This Nation can do better.

## THE HIGHWAY TRUST FUND

(Mr. NORCROSS asked and was given permission to address the House for 1 minute.)

Mr. NORCROSS. Madam Speaker, here we are once again. I rise to ask my colleagues to pass a long-term—a long-term—reauthorization to the highway trust fund before it crashes into a dead end, to the very worst that can happen to America.

This is about the dysfunction of Washington. It is what everybody detests: the lack of predictability; we will just kick the can down the road a little bit further. This is exactly what hurts our economy. Nobody can plan for what is going to happen in the next few months, let alone the next few years.

This is our country. Don't shut it down. Don't put a sign that says, ''Closed due to lack of construction.''

This is killing our economy. This is killing jobs in America, and I ask for us to pass a long-term bill. I know in Washington long term might seem a day or two. We are just asking for 6 years, to give predictability so our highways are the best that they can be, that we can have our commerce.

## NUCLEAR AGREEMENT WITH IRAN

(Mr. WILSON of South Carolina asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. WILSON of South Carolina. Madam Speaker, yesterday, Committee on Foreign Affairs Chairman ED ROYCE, with Ranking Member ELIOT ENGEL, conducted an informative hearing on the implications of the nuclear agreement with Iran.

The witnesses who provided enlightening testimony were the Honorable Stephen Rademaker, Dr. Michael Doran, Dr. Michael Makovsky, and Dr. Kenneth Pollack. Their varying opinions confirm my concerns, as expressed in a July 6 editorial from The Washington Post:

''If it is reached in the coming days, a nuclear deal with Iran will be, at best, an unsatisfying and risky compromise. Iran's emergence as a threshold nuclear power, with the ability to produce a weapon quickly, will not be prevented; it will be postponed by 10 to 15 years. In exchange, Tehran will reap hundreds of billions of dollars in sanctions relief it can use to revive its economy and fund the wars it is waging around the Middle East.''

The President needs to change course and recognize that moral relativism is dangerous with opponents who promote ''Death to America, Death to Israel.'' The President can avoid a legacy of fanatics with nuclear warheads on ICBMs targeting American families.

In conclusion, God bless our troops, and the President, by his actions, must never forget September the 11th in the global war on terrorism.

□ 0915

## INFRASTRUCTURE

(Mrs. LAWRENCE asked and was given permission to address the House for 1 minute.)

Mrs. LAWRENCE. Madam Speaker, we are less than 3 weeks away from the expiration of the national highway trust fund, and we are, once again, talking about another extension.

The Michigan Infrastructure and Transportation Association estimates that Congress' failure to come up with a long-term plan has cost State of Michigan taxpayers more than $350 million. We have ample time and multiple plans to fix this problem. Which plan do you like?

We need to get to work. What about the Department of Transportation's GROW America Act, which raises $478 billion over 6 years? Or Michigan's Getting Beyond Gridlock plan that raises $410 billion over 6 years?

Republicans don't want to raise taxes. Democrats don't want to hurt the middle class or the lower-income families, but we must make those choices. We must take the vote, and we must keep our promise to America to fix our infrastructure. It is time to act.

## 21ST CENTURY CURES ACT

GENERAL LEAVE

Mr. UPTON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and to include extraneous material therein on H.R. 6.

The SPEAKER pro tempore (Mr. FITZPATRICK). Is there objection to the request of the gentleman from Michigan?

There was no objection.

The SPEAKER pro tempore. Pursuant to House Resolution 350 and rule XVIII, the Chair declares the House in the Committee of the Whole House on the state of the Union for the further consideration of the bill, H.R. 6.

Will the gentlewoman from North Carolina (Ms. FOXX) kindly retake the chair.

□ 0916

IN THE COMMITTEE OF THE WHOLE

Accordingly, the House resolved itself into the Committee of the Whole House on the state of the Union for the further consideration of the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes, with Ms. FOXX (Acting Chair) in the chair.

The Clerk read the title of the bill.

The Acting CHAIR. When the Committee of the Whole rose on Thursday, July 9, 2015, all time for general debate had expired.

Pursuant to the rule, the bill shall be considered for amendment under the 5-minute rule.

In lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce, printed in the bill, an amendment in the nature of a substitute consisting of the text of Rules Committee Print 114–22 is adopted.

The bill, as amended, shall be considered as the original bill for the purpose of further amendment under the 5-minute rule and shall be considered as read.

The text of the bill, as amended, is as follows:

H.R. 6

*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:*

***SEC. 2. NIH AND CURES INNOVATION FUND.***

*(a) ESTABLISHMENT.—There is hereby established in the Treasury of the United States a fund to be known as the NIH and Cures Innovation Fund.*

*(b) AMOUNTS MADE AVAILABLE TO FUND.—*

*(1) IN GENERAL.—There is authorized to be appropriated, and appropriated, to the NIH and Cures Innovation Fund, out of any funds in the Treasury not otherwise appropriated, $1,860,000,000 for each of fiscal years 2016 through 2020. The amounts appropriated to the NIH and Cures Innovation Fund by the preceding sentence shall be in addition to any amounts otherwise made available to the Department of Health and Human Services.*

*(2) ALLOCATION OF AMOUNTS.—Of the amounts made available from the NIH and Cures Innovation Fund for a fiscal year—*

*(A) $1,750,000,000 shall be for biomedical research of the National Institutes of Health under subsection (c)(1), of which—*

*(i) not less than $500,000,000 shall be for the Accelerating Advancement Program under subsection (d)(2);*

*(ii) not less than 35 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for early stage investigators as defined in subsection (g);*

*(iii) not less than 20 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for high-risk, high-reward research under section 409K of the Public Health Service Act, as added by section 1028; and*

*(iv) not more than 10 percent of such amounts (without subtracting the allocation for the Accelerating Advancement Program) shall be for intramural research; and*

*(B) $110,000,000 shall be for carrying out the provisions listed in subsection (c)(2).*

*(3) INAPPLICABILITY OF CERTAIN PROVISIONS.—Amounts in the NIH and Cures Innovation Fund (including amounts made available to the National Institutes of Health) shall not be subject to—*

*(A) any transfer authority of the Secretary of Health and Human Services or the Director of the National Institutes of Health under sections 241, 402A(c), or 402A(d) of the Public Health Service Act (42 U.S.C. 238j, 282a(c) and (d)) or any other provision of law (other than this section); or*

*(B) the Nonrecurring expenses fund under section 223 of division G of the Consolidated Appropriations Act, 2008 (42 U.S.C. 3514a).*

*(c) AUTHORIZED USES.—*

*(1) NIH BIOMEDICAL RESEARCH.—Amounts in the NIH and Cures Innovation Fund that are allocated pursuant to subsection (b)(2)(A) may only be used for the purpose of conducting or supporting biomedical research (including basic, translational, and clinical research) through the following:*

*(A) Research in which—*

*(i) a principal investigator has a specific project or specific objectives; and*

*(ii) funding is tied to pursuit of such project or objectives.*

*(B) Research in which—*

*(i) a principal investigator has shown promise in biomedical research; and*

(ii) funding is not tied to a specific project or specific objectives.

(C) Research to be carried out by an early stage investigator (as defined in subsection (g)).

(D) Research to be carried out by a small business concern (as defined in section 3 of the Small Business Act).

(E) The Accelerating Advancement Program under subsection (d)(2).

(F) Development and implementation of the strategic plan under subsection (d)(3).

(2) CURES DEVELOPMENT.—Amounts in the NIH and Cures Innovation Fund that are allocated pursuant to subsection (b)(2)(B) may only be used for the purpose of carrying out the following provisions:

(A) Section 229A of the Public Health Service Act, as added by section 1123 (relating to data on natural history of diseases).

(B) Section 2001 and the amendments made by such section (relating to development and use of patient experience data to enhance structured risk-benefit assessment framework).

(C) Section 2021 and the amendments made by such section (relating to qualification of drug development tools).

(D) Section 2062 and the amendments made by such section (relating to utilizing evidence from clinical experience).

(E) Section 2161 (relating to grants for studying the process of continuous drug manufacturing).

(F) Section 2201 and the amendments made by such section (relating to priority review for breakthrough devices).

(G) Section 2221 and the amendments made by such section (relating to third-party quality system assessments).

(H) Sections 2241, 2242, and 2243 and the amendments made by such sections (relating to health software).

(I) Section 513(j) of the Federal Food, Drug, and Cosmetic Act, as added by section 2223 (relating to training and oversight in least burdensome appropriate means concept).

(d) NIH INNOVATION FUND.—

(1) COORDINATION.—In conducting or supporting biomedical research pursuant to funds allocated pursuant to subsection (b)(2)(A), the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall—

(A) ensure coordination among the national research institutes, the national centers, and other departments, agencies, and offices of the Federal Government; and

(B) minimize unnecessary duplication.

(2) ACCELERATING ADVANCEMENT PROGRAM.—The Director of the National Institutes of Health shall establish a program, to be known as the Accelerating Advancement Program, under which—

(A) the Director partners with national research institutes and national centers to accomplish important biomedical research objectives; and

(B) for every $1 made available by the Director to a national research institute or national center for a research project, the institute or center makes $1 available for such project from funds that are not derived from the NIH and Cures Innovation Fund.

(3) STRATEGIC PLAN.—

(A) IN GENERAL.—The Director of the National Institutes of Health shall ensure that scientifically based strategic planning is implemented in support of research priorities, including through development, use, and updating of a research strategic plan that—

(i) 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;

(ii) identifies areas, to be known as strategic focus areas, in which the resources of the NIH and Cures Innovation Fund can contribute to the goals of expanding knowledge to address, and find more effective treatments for, unmet medical needs in the United States, including the areas of—

(I) biomarkers;

(II) precision medicine;

(III) infectious diseases, including pathogens listed as a qualifying pathogen under section 505E(f) of the Federal Food, Drug, and Cosmetic Act or listed or designated as a tropical disease under section 524 of such Act; and

(IV) antibiotics;

(iii) includes objectives for each such strategic focus area; and

(iv) ensures that basic research remains a priority.

(B) UPDATES AND REVIEWS.—The Director of the National Institutes of Health shall review and, as appropriate, update the research strategic plan under subparagraph (A) not less than every 18 months.

(e) TRANSFER AUTHORITY.—The Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives may provide for the transfer of funds in the NIH and Cures Innovation Fund for the purposes specified in subsection (c).

(f) SUPPLEMENT, NOT SUPPLANT; LIMITATIONS.—Funds appropriated by subsection (b)—

(1) shall be used to supplement, not supplant, amounts otherwise made available to the Department of Health and Human Services;

(2) are subject to the requirements and limitations of the most recently enacted regular or full-year continuing appropriation Act or resolution (as of the date of obligation) for programs of the National Institutes of Health or the Food and Drug Administration, as applicable; and

(3) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than the purposes specified in subsection (c).

(g) DEFINITION.—In this subsection:

(1) The term ''early stage investigator'' means an investigator who—

(A) will be the principal investigator or the program director of the proposed research;

(B) has never been awarded, or has been awarded only once, a substantial, competing grant by the National Institutes of Health for independent research; and

(C) is within 10 years of having completed—

(i) the investigator's terminal degree; or

(ii) a medical residency (or the equivalent).

(2) The terms ''national center'' and ''national research institute'' have the meanings given to those terms in section 401(g) of the Public Health Service Act (42 U.S.C. 281(g)).

## 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 a semicolon; 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.''.

### 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) FIVE-YEAR PLANS FOR BIOMEDICAL RESEARCH STRATEGY.—

''(A) IN GENERAL.—For each successive five-year period beginning with the period of fiscal years 2016 through 2020, the Director of NIH, in consultation with the entities described in subparagraph (B), shall develop and maintain a biomedical research strategic plan that—

''(i) 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;

''(ii) 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

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

''(B) ENTITIES DESCRIBED.—The entities described in this subparagraph are the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

''(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 national research institutes and national centers that—

''(i) have a common template; and

''(ii) identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research.

''(3) CONTENTS OF PLANS.—

''(A) STRATEGIC FOCUS AREAS.—The strategic focus areas identified pursuant to paragraph (1)(A)(ii) 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 and trans-National Institutes of Health 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.

''(C) WORKFORCE.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that maintaining the biomedical workforce of the future, including the participation by scientists from groups traditionally underrepresented in the scientific workforce, remains 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 plan required by paragraphs (1) and (2); and

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

''(5) REVIEW; UPDATES.—

''(A) PROGRESS REVIEWS.—Not less than annually, the Director of 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)(A)(ii).

''(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 (2)(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 national 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. REDUCING ADMINISTRATIVE BURDENS OF RESEARCHERS.**

(a) PLAN PREPARATION AND IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health shall prepare a plan, including time frames, and implement measures to reduce the administrative burdens of researchers funded by the National Institutes of Health, taking into account the recommendations, evaluations, and plans researched by the following entities:

(1) The Scientific Management Review Board.

(2) The National Academy of Sciences.

(3) The 2007 and 2012 Faculty Burden Survey conducted by The Federal Demonstration Partnership.

(4) Relevant recommendations from the Research Business Models Working Group.

(b) REPORT.—Not later than two years after the date of enactment of this Act, 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 (a).

**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.''.

**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.''.

**SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED COMMUNITIES IN CLINICAL TRIALS.**

It is the sense of Congress that the National Institute on Minority Health and Health Disparities (NIMHD) should include within its strategic plan ways to increase representation of underrepresented communities in clinical trials.

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

**SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PROGRAMS OF THE NATIONAL INSTITUTES OF HEALTH.**

(a) IN GENERAL.—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; relating to 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 inconsistent 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.''.

(b) UPDATE OF OTHER LOAN REPAYMENT PROGRAMS.—

(1) Section 464z–5(a) of the Public Health Service Act (42 U.S.C.285t–2(a)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in subsection (a) of such section.''.

(2) Section 487A(a) of such Act (42 U.S.C. 288–1(a)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount

specified in this subsection in the same manner as it applies to the maximum amount specified in subsection (a) of such section.''.

(3) Section 487B(a) of such Act (42 U.S.C. 288–2(a)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.''.

(4) Section 487C(a)(1) of such Act (42 U.S.C. 288–3(a)(1)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.''.

(5) Section 487E(a)(1) of such Act (42 U.S.C. 288–5(a)(1)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.''.

(6) Section 487F(a) of such Act (42 U.S.C. 288–5a(a)), as added by section 205 of Public Law 106–505, is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.''.

(7) Section 487G of such Act (42 U.S.C. 288–6, as redesignated by subsection (a)(1)), is further amended—

(A) in subsection (a)(1), by striking ''$35,000'' and inserting ''$50,000''; and

(B) in subsection (b), by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in subsection (a)(1) in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.''.

**SEC. 1042. 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.

### 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 STUDY NETWORK SENSE OF CONGRESS.**

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical study 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 study 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 study 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 study network to encourage their participation; and

(4) once a global pediatric clinical study 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.

**SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.**

(a) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatrics and experts on geriatrics to provide input on—

(1) appropriate age groupings to be included in research studies involving human subjects; and

(2) acceptable scientific justifications for excluding participants from a range of age groups from human subjects research studies.

(b) GUIDELINES.—Not later than 180 days after the conclusion of the workshop under subsection (a), the Director of the National Institutes of Health shall publish guidelines—

(1) addressing the consideration of age as an inclusion variable in research involving human subjects; and

(2) identifying criteria for justifications for any age-related exclusions in such research.

(c) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

(1) make the findings and conclusions resulting from the workshop under subsection (a) available to the public on the website of the National Institutes of Health; and

(2) not less than biennially, disclose to the public on such website the number of children included in research that is conducted or supported by the National Institutes of Health, disaggregated by developmentally appropriate age group, race, and gender.

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

**SEC. 1101. 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—

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

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

''(C) ensure that 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 includes at least—

''(i) the disease or indication being studied;

''(ii) inclusion criteria such as age, gender, diagnosis or diagnoses, laboratory values, or imaging results; and

''(iii) exclusion criteria such as specific diagnosis or diagnoses, laboratory values, or prohibited medications; and

''(D) to the extent possible, in carrying out this paragraph, make use of standard health care terminologies, such as the International Classification of Diseases or the Current Procedural Terminology, that facilitate electronic matching to data in electronic health records or other relevant health information technologies.''.

(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, the Food and Drug Administration, and standard setting organizations such as CDISC that have experience working with Federal agencies to standardize health data submissions) 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 18 months 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 cooperative agreement, contract, or grant for a period of 7 years, to be known as the Clinical Trial Data System Agreement, with one or more eligible entities to implement a pilot program with respect to all clinical trial data obtained from qualified clinical trials for purposes of registered users conducting further research on such data.

(b) APPLICATION.—Eligible entities seeking to enter into a cooperative agreement, contract, or grant 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 in accordance with this section. The Secretary shall not enter into a cooperative agreement, contract, or grant under this section with an eligible entity unless such entity submits an application including the following:

(1) A certification that the eligible entity 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) Information demonstrating that the eligible entity can 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 information demonstrating that the eligible entity can de-identify clinical trial data consistent with the requirements of section 164.514 of title 45, Code of Federal Regulations (or successor regulations).

(3) A description of the system the eligible entity will use to store and maintain such data, and information demonstrating that this system will comply with applicable standards and requirements for ensuring the security of the clinical trial data.

(4) A certification that the eligible entity will allow only registered users to access and use de-identified clinical trial data, gathered from qualified clinical trials, and that the eligible entity will allow each registered user to access and use such data only after such registered user agrees in writing to the terms described in (e)(4)(B), and such other carefully controlled contractual terms as may be defined by the Secretary.

(5) Evidence demonstrating the ability of the eligible entity to ensure that registered users disseminate the results of the research conducted in accordance with this section to interested parties to serve as a guide to future medical product development or scientific research.

(6) The plan of the eligible entity for securing funding for the activities it would conduct under the clinical trial data system agreement from governmental sources and private foundations, entities, and individuals.

(7) 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.

(8) An agreement that the eligible entity will work with the Comptroller General of the United States for purposes of the study and report under subsection (d).

(c) EXTENSION, EXPANSION, TERMINATION.—The Secretary, acting through the Commissioner of Food and Drugs and the Director of the National Institutes of Health, upon the expiration of the 7-year period referred to in subsection (a), may extend (including permanently), expand, or terminate the pilot program established under such subsection, in whole or in part.

(d) STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study and issue a report to the Congress and the Secretary with respect to the pilot program established under subsection (a), not later than 6 years after the date on which the pilot program is established under subsection (a).

(2) STUDY.—The study under paragraph (1) shall—

(A) review the effectiveness of the pilot program established under subsection (a); and

(B) be designed to formulate recommendations on improvements to the program.

(3) REPORT.—The report under paragraph (1) shall contain at least the following information:

(A) The new discoveries, research inquiries, or clinical trials that have resulted from accessing clinical trial data under the pilot program established under subsection (a).

(B) The number of times scientists have accessed such data, disaggregated by research area and clinical trial phase.

(C) An analysis of whether the program has helped to reduce adverse events in clinical trials.

(D) An analysis of whether scientists have raised any concerns about the burden of having to share data with the system established under the program and, if so, a description of such concerns.

(E) An analysis of privacy and data integrity practices used in the program.

(e) 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 section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(g))), a device (as defined in section 201(h) of such Act (21 U.S.C. 331(h)), 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—

(i) was 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) was 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.

(4) The term ''registered user'' means a scientific or medical researcher who has—

(A) a legitimate biomedical research purpose for accessing information from the clinical trials data system and has appropriate qualifications to conduct such research; and

(B) agreed in writing not to transfer to any other person that is not a registered user de-identified clinical trial data from qualified clinical trials accessed through an eligible entity, use such data for reasons not specified in the research proposal, or seek to re-identify qualified clinical trial participants.

(5) The term ''Secretary'' means the Secretary of Health and Human Services.

**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 neurological 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 Research 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 $5,000,000 for each of fiscal years 2016 through 2020.''.

**SEC. 1123. DATA ON NATURAL HISTORY OF DISEASES.**

(a) SENSE OF CONGRESS.—It is the sense of the Congress that studies on the natural history of diseases can help to facilitate and expedite the development of medical products for such diseases.

(b) AUTHORITY.—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. DATA ON NATURAL HISTORY OF DISEASES.**

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, for the purposes described in subsection (b)—

''(1) participate in public-private partnerships engaged in one or more activities specified in subsection (c); and

''(2) award grants to patient advocacy groups or other organizations determined appropriate by the Secretary.

''(b) PURPOSES DESCRIBED.—The purposes described in this subsection are to establish or facilitate the collection, maintenance, analysis, and interpretation of data regarding the natural history of diseases, with a particular focus on rare diseases.

''(c) ACTIVITIES OF PUBLIC-PRIVATE PARTNERSHIPS.—The activities of public-private partnerships in which the Secretary may participate for purposes of this section include—

''(1) cooperating with other entities that sponsor or maintain disease registries, including disease registries and disease registry platforms for rare diseases;

''(2) developing or enhancing a secure information technology system that—

''(A) has the capacity to support data needs across a wide range of disease studies;

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

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

''(3) providing advice to clinical researchers, patient advocacy groups, and other entities with respect to—

''(A) the design and conduct of disease studies;

''(B) the modification of any such ongoing studies; and

''(C) addressing associated patient privacy issues.

''(d) AVAILABILITY OF DATA ON NATURAL HISTORY OF DISEASES.—Data relating to the natural history of diseases obtained, aggregated, or otherwise maintained by a public-private partnership in which the Secretary participates under subsection (a) shall be made available, consistent with otherwise applicable Federal and State privacy laws, to the public (including patient advocacy groups, researchers, and drug developers) to help to facilitate and expedite medical product development programs.

''(e) CONFIDENTIALITY.—Notwithstanding subsection (d), nothing in this section authorizes the disclosure of any information that is a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2016 through 2020.''.

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

(a) IN GENERAL.—(1) 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:

''(1) 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).

''(2) 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 covered 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 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 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) does 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 expect 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.''.

(2) The table of sections in section 13001(b) of such Act is amended by adding at the end of the items relating to subtitle D the following new items:

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

''Sec. 13441. References.
''Sec. 13442. Defining health data research as part of health care operations.
''Sec. 13443. Treating disclosures of protected health information for research similarly to disclosures of such information for public health purposes.
''Sec. 13444. Permitting remote access to protected health information by researchers.
''Sec. 13445. Allowing one-time authorization of use and disclosure of protected health information for research purposes.''.

(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 Regulations, 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 the 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 lifesaving 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, nonprofit organizations 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 by the Secretary 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 appointed 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) 9 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 representatives 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 on which the Council is incorporated and its Board of Directors is fully constituted, 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) APPOINTMENT AND INCORPORATION.—Not later than 6 months after the date of enactment of the 21st Century Cures Act—*

*''(1) the Comptroller General of the United States shall appoint the appointed members of the Board of Directors under subsection (a)(1)(C); and*

*''(2) the ex officio members of the Board of Directors under subsection (a)(1)(B) shall serve as incorporators and shall take whatever actions are necessary to incorporate the Council.*

*''(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 participating 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 each of fiscal years 2016 through 2023, there is authorized to be appropriated $10,000,000 to the Council for purposes of carrying out the duties of the Council under this part.''.*

***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 understanding 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 3 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. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) FINDINGS.—Congress finds the following:

(1) Development of new drugs has become increasingly challenging and resource intensive.

(2) Development of drug development tools can benefit the availability of new medical therapies by helping to translate scientific discoveries into clinical applications.

(3) Biomedical research consortia (as defined in section 507(f) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)) can play a valuable role in helping to develop and qualify drug development tools.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) Congress should promote and facilitate a collaborative effort among the biomedical research consortia described in subsection (a)(3)—

(A) to 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 drug development tools;

(B) to coordinate efforts toward developing and qualifying drug development tools in key therapeutic areas; and

(C) to encourage the development of accessible databases for collecting relevant drug development tool data for such purposes; and

(2) an entity seeking to qualify a drug development tool should be encouraged, in addition to consultation with the Secretary, to consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the requestor and benefit the process for such qualification.

(c) QUALIFICATION OF DRUG DEVELOPMENT TOOLS.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506F the following new section:

**''SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.**

''(a) PROCESS FOR QUALIFICATION.—

''(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

''(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

''(ii) the Secretary accepts or declines to accept such letter of intent;

''(B)(i) if the Secretary accepts the letter of intent, a requestor submits a qualification plan to the Secretary; and

''(ii) the Secretary accepts or declines to accept the qualification plan; and

''(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

''(ii) the Secretary determines whether to accept such qualification package for review; and

''(iii) if the Secretary accepts such qualification package for review, the Secretary conducts such review in accordance with this section.

''(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

''(A) IN GENERAL.—The succeeding provisions of this paragraph shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as 'qualification submissions').

''(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the submission and the available resources of the Food and Drug Administration to review the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

''(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

''(i) 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; and

''(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

''(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

''(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

''(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

''(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

''(4) 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 (3).

''(b) EFFECT OF QUALIFICATION.—

''(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

''(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

''(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

''(B) supporting the 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 OR MODIFICATION.—

''(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

''(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall, on request, be granted a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

''(c) TRANSPARENCY.—

''(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the

*Internet website of the Food and Drug Administration the following:*

*''(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—*

*''(i) the stage of the review process applicable to the submission;*

*''(ii) the date of the most recent change in stage status;*

*''(iii) whether the external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and*

*''(iv) submissions from requestors under the qualification process under subsection (a), 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 such qualification submissions.*

*''(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.*

*''(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).*

*''(E) A comprehensive list of—*

*''(i) all drug development tools qualified under subsection (a); and*

*''(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.*

*''(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 section 1905 of title 18, United States Code.*

*''(3) APPLICABILITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.*

*''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—*

*''(1) to 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) to limit the authority of the Secretary to approve or license products under this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).*

*''(e) DEFINITIONS.—In this section:*

*''(1) BIOMARKER.—(A) The term 'biomarker' 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) such term includes a surrogate endpoint.*

*''(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965, patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.*

*''(3) CLINICAL OUTCOME ASSESSMENT.—(A) The term 'clinical outcome assessment' 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) such term includes a patient-reported outcome.*

*''(4) CONTEXT OF USE.—The term 'context of use' means, with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.*

*''(5) DRUG DEVELOPMENT TOOL.—The term 'drug development tool' includes—*

*''(A) a biomarker;*

*''(B) a clinical outcome assessment; and*

*''(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.*

*''(6) 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 any other person.*

*''(7) QUALIFICATION.—The terms 'qualification' and 'qualified' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.*

*''(8) REQUESTOR.—The term 'requestor' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.*

*''(9) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—*

*''(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or*

*''(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).*

*''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2016 through 2020.''.*

*(d) GUIDANCE.—*

*(1) IN GENERAL.—The Secretary of Health and Human Services shall, in consultation with biomedical research consortia (as defined in subsection (f) of section 507 the Federal Food, Drug, and Cosmetic Act (as added by subsection (c))) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—*

*(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);*

*(B) makes recommendations for demonstrating that a surrogate endpoint is reasonably likely to predict clinical benefit for the purpose of supporting the accelerated approval of a drug under section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c));*

*(C) with respect to the qualification process under such section 507—*

*(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;*

*(ii) outlines reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and*

*(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification plans and full qualification submissions under such section; and*

*(D) includes such other information as the Secretary determines appropriate.*

*(2) TIMING.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (c)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.*

*(3) TAXONOMY.—*

*(A) IN GENERAL.—For purposes of informing guidance under this subsection, the Secretary of Health and Human Services shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.*

*(B) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 12 months after the close of the public comment period.*

*(e) MEETING AND REPORT.—*

*(1) MEETING.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c).*

*(2) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall make publicly available on the Internet website of the Food and Drug Administration a report. Such report shall include, with respect to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c), information on—*

*(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (f) of such section);*

*(B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package (as such terms are defined in such subsection), respectively;*

*(C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package; and*

*(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and*

*(3) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment (as such terms are defined in subsection (f) of such section 507).*

***SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT PLAN.***

*(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding the following subsection:*

*''(g) ACCELERATED APPROVAL DEVELOPMENT PLAN.—*

*''(1) IN GENERAL.—In the case of a drug that the Secretary determines may be eligible for accelerated approval in accordance with subsection (c), the sponsor of such drug may request, at any time after the submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, that the Secretary agree to an accelerated approval development plan described in paragraph (2).*

*''(2) PLAN DESCRIBED.—A plan described in this paragraph, with respect to a drug described in paragraph (1), is an accelerated approval development plan, which shall include agreement on—*

*''(A) the surrogate endpoint to be assessed under such plan;*

*''(B) the design of the study that will utilize the surrogate endpoint; and*

''(C) the magnitude of the effect of the drug on the surrogate endpoint that is the subject of the agreement that would be sufficient to form the primary basis of a claim that the drug is effective.

''(3) MODIFICATION; TERMINATION.—The Secretary may require the sponsor of a drug that is the subject of an accelerated approval development plan to modify or terminate the plan if additional data or information indicates that—

''(A) the plan as originally agreed upon is no longer sufficient to demonstrate the safety and effectiveness of the drug involved; or

''(B) the drug is no longer eligible for accelerated approval under subsection (c).

''(4) SPONSOR CONSULTATION.—If the Secretary requires the modification or termination of an accelerated approval development plan under paragraph (3), the sponsor shall be granted a request for a meeting to discuss the basis of the Secretary's decision before the effective date of the modification or termination.

''(5) DEFINITION.—In this section, the term 'accelerated approval development plan' means 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 that—

''(A) is reasonably likely to predict clinical benefit; and

''(B) is intended to be the basis of the accelerated approval of a drug in accordance with subsection (c).''.

(b) TECHNICAL AMENDMENTS.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by striking ''(f) AWARENESS EFFORTS'' and inserting ''(e) AWARENESS EFFORTS''; and

(2) by striking ''(e) CONSTRUCTION'' and inserting ''(f) CONSTRUCTION''.

### 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. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

''(a) IN GENERAL.—The Secretary shall issue and periodically update guidance to assist sponsors in the development of a precision drug or biological product. Such guidance shall—

''(1) define the term 'precision drug or biological product'; and

''(2) address the topics described in subsection (b).

''(b) CERTAIN ISSUES.—The topics to be addressed by guidance under subsection (a) are—

''(1) the evidence needed to support the use of biomarkers (as defined in section 507(e)) that identify subsets of patients as likely responders to therapies in order to streamline the conduct of clinical trials;

''(2) recommendations for the design of studies to demonstrate the validity of a biomarker as a predictor of drug or biological product response;

''(3) the manner and extent to which a benefit-risk assessment may be affected when clinical trials are limited to patient population subsets that are identified using biomarkers;

''(4) the development of companion diagnostics in the context of a drug development program; and

''(5) considerations for developing biomarkers that inform prescribing decisions for a drug or biological product, and when information regarding a biomarker may be included in the approved prescription labeling for a precision drug or biological product.

''(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.

#### ''SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

''(a) IN GENERAL.—In the case of a precision drug or biological product that is the subject of an application submitted under section 505(b)(1), or section 351(a) of the Public Health Service Act, for the treatment of a serious or life-threatening disease or condition and has been designated under section 526 as a drug for a rare disease or condition, the Secretary may—

''(1) consistent with applicable standards for approval, rely upon data or information previously submitted by the sponsor of the precision drug or biological product, or another sponsor, provided that the sponsor of the precision drug or biological product has obtained a contractual right of reference to such other sponsor's data and information, in an application approved under section 505(c) or licensed under section 351(a) of the Public Health Service Act, as applicable—

''(A) for a different drug or biological product; or

''(B) for a different indication for such precision drug or biological product,

in order to expedite clinical development for a precision drug or biological product that is using the same or similar approach as that used to support approval of the prior approved application or license, as appropriate; and

''(2) as appropriate, consider the application for approval of such precision drug or biological product to be eligible for expedited review and approval programs described in section 506, including accelerated approval in accordance with subsection (c) of such section.

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

''(1) 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 section; or

''(2) confer any new rights, beyond those authorized under this Act prior to enactment of this section, with respect to a sponsor's ability to reference information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service 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 to 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 not 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 is amended by inserting after section 505E of such Act (21 U.S.C. 355f) the following:

#### ''SEC. 505F. 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 to support the approval of a new indication for a drug approved under section 505(b); and

''(2) to help to support or satisfy postapproval study requirements.

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

''(c) PROGRAM FRAMEWORK.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall 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.—

''(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties.

''(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

''(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate; or

''(ii) a contract, grant, or other arrangement, as determined appropriate by the Secretary with

*such a partnership or an independent research organization.*

*''(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 24 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 under subsection (a), 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 subsection (a)(1) or (a)(2); and*

*''(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 paragraph (1); and*

*''(3) not later than 48 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 nonspecified 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 Service 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. 505G. 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 under section 505F 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—*

*''(A) shall design and implement pilot demonstrations to utilize data captured through the Sentinel System surveillance infrastructure authorized under section 505(k) for purposes of, as appropriate—*

*''(i) generating evidence from clinical experience to improve characterization or assessment of risks or benefits of a drug approved under section 505(c);*

*''(ii) protecting the public health; or*

*''(iii) advancing patient-centered care; and*

*''(B) may make strategic linkages with sources of complementary public health data and infrastructure the Secretary determines appropriate and necessary.*

*''(2) CONSULTATION.—In developing the pilot demonstrations under this subsection, the Secretary shall—*

*''(A) consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process; and*

*''(B) develop a framework to promote appropriate transparency and dialogue about research conducted under these pilot demonstrations, including by—*

*''(i) providing adequate notice to a sponsor of a drug approved under section 505 or section 351 of the Public Health Service Act of the Secretary's intent to conduct analyses of such sponsor's drug or drugs under these pilot demonstrations;*

*''(ii) providing adequate notice of the findings related to analyses described in clause (i) and an opportunity for the sponsor of such drug or drugs to comment on such findings; and*

*''(iii) ensuring the protection from public disclosure of any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.*

*''(3) HIPAA PRIVACY RULE; HUMAN SUBJECT RESEARCH REGULATION.—The Secretary may deem such pilot demonstrations—*

*''(A) public health activities, for purposes of which a use or disclosure of protected health information would be permitted as described in section 164.512(b)(1) of title 45, Code of Federal Regulations (or any successor regulation); and*

*''(B) outside the scope of 'research' as defined in section 46.102(d) of title 45, Code of Federal Regulations (or any successor regulation).*

*''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2016 through 2020.''.*

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

*(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 2062, is further amended by inserting after section 505G of such Act the following:*

***''SEC. 505H. 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) PUBLIC AVAILABILITY OF INFORMATION ON PROGRAM.—The Secretary shall post on the public website of the Food and Drug Administration and update annually—*

*''(1) the number of applications reviewed under the streamlined data review program;*

*''(2) the average time for completion of review under the streamlined data review program versus other review of applications for new indications; and*

*''(3) the number of applications reviewed under the streamlined data review program for which the Food and Drug Administration made use of full data sets in addition to the qualified data summary.*

*''(d) 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) SENSE OF CONGRESS.—It is the sense of Congress that the streamlined data review program under section 505H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), should enable the Food and Drug Administration to make approval decisions for certain supplemental applications based on qualified data summaries (as defined in such section 505H).*

*(c) 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 505H 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 505H(c)(1)(B) of such Act; and*

*(2) in addition to issuing guidance under paragraph (1), 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.***

*Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:*

***''SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.***

*''(a) IN GENERAL.—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make publicly available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug. A manufacturer or distributor may satisfy the requirement of the preceding sentence by posting such policy as generally applicable to all of such manufacturer's or distributor's investigational drugs.*

*''(b) CONTENT OF POLICY.—A policy described in subsection (a) shall include making publicly available—*

*''(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);*

''(2) procedures for making such requests;

''(3) the general criteria the manufacturer or distributor will consider or use to approve such requests; and

''(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests.

''(c) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

''(d) REVISED POLICY.—A manufacturer or distributor that has made a policy publicly available as required by this section may revise the policy at any time.

''(e) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

''(1) the date that is 60 days after the date of enactment of the 21st Century Cures Act; or

''(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational new drug.''.

**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 Responsible Manufacturer Communications

**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 with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement'';

(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 material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of 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''; and

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

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

''(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.''.

**SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS.**

(a) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance on facilitating the responsible dissemination of truthful and nonmisleading scientific and medical information not included in the approved labeling of drugs and devices.

(b) DEFINITION.—In this section, the terms ''drug'' and ''device'' have the meaning given to such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

### Subtitle G—Antibiotic Drug Development

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

(a) PURPOSE.—The purpose of this section is to help to expedite the development and availability of treatments for serious or life-threatening bacterial or fungal infections in patients with unmet needs, while maintaining safety and effectiveness standards for such treatments, taking into account the severity of the infection and the availability or lack of alternative treatments.

(b) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 2001, is further amended by adding at the end the following new subsection:

''(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 infection, the Secretary—

''(A) may execute a written agreement with the sponsor on the process for developing data to support an application for approval of such drug, for use in a limited population of patients in accordance with this subsection;

''(B) shall proceed in accordance with this subsection only if a written agreement is reached under subparagraph (A);

''(C) shall provide the sponsor with an opportunity to request meetings under paragraph (2);

''(D) if a written agreement is reached under subparagraph (A), may approve the drug under this subsection for such use—

''(i) in a limited population of patients for which there is an unmet medical need;

''(ii) based on a streamlined development program; and

''(iii) only if the standards for approval under subsections (c) and (d) of this section or licensure under section 351 of the Public Health Service Act, as applicable, are met; and

''(E) in approving a drug in accordance with this subsection, subject to subparagraph (D)(iii), may rely upon—

''(i) traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, data sets of a limited size; and

''(ii)(I) additional data, including preclinical, pharmacologic, or pathophysiologic evidence;

''(II) nonclinical susceptibility and pharmacokinetic data;

''(III) data from phase 2 clinical trials; and

''(IV) such other confirmatory evidence as the Secretary determines appropriate to approve the drug.

''(2) FORMAL MEETINGS.—

''(A) IN GENERAL.—To help to expedite and facilitate the development and review of a drug for which a sponsor intends to request approval in accordance with this subsection, the Secretary may, at the request of the sponsor, conduct meetings that provide early consultation, timely advice, and sufficient opportunities to develop an agreement described in paragraph (1)(A) and help the sponsor design and conduct a drug development program as efficiently as possible, including the following types of meetings:

''(i) An early consultation meeting.

''(ii) An assessment meeting.

''(iii) A postapproval meeting.

''(B) NO ALTERING OF GOALS.—Nothing in this paragraph shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

''(C) BREAKTHROUGH THERAPIES.—In the case of a drug designated as a breakthrough therapy under section 506(a), the sponsor of such drug may elect to utilize meetings provided under such section with respect to such drug in lieu of meetings described in subparagraph (A).

''(3) LABELING REQUIREMENT.—The labeling of an antibacterial or antifungal drug approved in accordance with this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than, the brand name of the product. The prescribing information for such antibacterial or antifungal drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

''(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval in accordance with this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval in accordance with section 506(c)(1).

''(5) TERMINATION OF REQUIREMENTS OR CONDITIONS.—If a drug is approved in accordance with this subsection for an indication in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, other than in accordance with this subsection, for—

''(A) the same indication and the same conditions of use, the Secretary shall remove any labeling requirements or postmarketing conditions that were made applicable to the drug under this subsection; or

''(B) a different indication or condition of use, the Secretary shall not apply the labeling requirements and postmarketing conditions that were made applicable to the drug under this subsection to the subsequent approval of the drug for such different indication or condition of use.

''(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit the approval of a drug for use in a limited population of patients in accordance with this subsection, in combination with—

''(A) an agreement on the design and size of a clinical trial pursuant to subparagraphs (B) and (C) of subsection (b)(5);

''(B) designation and treatment of the drug as a breakthrough therapy under section 506(a);

''(C) designation and treatment of the drug as a fast track product under section 506(b); or

''(D) accelerated approval of the drug in accordance with section 506(c).

''(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

''(A) to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d));

''(B) to waive or otherwise preclude the application of requirements under subsection (o);

''(C) to otherwise, in any way, 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; or

''(D) to restrict in any manner, the prescribing of antibiotics or other products by health care providers, or to otherwise limit or restrict the practice of health care.

''(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.

''(9) DEFINITIONS.—In this subsection:

''(A) EARLY CONSULTATION MEETING.—The term 'early consultation meeting' means a pre-investigational new drug meeting or an end-of-phase-1 meeting that—

''(i) is conducted to review and reach a written agreement—

''(I) on the scope of the streamlined development plan for a drug for which a sponsor intends to request approval in accordance with this subsection; and

''(II) which, as appropriate, may include agreement on the design and size of necessary preclinical and clinical studies early in the development process, including clinical trials whose data are intended to form the primary basis for an effectiveness claim; and

''(ii) provides an opportunity to discuss expectations of the Secretary regarding studies or other information that the Secretary deems appropriate for purposes of applying paragraph (5), relating to the termination of labeling requirements or postmarketing conditions.

''(B) ASSESSMENT MEETING.—The term 'assessment meeting' means an end-of-phase 2 meeting, pre-new drug application meeting, or pre-biologics license application meeting conducted to resolve questions and issues raised during the course of clinical investigations, and details addressed in the written agreement regarding post-approval commitments or expansion of approved uses.

''(C) POSTAPPROVAL MEETING.—The term 'postapproval meeting' means a meeting following initial approval or licensure of the drug for use in a limited population, to discuss any issues identified by the Secretary or the sponsor regarding postapproval commitments or expansion of approved uses.''.

(c) GUIDANCE.—Not later than 18 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, process, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population in accordance with section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(d) CONFORMING AMENDMENTS.—

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

(A) by striking ''(j)'' and inserting ''(j)(1)'';

(B) by inserting ''505(z),'' after ''505(p),''; and

(C) by adding at the end the following new paragraph:

''(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 infection shall be construed to refer to a biological product intended to treat a serious or life-threatening bacterial or fungal infection; and

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

(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 new subsection:

''(dd) If it is a drug approved in accordance with section 505(z) and its labeling does not meet the requirements under paragraph (3) of such subsection, subject to paragraph (5) of such subsection.''.

(e) EVALUATION.—

(1) ASSESSMENT.—Not later than 48 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish for public comment an assessment of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b). Such assessment shall determine if the limited-use pathway established under such section 505(z) has improved or is likely to improve patient access to novel antibacterial or antifungal treatments and assess how the pathway could be expanded to cover products for serious or life-threatening diseases or conditions beyond bacterial and fungal infections.

(2) MEETING.—Not later than 90 days after the date of the publication of such assessment, the Secretary, acting through the Commissioner of Food and Drugs, shall hold a public meeting to discuss the findings of the assessment, during which public stakeholders may present their views on the success of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), and the appropriateness of expanding such program.

(f) EXPANSION OF PROGRAM.—If the Secretary of Health and Human Services determines, based on the assessment under subsection (e)(1), evaluation of the assessment, and any other relevant information, that the public health would benefit from expansion of the limited-use pathway established under section 505(z) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)) beyond the drugs approved in accordance with such section, the Secretary may expand such limited-use pathway in accordance with such a determination. The approval of any drugs under any such expansion shall be subject to the considerations and requirements described in such section 505(z) for purposes of expansion to other serious or life-threatening diseases or conditions.

(g) MONITORING.—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 shall use an 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 shall make summaries of 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 receiving 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) PURPOSE; IDENTIFICATION OF CRITERIA.—

''(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 (2), 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 1 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 LIST.—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 differ from other drugs 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 by the Secretary to be appropriate for the drug.*

*''(C) REQUIRED STATEMENTS OF 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 shall 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 of this Act 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—*

*''(1) to 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 section 510, 513, or 515;*

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

*''(A) an antimicrobial drug; or*

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

*''(3) unless specifically stated, to 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) CLERICAL AMENDMENT.—The table of contents in section 2 of the Food and Drug Administration Amendments Act of 2007 is amended by striking the item relating to section 1111.*

*(3) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 2121, is further amended by adding at the end the following:*

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

*(4) 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 USE OF DISARM DRUGS.***

*(a) ADDITIONAL PAYMENT FOR DISARM DRUGS UNDER MEDICARE.—*

*(1) IN GENERAL.—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) As part of the annual rulemaking conducted with respect to payment for subsection (d) hospitals for each fiscal year beginning with fiscal year 2018, the Secretary shall—*

*''(I) include a list of the DISARM drugs for such fiscal year; and*

*''(II) with respect to discharges by eligible hospitals that involve a drug so listed, provide for an additional payment to be made under this subsection in accordance with the provisions of this subparagraph.*

*''(ii) Additional payments may not be made for a drug under this subparagraph—*

*''(I) other than during the 5-fiscal-year period beginning with the fiscal year for which the drug is first included in the list described in clause (i)(I); and*

*''(II) with respect to which payment has ever been made pursuant to subparagraph (K).*

*''(iii) For purposes of this subparagraph, the term 'DISARM 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 December 1, 2014, and that the Food and Drug Administration determines is an antimicrobial product (as defined in clause (iv)) and is intended to treat an infection—*

*''(I) for which there is an unmet medical need; and*

*''(II) which is associated with high rates of mortality or significant patient morbidity, as determined in consultation with the Director of the Centers for Disease Control and Prevention and the infectious disease professional community.*

*''(iv) For purposes of clause (iii), the term 'antimicrobial product' means a product that either—*

*''(I) 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*

*''(II) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act.*

*Such determination may be revoked only upon a finding that the request for such determination contained an untrue statement of material fact.*

*''(v) For purposes of this subparagraph, the term 'eligible hospital' means a subsection (d) hospital that participates in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar surveillance system that includes reporting about antimicrobial drugs is determined by the Secretary to be available to such hospitals, such similar surveillance system as the Secretary may specify).*

*''(vi) Subject to the succeeding provisions of this subparagraph, the additional payment under this subparagraph, with respect to a drug, shall be in the amount provided for such drug under section 1847A.*

*''(vii) As part of the rulemaking referred to in clause (i) for each fiscal year, the Secretary shall estimate—*

*''(I) total add-on payments (as defined in subclause (I) of clause (ix)); and*

*''(II) total hospital payments (as defined in subclause (II) of such clause).*

*''(viii) If the total add-on payments estimated pursuant to clause (vii)(I) for a fiscal year exceed 0.02 percent of the total hospital payments estimated pursuant to clause (vii)(II) for such fiscal year, the Secretary shall reduce in a pro rata manner the amount of each additional payment under this subsection pursuant to this subparagraph for such fiscal year in order to ensure that the total add-on payments estimated for such fiscal year do not exceed 0.02 percent of the total hospital payments estimated for such fiscal year.*

*''(ix) In this subparagraph:*

*''(I) The term 'total add-on payments' means, with respect to a fiscal year, the total amount of the additional payments under this subsection pursuant to this subparagraph for discharges in such fiscal year without regard to the application of clause (viii).*

*''(II) The term 'total hospital payments' means, with respect to a fiscal year, the total amount of payments made under this subsection for all discharges in such fiscal year.''.*

*(2) CONFORMING AMENDMENTS.—*

*(A) NO DUPLICATIVE NTAP PAYMENTS.—Section 1886(d)(5)(K)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended by inserting ''and if additional payment has never been made under this subsection pursuant to subparagraph (M) with respect to the service or technology'' before the period at the end.*

*(B) ACCESS TO PRICE INFORMATION.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is amended—*

*(i) in clause (ii)—*

*(I) by striking ''for each'' and inserting '', for each''; and*

*(II) by striking ''and'' at the end;*

*(ii) in clause (iii)—*

*(I) in subclause (II), by inserting ''or under section 1886(d) pursuant to paragraph (5)(M) of such section,'' after ''1847A,'';*

*(II) in the matter following subclause (III), by striking ''or 1881(b)(13)(A)(ii)'' and inserting '', section 1881(b)(13)(A)(ii), or section 1886(d)(5)(M)''; and*

*(III) by striking the period at the end and inserting ''; and''; and*

*(iii) in clause (iv), by striking the semicolon at the end and inserting a period.*

*(b) STUDY AND REPORT ON REMOVING BARRIERS TO DEVELOPMENT OF DISARM 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 DISARM drugs, as defined in section 1886(d)(5)(M)(iii) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(M)(iii)), as added by subsection (a)(1); 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 vaccine 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 consistency 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 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 valid 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, with the agreement of the vaccine developer requesting a meeting under such subparagraph, include in such meeting representatives of—*

*''(i) the Food and Drug Administration; and*

*''(ii) the National Vaccine Program.*

*''(C) The Secretary shall convene a meeting requested with a valid justification 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 commercial or financial information that is privileged or confidential and 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 120 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 significant 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 to such information may have implications for the vaccine developer's vaccine research and development.''.*

***Subtitle I—Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations***

***SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.***

*(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by sections 2062 and 2063, is further amended by inserting after section 505H of such Act the following:*

***''SEC. 505I. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.***

*''(a) DESIGNATION.—*

*''(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—*

*''(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed for marketing under section 505(c) of this Act or section 351(a) of the Public Health Service Act but was not so approved or licensed for the new indication;*

*''(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and*

*''(ii) the Secretary approves the application or supplemental application; and*

*''(C) the application or supplemental application for the new indication contains the consent of the applicant to notice being given by the Secretary under paragraph (4) respecting the designation of the drug.*

*''(2) REVOCATION OF DESIGNATION.—*

*''(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under paragraph (1) shall not be revoked for any reason.*

*''(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.*

*''(3) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1) shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.*

*''(4) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under paragraph (1) shall be made available to the public.*

*''(b) EXTENSION.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—*

*''(1)(A) the 4-, 5-, and 7½-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, and the 7-year period described in section 527, as applicable, shall be extended by 6 months; or*

*''(B) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act and the 7-year period described in section 527, as applicable, shall be extended by 6 months; and*

*''(2)(A) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or*

*''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).*

*''(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.*

*''(d) LIMITATIONS.—The extension described in subsection (b) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b).*

*''(e) DEFINITION.—In this section, the term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).''.*

*(b) APPLICATION.—Section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug for which an application or supplemental application described in subsection (a)(1)(B)(i) of such section 505G is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on or after the date of the enactment of this Act.*

*(c) CONFORMING AMENDMENTS.—*

*(1) RELATION TO PEDIATRIC EXCLUSIVITY FOR DRUGS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—*

*(A) in subsection (b), by adding at the end the following:*

*''(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.''; and*

*(B) in subsection (c), by adding at the end the following:*

*''(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.''.*

*(2) RELATION TO EXCLUSIVITY FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT ARE DRUGS.—Subsection (b) of section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—*

*(A) by amending the subsection heading to read as follows: ''RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—''; and*

(B) by striking ''any extension of the period under section 505A'' and inserting ''any extension of the periods under sections 505A and 505G, as applicable,''.

(3) RELATION TO PEDIATRIC EXCLUSIVITY FOR BIOLOGICAL PRODUCTS.—Section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by adding at the end the following:

''(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.''.

**SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM.**

(a) IN GENERAL.—Section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

(1) in subsection (a)—

(A) in paragraph (3), by amending subparagraph (A) to read as follows:

''(A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.''; and

(B) in paragraph (4)—

(i) in subparagraph (E), by striking ''and'' at the end;

(ii) in subparagraph (F), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(G) is for a drug or biological product for which a priority review voucher has not been issued under section 524 (relating to tropical disease products).''; and

(2) in subsection (b), by striking paragraph (5) and inserting the following:

''(5) TERMINATION OF AUTHORITY.—

''(A) IN GENERAL.—The Secretary may not award any priority review vouchers under paragraph (1) after December 31, 2018.

''(B) EXCEPTION.—Notwithstanding subparagraph (A), the sponsor of a drug that is designated under subsection (d) as a drug for a rare pediatric disease and that is the subject of a rare pediatric disease product application that is submitted during the period beginning on the date of enactment of the 21st Century Cures Act and ending the date specified in subparagraph (A) shall remain eligible to receive a priority review voucher under paragraph (1) irrespective of whether the rare pediatric disease product application with respect to such drug is approved after the end of such period.''.

(b) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the effectiveness of awarding priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) in providing incentives for the development of drugs that treat or prevent rare pediatric diseases (as defined in subsection (a)(3) of such section) that would not otherwise have been developed. In conducting such study, the Comptroller General shall examine the following:

(A) The indications for which each drug for which a priority review voucher was awarded under such section 529 was approved under section 505 of such Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) Whether the priority review voucher impacted a sponsor's decision to invest in developing a drug to treat or prevent a rare pediatric disease.

(C) An analysis of the drugs that utilized such priority review vouchers, which shall include—

(i) the indications for which such drugs were approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) whether unmet medical needs were addressed through the approval of such drugs, including, for each such drug—

(I) if an alternative therapy was previously available to treat the indication; and

(II) the benefit or advantage the drug provided over another available therapy;

(iii) the number of patients potentially treated by such drugs;

(iv) the value of the priority review voucher if transferred; and

(v) the length of time between the date on which a priority review voucher was awarded and the date on which it was used.

(D) With respect to the priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)—

(i) the resources used by, and burden placed on, the Food and Drug Administration in implementing such program, including the effect of such program on the Food and Drug Administration's review of drugs for which a priority review voucher was not awarded or used;

(ii) the impact of the program on the public health as a result of the expedited review of applications for drugs that treat or prevent nonserious indications that are generally used by the broader public; and

(iii) alternative approaches to improving such program so that the program is appropriately targeted toward providing incentives for the development of clinically important drugs that—

(I) prevent or treat rare pediatric diseases; and

(II) would likely not otherwise have been developed to prevent or treat such diseases.

(2) REPORT.—Not later than December 31, 2017, the Comptroller General of the United States 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 containing the results of the study of conducted under paragraph (1).

## 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 to carry out this section $5,000,000 for each of fiscal years 2016 through 2020.

**SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.**

Section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) is amended—

(1) in subsection (f)—

(A) in paragraph (5)—

(i) by striking ''(5)'' and inserting ''(5)(A)'';

(ii) 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

(iii) 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 substance 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

(B) in paragraph (6)—

(i) by striking ''(6)'' and inserting ''(6)(A)''; and

(ii) by adding at the end the following:

''(B) In the case of re-exportation among members of the European Economic Area, within 30 days after each re-exportation, the person who exported the controlled substance from the United States delivers to the Attorney General—

''(i) documentation certifying that such re-exportation has occurred; and

''(ii) information concerning the consignee, country, and product.''; and

(2) by adding at the end the following:

''(g) LIMITATION.—Subject to paragraphs (5) and (6) of subsection (f) in the case of any controlled substance in schedule I or II or any narcotic drug in schedule III or IV, the Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation of any controlled substance among European Economic Area countries, 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 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 or prior to each re-exportation among members of the European Economic Area.''.

## Subtitle K—Enhancing Combination Products Review

**SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

Section 503(g)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by adding at the end the following new clause:

''(iii) Not later than 18 months after the date of the enactment of the 21st Century Cures Act, the Secretary shall issue final guidance that describes the responsibilities of each agency center regarding its review of combination products. The Secretary shall, after soliciting public comment, review and update the guidance periodically.''.

## Subtitle L—Priority Review for Breakthrough Devices

**SEC. 2201. 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 expertise 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 posed 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 development 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 M—Medical Device Regulatory Process Improvements*

#### *SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.*

(a) ESTABLISHMENT OF THIRD-PARTY QUALITY SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A (21 U.S.C. 360n–1) the following new section:

**''SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

''(a) ACCREDITATION AND ASSESSMENT.—

''(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.—The Secretary shall, in accordance with this section, establish a third-party quality system assessment program—

''(A) to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes;

''(B) under which accredited persons shall (as applicable) certify that a requestor's quality system meets the criteria included in the guidance issued under paragraph (5) with respect to the in-scope devices at issue; and

''(C) under which the Secretary shall rely on such certifications for purposes of determining the safety and effectiveness (or as applicable, substantial equivalence) of in-scope devices subject to the device-related changes involved, in lieu of compliance with the following submission requirements:

''(i) A premarket notification.

''(ii) A thirty-day notice.

''(iii) A Special PMA supplement.

''(2) DEFINITIONS.—For purposes of this section–

''(A) the term 'device-related changes' means changes made by a requestor with respect to in-scope devices, which are—

''(i) changes to a device found to be substantially equivalent under sections 513(i) and 510(k) to a predicate device, that—

''(I) would otherwise be subject to a premarket notification; and

''(II) do not alter—

''(aa) the intended use of the changed device; or

''(bb) the fundamental scientific technology of such device;

''(ii) manufacturing changes subject to a 30-day notice;

''(iii) changes that qualify for a Special PMA Supplement; and

''(iv) such other changes relating to the devices or the device manufacturing process as the Secretary determines appropriate;

''(B) the term 'in-scope device' means a device within the scope of devices agreed to by the requestor and the accredited person for purposes of a request for certification under this section;

''(C) the term 'premarket notification' means a premarket notification under section 510(k);

''(D) the term 'quality system' means the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of devices, as described in section 520(f);

''(E) the term 'requestor' means a device manufacturer that is seeking certification under this section of a quality system used by such manufacturer;

''(F) the term 'Special PMA' means a Special PMA supplement under section 814.39(d) of title 21, Code of Federal Regulations (or any successor regulations); and

''(G) the term 'thirty-day notice' means a notice described in section 515(d)(6).

''(3) ACCREDITATION PROCESS; ACCREDITATION RENEWAL.—Except as inconsistent with this section, the process and qualifications for accreditation of persons and renewal of such accreditation under section 704(g) shall apply with respect to accreditation of persons and renewal of such accreditation under this section.

''(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

''(A) INITIATION OF ASSESSMENT SERVICES.—

''(i) DATE ASSESSMENTS AUTHORIZED.—Beginning after the date on which the final guidance is issued under paragraph (5), an accredited person may conduct an assessment under this section.

''(ii) INITIATION OF ASSESSMENTS.—Use of one or more accredited persons to assess a requestor's quality system under this section with respect to in-scope devices shall be at the initiation of the person who registers and lists the devices at issue under section 510.

''(B) COMPENSATION.—Compensation for such accredited persons shall—

''(i) be determined by agreement between the accredited person and the person who engages the services of the accredited person; and

''(ii) be paid by the person who engages such services.

''(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a requestor's quality system, as described in this section, shall select the accredited person from a list of such persons published by the Secretary in accordance with section 704(g)(4).

''(5) GUIDANCE; CRITERIA FOR CERTIFICATION.—

''(A) IN GENERAL.—The criteria for certification of a quality system under this section shall be as specified by the Secretary in guidance issued under this paragraph.

''(B) CONTENTS; CRITERIA.—The guidance under this paragraph shall include specification of—

''(i) evaluative criteria to be used by an accredited person to assess and, as applicable, certify a requestor's quality system under this section with respect to in-scope devices; and

''(ii) criteria for accredited persons to apply for a waiver of, and exemptions from, the criteria under clause (i).

''(C) TIMEFRAME FOR ISSUING GUIDANCE.—The Secretary shall issue under this paragraph—

''(i) draft guidance not later than 12 months after the enactment of the 21st Century Cures Act; and

''(ii) final guidance not later than 12 months after issuance of the draft guidance under clause (i).

''(b) USE OF THIRD-PARTY ASSESSMENT.—

''(1) ASSESSMENT SUMMARY; CERTIFICATION.—

''(A) SUBMISSION OF ASSESSMENT TO SECRETARY.—An accredited person who assesses a requestor's quality system under subsection (a) shall submit to the Secretary a summary of the assessment—

''(i) within 30 days of the assessment; and

''(ii) which shall include (as applicable)—

''(I) the accredited person's certification that the requestor has satisfied the criteria specified in the guidance issued under subsection (a)(5) for quality system certification with respect to the in-scope devices at issue; and

''(II) any waivers or exemptions from such criteria applied by the accredited person.

''(B) TREATMENT OF ASSESSMENTS.—Subject to action by the Secretary under subparagraph (C), with respect to assessments which include a certification under this section—

''(i) the Secretary's review of the assessment summary shall be deemed complete on the day that is 30 days after the date on which the Secretary receives the summary under subparagraph (A); and

''(ii) the assessment summary and certification of the quality system of a requestor shall be deemed accepted by the Secretary on such 30th day.

''(C) ACTIONS BY SECRETARY.—

''(i) IN GENERAL.—Within 30 days of receiving an assessment summary and certification under subparagraph (A), the Secretary may, by written notice to the accredited person submitting such assessment certification, deem any such certification to be provisional beyond such 30-day period, suspended pending further review by the Secretary, or otherwise qualified or cancelled, based on the Secretary's determination that (as applicable)—

''(I) additional information is needed to support such certification;

''(II) such assessment or certification is unwarranted; or

''(III) such action with regard to the certification is otherwise justified according to such factors and criteria as the Secretary finds appropriate.

''(ii) ACCEPTANCE OF CERTIFICATION.—If following action by the Secretary under clause (i) with respect to a certification, the Secretary determines that such certification is acceptable, the Secretary shall issue written notice to the applicable accredited person indicating such acceptance.

''(2) NOTIFICATIONS TO SECRETARY BY CERTIFIED REQUESTORS OR ACCREDITED PERSONS FOR PROGRAM EVALUATION PURPOSES.—

''(A) ANNUAL SUMMARY REPORT FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO PREMARKET NOTIFICATION.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a premarket notification, shall ensure that an annual summary report is submitted to the Secretary by the accredited person which—

''(i) describes the changes made to the in-scope device; and

''(ii) indicates the effective dates of such changes.

''(B) PERIODIC NOTIFICATION FOR MANUFACTURING CHANGES OTHERWISE SUBJECT TO THIRTY-DAY NOTICE.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a thirty-day notice, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made; and

''(ii) indicate the effective dates of such changes.

''(C) PERIODIC NOTIFICATION FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO SPECIAL PMA SUPPLEMENT.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a Special PMA Supplement, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made, including a full explanation of the basis for the changes; and

''(ii) indicate the effective dates of such changes.

''(D) USE OF NOTIFICATIONS FOR PROGRAM EVALUATION PURPOSES.—Information submitted to the Secretary under subparagraphs (A) through (C) shall be used by the Secretary for purposes of the program evaluation under subsection (d).

''(c) DURATION AND EFFECT OF CERTIFICATION.—A certification under this section—

''(1) shall remain in effect for a period of 2 years from the date such certification is accepted by the Secretary, subject to paragraph (6);

''(2) may be renewed through the process described in subsection (a)(3);

''(3) shall continue to apply with respect to device-related changes made during such 2-year period, provided the certification remains in effect, irrespective of whether such certification is renewed after such 2-year period;

''(4) shall have no effect on the need to comply with applicable submission requirements specified in subsection (a)(1)(C) with respect to any change pertaining to in-scope devices which is not a device-related change under subsection (a)(2);

''(5) shall have no effect on the authority of the Secretary to conduct an inspection or otherwise determine whether the requestor has complied with the applicable requirements of this Act; and

''(6) may be revoked by the Secretary upon a determination that the requestor's quality system no longer meets the criteria specified in the guidance issued under subsection (a)(5) with respect to the in-scope devices at issue.

''(d) NOTICE OF REVOCATION.—The Secretary shall provide written notification to the requestor of a revocation pursuant to subsection (c)(6) not later than 10 business days after the determination described in such subsection. Upon receipt of the written notification, the requestor shall satisfy the applicable submission requirements specified in subsection (a)(1)(C) for any device-related changes effectuated after the date of such determination. After such revocation, such requestor is eligible to seek re-certification under this section of its quality system.

''(e) PROGRAM EVALUATION; SUNSET.—

''(1) PROGRAM EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall complete an evaluation of the third-party quality system assessment program under this section no later than January 31, 2021, based on—

''(i) analysis of information from a representative group of device manufacturers obtained from notifications provided by certified requestors or accredited persons under subsection (b)(2); and

''(ii) such other available information and data as the Secretary determines appropriate.

''(B) REPORT.—No later than 1 year after completing the evaluation under subparagraph (A), the Secretary shall issue a report of the evaluation's findings on the website of the Food and Drug Administration, which shall include the Secretary's recommendations with respect to continuation and as applicable expansion of the program under this section to encompass—

''(i) device submissions beyond those identified in subsection (a)(1)(C); and

''(ii) device changes beyond those described in subsection (a)(2)(A).

''(2) SUNSET.—This section shall cease to be effective October 1, 2022.

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to request and review the complete assessment of a certified requestor under this section on a for-cause basis.''.

(b) CONFORMING AMENDMENTS.—

(1) REQUIREMENTS FOR PREMARKET APPROVAL SUPPLEMENTS.—Section 515(d)(5)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(i)), as redesignated by section 2201, is further amended by inserting '', subject to section 524B'' after ''that affects safety or effectiveness''.

(2) REQUIREMENTS FOR THIRTY-DAY NOTICE.—Section 515(d)(5)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(ii)), as redesignated by section 2201, is further amended by inserting '', subject to section 524B'' after ''the date on which the Secretary receives the notice''.

(3) REQUIREMENTS FOR PREMARKET NOTIFICATION; TECHNICAL CORRECTION TO REFERENCE TO SECTION 510(K).—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended by striking ''of this subsection under subsection (m)'' and inserting ''of subsection (k) under subsection (m) or section 524B''.

(4) MISBRANDED DEVICES.—Section 502(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is amended by inserting ''or 524B'' after ''section 519''.

***SEC. 2222. 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) For purposes of clause (i), valid scientific evidence may include—*

*''(I) evidence described in well-documented case histories, including registry data, that are collected and monitored under a protocol determined to be acceptable by the Secretary;*

*''(II) studies published in peer-reviewed journals; and*

*''(III) data collected in countries other than the United States so long as such data otherwise meet 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 together with 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. 2223. 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 adding at the end 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 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 industry 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. 360e) is amended by adding at the end the following:*

*''(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. 2224. 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 response 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 shall 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 clause (i)(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—*

*''(i) the experience with, and reliance on, a standard by other Federal regulatory authorities and the device industry; and*

*''(ii) 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 after the close of the public comment period for the draft guidance under clause (i).''.*

***SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT TO CERTAIN CLASS I AND CLASS II DEVICES.***

*(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—*

*(1) by striking ''A report under subsection (k)'' and inserting ''(1) A report under subsection (k)''; and*

*(2) by adding at the end the following new paragraph:*

*''(2) Not later than 120 days after the date of the enactment of the 21st Century Cures Act, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—*

*''(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and*

*''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.*

*(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—*

*(1) by striking paragraph (1) and inserting the following new paragraph: ''(1) The Secretary shall—*

*''(A) not later than 60 days after the date of the enactment of the 21st Century Cures Act—*

*''(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and*

*''(ii) provide for a period of not less than 60 days for public comment beginning on the date of the publication of such notice; and*

*''(B) not later than 180 days after the date of the enactment of 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices included in the list published under subparagraph (A).'';*

*(2) in paragraph (2)—*

*(A) by striking ''1 day after the date of the publication of a list under this subsection,'' and inserting ''1 day after the date of publication of the final list under paragraph (1)(B),''; and*

*(B) by striking ''30-day period'' and inserting ''60-day period''; and*

*(3) by adding at the end the following new paragraph:*

*''(3) Upon the publication of the final list under paragraph (1)(B)—*

*''(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and*

*''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.*

***SEC. 2226. 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) When a device is specifically the subject of review by a classification panel, the Secretary shall—*

*''(i) ensure that adequate expertise is represented on the classification panel to assess—*

*''(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and*

*''(II) the technology of the device; and*

*''(ii) as part of the process to ensure adequate expertise under clause (i), give due consideration to the recommendations of the person whose premarket submission is subject to panel review on the expertise needed among the voting members of the panel.*

*''(C) For purposes of subparagraph (B)(ii), the term 'adequate expertise' means, with respect to the membership of the classification panel reviewing a premarket submission, that such membership 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 the panel chairperson''; and

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

''(B)(i) Any meeting of a classification panel for a device that is specifically the subject of review shall—

''(I) provide adequate time for initial presentations by the person whose device is specifically the subject of a classification panel 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 that is specifically the subject of review by the panel.''.

**SEC. 2227. 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 enactment 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. 2228. 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 guidance published under subsection (a) not later than 12 months after the comment period for such draft guidance closes.

***Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency***

**SEC. 2241. 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, is not used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans, 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, management, 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 adherence and health management tools;

''(E) is intended for use to analyze information to provide general health information that does not include patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition; or

''(F) is intended for use 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. 2242. 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.), as amended by section 2221(a), is further amended by adding at the end the following:

**''SEC. 524C. HEALTH SOFTWARE.**

''(a) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Except as provided in subsection (b), health software shall not be subject to regulation under this Act.

''(b) EXCEPTION.—

''(1) IN GENERAL.—Subsection (a) shall not apply with respect to a software product—

''(A) of a type described in subparagraph (F) of section 201(ss)(1); and

''(B) that the Secretary determines poses a significant risk to patient safety.

''(2) CONSIDERATIONS.—In making a determination under subparagraph (B) of paragraph (1) with respect to a product to which such paragraph applies, the Secretary shall consider the following:

''(A) The likelihood and severity of patient harm if the product were to not perform as intended.

''(B) The extent to which the product is intended to support the clinical judgment of a medical professional.

''(C) Whether there is a reasonable opportunity for a medical professional to review the basis of the information or treatment recommendation provided by the product.

''(D) The intended user and user environment, such as whether a medical professional 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 determined under subsection (b) to be subject to regulation under this Act to the center at the Food and Drug Administration charged with regulating devices.

''(d) REGULATION OF SOFTWARE.—

''(1) IN GENERAL.—The Secretary shall review existing regulations and guidance regarding the regulation of software under this Act. The Secretary may implement a new framework for the regulation of software and shall, as appropriate, modify such regulations and guidance or issue new regulations or guidance.

''(2) ISSUANCE BY ORDER.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may modify or issue regulations for the regulation of software under this Act by administrative order published in the Federal Register following the publication of a proposed order.

''(3) AREAS UNDER REVIEW.—The review of existing regulations and guidance under paragraph (1) may include review of the following areas:

''(A) Classification of software.

''(B) Standards for development of software.

''(C) Standards for validation and verification of software.

''(D) 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 of adverse events.

''(4) PROCESS FOR ISSUING PROPOSED REGULATIONS, ADMINISTRATIVE ORDER, AND GUIDANCE.—Not later than 18 months after the date of enactment of this section, the Secretary shall consult with external stakeholders (including patients, industry, health care providers, academia, and government) to gather input before issuing regulations, an administrative order, and guidance under this subsection.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as providing the Secretary with the authority to regulate under this Act any health software product of the type described in subparagraph (F) of section 201(ss)(1) unless and until the Secretary has made a determination described in subsection (b)(1)(B) with respect to such product.''.

**SEC. 2243. 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) not health software (other than software determined to be a risk to patient safety under section 524B(b)), and''.

***Subtitle O—Streamlining Clinical Trials***

**SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.**

(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services shall, to the extent possible and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

(b) 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, the FDA 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; and*

*(iii) to incorporate local considerations, community values, and mechanisms to protect vulnerable populations; and*

*(B) ensure that human subject research that is subject to the HHS Human Subject Regulations or to the FDA Human Subject 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 36 months after the date of enactment of this 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 Administration, shall issue such regulations and guidance and take such other actions as may be necessary to implement this section and help to facilitate the broader use of single, central, or lead institutional review boards. Such regulations and guidance shall clarify the requirements and policies relating to the following:*

*(A) Arrangements to avoid duplication described in paragraph (1)(A)(i), 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) standardizing the 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 under 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).*

*(c) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 36 months after the date of enactment of this Act.*

*(d) PROGRESS REPORT.—Not later than 24 months after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.*

*(e) DRAFT NIH POLICY.—Not later than 12 months after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health, shall finalize the draft policy entitled ''Draft NIH Policy on Use of a Single Institutional Review Board for Multi-Site Research''.*

*(f) DEFINITIONS.—*

*(1) HUMAN SUBJECT REGULATIONS.—In this section:*

*(A) FDA HUMAN SUBJECT REGULATIONS.—The term ''FDA Human Subject Regulations'' means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).*

*(B) HHS HUMAN SUBJECT REGULATIONS.—The term ''HHS Human Subject Regulations'' means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).*

*(C) VULNERABLE-POPULATIONS RULES.—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 research that is subject to the FDA Human Subject Regulations, 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) OTHER DEFINITIONS.—In this section:*

*(A) INSTITUTIONAL REVIEW BOARD.—The term ''institutional review board'' has the meaning that applies to the term ''institutional review board'' under the HHS Human Subject Regulations.*

*(B) LEAD INSTITUTIONAL REVIEW BOARD.—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.*

***SEC. 2262. 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 committee 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. 2263. 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 P—Improving Scientific Expertise and Outreach at FDA***

***SEC. 2281. 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''; and*

*(B) in paragraph (1), by inserting ''or a master's level degree in engineering, bioinformatics, or a related or emerging field,'' after the comma;*

*(5) in subsection (d)(2), 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 3 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. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.***

*It is the sense of Congress that the participation in, or sponsorship of, scientific conferences and meetings is essential to the mission of the Food and Drug Administration.*

***SEC. 2283. 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 established 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. 2284. 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.''.*

***SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.***

*(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 714 (21 U.S.C. 379d–3) the following:*

***''SEC. 714A. ADDITIONAL HIRING AUTHORITY.***

*''(a) IN GENERAL.—The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint qualified candidates to scientific, technical, or professional positions within the following centers of the Food and Drug Administration:*

*''(1) The Center for Drug Evaluation and Research.*

*''(2) The Center for Biologics Evaluation and Research.*

*''(3) The Center for Devices and Radiological Health.*

*Such positions shall be within the competitive service.*

*''(b) COMPENSATION.—*

*''(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Secretary may determine and fix—*

*''(A) the annual rate of pay of any individual appointed under subsection (a); and*

*''(B) for purposes of retaining qualified employees, the annual rate of pay for any highly qualified scientific, technical, or professional personnel appointed to a position at any of the centers listed under subsection (a) before the date of enactment of this section.*

*''(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the annual rate of pay of the President.*

*''(c) REPORT.—*

*''(1) IN GENERAL.—Not later than September 30, 2021, the Secretary shall submit a report to Congress that examines the extent to which the authority to appoint and retain personnel under this section enhanced the Food and Drug Administration's ability to meet the agency's critical need for highly qualified individuals for scientific, technical, or professional positions.*

*''(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on—*

*''(A) whether the authority to appoint personnel under this section should be reauthorized; and*

*''(B) other personnel authorities that would help the Food and Drug Administration to better recruit and retain highly qualified individuals for scientific, technical, or professional positions in the agency's medical product centers.''.*

*(b) RULE OF CONSTRUCTION.—The authority provided by section 714A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall not be construed to affect the authority provided under section 714 of such Act.*

***Subtitle Q—Exempting From Sequestration Certain User Fees***

***SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN USER FEES OF FOOD AND DRUG ADMINISTRATION.***

*The Balanced Budget and Emergency Deficit Control Act of 1985 is amended—*

*(1) in section 255(g)(1)(A) (2 U.S.C. 905(g)(1)(A)), by inserting after the item relating to ''Financial Agent Services'' the following new item:*

*''Food and Drug Administration, Salaries and Expenses, but only the portion of appropriations under such account corresponding to fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act (75–9911–0–1–554).''; and*

*(2) in section 256(h) (2 U.S.C. 906(h)), by adding at the end the following new paragraph:*

*''(5) Notwithstanding any other provision of law, this subsection shall not apply with respect to the portion of administrative expenses incurred by the Food and Drug Administration that are funded through fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act.''.*

***TITLE III—DELIVERY***

***Subtitle A—Interoperability***

***SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY.***

*(a) INTEROPERABILITY STANDARDS.—*

*(1) IN GENERAL.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following new section:*

***''SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY.***

*''(a) INTEROPERABILITY.—In order for health information technology to be considered interoperable, such technology must satisfy the following criteria:*

*''(1) SECURE TRANSFER.—The technology allows the secure transfer of all electronically accessible health information to and from any and all health information technology for authorized use under applicable State or Federal law.*

*''(2) COMPLETE ACCESS TO HEALTH INFORMATION.—The technology allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law without special effort by the requestor of such health information.*

*''(3) NO INFORMATION BLOCKING.—The technology is not configured, set up, or implemented to information block, as defined in section 3010A(d).*

*''(b) CATEGORIES FOR INTEROPERABILITY STANDARDS.—The categories described in this subsection, with respect to standards and the corresponding implementation specifications for determining if health information technology is interoperable, consistent with the criteria described in subsection (a), include at least categories of standards and implementation specifications with respect to the following:*

*''(1) Vocabulary and terminology.*

*''(2) Content and structure.*

*''(3) Transport.*

*''(4) Security.*

*''(5) Services.*

*''(6) Querying and requesting health information for access, exchange, and use.*

*''(c) ALLOWING FOR FLEXIBILITY.—A standard and implementation specification, with respect to such standard, that is determined under section 3001(c)(5)(D) to be compatible with baseline standards and implementation specifications (as defined in clause (ii) of such section) shall be treated as in compliance with this section.''.*

*(2) GUIDANCE.—Not later than January 1, 2017, the Secretary of Health and Human Services, in consultation with the National Coordinator of the Office of the National Coordinator for Health Information Technology, shall issue guidance with respect to the implementation of section 3010 of the Public Health Service Act, as added by paragraph (1), including with respect to defining and providing examples of authorized use under applicable State or Federal law of health information.*

*(b) IMPROVEMENTS TO RECOMMENDATION PROCESS.—*

*(1) HIT POLICY COMMITTEE TO INCORPORATE POLICIES FOR UPDATES TO INTEROPERABILITY STANDARDS.—Section 3002 of the Public Health Service Act (42 U.S.C. 300jj–12) is amended—*

*(A) in subsection (a)—*

*(i) by striking ''National Coordinator'' and inserting ''Secretary, in consultation with the National Coordinator,''; and*

*(ii) by adding at the end the following new sentence: ''The HIT Policy Committee is authorized only to provide policy and priority recommendations to the Secretary and not authorized to otherwise affect the development or modification of any standard, implementation specification, or certification criterion under this title.''; and*

*(B) in subsection (b)(2)—*

*(i) in subparagraph (A), in the first sentence—*

*(I) by striking ''The HIT Policy Committee'' and inserting ''Subject to subparagraph (D), the HIT Policy Committee''; and*

*(II) by inserting ''(including the areas in which modifications and additions to interoperability standards and implementation specifications, with respect to such interoperability standards, under section 3010 are needed for the electronic access, exchange, and use of health information for purposes of adoption of such modifications and additions under section 3004)'' after ''section 3004''.*

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

''(D) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Policy Committee on or after the date of the enactment of this subparagraph with respect to interoperability of health information technology shall be consistent with the criteria described in subsection (a) of section 3010.''.

(2) SUNSET OF HIT STANDARDS COMMITTEE.—Section 3003 of the Public Health Service Act (42 U.S.C. 300jj–13) is amended by adding at the end the following new subsection:

''(f) TERMINATION.—The HIT Standards Committee shall terminate on the date that is 90 days after the date of the enactment of this subsection.''.

(3) STANDARDS DEVELOPMENT ORGANIZATIONS.—Title XXX of the Public Health Service Act is amended by inserting after section 3003 the following new section:

**''SEC. 3003A. RECOMMENDATIONS FOR STANDARDS THROUGH CONTRACTS WITH STANDARDS DEVELOPMENT ORGANIZATIONS.**

''(a) CONTRACTS.—

''(1) IN GENERAL.—For purposes of activities conducted under this title, the Secretary shall enter into one or more contracts with health care standards development organizations accredited by the American National Standards Institute (or with the American National Standards Institute) to carry out, directly or through contracts with subcontractors, the duties described in subsection (b), as applicable.

''(2) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this section, the Secretary shall enter into the first contracts under paragraph (1).

''(3) PERIOD OF CONTRACT.—Each contract under paragraph (1) shall be for a period determined necessary by the Secretary, in consultation with the National Coordinator, to carry out the applicable duties described in subsection (b).

''(4) APPROPRIATE ENTITIES.—The Secretary shall ensure the most appropriate entities described in paragraph (1) are selected for each contract under such paragraph.

''(b) DUTIES.—

''(1) INITIAL CONTRACT.—The Secretary shall initially enter into one or more contracts under subsection (a)(1) with entities described in such subsection, under which the entities—

''(A) shall recommend to the Secretary—

''(i) for adoption under section 3004, an initial set of interoperability standards and implementation specifications, with respect to such standards, identified or, as appropriate, developed by such entities that are consistent with the criteria described in subsection (a) of section 3010, and with respect to the categories described in subsection (b) of such section; and

''(ii) as applicable, for purposes of section 3001(c)(5)(D), methods to test if health information technology is compatible with health information technology that applies baseline standards and implementation specifications (as defined in clause (ii) of such section); and

''(B) may provide to the Secretary recommendations described in paragraph (2).

''(2) SUBSEQUENT CONTRACTS.—Under each subsequent contract entered into under this section with entities described in subsection (a)(1) pursuant to subsection (c), the entities shall recommend to the Secretary—

''(A) for adoption under section 3004 any standards (including interoperability standards), implementation specifications, and, to the extent necessary, certification criteria (and modifications, including additions, to such standards, specifications, and, to the extent necessary, criteria), which are in accordance with the criteria described in section 3010; and

''(B) as applicable, for purposes of section 3001(c)(5)(D), methods to test if health information technology is compatible with baseline standards and implementation specifications (as defined in clause (ii) of such section).

''(3) SUBMISSION TO NIST.—Under each contract with an entity under this section, the entity shall submit to the Director of the National Institute of Standards and Technology each recommendation submitted to the Secretary by such entity under this section.

''(4) CONSULTATION.—For the purposes of developing methods to test interoperability standards and implementation specifications with respect to such standards, the entities with a contract under this section may consult with the Director of the National Institute of Standards and Technology.

''(c) MODIFICATIONS AND SUBSEQUENT CONTRACTS.—

''(1) IN GENERAL.—The Secretary, in consultation with the National Coordinator, shall periodically conduct hearings to evaluate and review the standards, implementation specifications, and certification criteria adopted under section 3004 for purposes of determining if modifications, including any additions, are needed with respect to such standards, specifications, and criteria.

''(2) CONTRACT TRIGGER.—Based on the needs for standards, implementation specifications, and certification criteria (and modifications, including additions, to such standards, specifications, and criteria) under this title, as determined by the Secretary, with due consideration to section 3010(b) and in consultation with the National Coordinator, the Secretary shall, as needed, enter into contracts under subsection (a) to carry out the duties described in subsection (b)(2) in addition to any contract entered into to carry out the duties described in subsection (b)(1).

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 for contracts under subsection (a), to remain available until expended.''.

(4) MODIFICATIONS TO ROLE OF THE NATIONAL COORDINATOR.—Section 3001(c)(1)(A) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(1)(A)) is amended by inserting ''for recommendations made before the date of the enactment of the 21st Century Cures Act,'' before ''review and determine''.

(c) ADOPTION.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by inserting after ''section 3001(c)'' the following: ''(or, subject to subsection (c), in the case of a standard, implementation specification, or criterion recommended on or after the date of the enactment of the 21st Century Cures Act, after the date of submission of the recommendation to the Secretary under section 3003A)''; and

(B) in paragraph (2)(B), by striking ''and the HIT Standards Committee'';

(2) in subsection (b)—

(A) in paragraph (3), by striking ''with the schedule published under section 3003(b)(2)'' and inserting ''with subsection (d)''; and

(B) by adding at the end the following new paragraph:

''(4) LIMITATION.—The Secretary may not adopt any policies, priorities, standards, implementation specifications, or certification criteria under this subsection or subsection (a) that are inconsistent with or duplicative of an interoperability standard or implementation specification with respect to such standard adopted under this section, in accordance with subsections (c) and (d). In the case of a standard, specification, or criterion that has been adopted under this section and is inconsistent or duplicative of such an interoperability standard or specification that is subsequently adopted under this section, such interoperability standard or specification shall supercede such other standard, specification, or criterion and such other standard, specification, or criterion shall no longer be considered adopted under this section beginning on the date that such interoperability standard or specification becomes effective.''; and

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

''(c) ADOPTION OF INITIAL INTEROPERABILITY STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—Notwithstanding the previous subsections of this section, the following shall apply in the case of the initial set of interoperability standards and implementation specifications with respect to such standards recommended under section 3003A:

''(1) REVIEW OF STANDARDS.—Not later than 90 days after the date of receipt of recommendations for such interoperability standards and implementation specifications, the Secretary, in consultation with the National Coordinator and representatives of other relevant Federal agencies, such as the National Institute of Standards and Technology, shall jointly review such standards and implementation specifications and shall determine whether or not to propose adoption of such standards and implementation specifications.

''(2) DETERMINATION TO ADOPT.—If, subject to subsection (d)(3), the Secretary determines—

''(A) to propose adoption of such standards and implementation specifications, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such standards and implementation specifications; or

''(B) not to propose adoption of such standards and implementation specifications, the Secretary shall notify the applicable entity with a contract under section 3003A in writing of such determination and the reasons for not proposing the adoption of the recommendation for such standards and implementation specifications.

''(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

''(d) RULES FOR ADOPTION.—In the case of a standard (including interoperability standard), implementation specification, or certification criterion adopted under this section on or after the date of the enactment of the 21st Century Cures Act, the following shall apply:

''(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), any such standard (including interoperability standard), implementation specification, or certification criterion shall be a standard, specification, or criterion that has been recommended by the entities with which the Secretary has entered into a contract under section 3003A.

''(2) SPECIAL RULE IF NO STANDARD, SPECIFICATION, OR CRITERION RECOMMENDED.—If no standard, implementation specification, or, to the extent necessary, certification criterion is recommended under paragraph (1)—

''(A) in the case of interoperability standards and implementation specifications with respect to such standards, relating to a category described in section 3010(b)—

''(i) paragraph (1) shall not apply; and

''(ii) paragraph (4) shall apply; or

''(B) in the case of any other standard, implementation specification, or, to the extent necessary, certification criterion, relating to a policy or priority to carry out this title, as determined by the Secretary, in consultation with the National Coordinator—

''(i) paragraph (1) shall not apply; and

''(ii) paragraph (4) shall apply.

''(3) AUTHORITY TO MODIFY IMPLEMENTATION SPECIFICATIONS.—If, following public comment pursuant to subsection (c), the Secretary would propose adoption of interoperability standards recommended under section 3003A but for the implementation specifications, with respect to such standards, so recommended, the Secretary may modify such implementation specifications and adopt such standards and specifications in accordance with subsection (c)(2).

''(4) EFFECTIVE DATE.—In the case of a standard, implementation specification, or certification criterion for which there is a determination to adopt such standard, implementation

*specification, or certification criterion, such standard, implementation specification, or certification criterion shall be considered adopted under this section and shall be effective beginning on the date that is 12 months after the date of publication of the final rule to adopt such standard, implementation specification, or certification criterion.*

*''(5) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this subsection, the Secretary shall give due consideration to any recommendations of the National Committee on Vital and Health Statistics established under section 306(k), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard, implementation specification, or certification criterion under this section. Any standard, implementation specification, or certification criterion adopted pursuant to this paragraph shall be promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.*

*''(e) ALLOWING FOR FLEXIBILITY THROUGH COMPATIBILITY WITH BASELINE STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—For purposes of this title, title XVIII of the Social Security Act, title XIX of such Act, and any other provision of law, a standard and implementation specification, with respect to such standard, that is determined under section 3001(c)(5)(D) to be compatible with baseline standards and implementation specifications (as defined in clause (ii) of such section) shall be treated as if such standard and specification were an interoperability standard and implementation specification, with respect to such interoperability standard, adopted under this section.''.*

*(d) REPORTS AND NOTIFICATIONS.—Section 3010 of the Public Health Service Act, as added by subsection (a), is amended by adding at the end the following new subsection:*

*''(c) DISSEMINATION OF INFORMATION.—*

*''(1) INITIAL SUMMARY REPORT.—Not later than July 1, 2017, the Secretary, after consultation with relevant stakeholders, shall submit to Congress and provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology a report on the following:*

*''(A) The initial set of interoperability standards and implementation specifications adopted under section 3004(c).*

*''(B) The strategies for achieving widespread interoperability.*

*''(C) Any barriers that are preventing widespread interoperability.*

*''(D) The plan and milestones, including specific steps, to achieve widespread interoperability.*

*''(2) ONGOING PUBLICATION OF RECOMMENDATIONS.—The Secretary shall provide for publication in the Federal Register, and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology, of all recommendations made under this section.''.*

*(e) CERTIFICATION AND OTHER ENFORCEMENT PROVISIONS.—*

*(1) CERTIFICATION OF QUALIFIED ELECTRONIC HEALTH RECORDS.—*

*(A) IN GENERAL.—Section 3007(b) of the Public Health Service Act (42 U.S.C. 300jj–17(b)) is amended by striking ''under section 3001(c)(3) to be in compliance with'' and all that follows through the period at the end and inserting ''under section 3001(c)(3)—*

*''(1) for certifications made before January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004; and*

*''(2) for certifications made on or after January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004 and to be interoperable in accordance with section 3010 and in compliance with interoperability standards adopted under section 3004.''.*

*(B) REQUIREMENTS OF SECRETARY.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended—*

*(i) in subparagraph (B), by inserting before the period at the end the following: ''and, for certifications made on or after January 1, 2018, with respect to health information technology, additional criteria to establish that the technology is interoperable, in accordance with section 3010, and in compliance with interoperability standards and implementation specifications, with respect to such standards, adopted under section 3004''; and*

*(ii) by adding at the end the following new subparagraphs:*

*''(C) ENFORCEMENT; DECERTIFICATIONS.—*

*''(i) REQUIREMENTS.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that any vendor of or other entity offering to health care providers (as defined in section 3010A(g)) qualified electronic health records seeking a certification of such records under such program on or after January 1, 2018, shall, as a condition of certification (and maintenance of certification) of such a record under such program—*

*''(I) provide to the Secretary an attestation—*

*''(aa) the entity has implemented interoperability standards and implementation specifications, with respect to such standards, adopted under section 3004 (including through application of subsection (e) of such section);*

*''(bb) that the entity, unless for a legitimate purpose specified by the Secretary, has not taken and will not take any action that constitutes information blocking (as defined in section 3010A(d)), with respect to such qualified electronic health records;*

*''(cc) that includes the pricing information described in clause (iii) for purposes of inclusion under subsection (f) of such information on the Internet website of the Department of Health and Human Services; that such information will be available on a public Internet website of such entity; and that the entity will voluntarily provide such information to customers prior to offering any qualified electronic health records or related product or service (including subsequent updates, add-ons, or additional products or services to be provided during the course of an on-going contract), prospective customers (such as persons who request or receive a quotation or estimate), and other persons who request such information;*

*''(dd) that the technology with respect to such records has published application programming interfaces, with respect to health information within such records, for search and indexing, semantic harmonization and vocabulary translation, and user interface applications;*

*''(ee) that the entity has successfully and rigorously tested the real world use of the record in the type of setting in which it would be marketed; and*

*''(ff) that the entity has in place data sharing programs or capabilities based on common data elements through such mechanisms as application programming interfaces without the requirement for vendor-specific interfaces;*

*''(II) publish application programming interfaces and associated documentation, with respect to health information within such records, for search and indexing, semantic harmonization and vocabulary translation, and user interface applications; and*

*''(III) demonstrate to the satisfaction of the Secretary that health information from such records are able to be exchanged, accessed, and used through the use of application programming interfaces without special effort, as authorized under applicable law.*

*''(ii) DECERTIFICATION.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that beginning January 1, 2019, any qualified electronic health records that do not satisfy the certification criteria described in subparagraph (B) or with respect to which the vendor or other entity described in clause (i) does not satisfy the requirements under such clause (or is determined to be in violation of the terms of the attestation or other requirements under such clause) shall no longer be considered as certified under such program.*

*''(iii) PRICING INFORMATION.—For purposes of clause (i)(I)(cc), the pricing information described in this clause, with respect to a vendor of or other entity offering a qualified electronic health record, is the following:*

*''(I) Additional types of costs or fees (whether fixed, recurring, transaction based, or otherwise) imposed by the entity (or any third-party from whom the entity purchases, licenses, or obtains any technology, products, or services in connection with the qualified electronic health record) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which such record is to be certified under this section; or in connection with any health information generated in the course of using any capability to which the record is to be so certified.*

*''(II) Limitations, whether by contract or otherwise, on the use of any capability to which the record is to be certified under this section for any purpose within the scope of the record's certification; or in connection with any health information generated in the course of using any capability to which the record is to be certified under this section.*

*''(III) Limitations, including technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which the record is to be certified under this section; or that could prevent or limit the access, use, exchange, or portability of any health information generated in the course of using any capability to which the record is to be so certified.*

*''(D) FLEXIBILITY THROUGH COMPATIBILITY.—*

*''(i) IN GENERAL.—Under any program kept or recognized under subparagraph (A), the Secretary shall provide for a method and process by which a vendor of or other entity offering to health care providers (as defined in section 3010A(g)) qualified electronic health records seeking a certification of such records under such program on or after January 1, 2018, may demonstrate, using such mechanisms as a reference implementation model or other means, that the standards and implementation specifications applied by such entity with respect to such records are compatible with baseline standards and implementation specifications, including by demonstrating such records are able to transmit information that is compatible with qualified electronic health records that would receive such information and that apply the baseline standards and implementation specifications. Such a method and process shall ensure that any such entity using a standard or implementation specification other than a baseline standard or implementation specification demonstrates, through testing, compatibility with the baseline standard and implementation specification with respect to receiving information.*

*''(ii) BASELINE STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—For purposes of clause (i), the term 'baseline standards and implementation specifications' means the interoperability standards and implementation specifications, with respect to such standards, adopted under section 3004 (without application of subsection (e) of such section).''.*

*(2) ADDITIONAL ENFORCEMENT PROVISIONS UNDER THE PUBLIC HEALTH SERVICE ACT.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.), as amended by subsections (a)(1) and (d), is further amended by adding at the end the following new section:*

***"SEC. 3010A. ENFORCEMENT MECHANISMS.***

*''(a) INSPECTOR GENERAL AUTHORITY.—The Inspector General of the Department of Health and Human Services shall have the authority to investigate claims of—*

*''(1)(A) vendors of, or other entities offering to health care providers (as defined in subsection (g)), qualified electronic health records (as defined in section 3000(13)) being in violation of an attestation (whether providing false information at the time of such attestation or by act or practice conducted after such attestation) made under section 3001(c)(5)(C)(i)(I), with respect to the use of such records by a health care provider with respect to items and services furnished under the Medicare program under title XVIII of the Social Security Act or Medicaid program under title XIX of such Act; and*

*''(B) vendors of, or other entities offering to health care providers (as defined in subsection (g)), health information technology having engaged in information blocking (as defined in subsection (d)), unless for a legitimate purpose specified by the Secretary, with respect to the use of such technology by a health care provider with respect to items and services furnished under such a program;*

*''(2) health care providers having engaged in information blocking (as so defined), with respect to the use of health information technology with respect to items and services furnished under such a program, unless for a legitimate purpose specified by the Secretary; and*

*''(3) health information system providers (such as operators of health information exchanges, clinical data registries, and other systems that facilitate the exchange of information) having engaged in information blocking (as so defined), unless for a legitimate purpose specified by the Secretary, with respect to the use of health information technology with respect to items and services furnished under such a program.*

*''(b) INFORMATION SHARING PROVISIONS.—*

*''(1) IN GENERAL.—The National Coordinator may serve as a technical consultant to the Inspector General of the Department of Health and Human Services and the Federal Trade Commission for purposes of carrying out this section. As such technical consultant, the National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (a) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.*

*''(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—*

*''(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section; and*

*''(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section.*

*Such information may be used by the Inspector General of the Department of Health and Human Services or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.*

*''(3) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act of 1995) shall not apply to the National Coordinator or to the Office of the National Coordinator for Health Information Technology with respect to the collection of complaints relating to claims described in subsection (a).*

*''(4) STANDARDIZED PROCESS.—The National Coordinator shall implement a standardized process for the public to submit reports on claims of—*

*''(A) health information technology products of vendors (or other entities offering such products to health care providers (as defined in subsection (g)) not being interoperable or resulting in information blocking; or*

*''(B) actions by such entities, health care providers, or health information system providers that result in such technology not being interoperable or in information blocking with respect to such technology; and*

*''(C) any other act described in subsection (a).*

*The standardized process shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.*

*''(c) PENALTY.—*

*''(1) IN GENERAL.—Any person or entity described in paragraph (1), (2), or (3) of subsection (a) determined to have committed on or after January 1, 2018, an act described in such respective paragraph with respect to the use of a qualified electronic health record or health information technology, as applicable under such respective paragraph, with respect to items and services furnished under the Medicare program under title XVIII of the Social Security Act or the Medicaid program under title XIX of such Act, shall be subject to a civil monetary penalty in such amount as determined appropriate by the Secretary through rulemaking.*

*''(2) APPLICATION.—Subject to paragraph (3), the provisions of section 1128A (other than subsections (a) and (b)) of such Act (42 U.S.C. 1320a–7a) shall apply to a civil money penalty applied under this subsection in the same manner as they apply to a civil money penalty or proceeding under subsection (a) of such section 1128A.*

*''(3) RECOVERY OF FUNDS.—Notwithstanding section 3302 of title 31, United States Code, or any other provision of law affecting the crediting of collections, the Inspector General of the Department of Health and Human Services may receive and retain for current use any amounts recovered under this subsection. In addition to amounts otherwise available to the Inspector General, funds received by the Inspector General under this paragraph shall be deposited, as an offsetting collection, to the credit of any appropriation available for purposes of carrying out this subsection and subsection (a) and shall be available without fiscal year limitation and without further appropriation.*

*''(d) INFORMATION BLOCKING.—*

*''(1) IN GENERAL.—For purposes of this section and section 3010, subject to paragraph (3), the term 'information blocking' means, with respect to the access, use, and exchange of qualified electronic health records and other health information technology, business, technical, and organizational practices, including practices described in paragraph (2), that—*

*''(A) prevent or materially discourage the access, exchange, or use of electronic health information; and*

*''(B) the actor knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) are likely to interfere with the access, exchange, or use of electronic health information.*

*''(2) PRACTICES DESCRIBED.—For purposes of paragraph (1), the practices described in this paragraph shall include the following:*

*''(A) Contract terms, policies, or business or organizational practices that restrict authorized use under applicable State or Federal law of electronic health information or restrict the authorized exchange under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified EHR technologies.*

*''(B) Charging unreasonable prices or fees (such as for health information exchange, portability, interfaces, and full export of health information) that make accessing, exchanging, or using electronic health information cost prohibitive.*

*''(C) Developing or implementing health information technology in nonstandard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information, especially in cases in which relevant interoperability standards or methods to measure interoperability have been adopted by the Secretary.*

*''(D) Developing or implementing health information technology in ways that are likely to lock in users or electronic health information, such as not allowing for the full export of health information; lead to fraud, waste, or abuse; or impede innovations and advancements in health information access, exchange, and use, including health information technology-enabled care delivery.*

*''(3) EXCEPTIONS.—*

*''(A) IN GENERAL.—The term 'information blocking' shall not include practices that—*

*''(i) are required by applicable law; or*

*''(ii) that the Secretary, through regulation, identifies as necessary to protect patient safety, to maintain the privacy or security of individuals' health information, or to promote competition and consumer welfare.*

*''(B) PROCESS.—For purposes of subparagraph (A)(ii), not later than 12 months after the date of the enactment of this section, the Secretary shall issue regulations following the notice and comment procedures of section 553 of title 5, United States Code, except that the Secretary may issue the first such regulation as an interim final regulation.*

*''(C) NO ENFORCEMENT BEFORE EXCEPTIONS IDENTIFIED.—The term 'information blocking' shall not include any practice or conduct occurring before the date that is 30 days after the date on which the first regulation (as described in subparagraph (B)) is issued under such subparagraph.*

*''(D) CONSULTATION.—To the extent that regulations issued under this paragraph define practices that are necessary to promote competition and consumer welfare, the Secretary may consult with the Federal Trade Commission in issuing such regulations.*

*''(E) APPLICATION.—The term 'information blocking', with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.*

*''(e) TREATMENT OF VENDORS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—In applying part C of title IX—*

*''(1) vendors shall be treated as a provider (as defined in section 921) for purposes of reporting requirements under such part, to the extent that such reports are related to attestation requirements under section 3001(c)(5)(C)(i)(I);*

*''(2) claims of information blocking described in subsection (a) shall be treated as a patient safety activity under such part for purposes of reporting requirements under such part; and*

*''(3) health care providers that are not members of patient safety organizations shall be treated in the same manner as health care providers that are such members for purposes of such reporting requirements with respect to claims of information blocking described in subsection (a).*

*''(f) RULEMAKING AND GUIDANCE.—*

*''(1) IN GENERAL.—Not later than 12 months after the date of the enactment of this section, the Secretary, in consultation with the National Coordinator and the Inspector General of the Department of Health and Human Services, shall, through rulemaking, implement the provisions of section 3001 of the 21st Century Cures Act, including amendments made by such section, relating to information blocking.*

*''(2) NON-DUPLICATION OF PENALTY STRUCTURES.—In carrying out paragraph (1), in determining the scope of penalties, assessments, or exclusions under such section 3001, including*

*amendments made by such section, relating to information blocking, the Secretary shall ensure to the extent possible that such penalties, assessments, and exclusions do not duplicate penalty, assessment, and exclusion structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before the date of the enactment of this section.*

*''(3) CLARIFICATION.—In carrying out paragraph (1), the Secretary shall ensure that health care providers are not penalized for actions of vendor of, and other entities offering to such providers, health information technology for the failure of such technology to meet requirements for such technology to be certified under this title.*

*''(4) GUIDANCE RELATING TO HIPAA.—Not later than January 1, 2017, the National Coordinator shall publish guidance to clarify the relationship of the provisions of the HIPAA privacy and security law, as defined in section 3009(a)(2) to information blocking, including—*

*''(A) examples of how such provisions may result in information blocking; and*

*''(B) clarifying that a health care provider (as defined in subsection (g)) who discloses health information as allowed under applicable State and Federal law is not liable for unlawful actions, including breaches that occur in the custody of the recipient unless the disclosure proximately cause the breach.*

*''(g) HEALTH CARE PROVIDER DEFINED.—For purposes of this section, the term 'health care provider' means a provider of services under subsection (u) of section 1861 of the Social Security Act and a supplier under subsection (d) of such section.*

*''(h) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts made available under subsection (c)(3), there is authorized to be appropriated $10,000,000 for fiscal year 2017 to carry out subsection (a), to remain available until expended.''.*

*(3) POSTINGS RELATING TO ENFORCEMENT ON HHS INTERNET WEBSITE.—Section 3001 of the Public Health Service Act (42 U.S.C. 300jj–11) is amended by adding at the end the following new subsection:*

*''(f) ENFORCEMENT INFORMATION POSTED ON HHS INTERNET WEBSITE.—*

*''(1) PRICING INFORMATION.—Not later than January 1, 2019, the National Coordinator shall post the information described in subsection (c)(5)(C)(I)(i)(cc) on the public Internet website of the Office of the National Coordinator for Health Information Technology in a manner that allows for comparison of functionality, price information, and other features among health information technology products that aids in making informed decisions for purchasing such a product.*

*''(2) ANNUAL POSTING.—For 2019 and each subsequent year, the Secretary shall post on the public Internet website of the Department of Health and Human Services a list of any qualified electronic health records with respect to which certification has been withdrawn under subsection (c)(5)(C)(ii) during such year and the vendor of or other entity offering to health care providers (as defined in section 3010A(g)) such qualified electronic health records.*

*''(3) PERIODIC REVIEW.—The Secretary shall periodically review and confirm that vendors of and other entities offering to health care providers (as defined in section 3010A(g)) qualified electronic health records have publicly published application programming interfaces and associated documentation as required by subsection (c)(5)(C)(i)(II) for purposes of certification and maintaining certification under any program kept or recognized under subsection (c)(5)(A).''.*

*(4) DEMONSTRATION REQUIRED FOR MEANINGFUL EHR USE UNDER MEDICARE.—*

*(A) ELIGIBLE PROFESSIONALS.—*

*(i) IN GENERAL.—Section 1848(o)(2)(A) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(A)) is amended by inserting after clause (iii) the following new clause:*

*''(iv) INTEROPERABILITY.—With respect to EHR reporting periods for payment years beginning with 2020, the eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act, with respect to the use of any certified EHR technology.''.*

*(ii) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—Subparagraph (B) of section 1848(a)(7) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)) is amended to read as follows:*

*''(B) SIGNIFICANT HARDSHIP EXCEPTION.—*

*''(i) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.*

*''(ii) DECERTIFICATION.—The Secretary shall exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines that such professional was determined to not be a meaningful EHR user because the certified EHR technology used by such professional is decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to an eligible professional only, subject to clause (iii), during the first payment year with respect to the first EHR reporting period to which such decertification applies.*

*''(iii) DURATION OF DECERTIFICATION.—*

*''(I) IN GENERAL.—Notwithstanding clause (iv)(I), in no case shall an exemption by reason of clause (ii) be for a period of less than 12 months.*

*''(II) EXTENSION.—An exemption under clause (ii) may be extended, on a case-by-case basis, for a period of an additional 12 months subject to the limitation described in clause (iv)(I).*

*''(iv) LIMITATION.—*

*''(I) IN GENERAL.—Subject to subclause (II), in no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.*

*''(II) EXCEPTION.—Subclause (I) shall not apply to an exemption by reason of clause (ii) to the extent necessary to satisfy clause (iii)(I).''.*

*(iii) FURTHER APPLICATION.—Section 1848(o)(2) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)) is amended by adding at the end the following new subparagraph:*

*''(E) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—In the case of certified EHR technology used by an eligible professional that is decertified under section 3001(c)(5)(C), during the first payment year with respect to the first EHR reporting period to which such decertification applies, the Secretary shall not treat the professional as not being a meaningful EHR user solely because the technology used by such professional was so decertified. The treatment of a professional under the previous sentence shall be for a period of at least 12 months and may, on a case-by-case basis, be for a period of an additional 12 months.''.*

*(B) ELIGIBLE HOSPITALS.—*

*(i) IN GENERAL.—Section 1886(n)(3)(A) of the Social Security Act (42 U.S.C. 1395ww(n)(3)(A)) is amended by inserting after clause (iii) the following new clause:*

*''(iv) INTEROPERABILITY.—With respect to EHR reporting periods for payment years beginning with 2020, the hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the hospital has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act, with respect to the use of any certified EHR technology.''.*

*(ii) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—Subclause (II) of section 1886(b)(3)(B)(ix) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)) is amended to read as follows:*

*''(II)(aa) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.*

*''(bb) The Secretary shall exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines that such hospital was determined to not be a meaningful EHR user because the certified EHR technology used by such hospital is decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to a subsection (d) hospital only, subject to items (cc) and (dd), during the first payment year with respect to the first EHR reporting period to which such decertification applies.*

*''(cc) Notwithstanding item (ee), in no case shall an exemption by reason of item (bb) be for a period of less than 12 months.*

*''(dd) An exemption under item (bb) may, on a case-by-case basis, be extended for a period of an additional 12 months subject to the limitation described in item (ee).*

*''(ee) Subject to item (ff), in no case may a hospital be granted an exemption under this subclause for more than 5 years.*

*''(ff) Item (ee) shall not apply to an exemption by reason of item (bb) to the extent necessary to satisfy item (cc).''.*

*(C) DEMONSTRATION REQUIRED FOR MEANINGFUL EHR USE UNDER MEDICAID.—Section 1903(t)(2) of the Social Security Act (42 U.S.C. 1396b(t)(2)) is amended by adding at the end the following: ''An eligible professional shall not qualify as a Medicaid provider under this subsection, with respect to a year beginning with 2020, unless such provider demonstrates to the Secretary, through means such as an attestation, that the provider has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act, with respect to the use of any certified EHR technology.''.*

*(5) GUIDANCE.—Not later than January 1, 2018, the Secretary of Health and Human Services shall issue guidance to further the voluntary transition of health care providers between different certified EHR technology (as defined in section 3000(1) of the Public Health Service Act (42 U.S.C. 300jj(1)) by removing disincentives to such transition, which may include applying to instances of such a transition the hardship exemption authority under section 1848(a)(7) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)), section 1886(b)(3)(B)(ix) of such Act (42 U.S.C. 1395ww(b)(3)(B)(ix)), and other provisions of law in existence as of the date of the enactment of this Act. In developing such guidance, the Secretary may consult with the relevant Federal agencies.*

*(f) DEFINITIONS.—*

*(1) CERTIFIED EHR TECHNOLOGY.—Paragraph (1) of section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended to read as follows:*

*''(1) CERTIFIED EHR TECHNOLOGY.—The term 'certified EHR technology' means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting the certification criteria defined in subparagraph (B) of such section that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals) including, beginning January 1, 2018, with respect*

*to which the vendor or other entity offering such technology is in compliance with the requirements under section 3001(c)(5)(C)(i).''.*

*(2) WIDESPREAD INTEROPERABILITY.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended by adding at the end the following new paragraph:*

*''(15) WIDESPREAD INTEROPERABILITY.—The term 'widespread interoperability' means that, on a nationwide basis—*

*''(A) health information technology is interoperable, in accordance with section 3010; and*

*''(B) such technology is employed by meaningful EHR users under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act and by other clinicians and health care providers.''.*

*(g) CONFORMING AMENDMENTS.—*

*(1) VOLUNTARY USE OF STANDARDS.—Section 3006 of the Public Health Service Act (42 U.S.C. 300jj–16) is amended—*

*(A) in subsection (a)(1), by inserting '', including an interoperability standard or implementation specification, with respect to such interoperability standard, adopted under such section'' after ''section 3004''.*

*(B) in subsection (b), by inserting '', including the interoperability standards and implementation specifications, with respect to such interoperability standards, adopted under such section'' after ''section 3004''.*

*(2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300jj–19(a)(2)(A)) is amended by striking ''title IV'' and inserting ''title XIII''.*

*(3) COORDINATION OF FEDERAL ACTIVITIES.—Section 13111 of the HITECH Act is amended—*

*(A) in subsection (a), by inserting before the period at the end the following: ''(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act and in compliance with interoperability standards and implementation specifications, with respect to such interoperability standards, adopted under section 3004 of such Act )''; and*

*(B) in subsection (b), by inserting ''(and, beginning on January 1, 2018, including an interoperability standard or implementation specification, with respect to such interoperability standard, adopted under section 3004 of such Act)'' before ''the President''.*

*(4) APPLICATION TO PRIVATE ENTITIES.—Section 13112 of the HITECH Act is amended by inserting before the period at the end the following: ''(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act and in compliance with interoperability standards and implementation specifications, with respect to such interoperability standards, adopted under section 3004 of such Act)''.*

*(5) NIST TESTING.—Section 13201 of the HITECH Act (42 U.S.C. 17911) is amended—*

*(A) in subsection (a), by inserting ''(or, beginning January 1, 2018, in coordination with the entities with contracts under section 3003A, with respect to standards, and implementation specifications under section 3004)'' before '', the Director''; and*

*(B) in subsection (b), by inserting ''(or, beginning January 1, 2018, in coordination with the entities with contracts under section 3003A, with respect to standards and implementation specifications under section 3004)'' before '', the Director''; and*

*(C) by adding at the end the following new subsection:*

*''(c) FUNDING.—For purposes of carrying out this section, in addition to any other funds made available to carry out this section, there is authorized to be appropriated $15,000,000, to remain available until expended.''.*

*(6) COORDINATION WITH RECOMMENDATIONS FOR ACHIEVING WIDESPREAD EHR INTEROPERABILITY.—Section 106 of the Medicare Access and CHIP Reauthorization Act of 2015 (Public Law 114–10) is amended by striking subsection (b).''.*

*(h) PATIENT ENGAGEMENT AND EMPOWERMENT.—It is the sense of Congress that—*

*(1) if the strategic goals that Congress set forth in the HITECH Act are to be achieved, interoperability is best achieved with individuals and authorized representatives having equal access to the health information of such individuals in electronic format;*

*(2) patients have the right to the entirety of the health information of such individuals, including such information contained in an electronic health record of such individuals;*

*(3) such right extends to both structured and unstructured data;*

*(4) such right extends to authorized representatives of the individual involved, such as care takers of such individual, family members of such individual, and guardians of such individual; and*

*(5) to further facilitate access of an individual to health information of such individual—*

*(A) health care providers should not have the ability to deny a request of the individual for access to the entirety of such health information of such individual;*

*(B) health care providers do not need the consent of individuals to share personal health information of such individuals with other covered entities, in compliance with the HIPAA privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 for the purposes of supporting patient care, except in situations where consent is specifically required under such regulations, such as in cases related to the psychiatric records of the individual involved;*

*(C) mechanisms should be utilized that allow for the bidirectional exchange of information through such mechanisms as web portals, appointments, and prescription refills, for the purpose of patients partnering with providers to assist in managing health and care;*

*(D) mechanisms described in subparagraph (C) should allow for connecting individuals across the continuum of care;*

*(E) an individual has the right to access the health information of the individual without cost to the individual;*

*(F) mechanisms described in subparagraph (C) should allow for data of an individual generated by the individual to be integrated into such platforms as electronic health records;*

*(G) such access should be timely, in accordance with the HIPAA privacy regulations described in subparagraph (B), and take into account communications preferences of the individual involved;*

*(H) an individual should have the right to be confident that the data in the electronic health record of the individual pertains to such individual; and*

*(I) the right described in subparagraph (H) will promote safety and care coordination for individuals.*

### *Subtitle B—Telehealth*

#### *SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE PROGRAM.*

*(a) PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.—Not later than 1 year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall provide to the committees of jurisdiction of the House of Representatives and the Senate information on the following:*

*(1) The populations of Medicare beneficiaries, such as those who are dually eligible for the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) and those with chronic conditions, whose care may be improved most in terms of quality and efficiency by the expansion, in a manner that meets or exceeds the existing in-person standard of care under the Medicare program under title XVIII of such Act, of telehealth services under section 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).*

*(2) Activities by the Center for Medicare and Medicaid Innovation which examine the use of telehealth services in models, projects, or initiatives funded through section 1115A of the Social Security Act (42 U.S.C. 1315a).*

*(3) The types of high volume services (and related diagnoses) under such title XVIII which might be suitable to the furnishing of services via telehealth.*

*(4) Barriers that might prevent the expansion of telehealth services under section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) beyond such services that are in effect as of the date of the enactment of this Act.*

*(b) PROVISION OF INFORMATION BY MEDPAC.—Not later than March 15, 2017, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall, using quantitative and qualitative research methods, provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—*

*(1) the telehealth services for which payment can be made, as of the date of the enactment of this Act, under the fee-for-service program under parts A and B of title XVIII of such Act;*

*(2) the telehealth services for which payment can be made, as of such date, under private health insurance plans;*

*(3) with respect to services identified under paragraph (2) but not under paragraph (1), ways in which payment for such services might be incorporated into such fee-for-service program (including any recommendations for ways to accomplish this incorporation).*

*(c) SENSE OF CONGRESS.—It is the sense of Congress that—*

*(1) eligible originating sites should be expanded beyond those originating sites described in section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)); and*

*(2) any expansion of telehealth services under the Medicare program should—*

*(A) recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;*

*(B) meet or exceed the conditions of coverage and payment with respect to the Medicare program under title XVIII unless specifically address in subsequent statute, of such Act if the service were furnished in person, including standards of care; and*

*(C) involve clinically appropriate means to furnish such services.*

### *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. TREATMENT OF CERTAIN ITEMS AND DEVICES.

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(r) PAYMENT FOR CERTAIN DISPOSABLE DEVICES.—

''(1) IN GENERAL.—The Secretary shall make separate payment in the amount established under paragraph (3) to a home health agency for a device described in paragraph (2) when furnished to an individual who receives home health services for which payment is made under section 1895(b).

''(2) DEVICE DESCRIBED.—For purposes of paragraph (1), a device described in this paragraph is a disposable device for which, as of January 1, 2015, there is—

''(A) a Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device; and

''(B) a separate Level I HCPCS code for a professional service that uses durable medical equipment instead of such device.

''(3) PAYMENT AMOUNT.—The Secretary shall establish the separate payment amount for such a device such that such amount does not exceed the payment that would be made for the HCPCS code described in paragraph (2)(A) under section 1833(t) (relating to payment for covered OPD services).''.

(b) CONFORMING AMENDMENT.—Section 1861(m)(5) of the Social Security Act (42 U.S.C. 1395x(m)(5)) is amended by inserting ''and devices described in section 1834(r)(2)'' after ''durable medical equipment''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to devices furnished on or after January 1, 2017.

### Subtitle E—Local Coverage Decision Reforms

#### SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS.

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

''(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each medicare administrative contractor that develops a local coverage determination to make available on the website of such contractor and on the Medicare website, at least 45 days before the effective date of such determination, the following information:

''(i) Such determination in its entirety.

''(ii) Where and when the proposed determination was first made public.

''(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

''(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

''(v) An explanation of the rationale that supports such determination.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) 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) are with respect to coverage, coding, or payment under this title for such products.

The second sentence of paragraph (2) shall apply to this paragraph in the same manner as such sentence applies to paragraph (2).''.

### Subtitle G—Medicare Site-of-Service Price Transparency

#### SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 3061, is further amended by adding at the end the following new subsection:

''(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—

''(1) 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 surgical center under this title, the Secretary 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—

''(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

''(B) the estimated amount of beneficiary liability applicable to the item or service.

''(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

''(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

''(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

''(B) may utilize mechanisms in existence on the date of the enactment of this subsection, 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 estimated amounts under such paragraph.

''(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Supplemental Medical Insurance Trust Fund under section 1841 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. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER MEDICARE PARTS C AND D.

(a) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(1) IN GENERAL.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–10(c)) is amended by adding at the end the following:

''(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

''(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

''(B) REQUIREMENT FOR NOTICES.—

''(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

''(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

''(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

''(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

''(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

''(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

''(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

''(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

''(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

''(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

''(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

''(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

''(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

''(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

''(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

''(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

''(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would

*prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and*

*''(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.*

*''(iv) TIMING OF NOTICES.—*

*''(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 60 days after an initial notice described in clause (ii) is provided to the beneficiary.*

*''(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.*

*''(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—*

*''(i) IN GENERAL.—For purposes of this paragraph, the term 'at-risk beneficiary for prescription drug abuse' means a part D eligible individual who is not an exempted individual described in clause (ii) and—*

*''(I) who is identified as such an at-risk beneficiary through the use of clinical guidelines developed by the Secretary in consultation with PDP sponsors and other stakeholders described in section 3141(f)(2)(A) of the 21st Century Cures Act; or*

*''(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).*

*''(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—*

*''(I) receives hospice care under this title;*

*''(II) is a resident of a long-term care facility, of an intermediate care facility for the mentally retarded, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or*

*''(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).*

*''(D) SELECTION OF PRESCRIBERS AND PHARMACIES.—*

*''(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph), select—*

*''(I) one or more individuals who are authorized to prescribe frequently abused drugs (referred to in this paragraph as 'prescribers') who may write prescriptions for such drugs for such beneficiary; and*

*''(II) one or more pharmacies that may dispense such drugs to such beneficiary.*

*''(ii) REASONABLE ACCESS.—In making the selections under this subparagraph—*

*''(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and*

*''(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences and in the case of natural disasters and similar emergency situations.*

*''(iii) BENEFICIARY PREFERENCES.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—*

*''(I) review such preferences;*

*''(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and*

*''(III) inform the beneficiary of such selection or change of selection.*

*''(iv) EXCEPTION REGARDING BENEFICIARY PREFERENCES.—In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii).*

*''(v) CONFIRMATION.—Before selecting a prescriber (or prescribers) or pharmacy (or pharmacies) under this subparagraph, a PDP sponsor must request and receive confirmation from such a prescriber or pharmacy acknowledging and accepting that the beneficiary involved is in the drug management program for at-risk beneficiaries.*

*''(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, and the selection of prescriber or pharmacy under subparagraph (D) with respect to such individual shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.*

*''(F) TERMINATION OF IDENTIFICATION.—*

*''(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—*

*''(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); and*

*''(II) the end of such maximum period of identification as the Secretary may specify.*

*''(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.*

*''(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term 'frequently abused drug' means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.*

*''(H) DATA DISCLOSURE.—In the case of an at-risk beneficiary for prescription drug abuse whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, such PDP sponsor shall disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part to other PDP sponsors that request such data.*

*''(I) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—*

*''(i) provided by medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and*

*''(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.*

*''(J) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D—21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.''.*

*(2) INFORMATION FOR CONSUMERS.—Section 1860D–4(a)(1)(B) of the Social Security Act (42 U.S.C. 1395w–104(a)(1)(B)) is amended by adding at the end the following:*

*''(v) The drug management program for at-risk beneficiaries under subsection (c)(5).''.*

*(b) UTILIZATION MANAGEMENT PROGRAMS.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)), as amended by subsection (a)(1), is further amended—*

*(1) in paragraph (1), by inserting after subparagraph (D) the following new subparagraph:*

*''(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).''; and*

*(2) by adding at the end the following new paragraph:*

*''(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—*

*''(A) IN GENERAL.—A tool described in this paragraph is any of the following:*

*''(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.*

*''(ii) Retrospective utilization review to identify—*

*''(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and*

*''(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.*

*''(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).*

*''(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—*

*''(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and*

*''(ii) the name and prescription records of individuals described in paragraph (5)(C).''.*

*(c) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—*

*(1) IN GENERAL.—Section 1893 of the Social Security Act (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:*

*''(j) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—*

*''(1) ACCESS TO INFORMATION.—Under contracts entered into under this section with Medicare drug integrity contractors (including any successor entity to a Medicare drug integrity contractor), the Secretary shall authorize such contractors to directly accept prescription and necessary medical records from entities such as pharmacies, prescription drug plans, MA–PD plans, and physicians with respect to an individual in order for such contractors to provide*

*information relevant to the determination of whether such individual is an at-risk beneficiary for prescription drug abuse, as defined in section 1860D–4(c)(5)(C).*

*''(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor or MA organization refers information to a contractor described in paragraph (1) in order for such contractor to assist in the determination described in such paragraph, the contractor shall—*

*''(A) acknowledge to the sponsor or organization receipt of the referral; and*

*''(B) in the case that any PDP sponsor or MA organization contacts the contractor requesting to know the determination by the contractor of whether or not an individual has been determined to be an individual described such paragraph, shall inform such sponsor or organization of such determination on a date that is not later than 15 days after the date on which the sponsor or organization contacts the contractor.*

*''(3) MAKING DATA AVAILABLE TO OTHER ENTITIES.—*

*''(A) IN GENERAL.—For purposes of carrying out this subsection, subject to subparagraph (B), the Secretary shall authorize MEDICs to respond to requests for information from PDP sponsors and MA organizations, State prescription drug monitoring programs, and other entities delegated by such sponsors or organizations using available programs and systems in the effort to prevent fraud, waste, and abuse.*

*''(B) HIPAA COMPLIANT INFORMATION ONLY.—Information may only be disclosed by a MEDIC under subparagraph (A) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).''.*

*(2) OIG STUDY AND REPORT ON EFFECTIVENESS OF MEDICS.—*

*(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the effectiveness of Medicare drug integrity contractors with which the Secretary of Health and Human Services has entered into a contract under section 1893 of the Social Security Act (42 U.S.C. 1395ddd) in identifying, combating, and preventing fraud under the Medicare program, including under the authority provided under section 1893(j) of the Social Security Act, added by paragraph (1).*

*(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A). Such report shall include such recommendations for improvements in the effectiveness of such contractors as the Inspector General determines appropriate.*

*(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:*

*''(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.''.*

*(e) SENSE OF CONGRESS REGARDING USE OF TECHNOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of Congress that MA organizations and PDP sponsors should consider using e-prescribing and other health information technology tools to support combating fraud under MA–PD plans and prescription drug plans under parts C and D of the Medicare program.*

*(f) EFFECTIVE DATE.—*

*(1) IN GENERAL.—The amendments made by this section shall apply to prescription drug plans (and MA–PD plans) for plan years beginning more than 1 year after the date of the enactment of this Act.*

*(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—*

*(A) IN GENERAL.—Not later than January 1, 2016, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title of such Act, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B).*

*(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—*

*(i) the anticipated impact of drug management programs for at-risk beneficiaries under paragraph (5) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA–PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of such paragraph);*

*(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as an at-risk beneficiary for prescription drug abuse under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act that allow an automatic escalation to external review of claims submitted under such part);*

*(iii) the types of enrollees that should be treated as exempted individuals, as described in subparagraph (C)(ii) of such paragraph;*

*(iv) the manner in which terms and definitions in such paragraph should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in subparagraph (C) of such paragraph;*

*(v) the information to be included in the notices described in subparagraph (B) of such paragraph and the standardization of such notices; and*

*(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) with respect to the implementation of such program.*

*(g) RULEMAKING.—The Secretary of Health and Human Services shall promulgate regulations based on the input gathered pursuant to subsection (f)(2)(A).*

## *TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS*

### *Subtitle A—Medicaid and Medicare Reforms*

#### *SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT (DME) TO MEDICARE PAYMENT RATES.*

*(a) MEDICAID REIMBURSEMENT.—*

*(1) IN GENERAL.—Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended—*

*(A) in paragraph (25), by striking ''or'' at the end;*

*(B) in paragraph (26), by striking the period at the end and inserting ''; or''; and*

*(C) by inserting after paragraph (26) the following new paragraph:*

*''(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n), as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.''.*

*(2) EFFECTIVE DATE.—The amendments made by this subsection shall be effective with respect to payments for items furnished on or after January 1, 2020.*

*(b) MEDICARE OMBUDSMAN.—Section 1808(c) of the Social Security Act (42 U.S.C. 1395b(c)), as amended by section 3101, is further amended by adding at the end the following new paragraph:*

*''(5) MONITORING DME REIMBURSEMENT UNDER MEDICAID.—The ombudsmen under each of paragraphs (1) and (4) shall evaluate the impact of the competitive acquisition program under section 1847, including as applied under section 1903(i)(27), on beneficiary health status and health outcomes.''.*

#### *SEC. 4002. EXCLUDING AUTHORIZED GENERICS FROM CALCULATION OF AVERAGE MANUFACTURER PRICE.*

*(a) IN GENERAL.—Subparagraph (C) of section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)) is amended—*

*(1) in the subparagraph heading, by striking ''INCLUSION'' and inserting ''EXCLUSION'';*

*(2) by striking ''a new drug application'' and inserting ''the manufacturer's new drug application''; and*

*(3) by striking ''inclusive'' and inserting ''exclusive''.*

*(b) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2015.*

#### *SEC. 4003. MEDICARE PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY AND OTHER MEDICARE IMAGING PAYMENT PROVISION.*

*(a) PHYSICIAN FEE SCHEDULE.—*

*(1) PAYMENT INCENTIVE FOR TRANSITION.—*

*(A) IN GENERAL.—Section 1848(b) of the Social Security Act (42 U.S.C. 1395w–4(b)) is amended by adding at the end the following new paragraph:*

*''(9) SPECIAL RULE TO INCENTIVIZE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—*

*''(A) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service (including the imaging portion of a service) that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global service) of such service that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 20 percent.*

*''(B) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service (including the imaging portion of a service) that is an X-ray taken using computed radiography technology—*

*''(i) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for the technical component (including the technical component portion of a global service) of such service that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 7 percent; and*

*''(ii) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global service) of such service that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 10 percent.*

*''(C) COMPUTED RADIOGRAPHY TECHNOLOGY DEFINED.—For purposes of this paragraph, the term 'computed radiography technology' means*

cassette-based imaging which utilizes an imaging plate to create the image involved.

''(D) IMPLEMENTATION.—In order to implement this paragraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.''.

(B) EXEMPTION FROM BUDGET NEUTRALITY.—Section 1848(c)(2)(B)(v) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)(v)) is amended by adding at the end the following new subclause:

''(X) REDUCED EXPENDITURES ATTRIBUTABLE TO INCENTIVES TO TRANSITION TO DIGITAL RADIOGRAPHY.—Effective for fee schedules established beginning with 2017, reduced expenditures attributable to subparagraph (A) of subsection (b)(9) and effective for fee schedules established beginning with 2018, reduced expenditures attributable to subparagraph (B) of such subsection.''.

(2) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—

(A) IN GENERAL.—Section 1848(b)(4) of the Social Security Act (42 U.S.C. 1395w–4(b)(4)) is amended by adding at the end the following new subparagraph:

''(E) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—

''(i) IN GENERAL.—For services furnished on or after January 1, 2017, the Secretary shall not apply a multiple procedure payment reduction to the professional component of imaging services unless the Secretary has published as part of a Medicare Physician Fee Schedule Proposed Rule the empirical analysis described in clause (ii) with tables made available on the website of the Centers for Medicare & Medicaid Services.

''(ii) EMPIRICAL ANALYSIS DESCRIBED.—The empirical analysis described in this clause is an analysis of the Resource-Based Relative Value Scale Data Manager information or other information that is used to determine what, if any, efficiencies exist within the professional component of imaging services when two or more studies are furnished to the same individual on the same day. Such empirical analysis shall include—

''(I) information detailing which physician work activities overlap and the reductions applicable to such overlap;

''(II) a discussion of the clinical aspects that informed the assignment of the reduction percentages described in subclause (I);

''(III) to the extent that such reductions are used for proposed payment reductions, an explanation of how the percentage reductions for preservice, intra-service, and post-service work were determined and calculated;

''(IV) other data used to determine a reduction; and

''(V) a demonstration that the Secretary has consulted with practicing radiologists to gain knowledge of how radiologists interpret studies of multiple body parts on the same individual on the same day.''.

(B) CONFORMING AMENDMENT.—Section 220(i) of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 1395w–4 note) is repealed.

(b) PAYMENT INCENTIVE FOR TRANSITION UNDER HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395(t)(16)) is amended by adding at the end the following new subparagraph:

''(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

''(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

''(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

''(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

''(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

''(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this paragraph—

''(I) shall not be considered an adjustment under paragraph (2)(E); and

''(II) shall not be implemented in a budget neutral manner.

''(iv) IMPLEMENTATION.—In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.''.

**SEC. 4004. TREATMENT OF INFUSION DRUGS FURNISHED THROUGH DURABLE MEDICAL EQUIPMENT.**

Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—

(1) in subparagraph (C), by inserting ''(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)'' after ''2005''; and

(2) in subparagraph (D)—

(A) by striking ''infusion drugs'' and inserting ''infusion drugs or biologicals'' each place it appears; and

(B) in clause (i)—

(i) by striking ''2004'' and inserting ''2004, and before January 1, 2017''; and

(ii) by striking ''for such drug''.

**SEC. 4005. EXTENSION AND EXPANSION OF PRIOR AUTHORIZATION FOR POWER MOBILITY DEVICES (PMDS) AND ACCESSORIES AND PRIOR AUTHORIZATION AUDIT LIMITATIONS.**

Section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) is amended—

(1) in paragraph (15), by adding at the end the following new subparagraph:

''(D) LIMITATION ON AUDITS AFTER ADVANCE DETERMINATION.—A claim for an item that has received a provisional affirmation under an advance determination under this paragraph or a prior authorization under paragraph (23) shall not be subject to review under section 1893(h) but may be subject to audits for potential fraud, inappropriate utilization, changes in billing patterns, or information that could not have been considered during the advance determination (such as proof of item delivery).''; and

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

''(23) PRIOR AUTHORIZATION FOR POWER MOBILITY DEVICES (PMDS) AND ACCESSORIES.—Not later than 90 days after the date of the enactment of this paragraph, the Secretary shall, using funds provided under paragraph (2) of section 402(a) of the Social Security Amendments of 1967 and other funds available to the Secretary—

''(A) extend at least through August 31, 2018, the PMD Prior Authorization Demonstration (being conducted under paragraph (1)(J) of such section);

''(B) begin to expand, as appropriate, such demonstration to include additional power mobility devices and accessories as part of initial claims for payment under this part for such devices; and

''(C) begin to expand such demonstration to such additional States or geographic areas as may be appropriate.''.

**SEC. 4006. CIVIL MONETARY PENALTIES FOR VIOLATIONS RELATED TO GRANTS, CONTRACTS, AND OTHER AGREEMENTS.**

(a) IN GENERAL.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended by adding at the end the following new subsection:

''(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (r)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary of Health and Human Services provides funding—

''(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)(6)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

''(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

''(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

''(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

''(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than $10,000 for each specified claim; in cases under paragraph (2), not more than $50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than $50,000 for each false record or statement; in cases under paragraph (4), not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than $15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary Health and Human Services described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary of Health and Human Services may make a determination in the same proceeding to exclude the

person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

''(p) The provisions of subsections (c), (d), and (g) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a).

''(q) With respect to a penalty or assessment under subsection (o), the Inspector General of the Department is authorized to receive, and to retain for current use, such amounts of such penalty or assessment as are necessary to provide reimbursement for the costs of conducting investigations and audits with respect to such subsection and for monitoring compliance plans with respect to such subsection when such penalty or assessment is ordered by a court, voluntarily agreed to by the payor, or otherwise. Funds received by such Inspector General as reimbursement under the preceding sentence shall be deposited to the credit of the appropriations from which initially paid, or to appropriations for similar purposes currently available at the time of deposit, and shall remain available for obligation for 1 year from the date of the deposit of such funds.

''(r) For purposes of this subsection and subsections (o), (p), and (q):

''(1) The term 'Department' means the Department of Health and Human Services.

''(2) The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

''(3) The term 'other agreement' includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or sub-award (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

''(4) The term 'program beneficiary' means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary of Health and Human Services provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

''(5) The term 'recipient' includes a sub-recipient or subcontractor.

''(6) The term 'specified claim' means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

''(A) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

''(B) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department's behalf or to advance a Department program or interest, and if the Department—

''(i) provides or has provided any portion of the money or property requested or demanded; or

''(ii) will reimburse such contractor, grantee or other recipient for any portion of the money or property which is requested or demanded.

''(7) The term 'specified State agency' means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary of Health and Human Services.

''(s) For purposes of subsection (o), the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.''.

(b) CONFORMING AMENDMENTS.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended—

(1) in subsection (d)—

(A) in paragraph (1), by inserting ''or specified claims'' after ''claims'';

(B) in paragraph (2), by inserting ''or specified claims'' after ''claims'';

(2) in subsection (e), by inserting ''or specified claim'' after ''claim''; and

(3) in subsection (f)—

(A) by inserting ''or specified claim (as defined in subsection (r)(6))'' after ''district where the claim'';

(B) by inserting ''(or, with respect to a person described in subsection (o), the person)'' after ''claimant'';

(C) by inserting ''that are not received by the Inspector General of the Department of Health and Human Services under subsection (q) as reimbursement'' after ''amounts recovered''; and

(D) by inserting ''(or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (r)(7))'' after ''or a State agency''.

### Subtitle B—Other Reforms

**SEC. 4041. SPR DRAWDOWN.**

(a) DRAWDOWN AND SALE.—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), except as provided in subsection (b) the Secretary of Energy shall draw down and sell—

(1) 4,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2018;

(2) 5,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2019;

(3) 8,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2020;

(4) 8,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2021;

(5) 10,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2022;

(6) 15,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2023;

(7) 15,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2024; and

(8) 15,000,000 barrels of crude oil from the Strategic Petroleum Reserve during fiscal year 2025.

Amounts received for a sale under this subsection shall be deposited in the General Fund of the Treasury during the fiscal year in which the sale occurs.

(b) EMERGENCY PROTECTION.—The Secretary shall not draw down and sell crude oil under this section in amounts that would result in a Strategic Petroleum Reserve that contains an inventory of petroleum products representing less than 90 days of emergency reserves, based on the average daily level of net imports of crude oil and petroleum products in the previous calendar year.

(c) PROCEEDS.—Proceeds from a sale under this section shall be deposited into the general fund of the Treasury of the United States.

### Subtitle C—Miscellaneous

**SEC. 4061. LYME DISEASE AND OTHER TICK-BORNE DISEASES.**

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following new part:

**''PART W—LYME DISEASE AND OTHER TICK-BORNE DISEASES**

**''SEC. 399OO. RESEARCH.**

''(a) IN GENERAL.—The Secretary shall conduct or support epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases.

''(b) BIENNIAL REPORTS.—The Secretary shall ensure that each biennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to Lyme disease and other tick-borne diseases, including an assessment of the progress made in improving the outcomes of Lyme disease and such other tick-borne diseases.

**''SEC. 399OO–1. WORKING GROUP.**

''(a) ESTABLISHMENT.—The Secretary shall establish a permanent working group, to be known as the Interagency Lyme and Tick-Borne Disease Working Group (in this section and section 399OO–2 referred to as the 'Working Group'), to review all efforts within the Department of Health and Human Services concerning Lyme disease and other tick-borne diseases to ensure interagency coordination, minimize overlap, and examine research priorities.

''(b) RESPONSIBILITIES.—The Working Group shall—

''(1) not later than 24 months after the date of enactment of this part, and every 24 months thereafter, develop or update a summary of—

''(A) ongoing Lyme disease and other tick-borne disease research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, intervention, and access to services and supports for individuals with Lyme disease or other tick-borne diseases;

''(B) advances made pursuant to such research;

''(C) the engagement of the Department of Health and Human Services with persons that participate at the public meetings required by paragraph (5); and

''(D) the comments received by the Working Group at such public meetings and the Secretary's response to such comments;

''(2) ensure that a broad spectrum of scientific viewpoints is represented in each such summary;

''(3) monitor Federal activities with respect to Lyme disease and other tick-borne diseases;

''(4) make recommendations to the Secretary regarding any appropriate changes to such activities; and

''(5) ensure public input by holding annual public meetings that address scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

''(c) MEMBERSHIP.—

''(1) IN GENERAL.—The Working Group shall be composed of a total of 14 members as follows:

''(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of—

''(i) the Office of the Assistant Secretary for Health;

''(ii) the Food and Drug Administration;

''(iii) the Centers for Disease Control and Prevention;

''(iv) the National Institutes of Health; and

''(v) such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

''(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

''(i) Physicians and other medical providers with experience in diagnosing and treating Lyme disease and other tick-borne diseases.

''(ii) Scientists or researchers with expertise.

''(iii) Patients and their family members.

''(iv) Nonprofit organizations that advocate for patients with respect to Lyme disease and other tick-borne diseases.

''(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

''(2) APPOINTMENT.—The members of the Working Group shall be appointed by the Secretary, except that of the non-Federal public members under paragraph (1)(B)—

*''(A) one shall be appointed by the Speaker of the House of Representatives; and*

*''(B) one shall be appointed by the majority leader of the Senate.*

*''(3) DIVERSITY OF SCIENTIFIC PERSPECTIVES.—In making appointments under paragraph (2), the Secretary, the Speaker of the House of Representatives, and the majority leader of the Senate shall ensure that the non-Federal public members of the Working Group represent a diversity of scientific perspectives.*

*''(4) TERMS.—The non-Federal public members of the Working Group shall each be appointed to serve a 4-year term and may be reappointed at the end of such term.*

*''(d) MEETINGS.—The Working Group shall meet as often as necessary, as determined by the Secretary, but not less than twice each year.*

*''(e) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act.*

*''(f) REPORTING.—Not later than 24 months after the date of enactment of this part, and every 24 months thereafter, the Working Group—*

*''(1) shall submit a report on its activities, including an up-to-date summary under subsection (b)(1) and any recommendations under subsection (b)(4), to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate;*

*''(2) shall make each such report publicly available on the website of the Department of Health and Human Services; and*

*''(3) shall allow any member of the Working Group to include in any such report minority views.*

***''SEC. 399OO–2. STRATEGIC PLAN.***

*''Not later than 3 years after the date of enactment of this section, and every 5 years thereafter, the Secretary shall submit to the Congress a strategic plan, informed by the most recent summary under section 399OO–1(b)(1), for the conduct and support of Lyme disease and tick-borne disease research, including—*

*''(1) proposed budgetary requirements;*

*''(2) a plan for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms and chronic or persistent infection and co-infections;*

*''(3) a plan for improving diagnosis, treatment, and prevention;*

*''(4) appropriate benchmarks to measure progress on achieving the improvements described in paragraphs (2) and (3); and*

*''(5) a plan to disseminate each summary under section 399OO–1(b)(1) and other relevant information developed by the Working Group to the public, including health care providers, public health departments, and other relevant medical groups.''.*

*(b) NO ADDITIONAL AUTHORIZATION OF APPROPRIATIONS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section and the amendment made by this section, and this section and such amendment shall be carried out using amounts otherwise available for such purpose.*

The Acting CHAIR. No further amendment to the bill, as amended, shall be in order except those printed in House Report 114–193. Each such further amendment may be offered only in the order printed in the report, by a Member designated in the report, shall be considered read, shall be debatable for the time specified in the report equally divided and controlled by the proponent and an opponent, shall not be subject to amendment, and shall not be subject to a demand for division of the question.

AMENDMENT NO. 1 OFFERED BY MR. BRAT

The Acting CHAIR. It is now in order to consider amendment No. 1 printed in House Report 114–193.

Mr. BRAT. Madam Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 5, beginning on line 6, strike paragraph (1) and insert the following:

(1) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the NIH and Cures Innovation Fund $1,860,000,000 for each of fiscal years 2016 through 2020.

Page 13, beginning on line 3, strike subsection (f).

The Acting CHAIR. Pursuant to House Resolution 350, the gentleman from Virginia (Mr. BRAT) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Virginia.

Mr. BRAT. Madam Chair, I yield myself 2 minutes.

I rise to support my amendment against the creation of a new mandatory program.

Some on the other side have called my amendment a poison pill. I consider that a compliment. A poison pill was reserved for the man who brought human reason to Greece. I similarly would like to bring a bit of reason to bear on the budget process of the United States.

We are currently $127 trillion light on mandatory spending at present. This means by 2027, all Federal revenues will be spent on only mandatory programs. This is a disaster.

My children right now are 13 and 16. By the time they are about 30, we will have zero dollars for running the government because all dollars will be spent on these mandatory programs.

We all want cures, and I am for the underlying bill—make no mistake—but in economics, rationality requires that we rank our preferences in order and fund the best programs. This is one of them.

There is no issue finding $2 billion out of a $3.5 trillion budget, but currently, there is no discipline up here in this city. We just fund everything and hand the bill to the next generation.

Every mandatory program starts off with high hopes, but go to the trustee reports on the major mandatory programs today, and you will find that they are all insolvent by around 2030 as well.

Today, you will hear all sorts of fancy terminology about pay-fors and oil reserves and deficits, but don't be fooled. Our annual deficit spending is about $500 billion right now and on its way to a trillion in a few more years.

We are off course on every front. We always talk about the children, but at present, we are handing our children $18 trillion in debt and another $127 trillion in mandatory programs.

You want the truth? The children are the only group up here on Capitol Hill without a lobbyist, and that is why they are getting trashed.

If you want a cure, go to a doctor; but if you want to clean up the U.S. economy, please consult an economist or two. The numbers in the story I have given are not in dispute. The only issue is whether we have the resolve to balance our budgets and leave our children a brighter day.

I urge a ''yes'' vote on the amendment, and I reserve the balance of my time.

Mr. UPTON. Madam Chair, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman from Michigan is recognized for 5 minutes.

Mr. UPTON. Madam Chair, I yield myself 1 minute.

Madam Chair, I strongly oppose this amendment because making this funding discretionary and subject to later appropriations is critically shortsighted for two reasons.

We thought that this might be a placebo amendment, but yes, it really is a poison pill that would undermine the victories the Republicans secured in 21st Century Cures, including transformative regulatory reforms at FDA and permanent entitlement savings in both Medicare and Medicaid.

Second, supporting the amendment means voting against the critical balance that we found to pay for these investments using mandatory savings in a way that reduces the deficit in working with the Appropriations Committee.

According to the CBO, this bill will reduce the deficit by some $500-plus million over the first 10 years, and we conservatively estimate that it cuts $7 billion in the second decade.

Third, more than 100 organizations have joined together to oppose this amendment. They represent a cross-section of organizations, including patient groups, universities, veterans, innovators, and medical providers.

I would ask my colleagues to vote ''no'' on the Brat amendment, and I reserve the balance of my time.

Mr. BRAT. Madam Chair, I yield 1 minute to the gentleman from California (Mr. MCCLINTOCK).

Mr. MCCLINTOCK. Madam Chair, the greatest danger facing our country is a national debt that now exceeds our entire economy. This year, we spent $230 billion just to pay interest on that debt.

The CBO warns that, on our current trajectory, interest payments will exceed our entire defense budget just 8 years from now. Behold the chaos in Greece, and consider that our Nation is not far behind.

Congress has labored mightily to enact a budget that saves us from this dismal future, but having set that course, we must stay that course. The underlying bill makes many worthy changes in law, but it evades the discipline the budget requires to save our country from the fate of Greece.

Mr. BRAT's amendment places this bill back within the boundaries of the

budget without budget gimmickry and can be easily accommodated by cutting lower priority spending. The question before us is whether we will fund our priorities responsibly or follow Greece to ruin.

Mr. UPTON. Madam Chair, I yield 1 minute to the gentleman from New Jersey (Mr. PALLONE), my friend and the ranking member of the Energy and Commerce Committee.

Mr. PALLONE. Madam Chairwoman, if we want to speed the pace of innovation and development of new treatment and cures, we must increase funding to NIH.

We all know the numbers. NIH has $8.2 billion less to spend in fiscal year 2015 than it had in fiscal year 2003, when adjusted for inflation. That funding erosion has reduced the application success rate, leaving promising research ideas to languish due to lack of funding. It has also left many young and midcareer scientists wondering whether they can support themselves through a career in biomedical research.

The NIH and Cures innovation fund aims to reverse that trajectory by providing $8.7 in mandatory funding over a 5-year period. Providing mandatory funding through the innovation fund would ensure that NIH has increased funding to make critical investments in research that will help us deliver on the promise of the 21st Century Cures Act, to accelerate the pace of scientific advancement that leads to life-improving and lifesaving treatments and cures.

Madam Chairwoman, without this funding stream, H.R. 6, I think, will be ineffective; and I urge Members to reject the Brat amendment.

I am in strong opposition to the Brat amendment.

Mr. BRAT. Madam Chair, I yield 1 minute to the gentleman from Pennsylvania (Mr. PERRY).

Mr. PERRY. Madam Chair, I support the 21st Century Cures Act underlying text, and I thank the chairman. It has been masterful work.

And who wouldn't? Who doesn't want to do something in Congress about these horrific, debilitating diseases that plague our families? We all do, but targeting additional NIH funding for cures remains critical. We absolutely all support it, but I don't support how we are paying for it—because we are not.

Many of us who preach about the problems associated with mandatory spending have used the same board I use in my townhall meetings. People have seen this, and they know where we are headed. It is the biggest driver of future debt.

We are creating more mandatory spending as we speak, and we are placing the burden of paying for it on people that aren't even alive yet. It is incredible.

I have championed the need for providing a cure for rare diseases and the things that plague members of our citizenry since I have been here. One thing missing from this bill is the legalization of CBD. This act seems to forget about children with epilepsy and their desperate need for a cure.

I ask for support of this amendment simply to shift the money from mandatory to discretionary and force us to make the tough decisions we came here to make.

Mr. UPTON. Madam Chair, I yield 1 minute to the gentleman from Texas (Mr. GENE GREEN), the ranking member on the Health Subcommittee.

Mr. GENE GREEN of Texas. Madam Chair, I thank the chair of the committee for yielding.

If you like how we are doing research right now, then you need to support the Brat amendment because we are not funding research adequately. Everybody says that. That is why there are so many supporters in the private sector and also 230 cosponsors of this bill.

The sponsor of the amendment called it a poison pill. I don't think there is anything more appropriate than that for this amendment, because this bill is intended to save people's lives and to make people have a better lifestyle. When you take a poison pill, you die. That is what will happen if we do not do mandatory spending in this bill.

This bill is paid for. You can rail against mandatory spending, but there are cuts in other parts of the Federal budget that will pay for this. Don't let anybody delude themselves into thinking that this is increasing spending.

We are cutting spending while we are trying to redirect it to the NIH and FDA to have these new therapies and also get them through the approval process.

Mr. BRAT. Madam Chair, I yield 1 minute to the gentleman from California (Mr. ISSA).

Mr. ISSA. Madam Chair, in this short 1 minute, I will close by reminding people that Ronald Reagan so notably said: ''Nothing lasts longer than a temporary government program.''

This is a permanent program that is only paid for in offsets at one-quarter what it costs, and that is an estimate. If the cost goes up, it will spend even more.

Understand that we are selling the strategic petroleum reserves to pay for the vast majority of this 5-year program, and then we are taking 10 years to pay for the remainder.

This is a gimmick. It is not paid for. Do not be fooled. If you are a fiscal conservative, you must consider this not a permanent entitlement and vote for the Brat amendment because, if you don't, what you are doing is unfairly adding to this debt.

I would vote for this if it was paid for. Madam Chair, it is not paid for. It is a fraudulent pay-for by any possible means of this body.

Please, vote for the Brat amendment because this is not a pay-for entitlement.

Mr. BRAT. I yield back the balance of my time.

□ 0930

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR. Members are reminded to refrain from trafficking the well while another Member is under recognition.

Mr. UPTON. Madam Chair, I yield to the gentleman from Pennsylvania (Mr. FATTAH) for a unanimous consent request.

(Mr. FATTAH asked and was given permission to revise and extend his remarks.)

Mr. FATTAH. Madam Chair, I rise in favor of the underlying bill and in opposition to this poison-pill amendment.

Mr. UPTON. Madam Chairman, let me just say to the gentleman from California, it is paid for. CBO has certified that all of it is paid for.

Madam Chair, I yield the balance of my time to the gentlewoman from Indiana (Mrs. BROOKS), a member of the committee.

Mrs. BROOKS of Indiana. Madam Chairman, I rise today to voice my unwavering support for 21st Century Cures and vehement opposition to the amendment before us.

What the authors of this specific amendment fail to grasp is that 21st Century Cures will actually advance real conservative reforms to the entitlement system that will reduce the deficit and save our Nation billions of dollars.

There are real cuts in this bill. CBO has scored it. And since when are we ignoring CBO?

These reforms didn't happen overnight. This legislation is the result of well over a year of thoughtful and purposeful negotiations.

Unfortunately, the backers of this amendment cannot see the forest for the trees. Contrary to the misinformation that led them to craft it, the innovation fund is not forever on autopilot. It sunsets after 5 years. Those are 5 solid years where we can recruit the top minds to investigate cures that will change and save lives, yes, the lives of our children and the next generation.

I urge my colleagues to stand with me in opposition, in addition to the over 100 groups who are opposed to the Brat amendment, groups of patient groups, universities, veterans, innovators, medical providers. Every one of these groups urges Members to vote ''no'' on the Brat amendment, and I urge my colleagues to do the same.

Mr. UPTON. Madam Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Virginia (Mr. BRAT).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. BRAT. Madam Chair, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Virginia will be postponed.

AMENDMENT NO. 2 OFFERED BY MR. YOUNG OF INDIANA

The Acting CHAIR. It is now in order to consider amendment No. 2 printed in House Report 114–193.

Mr. YOUNG of Indiana. Madam Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 6, line 19, strike ''409K'' and insert ''409L''.

Page 15, after line 6, insert the following:

**SEC. 1002. PRIZE COMPETITIONS.**

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. PRIZE COMPETITIONS FOR IMPROVING HEALTH OUTCOMES AND REDUCING FEDERAL EXPENDITURES.**

''(a) ESTABLISHMENT; GOALS.—The Director of NIH shall establish and implement an Innovation Prizes Program for one or both of the following goals:

''(1) Identifying and funding areas of biomedical science that could realize significant advancements through the creation of a prize competition.

''(2) Improving health outcomes, particularly with respect to human diseases and conditions for which public and private investment in research is disproportionately small relative to Federal Government expenditures on prevention and treatment activities, thereby reducing Federal expenditures on health programs.

''(b) DESIGN OF PRIZE COMPETITIONS.—Not later than 6 months after the date of enactment of this section, the Director of NIH shall—

''(1) design prize competitions—

''(A) to cooperate with competitors to realize innovations to identify and address areas of biomedical science that could realize significant advancements through the creation of a prize competition; and

''(B) to award one or more prizes—

''(i) if appropriate, at the beginning of or during the competitions, to the competitors whose innovations are most promising or demonstrate progress; and

''(ii) at the end of the competitions, to the competitors whose innovations prove to be the best solutions;

''(2) ensure that the design of such competitions—

''(A) is realistic, given the amount of funds to be awarded as prizes;

''(B) does not reflect any bias concerning the type of innovations which will prove to be the best solutions; and

''(C) allows any person to participate as a competitor without regard to the person's place of incorporation, primary place of business, citizenship, and residency, as applicable; and

''(3) submit to the Congress a report on the design of such competitions.

''(c) INNOVATION PRIZES ADVISORY BOARD.—

''(1) ESTABLISHMENT.—The Director of NIH shall establish and maintain a board, to be known as the I-Prize Board, to advise and assist the Director of NIH in carrying out this section.

''(2) COMPOSITION; TERMS.—

''(A) COMPOSITION.—The I-Prize Board shall be composed of 9 voting members as follows:

''(i) The Director of NIH (or the Director's designee).

''(ii) Four members appointed by the Director of NIH.

''(iii) One member appointed by the Speaker of the House of Representatives.

''(iv) One member appointed by the majority leader of the Senate.

''(v) One member appointed by the minority leader of the House of Representatives.

''(vi) One member appointed by the minority leader in the Senate.

''(B) INCLUSION OF CERTAIN EXPERTS.—The members of the I-Prize Board appointed under clauses (ii) through (vi) of subparagraph (A) shall, collectively, include medical, economic, budgetary, innovation, or venture capital experts from for-profit and not-for-profit private sector entities with experience in awarding prizes similar to the prizes under this section.

''(C) TERMS.—The appointed members of the I-Prize Board shall each be appointed for a term of 5 years.

''(D) APPOINTMENT OF INITIAL MEMBERS.—The initial appointed members of the I-Prize Board shall be appointed not later than 120 days after the date of enactment of this section.

''(3) RESPONSIBILITIES.—The I-Prize Board shall be responsible for advising the Director of NIH by—

''(A) identifying areas of biomedical science that could realize significant advancements through the creation of a prize competition;

''(B) making recommendations on establishing the criteria for prize competitions under this section;

''(C) making recommendations on which business organizations or other entities have successfully met the criteria established for the prize competition; and

''(D) gaining insight from researchers, health economists, academia, and industry on how to conduct prize competitions.

''(d) RESTRICTIONS.—

''(1) NO FINANCIAL CONFLICTS OF INTEREST.—Any member of the I-Prize Board, and any officer or employee of the National Institutes of Health responsible for carrying out this section, may not personally or substantially participate in the consideration or determination by the I-Board of any matter that would directly or predictably effect any financial interest of—

''(A) the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual; or

''(B) of any business organization or other entity—

''(i) of which the individual is an officer or employee;

''(ii) with respect to which the individual is negotiating for employment; or

''(iii) in which the individual has any other financial interest.

''(2) NO AWARDS TO COMPETITORS LIKELY TO REAP FINANCIAL BENEFIT FROM INNOVATION.—The Director of NIH may not, with respect to an innovation, award a prize under this section to any individual or entity that has a vested financial interest in any product or procedure that is likely to be developed or marketed because of such innovation.

''(e) PROCESS OF AWARD.—The full monetary amount of any prize awarded under this section shall be made available to the prize winner not later than 90 days after the date of such award.

''(f) SIMULATION.—The Director of NIH may—

''(1) award one or more contracts—

''(A) to perform a simulation of the prize competitions to be conducted under this section, based on the designs developed under subsection (b); and

''(B) to use the simulation to assess the effectiveness of the design; and

''(2) not later than 4 months after awarding such one or more contracts, submit to the Congress a report on the results of the simulation and assessment.

''(g) IMPLEMENTATION OF PRIZE COMPETITIONS.—

''(1) IN GENERAL.—The Director of NIH may enter into an agreement with one or more entities described in section 501(c), and exempt from tax under section 501(a), of the Internal Revenue Code of 1986 to implement prize competitions based on the designs developed under subsection (b).

''(2) MINIMUM PERCENTAGE FOR PRIZES.—If the Director of NIH enters into an agreement under paragraph (1) to provide funds or other assistance (including in-kind contributions and testing or other technical support) to an entity to implement a prize competition under this section—

''(A) not more than 15 percent of such assistance shall be for administration of the prize competition; and

''(B) not less than 85 percent of such assistance shall be for activities in direct support of competitors such as demonstration, testing, education, and prize awards.

''(h) TRACKING; REPORTING.—The Director of NIH shall—

''(1) collect information on—

''(A) the medical efficacy of innovations funded through the prize competitions under this section; and

''(B) the actual and potential effect of the innovations on Federal expenditures; and

''(2) not later than one year after the conclusion of the prize competitions under this section, and not later than the end of each of the 4 succeeding years, submit to the Congress a report on the information collected under paragraph (1).

''(i) INTELLECTUAL PROPERTY.—

''(1) PROHIBITION ON THE GOVERNMENT ACQUIRING INTELLECTUAL PROPERTY RIGHTS.—The Federal Government may not gain an interest in intellectual property developed by a participant in a prize competition under this section without the written consent of the participant.

''(2) LICENSES.—The Federal Government may negotiate a license for the use of intellectual property developed by a participant in a prize competition under this section.''.

Page 26, line 11, insert '', as amended by section 1002 of this Act,'' after ''et seq.)''

Page 26, line 13, strike ''**409K**'' and insert ''**409L**''.

The Acting CHAIR. Pursuant to House Resolution 350, the gentleman from Indiana (Mr. YOUNG) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Indiana.

Mr. YOUNG of Indiana. Madam Chair, I want to thank Mr. UPTON for his work on the 21st Century Cures Act, finally making medical breakthroughs a national priority. With this bill, we will extend the longevity and improve the lives of millions of Americans now and in the future. And in the process, we will dramatically reduce the taxpayer money we spend to treat sick Americans.

With all that in mind, I want to highlight an amendment that my thoughtful and hard-working colleague, Dr. HARRIS of Maryland, and I have worked on, and I urge my colleagues' support. This amendment would create within NIH a structure for a medical prize program.

The United States is currently spending $632 billion per year through just one program, Medicare, to cover health services of qualified beneficiaries. To help lower taxpayer costs as well as

improve patient outcomes, this amendment will offer modest monetary rewards to those outside of government who can develop significant medical breakthroughs.

The medical prize program will encourage scientists and entrepreneurs, especially those that don't typically receive NIH grants, to develop cost-saving, life-improving cures for some of the most debilitating diseases that afflict our young and old.

With those thoughts in mind, I urge your support of the amendment, and I reserve the balance of my time.

Mr. PALLONE. Madam Chair, I claim time in opposition to the amendment.

The Acting CHAIR. The gentleman from New Jersey is recognized for 5 minutes.

Mr. PALLONE. Madam Chair, while I appreciate the efforts of the amendment's sponsors, I cannot support the Young-Harris amendment.

As currently drafted, the amendment threatens to undermine the independent peer review process that is the bedrock of NIH funding by injecting politics into the development and implementation of the prize competition.

The amendment would create an innovation prize advisory board to assist the NIH Director in carrying out the prize competition that is composed of nine members, four of which are politically appointed. It would also take away resources from existing research grant programs and other research efforts at NIH.

It would require NIH to put money on reserve for the prize competition, money that would go back into the Treasury instead of funding research if the prize is not won in a given fiscal year.

While I am not opposed to the potential of setting up a prize-like system—in fact, NIH already has such authority—I would prefer to work with the sponsors on the language to find a more appropriate way to accomplish their goals. Therefore, I would urge my colleagues to vote ''no.''

Mr. UPTON. Will the gentleman yield?

Mr. PALLONE. I yield to the gentleman from Michigan.

Mr. UPTON. I would just like to say as chairman of the committee that I look forward to working with the gentleman on the language. I think this is an important amendment. I am going to speak in favor of it on Mr. YOUNG's time in a moment.

But I just want to pledge that we will work with you on language that certainly we can all accept, knowing that the goal is a very good one.

Mr. PALLONE. I appreciate that. Thank you.

I reserve the balance of my time.

Mr. YOUNG of Indiana. Madam Chair, I would just add that the purpose of this amendment, obviously, well received on both sides of the aisle—perhaps there are particulars we can work on—is to catalyze more innovation among the thousands, tens of thousands of entrepreneurs and innovators around this country, really around the world.

If we can get more minds collectively thinking about medical breakthroughs, about actually curing diseases, as a preventative measure, we can save significant amounts of money in the long term. We can dramatically improve lives in the shorter term.

This is a model that opens up Federal Government funding as a reward for these innovations to our Nation's innovators, our entrepreneurs, our doers.

Right now, the NIH grant process is suboptimal for a lot of these individuals. I can speak to one individual. He used to be my neighbor, Fazni Aziz, of Bloomington, Indiana. He is a Thomas Edison-like figure, and he used to have a workshop right next to his house. He developed medical devices on his own and sold them off to larger companies.

Fazni Aziz would not receive an NIH grant. He will never apply for one. He doesn't have time to apply for one. Would he target a medical innovation on account of a prize that is offered? Indeed. We have consulted with him.

So for the people like Fazni Aziz around the world that can help Americans, we have developed this prize program.

Madam Chair, I yield 1 minute to the gentleman from Michigan (Mr. UPTON), the chairman.

Mr. UPTON. Madam Chair, I do rise in support of this important amendment that, with Mr. YOUNG and Dr. HARRIS, would authorize the NIH to conduct a prize program. The intent of the amendment is, in fact, to incentivize health innovation by offering competitors the chance to win a prize for developing breakthroughs. We ought to be encouraging that.

Importantly, individuals who win the prize competition would keep all of the intellectual property rights. I think that is very important.

So I would ask my colleagues to support the amendment. I look forward to working with both sides of the aisle to make sure that we can, in fact, perfect it as we get to the end of the cycle and, ultimately, to the President's desk.

Mr. PALLONE. Madam Chair, I yield back the balance of my time.

Mr. YOUNG of Indiana. Madam Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Indiana (Mr. YOUNG).

The amendment was agreed to.

AMENDMENT NO. 3 OFFERED BY MS. LEE

The Acting CHAIR. It is now in order to consider amendment No. 3 printed in House Report 114–193.

Ms. LEE. Madam Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 13, strike lines 8 through 13 (and make such conforming changes as may be necessary).

The Acting CHAIR. Pursuant to House Resolution 350, the gentlewoman from California (Ms. LEE) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from California.

Ms. LEE. Madam Chair, I am very pleased to offer this amendment with my colleagues, two great women, Representative JAN SCHAKOWSKY and Representative YVETTE CLARKE.

Our amendment is very simple. It would strike a provision in this bill that applies to any policy riders included in the annual Labor, Health and Human Services and Agricultural appropriations bills to the new National Institutes of Health funds and the Federal Drug Administration funds included in H.R. 6, the 21st Century Cures Act.

This provision reiterates the current law restrictions on appropriations bills, like the Hyde amendment, which is restrictive and discriminatory against low-income women to make their own reproductive healthcare decisions. Now this would apply to this new fund created for the NIH in this bill.

Let's be clear what this is really about. It is yet another attempt to insert abortion restrictions and other inappropriate riders into an unrelated bill.

This is a bill to increase biomedical innovative research. The 21st Century Cures Act should have been a noncontroversial, bipartisan effort. But anti-choice leaders could not help but add this to the bill after—mind you, after—it had passed out of committee on a bipartisan vote. It is really outrageous and part of a larger effort to force the inclusion of these harmful Hyde restrictions in multiple and unrelated bills.

We know that these dangerous policies disproportionately affect low-income women and women of color. So our amendment is about removing these inappropriate and consistent attacks on a woman's right to make her own healthcare decisions.

I urge my colleagues to vote ''yes'' to protecting a woman's right to choose.

I reserve the balance of my time.

Mr. UPTON. Madam Chair, I claim time in opposition to the amendment.

The Acting CHAIR. The gentleman from Michigan is recognized for 5 minutes.

Mr. UPTON. Madam Chair, I yield 2 minutes to the gentleman from Pennsylvania (Mr. PITTS), the chairman of the Health Subcommittee.

Mr. PITTS. Madam Chair, I rise in opposition to the Lee amendment. If passed, this amendment would allow the National Institutes of Health to use taxpayer dollars to conduct experiments involving abortion or to hone abortion techniques.

Let me be clear. The underlying bill simply applies current Federal health policies that have been approved by both Republican and Democrat majorities for decades to new funds appropriated in the Cures bill. It is nothing

more than the status quo applied to new funding.

There is a reason why these policies are the status quo. Americans do not want their tax dollars used to destroy unborn lives. A poll conducted just this January showed 68 percent of Americans oppose taxpayer funding for abortion.

H.R. 6, the 21st Century Cures Act, is about finding cures and protecting the health and well-being of Americans. It would be a terrible injustice if a bill designed to save lives were to become a conduit for the destruction of the most vulnerable, the voiceless unborn who are still too young to be heard crying out for help.

I urge all Members to oppose this amendment.

Ms. LEE. Madam Chair, I yield 1 minute to the gentlewoman from Illinois (Ms. SCHAKOWSKY), a cosponsor of this amendment.

Ms. SCHAKOWSKY. Madam Chair, I am proud to join Congresswoman LEE and Congresswoman CLARKE in offering this amendment.

Our amendment would strike the policy riders that were added to the 21st Century Cures Act after it passed unanimously the Energy and Commerce Committee, 51–0.

□ 0945

Most notably, our amendment would remove the unnecessary addition of the Hyde amendment. The Hyde amendment is a discriminatory policy that denies millions of women the full range of healthcare choices, and it has no business being included in this legislation.

It is time for us to stop using these bills as a way to discriminate against women. Going forward, as far as I am concerned, I will not support any bill that adds such language.

It is time for us to stop taking away health services from low-income women, from women serving in the military, from Federal employees, and from every woman who relies on the Federal Government for her health insurance. All women, regardless of their incomes and what insurance they have, deserve to make their own health choices.

This harmful provision is unrelated to the goals of this otherwise bipartisan landmark legislation, and I ask that Members vote in favor of our amendment.

Mr. UPTON. Madam Chair, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. BLACKBURN), the vice chair of the Energy and Commerce Committee.

Mrs. BLACKBURN. Madam Chairman, I do rise in opposition to this amendment. I think it is important to realize a couple of things.

The American people have spoken out on this issue. Sixty-eight percent of all Americans oppose taxpayer dollars being used for abortions. Seventy-one percent of all millennials oppose this.

What the Lee amendment would do is strip away bipartisan agreements that we use in appropriations bills. This is not something that is new. It is not language that is new.

The Hyde amendment and the Hyde language has been around for a very long time. The Lee amendment would reverse important limitations to protect these taxpayer dollars.

I have mentioned the opposition to abortion. There is also prohibition for the use of public funds to advocate for gun control, limit Federal grants from being awarded to tax cheats. Do we really want tax cheats being able to get Federal dollars?

It limits extravagant conference spending for public employees. Do we really want them to be able to waste these dollars? Of course not. Of course not.

That is why this language is in the bill. I encourage my colleagues to vote against the Lee amendment.

Ms. LEE. Madam Chair, I yield 1 minute to the gentlewoman from New York (Ms. CLARKE), another cosponsor of this amendment.

Ms. CLARKE of New York. Madam Chair, today I rise in support of the Lee-Schakowsky-Clarke amendment, and I thank them for their leadership in advancing this amendment.

H.R. 6, the 21st Century Cures Act, which received unanimous support from members of the Energy and Commerce Committee, demonstrates that Democrats and Republicans can work together in an effort to develop medicines, treatments, and cures that will save lives.

Unfortunately, our bipartisan consensus has been undermined by a last-minute inclusion of an antichoice provision in this bill. This new provision, which is a cynical poison pill and lacks germaneness to the underlying bill, would place restrictions on women's ability to access health services.

It fails to respect the personal dignity of women by limiting their healthcare options. It interferes with the private relationship between a woman and her doctor, and it denies women what I believe is their fundamental right to have control over their own bodies.

I am deeply concerned that this new provision will only serve as confirmation for the skeptics, who believe that Members of Congress are simply unable to work with each other in the public interest.

We have the opportunity to disprove the skeptic by voting for this amendment and stripping out this provision.

Mr. UPTON. Madam Chair, could I ask how much time is remaining on each side?

The Acting CHAIR. The gentleman from Michigan has 2 minutes remaining, and the gentlewoman from California has 1 minute remaining.

Mr. UPTON. Madam Chair, I yield myself such time as I may consume.

Madam Chair, I do rise in opposition to the Lee amendment. The Lee amendment would strip dozens of important limitations and restrictions that routinely apply to funding appropriated by Congress with bipartisan support and through the normal appropriation process.

For example, this amendment would strike limitations that, as has been noted, would prevent taxpayer dollars from being used to destroy life. And, frankly, they have been in place since the seventies, going back to the Henry Hyde days in the House.

The Lee amendment would also strike other commonsense protections that normally apply to appropriated funds. This includes restrictions that prevent Federal grants from being awarded to tax cheats.

The Lee amendment would be a vote, should it pass, to allow abuse of taxpayer funds. So I would urge the House to reject this amendment.

We carefully wrote provisions that the riders that are in place would apply to each of the years of the NIH funds. And I think that that is appropriate, that the Lee amendment would undermine that.

So I would urge my colleagues to vote ''no.''

I yield back the balance of my time.

Ms. LEE. I yield 1 minute to the gentlewoman from Colorado (Ms. DEGETTE), a leader of this bill and sponsor.

Ms. DEGETTE. Madam Chair, I rise in strong support of the Lee amendment, which removes completely unnecessary and intrusive policy riders attached to the funding provisions of the underlying bill after its unanimous passage from our committee.

At best, these policy riders are immaterial provisions that have no effect on the policies and activities of the NIH or FDA. Many of them interfere with researchers and the scientific understanding that can make us all safer and healthier.

The inclusion of the Hyde amendment, among these riders, is especially offensive. The last I heard, neither the NIH or the FDA ever performed abortions. And so Hyde's restrictions remind us that even bipartisan efforts are not immune from political attacks.

Women consist of more than half the patients in America, and their healthcare needs should not be insulted and restricted by this Congress.

I want to thank my colleagues, Congresswomen LEE, SCHAKOWSKY, and CLARKE, for introducing this amendment. We should remove these policy riders and keep 21st Century Cures' focus on the great potential to do more for patients.

Ms. LEE. I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from California (Ms. LEE).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. UPTON. Madam Chair, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentlewoman from California will be postponed.

AMENDMENT NO. 4 OFFERED BY MR. CASTRO OF TEXAS

The Acting CHAIR. It is now in order to consider amendment No. 4 printed in House Report 114–193.

Mr. CASTRO of Texas. Madam Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 32, line 8, insert before the period the following: '', including underrepresented individuals in the sciences, such as women and other minorities''.

The Acting CHAIR. Pursuant to House Resolution 350, the gentleman from Texas (Mr. CASTRO) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman.

Mr. CASTRO of Texas. Madam Chair, I thank Chairman UPTON, Ranking Member PALLONE, and also Congresswoman DEGETTE for their work on this bill.

My amendment seeks to ensure that, when the NIH reports on its retention of young scientists, it includes data specifically related to women and other underrepresented minority populations in the scientific community.

Madam Chair, I reserve the balance of my time.

Mr. UPTON. Madam Chair, I claim time in opposition, although I do not oppose this amendment.

The Acting CHAIR. Without objection, the gentleman from Michigan is recognized for 5 minutes.

There was no objection.

Mr. UPTON. Madam Chair, we support this amendment. I think that it is important. It would include underrepresented individuals in the sciences in the NIH report on efforts to attract, retain, and develop emerging scientists.

It is important to ensure that the NIH is indeed focused on including all qualified individuals dedicated to finding cures.

I know no one that is opposed to this amendment. We support it. I appreciate your hard work on this and look forward to having it be part of the process as it moves forward.

I yield back the balance of my time.

Mr. CASTRO of Texas. Madam Chair, I yield 1 minute to the gentleman from New Jersey (Mr. PALLONE), the ranking member.

Mr. PALLONE. Madam Chairwoman, this amendment would require the NIH to report on their specific efforts to attract more women and racial and ethnic minorities into the biomedical workforce.

It is clear that we must reverse the harmful trend of limited participation by women and racial and ethnic minorities in the biomedical workforce.

To remain the world's leader in research, we must encourage the best and brightest from all populations to pursue biomedical research careers.

Without robust participation by women and ethnic minorities, we risk losing our position as having the best biomedical workforce in the world.

So I urge my colleagues to vote ''yes'' on this amendment.

Mr. CASTRO of Texas. Mr. Chair, I yield 1 minute to the gentlewoman from Texas (Ms. JACKSON LEE).

Ms. JACKSON LEE. Mr. Chair, this gives me an opportunity to not only thank the gentleman for his very astute amendment, but to thank the sponsors of this bill, Mr. PALLONE, Mr. GREEN, Ms. DEGETTE, Mr. UPTON, for all the work that has been done.

Having served a number of years on the House Science Committee, I want to thank the gentleman from Texas because all we heard very often was the value of investing in minorities and women as the new cutting edge of scientific research.

We know that this bill is expansive, but we are delighted with your emphasis on the recruiting of women and minorities, particularly for the young emerging scientists, and primarily because they begin to fuel the next generation of research and the next generation of the solving of problems, which is the American Cures Act.

So I rise to support the gentleman's amendment and say to you that the documentation is long, that these individuals will then fill the laboratories of America and begin to do cutting-edge research to be able to create a better life for all of us.

I thank the gentleman. I support his amendment.

Mr. CASTRO of Texas. Mr. Chair, I thank Chairman UPTON and the Republicans for their cooperation on this amendment.

I yield back the balance of my time.

The Acting CHAIR (Mr. HILL). The question is on the amendment offered by the gentleman from Texas (Mr. CASTRO).

The amendment was agreed to.

AMENDMENT NO. 5 OFFERED BY MS. SLAUGHTER

The Acting CHAIR. It is now in order to consider amendment No. 5 printed in House Report 114–193.

Ms. SLAUGHTER. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 152, insert after line 9 the following new subsection:

(c) STUDY AND REPORT ON THE IMPACT OF ADDITIONAL MEDICARE PAYMENT FOR DISARM DRUGS ON USAGE PRACTICES AND DEVELOPMENT OF RESISTANCE.—

(1) STUDY.—The Director of the Centers for Disease Control and Prevention shall conduct a study to examine the effects of the additional payment for DISARM drugs under the Medicare program provided under subparagraph (M) of section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)), as added by subsection (a), on—

(A) the usage of DISARM drugs (as defined by clause (iii) of such subparagraph) by subsection (d) hospitals (as defined in section 1886(d)(1)(B) of such Act); and

(B) the development of resistance by individuals to such DISARM drugs.

(2) REPORT.—Not later than three years after the date of the enactment of this Act, such Director shall submit to Congress a report on the study conducted under paragraph (1).

The Acting CHAIR. Pursuant to House Resolution 350, the gentlewoman from New York (Ms. SLAUGHTER) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from New York.

Ms. SLAUGHTER. Mr. Chair, I rise today in support of my amendment which directs the CDC, the Centers for Disease Control, to study whether incentivizing the use of new antibiotics, which the underlying bill does, will lead to antibiotic resistance and cause these lifesaving drugs to be less effective.

Section 2123 of the 21st Century Cures Act authorizes additional payments to hospitals for using newly developed antibiotics.

□ 1000

Of course, the reason we need new antibiotics is that we have frittered away one of the greatest medical achievements of the 21st century by overusing the ones that we already have and hastening the development of bacterial resistance.

I fear that paying hospitals more to use a new generation of antibiotics will just repeat the cycle of overuse and develop more drug-resistant superbugs. Quite simply, the taxpayers should not foot the bill for practices that are making antibiotics less effective.

This amendment directs the CDC to study the effect the bill would have on drugs that are part of the foundation of modern medicine. I urge my colleagues, many of whom have expressed their alarm at the rise of antibiotic resistance, to support the amendment.

I am certainly not alone in my concern about this section of the bill. I know there are several Members, myself included, who will feel safer if section 2123 was removed entirely.

A recent report from the United Kingdom review on antimicrobial resistance, led by brilliant economist Jim O'Neill, noted that increasing reimbursements for new antibiotics risks undermining ''good infection control and antibiotic stewardship practices within hospitals.'' The study required by this amendment will provide valuable data on the link between efforts to incentivize development of new antibiotics and the development of resistance to make sure we don't repeat the cycle.

Mr. Chairman, I want to be clear about what is at stake here. Worldwide, antibiotic-resistant infections already kill 700,000 people every year. If we don't act now, by the year 2050, according to Mr. O'Neill's study, the annual death toll will rise to 10 million a year, and the costs will be $100 trillion.

The World Health Organization has told us that the very future of medicine is at stake. Without antibiotics,

modern medical advances such as joint replacements and organ transplants would be impossible, and even the routine procedures such as dental work and caesarean sections would be too risky to perform.

We have to remember that our urgent need for new antibiotics is due to our widespread misuse and overuse of the current antibiotics that led to the crisis of antibiotic resistance. We have to cure that before we use new antibiotics.

Mr. Chairman, 30 to 50 percent of the antibiotics prescribed to humans are unnecessary, but 80 percent of the antibiotics produced in the United States are used on industrial farms where they are routinely fed to healthy animals. It is an absolute recipe for creating antibiotic resistance. We can't afford to keep using such precious, live-saving resources so thoughtlessly. The changes in how our current antibiotics are used are desperately needed.

Unfortunately, my amendment doesn't do what I would really like to do, which would be to protect eight classes of antibiotics just for use in human health by not allowing their use on the farm except for sick animals.

Remember, as I said before, these antibiotics, 80 percent, are fed to well animals every single day. However, the amendment will ensure that we can know whether incentives to develop new antibiotics continue the problem of resistance. Having effective antibiotic for humans is too important not to get this right.

Mr. Chairman, I urge my colleagues to support the amendment, and I reserve the balance of my time.

Mr. UPTON. Mr. Chairman, although I am not in opposition to the amendment, I claim the time.

The Acting CHAIR. Without objection, the gentleman from Michigan is recognized for 5 minutes.

There was no objection.

Mr. UPTON. Mr. Chairman, we strongly support this amendment, and I congratulate the gentlewoman for offering it.

Mr. Chairman, I yield 3 minutes to the gentleman from Texas (Mr. BARTON), the former chairman, ranking member, subcommittee chair, ranking member, and now chairman emeritus and former deputy whip.

(Mr. BARTON asked and was given permission to revise and extend his remarks.)

Mr. BARTON. Mr. Chairman, I thank the gentleman.

Mr. Chairman, if you look up here at the podium right behind me on the Republican side, what do you see? Carved into the balustrade is the word ''liberty.'' If you look on the Democratic side, what do you see? You see the word ''justice.'' If you look straight down the center aisle right between them, what do you see? It is ''tolerance.''

Mr. Chairman, the bill that is before us today is a culmination of 4 years of hard work between both political parties and both leaderships of the Energy and Commerce Committee on both sides of the aisle in which a lot of tolerance has been exhibited.

Conservatives on the Republican side haven't gotten everything that we want in this bill, and liberals on the Democratic side haven't gotten everything they want on this bill, but the work product is a culmination of an open process that Chairman UPTON and subcommittee Chairman PITTS have put together.

Every member of the committee has been invited to numerous working groups—probably 10, 15, I don't know—and have been given every opportunity to have input into what they want and what they don't want.

This bill would become law, and it will stay law. It will become law, and it will unite the medical research community. There are things in this bill that I have worked on for 10 years that will help find cures sooner rather than later.

Mr. Chairman, I had a woman in my office in Texas 4 days ago. Her son has autism, and he is 11 years old. He is her only child. They literally don't know what to do. He speaks one word at a time. He becomes violent.

She has almost given up hope, but we are doing amazing research in autism. This bill will facilitate and expedite that. I am tired of telling parents of children: I don't know. I can't help you.

I want to say: Here is what we are doing.

This bill does that.

Now, Mr. Chairman, there is a $2 billion mandatory program for 5 years called the innovation fund. Some of my conservative friends have said: Oh, we can't vote for the bill because of that program.

What was Medicare part D? It was a mandatory program—$40 billion that was not offset. Every Republican in the House voted for that—I might point out every Democrat voted against it—and that was voluntary. The people could participate or not participate, but it was mandatory that the Federal Government had to spend the money.

Last year, we voted on a program for veterans, $10 billion. Every Republican in the House voted for that. It wasn't offset.

Now, I would rather that we have everything discretionary. I wish the whole Federal budget was discretionary except for Social Security, but it is not.

The Acting CHAIR. The time of the gentleman has expired.

Mr. UPTON. Mr. Chairman, I yield the gentleman an additional 15 seconds.

Mr. BARTON. Mr. Chairman, let's come together. Let's vote for something that we can all be proud of so that we can tell the parents of children with autism that there is hope and there is a future.

Vote ''yes.'' Please vote ''yes.''

Ms. SLAUGHTER. Mr. Chairman, I very much want to thank Mr. UPTON for his graciousness in accepting this, and I look forward to working with him further on this issue.

Mr. Chairman, I yield the balance of my time to the gentleman from Texas, Congressman GENE GREEN.

Mr. GENE GREEN of Texas. Mr. Chairman, I want to thank our ranking member on the Rules Committee for bringing up this amendment. I support the amendment.

Mr. Chairman, this bill also includes some great provisions in there for the next generation of research on antibiotics. Congressman JOHN SHIMKUS and I worked on it this session, and previously, over the last two sessions, Congressman Phil Gingrey and I worked on it.

What this amendment addresses is it is not just a new generation, but we also need to not overuse what we have. That is a problem in our country. As I say, I have sinus infections, but those antibiotics won't help it. We need to make sure we don't overuse.

Mr. Chairman, I am glad our colleague has come up with the amendment, and I support her amendment.

Ms. SLAUGHTER. Mr. Chair, I yield back the balance of my time.

Mr. UPTON. Mr. Chairman, I yield the balance of my time to the gentleman from Illinois (Mr. ROSKAM), a member of the important Ways and Means Committee.

Mr. ROSKAM. Thank you, Chairman UPTON.

Mr. Chairman, my DISARM Act is part of this H.R. 6 Cures Act, and I thank Chairman UPTON and his staff for including it. It is a focal point of a lot of discussion on both sides of the aisle as it relates to antibiotics.

Mr. Chairman, there is an incredible health threat that has manifested itself interestingly and sadly in two important ways near my constituency in the Chicago area.

Back in December of 2013, 44 patients at Lutheran General Hospital cultured positive for CRE, which is known as the nightmare bacteria. To put this in perspective, previously, only 96 cases had been reported to the CDC before. Nearby, in Algonquin, Illinois, two cases of an ostensibly drug-resistant tuberculosis were also diagnosed. Now, according to the CDC, 23,000 patients die annually from this.

What the DISARM Act does—which is embedded in Cures, H.R. 6—is it gets researchers and scientists back in the business of antibiotic research and development by modernizing how Medicare views treatments for infections that are considered to be unmet medical needs.

It reimburses target antibiotics at cost to ensure a functioning marketplace where the right treatment is used at the right time for the right patient helping to reinvigorate the pipeline of drugs and development, and it is a critical piece of the drug resistance puzzle.

Mr. Chairman, I urge passage of Cures, H.R. 6, and I thank Chairman UPTON.

Mr. UPTON. Mr. Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from New York (Ms. SLAUGHTER).

The amendment was agreed to.

AMENDMENT NO. 6 OFFERED BY MR. FITZPATRICK

The Acting CHAIR. It is now in order to consider amendment No. 6 printed in House Report 114–193.

Mr. FITZPATRICK. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 235, after line 2, insert the following:

**Subtitle R—Other Provisions**

**SEC. 2321. SENSE OF CONGRESS.**

It is the sense of the Congress that recording unique device identifiers at the point-of-care in electronic health record systems could significantly enhance the availability of medical device data for postmarket surveillance purposes.

The Acting CHAIR. Pursuant to House Resolution 350, the gentleman from Pennsylvania (Mr. FITZPATRICK) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Pennsylvania.

Mr. FITZPATRICK. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, first, I want to express my deep appreciation to Chairman UPTON and Ranking Member DEGETTE on this bill. The funding and these innovative reforms will save lives, and that is something that everyone in this Chamber should be proud of. There are a lot of wonderful provisions in this bill, and we should see those provisions through.

I am a member, Mr. Chairman, of the Rare Disease Caucus. Like most of us here, I have met with constituents with incredible stories of courage and stories of their battle with diseases without treatments. It would be easy to fall victim to despair, but they don't.

They remain beacons of hope, hope for a treatment and hope for a world where no one else has to go through what they did. They look to us to support them and to fight alongside them for these treatments in lifesaving research, and I am proud to stand with them and to fight for them.

There is a part of this bill that I believe will do more harm than good, and that is the part that deals with easing medical device safety regulations. While we bring our research and treatments into the 21st century, I think it is equally important we bring our medical device safety regulations into the 21st century as well.

As part of a 21st century approach to medical devices, the FDA has established a unique device identification system to adequately identify medical devices through their distribution and use. These codes can significantly improve safety and help track down dangerous recalled products.

Currently, these UDIs are not incorporated into all electronic health records, which make it difficult to fully achieve the benefits to patient safety. For example, a claim form might list a procedure like a routine surgery to remove uterine fibroids, but not note the make or model of the device used, such as the laparoscopic power morcellator, a device that the FDA placed a black box warning on, some manufacturers have recalled, and some insurance companies have stopped covering as a result of its devastatingly adverse effects on women's health.

It is this tragedy surrounding the power morcellator that has driven me to action, and it is why I offered eight amendments to the Rules Committee which would strengthen our safety laws.

This week, I have heard from dozens of these individuals affected by complications from power morcellation. One doctor from California sent me a note about how her sister died 9 months after a routine surgery with a power morcellator. A woman from Massachusetts described her battle with the cancer that was spread by the morcellator. These constituents wrote their letters to Members of Congress and copied my office.

Another constituent in New York lost her sister to cancer spread by the morcellator and described her sister's tragedy as ''a routine surgery ending with a death sentence.'' A constituent of mine, a doctor and a mother of six children, is courageously fighting an aggressive cancer that was spread by the blades of the device.

What happened, Mr. Chairman, with the power morcellator should never be allowed to happen again, and I think that we missed an opportunity with this bill to tackle this problem head-on.

In 2011, the Institute of Medicine found the current, four-decade-old medical device safety process known as 510(k) inadequate, noting ''510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices.''

I wish the bill had addressed this gap that allowed the power morcellator to slip through and cause unnecessary harm to way too many families.

□ 1015

It is time we take our medical device safety regulations into the 21st century. I ask my colleagues to join me in this effort and to support this amendment of mine today, which is a small but important step.

I am proud to stand for patient safety. I urge my colleagues to stand with me and the thousands of others who have been injured or killed by unsafe medical devices.

Mr. Chairman, I yield to the gentleman from Pennsylvania (Mr. PITTS).

Mr. PITTS. Mr. Chair, I rise today in support of the amendment offered by Representative FITZPATRICK.

The Fitzpatrick amendment would put forward a sense of Congress that our healthcare system should find ways to incorporate information from medical devices into the care of our Nation's patients.

I believe that such information can prove a valuable tool advancing quality health care in this country, but it must be done carefully to ensure that the value to patients, healthcare providers, industry, and the government is realized.

Mr. PALLONE. Mr. Chairman, I rise in opposition, although I do want to speak in favor of the amendment.

The Acting CHAIR. Without objection, the gentleman from New Jersey is recognized for 5 minutes.

There was no objection.

Mr. PALLONE. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, the amendment offered today by Congressman FITZPATRICK expresses a sense of Congress that recording unique device identifiers within electronic health records could significantly enhance the availability of medical device data for purposes of postmarket surveillance.

I have long supported the use of UDIs. In the Food and Drug Administration Amendment Act of 2007, we required FDA to establish a unique device identification system; and in the Food and Drug Administration Safety and Innovation Act of 2012, we required FDA to promulgate final implementing regulations on how UDIs should be used.

Better integrating the use of UDIs into our health system will lead to improved medical devices and care across our healthcare system that will modernize how FDA monitors the safety of medical devices after they have been approved or cleared, and it will enable FDA and providers to identify medical devices with a history of safety issues. It also will facilitate recalls and make it easier for patients to learn when their medical device, such as a knee implant, is subject to a recall.

The unique device identifier is one more tool that can help FDA and our healthcare system improve their monitoring of the safety of medical devices. Incorporating UDIs into electronic health records will take time, but it is a worthy goal, and one that I support.

I urge my colleagues to support the amendment offered by Congressman FITZPATRICK.

I yield back the balance of my time.

Mr. FITZPATRICK. Mr. Chairman, I would like to thank Ranking Member PALLONE and Chairman PITTS for their support of this amendment.

This amendment will, as I said, take a small step toward improving medical device safety in the United States.

As I said earlier in my remarks, I have seven amendments that did not make it out of Rules Committee, and I hope to be able to work with the chairman and the ranking member on those issues as well.

I urge my colleagues to support the amendment, and I yield back the balance of my time.

Mr. PASCRELL. Mr. Chair, I rise today in support of the Fitzpatrick Amendment.

The unique device identifier (UDI) is an extremely important patient-safety tool, and can help identify safety concerns with devices more quickly or disprove a suspected problem. I support the inclusion of UDI in electronic health records, as this amendment encourages. But I have also been working in the Ways and Means Committee to include the UDI in Medicare claims.

As is the case with any new medical technology, not all adverse events are detected in the product's market approval or clearance processes. However, we can mitigate the impact on patients with a robust post-market surveillance program.

In 2013 and 2014 alone, the FDA recalled more than 120 medical devices, but in many cases, the recall occurs only after the devices have been implanted in or used by hundreds or thousands of patients. This can result in extensive revision surgeries, severe pain or other medical problems, and in some cases, even death. In a 2001 device recall case, Sweden's post-market surveillance program successfully identified the faulty device after it had been implanted in 30 patients. By contrast, the same device was implanted into 3,000 U.S. patients before the gravity of the problem was recognized.

The FDA's Sentinel Initiative, which has been very successful in tracking and evaluating adverse events linked to the use of pharmaceuticals, relies primarily on data from health insurance claims. Because claims currently lack information on the specific devices used in patients' care, Sentinel cannot be expanded to include medical devices as Congress has directed FDA to do. This is a missed opportunity.

Patients deserve access to innovative new devices that improve their health and their lives. And a vote for this amendment tells patients that we owe it to them and to be able to quickly identify problems with devices when they arise.

I urge my colleagues to support this amendment.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Pennsylvania (Mr. FITZPATRICK).

The amendment was agreed to.

AMENDMENT NO. 7 OFFERED BY MR. POLIS

The Acting CHAIR. It is now in order to consider amendment No. 7 printed in House Report 114–193.

Mr. POLIS. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 235, insert after line 2 the following new subtitle:

**Subtitle R—Other Provisions**

**SEC. 2321. STUDY ON TWO-TIERED APPROVAL PROCESS FOR DEVICES BY FDA.**

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report assessing the feasibility, benefits, and risks associated with establishing an expedited, two-tiered approval process for devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that would enable devices to be lawfully marketed as of the date on which the device has been shown to be safe—

(1) regardless of whether the device has been shown to be effective; and

(2) so long as the person submitting the application for approval of the device has made no false claims with respect to whether the device is safe or effective.

(b) INCLUDED ELEMENTS OF REPORT.—The report described in subsection (a) shall include—

(1) an analysis of the impact of such a process on survival rates and quality of life measures for seniors and individuals with disabilities;

(2) an analysis of the impact of such a process on survival rates and quality of life measures of individuals suffering from life-threatening or irreversibly debilitating human diseases or conditions;

(3) an estimation of the impact such a process would have on national health care costs;

(4) an analysis of the extent to which such a process could be designed so as to guarantee that patient safety is not compromised;

(5) an analysis of the extent to which fraudulent or ineffective devices could be marketed to patients under such a process and how such risks could be successfully mitigated;

(6) proposals for providing device manufacturers with incentives to show the effectiveness of devices after the Secretary of Health and Human Services has approved such devices to be lawfully marketed under such a system, such as—

(A) by permitting only limited marketing of a device, the effectiveness of which has not yet been shown; or

(B) by revoking approval of any device, the effectiveness of which has not been shown within a specified timeframe; and

(7) recommendations for whether such a process should be applicable to all devices or to only devices that have been granted specific designations by the Secretary or been determined eligible to be approved under specific approval programs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

The Acting CHAIR. Pursuant to House Resolution 350, the gentleman from Colorado (Mr. POLIS) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Colorado.

Mr. POLIS. Mr. Chairman, I would like to start by commending Chairman UPTON, Ranking Member PALLONE, Ms. DEGETTE, Mr. GREEN, and so many others. I am proud to join as a cosponsor for the 21st Century Cures Act, which is really a first step to updating our approval process to help countless Americans gain access to lifesaving drugs and devices.

This bill will save lives. I am proud to support it and send a strong message that we need to move forward with reform.

But at the same time we are passing this bill, we should start thinking about what the next step is. Passage of this bill should not foreclose additional opportunities in the future to improve access to lifesaving medical device products and lifesaving drugs.

Most importantly, this body can move forward with the next generation and start the process to help people get access to medical technology that can help keep people healthy, independent, save lives, and save money.

It is in that spirit that I put forward my amendment, which would look at a two-tiered approval process for medical devices, that would allow devices to come to market once they have demonstrated safety while the FDA is still reviewing them for efficacy.

This solves a real problem in the world. In the U.S., the cost of bringing a medical device to market through the approval process is $30 million to $100 million. Those are costs that are then added to consumers of the medical device. That makes it even more difficult for niche medical devices that may help rare and unusual conditions because they are priced prohibitively.

In addition, there is the aspect of the timeline. In the European market, for instance, if somebody creates a new device to prevent blood clots, it reaches the market in 7 to 11 months. In the U.S. market, they are looking at a timeline of 2½ to 4 years. Think of how many sufferers might die or have additional health problems simply because our own government is keeping that lifesaving product off the market, even though it has been demonstrated as safe.

An additional result is that some medical technology companies are bypassing the U.S. market altogether when they develop new devices, which can result in years-long delays for access to U.S. patients and, in some cases, companies who view the U.S. approval system as too expensive market their devices exclusively in other nations.

I think it is important to talk about what comes next. I think that with both devices and drugs, we need to look at the potential for a two-tiered process that allows a provisional approval and access to the U.S. market. That doesn't mean that insurance will cover it. That doesn't mean, clearly, that they can make any health claims with regard to the efficacy of their product. That is in existing law. But with regard to the safety being demonstrated, the provisional marketing of the product in America can save lives and will save lives.

I reserve the balance of my time.

Mr. GENE GREEN of Texas. Mr. Chairman, I claim the time in opposition.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. GENE GREEN of Texas. Mr. Chairman, I rise not necessarily in opposition to the amendment, but concerning the amendment offered by my colleague, Congressman POLIS.

I want to thank the Congressman for his efforts to advance medical device

development and would like to work with him on the legislation to enhance patient access to therapies.

However, I am concerned this amendment as drafted would lower the approval standard for medical devices and suggest that patients should be exposed to products that are not proven effective.

The FDA approval is a global gold standard for safety and effectiveness. While I support efforts to modernize and improve the standard, safety cannot be evaluated in a vacuum, and patients should not be offered treatments that have not been studied or proven useful to their care.

I have great respect for my colleague, Congressman POLIS, and appreciate his commitment to improving our healthcare system. I would like to work with him forward on that because he was correct in his statement, this doesn't mean it will be reimbursed. So we are proving a device is safe but it is not effective. I think there is a way, maybe, we can still make sure that not only we want it to be safe, but we want also to solve the problem or have a cure for whatever particular illness.

Mr. UPTON. Will the gentleman yield?

Mr. GENE GREEN of Texas. I yield to the gentleman from Michigan.

Mr. UPTON. Mr. Chairman, I would like to give my commitment, too. I would like to work with the gentleman from Colorado. This is an important issue. I believe it has got merit, but we have got to make sure that it is designed just the right way.

I want to say it is probably the lateness of the timing of the amendment when it came forward. It is my understanding the gentleman may withdraw the amendment—I would appreciate that—and allow us some time to really get together and see if there might be another day.

Mr. PALLONE. Will the gentleman yield?

Mr. GENE GREEN of Texas. I yield to the gentleman from New Jersey.

Mr. PALLONE. Mr. Chairman, I just want to join with my other colleagues, Mr. GREEN and also the chairman, that we do understand the purpose of the Polis amendment, but we do have problems with it at the same time. We would like to have a conversation with Mr. POLIS about it. I understand he is going to withdraw it. Then we would follow up and have a conversation and perhaps a meeting with the FDA as well.

Mr. GENE GREEN of Texas. Mr. Chairman, I reserve the balance of my time.

Mr. POLIS. Mr. Chairman, I thank both the chair and the ranking member.

This is a very important discussion to have, both with regard to devices and also with regard to drugs.

We know that there are treatments that are available overseas. I represent a district with, by the way, one of the largest veterinary hospitals in our country, Colorado State University Veterinary Teaching Hospital, and I can tell you that there are actually treatments, advance treatments available today for animals with cancer, like horses, that are not yet approved for humans and are lifesaving.

If we can provide access in a shortened timeframe—I understand that while medical devices might cost $30 million to $100 million to bring to market, drugs often cost over $1 billion to bring to market.

There are additional opportunities, by the way, in making sure that, as part of this provisional process, at least with regard to drugs, the data can be gathered, too. So it can serve a dual function and might, at the same time complying with some of the needs or an updating of the needs of some of the phases of FDA efficacy trials, it can actually be available through a market-oriented plan where people, consumers who are fully informed and, of course, to whom no health claims have been made, can choose to purchase the product, just as they can today, by the way, but they have to buy it overseas and import it for their own personal use. I have constituents who do that. But I think we can facilitate that process.

I deeply appreciate working with the chair and the ranking member of the committee and the subcommittee with regard to helping to bring access to lifesaving medical devices and pharmaceutical products to our shore.

Mr. FITZPATRICK. Will the gentleman yield?

Mr. POLIS. I yield to the gentleman from Pennsylvania.

Mr. FITZPATRICK. Mr. Chairman, I was actually going to rise in opposition to the amendment, although now it is being withdrawn I see an opportunity here for, perhaps, us to work together on the medical device safety issue.

I was going to object and vote against the amendment because it is my concern that the amendment would actually loosen medical device safety regulations and permit safe but ineffective devices to get to the market. I know that this sort of came late in the process. I would have objected because I had seven amendments before the committee to strengthen medical device regulations. But since the amendment is being withdrawn, I would see an opportunity for us perhaps to work together, take a step back and look at all the FDA regulations on medical device safety.

Mr. POLIS. Mr. Chairman, I ask unanimous consent to withdraw my amendment.

The Acting CHAIR. Is there objection to the request of the gentleman from Colorado?

There was no objection.

AMENDMENT NO. 8 OFFERED BY MS. JACKSON LEE

The Acting CHAIR. It is now in order to consider amendment No. 8 printed in House Report 114–193.

Ms. JACKSON LEE. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 352, after line 8, insert the following:

**SEC. 4062. OUTREACH TO HISTORICALLY BLACK COLLEGES AND UNIVERSITIES.**

The Secretary of Health and Human Services shall conduct outreach to historically Black colleges and universities, Hispanic-serving institutions, Native American colleges, and rural colleges to ensure that health professionals from underrepresented populations are aware of research opportunities under this Act.

The Acting CHAIR. Pursuant to House Resolution 350, the gentlewoman from Texas (Ms. JACKSON LEE) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from Texas.

Ms. JACKSON LEE. Mr. Chairman, let me add my appreciation to Mr. UPTON, Ms. DEGETTE, Mr. PITTS, Mr. PALLONE, and Mr. GREEN, and I ask the simple question: When have we had a historic opportunity on the floor of the House to have such a major investment—major investment—in the lives and health of Americans, quality investment involving a mandatory fund that will open America's labs and put more people in labs and be able to give people relief on some of the issues that we have heard discussed today?

I thank Mr. BARTON for raising the sadness that comes of parents that cannot find answers. Many of them are my constituency who have children with sickle cell, as we have been attempting to research this disease for many, many years; or the lupus that took advantage of a very active civic leader and caused the hospitalization for months; or this issue of triple negative breast cancer that many people are not aware of.

The amendment I have today is to emphasize the importance of outreach to our Historically Black Colleges, Hispanic-Serving, Indian, Native American, and rural colleges.

Let me explain for a brief moment the importance of this particular message.

Physicians are a gateway to the patient. In short, the Jackson Lee amendment seeks to open up the physician gateway for patients and to researchers. It is to emphasize STEM education. It is to talk about the different medical illnesses and how important it is to reach out to these particular institutions to produce more medical professionals.

According to the Centers for Disease Control and Prevention, sickle cell trait is common among African Americans and occurs in about 1 in 12. Additionally, race and ethnicity have also been shown to affect the effectiveness in response to certain drugs.

We need these students from these colleges to be in our labs, to be physicians, and to welcome minorities into the clinical labs; because we have evidence to show of the short numbers of individuals who volunteer for clinicals, and minorities are at the low end.

□ 1030

I encourage my colleagues to support the Jackson Lee amendment. Open the doors of research and patient care through doctors, and open the doors of solving some of these very difficult diseases.

I reserve the balance of my time.

Mr. UPTON. Mr. Chairman, I claim the time in opposition, although I support the amendment.

The Acting CHAIR. Without objection, the gentleman from Michigan is recognized for 5 minutes.

There was no objection.

Mr. UPTON. Mr. Chairman, I yield myself 2 minutes.

I appreciate this amendment. It is a good amendment, and it builds on what a member of our committee, BOBBY RUSH, did in the full committee markup.

It directs the Secretary of HHS to perform outreach to Historically Black Colleges and Universities, to Hispanic-serving institutions, Native American colleges, and rural colleges to ensure health professionals from unrepresented areas are, in fact, aware of research opportunities under this act. It is a real complement to what was done before.

Mr. RUSH, as I remember, grabbed me on the House floor literally during our markup process and was very supportive of a number of amendments through the night. In fact, we worked on those amendments and included them in the manager's amendment. I offered them the very next morning, and they were accepted on a voice vote. This is clearly a bipartisan amendment. It is essential that we include everyone as we find cures for all.

Ms. JACKSON LEE and I have worked together on a number of health-related issues over the years, on date rape drugs and other issues that really strike to the heart. So I appreciate her value in adding this amendment, and I very strongly support it.

Mr. Chairman, I yield 1 minute to the gentleman from Pennsylvania (Mr. FATTAH).

Mr. FATTAH. Mr. Chairman, this is a special day. This is probably the first day that I would have preferred to have been a member of the chairman's committee rather than of the Appropriations Committee. The committee should be congratulated for its great work on this bill, and I am happy to be an original cosponsor.

I rise in support of the amendment. It is critically important that we have serious outreach to all of our universities and medical centers, including African American, Hispanic, Native American universities, and those in the most rural parts of our country.

I thank the gentleman and DIANA DEGETTE and all of those who worked on this great piece of legislation.

Ms. JACKSON LEE. Mr. Chairman, how much time is remaining?

The Acting CHAIR. The gentlewoman from Texas has 2½ minutes remaining.

Ms. JACKSON LEE. Mr. Chairman, I am delighted to yield 30 seconds to the gentleman from New Jersey (Mr. PALLONE), the distinguished ranking member of the Energy and Commerce Committee.

Mr. PALLONE. Mr. Chairman, I just want to urge support for this amendment.

We need to make sure that emerging scientists from all populations understand Congress' commitment to ensuring that the funding is there to support our biomedical workforce.

Requiring the Secretary to do outreach to colleges and universities that educate large numbers of students from underrepresented groups will ensure that all groups know of our commitment to making sure that funding is not a barrier to a career in biomedical research.

I urge my colleagues to vote ''yes'' on the SHEILA JACKSON LEE amendment.

Ms. JACKSON LEE. In reclaiming my time, Mr. Chairman, I thank Mr. UPTON. I certainly thank Mr. FATTAH, Mr. PALLONE, and, again, my dear friend from Texas (Mr. GREEN) for his great leadership.

Let me indicate that certain medical illnesses have been known to have a higher prevalence amongst certain demographic groups, including type 2 diabetes, lupus, sickle cell anemia, triple-negative breast cancer, and many other forms of diseases impacting our children, ones with early birth.

So I ask my colleagues again to support this because increased diversity in research trials could help researchers find better, more precise ways to fight diseases that disproportionately impact certain populations and may be important for the safe and effective use of therapies.

Again, I think this is a historic day, and I join with Mr. UPTON to say that we have been friends. We started with the first bill together, and all of these Members have come together to put a historic mark on this Nation to say that we will not take a back step to any nation on research and on improving the quality of life for all of our citizens.

I must say that this is a historic day as well for minorities. I thank Mr. RUSH for his constant service, and I take note of the fact that increased in this is the ability to raise the FDA loans that people might get to $50,000, which will help many minorities. I hold this chart to show that minorities don't volunteer for clinicals without the outreach.

Finally, I am delighted to have a letter from United Negro College Fund President Michael Lomax, who indicates that 25 percent of African American graduates with degrees in science, technology, engineering, and math come from our Historically Black Colleges.

They are waiting in line to be a part of these clinicals, to be doctors and researchers, and we must give them that opportunity. It is a historic day.

UNITED NEGRO COLLEGE FUND, INC.,
*Washington, DC, July 9, 2015.*

Hon. SHEILA JACKSON LEE,
*House of Representatives,*
*Washington, DC.*

DEAR REPRESENTATIVE JACKSON LEE: On behalf of UNCF (the United Negro College Fund), our 37 member private historically black colleges and universities (HBCUs) and the students we serve, I write to express our strong support for your amendment to H.R. 6, the 21st Century Cures Act, which would require the U.S. Department of Health and Human Services to increase its outreach to underrepresented health professionals and researchers regarding federal research opportunities.

As you know, Historically Black Colleges and Universities (HBCUs) are making strong contributions to the nation's scientific, technological, and research workforce. HBCUs enroll 10 percent of African American undergraduates, but produce 25 percent of African American graduates with degrees in science, technology, engineering, and mathematics (STEM) fields. According to the National Science Foundation (NSF), ten of the top eleven baccalaureate institutions producing African American STEM doctorate recipients are HBCUs. Four HBCU medical institutions supply over 50 percent of African Americans who receive doctoral degrees in medicine, dentistry, and the biomedical sciences each year.

Despite these contributions, federal efforts to tap into this talent pool in the dissemination of federal research grants at the National Institutes of Health, the NSF, and other federal science agencies continues to lag behind. Your amendment will help draw greater attention to the disproportionately low representation of minority researchers in U.S. Department of Health and Human Services-supported biomedical and behavioral research.

We are grateful for your recognition of the vital need to diversify and strengthen the nation's scientific and research workforce and thank you for your ongoing advocacy to drive improvement.

Sincerely,

MICHAEL L. LOMAX, PH.D.,
*President and CEO, UNCF.*

Ms. JACKSON LEE. I cannot conclude my remarks without saying that just a few minutes ago, by video, I witnessed the flag of South Carolina—the rebel flag—being taken down.

I would only say that it is a unifying factor. This bill is a unifying factor, and it is going to help all of us. I ask my colleagues to support the Jackson Lee amendment.

Mr. Chair, I have an amendment at the desk. It is listed in the Rule as Jackson Lee #8.

I wish to thank the Chair and Ranking Member of the Committee on Rules for making the Jackson Lee Amendment in order.

I thank Energy and Commerce Committee Chairman UPTON and Ranking Member PALLONE for their collaborative effort that resulted in this bipartisan legislation being reported favorably to the House by a vote of 51–0.

I thank them all for this opportunity to explain the Jackson Lee Amendment, which makes a good bill even better by ensuring that the national goals of finding and bringing more cures and treatments to patients and strengthening the biomedical innovation ecosystem in the United States is aided by an expanding pool of diverse and talented medical researchers.

Specifically, the Jackson Lee Amendment provides:

The Secretary of Health and Human Services shall conduct outreach to historically Black colleges and universities, Hispanic-serving institutions, Native American colleges, and rural colleges to ensure that health professionals from underrepresented populations are aware of research opportunities under this Act.

Many racial health disparities stem from lack of access to quality healthcare and proper health awareness.

Unfortunately this means that incidence of disease does not always match trial populations.

For example, consider that:

1. African-Americans represent 12% of the U.S. population but only 5% of clinical trial participants.

2. Hispanics make up 16% of the population but only 1% of clinical trial participants.

3. Sex distribution in cardiovascular device trials is 67% male.

Other significant barriers to diversified clinical trials, which are the key to sound medical research and the foundation for medical cures and breakthroughs, as reported by investigators and coordinators are insurance status, patient inconvenience costs, availability of transportation, distance to the study site, and patient and family concerns about risk.

But the most significant barriers limiting clinical participation are race, age, and sex of participants:

1. Women and minority patients are more difficult to recruit.

2. Women and minority physicians have less experience and are relatively more costly to engage.

3. Minority patients with limited English proficiency can require costly translation services.

The first step in engaging women and minorities in clinical trials is finding them.

Research has shown that minority patients seek physicians of their own race, so bringing these doctors into trials is critical.

''Physicians are the gateway to the patient''.

There are disturbing statistics on the number of African Americans, Hispanics and Native Americans pursuing academic qualification and participating in scientific research.

Many barriers exist that account for the low rate of participation among diverse communities, including patient fear of experimentation and lack of understanding or education with regard to the importance of clinical trials in creating new treatments and cures.

The Jackson Lee Amendment is intended to aid in the necessary effort to diversify the pool of doctors and medical researchers conducting clinical trials, and thereby helping to diversify the participants in the clinical trials.

In short, the Jackson Lee Amendment seeks to open the ''physician gateway'' to the patient.

The Journal on STEM Education reported in 2011 that only 8.34% of the STEM doctorates awarded in 2006 were given to URMs, despite making up approximately 28% of the U.S. population.

Furthermore, GAO noted that while the percentage of underrepresented minorities nationwide increased from 13% to 19% from 1994 to 2003, the total number of STEM doctorates awarded to the same group dropped during this period from 8,335 to 7,310.

In response, the National Institute of General Medical Sciences (NIGMS) created the Minority Opportunities in Research (MORE) Division and similar academic intervention programs.

The MORE programs are comprised of four primary components: research experience, mentoring and advisement, supplemental instruction and workshops, and financial support.

In 2007, NIGMS' annual budget was $1.9 billion, of which nearly $126 million was spent on its MORE programs.

This amount includes the Minority Biomedical Research Support–Research Initiative for Scientific Enhancement (MBRS–RISE) program, the Minority Access to Research Careers (MARC), Post-baccalaureate Research Education Program (PREP), and the Bridges to the Baccalaureate and Bridges to the Ph.D. programs.

The amount of funds dedicated to these programs reflects the commitment by the science and research community to the goals of the MORE Division in addressing this problem.

Certain medical illnesses have been known to have higher prevalence in certain demographic groups, including type II diabetes, lupus, sickle cell anemia, and Triple Negative Breast Cancer for which African Americans are more than twice as likely to be diagnosed on average.

According to the Centers for Disease Control and Prevention, sickle cell trait is common among African Americans and occurs in about 1 in 12, and sickle cell disease occurs in about 1 out of every 500 African-American births, compared to about 1 out of every 36,000 Hispanic-American births.

Race and ethnicity have also been shown to affect the effectiveness of and response to certain drugs, such as anti-hypertensive therapies in the treatment of hypertension in African Americans and anti-depressants in Hispanics.

Increased diversity in research trials could help researchers find better, more precise ways to fight diseases that disproportionately impact certain populations, and may be important for the safe and effective use of new therapies.

But before we can engage more women and minorities to participate in clinical trials, we must be able to find them.

And the key to finding minority patients is to find more physicians from their racial and ethnic groups because research has shown that physicians are the gateway to the patient.

The Jackson Lee Amendment opens that gateway.

I urge support for the Jackson Lee Amendment.

I yield back the balance of my time.

Mr. UPTON. Mr. Chairman, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from Texas (Ms. JACKSON LEE).

The amendment was agreed to.

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, proceedings will now resume on those amendments printed in House Report 114–193 on which further proceedings were postponed, in the following order:

Amendment No. 1 by Mr. BRAT of Virginia.

Amendment No. 3 by Ms. LEE of California.

The Chair will reduce to 2 minutes the minimum time for any electronic vote after the first vote in this series.

AMENDMENT NO. 1 OFFERED BY MR. BRAT

The Acting CHAIR. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from Virginia (Mr. BRAT) on which further proceedings were postponed and on which the noes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 141, noes 281, not voting 11, as follows:

[Roll No. 431]

AYES—141

| | | |
|---|---|---|
| Abraham | Graves (GA) | Poe (TX) |
| Aderholt | Graves (LA) | Poliquin |
| Amash | Grothman | Posey |
| Amodei | Hardy | Price, Tom |
| Babin | Harris | Ratcliffe |
| Barr | Hartzler | Renacci |
| Bishop (MI) | Heck (NV) | Ribble |
| Bishop (UT) | Hensarling | Rice (SC) |
| Black | Hice, Jody B. | Rigell |
| Blum | Holding | Roby |
| Brady (TX) | Huelskamp | Rohrabacher |
| Brat | Huizenga (MI) | Rokita |
| Bridenstine | Hultgren | Rooney (FL) |
| Brooks (AL) | Hunter | Ross |
| Buck | Hurd (TX) | Rothfus |
| Byrne | Hurt (VA) | Rouzer |
| Carter (GA) | Issa | Royce |
| Carter (TX) | Jenkins (KS) | Russell |
| Chabot | Johnson, Sam | Ryan (WI) |
| Chaffetz | Jolly | Sanford |
| Clawson (FL) | Jones | Schweikert |
| Coffman | Jordan | Scott, Austin |
| Collins (GA) | Joyce | Sensenbrenner |
| Conaway | King (IA) | Sessions |
| Cook | Labrador | Smith (MO) |
| Crawford | LaMalfa | Smith (NE) |
| Culberson | Lamborn | Smith (TX) |
| DeSantis | Loudermilk | Stewart |
| DesJarlais | Love | Stutzman |
| Duffy | Lummis | Thornberry |
| Duncan (SC) | Marchant | Tipton |
| Duncan (TN) | Massie | Trott |
| Emmer (MN) | McClintock | Walberg |
| Farenthold | Meadows | Walker |
| Fincher | Messer | Walorski |
| Fleischmann | Mica | Weber (TX) |
| Fleming | Miller (FL) | Webster (FL) |
| Forbes | Moolenaar | Wenstrup |
| Fortenberry | Mooney (WV) | Westerman |
| Foxx | Mulvaney | Westmoreland |
| Franks (AZ) | Newhouse | Williams |
| Garrett | Noem | Wilson (SC) |
| Gibbs | Palazzo | Wittman |
| Gohmert | Palmer | Woodall |
| Goodlatte | Paulsen | Yoho |
| Gosar | Pearce | Young (IN) |
| Gowdy | Perry | Zinke |

NOES—281

| | | |
|---|---|---|
| Adams | Brown (FL) | Clyburn |
| Aguilar | Brownley (CA) | Cohen |
| Allen | Buchanan | Cole |
| Ashford | Bucshon | Collins (NY) |
| Barletta | Burgess | Comstock |
| Barton | Bustos | Connolly |
| Beatty | Butterfield | Conyers |
| Becerra | Calvert | Cooper |
| Benishek | Capps | Costa |
| Bera | Capuano | Costello (PA) |
| Beyer | Cárdenas | Courtney |
| Bilirakis | Carney | Cramer |
| Bishop (GA) | Carson (IN) | Crenshaw |
| Blackburn | Cartwright | Crowley |
| Blumenauer | Castor (FL) | Cuellar |
| Bonamici | Castro (TX) | Cummings |
| Bost | Chu, Judy | Curbelo (FL) |
| Boustany | Cicilline | Davis (CA) |
| Boyle, Brendan F. | Clark (MA) | Davis, Danny |
| | Clarke (NY) | Davis, Rodney |
| Brady (PA) | Clay | DeFazio |
| Brooks (IN) | Cleaver | DeGette |

Delaney
DeLauro
DelBene
Denham
Dent
Deutch
Diaz-Balart
Dingell
Doggett
Dold
Donovan
Doyle, Michael F.
Duckworth
Edwards
Ellison
Ellmers (NC)
Eshoo
Esty
Farr
Fattah
Fitzpatrick
Flores
Foster
Frankel (FL)
Frelinghuysen
Fudge
Gabbard
Gallego
Garamendi
Gibson
Graham
Granger
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Guinta
Guthrie
Hahn
Hanna
Harper
Hastings
Heck (WA)
Herrera Beutler
Higgins
Hill
Himes
Hinojosa
Honda
Hoyer
Hudson
Huffman
Israel
Jackson Lee
Jeffries
Jenkins (WV)
Johnson (GA)
Johnson (OH)
Johnson, E. B.
Kaptur
Katko
Keating
Kelly (IL)
Kelly (MS)
Kelly (PA)
Kildee
Kilmer
Kind
King (NY)
Kinzinger (IL)
Kirkpatrick
Kline
Knight
Kuster
Lance
Langevin
Larsen (WA)
Larson (CT)
Latta
Lawrence
Lee
Levin
Lewis
Lieu, Ted
Lipinski
LoBiondo
Loebsack
Long
Lowenthal
Lowey
Lucas
Luetkemeyer
Lujan Grisham (NM)
Luján, Ben Ray (NM)
Lynch
MacArthur
Maloney, Carolyn
Maloney, Sean
Marino
Matsui
McCarthy
McCaul
McCollum
McDermott
McGovern
McHenry
McKinley
McMorris Rodgers
McNerney
McSally
Meehan
Meeks
Meng
Miller (MI)
Moore
Moulton
Mullin
Murphy (FL)
Murphy (PA)
Nadler
Napolitano
Neal
Nolan
Norcross
Nugent
Nunes
O'Rourke
Olson
Pallone
Pascrell
Payne
Pelosi
Perlmutter
Peters
Peterson
Pingree
Pittenger
Pitts
Pocan
Polis
Pompeo
Price (NC)
Quigley
Rangel
Reed
Reichert
Rice (NY)
Richmond
Rogers (AL)
Rogers (KY)
Ros-Lehtinen
Roskam
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan (OH)
Sánchez, Linda T.
Sarbanes
Scalise
Schakowsky
Schiff
Schrader
Scott (VA)
Scott, David
Serrano
Sewell (AL)
Sherman
Shimkus
Shuster
Simpson
Sinema
Sires
Slaughter
Smith (NJ)
Smith (WA)
Speier
Stefanik
Stivers
Swalwell (CA)
Takai
Takano
Thompson (CA)
Thompson (MS)
Thompson (PA)
Tiberi
Titus
Tonko
Torres
Tsongas
Turner
Upton
Valadao
Van Hollen
Vargas
Veasey
Vela
Velázquez
Visclosky
Wagner
Walden
Walters, Mimi
Walz
Wasserman Schultz
Waters, Maxine
Watson Coleman
Welch
Whitfield
Wilson (FL)
Womack
Yarmuth
Yoder
Young (AK)
Young (IA)
Zeldin

NOT VOTING—11

Bass
DeSaulnier
Engel
Graves (MO)
Gutiérrez
Kennedy
Lofgren
Neugebauer
Roe (TN)
Salmon
Sanchez, Loretta

□ 1107

Messrs. RICHMOND, MARINO, KNIGHT, HUFFMAN, and RYAN of Ohio changed their vote from ''aye'' to ''no.''

Mrs. WALORSKI and Mr. TROTT changed their vote from ''no'' to ''aye.''

So the amendment was rejected.

The result of the vote was announced as above recorded.

AMENDMENT NO. 3 OFFERED BY MS. LEE

The Acting CHAIR. The unfinished business is the demand for a recorded vote on the amendment offered by the gentlewoman from California (Ms. LEE) on which further proceedings were postponed and on which the noes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The Acting CHAIR. This will be a 2-minute vote.

The vote was taken by electronic device, and there were—ayes 176, noes 245, not voting 12, as follows:

[Roll No. 432]

AYES—176

Adams
Aguilar
Ashford
Beatty
Becerra
Bera
Beyer
Bishop (GA)
Blumenauer
Bonamici
Boyle, Brendan F.
Brady (PA)
Brown (FL)
Brownley (CA)
Bustos
Butterfield
Capps
Capuano
Cárdenas
Carney
Carson (IN)
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Conyers
Cooper
Costa
Courtney
Crowley
Cummings
Davis (CA)
Davis, Danny
DeFazio
DeGette
Delaney
DeLauro
DelBene
Deutch
Dingell
Doggett
Doyle, Michael F.
Duckworth
Edwards
Ellison
Eshoo
Esty
Farr
Fattah
Foster
Frankel (FL)
Fudge
Gabbard
Gallego
Garamendi
Graham
Grayson
Green, Al
Green, Gene
Grijalva
Hahn
Hastings
Heck (WA)
Higgins
Himes
Hinojosa
Honda
Hoyer
Huffman
Israel
Jackson Lee
Jeffries
Johnson (GA)
Johnson, E. B.
Keating
Kelly (IL)
Kildee
Kilmer
Kind
Kirkpatrick
Kuster
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lee
Levin
Lewis
Lieu, Ted
Loebsack
Lowenthal
Lowey
Lujan Grisham (NM)
Luján, Ben Ray (NM)
Lynch
Maloney, Carolyn
Maloney, Sean
Matsui
McCollum
McDermott
McGovern
McNerney
Meeks
Meng
Moore
Moulton
Murphy (FL)
Nadler
Napolitano
Neal
Nolan
Norcross
O'Rourke
Pallone
Pascrell
Payne
Pelosi
Perlmutter
Peters
Pingree
Pocan
Polis
Price (NC)
Quigley
Rangel
Rice (NY)
Richmond
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan (OH)
Sánchez, Linda T.
Sarbanes
Schakowsky
Schiff
Schrader
Scott (VA)
Scott, David
Serrano
Sewell (AL)
Sherman
Sinema
Sires
Slaughter
Smith (WA)
Speier
Swalwell (CA)
Takai
Takano
Thompson (CA)
Thompson (MS)
Titus
Tonko
Torres
Tsongas
Van Hollen
Vargas
Veasey
Vela
Velázquez
Visclosky
Walz
Wasserman Schultz
Waters, Maxine
Watson Coleman
Welch
Wilson (FL)
Yarmuth

NOES—245

Abraham
Aderholt
Allen
Amash
Amodei
Babin
Barletta
Barr
Barton
Benishek
Bilirakis
Bishop (MI)
Bishop (UT)
Black
Blackburn
Blum
Bost
Boustany
Brady (TX)
Brat
Bridenstine
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Burgess
Byrne
Calvert
Carter (GA)
Carter (TX)
Cartwright
Chabot
Chaffetz
Clawson (FL)
Coffman
Cole
Collins (GA)
Collins (NY)
Comstock
Conaway
Cook
Costello (PA)
Cramer
Crawford
Crenshaw
Cuellar
Culberson
Curbelo (FL)
Davis, Rodney
Denham
Dent
DeSantis
DesJarlais
Diaz-Balart
Dold
Donovan
Duffy
Duncan (SC)
Duncan (TN)
Ellmers (NC)
Emmer (MN)
Farenthold
Fincher
Fitzpatrick
Fleischmann
Fleming
Flores
Forbes
Fortenberry
Foxx
Franks (AZ)
Frelinghuysen
Garrett
Gibbs
Gibson
Gohmert
Goodlatte
Gosar
Gowdy
Granger
Graves (GA)
Graves (LA)
Griffith
Grothman
Guinta
Guthrie
Hanna
Hardy
Harper
Harris
Hartzler
Heck (NV)
Hensarling
Herrera Beutler
Hice, Jody B.
Hill
Holding
Hudson
Huelskamp
Huizenga (MI)
Hultgren
Hunter
Hurd (TX)
Hurt (VA)
Issa
Jenkins (KS)
Jenkins (WV)
Johnson (OH)
Johnson, Sam
Jolly
Jones
Jordan
Joyce
Kaptur
Katko
Kelly (MS)
Kelly (PA)
King (IA)
King (NY)
Kinzinger (IL)
Kline
Knight
Labrador
LaMalfa
Lamborn
Lance
Latta
Lipinski
LoBiondo
Long
Loudermilk
Love
Lucas
Luetkemeyer
Lummis
MacArthur
Marchant
Marino
Massie
McCarthy
McCaul
McClintock
McHenry
McKinley
McMorris Rodgers
McSally
Meadows
Meehan
Messer
Mica
Miller (FL)
Miller (MI)
Moolenaar
Mooney (WV)
Mullin
Mulvaney
Murphy (PA)
Newhouse
Noem
Nugent
Nunes
Olson
Palazzo
Palmer
Paulsen
Pearce
Perry
Peterson
Pittenger
Pitts
Poe (TX)
Poliquin
Pompeo
Posey
Price, Tom
Ratcliffe
Reed
Reichert
Renacci
Ribble
Rice (SC)
Rigell
Roby
Rogers (AL)
Rogers (KY)
Rohrabacher
Rokita
Ros-Lehtinen
Roskam
Ross
Rothfus
Rouzer
Royce
Russell
Ryan (WI)
Sanford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Sessions
Shimkus
Shuster
Simpson
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (TX)
Stefanik
Stewart
Stivers
Stutzman
Thompson (PA)
Thornberry
Tiberi
Tipton
Trott
Turner
Upton
Valadao
Wagner
Walberg
Walden
Walker
Walorski
Walters, Mimi
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Westmoreland
Whitfield
Williams
Wilson (SC)
Wittman
Womack
Woodall
Yoder
Yoho
Young (AK)
Young (IA)
Young (IN)
Zeldin
Zinke

NOT VOTING—12

Bass
DeSaulnier
Engel
Graves (MO)
Gutiérrez
Kennedy
Lofgren
Neugebauer
Roe (TN)
Rooney (FL)
Salmon
Sanchez, Loretta

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR (during the vote). There is 1 minute remaining.

□ 1115

Mr. GRAYSON changed his vote from ''no'' to ''aye.''

So the amendment was rejected.

The result of the vote was announced as above recorded.

The Acting CHAIR. There being no further amendments, the Committee rises.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. COLLINS of Georgia) having assumed the chair, Mr. HILL, Acting Chair of the Committee of the Whole House on the

state of the Union, reported that that Committee, having had under consideration the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes, and, pursuant to House Resolution 350, he reported the bill, as amended by that resolution, back to the House with sundry further amendments adopted in the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

Is a separate vote demanded on any further amendment reported from the Committee of the Whole? If not, the Chair will put them en gros.

The amendments were agreed to.

The SPEAKER pro tempore. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

The SPEAKER pro tempore. The question is on passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

RECORDED VOTE

Mr. UPTON. Mr. Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, this 5-minute vote on passage will be followed by a 5-minute vote on approval of the Journal, if ordered.

The vote was taken by electronic device, and there were—ayes 344, noes 77, not voting 12, as follows:

[Roll No. 433]

AYES—344

Abraham
Adams
Aderholt
Aguilar
Allen
Amodei
Ashford
Barletta
Barr
Barton
Beatty
Becerra
Benishek
Bera
Beyer
Bilirakis
Bishop (GA)
Bishop (MI)
Blackburn
Blum
Blumenauer
Bonamici
Bost
Boyle, Brendan F.
Brady (PA)
Brady (TX)
Brooks (IN)
Brown (FL)
Brownley (CA)
Buchanan
Bucshon
Burgess
Bustos
Butterfield
Calvert
Capps
Capuano
Cárdenas
Carney
Carson (IN)
Carter (GA)
Cartwright
Castor (FL)
Castro (TX)
Chabot
Chaffetz
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clawson (FL)
Clay
Cleaver
Clyburn
Coffman
Cohen
Cole
Collins (GA)
Collins (NY)
Comstock
Connolly
Conyers
Cook
Cooper
Costa
Costello (PA)
Courtney
Cramer
Crenshaw
Crowley
Cuellar
Cummings
Curbelo (FL)
Davis (CA)
Davis, Danny
Davis, Rodney
DeFazio
DeGette
Delaney
DelBene
Denham
Dent
DeSantis
Deutch
Diaz-Balart
Dingell
Doggett
Dold
Donovan
Doyle, Michael F.
Duckworth
Duncan (SC)
Duncan (TN)
Edwards
Ellison
Ellmers (NC)
Emmer (MN)
Esty
Fattah
Fleischmann
Flores
Fortenberry
Foster
Foxx
Frankel (FL)
Franks (AZ)
Frelinghuysen
Fudge
Gabbard
Gallego
Garamendi
Gibson
Gohmert
Gowdy
Graham
Granger
Graves (LA)
Grayson
Green, Al
Green, Gene
Griffith
Guinta
Guthrie
Hahn
Hanna
Hardy
Harper
Harris
Hastings
Heck (NV)
Heck (WA)
Herrera Beutler
Higgins
Hill
Himes
Hinojosa
Honda
Hoyer
Hudson
Huffman
Huizenga (MI)
Hultgren
Hunter
Hurd (TX)
Hurt (VA)
Israel
Jackson Lee
Jeffries
Jenkins (KS)
Jenkins (WV)
Johnson (GA)
Johnson (OH)
Johnson, E. B.
Jolly
Joyce
Kaptur
Katko
Keating
Kelly (IL)
Kelly (MS)
Kelly (PA)
Kildee
Kilmer
Kind
King (IA)
King (NY)
Kinzinger (IL)
Kirkpatrick
Kline
Knight
Kuster
LaMalfa
Lance
Langevin
Larsen (WA)
Larson (CT)
Latta
Lawrence
Levin
Lewis
Lieu, Ted
Lipinski
LoBiondo
Loebsack
Long
Lowenthal
Lowey
Lucas
Luetkemeyer
Lujan Grisham (NM)
Luján, Ben Ray (NM)
Lynch
MacArthur
Maloney, Carolyn
Maloney, Sean
Marchant
Marino
Matsui
McCarthy
McCaul
McCollum
McDermott
McGovern
McHenry
McKinley
McMorris Rodgers
McNerney
McSally
Meadows
Meehan
Meeks
Meng
Messer
Mica
Miller (MI)
Moolenaar
Moore
Moulton
Mullin
Murphy (FL)
Murphy (PA)
Napolitano
Neal
Newhouse
Noem
Nolan
Norcross
Nugent
Nunes
O'Rourke
Olson
Pallone
Pascrell
Paulsen
Payne
Pelosi
Perlmutter
Peters
Peterson
Pingree
Pittenger
Pitts
Pocan
Poliquin
Polis
Pompeo
Posey
Price (NC)
Quigley
Rangel
Reed
Reichert
Ribble
Rice (NY)
Richmond
Rigell
Roby
Rogers (AL)
Rogers (KY)
Rohrabacher
Rooney (FL)
Ros-Lehtinen
Roskam
Ross
Rothfus
Rouzer
Roybal-Allard
Royce
Ruiz
Ruppersberger
Rush
Russell
Ryan (OH)
Ryan (WI)
Sánchez, Linda T.
Sarbanes
Scalise
Schakowsky
Schiff
Schrader
Schweikert
Scott (VA)
Scott, Austin
Scott, David
Serrano
Sessions
Sewell (AL)
Sherman
Shimkus
Shuster
Simpson
Sinema
Sires
Slaughter
Smith (NJ)
Smith (WA)
Stefanik
Stivers
Swalwell (CA)
Takai
Takano
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tiberi
Titus
Tonko
Torres
Trott
Tsongas
Turner
Upton
Valadao
Van Hollen
Vargas
Veasey
Vela
Velázquez
Visclosky
Wagner
Walberg
Walden
Walorski
Walters, Mimi
Walz
Wasserman Schultz
Waters, Maxine
Watson Coleman
Webster (FL)
Welch
Whitfield
Wilson (FL)
Wilson (SC)
Womack
Woodall
Yarmuth
Yoder
Yoho
Young (AK)
Young (IA)
Young (IN)
Zeldin
Zinke

NOES—77

Amash
Babin
Black
Boustany
Brat
Bridenstine
Brooks (AL)
Buck
Byrne
Carter (TX)
Conaway
Crawford
Culberson
DeLauro
DesJarlais
Duffy
Eshoo
Farenthold
Farr
Fincher
Fitzpatrick
Fleming
Forbes
Garrett
Gibbs
Goodlatte
Gosar
Graves (GA)
Grijalva
Grothman
Hartzler
Hensarling
Hice, Jody B.
Holding
Huelskamp
Issa
Johnson, Sam
Jones
Jordan
Labrador
Lamborn
Lee
Loudermilk
Love
Lummis
Massie
McClintock
Miller (FL)
Mooney (WV)
Mulvaney
Nadler
Neugebauer
Palazzo
Palmer
Pearce
Perry
Poe (TX)
Price, Tom
Ratcliffe
Renacci
Rice (SC)
Rokita
Sanford
Sensenbrenner
Smith (MO)
Smith (NE)
Smith (TX)
Speier
Stewart
Stutzman
Tipton
Walker
Weber (TX)
Wenstrup
Westerman
Westmoreland
Williams

NOT VOTING—12

Bass
Bishop (UT)
DeSaulnier
Engel
Graves (MO)
Gutiérrez
Kennedy
Lofgren
Roe (TN)
Salmon
Sanchez, Loretta
Wittman

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1126

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PERSONAL EXPLANATION

Mr. DESAULNIER. Mr. Speaker, I regret that I was unable to vote on Friday, July 10 as I was attending the memorial services of a dear friend in my congressional district. Had I been present, I would have cast the following votes: rollcall No. 431: "no;" rollcall No. 432: "aye;" rollcall No. 433: "aye."

PERSONAL EXPLANATION

Ms. LORETTA SANCHEZ of California. Mr. Speaker, I missed votes on H.R. 6, the 21st Century Cures Act. Specifically, I missed an amendment by Rep. DAVE BRAT (R–VA) (rollcall No. 431), amendment by Rep. BARBARA LEE (D–CA) (rollcall No. 432), and Final Passage of H.R. 6 (rollcall No. 433). Had I been present, I would have voted "nay" on the amendment by Rep. DAVE BRAT (R–VA) (rollcall No. 431), "yea" on the amendment by Rep. BARBARA LEE (D–CA) (rollcall no. 432), and "yea" on the Final Passage of H.R. 6 (rollcall No. 433).

PERSONAL EXPLANATION

Mr. GUTIÉRREZ. Mr. Speaker, I was unavoidably absent in the House chamber for votes on Friday, July 10, 2015.

Had I been present, I would have voted "nay" on rollcall vote 431, "yea" on rollcall vote 432, and "yea" on rollcall vote 433 in support of H.R. 6—21st Century Cures Act.

## THE JOURNAL

The SPEAKER pro tempore. The unfinished business is the question on agreeing to the Speaker's approval of the Journal, which the Chair will put de novo.

The question is on the Speaker's approval of the Journal.

Pursuant to clause 1, rule I, the Journal stands approved.

## REPORT ON H.R. 3020, DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2016

Mr. COLE, from the Committee on Appropriations, submitted a privileged report (Rept. No. 114–195) on the bill (H.R. 3020) making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2016, and for other