United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 114th CONGRESS, FIRST SESSION

Vol. 161 WASHINGTON, FRIDAY, JULY 10, 2015 No. 107

Senate

The Senate was not in session today. Its next meeting will be held on Monday, July 13, 2015, at 3 p.m.

House of Representatives

FRIDAY, JULY 10, 2015

The House met at 9 a.m. and was called to order by the Speaker.

PRAYER

The Chaplain, the Reverend Patrick J. Conroy, offered the following prayer:

We give You thanks, O God, for giving us another day. Please help us to use it well.

We ask Your blessing upon this assembly and upon all to whom the authority of government is given. Help them to meet their responsibilities during these days, to attend to the immediate needs and concerns of the moment, all the while enlightened by the majesty of Your creation and Your eternal Spirit.

We give You thanks that we all can know and share the fruits of Your Spirit, especially in this time the virtue of tolerance and reconciliation, of justice and righteousness.

Watch over this House and cause Your blessing to be upon each Member that they might serve all the people in their home districts, those who voted for them and those who did not.

May all that is done within the people's House this day be for Your greater honor and glory.

Amen.

THE JOURNAL

The SPEAKER. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

Mr. WOMACK. Mr. Speaker, pursuant to clause 1, rule I, I demand a vote on agreeing to the Speaker's approval of the Journal.

The SPEAKER. The question is on the Speaker's approval of the Journal.

The question was taken; and the Speaker announced that the ayes appeared to have it.

Mr. WOMACK. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER. Pursuant to clause 8, rule XX, further proceedings on this question will be postponed.

The point of no quorum is considered withdrawn.

PLEDGE OF ALLEGIANCE

The SPEAKER. Will the gentlewoman from New York (Ms. STEFANIK) come forward and lead the House in the Pledge of Allegiance.

Ms. STEFANIK led the Pledge of Allegiance as follows:

> I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

ANNOUNCEMENT BY THE SPEAKER

The SPEAKER. The Chair will entertain up to five requests for 1-minute speeches on each side of the aisle.

EXPRESSING GRATITUDE TO THE REAGAN SISTERS

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

Mr. WOMACK. Mr. Speaker, they say that great things come in small packages, and that could not be more true of the Reagan sisters of Rogers, Arkansas. I rise today in gratitude to them.

Agnes Lytton, Mary Sue, and Betty Lynn Reagan were born and raised in northwest Arkansas and attended the University of Arkansas-Fayetteville.

While Agnes Lytton left Arkansas to pursue a career in library science, Mary Sue and Betty Lynn, who stood about 5 feet tall, were giants in the classroom, spending a combined 94 years teaching history and government to students in the Rogers School District.

Throughout their distinguished careers, both were decorated with countless awards and accolades, and in 1989 the city of Rogers named its newest school Reagan Elementary as a token of our appreciation for their dedication to our students and their faithful support of the community. As their former mayor, I can attest to both.

Although these most respected members of our community have passed on, they won't soon be forgotten, and now their legacies will live on at the U of A, as it was announced on Monday that the sisters, in a final tribute to northwest Arkansas education, designated a $1.2 million estate gift to support the libraries of their alma mater.

Printed on recycled paper.

I can say without hesitation that the Reagan sisters made northwest Arkansas a better place, and for that, we are eternally grateful.

THE CONFEDERATE FLAG

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

Mr. NADLER. Madam Speaker, we must not display the Confederate battle flag in any Federal park or cemetery or building. The Confederate flag represents racism, slavery, and treason, waging war against the United States, killing American soldiers.

We are told it represents the Southern heritage. It does represent part of the Southern, of the American heritage, a shameful part: the defense of slavery, of owning people body and soul, of the doctrine of racial superiority, and the practice of racial oppression.

Other countries and peoples have shameful parts of their heritages. Germany, for example, has a Nazi heritage. The Germans are properly ashamed of it. They prohibit, by law, the display of Nazi imagery. The First Amendment won't let us go that far, but we should not honor the shameful parts of our history.

As we continue the ongoing struggle to eradicate racism from American life, we must no longer honor racism and treason by allowing the Confederate flag on any Federal property.

21ST CENTURY CURES INITIATIVE

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

Mr. COSTELLO of Pennsylvania. Madam Speaker, the 21st Century Cures initiative has a lot of positive measures to help medical innovation reach its full potential. I would like to focus on just one of the many reasons to support this legislation.

I had the pleasure of meeting with the family of Garrett Coyne, staunch advocates for cures for rare diseases. Garrett is a 5-year-old resident of Gilbertsville, who 10 months ago was diagnosed with a rare neurodegenerative disorder often called Batten disease. Garrett was born and developed normally, but since September the disease has left him legally blind and has greatly weakened his physical and mental abilities. Unfortunately, Batten disease presently has no treatment, no cure, and is not preventable.

While the road ahead for Garrett and his family is daunting, there is hope. It is because of provisions in the 21st Century bill that researchers will have the tools to work toward developing medical advancement for Batten disease.

By modernizing medical innovation and increasing NIH funding, a more promising future for patients, families, and innovators is in front of us. I am supporting the 21st Century Cures bill for many reasons, but the main one is this effort to help children, like 5-year-old Garrett and other constituents in my district who are challenged daily with the struggles of a rare disease. I encourage my colleagues to join me.

THE CONFEDERATE FLAG BELONGS IN THE ASHBIN OF HISTORY

(Ms. WASSERMAN SCHULTZ asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. WASSERMAN SCHULTZ. Madam Speaker, I rise today to condemn House Republicans' secretive attempt in the dead of Wednesday night to permit the display of the racist Confederate flag in national parks and cemeteries.

In the wake of the Charleston murders, our Nation is moving toward the removal of the flag from public places. Later today, the State of South Carolina will remove the flag from its capitol grounds. And yet, while this is happening, the Republican majority has sought to associate itself and this body with the racist legacy of the Confederate flag.

To add insult to injury, yesterday, when House Democrats tried to bring up a resolution removing any State flag displaying the Confederate battle flag from the Capitol except in very limited circumstances, the majority turned their backs and ignored the cries of millions of Americans who are calling for its permanent ban.

Republican leadership ought to be ashamed for associating themselves with this symbol of racism, hatred, and intolerance. This body should move swiftly to relegate the Confederate flag to museums and the ashbin of history.

BASIN AND RANGE NATIONAL MONUMENT

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

Mr. HARDY. Madam Speaker, what were you doing last night at midnight? If you were like me and most Americans, you were probably asleep.

But last night, while America was sleeping, the White House was busy. The White House was busy notifying the public, literally in the dark of the night, about the President's intentions to designate more than 700,000 acres of Lincoln and Nye Counties as the Basin and Range National Monument.

Madam Speaker, at 2 p.m. this afternoon, you won't see a debate on the floor of the House, the people's House, on the Basin and Range Monument. There will be no vote for Nevada's elected representatives, but there will be a photo op to capture the exchange of political favor for one Nevadan. It will be a scene demonstrating that having friends in high places is more important than popular will of the people.

But legacy building in the twilight of one's career shouldn't be the driver for our Nation's public lands. According to press reports, it is said when asked about the heartfelt concerns of Nevadans who oppose the monument, the President responded: ''I don't care. I want this done.''

Madam Speaker, I do care.

LONG-TERM FUNDING WILL HELP THE NATION

(Mr. TED LIEU of California asked and was given permission to address the House for 1 minute.)

Mr. TED LIEU of California. Madam Speaker, when it comes to the highway trust fund, it feels like the movie ''Groundhog Day'' over and over again, where once again we are faced with the expiration of this important fund.

We know from a recent Department of Transportation report that 54 percent of our roads and highways are deemed to be poor, one in four bridges are structurally deficient, and we need to fund this highway trust fund at its full capacity, and we need to do it on a long-term basis. We can't continue to do it on a short-term basis. It is not helpful to our State and local governments. We can't get projects off the ground.

I request that the Republican majority put a bill on the floor that funds the highway trust fund on a long-term basis. And we know that this will help our Nation, because for every dollar we invest in infrastructure, we get over $2 back in economic output.

MILITARY REDUCTIONS SEND THE WORST POSSIBLE MESSAGE TO OUR ADVERSARIES

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

Mr. CARTER of Texas. Madam Speaker, I have long opposed reductions in our military, and I continue to believe that our Nation should maintain a robust land force. The announcement to reduce the Army by 40,000 troops sends the worst possible message to our Nation's adversaries. Cuts that extend into heavy armored combat units go even further to weaken our national defense and put us at risk.

I am especially disappointed about the Army's plan to cut so heavily from Fort Hood and the State of Texas. The Army's decision to implement a roughly 9 percent reduction at the Great Place is outrageous. I have serious concerns about the logic and analysis that went into this decision to reduce so many troops from Texas.

Perhaps the most sickening part of the whole matter, however, is the damage these cuts will do to the soldiers and their families who will be asked to leave the Army after decades of sacrifice in time of war. In the coming days, I will be pressing the Army for clarification on their analysis and justification for their decisions.

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. 1. Short title; table of contents.
Sec. 2. NIH and Cures Innovation Fund.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

Sec. 1001. National Institutes of Health reauthorization.

Subtitle B—National Institutes of Health Planning and Administration

Sec. 1021. NIH research strategic plan.
Sec. 1022. Increasing accountability at the National Institutes of Health.
Sec. 1023. Reducing administrative burdens of researchers.
Sec. 1024. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
Sec. 1025. NIH travel.
Sec. 1026. Other transactions authority.
Sec. 1027. NCATS phase IIB restriction.
Sec. 1028. High-risk, high-reward research.
Sec. 1029. Sense of Congress on increased inclusion 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.
Sec. 1042. Report.

Subtitle D—Capstone Grant Program

Sec. 1061. Capstone award.

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

Sec. 1081. National pediatric research network.
Sec. 1082. Global pediatric clinical study network sense of Congress.
Sec. 1083. Appropriate age groupings in clinical research.

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.

Subtitle G—Facilitating Collaborative Research

Sec. 1121. Clinical trial data system.
Sec. 1122. National neurological diseases surveillance system.
Sec. 1123. Data on natural history of diseases.
Sec. 1124. Accessing, sharing, and using health data for research purposes.

Subtitle H—Council for 21st Century Cures

Sec. 1141. Council for 21st Century Cures.

TITLE II—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

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

Subtitle B—Qualification and Use of Drug Development Tools

Sec. 2021. Qualification of drug development tools.

Sec. 2022. Accelerated approval development plan.

Subtitle C—FDA Advancement of Precision Medicine

Sec. 2041. Precision medicine guidance and other programs of Food and Drug Administration.

Subtitle D—Modern Trial Design and Evidence Development

Sec. 2061. Broader application of Bayesian statistics and adaptive trial designs.
Sec. 2062. Utilizing evidence from clinical experience.
Sec. 2063. Streamlined data review program.

Subtitle E—Expediting Patient Access

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

Subtitle F—Facilitating Responsible Manufacturer Communications

Sec. 2101. Facilitating dissemination of health care economic information.
Sec. 2102. Facilitating responsible communication of scientific and medical developments.

Subtitle G—Antibiotic Drug Development

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

Subtitle H—Vaccine Access, Certainty, and Innovation

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

Subtitle I—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.
Sec. 2152. Reauthorization of rare pediatric disease priority review voucher incentive program.

Subtitle J—Domestic Manufacturing and Export Efficiencies

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

Subtitle K—Enhancing Combination Products Review

Sec. 2181. Enhancing combination products review.

Subtitle L—Priority Review for Breakthrough Devices

Sec. 2201. Priority review for breakthrough devices.

Subtitle M—Medical Device Regulatory Process Improvements

Sec. 2221. Third-party quality system assessment.
Sec. 2222. Valid scientific evidence.
Sec. 2223. Training and oversight in least burdensome appropriate means concept.
Sec. 2224. Recognition of standards.
Sec. 2225. Easing regulatory burden with respect to certain class I and class II devices.
Sec. 2226. Advisory committee process.
Sec. 2227. Humanitarian device exemption application.
Sec. 2228. CLIA waiver study design guidance for in vitro diagnostics.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

Sec. 2241. Health software.
Sec. 2242. Applicability and inapplicability of regulation.
Sec. 2243. Exclusion from definition of device.

Subtitle O—Streamlining Clinical Trials

Sec. 2261. Protection of human subjects in research; applicability of rules.
Sec. 2262. Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions.
Sec. 2263. Alteration or waiver of informed consent for clinical investigations.

Subtitle P—Improving Scientific Expertise and Outreach at FDA

Sec. 2281. Silvio O. Conte Senior Biomedical Research Service.
Sec. 2282. Enabling FDA scientific engagement.
Sec. 2283. Reagan-Udall Foundation for the Food and Drug Administration.
Sec. 2284. Collection of certain voluntary information exempted from Paperwork Reduction Act.
Sec. 2285. Hiring authority for scientific, technical, and professional personnel.

Subtitle Q—Exempting From Sequestration Certain User Fees

Sec. 2301. Exempting from sequestration certain user fees of Food and Drug Administration.

TITLE III—DELIVERY

Subtitle A—Interoperability

Sec. 3001. Ensuring interoperability of health information technology.

Subtitle B—Telehealth

Sec. 3021. Telehealth services under the Medicare program.

Subtitle C—Encouraging Continuing Medical Education for Physicians

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

Subtitle D—Disposable Medical Technologies

Sec. 3061. Treatment of certain items and devices.

Subtitle E—Local Coverage Decision Reforms

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

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-Service Price Transparency

Sec. 3121. Medicare site-of-Service price transparency.

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.

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.
Sec. 4002. Excluding authorized generics from calculation of average manufacturer price.
Sec. 4003. Medicare payment incentive for the transition from traditional x-ray imaging to digital radiography and other Medicare imaging payment provision.
Sec. 4004. Treatment of infusion drugs furnished through durable medical equipment.
Sec. 4005. Extension and expansion of prior authorization for power mobility devices (PMDs) and accessories and prior authorization audit limitations.
Sec. 4006. Civil monetary penalties for violations related to grants, contracts, and other agreements.

Subtitle B—Other Reforms

Sec. 4041. SPR drawdown.

Subtitle C—Miscellaneous

Sec. 4061. Lyme disease and other tick-borne diseases.

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 short-sighted 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
Aderholt
Amash
Amodei
Babin
Barr
Bishop (MI)
Bishop (UT)
Black
Blum
Brady (TX)
Brat
Bridenstine
Brooks (AL)
Buck
Byrne
Carter (GA)
Carter (TX)
Chabot
Chaffetz
Clawson (FL)
Coffman
Collins (GA)
Conaway
Cook
Crawford
Culberson
DeSantis
DesJarlais
Duffy
Duncan (SC)
Duncan (TN)
Emmer (MN)
Farenthold
Fincher
Fleischmann
Fleming
Forbes
Fortenberry
Foxx
Franks (AZ)
Garrett
Gibbs
Gohmert
Goodlatte
Gosar
Gowdy
Graves (GA)
Graves (LA)
Grothman
Hardy
Harris
Hartzler
Heck (NV)
Hensarling
Hice, Jody B.
Holding
Huelskamp
Huizenga (MI)
Hultgren
Hunter
Hurd (TX)
Hurt (VA)
Issa
Jenkins (KS)
Johnson, Sam
Jolly
Jones
Jordan
Joyce
King (IA)
Labrador
LaMalfa
Lamborn
Loudermilk
Love
Lummis
Marchant
Massie
McClintock
Meadows
Messer
Mica
Miller (FL)
Moolenaar
Mooney (WV)
Mulvaney
Newhouse
Noem
Palazzo
Palmer
Paulsen
Pearce
Perry
Poe (TX)
Poliquin
Posey
Price, Tom
Ratcliffe
Renacci
Ribble
Rice (SC)
Rigell
Roby
Rohrabacher
Rokita
Rooney (FL)
Ross
Rothfus
Rouzer
Royce
Russell
Ryan (WI)
Sanford
Schweikert
Scott, Austin
Sensenbrenner
Sessions
Smith (MO)
Smith (NE)
Smith (TX)
Stewart
Stutzman
Thornberry
Tipton
Trott
Walberg
Walker
Walorski
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Westmoreland
Williams
Wilson (SC)
Wittman
Woodall
Yoho
Young (IN)
Zinke

NOES—281

Adams
Aguilar
Allen
Ashford
Barletta
Barton
Beatty
Becerra
Benishek
Bera
Beyer
Bilirakis
Bishop (GA)
Blackburn
Blumenauer
Bonamici
Bost
Boustany
Boyle, Brendan F.
Brady (PA)
Brooks (IN)
Brown (FL)
Brownley (CA)
Buchanan
Bucshon
Burgess
Bustos
Butterfield
Calvert
Capps
Capuano
Cárdenas
Carney
Carson (IN)
Cartwright
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Cole
Collins (NY)
Comstock
Connolly
Conyers
Cooper
Costa
Costello (PA)
Courtney
Cramer
Crenshaw
Crowley
Cuellar
Cummings
Curbelo (FL)
Davis (CA)
Davis, Danny
Davis, Rodney
DeFazio
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

purposes, which was referred to the Union Calendar and ordered to be printed.

The SPEAKER pro tempore (Ms. STEFANIK). Pursuant to clause 1, rule XXI, all points of order are reserved on the bill.

□ 1130

THE VENEZUELA OF YESTERDAY, TODAY, AND TOMORROW

(Ms. ROS-LEHTINEN asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. ROS-LEHTINEN. Madam Speaker, I urge my colleagues to visit the graphic display that is exhibited right now at the Rayburn foyer called the Venezuela of Yesterday, Today, and Tomorrow.

This exhibit carries the hopes and dreams of Venezuelans and Venezuelan Americans who worked hard to restore democracy, freedom, and prosperity to their homeland.

The Maduro regime has destroyed the economy of a once wealthy nation, causing widespread shortages and long lines for consumer goods.

Innocent men and women who demand the protection of democratic principles are arrested with false charges and tried by kangaroo courts, where their fate is already sealed.

Madam Speaker, I urge all of my colleagues to join the Educational Foundation for Democracy and IVAC for a tour of this impressive collection of photos that documents the prosperous democratic past, the oppressive present, and the bright future that awaits Venezuela, for which they are fighting now.

CONFEDERATE BATTLE FLAG

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

Mr. COHEN. Madam Speaker, today is a proud day in the State of South Carolina and should be a proud day throughout the South in the United States of America, for the South Carolina legislature, under the direction of their Governor, took down the Confederate flag that flew on their capitol.

It should be a proud day for all, for the South is much more than the flag, and the South has much to be proud of. But the flag symbolizes things that are not something the South should not be proud of.

Patterson Hood, a member of a band called Drive-by Truckers, wrote a song called The Southern Thing and has a commentary in The New York Times Magazine this week, expressing why he hates hatred and sees the flag as divisive and why it should come down.

It was the right thing to do. And the Mississippi State flag should come down, which has the rebel flag as part of its insignia and is in the halls of the Congress. That flag, as has been asked by Representative BENNIE THOMPSON of Mississippi and Leader PELOSI, should also come down.

Signs of treason, signs of hate, signs of racism have no place in the United States of America's halls of Congress and should come down.

21ST CENTURY CURES ACT

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

Mr. ALLEN. Madam Speaker, I want to thank my colleagues today for passing the 21st Century Cures Act to create a path forward to expedite the delivery of lifesaving and life-improving cures that will change the lives of millions across this Nation.

I want to share the story of Arturo Solares from my district, who is 7½ years old and lives in Evans, Georgia. Arturo was diagnosed on his fourth birthday with autism. On that day, he had less than 50 words and was considered severely affected. The doctor didn't give his family much hope for the future.

Thanks to the dedication of his parents and innovation in our medical community there, today Arturo doesn't even need speech therapy. However, he still needs medications which are currently caught up in bureaucratic red tape.

This bill, the 21st Century Cures Act, provides a modern healthcare solution that gives hope to so many families like Arturo's and others across this great country.

I thank my colleagues for passing this legislation today that will improve the lives of future generations.

TARRANT COUNTY BLACK HISTORICAL & GENEALOGICAL SOCIETY

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

Mr. VEASEY. Madam Speaker, I rise today to honor the four surviving charter members of the Tarrant County Black Historical & Genealogical Society, those being Ms. Erma Johnson Hadley, Ms. Opal Lee, Mr. Frank Moss, and Reverend Arthur Slaughter.

The Tarrant County Black Historical & Genealogical Society began as a need for material relating to the Black history that was available to Tarrant County universities and libraries.

In 1974, the late Ms. Lenora Rolla began to collect personal papers, scrapbooks, clippings, photographic collections, artwork, and other relevant materials to create this society and, also, what is an incredible archive.

Following its inception, Ms. Hadley, Opal Lee, Frank Moss, and Reverend Slaughter continued the organization's work to educate Tarrant County residents about its rich African American history, and they will be honored during this month's Tarrant County Black Historical & Genealogical Biannual Member Luncheon at the Fort Worth Botanic Gardens.

Today, with the help of these four charter members, the society continues to collect, preserve, and enrich our community, and I applaud their efforts.

21ST CENTURY CURES ACT

(Mrs. ELLMERS of North Carolina asked and was given permission to address the House for 1 minute.)

Mrs. ELLMERS of North Carolina. Mr. Speaker, we have all heard the phrase ''if you have your health, you have everything.''

But for many who are suffering from debilitating diseases or caring for a family member with one, their ability to pursue life, liberty, and happiness is interrupted.

Mr. Speaker, the reason entitlement spending is so vast in this country is because we have diseases and conditions requiring countless dollars.

We are America, the greatest country in the world. We have big ideas, and we want to provide the best future for our children and our grandchildren.

The 21st Century Cures Act is just one of those big ideas that will produce numerous benefits for everyone. And for fiscal conservatives like myself, we should appreciate this bill and its passage with overwhelming support.

In our healthcare system, we diagnose disease, we treat symptoms, and we have thousands of new seniors on Medicare every day that we must take care of. The passage of this 21st Century Cures Act is a definitive way to take care of every American family.

Today we waged war on disease.

EXPORT-IMPORT BANK

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

Mr. NOLAN. Mr. Speaker, Members of the House, I rise in support of the urgent need to reauthorize the Ex-Im Bank.

I spent the better part of 20 years of my life in export trading, and I know what a great benefit it has been to the small business community and the banking community.

What happens is a small-town bank wants to provide financial support for local business people to export their goods and their products, but they don't know if a sales contract in Timbuktu or Abu Dhabi or Lagos or wherever is a legitimate contract. So they have to rely on some kind of expertise.

So that is why the local banks, that is why the local business community, supports the Ex-Im Bank, because they do that. And they do it for a fee.

Ironically enough, the Ex-Im Bank has generated almost $7 billion in profits over the last couple of decades, helping us with our deficit reduction and helping our small- and medium-sized companies to export their goods and services.

I ask all my colleagues to take a look at their district and see how many small businesses benefit from that and join me in support.

There are only a couple of ways to generate wealth, and exporting your goods is one of them.

CONGRATULATING WAYZATA HIGH SCHOOL GOLF TEAM

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

Mr. PAULSEN. Mr. Speaker, I rise to congratulate the Wayzata High School boys golf team on winning this year's Minnesota State championship.

After finishing in the runner-up position for the last two seasons, Wayzata broke through and won the State title by three strokes this year. It was a well-balanced performance by the entire team that allowed them to take the championship.

While many think of golf as an individual sport, it took strong performances from each and every golfer to bring home the State title. The game of golf, Mr. Speaker, can be very humbling, and it takes focus, mental toughness, and skill to compete at a very high level.

I commend these student athletes on their commitment and dedication not only to golf, but to their family obligations and their studies as well. The time commitments required to be a top high school athlete are not easy. And their friends, families, and communities are very proud.

Congratulations again to the Wayzata High School boys golf team.

TRANSPORTATION INFRASTRUCTURE

(Ms. NORTON asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. NORTON. Mr. Speaker, as you can see by this chart, the Federal gas user fee, at only $97 a year, buys drivers $515 in costs per driver because of bad roads.

Just released data also shows that up to 73 percent of the bridges in some States are deficient. Can you think of any other necessity, except the $97 gas user fee, that has not increased in 22 years? We are getting what we paid for in the hidden costs of bad roads and bridges.

The congressional response has been so disproportionate to the needs of the States that we are told that another short-term extension—that would be the 34th—12 legislative days from now could yield a veto.

The States say that these short-term extensions are useless. Only the next 2 weeks to get a long-term authorization is pushing it. Given the state of our bridges and roads, we have no alternative.

END OF THE MANHUNT

(Ms. STEFANIK asked and was given permission to address the House for 1 minute.)

Ms. STEFANIK. Mr. Speaker, as Americans across the country know, my district was the unfortunate home of a recent manhunt that captured the attention of our country.

For more than 3 weeks, two killers remained at large in our north country community after escaping from Clinton Correctional Facility. During this time period, hundreds and hundreds of brave law enforcement officers worked diligently to find these escaped convicts and protect our community.

Mr. Speaker, I rise today to thank these brave law enforcement officers who risked their safety to protect the families in our neighborhoods, and I rise to thank our local communities for their patience and support during this difficult time.

Going forward, we must find answers as to how this prison break occurred and do what is needed to stop this from ever happening again. But, for now, our north country community can sleep safer, knowing these two killers are no longer at large.

CHANGE IS NOT BAD

(Ms. JACKSON LEE asked and was given permission to address the House for 1 minute.)

Ms. JACKSON LEE. Mr. Speaker, I think it is important to again note what a historic day this was, with the passage of the 21st Century Cures Act, which opens the opportunity for billions of dollars to be invested in the Nation's clinics and laboratories to make America healthy and make America better.

This bill is from the Energy and Commerce Committee. I am very proud to be one of its cosponsors. And I would like to say back to my constituents in Texas, the Texas Medical Center, and all of the research that is being done: Here is an opportunity to work on those unique and special diseases impacting children with lupus and other diseases. That is why change is not bad.

Additionally, I join with the arguments in my district for changing the names of high schools that are not reflective of the Nation today, those named after confederate generals. The names of these high schools are not reflective of a unifying America.

Frankly, I believe that the school board should address this question and teach the children that that is the past history that was not a positive history and that we should reflect positively on unifying America and carrying the American flag.

Lastly, again, I say on the floor what a very special day, the solemnity in the way the rebel flag was finally put to rest, put to rest, and taken to a relic museum, where it belongs. And we can stand here under this shining American flag saying that we, too, are Americans.

□ 1145

KEEP PATENT SYSTEM STRONG

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

Mr. MASSIE. Mr. Speaker, when patent trolls use U.S. patents to game the system for illegitimate financial gain, it is much like counterfeiting because these are official U.S. documents. What would we do if we found a counterfeiter? Would we go after the counterfeiter, or would we devalue our currency to discourage counterfeiters?

Well, that sounds ridiculous. That would wreck our economy just to go after counterfeiters by devaluing the currency. But that is what the Innovation Act, H.R. 9, does to patents. It devalues all patents, and it is going to wreck our economy if we pass it.

Patents are the currency of invention. If you want invention to be strong in this country, you need to keep the patent system strong.

I urge my colleagues to vote against H.R. 9.

21ST CENTURY CURES ACT

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

Mr. KATKO. Mr. Speaker, I rise today to celebrate the overwhelming passage of the 21st Century Cures Act.

Across central New York, I heard from advocates and individuals suffering from diseases like Alzheimer's, ovarian cancer, multiple sclerosis, and epilepsy, to name a few. That is not just something I heard from my colleagues. Those diseases have stricken those in my family as well.

We owe it to the people and their families to support medical research so that individuals in our communities can live longer, healthier lives.

Today's legislation allows researchers and scientists to move forward in their efforts to produce lifesaving treatments, therapies, and cures for our loved ones. It will reduce medical uncertainty in the development of new medicine and remove barriers to increase research collaboration.

I dream of a time in a not too distant future when I can tell my children that what we did here on the floor of the House today saved lives and prevented them and their children from enduring some of the diseases that we have had to endure in our lifetime.

21ST CENTURY CURES ACT

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

Mr. THOMPSON of Pennsylvania. Mr. Speaker, moments ago with my support, the House of Representatives passed H.R. 6, the 21st Century Cures Act.

This bipartisan bill will bring our national healthcare system up to speed in the 21st century by taking advantage of the latest science and expediting the availability of safe and more effective treatments for all Americans.

Mr. Speaker, today there are more than 10,000 known diseases and conditions, but the United States of America only has cures and treatments for roughly 500 of them.

Diseases such as cancer, Parkinson's, and Alzheimer's will take the lives of roughly 1.8 million people this year in the United States alone. This 21st Century Cures Act will help change that, and it is an important step toward helping save the lives of our love ones.

Having served for nearly 30 years in the healthcare field, I applaud my colleagues on both sides of the aisle for passing this legislation.

TRIP FOR FREEDOM

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

Mr. CURBELO of Florida. Mr. Speaker, I want to strongly urge my colleagues to visit an exhibition happening right now in the Rayburn foyer.

The graphic display, which includes a remarkable collection of photos, is entitled the Venezuela of Yesterday, Today, and Tomorrow. It is a reminder of the hard work being done every day by Venezuelans and Venezuelan Americans in their pursuit to restore democracy in a country ravaged by economic turmoil and a regime filled with corrupt leaders who will persecute anyone who voices disagreement.

It is more important now than ever for the United States to remain firm in our support for the people of Venezuela. We must remain strong in solidarity with the people who fight for a truly democratic Venezuela free from tyranny and the fear of a regime that promotes violence against its own people.

Again, I encourage my colleagues to take advantage of this opportunity to join the Educational Foundation for Democracy and IVAC in the promotion of a better future for Venezuelans and everyone in our hemisphere.

IRAN NUCLEAR NEGOTIATIONS

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

Mr. DOLD. Mr. Speaker, another deadline has passed, and Iran continues to act like it has leverage. What is worse, by its action, the administration seems to agree.

Make no mistake about it, Iran desperately needs a deal to relieve its crippling sanctions. Given the parade of U.S. concessions over the past 19 months, we are a long way from the starting point of demanding that Iran's nuclear program be affirmatively and unequivocally dismantled.

Mr. Speaker, there should be no wiggle room that allows any path to a nuclear weapon. Yet Iran's violations of interim agreement have been met with shrugs and painful-to-see justifications by this administration.

How can we trust Iran to uphold any deal when it has clearly proven untrustworthy?

Why would we give the greatest state sponsor of terror another $150 billion that even the administration acknowledges may go to fund terrorism against the United States, Israel, other democracies, and our allies around the globe?

It is time to walk away, reestablish our leverage, and force Iran back to the table on our terms.

RECOGNIZING PHILLIP BURR

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

Mr. STEWART. Mr. Speaker, I want to take a moment to recognize one of my own constituents, Phillip Burr, from Burrville, Utah.

Phillip has dedicated his career to providing electricity to rural Utah while working for one of my favorite companies, Garkane Energy. He has also spread that passion globally, making trips to such places as Bolivia and, most recently, Haiti.

We all know that electricity is a critical element to improving quality of life and increasing access to basic necessities like healthcare, education, and clean water. After learning Haiti has less than 15 percent of its population with regular access to electricity, Phillip traveled there to help build a diesel solar hybrid distribution system that will provide safe, affordable, and reliable power to more than 1,600 consumers.

This type of service is what makes America great. I am honored to recognize him for his example of humanitarian service and to thank him for all the work he has done in his community and around the world.

Mr. Burr, I salute you.

125 YEARS OF STATEHOOD FOR WYOMING

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

Mrs. LUMMIS. Mr. Speaker, today, the great State of Wyoming, the Equality State, is celebrating her 125th anniversary of statehood.

Wyoming is a wondrous place, boasting our Nation's first national park, first national forest, and first national monument. Wyoming's scenic treasures are second to none in the world.

Our vast stores of resources—coal, uranium, timber, oil, gas, soda ash, and rare earth elements—all provide critical resources for our Nation.

Wyoming's freedom-loving, hard-working people have a deep sense of place and seamlessly weave the fabric of stewardship into it, inspiring the entire country and, really, the whole world.

I am proud to call Wyoming America's 44th star, my love, my life, and my home. I wish her a blessed 125th year of statehood.

BIRTHDAY WISHES

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

Mr. KELLY of Mississippi. Mr. Speaker, today, July 10, I rise to celebrate my son's birthday. I also rise in honor of my father's birthday, which was yesterday, and he would have been 74.

A representation of the future, I recognize John Forest Kelly, known to us as JFK. He was born in 1995 and will be 20 today.

In honor of the past, yesterday was my father, big John Kelly's birthday. He was born July 9, 1941. He was a great man and an inspiration to me. He served in the Mississippi Army National Guard from 1959 until he turned 60 in 2001 and retired as a first sergeant.

THANKING VIETNAM VETERANS

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

Mr. LAMALFA. Mr. Speaker, this last Wednesday, we took time out here in the Capitol to honor and remember our Vietnam veterans. This week was the 50th anniversary for the first deployment of our troops in Vietnam.

A lot of times, it is a war that wasn't understood by the American people or appreciated. What is wrong about that is that our troops were not always appreciated for what they did for us. They did it without complaint, they did it with sacrifice, and they did it with honor. So for us here in the Capitol to finally come around to that ideal and honor them was a very good thing.

For our Vietnam troops, we do appreciate you. We will do all we can to help you as you work through VA, as you work through Agent Orange. We know many of you are suffering these things, and you are not getting enough help from our Federal Government or that recognition.

So in recognition of what happened here this week on the 50th anniversary of the first deployment, we say to our Vietnam veterans: Welcome home, and God bless you.

SANCTUARY CITIES MUST END

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

Mr. BABIN. Mr. Speaker, the tragic killing of Kathryn Steinle at the hands

of a five-time deported illegal alien and a seven-time convicted felon should never have happened. But that is exactly what happens when a city ignores immigration laws.

The consequences of government-sanctioned lawlessness are real, and this is another in a long line of tragic wake-up calls that cry out for deporting criminal aliens.

Ms. Steinle's killer, a wanted criminal illegal alien, had been in custody but then was put back on the streets by San Francisco officials.

The Obama administration shares blame because they have done nothing to combat sanctuary city policies. Instead, they have encouraged them.

We swore an oath to protect the American people from enemies, foreign and domestic. This Congress should take action to combat sanctuary city policies and make sure that criminal aliens are deported.

I rise in strong support of legislation that I have cosponsored that would do just that, because it is time to put the safety of American citizens first.

ADJOURNMENT FROM FRIDAY, JULY 10, 2015, TO MONDAY, JULY 13, 2015

Mr. DOLD. Mr. Speaker, I ask unanimous consent that when the House adjourns today, it adjourn to meet on Monday, July 13, 2015, when it shall convene at noon for morning-hour debate and 2 p.m. for legislative business.

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

There was no objection.

APPOINTMENT OF ADDITIONAL CONFEREES ON H.R. 1735, NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2016

The SPEAKER pro tempore. Without objection, the Chair appoints the following additional conferees on H.R. 1735.

From the Permanent Select Committee on Intelligence, for consideration of matters within the jurisdiction of that committee under clause 11 of rule X: Messrs. NUNES, KING of New York, and SCHIFF.

From the Committee on Education and the Workforce, for consideration of sections 571 and 573 of the House bill and sections 561–63 of the Senate amendment, and modifications committed to conference: Messrs. ROKITA, BISHOP of Michigan, and SCOTT of Virginia.

From the Committee on Energy and Commerce, for consideration of sections 314, 632, 634, 3111–13, 3119, 3133, and 3141 of the House bill and sections 601, 632, 3118, and 3119 of the Senate amendment, and modifications committed to conference: Messrs. UPTON, BARTON, and PALLONE.

From the Committee on Foreign Affairs, for consideration of sections 1011, 1059, 1090, 1092, 1201, 1203–05, 1215, 1221, 1223, 1226, 1234–36, 1247–49, 1253, 1257, 1263, 1264, 1267, 1270, 1301, 1532, 1541, 1542, 1663, 1668–70, 2802, 3118, and 3119 of the House bill and sections 1011, 1012, 1082, 1201–05, 1207, 1209, 1223, 1225, 1228, 1251, 1252, 1261, 1264, 1265, 1272, 1301, 1302, 1531–33, 1631, 1654, and 1655 of the Senate amendment, and modifications committed to conference: Messrs. ROYCE, MARINO, and ENGEL.

From the Committee on Homeland Security, for consideration of sections 589 and 1041 of the Senate amendment, and modifications committed to conference: Mr. MCCAUL, Mrs. MILLER of Michigan, and Mr. THOMPSON of Mississippi.

From the Committee on the Judiciary, for consideration of sections 1040, 1052, 1085, 1216, 1641, and 2862 of the House bill and sections 1032, 1034, 1090, and 1227 of the Senate amendment, and modifications committed to conference: Messrs. GOODLATTE, ISSA, and CONYERS.

From the Committee on Natural Resources, for consideration of sections 312, 632, 634, 2841, 2842, 2851–53, and 2862 of the House bill and sections 313, 601, and 632 of the Senate amendment, and modifications committed to conference: Messrs. COOK, HARDY, and GRIJALVA.

From the Committee on Oversight and Government Reform, for consideration of sections 602, 631, 634, 838, 854, 855, 866, 871, 1069, and 1101–05 of the House bill and sections 592, 593, 631, 806, 830, 861, 1090, 1101, 1102, 1104, 1105, 1107–09, 1111, 1112, 1114, and 1115 of the Senate amendment, and modifications committed to conference: Messrs. HURD of Texas, RUSSELL, and CUMMINGS.

From the Committee on Rules, for consideration of section 1032 of the Senate amendment, and modifications committed to conference: Messrs. SESSIONS, BYRNE, and Ms. SLAUGHTER.

From the Committee on Science, Space, and Technology, for consideration of section 3136 of the House bill and section 1613 of the Senate amendment, and modifications committed to conference: Messrs. LUCAS, KNIGHT, and Ms. EDDIE BERNICE JOHNSON of Texas.

From the Committee on Small Business, for consideration of sections 831–34, 839, 840, 842–46, 854, and 871 of the House bill and sections 828, 831, 882, 883, and 885 of the Senate amendment, and modifications committed to conference: Messrs. CHABOT, HANNA, and Ms. VELÁZQUEZ.

From the Committee on Transportation and Infrastructure, for consideration of sections 302, 562, 569, 570a, 591, 1060a, 1073, 2811, and 3501 of the House bill and sections 601, 642, 1613, 3504, and 3505 of the Senate amendment, and modifications committed to conference: Messrs. GRAVES of Louisiana, CURBELO of Florida, and Ms. EDWARDS.

From the Committee on Veterans' Affairs, for consideration of sections 565, 566, 592, 652, 701, 721, 722, 1105, and 1431 of the House bill and sections 539, 605, 633, 719, 1083, 1084, 1089, 1091, and 1411 of the Senate amendment, and modifications committed to conference: Messrs. ROE of Tennessee, BILIRAKIS, and Ms. BROWN of Florida.

There was no objection.

The SPEAKER pro tempore. The Senate will be notified of the additional conferees.

□ 1200

HONORING JOHN DAVID CROW

The SPEAKER pro tempore. Under the Speaker's announced policy of January 6, 2015, the gentleman from Texas (Mr. FLORES) is recognized for 60 minutes as the designee of the majority leader.

Mr. FLORES. Mr. Speaker, I rise today to honor one of my constituents, John David Crow, of College Station, Texas, who passed away on June 17.

To say that John David Crow is a Texas football legend is an understatement. He was a Heisman Trophy winner, a four-time NFL Pro Bowl selection, a college football coach, and an administrator for the Texas A&M University Athletic Department.

John David was born on July 8, 1935, in Marion, Louisiana. When he was born, the umbilical cord was wrapped around his neck, causing nerve damage and permanently paralyzing the left half of his face. John David, however, never let that hardship hold him back.

As a junior at Springhill High School, he led the football team to win the Class 1A State championship in 1952. As a senior, he led the basketball team to win the Class 1A State championship in 1954.

After graduating from high school, John David married his high school sweetheart, Carolyn Gilliam, on July 2, 1954. Earlier that year, John David had committed to play football at Texas A&M University for legendary coach Paul ''Bear'' Bryant; so, in the fall of 1954, John David and Carolyn moved to College Station.

During his time at Texas A&M, John David would play running back, defensive positions, and special teams as a kick returner. He truly was the complete collegiate football package.

In 1956, he led the Aggies to their first ever road victory against archrival, the University of Texas, at Memorial Stadium in Austin. He also led the Aggies to a number one ranking during the 1957 season.

Some of the accolades that John David received as an Aggie included being named twice to the Southwest Conference all-conference team in 1956 and 1957. He also received all of the following recognitions in 1957: a consensus All-American, the Walter Camp Memorial Trophy, the Southwesterner of the Year and Amateur Athlete of the Year, the Chick Harley Award, the United Press Player of the Year, the United Press Back of the Year, and the Heisman Trophy.

John David was Texas A&M University's first Heisman Trophy winner and the only Heisman Trophy winner to

ever be coached by the legendary Bear Bryant. When Bear Bryant retired from coaching, he was quoted as saying: ''John David Crow was the finest player I ever coached. Watching film on him was like watching a grown man play with boys.''

John David would graduate from Texas A&M with a degree in business administration and was named to the Scholastic All-American team. He was also recognized as a Who's Who in American Colleges and Universities.

John David would go on to play in the NFL after being drafted in the first round to play for the then Chicago Cardinals, in Chicago and St. Louis, and playing for the San Francisco 49ers. He was named to the Pro Bowl four times and named to the NFL's 1960 All-Decade Team.

After retiring from the NFL, John David began his football coaching career, starting as an assistant for his former coach Bear Bryant at Alabama. He continued his career as an assistant coach in the NFL for the Cleveland Browns and the San Diego Chargers. In 1976, he was named athletic director and head football coach of Northeast Louisiana University.

In 1981, John David would leave Northeast Louisiana University to work for a private business for a couple of years. In 1983, he returned to his alma mater, Texas A&M University, first as associate athletic director, later as athletic director, and finally, as director of athletic development.

During this time, he was at the forefront of collegiate athletic gender equity as he helped expand women's athletics at Texas A&M to the powerhouse that it is today. In 2001, John David would retire from A&M, but he still maintained a presence on campus and in the Bryan/College Station community.

John David Crow was a great athlete, coach, and athletic administrator. He was inducted into the Texas A&M University Hall of Fame in 1968 and the Louisiana Hall of Fame in 1976. He was named to the National Football Foundation Hall of Fame in 1976 and the Texas Sports Hall of Fame in 1982. He was named a Distinguished Alumnus by Texas A&M University in 2004 and was honored during the Aggies' first year in the Southeastern Conference as an SEC Legend at the 2012 SEC Championship Game.

While John David was dedicated to his career, he was also very much dedicated to his wife, Carolyn, and to their family. He and Carolyn had three children: John, Jr., Annalisa, and Jeannie. They were also blessed with seven grandchildren.

John David was forever thankful for everything Carolyn did for their family. He was once quoted as saying: ''Whatever credit I get for doing anything, she deserves a lot more than I do. She has been the stabilizer for our family and very, very good to me.''

Mr. Speaker, John David Crow was a humble, kind, generous, and an all-around great man. The greatness that he evoked reached far beyond the football field. He truly embodied the core values of Texas A&M University—respect, integrity, leadership, excellence, loyalty, and selfless service.

He will be greatly missed and will long be remembered as a great athlete, coach, and athletic administrator. More importantly, he will be remembered as a loving husband, a father, a grandfather, and as a friend.

My wife, Gina, and I offer our deepest and heartfelt condolences to Carolyn and to the Crow family. We also lift up the family and friends of John David Crow in our thoughts and in our prayers.

Also, as I close this conversation about John David Crow, I ask that all Americans continue to pray for our country, for our military men and women who protect us from external threats, and for our first responders who protect us here at home.

HONORING JACK GILLEY

Mr. FLORES. Mr. Speaker, I rise today to honor Jack Calvin Gilley of Stratford, Texas, who passed away on May 9, 2015.

As a teacher and principal for 34 years, Mr. Gilley touched the lives of hundreds of students and schools throughout Oklahoma and the Texas Panhandle. I was fortunate enough to have Mr. Gilley as a principal during my time at Stratford Middle School.

Jack Gilley was born in Dawson County, Texas, in 1924. He proudly served in the United States Navy during World War II as a torpedoman on the USS Stockdale. He attended Panhandle A&M College on basketball and baseball scholarships. Additionally, he received his master's in education from West Texas State University in 1963.

In 1951, Jack married Donna Mal Oldaker. They were married for nearly 59 years, until her passing in 2010. Donna and Jack had four daughters and were blessed with one granddaughter.

After retiring from teaching, Jack began his secondary profession of painting houses, refinishing furniture, and carpentry. He was a member of the First United Methodist Church of Stratford, as well as a member of the American Legion Post 262. He loved hunting pheasant and quail; eating breakfast and drinking coffee with his friends at the local cafe; and all things rodeo and all things sports, especially Duke basketball.

Mr. Speaker, Jack Gilley impacted many lives, including mine, as an educator and as a mentor. He will be greatly missed and long remembered as a loving husband, a father, a grandfather, and a friend.

My wife, Gina, and I offer our deepest and heartfelt condolences to the Gilley family, and we lift up the family and friends of Jack Gilley in our prayers.

Mr. Speaker, as I close, I ask that all Americans continue to pray for our country, for our military men and women who protect us from external threats, and for our first responders who protect us here at home.

Mr. Speaker, I yield back the balance of my time.

ADJOURNMENT

Mr. FLORES. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 12 o'clock and 14 minutes p.m.), under its previous order, the House adjourned until Monday, July 13, 2015, at noon for morning-hour debate.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

2130. A letter from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting the Commission's final rule — Accessible Emergency Information, and Apparatus Requirements for Emergency Information and Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010 [MB Docket No.: 12-107] received July 9, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); Added by Public Law 104-121, Sec. 251; to the Committee on Energy and Commerce.

2131. A letter from the Director, Defense Security Cooperation Agency, transmitting a notice of a proposed lease of defense articles to the Government of the Hashemite Kingdom of Jordan (Transmittal No.: 06-15), pursuant to Sec. 62(a) of the Arms Export Control Act (AECA); to the Committee on Foreign Affairs.

2132. A letter from the Chairman, National Transportation Safety Board, transmitting a list of the Board's 2015 commercial and inherently governmental commercial activities inventory, pursuant to the Federal Activities Inventory Reform (FAIR) Act of 1998, Pub. L. 105-270; to the Committee on Oversight and Government Reform.

2133. A letter from the ICE Regulatory Coordinator, ICE Office of Policy, Regulatory Division, Department of Homeland Security, transmitting the Department's final rule — Change to Existing Regulation Concerning the Interest Rate Paid on Cash Deposited to Secure Immigration Bonds [DHS Docket No.: ICEB-2013-0002] (RIN: 1653-AA66) received June 24, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); Added by Public Law 104-121, Sec. 251; to the Committee on the Judiciary.

2134. A letter from the Deputy Secretary, Department of Defense, transmitting a certification that other countries have contributed an amount not less than 40 percent of the $1.618 billion appropriated for the Iraq Train and Equip Fund, pursuant to Pub. L. 113-291, Sec. 1236; jointly to the Committees on Foreign Affairs and Armed Services.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. COLE: Committee on Appropriations. H.R. 3020. A bill 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 purposes (Rept. 114–195). Referred to the Committee of the Whole House on the state of the Union.

Mr. GOODLATTE: Committee on the Judiciary. H.R. 1155. A bill to provide for the establishment of a process for the review of rules and sets of rules, and for other purposes (Rept. 114–196, Pt. 1). Ordered to be printed.

PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XII, public bills and resolutions of the following titles were introduced and severally referred, as follows:

By Mrs. BLACKBURN (for herself and Mr. TOM PRICE of Georgia):

H.R. 3018. A bill to provide for a safe harbor period for the transition from the ICD-9 to the ICD-10 standard for health care claims; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Ms. DELAURO (for herself, Ms. ESTY, Mr. COURTNEY, Mr. LARSON of Connecticut, and Mr. HIMES):

H.R. 3019. A bill to amend title 38, United States Code, to direct the Secretary of Veterans Affairs to furnish, at the request of an eligible veteran, nursing home care and hospital care at State licensed or certified residential care facilities; to the Committee on Veterans' Affairs.

By Mr. POMPEO (for himself, Mr. MULLIN, Mr. SCHRADER, and Mr. MEEKS):

H.R. 3021. A bill to amend the Natural Gas Act to allow the use of aerial survey data for certain applications, and for other purposes; to the Committee on Energy and Commerce.

By Mr. ABRAHAM (for himself, Mr. SCALISE, Mr. RICHMOND, Mr. BOUSTANY, Mr. FLEMING, and Mr. GRAVES of Louisiana):

H.R. 3022. A bill to require that Grambling State University be eligible to receive funds under the Act of August 30, 1890; to the Committee on Agriculture.

By Mr. BUCK:

H.R. 3023. A bill to amend title 5, United States Code, to modify probationary periods with respect to positions within the competitive service and the Senior Executive Service, and for other purposes; to the Committee on Oversight and Government Reform.

By Mr. BOUSTANY (for himself and Mr. LEWIS):

H.R. 3024. A bill to amend title XVIII of the Social Security Act to permit review of certain Medicare payment determinations for disproportionate share hospitals, and for other purposes; to the Committee on Ways and Means.

By Mr. COOK:

H.R. 3025. A bill to amend title 18, United States Code, to provide a criminal penalty for launching drones that interfere with fighting wildfires affecting Federal property, and for other purposes; to the Committee on the Judiciary.

By Mr. COOK:

H.R. 3026. A bill to amend part A of title IV of the Social Security Act to clarify the authority of tribal governments in regard to the Temporary Assistance for Needy Families program; to the Committee on Ways and Means.

By Mr. GOSAR (for himself, Mr. GRIJALVA, Mr. FRANKS of Arizona, Mrs. KIRKPATRICK, Mr. SALMON, Ms. SINEMA, Mr. SCHWEIKERT, Mr. GALLEGO, and Ms. MCSALLY):

H.R. 3027. A bill to authorize the conveyance of four small parcels of land within the boundaries of the Imperial National Wildlife Refuge for the purposes of addressing a long-term boundary discrepancy; to the Committee on Natural Resources.

By Mr. JEFFRIES (for himself, Mrs. LAWRENCE, Ms. JACKSON LEE, Ms. BASS, Mr. MEEKS, and Ms. JUDY CHU of California):

H.R. 3028. A bill to amend the Omnibus Crime Control and Safe Streets Act of 1968 to provide that the Attorney General may give preferential consideration for grants under part Q of title I of that Act to applications from jurisdictions which have in place laws or ordinances to make available to the public grand jury transcripts and other records considered by grand juries, and for other purposes; to the Committee on the Judiciary.

By Ms. NORTON (for herself, Mr. VAN HOLLEN, Mr. BEYER, Ms. EDWARDS, Mr. RUPPERSBERGER, Mr. CONNOLLY, and Mr. CUMMINGS):

H.R. 3029. A bill to require the Office of Personnel Management to provide complimentary, comprehensive identity protection coverage to all individuals whose personally identifiable information was compromised during recent data breaches at Federal agencies; to the Committee on Oversight and Government Reform.

By Mr. PETERSON:

H.R. 3030. A bill to direct the Commandant of the Coast Guard to convey certain property from the United States to the City of Baudette, Minnesota; to the Committee on Transportation and Infrastructure.

By Mr. SALMON:

H.R. 3031. A bill to prohibit funding to the Voice of America; to the Committee on Foreign Affairs.

By Ms. SINEMA (for herself and Mr. HURT of Virginia):

H.R. 3032. A bill to amend the Securities Exchange Act of 1934 to repeal a certain reporting requirement of the Securities and Exchange Commission; to the Committee on Financial Services.

By Ms. CASTOR of Florida (for herself and Mrs. CAROLYN B. MALONEY of New York):

H. Con. Res. 60. Concurrent resolution expressing the sense of Congress that female athletes be paid the same as their male counterparts and organizers of world class competitions actively take part in combating the wage gap; to the Committee on Education and the Workforce.

By Mr. NOLAN:

H. Res. 357. A resolution expressing the sense of the House of Representatives regarding the need to eliminate partisan redistricting and gerrymandering; to the Committee on the Judiciary.

By Mr. CASTRO of Texas (for himself, Mr. SMITH of Texas, Mr. DOGGETT, Mr. CUELLAR, and Mr. HURD of Texas):

H. Res. 358. A resolution welcoming the United Nations Educational, Scientific and Cultural Organization (UNESCO) World Heritage Committee's inscription of the San Antonio Missions to the World Heritage list, recognizing the San Antonio Missions as having universal historical and cultural significance, and congratulating the people of San Antonio for their years of hard work to make this designation a reality; to the Committee on Foreign Affairs.

By Mr. KING of Iowa (for himself, Mr. FRANKS of Arizona, Mr. BABIN, Mr. HARRIS, Mr. HUELSKAMP, Mr. YOHO, and Mr. GOHMERT):

H. Res. 359. A resolution providing that the House of Representatives disagrees with the majority opinion in Obergefell et al. v. Hodges, and for other purposes; to the Committee on the Judiciary.

By Mr. RUSSELL (for himself, Mr. BENISHEK, Mr. BISHOP of Utah, Mr. BOUSTANY, and Mr. COLE):

H. Res. 360. A resolution recognizing the 50th anniversary of the National Collegiate Honors Council; to the Committee on Education and the Workforce.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 7 of rule XII of the Rules of the House of Representatives, the following statements are submitted regarding the specific powers granted to Congress in the Constitution to enact the accompanying bill or joint resolution.

By Mrs. BLACKBURN:

H.R. 3018.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 3

By Ms. DELAURO:

H.R. 3019.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8 of the United States Constitution

By Mr. COLE:

H.R. 3020.

Congress has the power to enact this legislation pursuant to the following:

The principal constitutional authority for this legislation is clause 7 of section 9 of article I of the Constitution of the United States (the appropriation power), which states: ''No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law. . . .'' In addition, clause 1 of section 8 of article I of the Constitution (the spending power) provides: ''The Congress shall have the Power . . . to pay the Debts and provide for the common Defence and general Welfare of the United States. . . .'' Together, these specific constitutional provisions establish the congressional power of the purse, granting Congress the authority to appropriate funds, to determine their purpose, amount, and period of availability, and to set forth terms and conditions governing their use.

By Mr. POMPEO:

H.R. 3021.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 3

By Mr. ABRAHAM:

H.R. 3022.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 1 of the United States Constitution

By Mr. BUCK:

H.R. 3023.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 1 of the United States

By Mr. BOUSTANY:

H.R. 3024.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 3—Business/Labor Regulation—The Congress shall have Power to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.

By Mr. COOK:

H.R. 3025.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8

By Mr. COOK:

H.R. 3026.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8

By Mr. GOSAR:

H.R. 3027.

Congress has the power to enact this legislation pursuant to the following:

Article IV, Section 3, Clause 2 (the Property Clause). Under this clause, Congress has the power to dispose of and make all needful rules and regulations respecting the territory or other property belonging to the United States. By virtue of this enumerated power, Congress has governing authority over the lands, terroritories, or other property of the United States- and with this authority Congress is vested with the power to all owners in fee, the ability to sell, lease, dispose, exchange, convey, or simply preserve land. The Supreme Court has described this enumerated grant as one ''without limitation'' Kleppe v New Mexico, 426 U.S. 529, 542–543 (1976) (''And while the furthest reaches of the power granted by the Property Clause have not been definitely resolved, we have repeatedly observed that the power over the public land thus entrusted to Congress is without limitation.'')

Historically, the the federal government transferred ownership of federal property to either private ownership or the states in order to pay off large Revolutionary War debts and to assist with the development of infrastructure. The transfers to private and state ownership by this legislation are constituional and necessary to resolve a long-term boundary discrepancy and to ensure private property owners are able to utilize and control their private property

By Mr. JEFFRIES:

H.R. 3028.

Congress has the power to enact this legislation pursuant to the following:

US Const. Art. II, Sec. 3, Cl. 3 (''[The President] shall take Care that the Laws be faithfully executed[.]''); and US Const. Art. I, Sec. 8, Cl. 18 (''Congress shall have the power . . . To make all Laws which shall be necessary and proper for carrying into Execution . . . all other Powers vested in this Constitution in the Government of the United States, or in any Department or Officer thereof.''). This bill would instruct the Attorney General to give preferential treatment to police forces that meet certain criteria when distributing grant money, therefore this bill is a valid exercise of Congressional authority per the Necessary and Proper Clause provided the Attorney General's duties, as an agent of the President, to enforce federal law and punish criminal wrongdoing.

By Ms. NORTON:

H.R. 3029.

Congress has the power to enact this legislation pursuant to the following:

Congress has the power to enact this legislation pursuant to the following: clause 18 of section 8 of article I of the Constitution.

By Mr. PETERSON:

H.R. 3030.

Congress has the power to enact this legislation pursuant to the following:

Article IV, section 3, Clause 2: The Congress shall have Power to dispose of and make all needful Rules and Regulations respecting the Territory or other Property belonging to the United States

By Mr. SALMON:

H.R. 3031.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 9, Clause 7—''No money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law; and a regular Statement and Account of the Receipts and Expenditures of all public Money shall be published from time to time.''

By Ms. SINEMA:

H.R. 3032.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 3; Article I, Section 8, Clause 18

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions, as follows:

H.R. 223: Mr. TONKO.

H.R. 244: Mr. SARBANES.

H.R. 292: Mr. MURPHY of Florida.

H.R. 358: Mr. WEBSTER of Florida.

H.R. 402: Mr. TOM PRICE of Georgia.

H.R. 448: Mr. AGUILAR.

H.R. 540: Mr. WILSON of South Carolina.

H.R. 546: Mr. HILL.

H.R. 578: Mr. JOYCE.

H.R. 592: Mr. COLE and Mrs. MILLER of Michigan.

H.R. 612: Mr. WITTMAN.

H.R. 702: Mr. COOPER, Mr. WEBSTER of Florida, Mr. NEWHOUSE, Mr. MOONEY of West Virginia, Mrs. HARTZLER, and Ms. SINEMA.

H.R. 721: Mr. POLIS, Mr. FINCHER, and Mr. COHEN.

H.R. 766: Mr. ROTHFUS.

H.R. 775: Ms. MOORE, Mrs. MILLER of Michigan, Ms. MCSALLY, and Ms. DELBENE.

H.R. 816: Mr. BURGESS.

H.R. 828: Mr. BROOKS of Alabama.

H.R. 829: Mr. O'ROURKE, Ms. DELBENE, and Mr. SCHIFF.

H.R. 845: Ms. BONAMICI.

H.R. 879: Mr. CONAWAY.

H.R. 921: Mr. HECK of Washington.

H.R. 928: Mr. DAVID SCOTT of Georgia.

H.R. 973: Mr. AGUILAR, Mr. SHUSTER, Ms. MCCOLLUM, Mr. VARGAS, and Mr. PERLMUTTER.

H.R. 997: Mr. MOONEY of West Virginia.

H.R. 999: Mr. VALADAO.

H.R. 1002: Mr. BENISHEK and Mr. TONKO.

H.R. 1151: Mr. LOBIONDO.

H.R. 1209: Mr. WALBERG, Mrs. BLACKBURN, Ms. MOORE, Mr. WELCH, and Mrs. TORRES.

H.R. 1218: Mr. PERLMUTTER.

H.R. 1233: Mr. REED and Mrs. HARTZLER.

H.R. 1270: Mr. BURGESS.

H.R. 1288: Mr. BLUM and Mrs. ELLMERS of North Carolina.

H.R. 1309: Mr. ROYCE.

H.R. 1354: Mr. HUFFMAN.

H.R. 1401: Mr. BENISHEK.

H.R. 1427: Mr. WALZ.

H.R. 1439: Mr. LANGEVIN.

H.R. 1464: Mr. HASTINGS.

H.R. 1486: Mr. FINCHER.

H.R. 1492: Ms. KUSTER.

H.R. 1549: Mr. MARINO.

H.R. 1550: Mr. CARNEY.

H.R. 1568: Mr. RODNEY DAVIS of Illinois, Ms. SLAUGHTER, Mr. PETERS, Ms. JACKSON LEE, Mr. COHEN, Ms. DELBENE, Ms. SPEIER, and Mr. QUIGLEY.

H.R. 1594: Mr. BLUMENAUER, Mr. FOSTER, Ms. SINEMA, Mr. KLINE, Mr. BOUSTANY, and Mrs. ELLMERS of North Carolina.

H.R. 1610: Mr. SCHWEIKERT.

H.R. 1624: Mr. SENSENBRENNER, Mr. GRAVES of Louisiana, Ms. JENKINS of Kansas, Ms. MCSALLY, Mr. ROGERS of Kentucky, and Mr. SIMPSON.

H.R. 1670: Mr. COSTELLO of Pennsylvania.

H.R. 1714: Mr. KIND.

H.R. 1745: Ms. EDWARDS.

H.R. 1769: Mr. KIND, Mr. PETERSON, Mr. SEAN PATRICK MALONEY of New York, Mr. MCKINLEY, Mr. KILMER, and Mr. WALZ.

H.R. 1784: Mr. GROTHMAN.

H.R. 1818: Mr. JOHNSON of Ohio.

H.R. 1875: Mr. MCDERMOTT.

H.R. 1877: Mr. NOLAN.

H.R. 1902: Mr. SERRANO.

H.R. 2030: Mr. BEN RAY LUJÁN of New Mexico.

H.R. 2061: Mr. NOLAN.

H.R. 2068: Mr. JOHNSON of Georgia.

H.R. 2121: Mr. UPTON, Mr. KILDEE, Mr. GRIFFITH, and Mr. SIRES.

H.R. 2141: Mr. FINCHER.

H.R. 2192: Mr. AGUILAR.

H.R. 2205: Mr. POE of Texas, Mr. WALZ, and Mr. BARR.

H.R. 2213: Mr. MEADOWS, Mr. PITTENGER, Mr. JONES, and Mr. FORBES.

H.R. 2244: Mr. GRIFFITH.

H.R. 2302: Ms. MICHELLE LUJAN GRISHAM of New Mexico.

H.R. 2303: Mrs. NAPOLITANO.

H.R. 2342: Mr. WALZ.

H.R. 2362: Mrs. LUMMIS and Mr. WALZ.

H.R. 2384: Mr. GOSAR.

H.R. 2403: Mr. BARR.

H.R. 2410: Mr. CARTWRIGHT.

H.R. 2464: Mr. COSTELLO of Pennsylvania and Mr. ABRAHAM.

H.R. 2510: Mr. POLIQUIN and Mr. VALADAO.

H.R. 2530: Mr. COHEN.

H.R. 2535: Mr. POLIS.

H.R. 2551: Mr. CLAWSON of Florida.

H.R. 2607: Mr. KATKO.

H.R. 2660: Mr. CAPUANO.

H.R. 2678: Mr. GOSAR.

H.R. 2680: Mr. BLUMENAUER and Ms. VELAZQUEZ.

H.R. 2713: Mr. RODNEY DAVIS of Illinois and Mr. TAKANO.

H.R. 2716: Mr. GOWDY.

H.R. 2725: Mr. POCAN and Mr. DESAULNIER.

H.R. 2734: Ms. NORTON, Mr. JOLLY, and Mr. COOPER.

H.R. 2765: Mr. GOSAR.

H.R. 2775: Mr. SWALWELL of California.

H.R. 2793: Mr. ALLEN, Mr. BUCK, Mr. WESTMORELAND, Mrs. LUMMIS, Mr. BABIN, Mrs. WAGNER, and Mr. MESSER.

H.R. 2861: Ms. TSONGAS and Mrs. LOWEY.

H.R. 2867: Mrs. KIRKPATRICK.

H.R. 2896: Mr. BLUM, Mr. COFFMAN, and Mrs. MIMI WALTERS of California.

H.R. 2902: Mr. BLUMENAUER, Mr. MEEKS, Mr. LARSON of Connecticut, Ms. TSONGAS, Mr. GRIJALVA, Mr. COHEN, Ms. DUCKWORTH, and Mr. KIND.

H.R. 2905: Mr. OLSON, Mr. CARTER of Texas, Mr. WEBER of Texas, Mr. CULBERSON, Mr. SESSIONS, Mr. CONAWAY, Mr. BURGESS, Mr. FARENTHOLD, Mr. SAM JOHNSON of Texas, and Mr. WALBERG.

H.R. 2908: Mr. KLINE and Mr. LIPINSKI.

H.R. 2911: Mr. CROWLEY and Mr. SAM JOHNSON of Texas.

H.R. 2916: Ms. MATSUI.

H.R. 2918: Ms. FRANKEL of Florida.

H.R. 2922: Mr. BURGESS and Mr. WITTMAN.

H.R. 2942: Mr. MCKINLEY.

H.R. 2972: Mrs. CAPPS.

H.R. 2976: Mr. AGUILAR.

H.R. 2977: Mr. COHEN.

H.R. 2978: Mrs. RADEWAGEN.

H.R. 2984: Mr. HUDSON.

H.R. 3002: Mr. MARINO and Mr. BROOKS of Alabama.

H.R. 3011: Mr. GROTHMAN and Mr. ABRAHAM.

H.J. Res. 13: Mr. ZELDIN.

H. Con. Res. 17: Mr. ASHFORD.

H. Con. Res. 30: Ms. KUSTER.

H. Res. 32: Ms. SLAUGHTER, Ms. BROWN of Florida, Mr. VAN HOLLEN, Ms. SPEIER, Mr. SMITH of Washington, Mr. ISRAEL, Mr. SHERMAN, Mr. NADLER, Mrs. BEATTY, Mr. RANGEL, Mr. CLEAVER, Mr. HECK of Washington, Mr. KILDEE, and Mr. HOLDING.

H. Res. 230: Mrs. COMSTOCK.

H. Res. 251: Mr. JEFFRIES.

H. Res. 289: Mr. QUIGLEY.

H. Res. 325: Ms. CLARK of Massachusetts.

EXTENSIONS OF REMARKS

COMMENDING LOCAL 2015 HIGH SCHOOL GRADUATES FOR THEIR DECISION TO ENLIST IN THE UNITED STATES AIR FORCE AND OUR COMMUNITY SALUTES OF NORTHERN VIRGINIA FOR HOSTING THE FIFTH ANNUAL ENLISTEE RECOGNITION CEREMONY

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to recognize 25 graduating seniors in my community for their record of academic and athletic accomplishments and for their admirable decision to enlist in the United States Air Force. I also express my appreciation to Our Community Salutes of Northern Virginia for providing this opportunity to be among the first to say to each of these young men and women: ''Thank you.''

I have had the privilege of working with Our Community Salutes of Northern Virginia since its inception in 2011. That year my office was contacted by one of the founding parents who upon learning that her son and other students at his school who had decided to enlist would not receive any recognition during graduation, joined with other parents to organize the first enlistee recognition ceremony of its kind in the region. The first ceremony recognized 9 students; this year we will be honoring 133 local students for choosing to serve our country in uniform.

With graduation season upon us, thousands of young people in my community, and millions across the nation, are preparing for the next chapter in their lives. Some will pursue higher education or vocational training, others will seek to enter the workforce immediately, and many will answer the call to serve their community and their country.

The United States of America has distinguished itself from other nations through the entrepreneurship and spirit of our people, the knowledge that we can achieve any goal if we set our minds to it, our inherent compassion and generosity, our fierce patriotism, and the extraordinary sacrifices and dedication to country exhibited by the members of our Armed Forces. The young men and women from our community who will be enlisting possess an abundance of each of these qualities. I join with their families and friends in congratulating and commending the following graduates on their enlistment in the United States Air Force:

John Ainslie, Philip Baitinger, Merrilee Carder, Valeria Catacora, Brian Daley, Nikhil Deo, Gary Dixon, John Forsythe, Maximino Gabino, Patrick Hailey, Jazlyn Keating, Jun Pyo Kim, Edward Kowalski, Kellen Lovan, Lane Renner, Tran Robinson, Alexa Rolph, Kelsea Ross, Demay Thong, Robinson Tran, Henry Tran, Justin Von Feldt, Shawn Von Feldt, James Wayne, and Logan Wood.

Mr. Speaker, I ask my colleagues to join me in applauding the courage and dedication of these graduates and in assuring them and their families that the full support and resources of the U.S. Congress and the American people will be behind them on every step of their journey in defense our nation's freedom.

21ST CENTURY CURES ACT

SPEECH OF

HON. CHARLES W. BOUSTANY, JR.

OF LOUISIANA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 9, 2015

The House in Committee of the Whole House on the state of the Union had under consideration the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes:

Mr. BOUSTANY. Mr. Chair, I rise today to express opposition to H.R. 6, the 21st Century Cures Act.

As a doctor, I strongly support medical innovation and research. Over the course of my 30 years practicing medicine, I saw tremendous leaps and bounds in treatment that saved lives. I appreciate the hard work put into creatively attempting to modernize the healthcare innovation infrastructure, specifically efforts to incorporate a patient perspective into the drug and device approval process, support advances in personalized medicine, and streamline clinical trials. However, I cannot support the sale of 64 million barrels of crude oil from the Strategic Petroleum Reserve being used to pay for these changes.

Over the past year, the price of oil has dropped from above $100 per barrel to below $50. Although the price of oil is currently at $54 a barrel on the global markets, this is far from stable. I do not understand why Congress would agree to sell 64 million barrels from the Strategic Petroleum Reserve when the price is low, flooding the global oil marketplace, and likely causing the price to drop even further. This has the potential to cause havoc for our own domestic oil and gas industry.

The decline in oil prices is hurting the states that had benefited from the domestic oil-production boom in recent years. My home state of Louisiana ranked second in the U.S. in oil production and second in natural gas production in 2013, with more than 64,000 Louisianans employed in extraction, pipeline and refining industries. This industry matters to everyone in Louisiana.

According to the American Petroleum Institute the U.S. oil and natural gas industry supports more than 9 million jobs nationwide, supports over 7% of GDP, and contributes more than $86 million to the Federal Treasury every day. Since oil prices began to drop, it has been widely reported that the oil and gas industry have been struggling to keep their employees on payroll. In April, the U.S. Bureau of Labor Statistics announced that Louisiana suffered a 3,300 job loss in the mining and logging sector. In June we saw two consecutive week losses in mining employment—that's the category that includes many oil and gas exploration and extraction jobs—have slipped below 100 in Louisiana.

I will not accept the false choice between supporting medical innovation and Louisiana oil and gas jobs. I believe it's irresponsible to flood the global market for petroleum with more product while Louisiana families are experiencing layoffs because of low global prices.

Many of my colleagues have stated that given the remarkable expansion of North American oil production, a reduction in the size of the reserve could be seen as responsible cost-effective public policy. I would disagree. Research shows that price spikes in transportation fuels is highly regressive, with most of the cost disproportionately hitting middle class and low-income groups. This vulnerability remains even though our work shows that the U.S. and much of the Western hemisphere will largely separate from physical trade flows with Middle East producers in the next few years.

According to the U.S. Energy Information Agency (EIA), the U.S. economy will continue to rely upon petroleum for many years, and work by EPRINC and many other research groups demonstrates that we will remain vulnerable to severe economic damage from disruptions in petroleum supplies in the world oil market. The SPR remains an important strategic asset for protecting the U.S. economy and security interests from this vulnerability.

Selling barrels from the Strategic Petroleum Reserve should be done in a thoughtful and strategic manner when global prices are high, not as another coffer for Congress to raid at its convenience and at the expense of Louisiana's oil & gas industry.

HONORING JAMES FORNI

HON. JARED HUFFMAN

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. HUFFMAN. Mr. Speaker, I rise today in honor of James Forni of Petaluma, who passed away on June 28, 2015 at the age of 36. A beloved husband, basketball coach, and friend to all, Mr. Forni has left us at too young an age. If there's any comfort to be found in the pain his family, students, and colleagues are feeling, perhaps it's the knowledge that James' legacy of kindness and compassion will remain with us indefinitely.

Some people are respected. Some people are loved. James Forni was both. A Petaluma native and local icon, Mr. Forni every day lived the values he instilled in his students, his friends, and his family: resilience, integrity, and strength. He was the soul at the very center of Casa Grande High School. Not only did

he coach football and basketball as well as teach physical education for over a decade, he played multiple sports as a member of the 1998 graduating class before continuing on to play football at College of Marin, University of Oregon, and University of Redlands.

Many people would retreat when faced with a fight. Eight years ago Mr. Forni was diagnosed with melanoma, but he didn't back down. Even when his energy lagged and his muscles ached, he was there for his team. He attended basketball games and practices throughout his treatment. He battled the disease for nearly a decade and coached through the end, guiding his team until this season's conclusion.

James Forni lived for others. He left a permanent mark on his school and community for which, years from now, we will continue to be grateful. It is therefore appropriate that we pay tribute to him today and express our heartfelt condolences to his wife Mary, his parents Jim and Jan, and his siblings Jill and Chris.

COMMENDING LOCAL 2015 HIGH SCHOOL GRADUATES FOR THEIR DECISION TO ENLIST IN THE UNITED STATES MARINE CORPS AND OUR COMMUNITY SALUTES OF NORTHERN VIRGINIA FOR HOSTING THE FIFTH ANNUAL ENLISTEE RECOGNITION CEREMONY

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to recognize 55 graduating seniors in my community for their record of academic and athletic accomplishments and for their admirable decision to enlist in the United States Marine Corps. I also express my appreciation to Our Community Salutes of Northern Virginia for providing this opportunity to be among the first to say to each of these young men and women: ''Thank you.''

I have had the privilege of working with Our Community Salutes of Northern Virginia since its inception in 2011. That year my office was contacted by one of the founding parents who upon learning that her son and other students at his school who had decided to enlist would not receive any recognition during graduation, joined with other parents to organize the first enlistee recognition ceremony of its kind in the region. The first ceremony recognized 9 students; this year we will be honoring 133 local students for choosing to serve our country in uniform.

With graduation season upon us, thousands of young people in my community, and millions across the nation, are preparing for the next chapter in their lives. Some will pursue higher education or vocational training, others will seek to enter the workforce immediately, and many will answer the call to serve their community and their country.

The United States of America has distinguished itself from other nations through the entrepreneurship and spirit of our people, the knowledge that we can achieve any goal if we set our minds to it, our inherent compassion and generosity, our fierce patriotism, and the extraordinary sacrifices and dedication to country exhibited by the members of our Armed Forces. The young men and women from our community who will be enlisting possess an abundance of each of these qualities. I join with their families and friends in congratulating and commending the following graduates on their enlistment in the United States Marine Corps:

Jeremy Ainey, Oscar Ayalafranco, Wesley Bacon, Taylor Basnight, Kaelin Bernard, Matthew Byvik, Jose Carrillomeja, Briana Chaisone, Grant Collins, Sebastian Crossley, Dominic Dagostino, Tyler Dewalt, Andrew Forbang, Austin Gilley, Jacob Gomez, Joseph Grant, Kaleb Hanson, William Harris, Logan Harvey, Chase Haynes, Sean Heim, Wyatt Helean, Michael Hill, John Hoang, Patrick Johnson, Tyree Johnson, Matthew Jones, Scot Khanna, Joseph Larock, Daniel Lee, Jose Martinez, Mason Matvich, Nash Means, Christopher Meraz, Jacob Miller, Mohamed Mohamed, Aninyou Morkos, Maddison Mozingo, Jose Munoz, Christopher Myers, Michael Odelldye, Joshua Peters, Kimberly Ramos, David Reeves, Alexander Rojas, Canas Rubia, Spicer Sabruno, Nicky Sanchez, William Schouviller, Taylor Terrell, Christian Trujillo, Jacob Vignaroli, Daniel Walton, Michael Wynd, Paul Zandbergen.

Mr. Speaker, I ask my colleagues to join me in applauding the courage and dedication of these graduates and in assuring them and their families that the full support and resources of the U.S. Congress and the American people will be behind them on every step of their journey in defense of our nation's freedom.

21ST CENTURY CURES ACT

SPEECH OF

HON. FRED UPTON

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 9, 2015

The House in Committee of the Whole House on the state of the Union had under consideration the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes:

Mr. UPTON. Mr. Chair, the following is my statement in its entirety:

We launched this effort a year-and-a-half ago. And with tomorrow's House vote, we mark an important milestone in our quest for 21st Century Cures—one step closer to the finish line.

There are so many individuals throughout our 18 month journey that helped get us to where we are today. Patients across the country. Advocates. Researchers. Innovators. Experts. Academics. Regulators. Some of the nation's brightest minds. To all we say thank you.

Thank you to the staff—on both sides of the aisle—who took the meetings, did the research, drafted the language, and sat at the negotiating table for countless hours to help us develop this incredible product. Gary Andres, Joan Hillebrands, Alexa Marrero, Clay Alspach, Paul Edattel, Josh Trent, Robert Horne, John Stone, Carly McWilliams, Katie Novaria, Adrianna Simonelli, Graham Pittman, Michelle Rosenberg, Traci Vitek, Sean Bonyun, Noelle Clemente, Macey Sevcik, Mark Ratner, Tom Wilbur, Bits Thomas, Marty Dannenfelser, Tim Pataki, Karen Christian, Peter Kielty, Jeff Carroll, Tiffany Guarascio, Lisa Cohen, Rachel Stauffer, Elizabeth Farrar, Matt Inzeo, Cole Leiter and all the Democratic staff, the staff of our members . . . thank you all. Thank you to House legislative counsel and the Congressional Budget Office for your efforts and dedication. Thank you to the members of both parties who brought their best ideas, partnered with one another to make their case, and delivered so many of the policies we welcome today.

I'd also like to thank HAL ROGERS and his staff. The Appropriations Committee has been a critical partner in this effort, working with us and developing the right approach to achieve our shared goal of helping patients in a fiscally responsible way.

I especially want to highlight my partner in this effort from day one, Ms. DEGETTE. She has been to Michigan, and I have travelled to Colorado—we have been on a number of road trips for Cures and I look forward to the next journey. I also want to thank Mr. PITTS, Mr. PALLONE, and Mr. GREEN for their partnership. We have made great strides but our work continues—and we won't stop until the ink is dry on the 21st Century Cures Act in the Oval Office.

I also want to give a hearty thank you to Max—a 6-year old ambassador for Cures. Although he is faced with the challenge of Noonan syndrome, he has been a little warrior in this effort. He joined us when we had our 51 to zero vote in the committee. And I am delighted Max will be by my side tomorrow on the floor for final passage.

Helping Max is why we're here. Helping my friends Brooke and Brielle is why we are here.

With a resounding vote, we will send a signal to the Senate—loud and clear—that the time is now for Cures 2015. I look forward to working with my Senate counterparts to continue the momentum and get 21st Century Cures to the president's desk.

We have a chance to do something big, and this is our time.

Vote yes.

COMMENDING LOCAL 2015 HIGH SCHOOL GRADUATES FOR THEIR DECISION TO ENLIST IN THE UNITED STATES ARMY AND OUR COMMUNITY SALUTES OF NORTHERN VIRGINIA FOR HOSTING THE FIFTH ANNUAL ENLISTEE RECOGNITION CEREMONY

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to recognize 48 graduating seniors in my community for their record of academic and athletic accomplishments and for their admirable decision to enlist in the United States Army. I also express my appreciation to Our Community Salutes of Northern Virginia for providing this opportunity to be among the first to say to each of these young men and women: ''Thank you.''

I have had the privilege of working with Our Community Salutes of Northern Virginia since its inception in 2011. That year my office was

contacted by one of the founding parents who upon learning that her son and other students at his school who had decided to enlist would not receive any recognition during graduation, joined with other parents to organize the first enlistee recognition ceremony of its kind in the region. The first ceremony recognized 9 students; this year we will be honoring 133 local students for choosing to serve our country in uniform.

With graduation season upon us, thousands of young people in my community, and millions across the nation, are preparing for the next chapter in their lives. Some will pursue higher education or vocational training, others will seek to enter the workforce immediately, and many will answer the call to serve their community and their country.

The United States of America has distinguished itself from other nations through the entrepreneurship and spirit of our people, the knowledge that we can achieve any goal if we set our minds to it, our inherent compassion and generosity, our fierce patriotism, and the extraordinary sacrifices and dedication to country exhibited by the members of our Armed Forces. The young men and women from our community who will be enlisting possess an abundance of each of these qualities. I join with their families and friends in congratulating and commending the following graduates on their enlistment in the United States Army:

Ronell Akwe, Gustabo Arguero, Eleanore Awwe, Angela Barfield, Ian Bliss, Tony Britvec, Ciara Carter, Dylan Cate, Robert Compton, Dylan Cook, Karon Cook, Gisel Diaz, Mason Dineen, Andrew Drescher, Ian Dumas, Yeni Dzib, Michael Fowlkes, Cristian Garcia, Adrianna Garner, Tabaria Harris, Kiee Harvey, Hunter Henson, Chase Henson, Nicholas Hwang, Lane Ingram, Olivia Jackson, Dylan Jeffries, Arielle Kirk, Andriy Kuranov, Daisey Kyaw, Eric Leach, Katelyn Lloyd, Joshua Marcano, Juan Martinez, Ofori Nana, Carlos Ortega, Thanh Tu Phung, Jordan Rivera, Julian Rivers, Tia Roush, Brian Steele, Louis Surface, Brian Vaughn, Dillon Welton, Steven Wesley, Donovan Wolford, Timothy Yemelyanov, Aisha Yunus.

Mr. Speaker, I ask my colleagues to join me in applauding the courage and dedication of these graduates and in assuring them and their families that the full support and resources of the U.S. Congress and the American people will be behind them on every step of their journey in defense our nation's freedom.

HONORING PRESIDENT HARVEY SCHMITT OF THE RALEIGH CHAMBER OF COMMERCE

HON. DAVID E. PRICE

OF NORTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. PRICE of North Carolina. Mr. Speaker, I rise today to recognize the distinguished career of Harvey Schmitt, who recently retired as President and CEO of the Raleigh Chamber of Commerce. In the twenty-one years Harvey has headed the Chamber, he has played an integral role in transforming Raleigh into a thriving city known internationally as one of the best places in America to live, work, and run a business.

Harvey has been a tireless promoter of the city's assets, often assuming the role of recruiter-in-chief. The enterprises he has helped bring to the Triangle include Red Hat, PNC, and the Carolina Hurricanes. He spearheaded the transformation of downtown Raleigh, creating the Downtown Raleigh Alliance, helping to revitalize Fayetteville Street, and leading the charge to build the downtown Raleigh convention center. He also promoted three billion dollars in school construction bonds to ensure that Triangle students learn in first-class facilities.

As Ranking Member of the Transportation, Housing and Urban Development Appropriations Subcommittee, I particularly appreciate Harvey's contribution to modernizing transportation in the Research Triangle. He and the Chamber created the Regional Transportation Alliance to advocate for improved highways and transit and a diversified system for the future.

Throughout his time at the Chamber, Harvey has been an invaluable asset to and a dedicated advocate for the Triangle. His tireless efforts and winning ways have left a lasting imprint on his adopted city. He has earned our enduring respect and gratitude, and we wish him the best in retirement.

DEPARTMENT OF THE INTERIOR, ENVIRONMENT, AND RELATED AGENCIES APPROPRIATIONS ACT, 2016

SPEECH OF

HON. TERRI A. SEWELL

OF ALABAMA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 8, 2015

The House in Committee of the Whole House on the state of the Union had under consideration the bill (H.R. 2822) making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2016, and for other purposes:

Ms. SEWELL of Alabama. Mr. Chair, today I rise in strong opposition to senseless Republican attempts to allow Confederate flags to be displayed and sold in national parks and cemeteries. The Confederate flag throughout history has been a symbol of extreme hatred, deliberate malice, and continued segregation. Any attempt by Congress to uphold and profit from such an image is completely reprehensible.

Recently, states across the country have done the right thing and removed the Confederate flag from their State Capitol grounds, including my home state of Alabama. In fact, on July 9th South Carolina lawmakers voted to ensure that this contentious symbol is removed from its state capitol grounds. It is unconscionable to think that while South Carolina's legislature was working until the early hours of the morning fighting for the removal of the Confederate flag, my Republican colleagues were attempting to undo efforts by the House to prohibit the Confederate flag from being sold and displayed at our national parks and federal cemeteries.

The Confederate flag is a part of America's past and that is where it should stay. Removing the Confederate flag does not detract from America's rich history in any way, but instead is recognition of the fact that this flag represents hatred not heritage, treason not pride. In order for us to come together as a nation, it is necessary to remove the vestiges of the past that connect racism and segregation.

The preamble to the Constitution reads ''We the people'', making it evident that America is supposed to be one cohesive nation. As Members of Congress we have the responsibility to ensure that our actions reflect the will of the people. The Confederate flag does nothing but continue to divide this great country. Let's stand behind our nation's purpose, that all men are created equal, by prohibiting the selling and displaying of the Confederate flag at national parks and federal cemeteries.

I urge my colleagues to stand with me and reject this amendment.

COMMENDING LOCAL 2015 HIGH SCHOOL GRADUATES FOR THEIR DECISION TO ENLIST IN THE UNITED STATES NAVY AND OUR COMMUNITY SALUTES OF NORTHERN VIRGINIA FOR HOSTING THE FIFTH ANNUAL ENLISTEE RECOGNITION CEREMONY

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to recognize 5 graduating seniors in my community for their record of academic and athletic accomplishments and for their admirable decision to enlist in the United States Navy. I also express my appreciation to Our Community Salutes of Northern Virginia for providing this opportunity to be among the first to say to each of these young men and women: ''Thank you.''

I have had the privilege of working with Our Community Salutes of Northern Virginia since its inception in 2011. That year my office was contacted by one of the founding parents who upon learning that her son and other students at his school who had decided to enlist would not receive any recognition during graduation, joined with other parents to organize the first enlistee recognition ceremony of its kind in the region. The first ceremony recognized 9 students; this year we will be honoring 133 local students for choosing to serve our country in uniform.

With graduation season upon us, thousands of young people in my community, and millions across the nation, are preparing for the next chapter in their lives. Some will pursue higher education or vocational training, others will seek to enter the workforce immediately, and many will answer the call to serve their community and their country.

The United States of America has distinguished itself from other nations through the entrepreneurship and spirit of our people, the knowledge that we can achieve any goal if we set our minds to it, our inherent compassion and generosity, our fierce patriotism, and the extraordinary sacrifices and dedication to country exhibited by the members of our Armed Forces. The young men and women from our community who will be enlisting possess an abundance of each of these qualities. I join with their families and friends in congratulating and commending the following

graduates on their enlistment in the United States Navy:

Gabriel Berrios, Owen Buzan, Kim Alexandria, Holly Speacht, and Sara Vasquez.

Mr. Speaker, I ask my colleagues to join me in applauding the courage and dedication of these graduates and in assuring them and their families that the full support and resources of the U.S. Congress and the American people will be behind them on every step of their journey in defense our nation's freedom.

PERSONAL EXPLANATION

HON. MIKE POMPEO

OF KANSAS

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. POMPEO. Mr. Speaker, on roll call no. 424 I was unable to cast my vote in person due to a previously scheduled engagement. Had I been present, I would have voted ''nay''.

IRAN NUCLEAR NEGOTIATIONS

HON. SANFORD D. BISHOP, JR.

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. BISHOP of Georgia. Mr. Speaker, Secretary of State John Kerry and partners from the P5+1 will meet in Vienna today to continue negotiations with Iran on that nation's nuclear activity. Statements from Iranian leaders such as Ayatollah Khamenei that disparage the United States and Israel remind us of the vital role that Congress has in this process. We must remain vigilant. We must ensure that any agreement holds Iran to the highest standards of transparency and accountability.

The opportunity for the United States to improve our relationship with Iran potentially could lead to greater stability in a region torn apart by war and religious strife. Nevertheless, we must not be naïve. The prospect of peace and stability can be reached only if we are secure that Iran will not threaten its neighbors and the world with nuclear aggression.

Secretary Kerry and his team of negotiators know the gravity of their work. I am confident that they want to see a good deal and will accept nothing less than an agreement that can withstand intense scrutiny. They cannot and should not be rushed into a deal. Nor should they cut corners as the deadline in presenting the details to Congress for a 30-day review approaches.

A good deal means that the international community must be permitted to inspect Iranian military and research installations to ensure that no illicit enrichment takes place. Inspectors must have full and unfettered access to be able to determine whether nuclear infrastructure has been dismantled so that its breakout capacity will be measured in years, not weeks. In addition, Iran must adhere to all U.N. Security Council Resolutions that require detailed explanations of previous nuclear efforts.

Until the U.S. Congress is assured that these measures have been implemented, sanctions must not be eased. The security of the U.S., Israel, and of our allies demands that we continue to apply pressure on the Ayatollah and his regime to ensure that they keep their word now and into the future.

TRIBUTE TO PAULA BELL

HON. DAVID YOUNG

OF IOWA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. YOUNG of Iowa. Mr. Speaker, I rise today to recognize and honor Paula Bell of Des Moines, Iowa, for receiving the 2014 Wells Fargo Volunteer of the Year Award for the Central Iowa Region.

Wells Fargo has been able to create an environment that fully embraces workplace giving. Last year, they set a company record by pledging $97.7 million to 30,000 nonprofits and schools. Wells Fargo has donated 6.4 million hours of service since 2011 and steps up in times of need, helping both domestically and abroad.

Paula Bell was granted this prestigious award, as well as $1000 to donate to a nonprofit organization of her choosing, for volunteering 200 of the 111,415 total hours that Wells Fargo team members in the Central Iowa Region logged in 2014. Paula's hard work and dedication to serving others truly embodies our Iowa values.

I applaud her for her commitment to giving back to the community and service to others. I know my colleagues in the House will join me in congratulating her for receiving this award. I wish her and her family all the best moving forward.

HONORING THE DEDICATED SERVICE OF LIEUTENANT COLONEL ERIC A. GIVENS, UNITED STATES ARMY RESERVE

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, it is with great pleasure that I rise to recognize the dedicated service of Lieutenant Colonel Eric A. Givens while serving with the Legislative Affairs Division at the Office of the Chief of Army Reserve from May 19, 2014, until March 8, 2015. During that short time, Eric made a lasting and positive impact on the Army Reserve through his efforts to foster and maintain relationships with Congressional members and staff.

As lead legislative liaison for military readiness and operations programs, Eric ensured that Army Reserve Soldiers' interests were clearly communicated to Members of Congress and their staffs as they considered the impacts of pending legislation. Additionally, Eric led efforts to draft, refine, and promote Administration-approved legislative proposals designed to ensure the well-being of Army Reserve Soldiers and to maintain the high-quality force the Nation has come to expect from its Army Reserve.

Ever the professional Soldier, LTC Givens arrived at the Legislative Affairs Division with nearly three decades of Army Reserve service that began with his enlistment in 1985. He received his commission as an officer in 1990 and joined the Active Guard and Reserve program in 1995. His years of experience in the field and as a staff officer at the Pentagon made him an invaluable resource to the Legislative Affairs Division, as his well-developed relationships bore fruit on a daily basis.

LTC Givens' presence in the office and on Capitol Hill brought joy to all who worked with him, and he will no doubt take that same spirit with him wherever his Army Reserve career leads. The Army Reserve's Legislative Affairs Division will remember him as a tireless proponent of Army Reserve equities, and as a Soldier who represents the best of what America has to offer.

The 11th Congressional District of Virginia has one of the highest veteran and military populations in the United States. As Representative of this district, it is critical that I receive accurate and timely information so that I can best represent the needs of our service members and ensure that they and their families receive the protections and benefits that they have earned. This would not be possible without the invaluable contributions of men and women like LTC Givens who tirelessly and effectively communicate with our office and advocate for their fellow soldiers.

On behalf of the United States Congress and the residents of the 11th District, I congratulate and thank LTC Givens and his wife, Lisa, for their service to our country and wish them the best for continued success.

HONORING THE EXTRAORDINARY LIFE OF JUDY STUDEBAKER WARREN

HON. SUSAN W. BROOKS

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mrs. BROOKS of Indiana. Mr. Speaker, I rise today to honor the life of a beloved friend, Judy Studebaker Warren. Judy, of the famous Studebaker automobile family, was a vibrant, caring, and passionate individual. Her love of life and contagious smile had a rippling effect of positivity on everyone around her. Sadly, after an almost two year battle with cancer, Judy passed away on July 5, 2015. It is my privilege to honor her extraordinary life on the floor of the United States House of Representatives.

A lifelong Hoosier, Judy grew up in Logansport, Indiana and graduated from Logansport High School. After high school she earned her bachelor's degree in sociology from Indiana University, where she was a proud member of the Pi Beta Phi Sorority and later became an active member of the Indiana University Alumni Association. She also served as President of the Junior League of Indianapolis, an organization she loved that benefitted from her energy and talents. Whether it was planning a fundraising gala for the Junior League or hosting a tailgate at an Indiana University football game, Judy was a gracious and amazing hostess who brought joy to everyone around her.

Judy's love of community and commitment to volunteering extended well beyond the Junior League of Indianapolis. She was the founding member of the Indianapolis Chapter of D.A.R.E. in the Pike Township School System

and created many inaugural events, including ArtSparkle for the Indianapolis Art Center, the Tribute for the Indiana State Museum, and REV to benefit Methodist Health Foundation.

She also had extensive board participation, serving on the boards of the Indianapolis Art Center, Indiana State Museum, Championship Auto Racing Auxiliary, The National Art Museum of Sports, The Oaks Academy, and Ballet Internationale, to name a few. Her other affiliations include the Governor's Residence Commission, St. Margaret's Hospital Guild, American Cancer Society Guild, Presidents Roundtable, Indiana Children's Wish Fund's Ball and Spotlight, and Keep Indianapolis Beautiful. She was cause-oriented and loved a challenge; give her a goal and she was a fundraising machine. But most of all, she always had fun—and made sure everyone else did, too.

Judy was an innovator and the Hoosier community was her beneficiary. She brought so much good to the City of Indianapolis, and her hard work did not go unnoticed. After she completed her Junior League of Indianapolis Presidency Mayor Bart Peterson named June 4, 2003 as Judy Warren Day in the City of Indianapolis. She also received Governor Daniels' Distinguished Hoosier Award in 2006 and Indianapolis Mayor Greg Ballard's Community Achievement Award in 2010.

Judy was an embodiment of all that is kind and generous. Judy is and always will be an inspiration to me. Her grace, bravery, and spirit will live on through those whose lives she touched. She is survived by her husband, Brick; son, Clay, and his wife Stasha; her mother, Vera; and her beloved grandchildren, Katie and Ethan. She is also survived by her stepson, Ryan, and his wife, Elizabeth; and their children, Elijiah Brick (E.B.), Martha Claire and George Taylor Warren. Judy Warren is an example of a great American woman who throughout her lifetime served her family, her friends, and community with passion and love.

H.R. 2999, THE FAIR VA ACCOUNTABILITY ACT

HON. MARK TAKANO

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. TAKANO. Mr. Speaker, I am proud to introduce H.R. 2999, the Fair VA Accountability Act, legislation that will bring real accountability to the VA while maintaining constitutional due process protections for civil service employees.

Last year, we were horrified to learn of widespread mismanagement at the VA. We all felt outraged that VA employees whose actions may have harmed veterans remained in their jobs or sat at home for months on paid administrative leave. There have been other bills introduced that seek to bring greater flexibility to the VA to remove problem employees, but I believe that many do this by destroying the bedrock principles of our civil service, limiting due process to an extent that runs counter to the constitutional protections we enjoy. I think these bills have another failing—they likely would result in outcomes far different than their sponsors and proponents intend. By violating the due process rights of our federal employees, these bills could very well ensure that if followed, VA may never be able to effectively remove bad employees when a court finds them unconstitutional.

The Fair VA Accountability Act increases accountability by allowing VA to immediately suspend without pay any employee whose misconduct poses a direct threat to veterans' health and safety. VA currently has the authority to fire employees with adequate pre-termination notice—usually 30 days. I agree that VA needs to do a better job of utilizing this authority. But the only realistic reason a VA employee should be fired on the spot would be if his or her conduct threatened veterans' health and safety.

I believe my bill provides the proper balance between the needs of the VA and the rights of VA employees. I also believe it provides sufficient due process rights to meet constitutional requirements and provide accused employees with a fair chance to tell their side of the story. Keep in mind that over 30 percent of VA employees are veterans themselves—the largest percentage of veteran employees among civilian agencies. I am proud to promote a policy that protects these employees' constitutional right to due process before losing their federal job.

In addition to the immediate removal provision, my bill increases accountability at the VA by addressing the ''revolving door'' problem, prohibiting senior VA executives from receiving VA contracts for at least a year after they leave the VA. It also limits the use of paid administrative leave to 14 days, to ensure employees don't continue to draw paychecks while sitting at home for months.

Finally, the Fair VA Accountability Act protects whistleblowers by requiring mandatory back-pay for any employee who proves that dismissal was a result of whistleblower retaliation. My bill also requires the IG to report on the percentage of employees fired who claimed whistleblower protections, and retains existing Title 5 protections for VA employees.

As stated in a letter of support by the American Federation of Government Employees, this language establishes ''highly effective mechanisms for increasing VA accountability while preserving the due process rights of front-line employees so that they can still make lifesaving disclosures about patient harm and other mismanagement without the fear of immediate job loss as at-will employees.''

RECOGNIZING THE 50TH ANNIVERSARY OF THE OLDE FORGE-SURREY SQUARE CIVIC ASSOCIATION

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to congratulate Olde Forge-Surrey Square on the occasion of its 50th anniversary.

Located in the heart of Fairfax County and the 11th Congressional District of Virginia, the Olde Forge-Surrey Square subdivision is set in a beautiful location, surrounded by large parks and streams. The residents take great pride in their community and are willing and eager participants in the community's civic association.

The Olde Forge-Surrey Square Civic Association is dedicated to promoting a high quality of life for all of the residents. There is an active Neighborhood Watch program, which helps to ensure the area remains safe and that neighbors stay connected. The Brandywine Pool is a local gathering place for all, and there are frequent barbeques and other community events. Recently the civic association took on a large project to renovate its playground. Through the generous contributions of the residents, as well as support of the local business community, the civic association was able to raise enough money to qualify for a grant from Fairfax County for a complete playground renovation.

As the former president of my own civic association, I understand that when residents invest their time, care, and energies in their communities, it benefits all. Fairfax County is considered one of the best places in the nation in which to work, live, and raise a family, largely because of the willingness of so many to become actively involved.

Mr. Speaker, I ask that my colleagues join me in congratulating the Olde Forge-Surrey Square Civic Association on its 50th anniversary and in thanking all of the residents for their tireless efforts and dedication to the community and region.

TRIBUTE TO BRIAN REECE

HON. DAVID YOUNG

OF IOWA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. YOUNG of Iowa. Mr. Speaker, I rise today to recognize and congratulate Brian Reece of Osceola, Iowa, on receiving the Presidential Award for Excellence in Mathematics and Science Teaching (PAEMST).

This program, administered by the National Science Foundation on behalf of the White House Office of Science and Technology Policy, recognizes exemplary teachers for their contributions to the teaching and learning of math and science. Each award recipient will be receiving a certificate signed by the President, along with a $10,000 award from the National Science Foundation. Each recipient will travel to Washington, D.C. for an awards ceremony at a later date.

Brian has been teaching mathematics for the past 19 years. Nine of those years have been spent at Central Academy, a public high school in Des Moines listed in the top one percent of educational programs by the College Board. He has taught in a number of Iowa school districts, as well as at the Des Moines Area Community College. Brian received his B.A. in Mathematics from Central College in Pella, Iowa, and furthered his mathematics education with a Master's of School Mathematics from Iowa State University.

Mr. Speaker, it is an honor to represent Iowans like Brian Reece who display dedication and pride in developing Iowa's next generation. I know all of my colleagues in the House join me in congratulating Brian for receiving this prestigious award and wishing him nothing but success in the future.

WELCOMING CHARLOTTE BETH STONE

HON. JOHN L. MICA

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. MICA. Mr. Speaker, as I rise today, it is my pleasure to announce the birth of Charlotte Beth Stone on June 3, 2015 at Virginia Hospital Center in Arlington, VA.

Charlotte is the daughter of Kevan Stone, my Special Projects Director, and Alexis Rice. Friends since High School in West Palm Beach, Florida, Alexis and Kevan married years later in Washington, D.C. at the historic Willard Hotel in May of 2014.

On this happy occasion, I ask my colleagues to join me in extending our warmest congratulations and wishes to the Stone and Rice families for continued health and happiness.

PERSONAL EXPLANATION

HON. MARK DeSAULNIER

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

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 my vote in support of H.R. 6, the 21st Century Cures Act, even though I am disappointed that the Republican Majority included last minute and unnecessary policy riders. I am cosponsor of the underlying bill which would encourage biomedical innovation and the development of new treatments and cures (Roll Call #433).

I would have also cast my vote in support of the amendment introduced by Representatives BARBARA LEE, JAN SCHAKOWSKY, and YVETTE CLARKE to H.R. 6, the 21st Century Cures Act. This amendment would remove harmful policy riders that aim to undermine women's access to reproductive health services from this otherwise noncontroversial, bipartisan effort. As a longtime supporter of a woman's right to access comprehensive reproductive healthcare, I oppose the inclusion of these unnecessary policy riders in this important bill (Roll Call #432).

I would have cast my vote in opposition to the Brat/McClintock/Garrett/Stutzman/Perry Amendment to H.R. 6, which would have turned the NIH and Cures Innovation Fund into a discretionary spending program, leading to immense uncertainty which would undercut the Fund's effectiveness and NIH's ability to maximize its work (Roll Call #431).

CONGRATULATING MARY AGEE ON HER RETIREMENT FROM NORTHERN VIRGINIA FAMILY SERVICE

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise today to congratulate Mary Agee of Fairfax, Virginia on her retirement after 43 years at Northern Virginia Family Service (NVFS).

Since its founding by community volunteers in 1924, NVFS has addressed the growing needs of communities throughout our region. NVFS works to improve the lives of its clients through a variety of programs in five mission initiatives: housing, child and family enrichment, health access, emergency assistance, and workforce development.

Ms. Agee began her career with the organization as a Family Counselor in 1972 and since 1988 has served as Executive Director and then Chief Executive Officer. Four decades of service to our community cannot be fairly summarized in one statement, but just a few examples illustrate the tremendous impact Ms. Agee's efforts have had on the lives of Northern Virginia families.

When she was named Deputy Director in 1978, NVFS had 11 staff, five of whom were full-time, and a budget of $187,000. Today, the nonprofit organization has 350 employees, approximately 3,600 volunteers, an operating budget of $32 million and offices in Arlington, Fairfax, Prince William and Loudoun counties, as well as the cities of Alexandria, Manassas and Manassas Park. NVFS is now the largest private, nonprofit human service organization in Northern Virginia. Each year, nearly 34,000 individuals and families turn to NVFS to find housing and emergency services, early childhood programs, health & mental health services, workforce development programs, legal assistance, anti-hunger programs, and intervention and prevention programs.

Additionally, NVFS has played a role in stabilizing families affected by national crises. After the tragedy of 9/11, NVFS lead the Survivors' Fund Project, providing direct assistance and long-term case management services to local victims, their families, and first responders. Ms. Agee considers this her proudest moment. In partnership with the Red Cross, NVFS led the Katrina Project for evacuees from New Orleans who relocated to our region. The success of this first-ever collaboration led the Red Cross to establish similar contracts across the nation.

Through Ms. Agee, NVFS has earned a reputation as a leader in the community by supporting community partnerships, taking a leadership role in multi-agency service delivery for clients, and working collaboratively with other human services agencies on advocacy issues. On an individual level, Ms. Agee has served as an inspiration and mentor to many in the human services community. She carefully works with colleagues to develop their strengths and to nurture relationships that benefit the community and people in need, rather than any particular organization. I had the great pleasure of collaborating with Ms. Agee during my 14 years on the Fairfax County Board of Supervisors. Her leadership was invaluable when the County launched homeless prevention and affordable housing initiatives during my tenure as Chairman, and she, along with the entire team at NVFS, was an invaluable partner for the County's many human service programs to assist our neighbors most in need.

Mr. Speaker, I ask my colleagues to join me in thanking Mary Agee for a lifetime of service to our community and in congratulating her on her retirement. When I was Chairman of the County Board, we often joked when retirement announcements like this were made that we should pass an ordinance not allowing such talented and dedicated people to leave public or community service, and I certainly wish that was the case here. I wish Mary and her family all the best in this next chapter of her life.

21ST CENTURY CURES ACT

SPEECH OF

HON. GUS M. BILIRAKIS

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 9, 2015

The House in Committee of the Whole House on the state of the Union had under consideration the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes:

Mr. BILIRAKIS. Mr. Chair, on a personal level, I have family members who have suffered with Parkinson's—I witness this debilitating disease through them. It is hard to see. Few things in America are truly ubiquitous—diseases, sadly, are one of those things.

In addition to the struggle chronic and rare disease patients face, physicians, researchers, clinicians, and medical device companies (among others) deal with an outdated and overly burdensome regulatory structure. These regulations stifle the development of new cures and treatments, whether they are drugs, biologics, or devices.

Given the reality, we have to ask: how can we get cures and treatments to the people who desperately need them?

That is the question the 21st Century Cures Initiative was created to answer. The 21st Century Cures Initiative is a bipartisan undertaking by members of the Energy and Commerce Committee to help our healthcare innovation infrastructure thrive and deliver more hope for all patients. This is a tremendous undertaking, and is much easier said than done.

It is about finding new ways to drive innovation. In addition to adequate funding and resources, we need to think critically about structural changes to streamline and modernize our health care system. We need to rethink what we have been doing and how we are doing it for the 21st Century.

This is what 21st Century Cures Initiative is giving us: an opportunity to address some of the structural barriers to new cures and promote new ways to incentivize developments. The 21st Century Cures Initiative has examined and seeks to accelerate the complete cycle of cures—from discovery to development to delivery and back again to discovery. This has resulted in the 21st Century Cures Act—a culmination of over a year's worth of engaging with patients, researchers, physicians, government, and private entities.

This year included numerous hearings and roundtables in Washington D.C. As legislators, we worked tirelessly to engage all stakeholders from across the spectrum. The only way we can answer the question—how do we get better cures and treatments?—is to work with everyone involved in the American health care system.

I am proud that I was able to have several provisions that were included in the final version of the Cures Act. These provisions will help to change the lives of patients in small to larger ways. I want to take a moment and highlight some of the provisions and some of the people that helped shape the policy.

Rare diseases are not a rare problem. Nearly 30 million Americans—1 in every 10 people—are living with a rare disease.

That is why I introduced the OPEN Act—the Orphan Product Extensions Now Act. It was included as a provision of the 21st Century Cures Act.

My bipartisan bill has the potential to help millions of people by incentivizing the testing of mainstream drugs—or repurposing them—to treat rare diseases and pediatric cancers, and it was included as a major provision in the 21st Century Cures Act.

The OPEN Act would unlock a new world of potential treatments—it would put FDA-approved, safe, and effective treatments ''on-label.''

Through the 21st Century Cures Act, Congress has a chance to come together to make a real difference in the lives of the 160 million Americans who suffer from a rare or chronic condition, as well as the family members and friends of all those afflicted.

The OPEN Act is one provision in the 21st Century Cures Act, but it is one I am proud to have authored, and one I believe will make a substantial difference in the lives of a lot of people.

I want to take this opportunity to thank all the people who helped make the OPEN Act a reality, and who fought for this legislation to be in the 21st Century Cures Act.

Julia Jenkins, Max Bronstein, Andy Russell, Harry Sporidis, Tim Perrin, everyone at the EveryLife Foundation for Rare Diseases, and the other 155 rare disease groups that supported the OPEN Act:

National MPS Society, With Purpose, National PKU Alliance, Taylor's Tale, RASopathies Network USA, Kids v Cancer, Let Them Be Little X2 Inc., Info and Resources for Idiopathic Pulmonary Hemosiderosis (IPH-NET), Noah's Hope, Mary Payton's Miracle Foundation, Hope4Bridget Foundation, Batten Disease Support & Research Association, Cure Sanfilippo Foundation, Beyond Batten Disease Foundation, Drew's Hope Scientific Research Foundation, International Pemphigus and Pemphigoid Foundation (IPPF), Cure AHC, Autoinflammatory Alliance, MLD Foundation, Fabry Support & Information Group, Children's PKU Network, FMD Chat;

National Tay-Sachs & Allied Diseases Association (NTSAD), Little Miss Hannah Foundation, Rare Disease United Foundation, Global Genes Project, Fibromuscular Dysplasia Society of America (FMDSA), Lymphatic Malformation Institute, Mastocytosis Society, EB Research Partnership, BRBN Alliance, Jonah's Just Begun, Abigail Alliance for Better Access to Developmental Drugs, Hannah's Hope Fund, GNE Myopathy International, The Ryan Foundation, Organic Acidemia Association, Cardio-Facio-Cutaneous International, NGLY1.org, Gwendolyn Strong Foundation, POMC Island One boy an Ocean of friends, Gene Giraffe Project, International FOP Association, Aware of Angels;

CureCADASIL, GT23 FOUNDATION, Desmoid Tumor Research Foundation (DTRF), The Association for Glycogen Storage Disease, Gene Spotlight Inc., Amyloidosis Foundation, Heriditary Neuropathy Foundation, Relapsing Polychondritis, Klippel-Feil Syndrome Freedom, CureDuchenne, Prader-Willi Syndrome Association, Bert's Big Adventure, Parent Project Muscular Dystrophy, Sarcoma Foundation of America, The Nicholas Conor Institute, Luck2Tuck Foundation, Team Sanfilippo Foundation, The Rally Foundation for Childhood Cancer Research, CARES Foundation, Inc., Help Extinguish Hunter Syndrome, Sephardic Health Organization for Referral & Education, Hunter Syndrome Research Coalition;

The Kortney Rose Foundation, Saving Case & Friends, Phelan-McDermid Syndrome Foundation, The Children's Medical Research Foundation, Inc., Cure SMA, Narcolepsy Network, Celiac Support Association, Caleb's Crusade Against Childhood Cancer, International Waldenstrom's Macroglobulinemia Foundation (IWMF), PKD Foundation, EDSers United Foundation, Choroideremia Research Foundation, Inc., Genetic Alliance, The Life Raft Group, The Will Luthcke Foundation, Angioma Alliance, Smashing Walnuts Foundation, Castleman Disease Collaborative Network/Castleman's Awareness & Research Effort, The GIST Cancer Awareness Foundation, The Truth 365, The Arms Wide Open Childhood Cancer Foundation, Sophia's Fund;

Journey4ACure, Princesses on a Mission, Inc., Noah's Light Foundation, Pediatric Cancer Foundation, West Virginia Kids Cancer Crusaders, Inc., Bear Necessities Cancer Foundation, A Kids' Brain Tumor Cure, RARE Science, Inc., ISMRD (the International Advocate for Glycoprotein Storage Diseases), Hermansky-Pudlak Syndrome Network Inc., Run4Rare, A–T Children's Project, The Global Foundation for Peroxisomal Disorders, The Adult Polyglucosan Body Disease Research Foundation (APBDRF), Alexa Nawrocki Pediatric Cancer Foundation, Beckwith-Wiedemann Children's Foundation International, The Brooke Healey Foundation, Talia's Legacy Children's Cancer Foundation, The Rare Childhood Cancer Advocacy Group, Alex's Army Childhood Cancer Foundation, The Catherine Elizabeth Blair Memorial Foundation, Stillbrave Childhood Cancer Foundation;

Cures Within Reach, ALL4Trey, Team Sabrina, Sofia's Hope, Inc., ALL4Trey, Delainee's Battle, Joey's Wings Foundation, The Bozeman 3, Team Ashley Bragg, Cole vs Cancer, Dominick One in a Million, Samuel Szabo Foundation, Wilms Tumor Survivor Group, Aiden's Army, Sofia's Hope, Inc., Mikey's Way Foundation, Team Serena, Supporting Our Cancer Kids, The Champ's Corner, Habitat for Hope, Ali's Angels Foundation, Gold Rush Cure Foundation;

Sickle Cell Warriors, Inc., The Rare Cancer Research Foundation, Carson Leslie Foundation, Amyloidosis Research Consortium, Pulmonary Fibrosis Advocates, The Coalition for Pulmonary Fibrosis, Mytonic Dystrophy Foundation, LMSarcoma Direct Research Foundation, BioPontis Alliance for Rare Diseases, Foundation for Ichthyosis & Related Skin Types, Inc., 5p-Society, The Santonio Holmes III & Long Foundation, National Fragile X Foundation, National Organization for Rare Disorders (NORD), OsteoPETrosis Society, Curing Retinal Blindness Foundation, The MAGIC Foundation, Cure HHT, DEFY Foundation, Chase After a Cure, DC Outreach Inc., Children's Cardiomyopathy Foundation, and the Bridget the Gap—SYNGAP Education and Research Foundation.

These groups' grassroots efforts were instrumental in the effort to get the OPEN Act in the 21st Century Cures Act.

I would like to thank all the participants of the two 21st Century Roundtables I held in my District in August of 2014. Your input was vital in the early stages of drafting the 21st Century Cures Act, and I will be forever appreciative:

Dr. Wayne Taylor, on behalf of the Leukemia and Lymphoma Society;

Mrs. Colleen Labbadia, on behalf of the Parent Project for Muscular Dystrophy (PPMD);

Ms. Patricia Stanco, MHS, on behalf of the ALS Association Florida Chapter;

Ms. Ashleigh Pike and Ms. Beth Pike—dysautonomia patient advocates;

Dr. Samantha Lindsay, on behalf of the Alpha–1 Foundation;

Ms. Janice Starling, on behalf of the American Association of Kidney Patients;

Mr. and Mrs. Michael and Gretchen Church, on behalf of the Parkinson's Action Network;

Dr. Clifton Gooch, FAAN, Professor and Chair, Department of Neurology, University of South Florida;

Dr. Dave Morgan, CEO and Director of USF's Byrd Alzheimer's Institute;

Dr. Richard Finkel, Chief Neurologist at Nemour's Children's Hospital;

Mr. Geary A. Havran, President of NDH Medical, Inc., and Chairman, Florida Medical Manufacturers Consortium (FMMC);

Ms. Lisa Novorska, CFO, Rochester Electro-Medical, Inc.;

Dr. Thomas Sellers, MPH., Center Director and Executive Vice President for Moffit Cancer Center;

Dr. Glen Hortin, Clinical Pathology Medical Director for the Southeast Region, for Quest Diagnostics.

Additionally, I want to thank Nick Manetto from PPMD and USAgainst Alzheimer's, Miriam O'Day from the Alpha–1 Foundation, John DeMuro from Moffitt, Monica Richter from USF, Jennifer Sheridan from PAN, Gary Dessatti, John Ray from FMMC, and Erin O'Malley and Virginia Biggar from USAgainstAlzheimer's.

I would also like to thank Candace Lerman, Laura Milford, and Max Schill. They are all rare disease patients and advocates who I have had the pleasure of meeting. Their in-person advocacy and their dedication to improve the lives of everyone with a rare disease is admirable. I am truly grateful to their contribution and support of this legislation.

I also want to recognize Noah Coughlan and Jonny Lee Miller. Noah is a young man who ran across the country—over 3,000 miles—three times to raise awareness for rare diseases. This is a feat achieved by very few, and is a tremendous physical feat demonstrating his dedication to this cause. Jonny Lee Miller is an actor and advocate who runs ultra-marathons to raise money and awareness for rare diseases.

To everyone else who was involved, supported the OPEN Act, tweeted about it, posted about it on Facebook, or advocated on behalf of the 30 million Americans with rare diseases, I sincerely thank you from the bottom of my heart.

Additionally, the 21st Century Cures Act includes another one of my bills, H.R. 2298, the Patient Safety and Prescription Drug Abuse Prevention Act. I began work on this bill three years ago, after a prescription drug abuse hearing. The problem was apparent, and a fix was desperately needed.

This provision will create a drug management program within Medicare to use the same tools used in Medicaid, TRICARE, and private insurance to deal with the growth in prescription drug abuse.

The Substance Abuse and Mental Health Administration (SAMHSA) estimates that there are 15.3 million Americans over the age of 12 that ''used prescription drugs non-medically in the last year.'' USA Today reported that in 2012, the average number of seniors misusing

or dependent on prescription pain relievers in the past year grew to an estimated 336,000, up from 132,000 a decade earlier, based on data from SAMHSA. Addiction does not recognize age, race, ethnicity, or income. Anyone could be susceptible including seniors.

The U.S. Department of Health and Human Services' Office of the Inspector General has recommended that Medicare have this type of a program. In a hearing, the Center for Medicare and Medicaid Services' Principal Deputy Administrator stated that they supported this policy, but needed a statutory change in the law to create such a program.

A change to the Medicare program is a herculean task. I want to thank some of the people that supported this provision and helped get this legislation over the finish line. Lindsay Berman from the Pew Charitable Trusts, Jerry Steffl, Jonathan Heafitz, Gary Kline, Sergio Santiviago, Richard Hoar, Heather Cutler, Nelson Bunn from the Major County Sheriffs Association, and Chuck DeWitt from the Major Cities Chiefs Association.

PERSONAL EXPLANATION

HON. LUIS V. GUTIÉRREZ

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. GUTIÉRREZ. Mr. Speaker, I was unavoidably absent in the House chamber today because I was at the 5th U.S. Circuit Court of Appeals hearing in New Orleans, LA, on President Barack Obama's immigration executive actions.

Had I been present, I would have voted ''nay'' on roll call vote 431.

I would have voted ''yea'' on roll call vote 432 and in favor of the Lee/Schakowsky/Clarke Amendment which would have struck from the underlying bill controversial policy riders that will undermine a woman's right to choose. This amendment would have protected women's health care choices and was especially vital to low-income and minority women's health.

I would have voted ''yea'' on roll call vote 433 in support of H.R. 6, the 21st Century Cures Act.

RECOGNIZING THE 2015 INSTITUTE FOR EXCELLENCE IN SALES & BUSINESS DEVELOPMENT LIFETIME ACHIEVEMENT WINNER MARK WEBER

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to recognize the recipients of the Lifetime Achievement presented by the Institute for Excellence in Sales & Business Development (IES&BD). The Institute was created to foster excellence in business sales and development practices and to help organizations maximize their efforts. This annual award recognizes individuals, teams, and organizations throughout the United States who demonstrate exemplary performance through leadership, risk taking, innovation, vision, and customer development.

The 2015 IES&BD Lifetime Achievement Award honoree is Mark Weber of NetApp, a data management and cloud storage provider based in Vienna, Virginia. With over 30 years of experience in technology sales and engineering, Mr. Weber is a proven leader in Information Technology with particular expertise in serving the public sector.

Mr. Weber began his career as a federal account manager for Hewlett-Packard and later joined Sun Microsystems where he managed a diverse portfolio and served in a variety of positions including regional executive director for federal, state, and local government sales.

At NetApp, as Senior Vice President for the Americas, Mr. Weber leads sales, channels, engineering, professional services, business development, finance, operations, and marketing across North America, South America, and U.S. Public Sector. Prior to his current role, Mr. Weber served as the President and General Manager of NetApp U.S. Public Sector for ten years. He was responsible for managing and developing government business at the federal, state, and local levels in addition to higher education and teaching hospitals.

Under his leadership, NetApp's Vienna office was ranked in the top 10 for the best places to work in D.C. for the sixth time by the Washington Business Journal as well as repeatedly listed in the Washingtonian's Best 50 Places to Work issue.

Mr. Weber's professionalism has earned him the respect and admiration of his peers. In 2014 he was recognized by the Wash100 Exec Ranks as an Innovative GovCon Technologist & Business Leader. He was also awarded the FedScoop50 Industry Leadership award in 2012 and 2013 and the Federal Computer Week's Federal 100 Award in 2011. Within NetApp, he has received the Club Award for nine straight years and is frequently recognized as Sales Leader of the Year within the larger organization.

Mr. Weber sits on the Advisory Council for the Department of Business & Economics at Catholic University in Washington, D.C., and is a board member of the Virginia Tech Science and Engineering Regional Growth Enterprise (VT-SERGE).

Mr. Speaker, I ask my colleagues to join me in recognizing Mark Weber for his many contributions to the federal IT procurement field and on congratulating him on receiving the 2015 Institute for Excellence in Sales & Business Development Lifetime Achievement Award.

21ST CENTURY CURES ACT

SPEECH OF

HON. TERRI A. SEWELL

OF ALABAMA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 9, 2015

The House in Committee of the Whole House on the state of the Union had under consideration the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes:

Ms. SEWELL of Alabama. Mr. Chair, today I stand in strong support of the 21st Century Cures Act. This bipartisan bill gives our nation's best and brightest the tools they need to understand—and eventually defeat disease—and reauthorizes both the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).

The 21st Century Cures Act has the potential to accelerate the discovery of drugs for life-threatening illnesses; repurpose drugs found ineffective for one condition and test them on another; promote an interoperable health system; enhance telehealth practices; and advance the development of more targeted, personalized treatments.

My district, the 7th Congressional District of Alabama, is home to the University of Alabama at Birmingham, the Southern Research Institute, and the University of Alabama. NIH funding is critical to the continuing vitality of these three leading institutions, as well as to the region.

The prospect of this act alone provides hope. Hope that cures can be discovered, hope that one day no diagnoses indicate inevitable ailment or death, and hope that one day treatments will yield more reward than risk.

Despite the potential of this bill, there are two amendments that threaten that hope and essentially aim to inhibit the health of several Americans. First, the Hyde Amendment has reared its ugly head yet again. It is a harmful and discriminatory bill that prevents women from making their own healthcare decisions. Further, it serves as a stark contradiction to efforts geared toward providing health positive resources for all.

Second, the Brat amendment aims to convert the federal funding of the NIH and the FDA from mandatory to discretionary. Such a transaction would stifle the progress both federal agencies have already made and will continue to make. It will singlehandedly reverse the trajectory of medical progress and halt further research efforts.

With only 5 percent of rare diseases having an FDA-approved treatment, it would be a gross understatement to say our medical systems have failed to keep pace. Viruses and diseases will not wait for us to catch up; they will mutate, grow ever more virulent, and continue to impact our public health. We need to leverage our investments to make potentially game-changing strides in treatment. We need 21st century solutions for 21st century threats.

An investment in health affects more than our physical well-being, and the 21st Century Cares Act reflects this. H.R. 6 is not only a health bill; it is a jobs bill. Our country has been the leader in both the medical device and biopharmaceutical industry for decades, helping us become the core of global medical innovation. This puts a target on our backs, as China and other countries have attempted to attempt to claim this role and thus, our jobs. U.S. medical device-related employment totals over 2 million jobs, and the U.S. biopharmaceutical industry is responsible for over 4 million U.S. jobs. NIH funding currently supports over 400,000 jobs at research institutions across the country, including jobs for young and upcoming scientists. Without this funding, our jobs are out there for the taking. Without this funding, the thousands of jobs in my district provided by the University of Alabama at Birmingham, the Southern Research Institute, and the University of Alabama are not safe. The policies in this legislation will help us fight off foreign competitors and allow us to continue innovating, so we can all protect medical jobs in our districts and add more.

We must get serious about addressing the unmet medical needs of the American people.

I urge my colleagues not to deprive the American people of the cures they deserve. Vote against these poison pill amendments because when it comes to the health of our constituents, there is no place or time for partisan politics. I urge my colleagues to oppose the Brat and Hyde amendments, and I urge them support H.R. 6.

RECOGNIZING NONE SUCH FARM

HON. MICHAEL G. FITZPATRICK

OF PENNSYLVANIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. FITZPATRICK. Mr. Speaker, I rise today to honor a very special company in the 8th Congressional District, None Such Farm, which recently was recognized as a Finalist for the Secretary of Defense Employer Support Freedom Award.

The Freedom Award is the highest recognition given by the U.S. Government to employers for their support of their workers who serve our country in the Guard and Reserve. Nomination requests come from a Guard or Reserve member who is employed by the organization they are nominating, or from a family member. The award was created to publicly recognize employers that provide exceptional support to their Guard and Reserve employees, and the Department of Defense deems it the highest of all employer recognition awards.

30 companies from across the country were selected as a Finalist for this prestigious award. None Such Farm is the only company representing the Commonwealth of Pennsylvania, and all of us in Bucks County are proud.

None Such Farm is owned and operated by the 3rd generation of the Yerkes Family in beautiful Buckingham, Pennsylvania. For over fifty years the Yerkes farm supplied sweet corn for the wholesale market in Philadelphia. In the late 1970's, as the wholesale market began to change, Bill and John Yerkes decided to build a Farm Market. Since 1978, the market has doubled in size, adding a Meat Shop to sell their own farm raised beef, along with a kitchen for high quality "ready to go" food. None Such Farm is a staple of Bucks County, with some of the best sweet corn around, along with delicious fruits, vegetables, and beautiful flowers.

Today, the Yerkes family heritage lives on—through Leslie, Jon and Scott Yerkes, who made the decision to preserve the 217 acre farm. As a County Commissioner and as a United States Congressman, I have seen the tremendous strides that None Such Farm has made and the dedication it has given to its customers and employees.

I am pleased to see the Department of Defense recognize None Such Farm for their good treatment and support of our nation's military families. Thank you to the Yerkes family for taking care of those who serve our country. I am proud of your commitment to our military, and wish you many years of success in the future.

RECOGNIZING THE 2014 HONOREES OF THE FAIRFAX COUNTY FEDERATION OF CITIZENS' ASSOCIATIONS

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to acknowledge the Fairfax County Federation of Citizens' Associations (the "Federation") and the honorees of its 65th Annual Awards Banquet. The Federation is a coalition of civic and homeowners associations. Each year, the Federation honors a few select individuals for their extraordinary contributions to our community. As a former two-term President of the Federation, I understand that those who volunteer their time, energies, and talents to civic activities play a vital role in making Fairfax County one of the best places in the nation in which to live, work, and raise a family. I am honored to recognize the following individuals for their service to our community:

2014 Citizen of the Year: Michael O'Reilly. A lifelong resident of Fairfax County, Michael O'Reilly is a true "model citizen" who never fails to heed the call to public service. Mr. O'Reilly served as Mayor of the Town of Herndon from 2004–2006. In 2009 he helped create the Governing Board of the Fairfax-Falls Church Partnership to Prevent and End Homelessness and has chaired the Board since its inception. He also currently serves as President of the Herndon Council for the Arts and as Co-chair of the Herndon Committee of the Dulles Regional Chamber.

Lifetime Achievement Award: Mary Agee. For the past 43 years, Mary Agee has made an enormous difference in the lives of Northern Virginians, particularly the low income and struggling. Joining Northern Virginia Family Service (NVFS) in 1972, Ms. Agee became the organization's leader 27 years ago. Under her leadership, NVFS has grown into a regional resource that employs 350 people, has approximately 3,400 volunteers, and provides assistance to more than 34,000 Northern Virginia residents every year. Although Ms. Agee is retiring from her position as President and Chief Executive of NVFS, her contributions and impact have left a permanent imprint on our community that will continue to help future generations of Fairfax residents.

Citation of Merit: Connie Hartke. Connie Hartke is best known as President of Rescue Reston, a grassroots organization formed to protect open space. Under her leadership, Rescue Reston secured more than 4,200 signatures in opposition to the construction of homes on the Reston National Golf Course and led citizen engagement efforts with the Board of Supervisors and Board of Zoning Appeals. Ms. Hartke is also a valued supporter of the Walker Nature Center, participating in numerous education programs including hikes, presentations, and environmental film nights.

Citation of Merit: Bruce Wright. Bruce Wright commutes by bicycle to most of the many meetings he attends as Chairman of Fairfax Advocates for Better Bicycling (FABB). Since 2005, Mr. Wright and FABB members have worked with Fairfax County and the Virginia Department of Transportation to ensure that bicycling is an integral part of the county's transportation network. Under his leadership, FABB advocated for the county's first Bicycle Master Plan. He has served on the Hunter Mill District Land Use Committee, the Reston Planning and Zoning Committee, the Tysons Land Use Task Force, the Fairfax County Trails & Sidewalks Committee, and on the Washington Area Bicyclist Association.

Special Gratitude Honoree: Supervisor Michael Frey. Supervisor Frey has represented the Sully District on the Fairfax County Board of Supervisors since the Sully District was created in 1991, and I was proud to serve with him during my 14 years on the Board. Prior to that, he worked for former Board Chairman Jack Herrity and former Springfield District Supervisor Elaine McConnell. Since the beginning of his tenure, Mr. Frey oversaw enormous growth and change in the Centreville/Chantilly area. His expertise in land use and development issues helped guide the area through this transitional period. His notable accomplishments include the creation of the Centreville Historic District, the acquisition of over 2,000 acres of parkland, and the establishment of a day labor center in Centreville. Mr. Frey has worked tirelessly for transportation improvements in western Fairfax to improve mobility and reduce congestion. A strong proponent of youth activities and opportunities for young children, Mr. Frey has been a leading advocate of youth sports. In addition, Mr. Frey was a strong supporter of the bid by Fairfax County to host the 2015 World Police and Fire Games and currently serves on the Board of Directors for the organization. Mr. Frey is retiring later this year from the Board of Supervisors, and I wish him well in his retirement and thank him for his 24 years of service to the County and the residents of the Sully District.

Special Gratitude Honoree: Supervisor Gerald "Gerry" Hyland. Supervisor Gerry Hyland has represented the Mount Vernon District on the Fairfax County Board of Supervisors since 1988, and I was proud to serve with him during my 14 years on the Board. As one of the longest-serving supervisors, Mr. Hyland has helped shape the tremendous growth and development of southern Fairfax County. He has been a force for renewal within the Mount Vernon District, working tirelessly on such major projects as the revitalization of the Route 1 corridor, the massive expansion of Fort Belvoir required under BRAC, and the transformation of Lorton from an industrial area once known for a prison and landfill into a thriving community known for its parkland, premier golf course, and the Workhouse Art Center. A tireless advocate for his constituents, he has helped manage the explosive growth of Mount Vernon to ensure that the quality of life enjoyed by the residents would not be diminished, but would rather be enhanced by this reinvention of the community. Mr. Hyland is retiring later this year from the Board of Supervisors, and I wish him well in his retirement and thank him for his 27 years of service to the County and the residents of the Mount Vernon District.

Mr. Speaker, I ask my colleagues to join me in thanking these incredible individuals and in congratulating them on being honored by the Fairfax County Federation of Citizens' Associations. Civic engagement is the root of a community, and Fairfax County residents enjoy an exceptional quality of life due in part to the efforts of these individuals. The contributions and leadership of these honorees

have been a great benefit to our community and truly merit our highest praise.

H.R. 2647—THE RESILIENT FEDERAL FORESTS ACT

HON. EARL BLUMENAUER

OF OREGON

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. BLUMENAUER. Mr. Speaker, yesterday, I voted against H.R. 2647, the Resilient Federal Forests Act. There are provisions in this bill that I support, such as preventing the practice of "fire borrowing," in which the Forest Service and the Department of the Interior pull funding from accounts meant for prevention of fire and use it to suppress fires. There are also provisions related to the Secure Rural Schools program that many of my colleagues in the Oregon delegation worked hard to include, and I appreciate their efforts.

I opposed the legislation overall. It goes too far in rolling back important environmental protections, beyond what is necessary to have a balanced approach. I am hopeful as this legislation works its way through the process that it is toned down and focused.

INTRODUCTION OF THE RECOVER ACT (REDUCING THE EFFECTS OF THE CYBERATTACK ON OPM VICTIMS EMERGENCY RESPONSE ACT OF 2015)

HON. ELEANOR HOLMES NORTON

OF THE DISTRICT OF COLUMBIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Ms. NORTON. Mr. Speaker, I rise to introduce the Reducing the Effects of the Cyberattack on OPM Victims Emergency Response Act of 2015 (the RECOVER Act), a bill to require the Office of Personnel Management (OPM) to provide complimentary and comprehensive identity protection coverage to all individuals whose personally identifiable information was compromised during recent OPM data breaches. Senator BEN CARDIN (D–MD) has introduced the companion bill in the Senate. Yesterday, OPM reported that more than 21.5 million current and former federal employees have had their personal information compromised in a second OPM data breach, five times more than the 4.2 million already reported, for a grand total of 25.7 million federal employees and retirees. OPM said that the 21.5 million individuals whose background check records were compromised would receive only three years of credit monitoring and identity theft protection services and $1 million in loss coverage, while the other 4.2 million individuals whose personnel records were compromised would receive 18 months of credit monitoring and $1 million in loss coverage. In light of the scope of OPM's data breach and the limited protection that is proposed, I, along with my House colleagues CHRIS VAN HOLLEN, DON BEYER, DONNA EDWARDS, C.A. DUTCH RUPPERSBERGER, ELIJAH CUMMINGS, GERALD CONNOLLY, and JOHN DELANEY introduce a bill that would provide free lifetime identity theft protection coverage that includes identity theft insurance for losses up to $5 million. This protection is particularly necessary since the breach was discovered a year after hackers had already infiltrated OPM's system.

OPM's proposed protection would not protect current and former federal workers if hackers simply waited for a period of years before exploiting the stolen identities. However, our bill would give current and former federal employees some peace of mind.

The RECOVER Act is necessary to reduce the angst of our dedicated public servants resulting from this entire ordeal. OPM failed to protect our current and former federal employees. It follows that the government must do the right thing to make up for its mistake.

CONGRATULTING THE 2015 LORDS AND LADIES FAIRFAX, THE RECIPIENT OF THE JAMES M. SCOTT COMMUNITY SPIRIT AWARD, AND THE CELEBRATE FAIRFAX! VOLUNTEERS OF THE YEAR

HON. GERALD E. CONNOLLY

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Friday, July 10, 2015

Mr. CONNOLLY. Mr. Speaker, I rise to recognize a dedicated group of men and women in Northern Virginia. Every year, each member of the Fairfax County Board of Supervisors selects two people from his or her district who have demonstrated outstanding volunteer service, heroism, or other exceptional commitments and contributions to our community. Since the program's inception in 1984, approximately 600 individuals have earned the honor of being named a Lord or Lady Fairfax by his or her representative on the Board of Supervisors. The Board also traditionally recognizes these individuals during a reception held in conjunction with the annual Celebrate Fairfax! Festival in June.

This year, the Fairfax County Board of Supervisors will recognize those individuals who have made tremendous impacts through their support of our public schools, parks, youth sports leagues, arts community, public safety, and human service programs. It is nearly impossible to fully describe the diversity of accomplishments by the honorees. Their efforts contribute greatly to the quality of life for the residents of Fairfax County and should be commended.

It is my honor to submit the names of the following 2015 Lords and Ladies Fairfax.

At-Large: Lady Katherine K. Hanley and Lord John P. McAnaw

Braddock District: Lady Donna Goldbranson and Lord Richard B. Chobot

Dranesville District: Lady Sarah C. Kirk and Lord Robert D. Vickers Jr.

Hunter Mill District: Lady L. Adelle Jones and Lord Kenneth R. Fredgren

Lee District: Lady Elizabeth M. McGhan and Lord Christopher M. Soule

Mason District: Lady Terri L. Fox and Lord Martin C. Faga

Mount Vernon District: Lady Elisabeth B. Lardner and Lord Martin W. Tillett

Providence District: Lady Peggy A. Koplitz and Lord Paul J. Wexler

Springfield District: Lady Kyra M. Beckman and Lord Jeffrey H. Saxe

Sully District: Lady Bonnie L. Hobbs and Lord Jerrold L. Foltz

I also commend the following recipients of the James M. Scott Community Spirit Award and the Celebrate Fairfax! Festival Volunteer of the Year Awards:

James M. Scott Community Spirit Award: Dominion

Celebrate Fairfax! Festival Volunteer of the Year Award: Tim Harazin

Mr. Speaker, I ask my colleagues to join me in expressing our gratitude to these men and women who volunteer their time and energy on behalf of our community. Their efforts provide immeasurable benefits to their fellow residents and serves to strengthen and enrich the Fairfax County community.

Daily Digest

Senate

Chamber Action

The Senate was not in session and stands adjourned until 3 p.m., on Monday, July 13, 2015.

Committee Meetings

No committee meetings were held.

House of Representatives

Chamber Action

Public Bills and Resolutions Introduced: 14 public bills, H.R. 3018–3019, 3021–3032; and 4 resolutions, H. Con. Res. 60; and H. Res. 358–360, were introduced. **Pages H5088**

Additional Cosponsors: **Pages H5089**

Reports Filed: Reports were filed today as follows:

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 purposes (H. Rept. 114–195); and

H.R. 1155, to provide for the establishment of a process for the review of rules and sets of rules, and for other purposes (H. Rept. 114–196, Part 1).

Page H5087

Journal: The House agreed to the Speaker's approval of the Journal by voice vote. **Pages H5033, S5082**

21st Century Cures Act: The House passed H.R. 6, to accelerate the discovery, development, and delivery of 21st century cures, by a recorded vote of 344 ayes to 77 noes, Roll No. 433. Consideration began yesterday, July 9th. **Pages H5035–82**

Pursuant to the rule, an amendment in the nature of a substitute consisting of the text of Rules Committee Print 114–22 shall be considered as adopted in the House and in the Committee of the Whole, in lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce now printed in the bill. The bill, as amended, shall be considered as the original bill for the purpose of further amendment under the five-minute rule and shall be considered as read.

Page H5035

Agreed to:

Young (IN) amendment (No. 2 printed in H. Rept. 114–193) that creates authority within NIH to conduct a prize program; the intent of the program would be to incentivize health innovation by offering competitors the chance to win a prize for creating breakthrough research and technology;

Pages H5071–72

Castro (TX) amendment (No. 4 printed in H. Rept. 114–193) that ensures under-represented individuals, such as women and minorities, are included in the Supporting Young Emerging Scientists Report; **Page H5074**

Slaughter amendment (No. 5 printed in H. Rept. 114–193) that directs the CDC to conduct a study to determine how the additional payments are affecting the development of drug resistance;

Pages H5074–76

Fitzpatrick amendment (No. 6 printed in H. Rept. 114–193) that expresses a sense of 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 post-market surveillance purposes; and **Pages H5076–77**

Jackson Lee amendment (No. 8 printed in H. Rept. 114–193) that directs the Secretary of Health and Human Services to conduct outreach to Historically Black Colleges and Universities; Hispanic Serving Institutions; Native American Colleges; and rural Colleges to ensure that health professionals

from under-represented populations are aware of research opportunities under this Act. **Pages H5078–80**

Rejected:

Brat amendment (No. 1 printed in H. Rept. 114–193) that sought to reform the NIH and Cures Innovation Fund to make it a discretionary spending program (by a recorded vote of 141 ayes to 281 noes, Roll No. 431); and **Pages H5069–70, H5080–81**

Lee amendment (No. 3 printed in H. Rept. 114–193) that sought to strike the provision that apply any policy riders included in the annual LHHS Appropriations Bill to NIH funds in H.R. 6; also strike the provision that apply any policy riders applied to the FDA in the annual Agriculture Appropriations bill to FDA funding in H.R. 6 (by a recorded vote of 176 ayes to 245 noes, Roll No. 432). **Pages H5072–73, H5081**

Withdrawn:

Polis amendment (No. 7 printed in H. Rept. 114–193) that was offered and subsequently withdrawn that would have directed the Food and Drug Administration to issue a report on the risks and benefits associated with a two-tiered approval process that would permit certain medical devices to provisionally come to market if they have demonstrated safety but not efficacy. **Pages H5077–78**

H. Res. 350, the rule providing for consideration of the bill (H.R. 6) was agreed to yesterday, July 9th.

Meeting Hour: Agreed by unanimous consent that when the House adjourns today, it adjourn to meet at 12 noon on Monday, July 13th for Morning Hour debate. **Page H5086**

National Defense Authorization Act for Fiscal Year 2016: The Chair appointed the following additional conferees on H.R. 1735, to authorize appropriations for fiscal year 2016 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, and to prescribe military personnel strengths for such fiscal year:

From the Permanent Select Committee on Intelligence, for consideration of matters within the jurisdiction of that committee under clause 11 of rule X: Representatives Nunes, King (NY), and Schiff.

From the Committee on Education and the Workforce, for consideration of secs. 571 and 573 of the House bill and secs. 561–63 of the Senate amendment, and modifications committed to conference: Representatives Rokita, Bishop (MI), and Scott (VA).

From the Committee on Energy and Commerce, for consideration of secs. 314, 632, 634, 3111–13, 3119, 3133, and 3141 of the House bill and secs. 601, 632, 3118, and 3119 of the Senate amendment, and modifications committed to conference: Representatives Upton, Barton, and Pallone.

From the Committee on Foreign Affairs, for consideration of secs. 1011, 1059, 1090, 1092, 1201, 1203–05, 1215, 1221, 1223, 1226, 1234–36, 1247–49, 1253, 1257, 1263, 1264, 1267, 1270, 1301, 1532, 1541, 1542, 1663, 1668–70, 2802, 3118, and 3119 of the House bill and secs. 1011, 1012, 1082, 1201–05, 1207, 1209, 1223, 1225, 1228, 1251, 1252, 1261, 1264, 1265, 1272, 1301, 1302, 1531–33, 1631, 1654, and 1655 of the Senate amendment, and modifications committed to conference: Representatives Royce, Marino, and Engel.

From the Committee on Homeland Security, for consideration of secs. 589 and 1041 of the Senate amendment, and modifications committed to conference: Representatives McCaul, Miller (MI), and Thompson (MS).

From the Committee on the Judiciary, for consideration of secs. 1040, 1052, 1085, 1216, 1641, and 2862 of the House bill and secs. 1032, 1034, 1090, and 1227 of the Senate amendment, and modifications committed to conference: Representatives Goodlatte, Issa, and Conyers.

From the Committee on Natural Resources, for consideration of secs. 312, 632, 634, 2841, 2842, 2851–53, and 2862 of the House bill and secs. 313, 601, and 632 of the Senate amendment, and modifications committed to conference: Representatives Cook, Hardy, and Grijalva.

From the Committee on Oversight and Government Reform, for consideration of secs. 602, 631, 634, 838, 854, 855, 866, 871, 1069, and 1101–05 of the House bill and secs. 592, 593, 631, 806, 830, 861, 1090, 1101, 1102, 1104, 1105, 1107–09, 1111, 1112, 1114, and 1115 of the Senate amendment, and modifications committed to conference: Representatives Hurd (TX), Russell, and Cummings.

From the Committee on Rules, for consideration of sec. 1032 of the Senate amendment, and modifications committed to conference: Representatives Sessions, Byrne, and Slaughter.

From the Committee on Science, Space, and Technology, for consideration of sec. 3136 of the House bill and sec. 1613 of the Senate amendment, and modifications committed to conference: Representatives Lucas, Knight, and Eddie Bernice Johnson (TX).

From the Committee on Small Business, for consideration of secs. 831–34, 839, 840, 842–46, 854, and 871 of the House bill and secs. 828, 831, 882, 883, and 885 of the Senate amendment, and modifications committed to conference: Representatives Chabot, Hanna, and Velázquez.

From the Committee on Transportation and Infrastructure, for consideration of secs. 302, 562, 569,

570a, 591, 1060a, 1073, 2811, and 3501 of the House bill and secs. 601, 642, 1613, 3504, and 3505 of the Senate amendment, and modifications committed to conference: Representatives Graves (LA), Curbelo (FL), and Edwards.

From the Committee on Veterans' Affairs, for consideration of secs. 565, 566, 592, 652, 701, 721, 722, 1105, and 1431 of the House bill and secs. 539, 605, 633, 719, 1083, 1084, 1089, 1091, and 1411 of the Senate amendment, and modifications committed to conference: Representatives Roe (TN), Bilirakis, and Brown (FL). **Page H5086**

Quorum Calls—Votes: Three recorded votes developed during the proceedings of today and appear on pages H5080–81, H5081, and H5082. There were no quorum calls.

Adjournment: The House met at 9 a.m. and adjourned at 12:14 p.m.

Committee Meetings

LEGISLATIVE MEASURE

Committee on Energy and Commerce: Subcommittee on Commerce, Manufacturing, and Trade held a hearing entitled ''H.R. 985, Concrete Masonry Products Research, Education, and Promotion Act of 2015''. Testimony was heard from Ellen Herbst, Chief Financial Officer and Assistant Secretary for Administration, Department of Commerce; Franklin Rusco, Director, Natural Resources and Environment-Energy Issues, Government Accountability Office; and public witnesses.

THE FUTURE OF HOUSING IN AMERICA: OVERSIGHT OF HUD'S PUBLIC AND INDIAN HOUSING PROGRAMS

Committee on Financial Services: Subcommittee on Housing and Insurance held a hearing entitled ''The Future of Housing in America: Oversight of HUD's Public and Indian Housing Programs''. Testimony was heard from Lourdes Castro Ramirez, Principal Deputy Assistant Secretary, Office of Public and Indian Housing, Department of Housing and Urban Development; and Daniel Garcia-Diaz, Director, Financial Markets and Community Investment, Government Accountability Office.

THE INTERNATIONAL SPACE STATION: ADDRESSING OPERATIONAL CHALLENGES

Committee on Science, Space, and Technology: Subcommittee on Space held a hearing entitled ''The International Space Station: Addressing Operational Challenges''. Testimony was heard from Bill Gerstenmaier, Associate Administrator, Human Exploration and Operations Mission Directorate, National Aeronautics and Space Administration; Paul K. Martin, Inspector General, National Aeronautics and Space Administration; Shelby Oakley, Acting Director, Acquisition and Sourcing Management, Government Accountability Office; and public witnesses.

Joint Meetings

No joint committee meetings we held.

COMMITTEE MEETINGS FOR MONDAY, JULY 13, 2015

(Committee meetings are open unless otherwise indicated)

Senate

No meetings/hearings scheduled.

House

No hearings are scheduled.

Next Meeting of the SENATE

3 p.m., Monday, July 13

Senate Chamber

Program for Monday: After the transaction of any morning business (not to extend beyond one hour), Senate will resume consideration of S. 1177, Every Child Achieves Act. At 5:30 p.m., Senate will vote on or in relation to Alexander (for Hatch/Markey) Amendment No. 2080 (to Amendment No. 2089), and Murray (for Kaine) Amendment No. 2118 (to Amendment No. 2089).

Next Meeting of the HOUSE OF REPRESENTATIVES

12 p.m., Monday, July 13

House Chamber

Program for Monday: To be announced.

Extensions of Remarks, as inserted in this issue

HOUSE

Bilirakis, Gus M., Fla., E1036
Bishop, Sanford D., Jr., Ga., E1034
Blumenauer, Earl, Ore., E1040
Boustany, Charles W., Jr., La., E1031
Brooks, Susan W., Ind., E1034
Connolly, Gerald E., Va., E1031, E1032, E1032, E1033, E1034, E1035, E1036, E1038, E1039, E1040
DeSaulnier, Mark, Calif., E1036
Fitzpatrick, Michael G., Pa., E1039
Gutiérrez, Luis V., Ill., E1038
Huffman, Jared, Calif., E1031
Mica, John L., Fla., E1036
Norton, Eleanor Holmes, The District of Columbia, E1040
Pompeo, Mike, Kans., E1034
Price, David E., N.C., E1033
Sewell, Terri A., Ala., E1033, E1038
Takano, Mark, Calif., E1035
Upton, Fred, Mich., E1032
Young, David, Iowa, E1034, E1035

Congressional Record

The *Congressional Record* (USPS 087–390). The Periodicals postage is paid at Washington, D.C. The public proceedings of each House of Congress, as reported by the Official Reporters thereof, are printed pursuant to directions of the Joint Committee on Printing as authorized by appropriate provisions of Title 44, United States Code, and published for each day that one or both Houses are in session, excepting very infrequent instances when two or more unusually small consecutive issues are printed one time. ¶Public access to the *Congressional Record* is available online through the U.S. Government Publishing Office, at *www.fdsys.gov*, free of charge to the user. The information is updated online each day the *Congressional Record* is published. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202–512–1800, or 866–512–1800 (toll-free). E-Mail, *contactcenter@gpo.gov*. ¶To place an order for any of these products, visit the U.S. Government Online Bookstore at: bookstore.gpo.gov. Mail orders to: Superintendent of Documents, P.O. Box 979050, St. Louis, MO 63197–9000, or phone orders to 866–512–1800 (toll-free), 202–512–1800 (D.C. area), or fax to 202–512–2104. Remit check or money order, made payable to the Superintendent of Documents, or use VISA, MasterCard, Discover, American Express, or GPO Deposit Account. ¶Following each session of Congress, the daily *Congressional Record* is revised, printed, permanently bound and sold by the Superintendent of Documents in individual parts or by sets. ¶With the exception of copyrighted articles, there are no restrictions on the republication of material from the *Congressional Record*.

POSTMASTER: Send address changes to the Superintendent of Documents, *Congressional Record*, U.S. Government Publishing Office, Washington, D.C. 20402, along with the entire mailing label from the last issue received.