
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. __]

The Committee on Rules, having had under consideration House Resolution ____, 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

AMENDMENT TO RULES COMMITTEE PRINT 114-
22
OFFERED BY MR. BRAT OF VIRGINIA

Page 5, beginning on line 6, strike paragraph (1)
and insert the following:

- 1 (1) AUTHORIZATION OF APPROPRIATIONS.—
- 2 There is authorized to be appropriated to the NIH
- 3 and Cures Innovation Fund \$1,860,000,000 for each
- 4 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

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**AMENDMENT TO
RULES COMMITTEE PRINT 114-22
OFFERED BY MR. YOUNG OF INDIANA AND MR.
HARRIS OF MARYLAND**

Page 6, line 19, strike “409K” and insert “409L”.

Page 15, after line 6, insert the following:

1 **SEC. 1002. PRIZE COMPETITIONS.**

2 Part B of title IV of the Public Health Service Act
3 (42 U.S.C. 284 et seq.) is amended by adding at the end
4 the following:

5 **“SEC. 409K. PRIZE COMPETITIONS FOR IMPROVING**
6 **HEALTH OUTCOMES AND REDUCING FED-**
7 **ERAL EXPENDITURES.**

8 “(a) ESTABLISHMENT; GOALS.—The Director of
9 NIH shall establish and implement an Innovation Prizes
10 Program for one or both of the following goals:

11 “(1) Identifying and funding areas of bio-
12 medical science that could realize significant ad-
13 vancements through the creation of a prize competi-
14 tion.

15 “(2) Improving health outcomes, particularly
16 with respect to human diseases and conditions for

1 which public and private investment in research is
2 disproportionately small relative to Federal Govern-
3 ment expenditures on prevention and treatment ac-
4 tivities, thereby reducing Federal expenditures on
5 health programs.

6 “(b) DESIGN OF PRIZE COMPETITIONS.—Not later
7 than 6 months after the date of enactment of this section,
8 the Director of NIH shall—

9 “(1) design prize competitions—

10 “(A) to cooperate with competitors to real-
11 ize innovations to identify and address areas of
12 biomedical science that could realize significant
13 advancements through the creation of a prize
14 competition; and

15 “(B) to award one or more prizes—

16 “(i) if appropriate, at the beginning of
17 or during the competitions, to the competi-
18 tors whose innovations are most promising
19 or demonstrate progress; and

20 “(ii) at the end of the competitions, to
21 the competitors whose innovations prove to
22 be the best solutions;

23 “(2) ensure that the design of such competi-
24 tions—

1 “(A) is realistic, given the amount of funds
2 to be awarded as prizes;

3 “(B) does not reflect any bias concerning
4 the type of innovations which will prove to be
5 the best solutions; and

6 “(C) allows any person to participate as a
7 competitor without regard to the person’s place
8 of incorporation, primary place of business, citi-
9 zenship, and residency, as applicable; and

10 “(3) submit to the Congress a report on the de-
11 sign of such competitions.

12 “(c) INNOVATION PRIZES ADVISORY BOARD.—

13 “(1) ESTABLISHMENT.—The Director of NIH
14 shall establish and maintain a board, to be known as
15 the I-Prize Board, to advise and assist the Director
16 of NIH in carrying out this section.

17 “(2) COMPOSITION; TERMS.—

18 “(A) COMPOSITION.—The I-Prize Board
19 shall be composed of 9 voting members as fol-
20 lows:

21 “(i) The Director of NIH (or the Di-
22 rector’s designee).

23 “(ii) Four members appointed by the
24 Director of NIH.

1 “(iii) One member appointed by the
2 Speaker of the House of Representatives.

3 “(iv) One member appointed by the
4 majority leader of the Senate.

5 “(v) One member appointed by the
6 minority leader of the House of Represent-
7 atives.

8 “(vi) One member appointed by the
9 minority leader in the Senate.

10 “(B) INCLUSION OF CERTAIN EXPERTS.—

11 The members of the I-Prize Board appointed
12 under clauses (ii) through (vi) of subparagraph
13 (A) shall, collectively, include medical, eco-
14 nomic, budgetary, innovation, or venture capital
15 experts from for-profit and not-for-profit pri-
16 vate sector entities with experience in awarding
17 prizes similar to the prizes under this section.

18 “(C) TERMS.—The appointed members of
19 the I-Prize Board shall each be appointed for a
20 term of 5 years.

21 “(D) APPOINTMENT OF INITIAL MEM-
22 BERS.—The initial appointed members of the I-
23 Prize Board shall be appointed not later than
24 120 days after the date of enactment of this
25 section.

1 “(3) RESPONSIBILITIES.—The I-Prize Board
2 shall be responsible for advising the Director of NIH
3 by—

4 “(A) identifying areas of biomedical
5 science that could realize significant advance-
6 ments through the creation of a prize competi-
7 tion;

8 “(B) making recommendations on estab-
9 lishing the criteria for prize competitions under
10 this section;

11 “(C) making recommendations on which
12 business organizations or other entities have
13 successfully met the criteria established for the
14 prize competition; and

15 “(D) gaining insight from researchers,
16 health economists, academia, and industry on
17 how to conduct prize competitions.

18 “(d) RESTRICTIONS.—

19 “(1) NO FINANCIAL CONFLICTS OF INTER-
20 EST.—Any member of the I-Prize Board, and any
21 officer or employee of the National Institutes of
22 Health responsible for carrying out this section, may
23 not personally or substantially participate in the
24 consideration or determination by the I-Board of

1 any matter that would directly or predictably effect
2 any financial interest of—

3 “(A) the individual or a relative (as such
4 term is defined in section 109(16) of the Ethics
5 in Government Act of 1978) of the individual;
6 or

7 “(B) of any business organization or other
8 entity—

9 “(i) of which the individual is an offi-
10 cer or employee;

11 “(ii) with respect to which the indi-
12 vidual is negotiating for employment; or

13 “(iii) in which the individual has any
14 other financial interest.

15 “(2) NO AWARDS TO COMPETITORS LIKELY TO
16 REAP FINANCIAL BENEFIT FROM INNOVATION.—The
17 Director of NIH may not, with respect to an innova-
18 tion, award a prize under this section to any indi-
19 vidual or entity that has a vested financial interest
20 in any product or procedure that is likely to be de-
21 veloped or marketed because of such innovation.

22 “(e) PROCESS OF AWARD.—The full monetary
23 amount of any prize awarded under this section shall be
24 made available to the prize winner not later than 90 days
25 after the date of such award.

1 “(f) SIMULATION.—The Director of NIH may—

2 “(1) award one or more contracts—

3 “(A) to perform a simulation of the prize
4 competitions to be conducted under this section,
5 based on the designs developed under sub-
6 section (b); and

7 “(B) to use the simulation to assess the ef-
8 fectiveness of the design; and

9 “(2) not later than 4 months after awarding
10 such one or more contracts, submit to the Congress
11 a report on the results of the simulation and assess-
12 ment.

13 “(g) IMPLEMENTATION OF PRIZE COMPETITIONS.—

14 “(1) IN GENERAL.—The Director of NIH may
15 enter into an agreement with one or more entities
16 described in section 501(c), and exempt from tax
17 under section 501(a), of the Internal Revenue Code
18 of 1986 to implement prize competitions based on
19 the designs developed under subsection (b).

20 “(2) MINIMUM PERCENTAGE FOR PRIZES.—If
21 the Director of NIH enters into an agreement under
22 paragraph (1) to provide funds or other assistance
23 (including in-kind contributions and testing or other
24 technical support) to an entity to implement a prize
25 competition under this section—

1 “(A) not more than 15 percent of such as-
2 sistance shall be for administration of the prize
3 competition; and

4 “(B) not less than 85 percent of such as-
5 sistance shall be for activities in direct support
6 of competitors such as demonstration, testing,
7 education; and prize awards.

8 “(h) TRACKING; REPORTING.—The Director of NIH
9 shall—

10 “(1) collect information on—

11 “(A) the medical efficacy of innovations
12 funded through the prize competitions under
13 this section; and

14 “(B) the actual and potential effect of the
15 innovations on Federal expenditures; and

16 “(2) not later than one year after the conclu-
17 sion of the prize competitions under this section, and
18 not later than the end of each of the 4 succeeding
19 years, submit to the Congress a report on the infor-
20 mation collected under paragraph (1).

21 “(i) INTELLECTUAL PROPERTY.—

22 “(1) PROHIBITION ON THE GOVERNMENT AC-
23 QUIRING INTELLECTUAL PROPERTY RIGHTS.—The
24 Federal Government may not gain an interest in in-
25 tellectual property developed by a participant in a

1 prize competition under this section without the
2 written consent of the participant.

3 “(2) LICENSES.—The Federal Government may
4 negotiate a license for the use of intellectual prop-
5 erty developed by a participant in a prize competi-
6 tion 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

11

AMENDMENT TO RULES COMMITTEE PRINT 114-

22

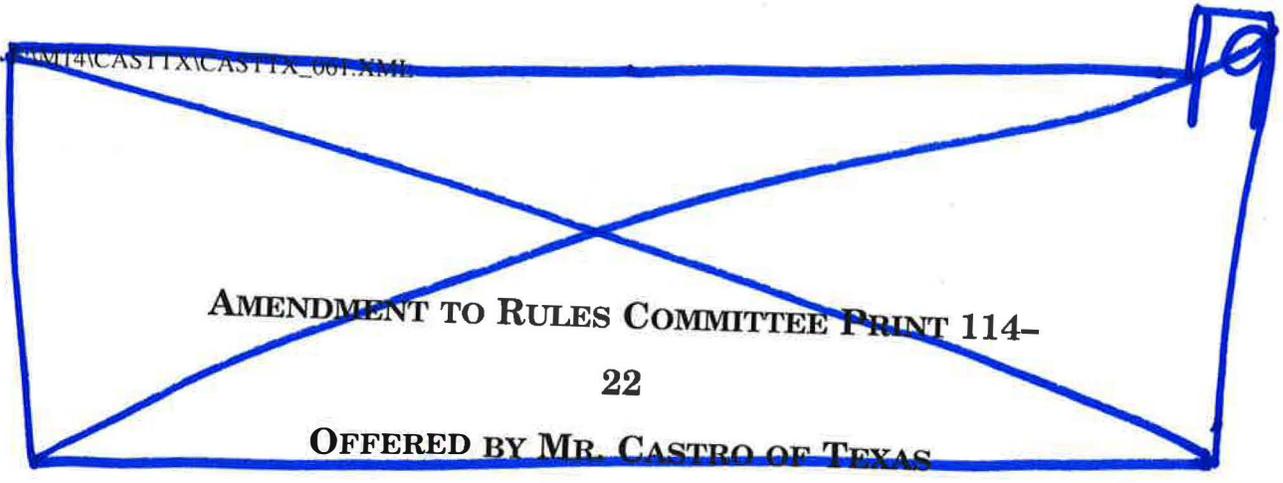
OFFERED BY MS. LEE OF CALIFORNIA

**[Showing text based on H.R. 6, as ordered reported by the
Committee on Energy and Commerce]**

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

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AMENDMENT TO RULES COMMITTEE PRINT 114-

22

OFFERED BY Ms. SLAUGHTER OF NEW YORK

H.R. 3, 21st Century Cures Act

Page 152, insert after line 9 the following new sub-section:

1 (c) STUDY AND REPORT ON THE IMPACT OF ADDI-
2 TIONAL MEDICARE PAYMENT FOR DISARM DRUGS ON
3 USAGE PRACTICES AND DEVELOPMENT OF RESIST-
4 ANCE.—

5 (1) STUDY.—The Director of the Centers for
6 Disease Control and Prevention shall conduct a
7 study to examine the effects of the additional pay-
8 ment for DISARM drugs under the Medicare pro-
9 gram provided under subparagraph (M) of section
10 1886(d)(5) of the Social Security Act (42 U.S.C.
11 1395ww(d)(5)), as added by subsection (a), on—

12 (A) the usage of DISARM drugs (as de-
13 fined by clause (iii) of such subparagraph) by
14 subsection (d) hospitals (as defined in section
15 1886(d)(1)(B) of such Act); and

16 (B) the development of resistance by indi-
17 viduals to such DISARM drugs.

1 (2) REPORT.—Not later than three years after
2 the date of the enactment of this Act, such Director
3 shall submit to Congress a report on the study con-
4 ducted under paragraph (1).



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

AMENDMENT TO
RULES COMMITTEE PRINT 114-22
OFFERED BY MR. FITZPATRICK OF
PENNSYLVANIA

Page 235, after line 2, insert the following:

1 **Subtitle R—Other Provisions**

2 **SEC. 2321. SENSE OF CONGRESS.**

3 It is the sense of the Congress that recording unique
4 device identifiers at the point-of-care in electronic health
5 record systems could significantly enhance the availability
6 of medical device data for postmarket surveillance pur-
7 poses.



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

1 claims with respect to whether the device is safe or
2 effective.

3 (b) INCLUDED ELEMENTS OF REPORT.—The report
4 described in subsection (a) shall include—

5 (1) an analysis of the impact of such a process
6 on survival rates and quality of life measures for
7 seniors and individuals with disabilities;

8 (2) an analysis of the impact of such a process
9 on survival rates and quality of life measures of indi-
10 viduals suffering from life-threatening or irreversibly
11 debilitating human diseases or conditions;

12 (3) an estimation of the impact such a process
13 would have on national health care costs;

14 (4) an analysis of the extent to which such a
15 process could be designed so as to guarantee that
16 patient safety is not compromised;

17 (5) an analysis of the extent to which fraudu-
18 lent or ineffective devices could be marketed to pa-
19 tients under such a process and how such risks
20 could be successfully mitigated;

21 (6) proposals for providing device manufactur-
22 ers with incentives to show the effectiveness of de-
23 vices after the Secretary of Health and Human
24 Services has approved such devices to be lawfully
25 marketed under such a system, such as—

1 (A) by permitting only limited marketing
2 of a device, the effectiveness of which has not
3 yet been shown; or

4 (B) by revoking approval of any device, the
5 effectiveness of which has not been shown with-
6 in a specified timeframe; and

7 (7) recommendations for whether such a proc-
8 ess should be applicable to all devices or to only de-
9 vices that have been granted specific designations by
10 the Secretary or been determined eligible to be ap-
11 proved under specific approval programs under the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 301 et seq.).



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

**AMENDMENT TO
RULES COMMITTEE PRINT 114-22
OFFERED BY MS. JACKSON LEE OF TEXAS**

Page 352, after line 8, insert the following:

1 **SEC. 4062. OUTREACH TO HISTORICALLY BLACK COLLEGES**
2 **AND UNIVERSITIES.**

3 The Secretary of Health and Human Services shall
4 conduct outreach to historically Black colleges and univer-
5 sities, Hispanic-serving institutions, Native American col-
6 leges, and rural colleges to ensure that health profes-
7 sionals from underrepresented populations are aware of
8 research opportunities under this Act.

