114TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
114–193

PROVIDING FOR CONSIDERATION OF THE BILL (H.R. 6) TO ACCELERATE THE DISCOVERY, DEVELOPMENT, AND DELIVERY OF 21ST CENTURY CURES, AND FOR OTHER PURPOSES

JULY 8, 2015.—Referred to the House Calendar and ordered to be printed

---

Mr. BURGESS, from the Committee on Rules, submitted the following

R E P O R T

[To accompany H. Res. 350]

The Committee on Rules, having had under consideration House Resolution 350, by a nonrecord vote, report the same to the House with the recommendation that the resolution be adopted.

SUMMARY OF PROVISIONS OF THE RESOLUTION

The resolution provides for consideration of H.R. 6, the 21st Century Cures Act, under a structured rule. The resolution provides one hour of general debate equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce. The resolution waives all points of order against consideration of the bill. The resolution provides that an amendment in the nature of a substitute consisting of the text of Rules Committee Print 114–22 shall be considered as adopted and the bill, as amended, shall be considered as read. The resolution waives all points of order against provisions in the bill, as amended. The resolution makes in order only those further amendments printed in this report. Each such amendment may be offered only in the order printed in this report, may be offered only by a Member designated in this report, shall be considered as read, shall be debatable for the time specified in this 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 in the House or in the Committee of the Whole. The resolution waives all points of order against the amendments printed in this report. The resolution provides one motion to recommit with or without instructions.

EXPLANATION OF WAIVERS

The waiver of all points of order against consideration of the bill includes waivers of the following:

• Clause 3(e)(1) of rule XIII ("Ramseyer"), requiring a committee report accompanying a bill amending or repealing statutes to show, by typographical device, parts of statute affected. The waiver is provided because the submission provided by the Committee on Energy and Commerce was insufficient to meet the standards established by the rule in its current form. The Committee on Rules continues to work with the House Office of Legislative Counsel and committees to determine the steps necessary to comply with the updated rule;

• Clause 10 of rule XXI, which prohibits the consideration of a bill if it has the net effect of increasing mandatory spending over the five-year or ten-year period. This waiver is necessary because the bill increases mandatory spending over the five-year period, however it is important to note that the bill complies with the rule over the ten-year period and reduces the deficit by more than $500 million over that ten-year period;

• Section 302(f) of the Congressional Budget Act, which prohibits consideration of legislation providing new budget authority in excess of a 302(a) allocation of such authority;

• Section 306 of the Congressional Budget Act, which prohibits consideration of legislation within the jurisdiction of the Committee on the Budget unless referred to or reported by the Budget Committee.

The waiver of all points of order against provisions in the bill, as amended, includes a waiver of clause 4 of rule XXI, which prohibits reporting a bill or joint resolution carrying an appropriation from a committee not having jurisdiction to report an appropriation.

Although the resolution waives all points of order against the amendments printed in this report, the Committee is not aware of any points of order. The waiver is prophylactic in nature.

SUMMARY OF THE AMENDMENTS MADE IN ORDER

1. Brat (VA), McClintock (CA), Garrett (NJ), Stutzman (IN), Perry (PA): Reforms the NIH and Cures Innovation Fund to make it a discretionary spending program. (10 minutes)

2. Young (IN), Harris (MD): 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. (10 minutes)

3. Lee, Barbara (CA), Schakowsky (IL), Clarke (NY): Strikes the provision that applies any policy riders included in the annual LHHS Appropriations Bill to NIH funds in H.R. 6. Also strikes the provision that applies any policy riders applied to the FDA in the annual Agriculture Appropriations bill to FDA funding in H.R. 6. (10 minutes)

4. Castro (TX): Ensures underrepresented individuals, such as women and minorities, are included in the Supporting Young Emerging Scientists Report. (10 minutes)

5. Slaughter (NY): Directs the CDC to conduct a study to determine how the additional payments are affecting the development of drug resistance. (10 minutes)

6. Fitzpatrick (PA): 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. (10 minutes)

7. Polis (CO): Directs 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. (10 minutes)

8. Jackson Lee (TX): 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 underrepresented populations are aware of research opportunities under this Act. (10 minutes)

TEXT OF AMENDMENTS MADE IN ORDER

1. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE BRAT OF VIRGINIA OR HIS DESIGNEE, DEBATABLE FOR 10 MINUTES

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).

---

2. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE YOUNG OF INDIANA OR HIS DESIGNEE, DEBATABLE FOR 10 MINUTES

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**".

---

3. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE LEE OF CALIFORNIA OR HER DESIGNEE, DEBATABLE FOR 10 MINUTES

Page 13, strike lines 8 through 13 (and make such conforming changes as may be necessary).

---

4. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE CASTRO OF TEXAS OR HIS DESIGNEE, DEBATABLE FOR 10 MINUTES

Page 32, line 8, insert before the period the following: ", including underrepresented individuals in the sciences, such as women and other minorities".

---

5. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE SLAUGHTER OF NEW YORK OR HER DESIGNEE, DEBATABLE FOR 10 MINUTES

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).

---

6. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE FITZPATRICK OF PENNSYLVANIA OR HIS DESIGNEE, DEBATABLE FOR 10 MINUTES

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.

---

7. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE POLIS OF COLORADO OR HIS DESIGNEE, DEBATABLE FOR 10 MINUTES

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.).

---

8. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE JACKSON LEE OF TEXAS OR HER DESIGNEE, DEBATABLE FOR 10 MINUTES

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.

○