT OF QUALIFICATION DETERMINATIONS; RESCISSION.—]

[''(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (c) for a specified context of use may be utilized by any person in such context for purposes described in paragraph (2), subject to paragraph (3).]

[''(2) UTILIZATION OF QUALIFIED DRUG DEVELOPMENT TOOL.—A drug development tool qualified under this section may be utilized for—]

[''(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under—]

[''(i) section 505 of this Act; or]

[“(ii) section 351 of the Public Health Service Act; or]

[“(B) supporting investigational use of a drug or biological product under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.]

[“(3) RESCISSION OF QUALIFICATION.—The Secretary may rescind a qualification determination under this section if the Secretary determines that the drug development tool is not appropriate for the specified context of use, including based on new information that calls into question the basis for such qualification.]

[“(e) DEFINITIONS.—In this section:]

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

[“(2) QUALIFICATION.—The terms ‘qualification’ and ‘qualified’ mean a determination by the Secretary that a drug development tool and its specified context of use can be relied on to have a specific interpretation and application in drug development and regulatory review under this Act.]

[“(3) CONTEXT OF USE.—The term ‘context of use’ means a statement that describes the circumstances under which the drug development tool is to be used in drug development and regulatory review.]

[“(4) DRUG DEVELOPMENT TOOL.—The term ‘drug development tool’ means—]

[“(A) biomarkers, including surrogate endpoints;]

[“(B) clinical outcome assessments, including patient-reported outcomes; and]

[“(C) any other methods, materials, or measures that the Secretary determines aid drug development and regulatory review for purposes of this section.]

[“(5) BIOMARKER.—The term ‘biomarker’—]

[“(A) means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and]

[“(B) includes surrogate endpoints.]

[“(6) SURROGATE ENDPOINT.—The term ‘surrogate endpoint’ means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is known to predict clinical benefit or is reasonably likely to predict clinical benefit, but is not itself a direct measurement of clinical benefit.]

[“(7) CLINICAL OUTCOME ASSESSMENT.—The term ‘clinical outcome assessment’—]

[“(A) means a measurement of a patient’s symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and]

[“(B) includes patient reported outcomes.]

[“(8) PATIENT REPORTED OUTCOME.—The term ‘patient reported outcome’ means a measurement based on a report from a patient regarding the status of the patient’s health condition without amendment or interpretation of the patient’s report by a clinician or anyone else.]

[“(9) MEDICAL RESEARCH CONSORTIA.—The term ‘medical research consortia’ means public-private partnerships of government agencies, institutions of higher education, patient advocacy groups,

industry representatives, clinical and scientific experts, and other relevant entities and individuals.]

[“(f) TRANSPARENCY.—]

[“(1) PUBLIC AVAILABILITY OF INFORMATION.—For purposes of this section, the following information shall be made publicly available by the Secretary:]

[“(A) submissions from requestors under the qualification process under subsection (c), including any data and evidence contained in such submissions, and any updates to such submissions;]

[“(B) the Secretary’s formal written determinations in response to submissions under subsection (c);]

[“(C) any rescissions of qualification under subsection (d)(3); and]

[“(D) summary reviews that document conclusions and recommendations for qualification determinations under subsection (c).]

[“(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of the Trade Secrets Act, 18 U.S.C. 1905.]

[“(3) APPLICABILITY.—The provisions of this subsection shall—]

[“(A) apply only with respect to requests for qualification of a drug development tool for a proposed context of use which are initiated on or after the date of enactment of the 21st Century Cures Act;]

[“(B) apply to information which is submitted to the Secretary for purposes of both—]

[“(i) a request for qualification under this section; and]

[“(ii) an application under section 505 of this Act or section 351 of the Public Health Service Act; and]

[“(C) not apply to information which is—]

[“(i) submitted to the Secretary solely for purposes of an application under section 505 of this Act or section 351 of the Public Health Service Act; and]

[“(ii) not submitted for purposes of a request for qualification under this section.]

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

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

[“(2) limit the authority of the Secretary to approve or license products pursuant to this Act or the Public Health Service Act (as applicable) as authorized under such Acts as in effect prior to the date of enactment of this section.”.]

[(c) MEETING AND REPORT.—]

[(1) PUBLIC MEETING.—Not later than 18 months after the enactment of the this Act, the Secretary shall hold a public meeting to discuss the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act (as added by this section).]

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

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

[(A) the number of requests, submitted as letters of intent, for qualification of a biomarker (including a surrogate endpoint), clinical outcome assessment, or other drug development tool;]

[(B) the number of—]

[(i) such requests accepted and determined to be eligible for submission of a qualification plan and full qualification package, respectively; and]

[(ii) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and]

[(C) the number of biomarkers (including surrogate endpoints), clinical outcome assessments, or other drug development tools qualified under such section.]

[SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT PLANS.

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

[“SEC. 507A. ACCELERATED APPROVAL DEVELOPMENT PLAN.

[“(a) IN GENERAL.—For purposes of facilitating early interactions with the Secretary for planning studies intended to be conducted for purposes of the accelerated approval of a drug under section 506(c), the Secretary shall establish processes for a sponsor to voluntarily submit, and for the Secretary to agree to, an accelerated approval development plan. Such a plan may be used but is not required to be submitted for such accelerated approval.]

[“(b) CONTENTS.—An accelerated approval development plan under subsection (a) shall include—]

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

[“(2) the agreement between the sponsor submitting the plan and the Secretary—]

[“(A) on the design of the study, including—]

[“(i) planned interim analyses if applicable, that will utilize the surrogate endpoint; and]

[“(ii) the minimum magnitude of the effect of the drug involved on the surrogate endpoint that would be reasonably likely to predict clinical benefit;]

[“(B) on any post-market commitments of the sponsor with respect to the drug; and]

[“(C) on what surrogate endpoint will be assessed in the study.]

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

[“(d) MODIFICATION OR TERMINATION.—An accelerated approval development plan may be modified or terminated if new evidence indicates that—]

[“(1) the plan as originally agreed upon is no longer sufficient to demonstrate safety and effectiveness of the drug involved; or]

[“(2) the drug is no longer eligible for accelerated approval under section 506(c).]

[“(e) DEFINITION.—In this section, the term ‘accelerated approval development plan’ refers to a development plan agreed upon by the Secretary and the sponsor submitting the plan that contains study parameters for the use of a surrogate endpoint intended to be the basis of the accelerated approval of a drug under section 506(c).”.]

[Subtitle C—FDA Advancement of Precision Medicine]

[SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER PROGRAMS OF FOOD AND DRUG ADMINISTRATION.

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

["Subchapter J—Precision Medicine]

["SEC. 591. DEFINITIONS.

["(a) PRECISION MEDICINE.—For purposes of this subchapter, the term 'precision medicine' or 'precision drug' means a drug that, either alone or in combination with other therapies, targets a subset of individuals with a disease, which subset—]

["(1) can be used to address the underlying cause of the disease in order to modify the progression of the disease, prevent the disease, or cure the disease; and]

["(2) is identified by—]

["(A) genotype, or genotype in combination with other biological characteristics; or]

["(B) any other biological characteristic, or means of identifying such a characteristic,

designated by the Secretary as an advanced analytical subset approach.]

[''(b) SERIOUS DISEASE.—For purposes of this subchapter, the term 'serious disease' has the meaning that applies in guidance issued pursuant to section 506 to the term 'serious condition'.]

[''SEC. 592. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

[''(a) IN GENERAL.—The Secretary shall issue and periodically update guidance on—]

[''(1) the requirements to meet the definition of a precision drug under section 591(a); and]

[''(2) information to assist sponsors in the development of such a drug, including clinical studies, in accordance with the requirements referred to in paragraph (1) and other relevant guidance issued by the Secretary.]

[''(b) CERTAIN ISSUES.—The topics addressed by guidance under subsection (a) may include the following:]

[''(1) Maximizing the use of scientific tools or methods to incorporate biomarkers into non-clinical and clinical development of a precision drug to evaluate how such drug modifies the progression of disease beyond well-established primary clinical endpoints.]

[“(2) Identifying surrogate endpoints that can reasonably be predicted to demonstrate preliminary evidence of clinical benefit for a precision drug for purposes of section 506(c) (relating to accelerated approval).]

[“(3) Recommendations on the appropriate evidence needed to demonstrate a clinical benefit by extrapolating from the approaches described in paragraphs (1) and (2).]

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

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

[“SEC. 593. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

[“(a) IN GENERAL.—Guidance under section 592 shall address the manner in which sections 526 and 527 (relating to orphan drugs), section 506 (relating to expedited approval programs), and other programs under this

Act for expedited or priority review will be applied to precision drugs.]

[''(b) RELIANCE ON PREVIOUSLY-SUBMITTED INVESTIGATIONS BY A SPONSOR.—In the case of an application for a precision drug under section 505(b)(1), or section 351(a) of the Public Health Service Act, that has been designated under section 526 as a drug for a rare disease for a serious condition, the Secretary may—]

[''(1) consistent with applicable standards for approval, rely upon data or information previously developed by the sponsor of a prior approved drug or indication (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information) for such drug or indication in order to expedite clinical development for a precision drug or indication that is using the same or similar precision medicine approach as that of the prior approved drug or indication; and]

[''(2) as appropriate under section 506, consider the application for approval of such precision drug to be eligible for expedited review, including under section 506(c) (relating to accelerated approval).]

[“SEC. 594. AGENCY GUIDANCE ON INTERPRETING EVIDENCE ON SERIOUS-DISEASES POPULATION SUBSETS.

[“(a) IN GENERAL.—To advance clinical development of precision drugs for serious diseases, the Secretary shall issue and periodically update guidance on identifying population subsets within the meaning of section 591(a) (relating to gene-related and other biological characteristics).]

[“(b) APPROACHES TO IDENTIFYING POPULATION SUBSETS.—Guidance under subsection (a) may address—]

[“(1) whether the population of individuals with one or more genetic risk factors for the disease involved can be divided into subsets for the purpose of identifying the subsets that may have favorable clinical responses to particular types of drugs; and]

[“(2) for such purpose—]

[“(A) whether, when there are multiple genetic risk factors, a separate subset should be identified for each such risk factor;]

[“(B) whether, in lieu of the approach described in subparagraph (A), subsets can be created by grouping or separating individuals with genetic risk factors on the basis of additional biological characteristics (such as

genotypes or particular molecular mechanisms);]

[“(C) whether, with respect to two or more serious diseases, subsets can be identified on the basis of genetic risk factors and other biological characteristics that are common to such diseases, notwithstanding the apparent differences in the diseases;]

[“(D) whether, with any of the approaches described in subparagraphs (A) through (C), a subset can be identified by extrapolating from scientific data concerning one or more other subsets, taking into account the issue of determining whether a proposed extrapolation-based subset has characteristics in common with the other subset or subsets that are scientifically sufficient to justify extrapolation;]

[“(E) what particular methodologies (such as biomarkers and in vitro assays) should be used to identify subsets as described in subparagraphs (A) through (D); and]

[“(F) the manner in which clinical trials should be designed on the basis of such subsets, including with respect to statistical methodologies, the number of subjects, the duration of

the trials, and standards for determining the trials have demonstrated a clinical benefit (or an effect on a surrogate endpoint or an intermediate clinical endpoint, as the case may be).]

[''(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The Secretary shall issue guidance under subsection (a) not later than 18 months after the date of the enactment of the 21st Century Cures Act.''.]

Subtitle D—Modern Trial Design and Evidence Development

[SEC. 2061. BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS.

[(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating adaptive trial design and Bayesian methods into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall conduct a public meeting and issue guidance in accordance with subsection (b).]

[(b) GUIDANCE ADDRESSING USE OF ADAPTIVE TRIAL DESIGNS AND BAYESIAN METHODS.—]

[(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (in this subsection referred to as the ''Secretary''), shall—]

[(A) update and finalize the draft guidance addressing the use of adaptive trial design for drugs and biological products; and]

[(B) issue draft guidance on the use of Bayesian methods in the development and regulatory review and approval or licensure of drugs and biological products.]

[(2) CONTENTS.—The guidances under paragraph (1) shall address—]

[(A) the use of adaptive trial designs and Bayesian methods in clinical trials, including clinical trials proposed or submitted to help satisfy the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));]

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

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

[(ii) the submission of resulting information to the Secretary;]

[(C) the types of quantitative and qualitative information that should be submitted for review; and]

[(D) recommended analysis methodologies.]

[(3) PUBLIC MEETING.—Prior to updating or developing the guidances required by paragraph (1), the Secretary shall consult with stakeholders including representatives of regulated industry, academia, patient advocacy organizations, and disease research foundations, through a public meeting to be held no later than 1 year after the date of enactment of this Act.]

[(4) SCHEDULE.—The Secretary shall publish—]

[(A) the final guidance required by paragraph (1)(A) not later than 18 months after the date of the public meeting required by paragraph (3); and]

[(B) the guidance required by paragraph (1)(B) not later than 48 months after the date of the public meeting required by paragraph (3).]

[SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

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

["SEC. 505H. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

["(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of evidence from clinical experience—]

["(1) to help support the approval of a new indication for a drug approved under section 505(b); and]

["(2) to help support or satisfy post-approval study requirements.]

["(b) EVIDENCE FROM CLINICAL EXPERIENCE DEFINED.—In this section, the term 'evidence from clinical experience' means data regarding the usage, or potential benefits or risks, of a drug derived from sources other than randomized clinical trials, including from observational trials, registries, and therapeutic use.]

["(c) PROGRAM FRAMEWORK.—]

["(1) IN GENERAL.—The Secretary shall—]

["(A) engage a public-private entity or independent research organization in fact-finding, stakeholder engagement, and drafting nec-

essary to produce a framework for the program under this section; and]

[“(B) not later than [12 months] after the date of enactment of this section, establish a draft framework for implementation of the program under this section.]

[“(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—]

[“(A) the current sources of data developed through clinical experience, including ongoing safety surveillance, registry, claims, and patient-centered outcomes research activities;]

[“(B) the gaps in current data collection activities;]

[“(C) the current standards and methodologies for collection and analysis of data generated through clinical experience; and]

[“(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.]

[“(3) CONSULTATION.—In developing the program framework under [this subsection], the Secretary, through the public-private partner or independent research organization, shall consult with

regulated industry, academia, organized medicine, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process.]

[''(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than [12 months] after the date of enactment of this section and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of evidence from clinical experience.]

[''(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—]

[''(1) utilize the program established in subsection (d), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—]

[''(A) the circumstances under which sponsors of drugs and the Secretary may rely on evidence from clinical experience for the purposes described in subsections (a)(1) or (a)(2);]

[''(B) the appropriate standards and methodologies for collection and analysis of evidence from clinical experience submitted for such purposes.]

[“(2) not later than [36 months] after the date of enactment of this section, issue draft guidance for industry as described in subparagraph (A); and]

[“(3) not later than [40 months] after the date of enactment of this section, after providing an opportunity for public comment on the draft guidance, issue final guidance.]

[“(f) RULE OF CONSTRUCTION.—]

[“(1) Subject to paragraph (2), nothing in this section prohibits the Secretary from using evidence from clinical experience for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such non-specified use.]

[“(2) This section shall not be construed to alter—]

[“(A) the standards of evidence under—]

[“(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or]

[“(ii) section 351(a) of the Public Health Services Act; or]

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

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

["SEC. 505I. COLLECTING EVIDENCE FROM CLINICAL EXPERIENCE THROUGH TARGETED EXTENSIONS OF THE SENTINEL SYSTEM.

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

["(b) PILOT DEMONSTRATIONS.—]

["(1) IN GENERAL.—The Secretary shall design and implement pilot demonstrations to—]

["(A) make strategic linkages between such data captured through the Sentinel System surveillance infrastructure and sources of complementary public health data and infrastructure the Secretary deems appropriate and necessary; and]

["(B) develop a governance mechanism and operational guidelines for the collection, analysis and use of such data intended to generate evidence from real world clinical experi-

ence to improve assessment of benefit-risk, protect public health, and advance patient-centered care.]

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

[“(3) CONSULTATION.—In developing the pilot demonstrations under this subsection, the Secretary shall consult with regulated industry, academia, organized medicine, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process.]

[“(4) PUBLIC HEALTH EXEMPTION.—The Secretary may—]

[“(A) deem such pilot demonstrations public health activities, permitting the use and disclosure of protected health information as described in 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in 46.101(b)(5) of title 46, Code of

Federal Regulations (or any successor regulation); and]

[“(B) deem safety surveillance performed at the request of the Food and Drug Administration or under such jurisdiction by a sponsor with responsibility for a drug approved under this section or section 351 of the Public Health Services Act using the infrastructure authorized at section 505(k) of the Food, Drug, and Cosmetic Act, including use of analytic tools and querying capabilities developed to implement the active post market surveillance system described in this section, public health activities as described in 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation).]

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

SEC. 2063. STREAMLINED DATA REVIEW PROGRAM.

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

"SEC. 505F. STREAMLINED DATA REVIEW PROGRAM.

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

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

"(1) the drug has been approved under section 505(c) of this Act or licensed under section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

"(2) the supplemental application is for approval or licensure (as applicable) under such section

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

''(3) there is an existing database acceptable to the Secretary regarding the safety of the drug developed for one or more indications of the drug approved under such section 505(c) or licensed under such section 351(a);

''(4) the supplemental application incorporates or supplements the data submitted in the application for approval or licensure referred to in paragraph (1); and

''(5) the full data sets used to develop the qualified data summaries are submitted, unless the Secretary determines that the full data sets are not required.

''(c) DEFINITIONS.—In this section:

''(1) The term 'qualified indication' means—

''(A) an indication for the treatment of cancer, as determined appropriate by the Secretary; or

''(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

"(2) The term 'qualified data summary' means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.".

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

(1) shall—

(A) issue final guidance for implementation of the streamlined data review program established under section 505F of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), not later than 24 months after the date of enactment of this Act; and

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

(2) in addition to issuing guidance under subparagraph (A), may issue such regulations as may be necessary for implementation of the program.

Subtitle E—Expediting Patient Access

SEC. 2081. SENSE OF CONGRESS.

It is the sense of Congress that the Food and Drug Administration should continue to expedite the approval of drugs designated as breakthrough therapies pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) by approving drugs so designated as early as possible in the clinical development process, regardless of the phase of development, provided that the Secretary of Health and Human Services determines that an application for such a drug meets the standards of evidence of safety and effectiveness under section 505 of such Act (21 U.S.C. 355), including the substantial evidence standard under subsection (d) of such section or under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

[SEC. 2082. EXPANDED ACCESS POLICY.

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

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

[(2) by inserting after subsection (c) the following new subsection:]

[“(d) EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.—]

[“(1) IN GENERAL.—Not later than 60 days after the initiation of any phase 2 or phase 3 human safety studies with respect to an investigational new drug, the sponsor of such studies shall make publicly available the policy of the sponsor with respect to requests submitted under subsection (b) for provision of such drug.]

[“(2) CONTENT OF POLICY.—A policy described in paragraph (1) shall include—]

[“(A) points of contact regarding the receipt and processing of such requests;]

[“(B) procedures for making such requests;]

[“(C) the general criteria for the sponsor’s consideration or approval of such requests; and]

[“(D) the length of time the sponsor anticipates will be necessary to acknowledge receipt of such requests.]

[“(3) NO GUARANTEE OF ACCESS.—The posting of policies by sponsors under paragraph (1) shall not serve as a guarantee of access to any specific investigational drug to any individual patient.”.]

[SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS.

[(a) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall finalize the draft guidance entitled ''Expanded Access to Investigational Drugs for Treatment Use—Qs & As'' and dated May 2013.]

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

Subtitle F—Facilitating Dissemination of Health Care Economic Information

[SEC. 2101. FACILITATING DISSEMINATION OF HEALTH CARE ECONOMIC INFORMATION.

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

[(1) by striking ''(a) If its'' and inserting ''(a)(1) If its'';]

[(2) by striking ''a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the

selection of drugs for managed care or other similar organizations'' and inserting ''a payor, formulary committee, or other similar entity, in the course of the payor, committee, or other similar entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations'';]

[(3) by striking ''directly relates'' and inserting ''relates'';]

[(4) by striking ''and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph'' and inserting '', is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any differences between the information and the indication approved under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a

payor, committee, or entity in accordance with this paragraph'';]

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

[''(2) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the data, inputs, clinical or other assumptions, methods, results, and other components comprising the analysis) that identifies, measures, or describes the consequences, including the separate or aggregated clinical consequences and costs of the represented health outcomes, of the use of a drug. Such analyses may be comparative to the use of another drug, to another health care intervention, or to no intervention.''.]

Subtitle G—Antibiotic Drug Development

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

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

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

[“(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—]

[“(1) PROCESS.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition, the Secretary—]

[“(A) shall provide the sponsor with an opportunity to request meetings under paragraph (2); and]

[“(B) may, consistent with an agreement between the sponsor and the Secretary, if any such agreement is reached, approve the drug under subsection (c) for such treatment in a limited population of patients for which there is an unmet medical need.]

[“(2) FORMAL MEETINGS.—]

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

[“(i) A clinical development planning meeting.]

[“(ii) An assessment meeting.]

[“(iii) A postapproval meeting.]

[“(B) RELATION TO COMPARABLE FORMAL MEETINGS.—A meeting conducted pursuant to a request described in subparagraph (A) shall not replace any meeting with the Secretary to which the sponsor of the drug is otherwise entitled, but may be conducted as part of a comparable formal meeting.]

[“(C) TIMING.—The Secretary shall meet with the sponsor of a drug pursuant to a request described in subparagraph (A) not later than 60 days after the date of the Secretary’s receipt of the request.]

[“(D) DEFINITIONS.—In this paragraph:]

[“(i) The term ‘assessment meeting’ means a meeting, other than a clinical development planning meeting, held prior to submission of an application for a drug under section 505(b) of this Act of section 351(a) of the Public Health Service Act, at which the sponsor of the drug and the Secretary meet—]

[“(I) to assess progress in implementing the clinical development program agreed to under paragraph (1);]

[“(II) to discuss the necessity of, and reach agreement with respect to, any postapproval commitments; and]

[“(III) to reach agreement on the efficacy or safety data necessary to support expansion of the approval or licensure of the drug beyond use in the limited population.]

[“(ii) The term ‘clinical development planning meeting’ means a meeting, other than an assessment meeting, at which the sponsor of the drug and the Secretary meet to discuss and reach an initial agreement with respect to the content of the clinical development program (including the matters described in paragraph (1)(B)) that is necessary to support approval or licensure of the drug for use in a limited population.]

[“(iii) The term ‘comparable formal meeting’—]

[“(I) means a formal meeting that is typically held during the drug development or approval process; and]

[“(II) includes any such meeting that is described in applicable guidance documents of the Food and Drug Administration that are in effect.]

[“(iv) The term ‘postapproval meeting’ means a meeting, held following initial approval or licensure of the drug for use in a limited population, to discuss any issues regarding postapproval commitments or expansion of approved uses agreed to under paragraph (1).]

[“(3) AGREEMENTS.—]

[“(A) FORM.—Any agreement that is reached between the Secretary and a sponsor of a drug under paragraph (1), including an agreement with respect to the design or size of clinical trials, shall be reduced to writing and made part of the administrative record by the Secretary.]

[“(B) EVIDENCE.—An agreement under paragraph (1) may provide for reliance on—]

[“(i) traditional endpoints, alternative endpoints, or a combination of traditional and alternative endpoints;]

[“(ii) datasets of limited size;]

[“(iii) pharmacologic or pathophysiologic data;]

[“(iv) data from phase 2 clinical studies;]

[“(v) data obtained in real-world settings; and]

[“(vi) such other confirmatory evidence as the Secretary deems necessary to approve the drug, as described in paragraph (1).]

[“(C) LABELING STATEMENT.—An agreement under paragraph (1) shall require the drug’s labeling, upon approval pursuant to the agreement, to prominently include in the prescribing information required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) the following statement: ‘This drug is indicated for use in a limited and specific population of patients.’.]

[“(D) CHANGES.—An agreement described in subparagraph (A) shall not be

changed after the development of such data begins, except—]

[“(i) with the written agreement of the sponsor of the drug; or]

[“(ii) pursuant to a decision by the director of the division responsible for reviewing the drug that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after data development began.]

[“(E) DECISION BY DIRECTOR.—A decision under subparagraph (D)(ii) shall be in writing. Before any such decision is made final, the Secretary shall provide to the sponsor of the drug an opportunity for a meeting at which—]

[“(i) the director of the division responsible for reviewing the drug and the sponsor will be present; and]

[“(ii) the director will document the scientific issues involved.]

[“(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval under this subsection to the same extent and in the same manner as such provisions

apply with respect to accelerated approval under section 506(c)(1).]

[“(5) WITHDRAWAL OF LIMITED POPULATION APPROVAL REQUIREMENTS.—If a drug is approved pursuant to this subsection for treatment in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, respectively, without such a limitation, the Secretary shall remove any labeling requirements or postmarketing conditions that were made applicable to the drug on the basis of such limitation.]

[“(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit designation and expedited review of a drug as a breakthrough therapy under section 506(a), approval of such a drug under section 506(g), designation and treatment of a drug as a fast track product under section 506(b), or accelerated approval of a drug under section 506(c), in combination with approval of the drug for use in a limited population of patients under this subsection.]

[“(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the standards of evidence under subsection (c) or (d) (includ-

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

[''(8) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when and whether the Secretary promulgates final regulations or guidance.''.]

[(2) GUIDANCE.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population under section 505(z) of the Federal

Food, Drug, and Cosmetic Act, as added by paragraph (1).]

[(b) LICENSURE OF CERTAIN BIOLOGICAL PRODUCTS.—Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended—]

[(1) by striking ''(j)'' and inserting ''(j)(1)'';]

[(2) by inserting ''505(z),'' after ''505(p),''; and]

[(3) by adding at the end the following:]

[''(2) In applying section 505(z) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—]

[''(A) references to an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition shall be construed to refer to biological products intended to treat a bacterial or fungal infection associated with a serious or life-threatening disease; and]

[''(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to licensure of a biological product under subsection (a) of this section.''.]

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

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

["(a) MONITORING.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall use the National Healthcare Safety Network or another appropriate monitoring system to monitor—]

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

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

["(b) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make the data derived from monitoring under this section publicly available for the purposes of—]

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

["(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those re-

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

SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

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

''SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

''(a) IDENTIFICATION OF CRITERIA PURPOSE.—

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

''(A) clearance or premarket approval of antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms to antimicrobial drugs; and

''(B) providing public notice of the availability of recognized interpretive criteria to meet premarket submission requirements or

other requirements under this Act for antimicrobial susceptibility testing devices.

"(2) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

"(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

"(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

"(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (1), based on the Secretary's review of, to the extent available and relevant—

"(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

"(B) Bayesian and pharmacometric statistical methodologies; and

"(C) such other evidence and information as the Secretary considers appropriate.

''(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

''(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

''(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

''(i) established by a nationally or internationally recognized standard development organization that—

''(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

"(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

"(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

"(ii) recognized in whole, or in part, by the Secretary under subsection (c).

"(B) OTHER LISTS.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect to legally marketed antimicrobial drugs, where—

"(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

"(ii) the Secretary withdraws under subsection (c)(1)(B) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

"(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

"(iv) because the characteristics of such a drug product differ from other drug products with the same active ingredient, the interpretive criteria with respect to such drug—

"(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph (A) or interpretive criteria otherwise listed under this subparagraph; and

"(II) are determined to be appropriate for the drug.

"(C) REQUIRED STATEMENTS ON LIMITATIONS OF INFORMATION.—The Interpretive Criteria Website shall include the following:

"(i) A statement that—

"(I) the Website provides information about the susceptibility of bacteria, fungi, or other microorganisms to a certain drug (or drugs); and

"(II) the safety and efficacy of the drug in treating clinical infections due to such bacteria, fungi, or other microorganisms may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in such trials is unknown.

"(ii) A statement that directs health care practitioners to consult the approved product labeling for specific drugs to determine the uses for which the Food and Drug Administration has approved the product.

"(iii) Any other statement that the Secretary determines appropriate to adequately convey the limitations of the data

supporting susceptibility test interpretive criteria standard listed on the Website.

"(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

"(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502, or the regulations promulgated thereunder.

"(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

"(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FROM STANDARD DEVELOPMENT ORGANIZATIONS.—

"(1) IN GENERAL.—Beginning on the date of the establishment of the Interpretive Criteria

Website, and at least every 6 months thereafter, the Secretary shall—

"(A) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

"(B) publish on the public website of the Food and Drug Administration a notice—

"(i) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

"(ii) recognizing the new or updated standards;

"(iii) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

"(iv) making any necessary updates to the lists under subsection (b)(2).

"(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards

under paragraph (1)(A), the Secretary may consider—

"(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

"(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

"(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

"(D) such other information or factors as the Secretary determines appropriate.

"(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(B) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary will review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards—

"(A) recognized by the Secretary under this subsection; or

"(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria standards which differ from those recognized pursuant to paragraph (1).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 or

section 351 of the Public Health Service Act, as applicable, for each such drug—

"(A) not later than 1 year after establishment of the Interpretive Criteria Website, shall submit to the Secretary a supplemental application for purposes of changing the drug's labeling to substitute a reference or hyperlink to such Website for any susceptibility test interpretive criteria and related information; and

"(B) may begin distribution of the drug involved upon receipt by the Secretary of the supplemental application for such change.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs lawfully introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of the establishment of the Interpretive Criteria Website, the labeling for such a drug shall include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

"(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

"(1) IN GENERAL.—Notwithstanding sections 501, 502, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

"(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

"(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

"(i) included in a standard recognized by the Secretary under subsection (c); or

"(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(B) The labeling of such device prominently and conspicuously—

"(i) includes a statement that—

''(I) the device provides information about the susceptibility of bacteria and fungi to certain drugs; and

''(II) the safety and efficacy of such drugs in treating clinical infections due to such bacteria or fungi may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in those instances is unknown;

''(ii) includes a statement directing health care practitioners to consult the approved labeling for drugs tested using such a device, to determine the uses for which the Food and Drug Administration has approved such drugs; and

''(iii) includes any other statement the Secretary determines appropriate to adequately convey the limitations of the data supporting the interpretive criteria described in subparagraph (A).

''(f) DEFINITIONS.—In this section:

''(1) The term 'antimicrobial susceptibility testing device' means a device that utilizes susceptibility

test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

''(2) The term 'qualified infectious disease product' means a qualified infectious disease product designated under section 505E(d).

''(3) The term 'susceptibility test interpretive criteria' means—

''(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

''(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

''(4)(A) The term 'antimicrobial drug' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

''(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

''(ii) may include a qualified infectious disease product designated under section 505E(d); and

''(iii) is subject to section 503(b)(1).

''(B) If provided by the Secretary through regulations, such term may include—

''(i) drugs other than systemic antibacterial and antifungal drugs; and

''(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) alter the standards of evidence—

''(A) under subsection (c) or (d) of section 505, including the substantial evidence standard in section 505(d), or under section 351 of the Public Health Service Act (as applicable); or

''(B) with respect to marketing authorization for devices, under sections 510, 513, or 515; or

''(2) apply with respect to any drug, device, or biological product, in any context other than—

''(A) the use of such drug or product as an antimicrobial drug; or

''(B) the use of an antimicrobial susceptibility testing device to characterize and report the in vitro susceptibility of certain bacteria, fungi, or other microorganisms to antimicrobial drugs in accordance with this section; and

''(3) unless specifically stated, have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.''.

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF RELATED AUTHORITY.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a; relating to identification of clinically susceptible concentrations of antimicrobials) is repealed.

(2) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(dd) If it is an antimicrobial drug and its labeling fails to conform with the requirements under section 511(d).''.

(3) RECOGNITION OF INTERPRETIVE CRITERIA AS DEVICE STANDARD.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after ''the

Secretary shall, by publication in the Federal Register'' the following: ''(or, with respect to susceptibility test interpretive criteria or standards recognized or otherwise listed under section 511, by posting on the Interpretive Criteria website in accordance with such section)''.

(c) REPORT TO CONGRESS.—Not later than two years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the progress made in implementing section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as amended by this section.

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding the updating of lists under paragraph (2) of subsection (b) section 511 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), and posted on the Interpretive Criteria Website established under paragraph (1) of such subsection (b).

(e) NO EFFECT ON HEALTH CARE PRACTICE.—Nothing in this subtitle (including the amendments made

by this subtitle) shall be construed to restrict, in any manner, the prescribing or administering of antibiotics or other products by health care practitioners, or to limit the practice of health care.

[SEC. 2123. ENCOURAGING THE DEVELOPMENT AND RESPONSIBLE USE OF NEW ANTIMICROBIAL DRUGS.

[(a) ADDITIONAL PAYMENT FOR NEW ANTIMICROBIAL DRUGS UNDER MEDICARE.—Section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:]

[''(M)(i) Effective for discharges beginning on or after October 1, 2015, the Secretary shall, after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise), recognize the costs of new antimicrobial drugs under the payment system established under this subparagraph.]

[''(ii) Pursuant to clause (i), the Secretary shall provide for additional payment to be made under this subsection with respect to discharges involving new antimicrobial drugs in the amount provided for under section A for drugs

and biological products that are described in section 1842(o)(1)(C).]

[''(iii) For purposes of this subparagraph, the term 'new antimicrobial drug' means a product that is approved for use, or a product for which an indication is first approved for use, by the Food and Drug Administration on or after January 1, 2015, and—]

[''(I)(aa) is intended to treat an infection caused by, or likely to be caused by, a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); or]

[''(bb) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act;]

[''(II) for which there is an 'unmet medical need' as determined by the Food and Drug Administration;]

[''(III) which is associated with high rates of mortality or significant patient morbidity, as determined by the Secretary, in consultation with the Director of the Centers for Disease Control and Preven-

tion and the infectious disease professional community; and]

[“(IV) is used in facilities that participate in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar reporting program relating to antimicrobial drugs is determined by the Secretary to be available to such facilities, such similar reporting program as the Secretary may specify).]

[“(iv)(I) The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a new antimicrobial drug at any time before or after the submission of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a new antimicrobial drug.]

[“(II) Except as provided in subclause (III), a designation under this subsection shall not be withdrawn for any reason.]

[“(III) The Secretary may revoke a designation of a drug as a new antimicrobial drug product if the Secretary finds that the request for such designation contained an untrue statement of material fact.]

[“(v) Not later than July 1, 2015, the Secretary shall first publish in the Federal Register a list of the new antimicrobial drugs.”.]

[(b) STUDY AND REPORT ON REMOVING BARRIERS TO DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—]

[(1) STUDY.—The Comptroller General of the United States shall, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention, conduct a study to—]

[(A) identify and examine the barriers that prevent the development of new antimicrobial drugs, as defined in section 1886(d)(5)(M)(iii) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(M)(iii)); and]

[(B) develop recommendations for actions to be taken in order to overcome any barriers identified under subparagraph (A).]

[(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).]

[Subtitle H— Vaccine Access, Certainty, and Innovation]

[SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

Section 2102(a) of the Public Health Service Act (42 U.S.C. 300aa–2(a)) is amended by adding at the end the following:]

[''(10) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—]

[''(A) STANDARD PERIODS OF TIME FOR MAKING RECOMMENDATIONS.—Upon the licensure of any vaccine or any new indication for a vaccine, the Director of the Program shall direct the Advisory Committee on Immunization Practices, at its next regularly scheduled meeting, to consider the use of the vaccine.]

[''(B) EXPEDITED REVIEW PURSUANT TO REQUEST BY SPONSOR OR MANUFACTURER.—If the Advisory Committee does not make recommendations with respect to the use of a vac-

cine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee, at the request of the sponsor of the vaccine, shall make such recommendations on an expedited basis.]

[''(C) EXPEDITED REVIEW FOR BREAKTHROUGH THERAPIES AND FOR USE DURING PUBLIC HEALTH EMERGENCIES.—If a vaccine is designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act and is licensed under section 351 of this Act, the Advisory Committee shall make recommendations with respect to the use of the vaccine on an expedited basis.]

[''(D) DEFINITION.—In this paragraph, the terms 'Advisory Committee on Immunization Practices' and 'Advisory Committee' mean the advisory committee on immunization practices established by the Secretary pursuant to section 222, acting through the Director of the Centers for Disease Control and Prevention.''.]

[SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF ACIP RECOMMENDATIONS.

[(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the process used by the Advisory Committee on Immunization Practices to evaluate the consistency of the Advisory Committee in formulating and issuing recommendations pertaining to vaccines.]

[(b) CONSIDERATIONS.—The review under subsection (a) shall include assessment of—]

[(1) the criteria used to evaluate new and existing vaccines;]

[(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and]

[(3) the extent to which the processes used by the working groups of the Advisory Committee on Immunization Practices are consistent among groups.]

[(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.]

[(d) REPORT.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress and make publicly available a report on the results of the review under subsection (a), including recommendations on improving the transparency and consistency of the process described in such subsection.]

[(e) DEFINITION.—In this section, the term ''Advisory Committee on Immunization Practices'' means the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.]

[SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVELOPERS.

Section 310 of the Public Health Service Act (42 U.S.C. 242o) is amended by adding at the end the following:]

[''(c)(1) In this subsection, the term 'vaccine developer' means a nongovernmental entity engaged in—]

[''(A)(i) the development of a vaccine with the intent to pursue licensing of the vaccine by the Food and Drug Administration; or]

[“(ii) the production of a vaccine licensed by the Food and Drug Administration; and]

[“(B) vaccine research.]

[“(2)(A) Upon the submission of a written request for a meeting by a vaccine developer, that includes a justification for the meeting, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts from the Centers for Disease Control and Prevention in immunization programs, epidemiology, and other relevant areas at which the Director (or the Director's designee), for the purpose of informing the vaccine developer's understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—]

[“(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer's potential vaccine profile; and]

[“(ii) potential implications of such perspectives for the vaccine developer's vaccine research and development planning.]

[“(B) In addition to the representatives specified in subparagraph (A), the Secretary may include in a meeting convened under such subparagraph representatives of—]

[“(i) the Food and Drug Administration; and]

[“(ii) the National Vaccine Program.]

[“(C) The Secretary shall convene a meeting requested under subparagraph (A) not later than 120 days after receipt of the request for the meeting.]

[“(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based or other demographically assessed disease epidemiological analyses or data that—]

[“(i) are specified in the request;]

[“(ii) have been published;]

[“(iii) have been performed by or are in the possession of the Centers;]

[“(iv) are not a trade secret or otherwise confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; and]

[“(v) do not contain individually identifiable information.]

[“(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 90 calendar days after receipt of the request for the analyses.]

[“(4) The Secretary shall promptly notify a vaccine developer if—]

[“(A) the Secretary becomes aware of any change to information that was—]

[“(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or]

[“(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and]

[“(B) the change may have implications for the vaccine developer's vaccine research and development.”.]

[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.

(a) IN GENERAL.—The Commissioner of Food and Drugs may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process

of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) DEFINITIONS.—In this section:

(1) The term ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) The term ''biological product'' has the meaning given to such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(3) The term ''institution of higher education'' has the meaning given to such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $_____ for each of fiscal years 2016 through 2019 to carry out this section.

[SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.

Section 1003(f) of the Controlled Substances Import and Export Act (21 U.S.C. 953(f)) is amended—]

[(1) in paragraph (5)—]

[(A) by striking ''(5)'' and inserting ''(5)(A)'';]

[(B) by inserting ", except that the controlled substance may be exported from the second country to another country that is a member of the European Economic Area" before the period at the end; and]

[(C) by adding at the end the following:]

["(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, provided that—]

["(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substances is exported pursuant to this paragraph; and]

["(ii) the conditions applicable with respect to the second country under such paragraphs are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph."; and]

[(2) by adding at the end the following:]

["(g) LIMITATION.—The Attorney General shall not promulgate nor enforce any regulation, subregulatory

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—]

[“(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]

[“(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States.”.]

Subtitle K—Priority Review for Breakthrough Devices

SEC. 2181. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 515(d)—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5); and

(2) by inserting after section 515A (21 U.S.C. 360e–1) the following:

"SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

''(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

''(1) representing breakthrough technologies;

''(2) for which no approved alternatives exist;

''(3) offering significant advantages over existing approved or cleared alternatives, including the potential to, compared to existing approved or cleared alternatives, reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

''(4) the availability of which is in the best interest of patients.

''(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

''(c) DESIGNATION PROCESS.—

''(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

''(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the Food and Drug Administration and is chaired by a senior manager.

''(3) DESIGNATION DETERMINATION.—A determination approving or denying a request under subsection (b) shall be considered a significant decision under section 517A and the Secretary shall provide a written, substantive summary of the basis for the determination in accordance with section 517A(a).

''(4) RECONSIDERATION.—

''(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial in accordance with section 517A(b)—

"(i) based upon the submission of documents by such person; or

"(ii) based upon such documents and a meeting or teleconference.

"(B) RESPONSE.—Reconsideration of a designation determination under this paragraph shall be conducted in accordance with section 517A(b).

"(5) WITHDRAWAL.—If the Secretary approves a priority review designation for a device under this section, the Secretary may not withdraw the designation based on the fact that the criteria specified in subsection (a) are no longer met because of the subsequent clearance or approval of another device that was designated under—

"(A) this section; or

"(B) section 515(d)(5) (as in effect immediately prior to the enactment of the 21st Century Cures Act).

"(d) PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (c), the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter ex-

pertise and experience, for each device for which a request is submitted under subsection (b);

"(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

"(C) adopt an efficient process for timely dispute resolution;

"(D) provide for interactive communication with the sponsor of the device during the review process;

"(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

"(F) disclose to the sponsor in advance the topics of any consultation concerning the sponsor's device that the Secretary intends to undertake with external experts or an advisory committee and provide the sponsor an opportunity to recommend such external experts;

"(G) for applications submitted under section 515(c), provide for advisory committee input, as the Secretary determines appropriate

(including in response to the request of the sponsor); and

''(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

''(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

''(A) coordinate with the sponsor regarding early agreement on a data development plan;

''(B) take steps to ensure that the design of clinical trials is as efficient as practicable, such as through adoption of shorter or smaller clinical trials, application of surrogate endpoints, and use of adaptive trial designs and Bayesian statistics, to the extent scientifically appropriate;

''(C) facilitate, to the extent scientifically appropriate, expedited and efficient develop-

ment and review of the device through utilization of timely postmarket data collection, with regard to applications for approval under section 515(c); and

"(D) agree to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes agreed to by the sponsor and the Secretary;

"(ii) changes that the Secretary determines are required to prevent an unreasonable risk to the public health; or

"(iii) the identification of a substantial scientific issue determined by the Secretary to be essential to the safety or effectiveness of the device involved.

"(e) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—The Secretary shall issue guidance on the implementation of this section. Such guidance shall include the following:

"(A) The process for a person to seek a priority review designation.

"(B) A template for requests under subsection (b).

''(C) The criteria the Secretary will use in evaluating a request for priority review.

''(D) The standards the Secretary will use in assigning a team of staff, including team leaders, to review devices designated for priority review, including any training required for such personnel on effective and efficient review.

''(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

''(f) CONSTRUCTION.—

''(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating

device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.''.

(b) CONFORMING AMENDMENT RELATED TO DESIGNATION DETERMINATIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g-1(a)(1)) is amended by inserting ''a request for designation under section 515B,'' after ''an application under section 515,''.

Subtitle L—Medical Device Regulatory Process Improvements

SEC. 2201. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

[To be provided.]

SEC. 2202. VALID SCIENTIFIC EVIDENCE.

Section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

(1) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(2) by striking ''(B) If the Secretary'' and inserting ''(B)(i) If the Secretary''; and

(3) by adding at the end the following:

''(ii) Valid scientific evidence for purposes of clause (i) may include:

''(I) evidence described in well-documented case histories, including registry data, that are collected and monitored under an acceptable protocol;

''(II) studies published in peer-reviewed journals; and

''(III) data collected in countries other than the United States so long as such data otherwise meets the criteria specified in this subparagraph.

''(iii) In the case of a study published in a peer-reviewed journal that is offered as valid scientific evidence for purposes of clause (i), the Secretary may request data underlying the study if—

''(I) the Secretary, in making such request, complies with the requirement of subparagraph (D)(ii) to consider the least burdensome appropriate means of evaluating device effectiveness or subsection (i)(1)(D) to consider the least burdensome means of determining substantial equivalence, as applicable;

"(II) the Secretary furnishes a written rationale for so requesting the underlying data accompanies such request; and

"(III) if the requested underlying data for such a study are unavailable, the Secretary shall consider such study to be part of the totality of the evidence with respect to the device, as the Secretary determines appropriate.".

SEC. 2203. TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.

(a) IN GENERAL.— Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by inserting after subsection (i) the following:

"(j) TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.—

"(1) TRAINING.—Each employee of the Food and Drug Administration who is involved in the review of premarket submissions under section 515 or section 510(k), including supervisors, shall receive training regarding the meaning and implementation of the least burdensome appropriate means concept in the context of the use of that term in subsections (a)(3)(D) and (i)(1)(D) of this section and in section 515(c)(5).

''(2) GUIDANCE DOCUMENTS.—

''(A) DRAFT UPDATED GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue a draft guidance document updating the October 4, 2002, guidance document entitled 'The Least Burdensome provision of the FDA Modernization Act of 1997: Concept and Principles; Final 11 Guidance for FDA and Industry'.

''(B) MEETING OF STAKEHOLDERS.—In developing such draft guidance document, the Secretary shall convene a meeting of stakeholders to ensure a full record to support the publication of such document.

''(3) OMBUDSMAN AUDIT.—Not later than 18 months after the date of issuance of final version of the draft guidance under paragraph (2), the ombudsman for the organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

''(A) conduct, or have conducted, an audit of the training described in paragraph (1); and

''(B) include in such audit interviews with a representative sample of persons from indus-

try regarding their experience in the device premarket review process.''.

(b) ADDITIONAL INFORMATION REGARDING PREMARKET APPLICATIONS.—Subsection (c) of section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 29 360e) is amended by adding at the end the follows:

''(5)(A) Whenever the Secretary requests additional information from an applicant regarding an application under paragraph (1), the Secretary shall consider the least burdensome appropriate means necessary to demonstrate device safety and effectiveness, and request information accordingly.

''(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

''(C) Nothing in this paragraph alters the standards for premarket approval of a device.''.

SEC. 2204. RECOGNITION OF STANDARDS.

Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

''(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

''(ii) Not later than 60 days after the Secretary receives such a request, the Secretary shall—

''(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

''(II) issue to the person who submitted such request a respond in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination;

''(iii) The Secretary make a response issued under clause (ii)(II) publicly available, in such manner as the Secretary determines appropriate.

''(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under subclause (I), in accordance with subparagraph (A).

"(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of part of a standard, including the scientific, technical, regulatory, or other basis for such recognition. "; and

(2) by adding at the end the following new paragraphs:

"(4) TRAINING ON USE OF STANDARDS.—The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

"(5) GUIDANCE.—

"(A) DRAFT GUIDANCE.—The Secretary shall publish guidance identifying the principles for recognizing standards under this section. In publishing such guidance, the Secretary shall consider the experience with, and reliance on, a standard by other Federal regulatory authori-

ties and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

''(B) TIMING.—The Secretary shall publish—

''(i) draft guidance under subparagraph (A) not later than 12 months after the date of the enactment of the 21st Century Cures Act; and

''(ii) final guidance not later than 12 months of the close of the public comment period for the draft guidance under clause (i).''.

SEC. 2205. NOTIFICATION OF MARKETING OF CERTAIN CLASS I DEVICES.

[To be provided.]

SEC. 2206. ADVISORY COMMITTEE PROCESS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking ''(5)'' and inserting ''(5)(A)''; and

(2) by adding at the end the following:

"(B) For review by a classification panel of a premarket submission for a device, the Secretary shall—

"(i) provide an opportunity for the person whose premarket submission is subject to panel review to provide recommendations on the expertise needed among the voting members of the panel; and

"(ii) give due consideration to such recommendations and ensure that adequate expertise is represented on advisory panels to assess—

"(I) the disease or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device.

"(C) For purposes of subparagraph (B)(ii), the term 'adequate expertise' means that the membership of the classification panel reviewing a premarket submission includes—

''(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

''(ii) at least one voting member who is knowledgeable about the technology of the device.''.

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end '', including by designating a representative who will be provided a time during the panel meeting to address the panel individually (or accompanied by experts selected by such representative) for the purpose of correcting misstatements of fact or providing clarifying information, subject to the discretion of panel chairperson.''.

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

''(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

''(I) provide adequate time for initial presentations by the person whose device is

specifically the subject of such review and by the Secretary; and

''(II) encourage free and open participation by all interested persons.

''(ii) Following the initial presentations described in clause (i), the panel may—

''(I) pose questions to a designated representative described in subparagraph (A)(iii); and

''(II) consider the responses to such questions in the panel's review of the device.''.

SEC. 2207. HUMANITARIAN DEVICE EXEMPTION APPLICATION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in paragraph (1) by striking ''fewer than 4,000'' and inserting ''not more than 8,000'';

(2) in paragraph (2)(A) by striking ''fewer than 4,000'' and inserting ''not more than 8,000''; and

(3) in paragraph (6)(A)(ii), by striking ''4,000'' and inserting ''8,000''

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enact-

ment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance document that defines the criteria for establishing ''probable benefit'' as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

SEC. 2208. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS.

(a) DRAFT REVISED GUIDANCE.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish a draft guidance that—

(1) revises section ''V. Demonstrating Insignificant Risk of an Erroneous Result'' – ''Accuracy'' of the guidance entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' and dated January 30, 2008; and

(2) includes guidance on the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services shall finalize the draft guid-

ance published under subsection (a) not later than 12 months after the comment period for such draft guidance closes.

[Subtitle M—Sensible Oversight for Technology Which Advances Regulatory Efficiency]

[SEC. 2221. HEALTH SOFTWARE.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:]

[''(ss)(1) The term 'health software' means software that does not, through use of an in vitro diagnostic device or signal acquisition system, acquire, process, or analyze an image or physiological signal, is not an accessory, is not an integral part of a device necessary to support the use of the device, and—]

[''(A) is intended for use for administrative or operational support or the processing and maintenance of financial records;]

[''(B) is intended for use in clinical, laboratory, or administrative workflow and related recordkeeping;]

[''(C)(i) is intended for use solely in the transfer, aggregation, conversion (in accordance with a present specification), storage, manage-

ment, retrieval, or transmission of data or information;]

[“(ii) utilizes a connectivity software platform, electronic or electrical hardware, or a physical communications infrastructure; and]

[“(iii) is not intended for use—]

[“(I) in active patient monitoring; or]

[“(II) in controlling or altering the functions or parameters of a device that is connected to such software;]

[“(D) is intended for use to organize and present information for health or wellness education or for use in maintaining a healthy lifestyle, including medication reminders and health management tools;]

[“(E) to provide general health information that does not include a patient-specific diagnosis, treatment, or course of action; or]

[“(F) is intended to analyze information to provide patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure or mitigation of a particular disease or condition.]

[“(2) The term ‘accessory’ means a product that—]

[“(A) is intended for use with one or more parent devices;]

[“(B) is intended to support, supplement, or augment the performance of one or more parent devices; and]

[“(C) shall be classified by the Secretary—]

[“(i) according to its intended use; and]

[“(ii) independently of any classification of any parent device with which it is used.”.]

[SEC. 2222. APPLICABILITY AND INAPPLICABILITY OF REGULATION.

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

[“SEC. 524B. HEALTH SOFTWARE.

[“(a) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Subject to subsection (b), health software shall not be subject to regulation under this Act.]

[“(b) EXCEPTION.—Subsection (a) shall not apply in the case of a software product of a type described in subparagraph (F) of section 201(ss)(1) that the Secretary determines poses a significant risk to patient safety. In making such a determination, the Secretary shall consider the following:]

[“(1) The likelihood and severity of patient harm if the product were to function improperly.]

[“(2) The clinical significance of the information or recommendations supplied by the product.]

[“(3) The extent to which the product is intended to replace the clinical judgment of a medical professional.]

[“(4) Whether a review of the means by which the analysis was performed by the product with respect to a particular disease or condition could be reasonably performed by a medical professional.]

[“(5) Whether there exists a means to independently evaluate and verify the accuracy of the analysis so performed.]

[“(6) The intended use of the product, including the intended user and user environment, such as whether a health care provider will use a software product of a type described in subparagraph (F) of section 201(ss)(1).]

[“(c) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating a software product of a type described in subparagraph (F) of section 201(ss)(1) to the center at the Food and Drug Administration charged with regulating devices.]

[“(d) REGULATION OF SOFTWARE.—]

[“(1) IN GENERAL.—Not later than 24 months after the date of the enactment of this section, the Secretary shall promulgate final regulations for the regulation of software under this Act. The Secretary shall include in such regulations a review of the extent to which the existing standards for the classification, review, and regulation of devices under the Federal Food, Drug, and Cosmetic Act should be modified with respect to software, including each of the following areas:]

[“(A) The classification of software.]

[“(B) Standards for the development of software.]

[“(C) Standards for the validation and verification of software.]

[“(D) The review of software.]

[“(E) Modifications to software.]

[“(F) Manufacturing of software.]

[“(G) Quality systems for software.]

[“(H) Labeling requirements for software.]

[“(I) Postmarketing requirements for reporting networks and the reporting of adverse events.]

[“(2) PROCESS FOR ISSUING PROPOSED REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, in consultation with stakeholders (including patients, industry, health care providers, academia, and government) issue proposed regulations under paragraph (1).”.]

[SEC. 2223. EXCLUSION FROM DEFINITION OF DEVICE.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—]

[(1) in subparagraph (2), by striking “or” after “or other animals,”;]

[(2) in subparagraph (3), by striking “and” and inserting “or”; and]

[(3) by inserting after subparagraph (3) the following:]

[“(4) is not health software (other than software determined to be a risk to patient safety under section 524B(b)), and”.]

Subtitle N—Streamlining Clinical Trials

[SEC. 2241. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 491 the following section:]

["SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

[''(a) PROTECTION OF HUMAN SUBJECTS.—]

[''(1) IN GENERAL.—All human subject research described in paragraph (2)(A) shall be conducted in accordance with the HHS Human Subject Regulations, and as applicable to the human subjects involved in such research, with the vulnerable-populations rules.]

[''(2) APPLICABILITY.—]

[''(A) IN GENERAL.—This section applies to human subject research that is—]

[''(i) conducted or supported by the Department of Health and Human Services; or]

[''(ii) otherwise subject to regulation by the Department under a provision of Federal law (other than this section).]

[“(B) OTHER FEDERAL DEPARTMENTS AND AGENCIES.—The Secretary shall make available assistance to any Federal department or agency seeking—]

[“(i) to improve the regulation or oversight of human subject research; or]

[“(ii) to apply the HHS Human Subject Regulations or the vulnerable-populations rules to human subject research that is conducted, supported, or regulated by such department or agency.]

[“(b) HHS HUMAN SUBJECT REGULATIONS; OTHER DEFINITIONS.—]

[“(1) HHS HUMAN SUBJECT REGULATIONS; VULNERABLE-POPULATIONS RULES.—For purposes of this section:]

[“(A) The term ‘HHS Human Subject Regulations’—]

[“(i) subject to clause (ii), means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations); or]

[“(ii) in the case of human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351

of this Act, means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).]

[“(B) The term ‘vulnerable-populations rules’—]

[“(i) subject to clause (ii), means the provisions of subparts B through D of such part 46 (or any successor regulations); or]

[“(ii) as applicable to the human subjects involved in research described in subparagraph (A), means the provisions applicable to vulnerable populations under part 56 of such title 21 (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).]

[“(2) HUMAN SUBJECT RESEARCH.—For purposes of this section:]

[“(A) Except as provided in subparagraph (B), the term ‘human subject research’ means research, as defined in subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations), that involves a human

subject, as defined in such subpart A (or any successor regulations).]

[“(B) In the case of an investigation that is subject to the provisions of part 50 of title 21, Code of Federal Regulations (or any successor regulations), the term ‘human subject’ has the meaning given such term in such part 50, and the term ‘human subject research’ means a clinical investigation as defined in such part 50.]

[“(3) OTHER DEFINITIONS.—For purposes of this section:]

[“(A) The term ‘institutional review board’ has the meaning that applies to the term ‘institutional review board’ under the HHS Human Subject Regulations.]

[“(B) The term ‘lead institutional review board’ means an institutional review board that otherwise meets the requirements of the HHS Human Subject Regulations and enters into a written agreement with an institution, another institutional review board, a sponsor, or a principal investigator to approve and oversee human subject research that is conducted at multiple locations. References to an institutional review

board include an institutional review board that serves a single institution as well as a lead institutional review board.]

[“(c) SCOPE OF AUTHORITY OF SECRETARY.—]

[“(1) IN GENERAL.—The HHS Human Subject Regulations (including provisions regarding exemptions) and the vulnerable-populations rules, as in effect on the day before the date of the enactment of the 21st Century Cures Act, continue to be in effect on and after such date, subject to paragraph (2).]

[“(2) MODIFICATIONS.—]

[“(A) COMPLIANCE WITH LAW.—Promptly after the date of the enactment of the Act referred to in paragraph (1), the Secretary shall promulgate regulations to make such modifications to the provisions of the HHS Human Subject Regulations as may be necessary to ensure that such provisions implement, and do not conflict with, this section.]

[“(B) OTHER MODIFICATIONS.—This section may not be construed as affecting the authority of the Secretary to modify the provisions of the HHS Human Subject Regulations or the vulnerable-populations rules, except to the extent that any such modification is in conflict

with this section. Any such modification shall be made by regulation or guidance, as applicable.]

[''(d) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—]

[''(1) IN GENERAL.—The Secretary shall—]

[''(A) make such modifications to the provisions of the HHS Human Subject Regulations and the vulnerable-populations rules as may be necessary—]

[''(i) to reduce regulatory duplication and unnecessary delays;]

[''(ii) to modernize such provisions in the context of multisite and cooperative research projects;]

[''(iii) to incorporate local considerations, community values, and mechanisms to protect vulnerable populations; and]

[''(iv) to ensure that human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, and is therefore subject to parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations), is not subject to

subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations); and]

[“(B) ensure that human subject research that is described in subparagraph (A)(iv), or is cooperative research as such term is defined in section 46.114 of title 45, Code of Federal Regulations (or any successor regulations), may—]

[“(i) use joint or shared review;]

[“(ii) rely upon the review of—]

[“(I) an independent institutional review board; or]

[“(II) an institutional review board of an entity other than the sponsor of the research; or]

[“(iii) use similar arrangements to avoid duplication of effort.]

[“(2) REGULATIONS AND GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary, acting through the relevant agencies and offices of the Department of Health and Human Services, including the Office for Human Research Protections and relevant agencies and offices of the Food and Drug Ad-

ministration, shall issue such regulations and guidance and take such other actions as may be necessary to implement this subsection. Such regulations and guidance shall include clarification of requirements and policies relating to the following:]

[''(A) Arrangements to avoid duplication described in paragraph (1)(C), including—]

[''(i) delineating the roles of institutional review boards in multisite or cooperative, multisite studies where one or more local institutional review boards are relied upon, or similar arrangements are used;]

[''(ii) the risks and benefits to human subjects;]

[''(iii) standardization of informed consent and other processes and legal documents; and]

[''(iv) incorporating community values through the use of local institutional review boards while continuing to use central or lead institutional review boards.]

[''(B) Concerns about regulatory and legal liability contributing to decisions by the sponsors of research to rely on local institutional review boards for multisite research.]

[''(3) CONSULTATION.—In issuing regulations or guidance pursuant to paragraph (2), the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology and medical device developers, clinical research organizations, patient groups, and others).''.]

SEC. 2242. USE OF NON-LOCAL INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS AND HUMAN DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

(1) in subsection (g)(3)—

(A) by striking ''local'' each place it appears; and

(B) in subparagraph (A)(i), by striking ''which has been''; and

(2) in subsection (m)(4)—

(A) by striking ''local'' each place it appears; and

(B) by striking subparagraph (A) and inserting the following new subparagraph:

''(A) in facilities in which clinical testing of devices is supervised by an institutional review com-

mittee established in accordance with the regulations of the Secretary, and''.

(b) REGULATIONS.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise or issue such regulations or guidance as may be necessary to carry out the amendments made by subsection (a).

SEC. 2243. ALTERATION OR WAIVER OF INFORMED CONSENT FOR CLINICAL INVESTIGATIONS.

(a) DEVICES.—Section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is amended—

(1) in subparagraph (D), by striking ''except where subject to such conditions as the Secretary may prescribe, the investigator'' and inserting the following: ''except where, subject to such conditions as the Secretary may prescribe—

''(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

''(ii) the investigator''; and

(2) in the matter following subparagraph (D), by striking ''subparagraph (D)'' and inserting ''subparagraph (D)(ii)''.

(b) DRUGS.—Section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended by striking ''except where it is not feasible or it is contrary to the best interests of such human beings'' and inserting ''except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings''.

Subtitle O—Improving Scientific Expertise and Outreach at FDA

SEC. 2261. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE.

(a) HIRING AND RETENTION AUTHORITY.—Section 228 of the Public Health Service Act (42 U.S.C. 237) is amended—

(1) in the section heading, by inserting ''AND BIOMEDICAL PRODUCT ASSESSMENT'' after ''RESEARCH'';

(2) in subsection (a)(1), by striking ''Silvio O. Conte Senior Biomedical Research Service, not to

exceed 500 members'' and inserting ''Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), the purpose of which is to recruit and retain competitive and qualified scientific and technical experts outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment'';

(3) by amending subsection (a)(2) to read as follows:

''(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.'';

(4) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''or clinical research evaluation'' and inserting '', clinical research evaluation or biomedical product assessment'' after ''evaluation''; and

(B) in paragraph (1), by inserting ''or a masters level degree in engineering, bioinformatics, or a related or emerging field,'' after the comma;

(5) in subsection (d), by striking ''and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code'' and inserting ''and shall not exceed the rate payable for the President'';

(6) by striking subsection (e); and

(7) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

(b) REPORT.—Not later than three years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit, and publish on the Website of the Department of Health and Human Services a report on the implementation of the amendments made by subsection (a), including whether the amendments have improved the ability of the Food and Drug Administration to hire and retain qualified experts to fulfill obligations specified under user fee agreements.

SEC. 2262. ENABLING FDA SCIENTIFIC ENGAGEMENT.

It is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the Food and Drug Administration.

SEC. 2263. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are estab-

lished by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.''; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking ''The ex officio members shall ensure'' and inserting ''The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure''.

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: ''For purposes of this section, the term 'employee of the Federal Government' does not include a 'special Government employee', as that term is defined in section 202(a) of title 18, United States Code.''.

(3) STAGGERED TERMS.—Subparagraph (A) of section 770(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended to read as follows:

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

''(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

''(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.''.

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking ''but shall not be greater than the compensation of the Commissioner''.

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking ''are held in separate accounts from funds received from entities under subsection (i)'' and inserting ''are managed as individual programmatic funds under subsection (i), according to best accounting practices''.

SEC. 2264. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

Chapter VII of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 708 of such Act (21 U.S.C. 379) the following:

''SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

''Chapter 35 of title 44, United States Code, shall not apply to the collection from patients, industry, academia, and other stakeholders, of voluntary information such as through voluntary surveys or questionnaires, initiated by the Secretary.''.

TITLE III—DELIVERY

Subtitle A—Interoperability

SEC. 3001. INTEROPERABILITY.

[To be provided.]

Subtitle B—Telemedicine

SEC. 3021. TELEMEDICINE.

[To be provided by the Energy and Commerce Bipartisan Telemedicine Working Group]

Subtitle C—Encouraging Continuing Medical Education for Physicians

[SEC. 3041. EXEMPTING FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES.

[(a) IN GENERAL.—Section 1128G(e)(10)(B) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is amended—]

[(1) in clause (iii), by inserting ", including peer-reviewed journals, journal reprints, journal supplements, medical conference reports, and medical textbooks" after "patient use"; and]

[(2) by adding at the end the following new clause:]

["(xiii) In the case of a covered recipient who is a physician, an indirect payment or transfer of value to the covered recipient—]

["(I) for speaking at, or preparing educational materials for, an

educational event for physicians or other health care professionals that does not commercially promote a covered drug, device, biological, or medical supply; or]

[''(II) that serves the sole purpose of providing the covered recipient with medical education, such as by providing the covered recipient with the tuition required to attend an educational event or with materials provided to physicians at an educational event.''.]

[(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to transfers of value made on or after the date of the enactment of this Act.]

Subtitle D—Disposable Medical Technologies

SEC. 3061. DISPOSABLE MEDICAL TECHNOLOGIES.

[To be provided.]

Subtitle E—Local Coverage Decision Reforms

[SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS.

[(a) IN GENERAL.—Section 1874A(g) of the Social Security Act (42 U.S.C. 1395kk–1(g)) is amended—]

[(1) in paragraph (5), by inserting ''paragraphs (1) through (4) of'' before ''this subsection'';]

[(2) by redesignating paragraph (5), as so amended, as paragraph (6);]

[(3) by inserting after paragraph (4) the following new paragraph:]

[''(5) LOCAL COVERAGE DETERMINATIONS.—]

[''(A) IN GENERAL.—Each medicare administrative contractor that develops a local coverage determination shall, with respect to such determination, make available on the website of such contractor on or before the date described in subparagraph (B) the following information:]

[''(i) Such determination in its entirety.]

[''(ii) A response to any comments submitted to the contractor with respect to

any proposed versions of such determination that the contractor made available.]

[“(iii) A summary of any evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.]

[“(iv) An explanation of the rationale that supports such determination.]

[“(B) DATE DESCRIBED.—The date described in this subparagraph is, with respect to a determination described in subparagraph (A), the date that is 45 days before the date on which the determination takes effect.”.]

[(b) EFFECTIVE DATE.—The amendment made by subsection (a)(3) shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of the enactment of this Act.]

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

SEC. 3101. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808(c) of the Social Security Act (42 U.S.C. 1395b–9(c)) is amended by adding at the end the following new paragraph:

''(4) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—Not later than 12 months after the date of the enactment of this paragraph, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

''(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

''(B) regard coverage, coding, or payment under this title for such products.''.

[Subtitle G—Medicare Site-of-service Price Transparency]

[SEC. 3131. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

[(a) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgery center under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Secretary of Health and Human Services shall, for 2017 and each year thereafter, make available to the public via a searchable website, with respect to an appropriate number of such items and services, the anticipated cost of each such item or service to the Federal Government and to the individual who is furnished such item or service during such year when such item or service is furnished in each of the following:]

[(1) Such a hospital outpatient department.]

[(2) Such an ambulatory surgical center.]

[(b) PERMISSIBLE CALCULATION OF ANTICIPATED COST TO THE INDIVIDUAL.—For purposes of subsection (a), the Secretary may calculate the anticipated cost of an item or service to the individual who is furnished such item or service by calculating the anticipated cost of such item or service, through cost sharing, to an individual who

does not receive coverage under a medicare supplemental policy certified under section 1882 of the Social Security Act (42 U.S.C. 1395ss) or any other supplemental insurance coverage.]

[(c) IMPLEMENTATION.—In carrying out this section, the Secretary—]

[(1) shall include in the notice described in section 1804(a) of the Social Security Act (42 U.S.C. 1395b–2(a)) a notification of the availability of the anticipated costs made available under subsection (a); and]

[(2) may utilize existing mechanisms, such as the portion of the website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare website), to make available such anticipated costs under such subsection.]

[(d) FUNDING.—For purposes of implementing this section, the Secretary shall provide for the transfer, from the Supplemental Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2015, to remain available until expended.]

[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.

[(a) PDP SAFETY PROGRAM.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—]

[(1) in paragraph (1)(D)—]

[(A) by inserting ", designed to" after "program"; and]

[(B) by inserting ", that includes the procedures described in paragraph (4)" after "waste"; and]

[(2) by adding at the end the following:]

["(4) SAFE PHARMACY ACCESS PROGRAM.—]

["(A) PDP SPONSOR PROCEDURES.—A PDP sponsor (or an MA organization offering an MA–PD plan) shall have in place procedures designed—]

["(i) to identify an individual who has obtained coverage for a covered part D drug that is a frequently abused schedule II, III, IV, or V controlled substance, as

determined in accordance with utilization guidelines established by the Secretary and the sponsor (or MA organization), and to notify such individuals that they have been so identified;]

[''(ii) to contract with pharmacies authorized to dispense such controlled substances to create a safe pharmacy network that meets the criteria specified in subparagraph (C);]

[''(iii) taking into account the location of the individual's residence (or residences), work site, mobility, and other relevant factors, to limit coverage to schedule II, III, IV, or V controlled substances for some or all classes of covered part D drugs for an individual identified under clause (i) (or under subparagraph (B)) to drugs dispensed by one or more pharmacies contracted with under clause (ii);]

[''(iv) to provide to the Secretary the name, and other information that the Secretary may require, of individuals so identified and of the fact of such individual's disenrollment (if any) from the plan of the

sponsor (or the MA–PD plan offered by the MA organization);]

[“(v) to provide for an appeals process whereby an individual so identified may appeal such identification on the basis that the identification was not appropriate;]

[“(vi) to provide for a process whereby an individual so identified may petition for the termination of such identification on the basis that the limitation on coverage is no longer necessary to prevent fraud and abuse by the individual; and]

[“(vii) to provide that coverage shall be provided for a schedule II, III, IV, or V controlled substance only if it is prescribed in accordance with an electronic prescribing program under subsection (e), except in such exceptional circumstances as the Secretary may permit.]

[“(B) SHARING INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall share information, with respect to the identity of an individual identified under subparagraph (A)(i) who disenrolls from a plan under subparagraph (A)(iv), with a PDP spon-

sor (or MA organization) that subsequently enrolls such individual under another plan in order that the provisions of subparagraph (A)(iii) would apply under such subsequent enrollment.]

[''(C) SAFE PHARMACY NETWORK CRITERIA.—The criteria specified in this subparagraph for a safe pharmacy network are the following:]

[''(i) The pharmacies in the network are able to properly monitor the usage of schedule II, III, IV, and V controlled substances.]

[''(ii) Such pharmacies and network meet such other drug safety criteria as the Secretary or the PDP sponsor (or MA organization) determines to be appropriate, such as use of a State prescription drug monitoring program, if such a program is available in the State.''.]

[(b) DUAL ELIGIBLES.—Section 1860D–1(b)(3)(D) of the Social Security Act (42 U.S.C. 1395w–101(b)(3)(D)) is amended by inserting '', subject to such limits as the Secretary may establish for individuals iden-

tified pursuant to section 1860D–4(c)(4)(A)(i)'' after ''the Secretary''.]

[(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning after the date that is 8 months after the date of the enactment of this Act.]