

# Union Calendar No. 142

114TH CONGRESS  
1ST SESSION

# H. R. 6

**[Report No. 114–190, Part I]**

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

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## IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. UPTON (for himself, Ms. DEGETTE, Mr. PITTS, Mr. PALLONE, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on 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

JULY 7, 2015

Additional sponsors: Mr. BARTON, Mr. CRAMER, Mr. BUCSHON, Mr. BILIRAKIS, Mrs. BLACKBURN, Mrs. BROOKS of Indiana, Mr. BURGESS, Mrs. ELLMERS of North Carolina, Mr. GRIFFITH, Mr. GUTHRIE, Mr. LANCE, Mr. MCKINLEY, Mrs. McMORRIS RODGERS, Mr. MULLIN, Mr. MURPHY of Pennsylvania, Mr. SHIMKUS, Mr. WALDEN, Mr. WHITFIELD, Mr. ROSKAM, Mr. HANNA, Mr. MCCAUL, Mrs. COMSTOCK, Mr. HARRIS, Mr. MARCHANT, Mr. YARMUTH, Ms. CASTOR of Florida, Mr. LOEBSACK, Ms. SCHAKOWSKY, Mr. TONKO, Ms. MOORE, Mr. VEASEY, Mrs. DINGELL, Mr. FATTAH, Mr. SCHRADER, Mr. NOLAN, Ms. ESHOO, Mr. WELCH, Mr. DAVID SCOTT of Georgia, Mr. PERLMUTTER, Mr. COURTNEY, Mr. COHEN, Mr. DESAULNIER, Mr. LONG, Mr. BUTTERFIELD, Ms. CLARKE of New York, Mr. MICHAEL F. DOYLE of Pennsylvania, Mr. RUSH, Mr. ENGEL, Mr. MCNERNEY, Ms. MATSUI, Mr. FLORES, Mr. JOHNSON of Ohio, Mr. GIBSON, Mr. KENNEDY, Mr. BEN RAY LUJÁN of New Mexico, Mr. WALZ, Mr. CASTRO of Texas, Mrs. BUSTOS, Ms. FRANKEL of Florida, Ms. BROWNLEY of California, Mr. COSTA, Mrs. WAGNER, Mr. RODNEY DAVIS of Illinois, Mr. SCALISE, Mr. LATTA, Mr. HARPER, Mr. OLSON, Mr. KINZINGER of Illinois, Mr. POMPEO, Mr. COLLINS of New York, Mrs. MIMI WALTERS of California, Mr. ALLEN, Mr. SARBANES, Ms. LEE, Mrs. MILLER of Michigan, Mr. HIGGINS, Mr. HUFFMAN, Mr.

KILDEE, Mr. QUIGLEY, Mr. TAKAI, Mr. HECK of Nevada, Mr. PIERLUISI, Mr. BENISHEK, Mrs. WALORSKI, Mr. ISRAEL, Mr. HULTGREN, Ms. KUSTER, Mr. YODER, Mr. DENT, Mr. CURBELO of Florida, Mrs. KIRKPATRICK, Mr. POLIS, Mr. O'ROURKE, Mr. HUDSON, Mr. CÁRDENAS, Mrs. CAPPS, Mr. ROE of Tennessee, Mr. BISHOP of Michigan, Mr. ROSS, Mr. PAYNE, Ms. NORTON, Mr. DOLD, Mr. TURNER, Mr. COFFMAN, Mr. SIRES, Mr. MEADOWS, Mr. COSTELLO of Pennsylvania, Mr. GUTIÉRREZ, Mr. MESSER, Mr. WALBERG, Mr. SALMON, Mr. JENKINS of West Virginia, Mr. POCAN, Mr. PETERS, Mrs. TORRES, Ms. LOFGREN, Ms. MENG, Mr. TAKANO, Mr. PITTENGER, Mr. DENHAM, Mr. BARLETTA, Mr. HARDY, Mr. RUPPERSBERGER, Mr. VARGAS, Mr. GARAMENDI, Mr. HECK of Washington, Mr. BERA, Mr. LUETKEMEYER, Mr. ZELDIN, Ms. CLARK of Massachusetts, Mr. BOST, Mrs. LAWRENCE, Ms. VELÁZQUEZ, Mr. ROGERS of Alabama, Ms. EDWARDS, Mr. YOUNG of Iowa, Mr. KATKO, Mr. MOULTON, Mr. FORTENBERRY, Mr. MCHENRY, Mr. HINOJOSA, Mr. CARTWRIGHT, Mr. JOYCE, Mr. VALADAO, Mr. ASHFORD, Mr. MOOLENAAR, Mr. DONOVAN, Mr. WENSTRUP, Mr. ELLISON, Mr. HASTINGS, Mrs. CAROLYN B. MALONEY of New York, Mr. NADLER, Ms. WASSERMAN SCHULTZ, Mr. TROTT, Ms. KAPTUR, Ms. KELLY of Illinois, Mr. RANGEL, Ms. FUDGE, Mr. MCGOVERN, Mr. REED, Mr. HUIZENGA of Michigan, Mr. LAMALFA, Mr. CRENSHAW, Ms. SINEMA, Ms. MCCOLLUM, Mr. WEBSTER of Florida, Ms. BORDALLO, Mr. GIBBS, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. CONAWAY, Mr. KNIGHT, Mr. WOMACK, Mr. DESJARLAIS, Mr. ROYCE, Mr. DIAZ-BALART, Ms. STEFANIK, Mr. ZINKE, Mr. CAPUANO, Ms. JACKSON LEE, Mr. TIBERI, Ms. HERRERA BEUTLER, Mr. VAN HOLLEN, Mr. GUINTA, Ms. ROSLEHTINEN, Mr. SIMPSON, Ms. BONAMICI, Mr. CICILLINE, Mr. LIPINSKI, Miss RICE of New York, Mr. PAULSEN, Ms. SPEIER, Mr. COOK, Mr. LANGEVIN, Mr. STIVERS, Mr. CLEAVER, Mr. COLLINS of Georgia, Mr. HUNTER, Ms. HAHN, Mr. RIGELL, Mr. CHABOT, Ms. DELBENE, Mr. LOBIONDO, Ms. ROYBAL-ALLARD, Mr. PERRY, Mr. DELANEY, Mr. LEWIS, Mr. TED LIEU of California, Mr. JOHNSON of Georgia, Ms. WILSON of Florida, Mr. KEATING, Ms. BROWN of Florida, Mr. KIND, Mr. MARINO, Mr. BRADY of Pennsylvania, Mr. FARR, Mr. CALVERT, Mr. LARSON of Connecticut, Ms. JUDY CHU of California, Mr. HOYER, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. MAXINE WATERS of California, Mr. LOWENTHAL, Mr. RYAN of Ohio, Mrs. DAVIS of California, Mr. KILMER, and Ms. DUCKWORTH

JULY 7, 2015

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

JULY 7, 2015

The Committee on Ways and Means discharged; committed to the Committee  
of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on May 19, 2015]

# **A BILL**

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

1 *Be it enacted by the Senate and House of Representa-*  
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) *SHORT TITLE.*—*This Act may be cited as the “21st*  
 5 *Century Cures Act”.*

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

*Sec. 1. Short title; table of contents.*

**TITLE I—DISCOVERY**

*Subtitle A—National Institutes of Health Funding*

*Sec. 1001. National Institutes of Health reauthorization.*

*Sec. 1002. NIH Innovation Fund.*

*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 commu-  
 nities 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. Sharing of data generated through NIH-funded research.*  
*Sec. 1102. 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 new antimicrobial 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. Medicare payment incentive for the transition from traditional x-ray imaging to digital radiography and other Medicare imaging payment provision.*  
*Sec. 4003. Implementation of Office of Inspector General recommendation to delay certain Medicare prescription drug plan prepayments.*



*Subtitle B—Cures Innovation Fund**Sec. 4041. Cures Innovation Fund.**Subtitle C—Other Reforms**Sec. 4061. SPR drawdown.**Subtitle D—Miscellaneous**Sec. 4081. Lyme disease and other tick-borne diseases.*

1                   **TITLE I—DISCOVERY**  
 2                   **Subtitle A—National Institutes of**  
 3                   **Health Funding**

4 **SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**  
 5 **IZATION.**

6           *Section 402A(a)(1) of the Public Health Service Act*  
 7 *(42 U.S.C. 282a(a)(1)) is amended—*

8                   *(1) in subparagraph (B), by striking at the end*  
 9                   *“and”;*

10                   *(2) in subparagraph (C), by striking at the end*  
 11 *the period and inserting a semicolon; and*

12                   *(3) by adding at the end the following new sub-*  
 13 *paragraphs:*

14                           *“(D) \$31,811,000,000 for fiscal year 2016;*

15                           *“(E) \$33,331,000,000 for fiscal year 2017;*

16                   *and*

17                           *“(F) \$34,851,000,000 for fiscal year 2018.”.*

18 **SEC. 1002. NIH INNOVATION FUND.**

19           *(a) USE OF INNOVATION FUND.—Section 402(b) of the*  
 20 *Public Health Service Act (42 U.S.C. 282(b)) is amended—*

1           (1) *in paragraph (23), by striking at the end*  
2           *“and”;*

3           (2) *in paragraph (24), by striking at the end the*  
4           *period and inserting “; and”; and*

5           (3) *by inserting after paragraph (24), the fol-*  
6           *lowing new paragraph:*

7           *“(25) shall, with respect to funds appropriated*  
8           *under section 402A(e) to the NIH Innovation Fund,*  
9           *allocate such funds to the national research institutes*  
10           *and national centers for conducting and supporting*  
11           *innovation fund initiatives identified under para-*  
12           *graph (3) of such section.”.*

13           ***(b) ESTABLISHMENT OF INNOVATION FUND.—Section***  
14           ***402A of the Public Health Service Act (42 U.S.C. 282a) is***  
15           ***amended—***

16           (1) *by redesignating subsection (e) as subsection*  
17           *(f); and*

18           (2) *by inserting after subsection (d) the following*  
19           *new subsection:*

20           ***“(e) NIH INNOVATION FUND.—***

21           ***“(1) ESTABLISHMENT.—For the purpose of allo-***  
22           ***cations under section 402(b)(25), there is established***  
23           ***a fund to be known as the NIH Innovation Fund. The***  
24           ***Director of NIH shall, with respect to funds appro-***  
25           ***priated to the NIH Innovation Fund, allocate such***

1 *funds to support biomedical research through the*  
2 *funding of basic, translational, and clinical research.*

3 “(2) *AMOUNTS MADE AVAILABLE TO FUND.*—

4 “(A) *IN GENERAL.*—Subject to subpara-  
5 *graph (B), there is authorized to be appro-*  
6 *priated, and appropriated, to the NIH Innova-*  
7 *tion Fund out of any funds in the Treasury not*  
8 *otherwise appropriated, \$2,000,000,000 for each*  
9 *of fiscal years 2016 through 2020. The amounts*  
10 *appropriated to the Fund by the preceding sen-*  
11 *tence shall be in addition to any amounts other-*  
12 *wise made available to the National Institutes of*  
13 *Health.*

14 “(B) *AVAILABILITY SUBJECT TO APPRO-*  
15 *PRIATIONS.*—Amounts in the Fund shall not be  
16 *available except to the extent and in such*  
17 *amounts as are provided in advance in appro-*  
18 *priation Acts.*

19 “(C) *ALLOCATION OF AMOUNTS.*—Of the  
20 *amounts made available from the NIH Innova-*  
21 *tion Fund for allocations under section*  
22 *402(b)(25) for a fiscal year—*

23 “(i) *not less than \$500,000,000 shall be*  
24 *for the Accelerating Advancement Program*  
25 *under paragraph (5);*

1           “(ii) not less than 35 percent of such  
2           amounts remaining after subtracting the al-  
3           location for the Accelerating Advancement  
4           Program shall be for early stage investiga-  
5           tors (as defined in paragraph (7));

6           “(iii) not less than 20 percent of such  
7           amounts remaining after subtracting the al-  
8           location for the Accelerating Advancement  
9           Program shall be for high-risk, high-reward  
10          research under section 409K; and

11          “(iv) not more than 10 percent of such  
12          amounts (without subtracting the allocation  
13          for the Accelerating Advancement Program)  
14          shall be for intramural research.

15          “(D) *INAPPLICABILITY OF CERTAIN PROVI-*  
16          *SIONS.—Amounts in the NIH Innovation Fund*  
17          *shall not be subject to—*

18                 “(i) any transfer authority of the Sec-  
19                 retary or the Director of NIH under section  
20                 241, subsection (c), subsection (d), or any  
21                 other provision of law (other than section  
22                 402(b)(25) and this subsection); or

23                 “(ii) the Nonrecurring expenses fund  
24                 under section 223 of division G of the Con-

1                    *olidated Appropriations Act, 2008 (42*  
2                    *U.S.C. 3514a).*

3                    “(3) *AUTHORIZED USES.—Amounts in the NIH*  
4                    *Innovation Fund established under paragraph (1)*  
5                    *may be used only to conduct or support innovative*  
6                    *biomedical research through the following:*

7                    “(A) *Research in which—*

8                                       “(i) *a principal investigator has a spe-*  
9                                       *cific project or specific objectives; and*

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

12                    “(B) *Research in which—*

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

15                                       “(ii) *funding is not tied to a specific*  
16                                       *project or specific objectives.*

17                    “(C) *Research to be carried out by an early*  
18                    *stage investigator (as defined in paragraph (7)).*

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

22                    “(E) *The Accelerating Advancement Pro-*  
23                    *gram under paragraph (5).*

24                    “(F) *Development and implementation of*  
25                    *the strategic plan under paragraph (6).*

1           “(4) *COORDINATION.*—*In funding programs and*  
2           *activities through the NIH Innovation Fund, the Sec-*  
3           *retary, acting through the Director of NIH, shall—*

4                   “(A) *ensure coordination among the na-*  
5                   *tional research institutes, the national centers,*  
6                   *and other departments, agencies, and offices of*  
7                   *the Federal Government; and*

8                   “(B) *minimize unnecessary duplication.*

9           “(5) *ACCELERATING ADVANCEMENT PROGRAM.*—  
10           *The Director of NIH shall establish a program, to be*  
11           *known as the Accelerating Advancement Program,*  
12           *under which—*

13                   “(A) *the Director of NIH partners with na-*  
14                   *tional research institutes and national centers to*  
15                   *accomplish important biomedical research objec-*  
16                   *tives; and*

17                   “(B) *for every \$1 made available by the Di-*  
18                   *rector of NIH to a national research institute or*  
19                   *national center for a research project, the insti-*  
20                   *tute or center makes \$1 available for such project*  
21                   *from funds that are not derived from the NIH*  
22                   *Innovation Fund.*

23           “(6) *STRATEGIC PLAN.*—

24                   “(A) *IN GENERAL.*—*The Director of NIH*  
25                   *shall ensure that scientifically based strategic*

1           *planning is implemented in support of research*  
2           *priorities, including through development, use,*  
3           *and updating of a research strategic plan that—*

4                   “(i) *is designed to increase the efficient*  
5                   *and effective focus of biomedical research in*  
6                   *a manner that leverages the best scientific*  
7                   *opportunities through a deliberative plan-*  
8                   *ning process;*

9                   “(ii) *identifies areas, to be known as*  
10                   *strategic focus areas, in which the resources*  
11                   *of the NIH Innovation Fund can contribute*  
12                   *to the goals of expanding knowledge to ad-*  
13                   *dress, and find more effective treatments for,*  
14                   *unmet medical needs in the United States,*  
15                   *including the areas of—*

16                           “(I) *biomarkers;*

17                           “(II) *precision medicine;*

18                           “(III) *infectious diseases, includ-*  
19                           *ing pathogens listed as a qualifying*  
20                           *pathogen under section 505E(f) of the*  
21                           *Federal Food, Drug, and Cosmetic Act*  
22                           *or listed or designated as a tropical*  
23                           *disease under section 524 of such Act;*  
24                           *and*

25                           “(IV) *antibiotics;*

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

3                   “(iv) ensures that basic research re-  
4                   mains a priority.

5                   “(B) *UPDATES AND REVIEWS.*—*The Direc-*  
6                   *tor shall review and, as appropriate, update the*  
7                   *research strategic plan under subparagraph (A)*  
8                   *not less than every 18 months.*

9                   “(7) *DEFINITION.*—*In this subsection, the term*  
10                  *‘early stage investigator’ means an investigator*  
11                  *who—*

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

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

18                   “(C) is within 10 years of having com-  
19                   pleted—

20                   “(i) the investigator’s terminal degree;

21                   or

22                   “(ii) a medical residency (or the equiv-  
23                   alent).”.

24                  (c) *SUPPLEMENT, NOT SUPPLANT; PROHIBITION*  
25                  *AGAINST TRANSFER.*—*Funds appropriated pursuant to sec-*



1 *tion 402A(e) of the Public Health Service Act, as inserted*  
2 *by subsection (b)—*

3 *(1) shall be used to supplement, not supplant, the*  
4 *funds otherwise allocated by the National Institutes of*  
5 *Health for biomedical research; and*

6 *(2) notwithstanding any transfer authority in*  
7 *any appropriation Act, shall not be used for any pur-*  
8 *pose other than allocating funds for conducting and*  
9 *supporting innovation fund initiatives as described in*  
10 *section 402(b)(25) of the Public Health Service Act,*  
11 *as added by subsection (a).*

12 ***Subtitle B—National Institutes of***  
13 ***Health Planning and Adminis-***  
14 ***tration***

15 ***SEC. 1021. NIH RESEARCH STRATEGIC PLAN.***

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

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

20 *“(5) shall ensure that scientifically based stra-*  
21 *tegic planning is implemented in support of research*  
22 *priorities as determined by the agencies of the Na-*  
23 *tional Institutes of Health, including through develop-*  
24 *ment, use, and updating of the research strategic plan*  
25 *under subsection (m);”;* and

1           (2) *by adding at the end the following:*

2           “(m) *RESEARCH STRATEGIC PLAN.—*

3                 “(1) *FIVE-YEAR PLANS FOR BIOMEDICAL RE-*  
4           *SEARCH STRATEGY.—*

5                         “(A) *IN GENERAL.—For each successive*  
6           *five-year period beginning with the period of fis-*  
7           *cal years 2016 through 2020, the Director of*  
8           *NIH, in consultation with the entities described*  
9           *in subparagraph (B), shall develop and main-*  
10          *tain a biomedical research strategic plan that—*

11                                 “(i) *is designed to increase the efficient*  
12           *and effective focus of biomedical research in*  
13           *a manner that leverages the best scientific*  
14           *opportunities through a deliberative plan-*  
15           *ning process;*

16                                 “(ii) *identifies areas, to be known as*  
17           *strategic focus areas, in which the resources*  
18           *of the National Institutes of Health can best*  
19           *contribute to the goal of expanding knowl-*  
20           *edge on human health in the United States*  
21           *through biomedical research; and*

22                                 “(iii) *includes objectives for each such*  
23           *strategic focus area.*

24                         “(B) *ENTITIES DESCRIBED.—The entities*  
25           *described in this subparagraph are the directors*

1           *of the national research institutes and national*  
2           *centers, researchers, patient advocacy groups,*  
3           *and industry leaders.*

4           “(2) *USE OF PLAN.*—*The Director of NIH and*  
5           *the directors of the national research institutes and*  
6           *national centers shall use the strategic plan—*

7                     “(A) *to identify research opportunities; and*

8                     “(B) *to develop individual strategic plans*  
9           *for the research activities of each of the national*  
10           *research institutes and national centers that—*

11                       “(i) *have a common template; and*

12                       “(ii) *identify strategic focus areas in*  
13           *which the resources of the national research*  
14           *institutes and national centers can best con-*  
15           *tribute to the goal of expanding knowledge*  
16           *on human health in the United States*  
17           *through biomedical research.*

18           “(3) *CONTENTS OF PLANS.*—

19                     “(A) *STRATEGIC FOCUS AREAS.*—*The stra-*  
20           *tegic focus areas identified pursuant to para-*  
21           *graph (1)(A)(ii) shall—*

22                       “(i) *be identified in a manner that—*

23                             “(I) *considers the return on in-*  
24           *vestment to the United States public*  
25           *through the investments of the National*

1 *Institutes of Health in biomedical re-*  
2 *search; and*

3 *“(II) contributes to expanding*  
4 *knowledge to improve the United*  
5 *States public’s health through bio-*  
6 *medical research; and*

7 *“(ii) include overarching and trans-*  
8 *National Institutes of Health strategic focus*  
9 *areas, to be known as Mission Priority*  
10 *Focus Areas, which best serve the goals of*  
11 *preventing or eliminating the burden of a*  
12 *disease or condition and scientifically merit*  
13 *enhanced and focused research over the next*  
14 *5 years.*

15 *“(B) RARE AND PEDIATRIC DISEASES AND*  
16 *CONDITIONS.—In developing and maintaining a*  
17 *strategic plan under this subsection, the Director*  
18 *of NIH shall ensure that rare and pediatric dis-*  
19 *eases and conditions remain a priority.*

20 *“(C) WORKFORCE.—In developing and*  
21 *maintaining a strategic plan under this sub-*  
22 *section, the Director of NIH shall ensure that*  
23 *maintaining the biomedical workforce of the fu-*  
24 *ture, including the participation by scientists*

1           *from groups traditionally underrepresented in*  
2           *the scientific workforce, remains a priority.*

3           “(4) *INITIAL PLAN.*—*Not later than 270 days*  
4           *after the date of enactment of this subsection, the Di-*  
5           *rector of NIH and the directors of the national re-*  
6           *search institutes and national centers shall—*

7                     “(A) *complete the initial strategic plan re-*  
8                     *quired by paragraphs (1) and (2); and*

9                     “(B) *make such initial strategic plan pub-*  
10                    *licly available on the website of the National In-*  
11                    *stitutes of Health.*

12           “(5) *REVIEW; UPDATES.*—

13                    “(A) *PROGRESS REVIEWS.*—*Not less than*  
14                    *annually, the Director of NIH, in consultation*  
15                    *with the directors of the national research insti-*  
16                    *tutes and national centers, shall conduct progress*  
17                    *reviews for each strategic focus area identified*  
18                    *under paragraph (1)(A)(ii).*

19                    “(B) *UPDATES.*—*Not later than the end of*  
20                    *the 5-year period covered by the initial strategic*  
21                    *plan under this subsection, and every 5 years*  
22                    *thereafter, the Director of NIH, in consultation*  
23                    *with the directors of the national research insti-*  
24                    *tutes and national centers, stakeholders in the*

1           *scientific field, advocates, and the public at*  
2           *large, shall—*

3                     *“(i) conduct a review of the plan, in-*  
4                     *cluding each strategic focus area identified*  
5                     *under paragraph (2)(B); and*

6                     *“(ii) update such plan in accordance*  
7                     *with this section.”.*

8   **SEC. 1022. INCREASING ACCOUNTABILITY AT THE NA-**  
9                     **TIONAL INSTITUTES OF HEALTH.**

10           *(a) APPOINTMENT AND TERMS OF DIRECTORS OF NA-*  
11           *TIONAL RESEARCH INSTITUTES AND NATIONAL CEN-*  
12           *TERS.—Subsection (a) of section 405 of the Public Health*  
13           *Service Act (42 U.S.C. 284) is amended to read as follows:*

14   *“(a) APPOINTMENT; TERMS.—*

15                     *“(1) APPOINTMENT.—The Director of the Na-*  
16                     *tional Cancer Institute shall be appointed by the*  
17                     *President and the directors of the other national re-*  
18                     *search institutes, as well as the directors of the na-*  
19                     *tional centers, shall be appointed by the Director of*  
20                     *NIH. The directors of the national research institutes,*  
21                     *as well as national centers, shall report directly to the*  
22                     *Director of NIH.*

23                     *“(2) TERMS.—*

1           “(A) *IN GENERAL.*—*The term of office of a*  
2           *director of a national research institute or na-*  
3           *tional center shall be 5 years.*

4           “(B) *REMOVAL.*—*The director of a national*  
5           *research institute or national center may be re-*  
6           *moved from office by the Director of NIH prior*  
7           *to the expiration of such director’s 5-year term.*

8           “(C) *REAPPOINTMENT.*—*At the end of the*  
9           *term of a director of a national research insti-*  
10          *tute or national center, the director may be re-*  
11          *appointed. There is no limit on the number of*  
12          *terms a director may serve.*

13          “(D) *VACANCIES.*—*If the office of a director*  
14          *of a national research institute or national cen-*  
15          *ter becomes vacant before the end of such direc-*  
16          *tor’s term, the director appointed to fill the va-*  
17          *cancy shall be appointed for a 5-year term start-*  
18          *ing on the date of such appointment.*

19          “(E) *TRANSITIONAL PROVISION.*—*Each di-*  
20          *rector of a national research institute or na-*  
21          *tional center serving on the date of enactment of*  
22          *the 21st Century Cures Act is deemed to be ap-*  
23          *pointed for a 5-year term under this subsection*  
24          *starting on such date of enactment.”.*

1           **(b) COMPENSATION TO CONSULTANTS OR INDIVIDUAL**  
2 *SCIENTISTS.*—*Section 202 of the Departments of Labor,*  
3 *Health and Human Services, and Education, and Related*  
4 *Agencies Appropriations Act, 1993 (Public Law 102–394;*  
5 *42 U.S.C. 238f note) is amended by striking “portable*  
6 *structures;” and all that follows and inserting “portable*  
7 *structures.”.*

8           **(c) REVIEW OF CERTAIN AWARDS BY DIRECTORS.**—  
9 *Section 405(b) of the Public Health Service Act (42 U.S.C.*  
10 *284(b)) is amended by adding at the end the following:*

11           *“(3) Before an award is made by a national research*  
12 *institute or by a national center for a grant for a research*  
13 *program or project (commonly referred to as an ‘R-series*  
14 *grant’), other than an award constituting a noncompeting*  
15 *renewal of such grant, or a noncompeting administrative*  
16 *supplement to such grant, the director of such national re-*  
17 *search institute or national center—*

18                   *“(A) shall review and approve the award; and*

19                   *“(B) shall take into consideration—*

20                           *“(i) the mission of the national research in-*  
21 *stitute or national center and the scientific pri-*  
22 *orities identified in the strategic plan under sec-*  
23 *tion 402(m); and*



1                   “(ii) whether other agencies are funding  
2                   programs or projects to accomplish the same  
3                   goal.”.

4           (d) *IOM STUDY ON DUPLICATION IN FEDERAL BIO-*  
5 *MEDICAL RESEARCH.*—*The Secretary of Health and*  
6 *Human Services shall enter into an arrangement with the*  
7 *Institute of Medicine of the National Academies (or, if the*  
8 *Institute declines, another appropriate entity) under which*  
9 *the Institute (or other appropriate entity) not later than*  
10 *2 years after the date of enactment of this Act will—*

11                   (1) *complete a study on the extent to which bio-*  
12 *medical research conducted or supported by Federal*  
13 *agencies is duplicative; and*

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

17 **SEC. 1023. REDUCING ADMINISTRATIVE BURDENS OF RE-**  
18 **SEARCHERS.**

19           (a) *PLAN PREPARATION AND IMPLEMENTATION OF*  
20 *MEASURES TO REDUCE ADMINISTRATIVE BURDENS.*—*The*  
21 *Director of the National Institutes of Health shall prepare*  
22 *a plan, including time frames, and implement measures to*  
23 *reduce the administrative burdens of researchers funded by*  
24 *the National Institutes of Health, taking into account the*

1 *recommendations, evaluations, and plans researched by the*  
2 *following entities:*

3 (1) *The Scientific Management Review Board.*

4 (2) *The National Academy of Sciences.*

5 (3) *The 2007 and 2012 Faculty Burden Survey*  
6 *conducted by The Federal Demonstration Partner-*  
7 *ship.*

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

10 (b) *REPORT.*—*Not later than two years after the date*  
11 *of enactment of this Act, the Director of the National Insti-*  
12 *tutes of Health shall submit to Congress a report on the*  
13 *extent to which the Director has implemented measures pur-*  
14 *suant to subsection (a).*

15 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**  
16 **HEALTH FROM THE PAPERWORK REDUCTION**  
17 **ACT REQUIREMENTS.**

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

20 (1) *in subparagraph (C), by striking “; or” and*  
21 *inserting a semicolon;*

22 (2) *in subparagraph (D), by striking the period*  
23 *at the end and inserting “; or”; and*

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

1           “(E) during the conduct of research by the Na-  
2           tional Institutes of Health.”.

3 **SEC. 1025. NIH TRAVEL.**

4           *It is the sense of Congress that participation in or*  
5 *sponsorship of scientific conferences and meetings is essen-*  
6 *tial to the mission of the National Institutes of Health.*

7 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

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

10           (1) in subsection (b), by striking “the appropria-  
11           tion of funds as described in subsection (g)” and in-  
12           serting “the availability of funds as described in sub-  
13           section (f)”;

14           (2) in subsection (e)(3), by amending subpara-  
15           graph (C) to read as follows:

16                   “(C) OTHER TRANSACTIONS AUTHORITY.—  
17           The Director of the Center shall have other trans-  
18           actions authority in entering into transactions  
19           to fund projects in accordance with the terms  
20           and conditions of this section.”;

21           (3) by striking subsection (f); and

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

1 **SEC. 1027. NCATS PHASE IIB RESTRICTION.**

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

4 *(1) prior to making the amendments under*  
5 *paragraph (2), by striking “IIB” each place it ap-*  
6 *pears and inserting “III”; and*

7 *(2) by striking “IIA” each place it appears and*  
8 *inserting “IIB”.*

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

10 *Part B of title IV of the Public Health Service Act*  
11 *(42 U.S.C. 284 et seq.) is amended by adding at the end*  
12 *the following:*

13 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**  
14 **GRAM.**

15 *“The director of each national research institute shall,*  
16 *as appropriate—*

17 *“(1) establish programs to conduct or support re-*  
18 *search projects that pursue innovative approaches to*  
19 *major contemporary challenges in biomedical research*  
20 *that involve inherent high risk, but have the potential*  
21 *to lead to breakthroughs; and*

22 *“(2) set aside a specific percentage of funding, to*  
23 *be determined by the Director of NIH for each na-*  
24 *tional research institute, for such projects.”.*

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

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

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

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

13 *(a) IN GENERAL.—Part G of title IV of the Public*  
 14 *Health Service (42 U.S.C. 288 et seq.) is amended—*

15 *(1) by redesignating the second section 487F (42*  
 16 *U.S.C. 288–6; relating to pediatric research loan re-*  
 17 *payment program) as section 487G; and*

18 *(2) by inserting after section 487G, as so redesign-*  
 19 *ated, the following:*

20 **“SEC. 487H. LOAN REPAYMENT PROGRAM.**

21 *“(a) IN GENERAL.—The Secretary shall establish a*  
 22 *program, based on workforce and scientific needs, of enter-*  
 23 *ing into contracts with qualified health professionals under*  
 24 *which such health professionals agree to engage in research*  
 25 *in consideration of the Federal Government agreeing to*  
 26 *pay, for each year of engaging in such research, not more*

1 *than \$50,000 of the principal and interest of the edu-*  
2 *cational loans of such health professionals.*

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

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

12       “(d) *APPLICABILITY OF CERTAIN PROVISIONS RE-*  
13 *GARDING OBLIGATED SERVICE.*—*Except to the extent in-*  
14 *consistent with this section, the provisions of sections 338B,*  
15 *338C, and 338E shall apply to the program established*  
16 *under this section to the same extent and in the same man-*  
17 *ner as such provisions apply to the National Health Service*  
18 *Corps Loan Repayment Program established under section*  
19 *338B.*

20       “(e) *AVAILABILITY OF APPROPRIATIONS.*—*Amounts*  
21 *appropriated for a fiscal year for contracts under subsection*  
22 *(a) are authorized to remain available until the expiration*  
23 *of the second fiscal year beginning after the fiscal year for*  
24 *which the amounts were appropriated.”.*

1       (b) *UPDATE OF OTHER LOAN REPAYMENT PRO-*  
2 *GRAMS.—*

3           (1) *Section 464z-5(a) of the Public Health Serv-*  
4 *ice Act (42 U.S.C.285t-2(a)) is amended—*

5               (A) *by striking “\$35,000” and inserting*  
6 *“\$50,000”; and*

7               (B) *by adding at the end the following new*  
8 *sentence: “Subsection (b) of section 487H shall*  
9 *apply with respect to the maximum amount*  
10 *specified in this subsection in the same manner*  
11 *as it applies to the maximum amount specified*  
12 *in subsection (a) of such section.”.*

13           (2) *Section 487A(a) of such Act (42 U.S.C. 288-*  
14 *1(a)) is amended—*

15               (A) *by striking “\$35,000” and inserting*  
16 *“\$50,000”; and*

17               (B) *by adding at the end the following new*  
18 *sentence: “Subsection (b) of section 487H shall*  
19 *apply with respect to the maximum amount*  
20 *specified in this subsection in the same manner*  
21 *as it applies to the maximum amount specified*  
22 *in subsection (a) of such section.”.*

23           (3) *Section 487B(a) of such Act (42 U.S.C. 288-*  
24 *2(a)) is amended—*

1           (A) by striking “\$35,000” and inserting  
2           “\$50,000”; and

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

9           (4) Section 487C(a)(1) of such Act (42 U.S.C.  
10          288–3(a)(1)) is amended—

11           (A) by striking “\$35,000” and inserting  
12           “\$50,000”; and

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

19           (5) Section 487E(a)(1) of such Act (42 U.S.C.  
20          288–5(a)(1)) is amended—

21           (A) by striking “\$35,000” and inserting  
22           “\$50,000”; and

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



1           *specified in this paragraph in the same manner*  
2           *as it applies to the maximum amount specified*  
3           *in such subsection (a) of such section.”.*

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

7                   (A) *by striking “\$35,000” and inserting*  
8                   *“\$50,000”; and*

9                   (B) *by adding at the end the following new*  
10                  *sentence: “Subsection (b) of section 487H shall*  
11                  *apply with respect to the maximum amount*  
12                  *specified in this subsection in the same manner*  
13                  *as it applies to the maximum amount specified*  
14                  *in such subsection (a) of such section.”.*

15           (7) *Section 487G of such Act (42 U.S.C. 288–6,*  
16           *as redesignated by section 1041(a)(1)), is further*  
17           *amended—*

18                   (A) *in subsection (a)(1), by striking*  
19                   *“\$35,000” and inserting “\$50,000”; and*

20                   (B) *in subsection (b), by adding at the end*  
21                  *the following new sentence: “Subsection (b) of*  
22                  *section 487H shall apply with respect to the*  
23                  *maximum amount specified in subsection (a)(1)*  
24                  *in the same manner as it applies to the max-*

1            *imum amount specified in such subsection (a) of*  
2            *such section.”.*

3    **SEC. 1042. REPORT.**

4            *Not later than 18 months after the date of the enact-*  
5            *ment of this Act, the Director of the National Institutes of*  
6            *Health shall submit to Congress a report on efforts of the*  
7            *National Institutes of Health to attract, retain, and develop*  
8            *emerging scientists.*

9                            ***Subtitle D—Capstone Grant***  
10                           ***Program***

11    **SEC. 1061. CAPSTONE AWARD.**

12            *Part G of title IV of the Public Health Service Act*  
13            *(42 U.S.C. 288 et seq.) is amended by adding at the end*  
14            *the following:*

15    **“SEC. 490. CAPSTONE AWARD.**

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

20            *“(b) PURPOSE.—Capstone Awards shall be made to fa-*  
21            *cilitate the successful transition or conclusion of research*  
22            *programs, or for other purposes, as determined by the Direc-*  
23            *tor of NIH, in consultation with the directors of the na-*  
24            *tional research institutes and national centers.*

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

5       “(d) *LIMITATION.*—Individuals who have received a  
6 Capstone Award shall not be eligible to have principle in-  
7 vestigator status on subsequent awards from the National  
8 Institutes of Health.”.

9       ***Subtitle E—Promoting Pediatric***  
10       ***Research Through the National***  
11       ***Institutes of Health***

12       ***SEC. 1081. NATIONAL PEDIATRIC RESEARCH NETWORK.***

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

15               *(1) in paragraph (1)—*

16                       *(A) by striking “in consultation with the*  
17 *Director of the Eunice Kennedy Shriver Na-*  
18 *tional Institute of Child Health and Human De-*  
19 *velopment and in collaboration with other ap-*  
20 *propriate national research institutes and na-*  
21 *tional centers that carry out activities involving*  
22 *pediatric research” and inserting “in collabora-*  
23 *tion with the national research institutes and*  
24 *national centers that carry out activities involv-*  
25 *ing pediatric research”;*

1                   (B) by striking subparagraph (B);

2                   (C) by striking “may be comprised of, as  
3 appropriate” and all that follows through “the  
4 pediatric research consortia” and inserting  
5 “may be comprised of, as appropriate, the pedi-  
6 atric research consortia”; and

7                   (D) by striking “; or” at the end and insert-  
8 ing a period; and

9                   (2) in paragraph (1), paragraph (2)(A), the first  
10 sentence of paragraph (2)(E), and paragraph (4), by  
11 striking “may” each place it appears and inserting  
12 “shall”.

13 **SEC. 1082. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK**

14                   **SENSE OF CONGRESS.**

15                   *It is the sense of Congress that—*

16                   (1) *the National Institutes of Health should en-*  
17 *courage a global pediatric clinical study network*  
18 *through the allocation of grants, contracts, or coopera-*  
19 *tive agreements to supplement the salaries of new and*  
20 *early investigators who participate in the global pedi-*  
21 *atric clinical study network;*

22                   (2) *National Institutes of Health grants, con-*  
23 *tracts, or cooperative agreements should be awarded,*  
24 *solely for the purpose of supplementing the salaries of*

1      *new and early investigators, to entities that partici-*  
2      *cate in the global pediatric clinical study network;*

3           (3) *the Food and Drug Administration should*  
4      *engage the European Medicines Agency and other for-*  
5      *foreign regulatory entities during the formation of the*  
6      *global pediatric clinical study network to encourage*  
7      *their participation; and*

8           (4) *once a global pediatric clinical study network*  
9      *is established and becomes operational, the Food and*  
10     *Drug Administration should continue to engage the*  
11     *European Medicines Agency and other foreign regu-*  
12     *latory entities to encourage and facilitate their par-*  
13     *ticipation in the network with the goal of enhancing*  
14     *the global reach of the network.*

15 **SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RE-**  
16 **SEARCH.**

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

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

1           (2) *acceptable scientific justifications for exclud-*  
2           *ing participants from a range of age groups from*  
3           *human subjects research studies.*

4           (b) *GUIDELINES.—Not later than 180 days after the*  
5           *conclusion of the workshop under subsection (a), the Direc-*  
6           *tor of the National Institutes of Health shall publish guide-*  
7           *lines—*

8                 (1) *addressing the consideration of age as an in-*  
9                 *clusion variable in research involving human subjects;*  
10                *and*

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

13           (c) *PUBLIC AVAILABILITY OF FINDINGS AND CONCLU-*  
14            *SIONS.—The Director of the National Institutes of Health*  
15            *shall—*

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

20               (2) *not less than biennially, disclose to the public*  
21                *on such website the number of children included in re-*  
22                *search that is conducted or supported by the National*  
23                *Institutes of Health, disaggregated by developmentally*  
24                *appropriate age group, race, and gender.*

1 ***Subtitle F—Advancement of the Na-***  
 2 ***tional Institutes of Health Re-***  
 3 ***search and Data Access***

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

6 *Section 402 of the Public Health Service Act (42*  
 7 *U.S.C. 282) (as amended by section 1021(2)) is further*  
 8 *amended by adding at the end the following:*

9 *“(n) SHARING OF DATA GENERATED THROUGH NIH-*  
 10 *FUNDED RESEARCH.—*

11 *“(1) AUTHORITY.—Subject to paragraph (2), the*  
 12 *Director of NIH may require recipients of the award*  
 13 *of an NIH grant or other financial support, provided*  
 14 *that the research is fully funded through such grant*  
 15 *or other support, to share scientific data generated*  
 16 *from research conducted through such support for re-*  
 17 *search purposes.*

18 *“(2) LIMITATION.—The Director of NIH shall*  
 19 *not require the sharing of data that is inconsistent*  
 20 *with applicable law and policy protecting—*

21 *“(A) privacy and confidentiality;*

22 *“(B) proprietary interests;*

23 *“(C) business confidential information;*

24 *“(D) intellectual property rights; and*

25 *“(E) other relevant rights.”.*

1 **SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL**  
2 **REGISTRY DATA BANK ON ELIGIBILITY FOR**  
3 **CLINICAL TRIALS.**

4 (a) *STANDARDIZATION.*—

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

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

9 (B) by inserting after paragraph (6) the fol-  
10 lowing:

11 “(7) *STANDARDIZATION.*—The Director of NIH  
12 shall—

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

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

17 “(C) ensure that information required to be  
18 submitted to the registry and results data bank,  
19 including recruitment information under para-  
20 graph (2)(A)(i)(II), is submitted by persons and  
21 posted by the Director of NIH in a standardized  
22 format and includes at least—

23 “(i) the disease or indication being  
24 studied;



1           “(ii) inclusion criteria such as age,  
2           gender, diagnosis or diagnoses, laboratory  
3           values, or imaging results; and

4           “(iii) exclusion criteria such as specific  
5           diagnosis or diagnoses, laboratory values, or  
6           prohibited medications; and

7           “(D) to the extent possible, in carrying out  
8           this paragraph, make use of standard health care  
9           terminologies, such as the International Classi-  
10          fication of Diseases or the Current Procedural  
11          Terminology, that facilitate electronic matching  
12          to data in electronic health records or other rel-  
13          evant health information technologies.”.

14          (2) *CONFORMING AMENDMENT.*—Clause (iv) of  
15          section 402(j)(2)(B) of the Public Health Service Act  
16          (42 U.S.C. 282(j)(2)(B)) is hereby stricken.

17          (b) *CONSULTATION.*—Not later than 90 days after the  
18          date of enactment of this Act, the Secretary of Health and  
19          Human Services shall consult with stakeholders (including  
20          patients, researchers, physicians, industry representatives,  
21          health information technology providers, the Food and Drug  
22          Administration, and standard setting organizations such as  
23          CDISC that have experience working with Federal agencies  
24          to standardize health data submissions) to receive advice  
25          on enhancements to the clinical trial registry data bank

1 *under section 402(j) of the Public Health Service Act (42*  
2 *U.S.C. 282(j)) (including enhancements to usability,*  
3 *functionality, and search capability) that are necessary to*  
4 *implement paragraph (7) of section 402(j) of such Act, as*  
5 *added by subsection (a).*

6 (c) *APPLICABILITY.—Not later than 18 months after*  
7 *the date of enactment of this Act, the Secretary of Health*  
8 *and Human Services shall begin implementation of para-*  
9 *graph (7) of section 402(j) of the Public Health Service Act,*  
10 *as added by subsection (a).*

11 ***Subtitle G—Facilitating***  
12 ***Collaborative Research***

13 ***SEC. 1121. CLINICAL TRIAL DATA SYSTEM.***

14 (a) *ESTABLISHMENT.—The Secretary, acting through*  
15 *the Commissioner of Food and Drugs and the Director of*  
16 *the National Institutes of Health, shall enter into a coopera-*  
17 *tive agreement, contract, or grant for a period of 7 years,*  
18 *to be known as the Clinical Trial Data System Agreement,*  
19 *with one or more eligible entities to implement a pilot pro-*  
20 *gram with respect to all clinical trial data obtained from*  
21 *qualified clinical trials for purposes of registered users con-*  
22 *ducting further research on such data.*

23 (b) *APPLICATION.—Eligible entities seeking to enter*  
24 *into a cooperative agreement, contract, or grant with the*  
25 *Secretary under this section shall submit to the Secretary*

1 *an application in such time and manner, and containing*  
2 *such information, as the Secretary may require in accord-*  
3 *ance with this section. The Secretary shall not enter into*  
4 *a cooperative agreement, contract, or grant under this sec-*  
5 *tion with an eligible entity unless such entity submits an*  
6 *application including the following:*

7           (1) *A certification that the eligible entity is not*  
8 *currently and does not plan to be involved in spon-*  
9 *soring, operating, or participating in a clinical trial*  
10 *nor collaborating with another entity for the purposes*  
11 *of sponsoring, operating, or participating in a clin-*  
12 *ical trial.*

13           (2) *Information demonstrating that the eligible*  
14 *entity can compile clinical trial data in standardized*  
15 *formats using terminologies and standards that have*  
16 *been developed by recognized standards developing or-*  
17 *ganizations with input from diverse stakeholder*  
18 *groups, and information demonstrating that the eligi-*  
19 *ble entity can de-identify clinical trial data consistent*  
20 *with the requirements of section 164.514 of title 45,*  
21 *Code of Federal Regulations (or successor regula-*  
22 *tions).*

23           (3) *A description of the system the eligible entity*  
24 *will use to store and maintain such data, and infor-*  
25 *mation demonstrating that this system will comply*

1       *with applicable standards and requirements for en-*  
2       *sureing the security of the clinical trial data.*

3           (4) *A certification that the eligible entity will*  
4       *allow only registered users to access and use de-iden-*  
5       *tified clinical trial data, gathered from qualified clin-*  
6       *ical trials, and that the eligible entity will allow each*  
7       *registered user to access and use such data only after*  
8       *such registered user agrees in writing to the terms de-*  
9       *scribed in (e)(4)(B), and such other carefully con-*  
10       *trolled contractual terms as may be defined by the*  
11       *Secretary.*

12           (5) *Evidence demonstrating the ability of the eli-*  
13       *gible entity to ensure that registered users disseminate*  
14       *the results of the research conducted in accordance*  
15       *with this section to interested parties to serve as a*  
16       *guide to future medical product development or sci-*  
17       *entific research.*

18           (6) *The plan of the eligible entity for securing*  
19       *funding for the activities it would conduct under the*  
20       *clinical trial data system agreement from govern-*  
21       *mental sources and private foundations, entities, and*  
22       *individuals.*

23           (7) *Evidence demonstrating a proven track*  
24       *record of—*

1           (A) being a neutral third party in working  
2           with medical product manufacturers, academic  
3           institutions, and the Food and Drug Adminis-  
4           tration; and

5           (B) having the ability to protect confiden-  
6           tial data.

7           (8) An agreement that the eligible entity will  
8           work with the Comptroller General of the United  
9           States for purposes of the study and report under sub-  
10          section (d).

11          (c) *EXTENSION, EXPANSION, TERMINATION.*—The Sec-  
12          retary, acting through the Commissioner of Food and Drugs  
13          and the Director of the National Institutes of Health, upon  
14          the expiration of the 7-year period referred to in subsection  
15          (a), may extend (including permanently), expand, or termi-  
16          nate the pilot program established under such subsection,  
17          in whole or in part.

18          (d) *STUDY AND REPORT.*—

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

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

3                   (A) *review the effectiveness of the pilot pro-*  
4 *gram established under subsection (a); and*

5                   (B) *be designed to formulate recommenda-*  
6 *tions on improvements to the program.*

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

9                   (A) *The new discoveries, research inquiries,*  
10 *or clinical trials that have resulted from access-*  
11 *ing clinical trial data under the pilot program*  
12 *established under subsection (a).*

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

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

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

23                   (E) *An analysis of privacy and data integ-*  
24 *egrity practices used in the program.*

25           (e) *DEFINITIONS.*—*In this section:*

1           (1) *The term “eligible entity” means an entity*  
2 *that has experienced personnel with clinical and other*  
3 *technical expertise in the biomedical sciences and bio-*  
4 *medical ethics and that is—*

5                   (A) *an institution of higher education (as*  
6 *such term is defined in section 1001 of the High-*  
7 *er Education Act of 1965 (20 U.S.C. 1001)) or*  
8 *a consortium of such institutions; or*

9                   (B) *an organization described in section*  
10 *501(c)(3) of title 26 of the Internal Revenue Code*  
11 *of 1986 and exempt from tax under section*  
12 *501(a) of such title.*

13           (2) *The term “medical product” means a drug*  
14 *(as defined in section 201(g) of the Federal Food,*  
15 *Drug, and Cosmetic Act (21 U.S.C. 331(g))), a device*  
16 *(as defined in section 201(h) of such Act (21 U.S.C.*  
17 *331(h)), a biological product (as defined in section*  
18 *351 of the Public Health Service Act (42 U.S.C.*  
19 *262)), or any combination thereof.*

20           (3) *The term “qualified clinical trial” means a*  
21 *clinical trial sponsored solely by an agency of the De-*  
22 *partment of Health and Human Services with respect*  
23 *to a medical product—*

24                   (A) *that—*

1           (i) was approved or cleared under sec-  
2           tion 505, 510(k), or 515, or has an exemp-  
3           tion for investigational use in effect under  
4           section 505 or 520(m), of the Federal Food,  
5           Drug, and Cosmetic Act (42 U.S.C. 301 et  
6           seq.); or

7           (ii) was licensed under section 351 of  
8           the Public Health Service Act (42 U.S.C.  
9           262) or has an exemption for investiga-  
10          tional use in effect under such section 351;  
11          or

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

15           (i) no additional work to support ap-  
16           proval, licensure, or clearance of such med-  
17           ical product is being or is planned to be un-  
18           dertaken by the sponsor of the original de-  
19           velopment program, its successors, assigns,  
20           or collaborators; and

21           (ii) the sponsor of the original inves-  
22           tigational development program has pro-  
23           vided its consent to the Secretary for inclu-  
24           sion of data regarding such product in the  
25           system established under this section.



1           (4) *The term “registered user” means a scientific*  
2           *or medical researcher who has—*

3                   (A) *a legitimate biomedical research pur-*  
4                   *pose for accessing information from the clinical*  
5                   *trials data system and has appropriate quali-*  
6                   *fications to conduct such research; and*

7                   (B) *agreed in writing not to transfer to any*  
8                   *other person that is not a registered user de-iden-*  
9                   *tified clinical trial data from qualified clinical*  
10                   *trials accessed through an eligible entity, use*  
11                   *such data for reasons not specified in the re-*  
12                   *search proposal, or seek to re-identify qualified*  
13                   *clinical trial participants.*

14           (5) *The term “Secretary” means the Secretary of*  
15           *Health and Human Services.*

16 **SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**  
17 **LANCE SYSTEM.**

18           *Part P of title III of the Public Health Service Act*  
19 *(42 U.S.C. 280g et seq.) is amended by adding at the end*  
20 *the following:*

21 **“SEC. 399V-6 SURVEILLANCE OF NEUROLOGICAL DISEASES.**

22           “(a) *IN GENERAL.—The Secretary, acting through the*  
23 *Director of the Centers for Disease Control and Prevention*  
24 *and in coordination with other agencies as determined ap-*  
25 *propriate by the Secretary, shall—*

1           “(1) enhance and expand infrastructure and ac-  
2           tivities to track the epidemiology of neurological dis-  
3           eases, including multiple sclerosis and Parkinson’s  
4           disease; and

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

10          “(b) RESEARCH.—The Secretary shall ensure that the  
11          National Neurological Diseases Surveillance System is de-  
12          signed in a manner that facilitates further research on neu-  
13          rological diseases.

14          “(c) CONTENT.—In carrying out subsection (a), the  
15          Secretary—

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

19                 “(2) to the extent practicable, shall provide for  
20                 the collection and storage of other available informa-  
21                 tion on neurological diseases, such as information  
22                 concerning—

23                         “(A) demographics and other information  
24                         associated or possibly associated with neuro-

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

3           *“(B) risk factors associated or possibly asso-*  
4           *ciated with neurological diseases, including ge-*  
5           *netic and environmental risk factors; and*

6           *“(C) diagnosis and progression markers;*

7           *“(3) may provide for the collection and storage*  
8           *of information relevant to analysis on neurological*  
9           *diseases, such as information concerning—*

10           *“(A) the epidemiology of the diseases;*

11           *“(B) the natural history of the diseases;*

12           *“(C) the prevention of the diseases;*

13           *“(D) the detection, management, and treat-*  
14           *ment approaches for the diseases; and*

15           *“(E) the development of outcomes measures;*

16           *and*

17           *“(4) may address issues identified during the*  
18           *consultation process under subsection (d).*

19           *“(d) CONSULTATION.—In carrying out this section, the*  
20           *Secretary shall consult with individuals with appropriate*  
21           *expertise, including—*

22           *“(1) epidemiologists with experience in disease*  
23           *surveillance or registries;*

24           *“(2) representatives of national voluntary health*  
25           *associations that—*

1           “(A) *focus on neurological diseases, includ-*  
2           *ing multiple sclerosis and Parkinson’s disease;*  
3           *and*

4           “(B) *have demonstrated experience in re-*  
5           *search, care, or patient services;*

6           “(3) *health information technology experts or*  
7           *other information management specialists;*

8           “(4) *clinicians with expertise in neurological*  
9           *diseases; and*

10          “(5) *research scientists with experience con-*  
11          *ducting translational research or utilizing surveil-*  
12          *lance systems for scientific research purposes.*

13          “(e) *GRANTS.—The Secretary may award grants to,*  
14          *or enter into contracts or cooperative agreements with, pub-*  
15          *lic or private nonprofit entities to carry out activities under*  
16          *this section.*

17          “(f) *COORDINATION WITH OTHER FEDERAL, STATE,*  
18          *AND LOCAL AGENCIES.—Subject to subsection (h), the Sec-*  
19          *retary shall make information and analysis in the National*  
20          *Neurological Diseases Surveillance System available, as ap-*  
21          *propriate—*

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

1        *search and Quality, the Department of Veterans Af-*  
2        *fairs, and the Department of Defense; and*

3                *“(2) to State and local agencies.*

4        *“(g) PUBLIC ACCESS.—Subject to subsection (h), the*  
5        *Secretary shall make information and analysis in the Na-*  
6        *tional Neurological Diseases Surveillance System available,*  
7        *as appropriate, to the public, including researchers.*

8        *“(h) PRIVACY.—The Secretary shall ensure that pri-*  
9        *vacancy and security protections applicable to the National*  
10        *Neurological Diseases Surveillance System are at least as*  
11        *stringent as the privacy and security protections under*  
12        *HIPAA privacy and security law (as defined in section*  
13        *3009(a)(2)).*

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

18                *“(1) the development and maintenance of the*  
19        *National Neurological Diseases Surveillance System;*

20                *“(2) the type of information collected and stored*  
21        *in the System;*

22                *“(3) the use and availability of such informa-*  
23        *tion, including guidelines for such use; and*

1           “(4) the use and coordination of databases that  
2           collect or maintain information on neurological dis-  
3           eases.

4           “(j) *DEFINITION.*—In this section, the term ‘national  
5           voluntary health association’ means a national nonprofit  
6           organization with chapters, other affiliated organizations,  
7           or networks in States throughout the United States.

8           “(k) *AUTHORIZATION OF APPROPRIATIONS.*—To carry  
9           out this section, there is authorized to be appropriated  
10          \$5,000,000 for each of fiscal years 2016 through 2020.”.

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

12          (a) *SENSE OF CONGRESS.*—It is the sense of the Con-  
13          gress that studies on the natural history of diseases can help  
14          to facilitate and expedite the development of medical prod-  
15          ucts for such diseases.

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

19          **“SEC. 229A. DATA ON NATURAL HISTORY OF DISEASES.**

20          “(a) *IN GENERAL.*—The Secretary may, for the pur-  
21          poses described in subsection (b)—

22                  “(1) participate in public-private partnerships  
23                  engaged in one or more activities specified in sub-  
24                  section (c); and

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

4           “(b) *PURPOSES DESCRIBED.*—The purposes described  
5           in this subsection are to establish or facilitate the collection,  
6           maintenance, analysis, and interpretation of data regard-  
7           ing the natural history of diseases, with a particular focus  
8           on rare diseases.

9           “(c) *ACTIVITIES OF PUBLIC-PRIVATE PARTNER-*  
10          *SHIPS.*—The activities of public-private partnerships in  
11          which the Secretary may participate for purposes of this  
12          section include—

13                 “(1) cooperating with other entities that sponsor  
14                 or maintain disease registries, including disease reg-  
15                 istries and disease registry platforms for rare dis-  
16                 eases;

17                 “(2) developing or enhancing a secure informa-  
18                 tion technology system that—

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

21                         “(B) is easily modified as knowledge is  
22                         gained during such studies; and

23                         “(C) is capable of handling increasing  
24                         amounts of data as more studies are carried out;  
25                         and

1           “(3) providing advice to clinical researchers, pa-  
2           tient advocacy groups, and other entities with respect  
3           to—

4                   “(A) the design and conduct of disease stud-  
5           ies;

6                   “(B) the modification of any such ongoing  
7           studies; and

8                   “(C) addressing associated patient privacy  
9           issues.

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

19           “(e) CONFIDENTIALITY.—Notwithstanding subsection  
20   (d), nothing in this section authorizes the disclosure of any  
21   information that is a trade secret or commercial or finan-  
22   cial information that is privileged or confidential and sub-  
23   ject to section 552(b)(4) of title 5, United States Code, or  
24   section 1905 of title 18, United States Code.



1       “(f) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*  
2 *authorized to be appropriated to carry out this section*  
3 *\$5,000,000 for each of fiscal years 2016 through 2020.*”.

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

6       (a) *IN GENERAL.*—(1) *The HITECH Act (title XIII*  
7 *of division A of Public Law 111–5) is amended by adding*  
8 *at the end of subtitle D of such Act (42 U.S.C. 17921 et*  
9 *seq.) the following:*

10       **“PART 4—ACCESSING, SHARING, AND USING**  
11                   **HEALTH DATA FOR RESEARCH PURPOSES**

12       **“SEC. 13441. REFERENCES.**

13       *“In this part:*

14               “(1) *THE RULE.*—*References to ‘the Rule’ refer*  
15 *to part 160 or part 164, as appropriate, of title 45,*  
16 *Code of Federal Regulations (or any successor regula-*  
17 *tion).*

18               “(2) *PART 164.*—*References to a specified section*  
19 *of ‘part 164’, refer to such specified section of part*  
20 *164 of title 45, Code of Federal Regulations (or any*  
21 *successor section).*

22       **“SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART**  
23                   **OF HEALTH CARE OPERATIONS.**

24       “(a) *IN GENERAL.*—*Subject to subsection (b), the Sec-*  
25 *retary shall revise or clarify the Rule to allow the use and*

1 *disclosure of protected health information by a covered enti-*  
2 *ty for research purposes, including studies whose purpose*  
3 *is to obtain generalizable knowledge, to be treated as the*  
4 *use and disclosure of such information for health care oper-*  
5 *ations described in subparagraph (1) of the definition of*  
6 *health care operations in section 164.501 of part 164.*

7       “(b) *MODIFICATIONS TO RULES FOR DISCLOSURES*  
8 *FOR HEALTH CARE OPERATIONS.—In applying section*  
9 *164.506 of part 164 to the disclosure of protected health in-*  
10 *formation described in subsection (a)—*

11               “(1) *the Secretary shall revise or clarify the Rule*  
12 *so that the disclosure may be made by the covered en-*  
13 *tity to only—*

14                       “(A) *another covered entity for health care*  
15 *operations (as defined in section 164.501 of part*  
16 *164);*

17                       “(B) *a business associate that has entered*  
18 *into a contract under section 164.504(e) of part*  
19 *164 with a disclosing covered entity to perform*  
20 *health care operations; or*

21                       “(C) *a business associate that has entered*  
22 *into a contract under section 164.504(e) of part*  
23 *164 for the purpose of data aggregation (as de-*  
24 *finied in section 164.501 of part 164); and*

1           “(2) the Secretary shall further revise or clarify  
2           the Rule so that the limitation specified by section  
3           164.506(c)(4) of part 164 does not apply to disclo-  
4           sures that are described by subsection (a).

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

9           “**SEC. 13443. TREATING DISCLOSURES OF PROTECTED**  
10                                   **HEALTH INFORMATION FOR RESEARCH SIMI-**  
11                                   **LARLY TO DISCLOSURES OF SUCH INFORMA-**  
12                                   **TION FOR PUBLIC HEALTH PURPOSES.**

13           “(a) *REMUNERATION.*—The Secretary shall revise or  
14           clarify the Rule so that disclosures of protected health infor-  
15           mation for research purposes are not subject to the limita-  
16           tion on remuneration described in section  
17           164.502(a)(5)(ii)(B)(2)(ii) of part 164.

18           “(b) *PERMITTED USES AND DISCLOSURES.*—The Sec-  
19           retary shall revise or clarify the Rule so that research ac-  
20           tivities, including comparative research activities, related  
21           to the quality, safety, or effectiveness of a product or activ-  
22           ity that is regulated by the Food and Drug Administration  
23           are included as public health activities for purposes of  
24           which a covered entity may disclose protected health infor-

1 *mation to a person described in section 164.512(b)(1)(iii)*  
2 *of part 164.*

3 **“SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED**  
4 **HEALTH INFORMATION BY RESEARCHERS.**

5 *“The Secretary shall revise or clarify the Rule so that*  
6 *subparagraph (B) of section 164.512(i)(1)(ii) of part 164*  
7 *(prohibiting the removal of protected health information by*  
8 *a researcher) shall not prohibit remote access to health in-*  
9 *formation by a researcher so long as—*

10 *“(1) appropriate security and privacy safe-*  
11 *guards are maintained by the covered entity and the*  
12 *researcher; and*

13 *“(2) the protected health information is not cop-*  
14 *ied or otherwise retained by the researcher.*

15 **“SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE**  
16 **AND DISCLOSURE OF PROTECTED HEALTH**  
17 **INFORMATION FOR RESEARCH PURPOSES.**

18 *“(a) IN GENERAL.—The Secretary shall revise or clar-*  
19 *ify the Rule to specify that an authorization for the use*  
20 *or disclosure of protected health information, with respect*  
21 *to an individual, for future research purposes shall be*  
22 *deemed to contain a sufficient description of the purpose*  
23 *of the use or disclosure if the authorization—*

24 *“(1) sufficiently describes the purposes such that*  
25 *it would be reasonable for the individual to expect*

1       *that the protected health information could be used or*  
 2       *disclosed for such future research;*

3           “(2) *either—*

4                   “(A) *states that the authorization will ex-*  
 5                   *pire on a particular date or on the occurrence of*  
 6                   *a particular event; or*

7                   “(B) *states that the authorization will re-*  
 8                   *main valid unless and until it is revoked by the*  
 9                   *individual; and*

10           “(3) *provides instruction to the individual on*  
 11       *how to revoke such authorization at any time.*

12       “(b) *REVOCATION OF AUTHORIZATION.—The Sec-*  
 13       *retary shall revise or clarify the Rule to specify that, if an*  
 14       *individual revokes an authorization for future research pur-*  
 15       *poses such as is described by subsection (a), the covered enti-*  
 16       *ty may not make any further uses or disclosures based on*  
 17       *that authorization, except, as provided in paragraph (b)(5)*  
 18       *of section 164.508 of part 164, to the extent that the covered*  
 19       *entity has taken action in reliance on the authorization.”.*

20       (2) *The table of sections in section 13001(b) of such*  
 21       *Act is amended by adding at the end of the items relating*  
 22       *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.”.*

1           **(b) REVISION OF REGULATIONS.**—Not later than 12  
2 months after the date of the enactment of this Act, the Sec-  
3 retary of Health and Human Services shall revise and clar-  
4 ify the provisions of title 45, Code of Federal Regulations,  
5 for consistency with part 4 of subtitle D of the HITECH  
6 Act, as added by subsection (a).

7                           **Subtitle H—Council for 21st**  
8   **Century Cures**

9           **SEC. 1141. COUNCIL FOR 21ST CENTURY CURES.**

10           Title II of the Public Health Service Act (42 U.S.C.  
11 202 *et seq.*) is amended by adding at the end the following:

12           **“PART E—COUNCIL FOR 21ST CENTURY CURES**

13           **“SEC. 281. ESTABLISHMENT.**

14           *“A nonprofit corporation to be known as the Council*  
15 *for 21st Century Cures (referred to in this part as the*  
16 *‘Council’) shall be established in accordance with this sec-*  
17 *tion. The Council shall be a public-private partnership*  
18 *headed by an Executive Director (referred to in this part*  
19 *as the ‘Executive Director’), appointed by the members of*  
20 *the Board of Directors. The Council shall not be an agency*  
21 *or instrumentality of the United States Government.*

1 **“SEC. 281A. PURPOSE.**

2       *“The purpose of the Council is to accelerate the dis-*  
3 *covery, development, and delivery in the United States of*  
4 *innovative cures, treatments, and preventive measures for*  
5 *patients.*

6 **“SEC. 281B. DUTIES.**

7       *“For the purpose described in section 281A, the Coun-*  
8 *cil shall—*

9               *“(1) foster collaboration and coordination among*  
10 *the entities that comprise the Council, including aca-*  
11 *demia, government agencies, industry, health care*  
12 *payors and providers, patient advocates, and others*  
13 *engaged in the cycle of discovery, development, and*  
14 *delivery of life-saving and health-enhancing innova-*  
15 *tive interventions;*

16               *“(2) undertake communication and dissemina-*  
17 *tion activities;*

18               *“(3) publish information on the activities funded*  
19 *under section 281D;*

20               *“(4) establish a strategic agenda for accelerating*  
21 *the discovery, development, and delivery in the*  
22 *United States of innovative cures, treatments, and*  
23 *preventive measures for patients;*

24               *“(5) identify gaps and opportunities within and*  
25 *across the discovery, development, and delivery cycle;*

1           “(6) develop and propose recommendations based  
2           on the gaps and opportunities so identified;

3           “(7) facilitate the interoperability of the compo-  
4           nents of the discovery, development, and delivery  
5           cycle;

6           “(8) propose recommendations that will facilitate  
7           precompetitive collaboration;

8           “(9) identify opportunities to work with, but not  
9           duplicate the efforts of, nonprofit organizations and  
10          other public-private partnerships; and

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

15       **“SEC. 281C. ORGANIZATION; ADMINISTRATION.**

16          “(a) BOARD OF DIRECTORS.—

17               “(1) ESTABLISHMENT.—

18                       “(A) IN GENERAL.—The Council shall have  
19                       a Board of Directors (in this part referred to as  
20                       the ‘Board of Directors’), which shall be com-  
21                       posed of the *ex officio* members under subpara-  
22                       graph (B) and the appointed members under  
23                       subparagraph (C). All members of the Board  
24                       shall be voting members.



1           “(B) *EX OFFICIO MEMBERS.*—*The ex officio*  
2           *members of the Board shall be the following indi-*  
3           *viduals or their designees:*

4                   “(i) *The Director of the National Insti-*  
5                   *tutes of Health.*

6                   “(ii) *The Commissioner of Food and*  
7                   *Drugs.*

8                   “(iii) *The Administrator of the Centers*  
9                   *for Medicare & Medicaid Services.*

10                   “(iv) *The heads of five other Federal*  
11                   *agencies deemed by the Secretary to be en-*  
12                   *gaged in biomedical research and develop-*  
13                   *ment.*

14           “(C) *APPOINTED MEMBERS.*—*The ap-*  
15           *pointed members of the Board shall consist of 17*  
16           *individuals, of whom—*

17                   “(i) *8 shall be appointed by the Comp-*  
18                   *troller General of the United States from a*  
19                   *list of nominations submitted by leading*  
20                   *trade associations—*

21                           “(I) *4 of whom shall be represent-*  
22                           *atives of the biopharmaceutical indus-*  
23                           *try;*

1                   “(II) 2 of whom shall be rep-  
2                   resentatives of the medical device in-  
3                   dustry; and

4                   “(III) 2 of whom shall be rep-  
5                   resentatives of the information and  
6                   digital technology industry; and

7                   “(ii) 9 shall be appointed by the  
8                   Comptroller General of the United States,  
9                   after soliciting nominations—

10                   “(I) 2 of whom shall be represent-  
11                   atives of academic researchers;

12                   “(II) 3 of whom shall be rep-  
13                   resentatives of patients;

14                   “(III) 2 of whom shall be rep-  
15                   resentatives of health care providers;  
16                   and

17                   “(IV) 2 of whom shall be rep-  
18                   resentatives of health care plans and  
19                   insurers.

20                   “(D) CHAIR.—The Chair of the Board shall  
21                   be selected by the members of the Board by ma-  
22                   jority vote from among the members of the  
23                   Board.

24                   “(2) TERMS AND VACANCIES.—

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

4           “(B) *VACANCY.*—*Any vacancy in the mem-*  
5           *bership of the Board—*

6                   “(i) *shall not affect the power of the re-*  
7                   *maining members to execute the duties of*  
8                   *the Board; and*

9                   “(ii) *shall be filled by appointment by*  
10                   *the appointed members described in para-*  
11                   *graph (1)(C) by majority vote.*

12           “(C) *PARTIAL TERM.*—*If a member of the*  
13           *Board does not serve the full term applicable*  
14           *under subparagraph (A), the individual ap-*  
15           *pointed under subparagraph (B) to fill the re-*  
16           *sulting vacancy shall be appointed for the re-*  
17           *mainder of the term of the predecessor of the in-*  
18           *dividual.*

19           “(3) *RESPONSIBILITIES.*—*Not later than 90 days*  
20           *after the date on which the Council is incorporated*  
21           *and its Board of Directors is fully constituted, the*  
22           *Board of Directors shall establish bylaws and policies*  
23           *for the Council that—*

24                   “(A) *are published in the Federal Register*  
25                   *and available for public comment;*

1           “(B) establish policies for the selection and,  
2 as applicable, appointment of—

3                   “(i) the officers, employees, agents, and  
4 contractors of the Council; and

5                   “(ii) the members of any committees of  
6 the Council;

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

10           “(D) establish specific duties of the Execu-  
11 tive Director.

12           “(4) MEETINGS.—

13                   “(A) IN GENERAL.—The Board of Directors  
14 shall—

15                           “(i) meet on a quarterly basis; and

16                           “(ii) submit to Congress, and make  
17 publicly available, the minutes of such meet-  
18 ings.

19           “(B) AGENDA.—The Board of Directors  
20 shall, not later than 3 months after the incorpo-  
21 ration of the Council—

22                           “(i) issue an agenda (in this part re-  
23 ferred to as the ‘agenda’) outlining how the  
24 Council will achieve the purpose described  
25 in section 281A; and

1                   “(ii) annually thereafter, in consulta-  
2                   tion with the Executive Director, review  
3                   and update such agenda.

4           “(b) *APPOINTMENT AND INCORPORATION.*—Not later  
5 than 6 months after the date of enactment of the 21st Cen-  
6 tury Cures Act—

7                   “(1) the Comptroller General of the United  
8                   States shall appoint the appointed members of the  
9                   Board of Directors under subsection (a)(1)(C); and

10                   “(2) the *ex officio* members of the Board of Di-  
11                   rectors under subsection (a)(1)(B) shall serve as  
12                   incorporators and shall take whatever actions are nec-  
13                   essary to incorporate the Council.

14           “(c) *NONPROFIT STATUS.*—In carrying out this part,  
15 the Board of Directors shall establish such policies and by-  
16 laws, and the Executive Director shall carry out such ac-  
17 tivities, as may be necessary to ensure that the Council  
18 maintains status as an organization that—

19                   “(1) is described in subsection (c)(3) of section  
20                   501 of the Internal Revenue Code of 1986; and

21                   “(2) is, under subsection (a) of such section, ex-  
22                   empt from taxation.

23           “(d) *EXECUTIVE DIRECTOR.*—The Executive Director  
24 shall—

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

3           “(2) subject to the oversight of the Board of Di-  
4           rectors, be responsible for the day-to-day management  
5           of the Council.

6   **“SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.**

7           “(a) *IN GENERAL.*—The Council shall establish a suffi-  
8           cient operational infrastructure to fulfill the duties specified  
9           in section 281B.

10          “(b) *PRIVATE SECTOR MATCHING FUNDS.*—The Coun-  
11          cil may accept financial or in-kind support from partici-  
12          pating entities or private foundations or organizations  
13          when such support is deemed appropriate.

14   **“SEC. 281E. TERMINATION; REPORT.**

15          “(a) *IN GENERAL.*—The Council shall terminate on  
16          September 30, 2023.

17          “(b) *REPORT.*—Not later than one year after the date  
18          on which the Council is established and each year thereafter,  
19          the Executive Director shall submit to the appropriate con-  
20          gressional committees a report on the performance of the  
21          Council. In preparing such report, the Council shall consult  
22          with a nongovernmental consultant with appropriate exper-  
23          tise.

1 **“SEC. 281F. FUNDING.**

2       *“For the each of fiscal years 2016 through 2023, there*  
 3 *is authorized to be appropriated \$10,000,000 to the Council*  
 4 *for purposes of carrying out the duties of the Council under*  
 5 *this part.”.*

6                   **TITLE II—DEVELOPMENT**  
 7       **Subtitle A—Patient-Focused Drug**  
 8                   **Development**

9 **SEC. 2001. DEVELOPMENT AND USE OF PATIENT EXPERI-**  
 10                   **ENCE DATA TO ENHANCE STRUCTURED RISK-**  
 11                   **BENEFIT ASSESSMENT FRAMEWORK.**

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

14                   *(1) in subsection (d), by striking “The Secretary*  
 15 *shall implement” and all that follows through “pre-*  
 16 *market approval of a drug.”; and*

17                   *(2) by adding at the end the following new sub-*  
 18 *sections:*

19       **“(x) STRUCTURED RISK-BENEFIT ASSESSMENT**  
 20 **FRAMEWORK.—**

21                   *“(1) IN GENERAL.—The Secretary shall imple-*  
 22 *ment a structured risk-benefit assessment framework*  
 23 *in the new drug approval process—*

24                   *“(A) to facilitate the balanced consideration*  
 25 *of benefits and risks; and*

1           “(B) to develop and implement a consistent  
2           and systematic approach to the discussion of,  
3           regulatory decisionmaking with respect to, and  
4           the communication of, the benefits and risks of  
5           new drugs.

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

9           “(y) *DEVELOPMENT AND USE OF PATIENT EXPERI-*  
10 *ENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT AS-*  
11 *SESSMENT FRAMEWORK.*—

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

16           “(A) an entity seeking to develop patient ex-  
17           perience data may submit to the Secretary—

18           “(i) initial research concepts for feed-  
19           back from the Secretary; and

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



1           “(B) the Secretary may request such an en-  
2           tity to submit such documents, data, and sum-  
3           maries and analyses; and

4           “(C) patient experience data may be devel-  
5           oped and used to enhance the structured risk-  
6           benefit assessment framework under subsection  
7           (x).

8           “(2) *PATIENT EXPERIENCE DATA.*—*In this sub-*  
9           *section, the term ‘patient experience data’ means data*  
10          *collected by patients, parents, caregivers, patient ad-*  
11          *vocacy organizations, disease research foundations,*  
12          *medical researchers, research sponsors, or other par-*  
13          *ties determined appropriate by the Secretary that is*  
14          *intended to facilitate or enhance the Secretary’s risk-*  
15          *benefit assessments, including information about the*  
16          *impact of a disease or a therapy on patients’ lives.”.*  
17          **(b) GUIDANCE.**—

18           **(1) IN GENERAL.**—*The Secretary of Health and*  
19          *Human Services shall publish guidance on the imple-*  
20          *mentation of subsection (y) of section 505 of the Fed-*  
21          *eral Food, Drug, and Cosmetic Act (21 U.S.C. 355),*  
22          *as added by subsection (a). Such guidance shall in-*  
23          *clude—*

24           **(A)** *with respect to draft guidance docu-*  
25          *ments, data, or summaries and analyses sub-*

1           mitted to the Secretary under paragraph (1)(A)  
2           of such subsection, guidance—

3                   (i) specifying the timelines for the re-  
4                   view of such documents, data, or summaries  
5                   and analyses by the Secretary; and

6                   (ii) on how the Secretary will use such  
7                   documents, data, or summaries and anal-  
8                   yses to update any guidance documents  
9                   published under this subsection or publish  
10                  new guidance;

11                (B) with respect to the collection and anal-  
12                ysis of patient experience data (as defined in  
13                paragraph (2) of such subsection (y)), guidance  
14                on—

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

19                           (I) the experience of a patient liv-  
20                           ing with a particular disease;

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

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

1                   (IV) *the effect of current thera-*  
2                   *peutic options on different aspects of*  
3                   *the disease; and*

4                   (ii) *the establishment and maintenance*  
5                   *of registries designed to increase under-*  
6                   *standing of the natural history of a disease;*

7                   (C) *methodological approaches that may be*  
8                   *used to assess patients' beliefs with respect to the*  
9                   *benefits and risks in the management of the pa-*  
10                   *tient's disease; and*

11                   (D) *methodologies, standards, and potential*  
12                   *experimental designs for patient-reported out-*  
13                   *comes.*

14                   (2) *TIMING.*—*Not later than 3 years after the*  
15                   *date of the enactment of this Act, the Secretary of*  
16                   *Health and Human Services shall issue draft guid-*  
17                   *ance on the implementation of subsection (y) of sec-*  
18                   *tion 505 of the Federal Food, Drug, and Cosmetic Act*  
19                   *(21 U.S.C. 355), as added by subsection (a). The Sec-*  
20                   *retary shall issue final guidance on the implementa-*  
21                   *tion of such subsection not later than one year after*  
22                   *the date on which the comment period for the draft*  
23                   *guidance closes.*

24                   (3) *WORKSHOPS.*—

1           (A) *IN GENERAL.*—Not later than 6 months  
2 after the date of the enactment of this Act and  
3 once every 6 months during the following 12-  
4 month period, the Secretary of Health and  
5 Human Services shall convene a workshop to ob-  
6 tain input regarding methodologies for devel-  
7 oping the guidance under paragraph (1), includ-  
8 ing the collection of patient experience data.

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

11                   (i) patients;

12                   (ii) representatives from patient advo-  
13 cacy organizations, biopharmaceutical com-  
14 panies, and disease research foundations;

15                   (iii) representatives of the reviewing  
16 divisions of the Food and Drug Administra-  
17 tion; and

18                   (iv) methodological experts with sig-  
19 nificant expertise in patient experience  
20 data.

21           (4) *PUBLIC MEETING.*—Not later than 90 days  
22 after the date on which the draft guidance is pub-  
23 lished under this subsection, the Secretary of Health  
24 and Human Services shall convene a public meeting  
25 to solicit input on the guidance.

1     ***Subtitle B—Qualification and Use***  
2             ***of Drug Development Tools***

3     ***SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.***

4             ***(a) FINDINGS.—Congress finds the following:***

5                     ***(1) Development of new drugs has become in-***  
6                     ***creasingly challenging and resource intensive.***

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

11                    ***(3) Biomedical research consortia (as defined in***  
12                    ***section 507(f) of the Federal Food, Drug, and Cos-***  
13                    ***metic Act, as added by subsection (c)) can play a val-***  
14                    ***uable role in helping to develop and qualify drug de-***  
15                    ***velopment tools.***

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

18                    ***(1) Congress should promote and facilitate a col-***  
19                    ***laborative effort among the biomedical research con-***  
20                    ***sortia described in subsection (a)(3)—***

21                             ***(A) to develop, through a transparent public***  
22                             ***process, data standards and scientific approaches***  
23                             ***to data collection accepted by the medical and***  
24                             ***clinical research community for purposes of***  
25                             ***qualifying drug development tools;***

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

4           (C) to encourage the development of acces-  
5           sible databases for collecting relevant drug devel-  
6           opment tool data for such purposes; and

7           (2) an entity seeking to qualify a drug develop-  
8           ment tool should be encouraged, in addition to con-  
9           sultation with the Secretary, to consult with bio-  
10          medical research consortia and other individuals and  
11          entities with expert knowledge and insights that may  
12          assist the requestor and benefit the process for such  
13          qualification.

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

18          **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.**

19                 **“(a) PROCESS FOR QUALIFICATION.**—

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

23                                 **“(A)(i)** a requestor initiates such process by  
24                                 submitting a letter of intent to the Secretary;  
25                                 and

1           “(i) the Secretary shall accept or decline to  
2           accept such letter of intent;

3           “(B)(i) if the Secretary accepts the letter of  
4           intent, a requestor shall submit a qualification  
5           plan to the Secretary; and

6           “(ii) the Secretary shall accept or decline to  
7           accept the qualification plan; and

8           “(C)(i) if the Secretary accepts the quali-  
9           fication plan, the requestor submits to the Sec-  
10          retary a full qualification package;

11          “(ii) the Secretary shall determine whether  
12          to accept such qualification package for review;  
13          and

14          “(iii) if the Secretary accepts such quali-  
15          fication package for review, the Secretary shall  
16          conduct such review in accordance with this sec-  
17          tion.

18          “(2) ACCEPTANCE AND REVIEW OF SUBMIS-  
19          SIONS.—

20                 “(A) IN GENERAL.—The succeeding provi-  
21                 sions of this paragraph shall apply with respect  
22                 to the treatment of a letter of intent, a qualifica-  
23                 tion plan, or a full qualification package sub-  
24                 mitted under paragraph (1) (referred to in this  
25                 paragraph as ‘qualification submissions’).

1           “(B) *ACCEPTANCE FACTORS; NONACCEPT-*  
2           *ANCE.—The Secretary shall determine whether to*  
3           *accept a qualification submission based on fac-*  
4           *tors which may include the scientific merit of the*  
5           *submission and the available resources of the*  
6           *Food and Drug Administration to review the*  
7           *qualification submission. A determination not to*  
8           *accept a submission under paragraph (1) shall*  
9           *not be construed as a final determination by the*  
10           *Secretary under this section regarding the quali-*  
11           *fication of a drug development tool for its pro-*  
12           *posed context of use.*

13           “(C) *PRIORITIZATION OF QUALIFICATION*  
14           *REVIEW.—The Secretary may prioritize the re-*  
15           *view of a full qualification package submitted*  
16           *under paragraph (1) with respect to a drug de-*  
17           *velopment tool, based on factors determined ap-*  
18           *propriate by the Secretary, including—*

19                   “(i) *as applicable, the severity, rarity,*  
20                   *or prevalence of the disease or condition*  
21                   *targeted by the drug development tool and*  
22                   *the availability or lack of alternative treat-*  
23                   *ments for such disease or condition; and*

24                   “(ii) *the identification, by the Sec-*  
25                   *retary or by biomedical research consortia*



1                   *and other expert stakeholders, of such a*  
2                   *drug development tool and its proposed con-*  
3                   *text of use as a public health priority.*

4                   “(D) *ENGAGEMENT OF EXTERNAL EX-*  
5                   *PERTS.—The Secretary may, for purposes of the*  
6                   *review of qualification submissions, through the*  
7                   *use of cooperative agreements, grants, or other*  
8                   *appropriate mechanisms, consult with bio-*  
9                   *medical research consortia and may consider the*  
10                   *recommendations of such consortia with respect*  
11                   *to the review of any qualification plan submitted*  
12                   *under paragraph (1) or the review of any full*  
13                   *qualification package under paragraph (3).*

14                   “(3) *REVIEW OF FULL QUALIFICATION PACK-*  
15                   *AGE.—The Secretary shall—*

16                   “(A) *conduct a comprehensive review of a*  
17                   *full qualification package accepted under para-*  
18                   *graph (1)(C); and*

19                   “(B) *determine whether the drug develop-*  
20                   *ment tool at issue is qualified for its proposed*  
21                   *context of use.*

22                   “(4) *QUALIFICATION.—The Secretary shall deter-*  
23                   *mine whether a drug development tool is qualified for*  
24                   *a proposed context of use based on the scientific merit*

1 *of a full qualification package reviewed under para-*  
2 *graph (3).*

3 *“(b) EFFECT OF QUALIFICATION.—*

4 *“(1) IN GENERAL.—A drug development tool de-*  
5 *termined to be qualified under subsection (a)(4) for a*  
6 *proposed context of use specified by the requestor may*  
7 *be used by any person in such context of use for the*  
8 *purposes described in paragraph (2).*

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

12 *“(A) supporting or obtaining approval or*  
13 *licensure (as applicable) of a drug or biological*  
14 *product (including in accordance with section*  
15 *506(c)) under section 505 of this Act or section*  
16 *351 of the Public Health Service Act; or*

17 *“(B) supporting the investigational use of a*  
18 *drug or biological product under section 505(i)*  
19 *of this Act or section 351(a)(3) of the Public*  
20 *Health Service Act.*

21 *“(3) RESCISSION OR MODIFICATION.—*

22 *“(A) IN GENERAL.—The Secretary may re-*  
23 *scind or modify a determination under this sec-*  
24 *tion to qualify a drug development tool if the*  
25 *Secretary determines that the drug development*

1           *tool is not appropriate for the proposed context*  
2           *of use specified by the requestor. Such a deter-*  
3           *mination may be based on new information that*  
4           *calls into question the basis for such qualifica-*  
5           *tion.*

6           “(B) *MEETING FOR REVIEW.*—*If the Sec-*  
7           *retary rescinds or modifies under subparagraph*  
8           *(A) a determination to qualify a drug develop-*  
9           *ment tool, the requestor involved shall be granted*  
10           *a request for a meeting with the Secretary to dis-*  
11           *cuss the basis of the Secretary’s decision to re-*  
12           *scind or modify the determination before the ef-*  
13           *fective date of the rescission or modification.*

14           “(c) *TRANSPARENCY.*—

15           “(1) *IN GENERAL.*—*Subject to paragraph (3), the*  
16           *Secretary shall make publicly available, and update*  
17           *on at least a biannual basis, on the Internet website*  
18           *of the Food and Drug Administration the following:*

19           “(A) *Information with respect to each qual-*  
20           *ification submission under the qualification*  
21           *process under subsection (a), including—*

22                   “(i) *the stage of the review process ap-*  
23                   *plicable to the submission;*

24                   “(ii) *the date of the most recent change*  
25                   *in stage status;*

1           “(iii) whether the external scientific ex-  
2           perts were utilized in the development of a  
3           qualification plan or the review of a full  
4           qualification package; and

5           “(iv) submissions from requestors  
6           under the qualification process under sub-  
7           section (a), including any data and evi-  
8           dence contained in such submissions, and  
9           any updates to such submissions.

10          “(B) The Secretary’s formal written deter-  
11          minations in response to such qualification sub-  
12          missions.

13          “(C) Any rescissions or modifications under  
14          subsection (b)(3) of a determination to qualify a  
15          drug development tool.

16          “(D) Summary reviews that document con-  
17          clusions and recommendations for determina-  
18          tions to qualify drug development tools under  
19          subsection (a).

20          “(E) A comprehensive list of—

21                 “(i) all drug development tools quali-  
22                 fied under subsection (a); and

23                 “(ii) all surrogate endpoints which  
24                 were the basis of approval or licensure (as  
25                 applicable) of a drug or biological product

1           *(including in accordance with section*  
2           *506(c)) under section 505 of this Act or sec-*  
3           *tion 351 of the Public Health Service Act.*

4           “(2) *RELATION TO TRADE SECRETS ACT.*—*Informa-*  
5           *tion made publicly available by the Secretary*  
6           *under paragraph (1) shall be considered a disclosure*  
7           *authorized by law for purposes of section 1905 of title*  
8           *18, United States Code.*

9           “(3) *APPLICABILITY.*—*Nothing in this section*  
10          *shall be construed as authorizing the Secretary to dis-*  
11          *close any information contained in an application*  
12          *submitted under section 505 of this Act or section 351*  
13          *of the Public Health Service Act that is confidential*  
14          *commercial or trade secret information subject to sec-*  
15          *tion 552(b)(4) of title 5, United States Code, or sec-*  
16          *tion 1905 of title 18, United States Code.*

17          “(d) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
18          *tion shall be construed—*

19                 “(1) *to alter the standards of evidence under sub-*  
20                 *section (c) or (d) of section 505, including the sub-*  
21                 *stantial evidence standard in such subsection (d), or*  
22                 *under section 351 of the Public Health Service Act (as*  
23                 *applicable); or*

24                 “(2) *to limit the authority of the Secretary to*  
25                 *approve or license products under this Act or the Pub-*

1        *lic Health Service Act, as applicable (as in effect be-*  
2        *fore the date of the enactment of the 21st Century*  
3        *Cures Act).*

4        “(e) *AUTHORIZATION OF APPROPRIATIONS.—There are*  
5        *authorized to be appropriated to carry out this section,*  
6        *\$10,000,000 for each of fiscal years 2016 through 2020.*

7        “(f) *DEFINITIONS.—In this section:*

8                “(1) *BIOMARKER.—(A) The term ‘biomarker’*  
9                *means a characteristic (such as a physiologic,*  
10                *pathologic, or anatomic characteristic or measure-*  
11                *ment) that is objectively measured and evaluated as*  
12                *an indicator of normal biologic processes, pathologic*  
13                *processes, or biological responses to a therapeutic*  
14                *intervention; and*

15                “(B) *such term includes a surrogate endpoint.*

16                “(2) *BIOMEDICAL RESEARCH CONSORTIA.—The*  
17                *term ‘biomedical research consortia’ means collabo-*  
18                *rative groups that may take the form of public-pri-*  
19                *vate partnerships and may include government agen-*  
20                *cies, institutions of higher education (as defined in*  
21                *section 101(a) of the Higher Education Act of 1965,*  
22                *patient advocacy groups, industry representatives,*  
23                *clinical and scientific experts, and other relevant enti-*  
24                *ties and individuals.*

1           “(3) *CLINICAL OUTCOME ASSESSMENT*.—(A) *The*  
2           *term ‘clinical outcome assessment’ means a measure-*  
3           *ment of a patient’s symptoms, overall mental state, or*  
4           *the effects of a disease or condition on how the patient*  
5           *functions; and*

6           “(B) *such term includes a patient-reported out-*  
7           *come.*

8           “(4) *CONTEXT OF USE*.—*The term ‘context of*  
9           *use’ means, with respect to a drug development tool,*  
10          *a statement that describes the circumstances under*  
11          *which the drug development tool is to be used in drug*  
12          *development and regulatory review.*

13          “(5) *DRUG DEVELOPMENT TOOL*.—*The term*  
14          *‘drug development tool’ includes—*

15                 “(A) *a biomarker;*

16                 “(B) *a clinical outcome assessment; and*

17                 “(C) *any other method, material, or meas-*  
18                 *ure that the Secretary determines aids drug de-*  
19                 *velopment and regulatory review for purposes of*  
20                 *this section.*

21          “(6) *PATIENT-REPORTED OUTCOME*.—*The term*  
22          *‘patient-reported outcome’ means a measurement*  
23          *based on a report from a patient regarding the status*  
24          *of the patient’s health condition without amendment*

1        *or interpretation of the patient’s report by a clinician*  
2        *or any other person.*

3            “(7) *QUALIFICATION.*—*The terms ‘qualification’*  
4        *and ‘qualified’ mean a determination by the Sec-*  
5        *retary that a drug development tool and its proposed*  
6        *context of use can be relied upon to have a specific*  
7        *interpretation and application in drug development*  
8        *and regulatory review under this Act.*

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

14            “(9) *SURROGATE ENDPOINT.*—*The term ‘surro-*  
15        *gate endpoint’ means a marker, such as a laboratory*  
16        *measurement, radiographic image, physical sign, or*  
17        *other measure, that is not itself a direct measurement*  
18        *of clinical benefit, and—*

19            *“(A) is known to predict clinical benefit*  
20        *and could be used to support traditional ap-*  
21        *proval of a drug or biological product; or*

22            *“(B) is reasonably likely to predict clinical*  
23        *benefit and could be used to support the acceler-*  
24        *ated approval of a drug or biological product in*  
25        *accordance with section 506(c).”.*



1       (d) *GUIDANCE.*—

2           (1) *IN GENERAL.*—*The Secretary of Health and*  
3 *Human Services shall, in consultation with bio-*  
4 *medical research consortia (as defined in subsection*  
5 *(f) of section 507 the Federal Food, Drug, and Cos-*  
6 *metic Act (as added by subsection (c))) and other in-*  
7 *terested parties through a collaborative public process,*  
8 *issue guidance to implement such section 507 that—*

9           (A) *provides a conceptual framework de-*  
10 *scribing appropriate standards and scientific*  
11 *approaches to support the development of bio-*  
12 *markers delineated under the taxonomy estab-*  
13 *lished under paragraph (3);*

14           (B) *makes recommendations for dem-*  
15 *onstrating that a surrogate endpoint is reason-*  
16 *ably likely to predict clinical benefit for the pur-*  
17 *pose of supporting the accelerated approval of a*  
18 *drug under section 506(c) of the Federal Food,*  
19 *Drug, and Cosmetic Act (21 U.S.C. 356(c));*

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

22           (i) *describes the requirements that enti-*  
23 *ties seeking to qualify a drug development*  
24 *tool under such section shall observe when*  
25 *engaging in such process;*

1                   (ii) outlines reasonable timeframes for  
2                   the Secretary's review of letters, qualifica-  
3                   tion plans, or full qualification packages  
4                   submitted under such process; and

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

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

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

25                  (3) *TAXONOMY.*—

1           (A) *IN GENERAL.*—For purposes of inform-  
2           ing guidance under this subsection, the Secretary  
3           of Health and Human Services shall, in con-  
4           sultation with biomedical research consortia and  
5           other interested parties through a collaborative  
6           public process, establish a taxonomy for the clas-  
7           sification of biomarkers (and related scientific  
8           concepts) for use in drug development.

9           (B) *PUBLIC AVAILABILITY.*—Not later than  
10          12 months after the date of the enactment of this  
11          Act, the Secretary of Health and Human Serv-  
12          ices shall make such taxonomy publicly available  
13          in draft form for public comment. The Secretary  
14          shall finalize the taxonomy not later than 12  
15          months after the close of the public comment pe-  
16          riod.

17       (e) *MEETING AND REPORT.*—

18           (1) *MEETING.*—Not later than 12 months after  
19          the date of the enactment of this Act, the Secretary of  
20          Health and Human Services shall convene a public  
21          meeting to describe and solicit public input regarding  
22          the qualification process under section 507 of the Fed-  
23          eral Food, Drug, and Cosmetic Act, as added by sub-  
24          section (c).

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

9                   (A) the number of requests submitted, as a  
10                  letter of intent, for qualification of a drug devel-  
11                  opment tool (as defined in subsection (f) of such  
12                  section);

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

18                  (C) the number of such requests for which  
19                  external scientific experts were utilized in the de-  
20                  velopment of a qualification plan or review of a  
21                  full qualification package; and

22                  (D) the number of qualification plans and  
23                  full qualification packages, respectively, sub-  
24                  mitted to the Secretary; and

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

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

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

10           “(g) *ACCELERATED APPROVAL DEVELOPMENT*  
11 *PLAN.—*

12           “(1) *IN GENERAL.—In the case of a drug that*  
13           *the Secretary determines may be eligible for acceler-*  
14           *ated approval in accordance with subsection (c), the*  
15           *sponsor of such drug may request, at any time after*  
16           *the submission of an application for the investigation*  
17           *of the drug under section 505(i) of this Act or section*  
18           *351(a)(3) of the Public Health Service Act, that the*  
19           *Secretary agree to an accelerated approval develop-*  
20           *ment plan described in paragraph (2).*

21           “(2) *PLAN DESCRIBED.—A plan described in*  
22           *this paragraph, with respect to a drug described in*  
23           *paragraph (1), is an accelerated approval develop-*  
24           *ment plan, which shall include agreement on—*

1           “(A) the surrogate endpoint to be assessed  
2           under such plan;

3           “(B) the design of the study that will utilize  
4           the surrogate endpoint; and

5           “(C) the magnitude of the effect of the drug  
6           on the surrogate endpoint that is the subject of  
7           the agreement that would be sufficient to form  
8           the primary basis of a claim that the drug is ef-  
9           fective.

10          “(3) *MODIFICATION; TERMINATION.*—The Sec-  
11          retary may require the sponsor of a drug that is the  
12          subject of an accelerated approval development plan  
13          to modify or terminate the plan if additional data or  
14          information indicates that—

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

18                 “(B) the drug is no longer eligible for accel-  
19                 erated approval under subsection (c).

20          “(4) *SPONSOR CONSULTATION.*—If the Secretary  
21          requires the modification or termination of an accel-  
22          erated approval development plan under paragraph  
23          (3), the sponsor shall be granted a request for a meet-  
24          ing to discuss the basis of the Secretary’s decision be-

1     *fore the effective date of the modification or termi-*  
2     *nation.*

3             “(5) *DEFINITION.*—*In this section, the term ‘ac-*  
4     *celerated approval development plan’ means a devel-*  
5     *opment plan agreed upon by the Secretary and the*  
6     *sponsor submitting the plan that contains study pa-*  
7     *rameters for the use of a surrogate endpoint that—*

8             “(A) *is reasonably likely to predict clinical*  
9     *benefit; and*

10            “(B) *is intended to be the basis of the accel-*  
11     *erated approval of a drug in accordance with*  
12     *subsection (c).”.*

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

16            (1) *by striking “(f) AWARENESS EFFORTS” and*  
17     *inserting “(e) AWARENESS EFFORTS”; and*

18            (2) *by striking “(e) CONSTRUCTION” and insert-*  
19     *ing “(f) CONSTRUCTION”.*

1     ***Subtitle C—FDA Advancement of***  
2                     ***Precision Medicine***

3     ***SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER***  
4                     ***PROGRAMS OF FOOD AND DRUG ADMINISTRA-***  
5                     ***TION.***

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

9                     ***“Subchapter J—Precision Medicine***

10     ***“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION***  
11                     ***MEDICINE.***

12             *“(a) IN GENERAL.—The Secretary shall issue and pe-*  
13 *riodically update guidance to assist sponsors in the develop-*  
14 *ment of a precision drug or biological product. Such guid-*  
15 *ance shall—*

16                     *“(1) define the term ‘precision drug or biological*  
17 *product’; and*

18                     *“(2) address the topics described in subsection*  
19 *(b).*

20             *“(b) CERTAIN ISSUES.—The topics to be addressed by*  
21 *guidance under subsection (a) are—*

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



1           “(2) recommendations for the design of studies to  
2           demonstrate the validity of a biomarker as a pre-  
3           dictor of drug or biological product response;

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

8           “(4) the development of companion diagnostics  
9           in the context of a drug development program; and

10           “(5) considerations for developing biomarkers  
11           that inform prescribing decisions for a drug or bio-  
12           logical product, and when information regarding a  
13           biomarker may be included in the approved prescrip-  
14           tion labeling for a precision drug or biological prod-  
15           uct.

16           “(c) *DATE CERTAIN FOR INITIAL GUIDANCE.*—The  
17           Secretary shall issue guidance under subsection (a) not  
18           later than 18 months after the date of the enactment of the  
19           21st Century Cures Act.

20           **“SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-**  
21                           **DRUG AND EXPEDITED-APPROVAL PRO-**  
22                           **GRAMS.**

23           “(a) *IN GENERAL.*—In the case of a precision drug  
24           or biological product that is the subject of an application  
25           submitted under section 505(b)(1), or section 351(a) of the

1 *Public Health Service Act, for the treatment of a serious*  
2 *or life-threatening disease or condition and has been des-*  
3 *ignated under section 526 as a drug for a rare disease or*  
4 *condition, the Secretary may—*

5           “(1) *consistent with applicable standards for ap-*  
6 *proval, rely upon data or information previously sub-*  
7 *mitted by the sponsor of the precision drug or biologi-*  
8 *cal product, or another sponsor, provided that the*  
9 *sponsor of the precision drug or biological product*  
10 *has obtained a contractual right of reference to such*  
11 *other sponsor’s data and information, in an applica-*  
12 *tion approved under section 505(c) or licensed under*  
13 *section 351(a) of the Public Health Service Act, as*  
14 *applicable—*

15           “(A) *for a different drug or biological prod-*  
16 *uct; or*

17           “(B) *for a different indication for such pre-*  
18 *cision drug or biological product,*  
19 *in order to expedite clinical development for a preci-*  
20 *sion drug or biological product that is using the same*  
21 *or similar approach as that used to support approval*  
22 *of the prior approved application or license, as ap-*  
23 *propriate; and*

24           “(2) *as appropriate, consider the application for*  
25 *approval of such precision drug or biological product*

1       to be eligible for expedited review and approval pro-  
2       grams described in section 506, including accelerated  
3       approval in accordance with subsection (c) of such  
4       section.

5       “(b) *RULE OF CONSTRUCTION.*—Nothing in this sec-  
6       tion shall be construed to—

7               “(1) limit the authority of the Secretary to ap-  
8       prove products pursuant to this Act and the Public  
9       Health Service Act as authorized prior to the date of  
10      enactment of this section; or

11              “(2) confer any new rights, beyond those author-  
12      ized under this Act prior to enactment of this section,  
13      with respect to a sponsor’s ability to reference infor-  
14      mation contained in another application submitted  
15      under section 505(b)(1) of this Act or section 351(a)  
16      of the Public Health Service Act.”.

17       ***Subtitle D—Modern Trial Design***  
18       ***and Evidence Development***

19       ***SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-***  
20       ***TICS AND ADAPTIVE TRIAL DESIGNS.***

21       “(a) *PROPOSALS FOR USE OF INNOVATIVE STATISTICAL*  
22       *METHODS IN CLINICAL PROTOCOLS FOR DRUGS AND BIO-*  
23       *LOGICAL PRODUCTS.*—For purposes of assisting sponsors in  
24       incorporating adaptive trial design and Bayesian methods  
25       into proposed clinical protocols and applications for new

1 *drugs under section 505 of the Federal Food, Drug, and*  
2 *Cosmetic Act (21 U.S.C. 355) and biological products under*  
3 *section 351 of the Public Health Service Act (42 U.S.C.*  
4 *262), the Secretary shall conduct a public meeting and issue*  
5 *guidance in accordance with subsection (b).*

6 *(b) GUIDANCE ADDRESSING USE OF ADAPTIVE TRIAL*  
7 *DESIGNS AND BAYESIAN METHODS.—*

8 *(1) IN GENERAL.—The Secretary of Health and*  
9 *Human Services, acting through the Commissioner of*  
10 *Food and Drugs (in this subsection referred to as the*  
11 *“Secretary”), shall—*

12 *(A) update and finalize the draft guidance*  
13 *addressing the use of adaptive trial design for*  
14 *drugs and biological products; and*

15 *(B) issue draft guidance on the use of*  
16 *Bayesian methods in the development and regu-*  
17 *latory review and approval or licensure of drugs*  
18 *and biological products.*

19 *(2) CONTENTS.—The guidances under paragraph*  
20 *(1) shall address—*

21 *(A) the use of adaptive trial designs and*  
22 *Bayesian methods in clinical trials, including*  
23 *clinical trials proposed or submitted to help to*  
24 *satisfy the substantial evidence standard under*

1           *section 505(d) of the Federal Food, Drug, and*  
2           *Cosmetic Act (21 U.S.C. 355(d));*

3                   *(B) how sponsors may obtain feedback from*  
4           *the Secretary on technical issues related to mod-*  
5           *eling and simulations prior to—*

6                           *(i) completion of such modeling or sim-*  
7                           *ulations; or*

8                           *(ii) the submission of resulting infor-*  
9                           *mation to the Secretary;*

10                   *(C) the types of quantitative and qualitative*  
11           *information that should be submitted for review;*  
12           *and*

13                   *(D) recommended analysis methodologies.*

14           *(3) PUBLIC MEETING.—Prior to updating or de-*  
15           *veloping the guidances required by paragraph (1), the*  
16           *Secretary shall consult with stakeholders, including*  
17           *representatives of regulated industry, academia, pa-*  
18           *tient advocacy organizations, and disease research*  
19           *foundations, through a public meeting to be held not*  
20           *later than 1 year after the date of enactment of this*  
21           *Act.*

22           *(4) SCHEDULE.—The Secretary shall publish—*

23                   *(A) the final guidance required by para-*  
24           *graph (1)(A) not later than 18 months after the*

1           *date of the public meeting required by paragraph*  
2           *(3); and*

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

6 **SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**  
7                   **ENCE.**

8           *Chapter V of the Federal Food, Drug, and Cosmetic*  
9 *Act is amended by inserting after section 505E of such Act*  
10 *(21 U.S.C. 355f) the following:*

11 **“SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**  
12                   **ENCE.**

13           *“(a) IN GENERAL.—The Secretary shall establish a*  
14 *program to evaluate the potential use of evidence from clin-*  
15 *ical experience—*

16                   *“(1) to help to support the approval of a new in-*  
17           *dications for a drug approved under section 505(b);*  
18           *and*

19                   *“(2) to help to support or satisfy postapproval*  
20           *study requirements.*

21           **“(b) EVIDENCE FROM CLINICAL EXPERIENCE DE-**  
22 *FINED.—In this section, the term ‘evidence from clinical ex-*  
23 *perience’ means data regarding the usage, or the potential*  
24 *benefits or risks, of a drug derived from sources other than*

1 *randomized clinical trials, including from observational*  
2 *studies, registries, and therapeutic use.*

3 “(c) *PROGRAM FRAMEWORK.*—

4 “(1) *IN GENERAL.*—*Not later than 18 months*  
5 *after the date of enactment of this section, the Sec-*  
6 *retary shall establish a draft framework for imple-*  
7 *mentation of the program under this section.*

8 “(2) *CONTENTS OF FRAMEWORK.*—*The frame-*  
9 *work shall include information describing—*

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

14 “(B) *the gaps in current data collection ac-*  
15 *tivities;*

16 “(C) *the current standards and methodolo-*  
17 *gies for collection and analysis of data generated*  
18 *through clinical experience; and*

19 “(D) *the priority areas, remaining chal-*  
20 *lenges, and potential pilot opportunities that the*  
21 *program established under this section will ad-*  
22 *dress.*

23 “(3) *CONSULTATION.*—

24 “(A) *IN GENERAL.*—*In developing the pro-*  
25 *gram framework under this subsection, the Sec-*

1            *retary shall consult with regulated industry, aca-*  
2            *demia, medical professional organizations, rep-*  
3            *resentatives of patient advocacy organizations,*  
4            *disease research foundations, and other interested*  
5            *parties.*

6            “(B) *PROCESS.—The consultation under*  
7            *subparagraph (A) may be carried out through*  
8            *approaches such as—*

9                    “(i) *a public-private partnership with*  
10                    *the entities described in such subparagraph*  
11                    *in which the Secretary may participate; or*

12                    “(ii) *a contract, grant, or other ar-*  
13                    *rangement, as determined appropriate by*  
14                    *the Secretary with such a partnership or an*  
15                    *independent research organization.*

16            “(d) *PROGRAM IMPLEMENTATION.—The Secretary*  
17            *shall, not later than 24 months after the date of enactment*  
18            *of this section and in accordance with the framework estab-*  
19            *lished under subsection (c), implement the program to*  
20            *evaluate the potential use of evidence from clinical experi-*  
21            *ence.*

22            “(e) *GUIDANCE FOR INDUSTRY.—The Secretary*  
23            *shall—*

24                    “(1) *utilize the program established under sub-*  
25                    *section (a), its activities, and any subsequent pilots or*



1 *written reports, to inform a guidance for industry*  
2 *on—*

3 *“(A) the circumstances under which spon-*  
4 *sors of drugs and the Secretary may rely on evi-*  
5 *dence from clinical experience for the purposes*  
6 *described in subsection (a)(1) or (a)(2); and*

7 *“(B) the appropriate standards and meth-*  
8 *odologies for collection and analysis of evidence*  
9 *from clinical experience submitted for such pur-*  
10 *poses;*

11 *“(2) not later than 36 months after the date of*  
12 *enactment of this section, issue draft guidance for in-*  
13 *dustry as described in paragraph (1); and*

14 *“(3) not later than 48 months after the date of*  
15 *enactment of this section, after providing an oppor-*  
16 *tunity for public comment on the draft guidance,*  
17 *issue final guidance.*

18 *“(f) RULE OF CONSTRUCTION.—*

19 *“(1) Subject to paragraph (2), nothing in this*  
20 *section prohibits the Secretary from using evidence*  
21 *from clinical experience for purposes not specified in*  
22 *this section, provided the Secretary determines that*  
23 *sufficient basis exists for any such nonspecified use.*

24 *“(2) This section shall not be construed to*  
25 *alter—*

1           “(A) *the standards of evidence under—*  
 2                 “(i) *subsection (c) or (d) of section 505,*  
 3                 *including the substantial evidence standard*  
 4                 *in such subsection (d); or*  
 5                 “(ii) *section 351(a) of the Public*  
 6                 *Health Service Act; or*  
 7           “(B) *the Secretary’s authority to require*  
 8           *postapproval studies or clinical trials, or the*  
 9           *standards of evidence under which studies or*  
 10           *trials are evaluated.*

11   **“SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPE-**  
 12                   **RIENCE THROUGH TARGETED EXTENSIONS**  
 13                   **OF THE SENTINEL SYSTEM.**

14           “(a) *IN GENERAL.—The Secretary shall, in parallel to*  
 15           *implementing the program established under section 505F*  
 16           *and in order to build capacity for utilizing the evidence*  
 17           *from clinical experience described in that section, identify*  
 18           *and execute pilot demonstrations to extend existing use of*  
 19           *the Sentinel System surveillance infrastructure authorized*  
 20           *under section 505(k).*

21           “(b) *PILOT DEMONSTRATIONS.—*

22                 “(1) *IN GENERAL.—The Secretary—*

23                         “(A) *shall design and implement pilot dem-*  
 24                         *onstrations to utilize data captured through the*  
 25                         *Sentinel System surveillance infrastructure au-*

1           *thorized under section 505(k) for purposes of, as*  
2           *appropriate—*

3                     *“(i) generating evidence from clinical*  
4                     *experience to improve characterization or*  
5                     *assessment of risks or benefits of a drug ap-*  
6                     *proved under section 505(c);*

7                     *“(ii) protecting the public health; or*

8                     *“(iii) advancing patient-centered care;*

9                     *and*

10                    *“(B) may make strategic linkages with*  
11                    *sources of complementary public health data and*  
12                    *infrastructure the Secretary determines appro-*  
13                    *priate and necessary.*

14                    *“(2) CONSULTATION.—In developing the pilot*  
15                    *demonstrations under this subsection, the Secretary*  
16                    *shall—*

17                             *“(A) consult with regulated industry, aca-*  
18                             *demia, medical professional organizations, rep-*  
19                             *resentatives of patient advocacy organizations,*  
20                             *disease research foundations, and other interested*  
21                             *parties through a public process; and*

22                             *“(B) develop a framework to promote ap-*  
23                             *propriate transparency and dialogue about re-*  
24                             *search conducted under these pilot demonstra-*  
25                             *tions, including by—*

1           “(i) providing adequate notice to a  
2           sponsor of a drug approved under section  
3           505 or section 351 of the Public Health  
4           Service Act of the Secretary’s intent to con-  
5           duct analyses of such sponsor’s drug or  
6           drugs under these pilot demonstrations;

7           “(ii) providing adequate notice of the  
8           findings related to analyses described in  
9           clause (i) and an opportunity for the spon-  
10          sor of such drug or drugs to comment on  
11          such findings; and

12          “(iii) ensuring the protection from  
13          public disclosure of any information that is  
14          a trade secret or confidential information  
15          subject to section 552(b)(4) of title 5, United  
16          States Code, or section 1905 of title 18,  
17          United States Code.

18          “(3) *PUBLIC HEALTH EXEMPTION.*—The Sec-  
19          retary may—

20                 “(A) deem such pilot demonstrations public  
21                 health activities, permitting the use and disclo-  
22                 sure of protected health information as described  
23                 in section 164.512(b)(1)(iii) of title 45, Code of  
24                 Federal Regulations (or any successor regula-  
25                 tion) and exempted as a public health activity as

1           *described in section 46.101(b)(5) of title 46, Code*  
2           *of Federal Regulations (or any successor regula-*  
3           *tion); and*

4           *“(B) deem safety surveillance performed at*  
5           *the request of the Food and Drug Administration*  
6           *or under such jurisdiction by a sponsor with re-*  
7           *sponsibility for a drug approved under this sec-*  
8           *tion or section 351 of the Public Health Services*  
9           *Act using the Sentinel System surveillance infra-*  
10           *structure authorized under section 505(k), in-*  
11           *cluding use of analytic tools and querying capa-*  
12           *bilities developed to implement the active*  
13           *postmarket surveillance system described in this*  
14           *section, public health activities as described in*  
15           *section 164.512(b)(1)(iii) of title 45, Code of*  
16           *Federal Regulations (or any successor regula-*  
17           *tion) and exempted as a public health activity as*  
18           *described in section 46.101(b)(5) of title 46, Code*  
19           *of Federal Regulations (or any successor regula-*  
20           *tion).*

21           “(c) *AUTHORIZATION OF APPROPRIATIONS.—There are*  
22           *authorized to be appropriated to carry out this section*  
23           *\$3,000,000 for each of fiscal years 2016 through 2020.”.*

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

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

6 **“SEC. 505H. STREAMLINED DATA REVIEW PROGRAM.**

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

15       “(b) *ELIGIBILITY.*—In carrying out the streamlined  
16 data review program under subsection (a), the Secretary  
17 may authorize the holder of the approved application to in-  
18 clude one or more qualified data summaries described in  
19 subsection (a) in a supplemental application if—

20               “(1) the drug has been approved under section  
21 505(c) of this Act or licensed under section 351(a) of  
22 the Public Health Service Act for one or more indica-  
23 tions, and such approval or licensure remains in ef-  
24 fect;

25               “(2) the supplemental application is for ap-  
26 proval or licensure (as applicable) under such section

1 505(c) or 351(a) of the use of the drug for a new  
2 qualified indication under such section 505(c) or  
3 351(a);

4 “(3) there is an existing database acceptable to  
5 the Secretary regarding the safety of the drug devel-  
6 oped for one or more indications of the drug approved  
7 under such section 505(c) or licensed under such sec-  
8 tion 351(a);

9 “(4) the supplemental application incorporates  
10 or supplements the data submitted in the application  
11 for approval or licensure referred to in paragraph (1);  
12 and

13 “(5) the full data sets used to develop the quali-  
14 fied data summaries are submitted, unless the Sec-  
15 retary determines that the full data sets are not re-  
16 quired.

17 “(c) *PUBLIC AVAILABILITY OF INFORMATION ON PRO-*  
18 *GRAM.*—The Secretary shall post on the public website of  
19 the Food and Drug Administration and update annually—

20 “(1) the number of applications reviewed under  
21 the streamlined data review program;

22 “(2) the average time for completion of review  
23 under the streamlined data review program versus  
24 other review of applications for new indications; and

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

5           “(d) DEFINITIONS.—In this section:

6           “(1) The term ‘qualified indication’ means—

7                   “(A) an indication for the treatment of can-  
8                   cer, as determined appropriate by the Secretary;  
9                   or

10                   “(B) such other types of indications as the  
11                   Secretary determines to be subject to the stream-  
12                   lined data review program under this section.

13           “(2) The term ‘qualified data summary’ means  
14           a summary of clinical data intended to demonstrate  
15           safety and effectiveness with respect to a qualified in-  
16           dication for use of a drug.”.

17           (b) SENSE OF CONGRESS.—It is the sense of Congress  
18           that the streamlined data review program under section  
19           505H of the Federal Food, Drug, and Cosmetic Act, as  
20           added by subsection (a), should enable the Food and Drug  
21           Administration to make approval decisions for certain sup-  
22           plemental applications based on qualified data summaries  
23           (as defined in such section 505H).

24           (c) GUIDANCE; REGULATIONS.—The Commissioner of  
25           Food and Drugs—



1 (1) *shall—*

2 (A) *issue final guidance for implementation*  
3 *of the streamlined data review program estab-*  
4 *lished under section 505H of the Federal Food,*  
5 *Drug, and Cosmetic Act, as added by subsection*  
6 *(a), not later than 24 months after the date of*  
7 *enactment of this Act; and*

8 (B) *include in such guidance the process for*  
9 *expanding the types of indications to be subject*  
10 *to the streamlined data review program, as au-*  
11 *thorized by section 505H(c)(1)(B) of such Act;*  
12 *and*

13 (2) *in addition to issuing guidance under para-*  
14 *graph (1), may issue such regulations as may be nec-*  
15 *essary for implementation of the program.*

16 ***Subtitle E—Expediting Patient***  
17 ***Access***

18 ***SEC. 2081. SENSE OF CONGRESS.***

19 *It is the sense of Congress that the Food and Drug Ad-*  
20 *ministration should continue to expedite the approval of*  
21 *drugs designated as breakthrough therapies pursuant to sec-*  
22 *tion 506(a) of the Federal Food, Drug, and Cosmetic Act*  
23 *(21 U.S.C. 356(a)) by approving drugs so designated as*  
24 *early as possible in the clinical development process, regard-*  
25 *less of the phase of development, provided that the Secretary*

1 of Health and Human Services determines that an applica-  
2 tion for such a drug meets the standards of evidence of safe-  
3 ty and effectiveness under section 505 of such Act (21 U.S.C.  
4 355), including the substantial evidence standard under  
5 subsection (d) of such section or under section 351(a) of the  
6 Public Health Service Act (42 U.S.C. 262(a)).

7 **SEC. 2082. EXPANDED ACCESS POLICY.**

8 Chapter V of the Federal Food, Drug, and Cosmetic  
9 Act is amended by inserting after section 561 (21 U.S.C.  
10 360bbb) the following:

11 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**  
12 **VESTIGATIONAL DRUGS.**

13 “(a) *IN GENERAL.*—The manufacturer or distributor  
14 of one or more investigational drugs for the diagnosis, mon-  
15 itoring, or treatment of one or more serious diseases or con-  
16 ditions shall make publicly available the policy of the man-  
17 ufacturer or distributor on evaluating and responding to  
18 requests submitted under section 561(b) for provision of  
19 such a drug. A manufacturer or distributor may satisfy the  
20 requirement of the preceding sentence by posting such policy  
21 as generally applicable to all of such manufacturer’s or dis-  
22 tributor’s investigational drugs.

23 “(b) *CONTENT OF POLICY.*—A policy described in sub-  
24 section (a) shall include making publicly available—

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

4           “(2) procedures for making such requests;

5           “(3) the general criteria the manufacturer or dis-  
6           tributor will consider or use to approve such requests;  
7           and

8           “(4) the length of time the manufacturer or dis-  
9           tributor anticipates will be necessary to acknowledge  
10          receipt of such requests.

11          “(c) *NO GUARANTEE OF ACCESS.*—The posting of poli-  
12          cies by manufacturers and distributors under subsection (a)  
13          shall not serve as a guarantee of access to any specific inves-  
14          tigational drug by any individual patient.

15          “(d) *REVISED POLICY.*—A manufacturer or dis-  
16          tributor that has made a policy publicly available as re-  
17          quired by this section may revise the policy at any time.

18          “(e) *APPLICATION.*—This section shall apply to a  
19          manufacturer or distributor with respect to an investiga-  
20          tional drug beginning on the later of—

21                 “(1) the date that is 60 days after the date of en-  
22                 actment of the 21st Century Cures Act; or

23                 “(2) the first initiation of a phase 2 or phase 3  
24                 study (as such terms are defined in section 312.21(b)  
25                 and (c) of title 21, Code of Federal Regulations (or



1           (2) by striking “a formulary committee, or other  
2           similar entity, in the course of the committee or the  
3           entity carrying out its responsibilities for the selec-  
4           tion of drugs for managed care or other similar orga-  
5           nizations” and inserting “a payor, formulary com-  
6           mittee, or other similar entity with knowledge and ex-  
7           pertise in the area of health care economic analysis,  
8           carrying out its responsibilities for the selection of  
9           drugs for coverage or reimbursement”;

10           (3) by striking “directly relates” and inserting  
11           “relates”;

12           (4) by striking “and is based on competent and  
13           reliable scientific evidence. The requirements set forth  
14           in section 505(a) or in section 351(a) of the Public  
15           Health Service Act shall not apply to health care eco-  
16           nomic information provided to such a committee or  
17           entity in accordance with this paragraph” and in-  
18           serting “, is based on competent and reliable scientific  
19           evidence, and includes, where applicable, a con-  
20           spicuous and prominent statement describing any  
21           material differences between the health care economic  
22           information and the labeling approved for the drug  
23           under section 505 or under section 351 of the Public  
24           Health Service Act. The requirements set forth in sec-  
25           tion 505(a) or in subsections (a) and (k) of section

1       351 of the Public Health Service Act shall not apply  
2       to health care economic information provided to such  
3       a payor, committee, or entity in accordance with this  
4       paragraph”; and

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

7       “(2)(A) For purposes of this paragraph, the term  
8       ‘health care economic information’ means any analysis (in-  
9       cluding the clinical data, inputs, clinical or other assump-  
10      tions, methods, results, and other components underlying or  
11      comprising the analysis) that identifies, measures, or de-  
12      scribes the economic consequences, which may be based on  
13      the separate or aggregated clinical consequences of the rep-  
14      resented health outcomes, of the use of a drug. Such analysis  
15      may be comparative to the use of another drug, to another  
16      health care intervention, or to no intervention.

17              “(B) Such term does not include any analysis that re-  
18      lates only to an indication that is not approved under sec-  
19      tion 505 or under section 351 of the Public Health Service  
20      Act for such drug.”.

21   **SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION**  
22                           **OF SCIENTIFIC AND MEDICAL DEVELOP-**  
23                           **MENTS.**

24              (a) *GUIDANCE*.—Not later than 18 months after the  
25      date of enactment of this Act, the Secretary of Health and

1 *Human Services shall issue draft guidance on facilitating*  
2 *the responsible dissemination of truthful and nonmisleading*  
3 *scientific and medical information not included in the ap-*  
4 *proved labeling of drugs and devices.*

5 (b) *DEFINITION.—In this section, the terms “drug”*  
6 *and “device” have the meaning given to such terms in sec-*  
7 *tion 201 of the Federal Food, Drug, and Cosmetic Act (21*  
8 *U.S.C. 321).*

9 ***Subtitle G—Antibiotic Drug***  
10 ***Development***

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

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

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

1       “(z) *APPROVAL OF CERTAIN ANTIBACTERIAL AND*  
2 *ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION*  
3 *OF PATIENTS.—*

4               “(1) *PROCESS.—At the request of the sponsor of*  
5 *an antibacterial or antifungal drug that is intended*  
6 *to treat a serious or life-threatening infection, the*  
7 *Secretary—*

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

13                      “(B) *shall proceed in accordance with this*  
14 *subsection only if a written agreement is reached*  
15 *under subparagraph (A);*

16                      “(C) *shall provide the sponsor with an op-*  
17 *portunity to request meetings under paragraph*  
18 *(2);*

19                      “(D) *if a written agreement is reached*  
20 *under subparagraph (A), may approve the drug*  
21 *under this subsection for such use—*

22                               “(i) *in a limited population of pa-*  
23 *tients for which there is an unmet medical*  
24 *need;*



1           “(ii) based on a streamlined develop-  
2           ment program; and

3           “(iii) only if the standards for ap-  
4           proval under subsections (c) and (d) of this  
5           section or licensure under section 351 of the  
6           Public Health Service Act, as applicable,  
7           are met; and

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

11           “(i) traditional endpoints, alternate  
12           endpoints, or a combination of traditional  
13           and alternate endpoints, and, as appro-  
14           priate, data sets of a limited size; and

15           “(ii)(I) additional data, including pre-  
16           clinical, pharmacologic, or pathophysiologic  
17           evidence;

18           “(II) nonclinical susceptibility and  
19           pharmacokinetic data;

20           “(III) data from phase 2 clinical  
21           trials; and

22           “(IV) such other confirmatory evidence  
23           as the Secretary determines appropriate to  
24           approve the drug.

25          “(2) FORMAL MEETINGS.—

1           “(A) *IN GENERAL.*—*To help to expedite and*  
2           *facilitate the development and review of a drug*  
3           *for which a sponsor intends to request approval*  
4           *in accordance with this subsection, the Secretary*  
5           *may, at the request of the sponsor, conduct meet-*  
6           *ings that provide early consultation, timely ad-*  
7           *vice, and sufficient opportunities to develop an*  
8           *agreement described in paragraph (1)(A) and*  
9           *help the sponsor design and conduct a drug de-*  
10          *velopment program as efficiently as possible, in-*  
11          *cluding the following types of meetings:*

12                   “(i) *An early consultation meeting.*

13                   “(ii) *An assessment meeting.*

14                   “(iii) *A postapproval meeting.*

15          “(B) *NO ALTERING OF GOALS.*—*Nothing in*  
16          *this paragraph shall be construed to alter agreed*  
17          *upon goals and procedures identified in the let-*  
18          *ters described in section 101(b) of the Prescrip-*  
19          *tion Drug User Fee Amendments of 2012.*

20          “(C) *BREAKTHROUGH THERAPIES.*—*In the*  
21          *case of a drug designated as a breakthrough ther-*  
22          *apy under section 506(a), the sponsor of such*  
23          *drug may elect to utilize meetings provided*  
24          *under such section with respect to such drug in*  
25          *lieu of meetings described in subparagraph (A).*

1           “(3) *LABELING REQUIREMENT.*—*The labeling of*  
2           *an antibacterial or antifungal drug approved in ac-*  
3           *cordance with this subsection shall contain the state-*  
4           *ment ‘Limited Population’ in a prominent manner*  
5           *and adjacent to, and not more prominent than, the*  
6           *brand name of the product. The prescribing informa-*  
7           *tion for such antibacterial or antifungal drug re-*  
8           *quired by section 201.57 of title 21, Code of Federal*  
9           *Regulations (or any successor regulation) shall also*  
10          *include the following statement: ‘This drug is indi-*  
11          *cated for use in a limited and specific population of*  
12          *patients.’.*

13           “(4) *PROMOTIONAL MATERIALS.*—*The provisions*  
14          *of section 506(c)(2)(B) shall apply with respect to ap-*  
15          *proval in accordance with this subsection to the same*  
16          *extent and in the same manner as such provisions*  
17          *apply with respect to accelerated approval in accord-*  
18          *ance with section 506(c)(1).*

19           “(5) *TERMINATION OF REQUIREMENTS OR CON-*  
20          *DITIONS.*—*If a drug is approved in accordance with*  
21          *this subsection for an indication in a limited popu-*  
22          *lation of patients and is subsequently approved or li-*  
23          *censed under this section or section 351 of the Public*  
24          *Health Service Act, other than in accordance with*  
25          *this subsection, for—*

1           “(A) *the same indication and the same con-*  
2           *ditions of use, the Secretary shall remove any la-*  
3           *beling requirements or postmarketing conditions*  
4           *that were made applicable to the drug under this*  
5           *subsection; or*

6           “(B) *a different indication or condition of*  
7           *use, the Secretary shall not apply the labeling re-*  
8           *quirements and postmarketing conditions that*  
9           *were made applicable to the drug under this sub-*  
10          *section to the subsequent approval of the drug for*  
11          *such different indication or condition of use.*

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

17                 “(A) *an agreement on the design and size of*  
18                 *a clinical trial pursuant to subparagraphs (B)*  
19                 *and (C) of subsection (b)(5);*

20                 “(B) *designation and treatment of the drug*  
21                 *as a breakthrough therapy under section 506(a);*

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

24                 “(D) *accelerated approval of the drug in ac-*  
25                 *cordance with section 506(c).*

1           “(7) *RULE OF CONSTRUCTION.*—*Nothing in this*  
2           *subsection shall be construed—*

3                   “(A) *to alter the standards of evidence*  
4                   *under subsection (c) or (d) (including the sub-*  
5                   *stantial evidence standard in subsection (d));*

6                   “(B) *to waive or otherwise preclude the ap-*  
7                   *plication of requirements under subsection (o);*

8                   “(C) *to otherwise, in any way, limit the au-*  
9                   *thority of the Secretary to approve products pur-*  
10                   *suant to this Act and the Public Health Service*  
11                   *Act as authorized prior to the date of enactment*  
12                   *of this subsection; or*

13                   “(D) *to restrict in any manner, the pre-*  
14                   *scribing of antibiotics or other products by*  
15                   *health care providers, or to otherwise limit or re-*  
16                   *strict the practice of health care.*

17           “(8) *EFFECTIVE IMMEDIATELY.*—*The Secretary*  
18           *shall have the authorities vested in the Secretary by*  
19           *this subsection beginning on the date of enactment of*  
20           *this subsection, irrespective of when and whether the*  
21           *Secretary promulgates final regulations or guidance.*

22           “(9) *DEFINITIONS.*—*In this subsection:*

23                   “(A) *EARLY CONSULTATION MEETING.*—*The*  
24                   *term ‘early consultation meeting’ means a pre-*

1           *investigational new drug meeting or an end-of-*  
2           *phase-1 meeting that—*

3                   “(i) *is conducted to review and reach*  
4                   *a written agreement—*

5                           “(I) *on the scope of the stream-*  
6                           *lined development plan for a drug for*  
7                           *which a sponsor intends to request ap-*  
8                           *proval in accordance with this sub-*  
9                           *section; and*

10                           “(II) *which, as appropriate, may*  
11                           *include agreement on the design and*  
12                           *size of necessary preclinical and clin-*  
13                           *ical studies early in the development*  
14                           *process, including clinical trials whose*  
15                           *data are intended to form the primary*  
16                           *basis for an effectiveness claim; and*

17                           “(ii) *provides an opportunity to dis-*  
18                           *cuss expectations of the Secretary regarding*  
19                           *studies or other information that the Sec-*  
20                           *retary deems appropriate for purposes of*  
21                           *applying paragraph (5), relating to the ter-*  
22                           *mination of labeling requirements or post-*  
23                           *marketing conditions.*

24                           “(B) *ASSESSMENT MEETING.—The term ‘as-*  
25                           *essment meeting’ means an end-of-phase 2 meet-*

1            *ing, pre-new drug application meeting, or pre-*  
2            *biologics license application meeting conducted*  
3            *to resolve questions and issues raised during the*  
4            *course of clinical investigations, and details ad-*  
5            *dressed in the written agreement regarding post-*  
6            *approval commitments or expansion of approved*  
7            *uses.*

8            *“(C) POSTAPPROVAL MEETING.—The term*  
9            *‘postapproval meeting’ means a meeting fol-*  
10           *lowing initial approval or licensure of the drug*  
11           *for use in a limited population, to discuss any*  
12           *issues identified by the Secretary or the sponsor*  
13           *regarding postapproval commitments or expan-*  
14           *sion of approved uses.”.*

15           *(c) GUIDANCE.—Not later than 18 months after the*  
16           *date of enactment of this Act, the Secretary of Health and*  
17           *Human Services, acting through the Commissioner of Food*  
18           *and Drugs, shall issue draft guidance describing criteria,*  
19           *process, and other general considerations for demonstrating*  
20           *the safety and effectiveness of antibacterial and antifungal*  
21           *drugs to be approved for use in a limited population in*  
22           *accordance with section 505(z) of the Federal Food, Drug,*  
23           *and Cosmetic Act, as added by subsection (b).*

24           *(d) CONFORMING AMENDMENTS.—*

1           (1) *LICENSURE OF CERTAIN BIOLOGICAL PROD-*  
2           *UCTS.—Section 351(j) of the Public Health Service*  
3           *Act (42 U.S.C. 262(j)) is amended—*

4                   (A) *by striking “(j)” and inserting “(j)(1)”;*

5                   (B) *by inserting “505(z),” after “505(p),”;*

6                   *and*

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

9           “(2) *In applying section 505(z) of the Federal Food,*  
10           *Drug, and Cosmetic Act to the licensure of biological prod-*  
11           *ucts under this section—*

12                   “(A) *references to an antibacterial or antifungal*  
13                   *drug that is intended to treat a serious or life-threat-*  
14                   *ening infection shall be construed to refer to a biologi-*  
15                   *cal product intended to treat a serious or life-threat-*  
16                   *ening bacterial or fungal infection; and*

17                   “(B) *references to approval of a drug under sec-*  
18                   *tion 505(c) of such Act shall be construed to refer to*  
19                   *a licensure of a biological product under subsection*  
20                   *(a) of this section.”.*

21           (2) *MISBRANDING.—Section 502 of the Federal*  
22           *Food, Drug, and Cosmetic Act (21 U.S.C. 352) is*  
23           *amended by adding at the end the following new sub-*  
24           *section:*



1       “(dd) If it is a drug approved in accordance with sec-  
2 tion 505(z) and its labeling does not meet the requirements  
3 under paragraph (3) of such subsection, subject to para-  
4 graph (5) of such subsection.”.

5       (e) EVALUATION.—

6           (1) ASSESSMENT.—Not later than 48 months  
7 after the date of enactment of this Act, the Secretary  
8 of Health and Human Services shall publish for pub-  
9 lic comment an assessment of the program established  
10 under section 505(z) of the Federal Food, Drug, and  
11 Cosmetic Act, as added by subsection (b). Such assess-  
12 ment shall determine if the limited-use pathway es-  
13 tablished under such section 505(z) has improved or  
14 is likely to improve patient access to novel anti-  
15 bacterial or antifungal treatments and assess how the  
16 pathway could be expanded to cover products for seri-  
17 ous or life-threatening diseases or conditions beyond  
18 bacterial and fungal infections.

19           (2) MEETING.—Not later than 90 days after the  
20 date of the publication of such assessment, the Sec-  
21 retary, acting through the Commissioner of Food and  
22 Drugs, shall hold a public meeting to discuss the find-  
23 ings of the assessment, during which public stake-  
24 holders may present their views on the success of the  
25 program established under section 505(z) of the Fed-

1        *eral Food, Drug, and Cosmetic Act, as added by sub-*  
2        *section (b), and the appropriateness of expanding*  
3        *such program.*

4        *(f) EXPANSION OF PROGRAM.—If the Secretary of*  
5        *Health and Human Services determines, based on the as-*  
6        *essment under subsection (e)(1), evaluation of the assess-*  
7        *ment, and any other relevant information, that the public*  
8        *health would benefit from expansion of the limited-use path-*  
9        *way established under section 505(z) of the Federal Food,*  
10       *Drug, and Cosmetic Act (as added by subsection (b)) beyond*  
11       *the drugs approved in accordance with such section, the*  
12       *Secretary may expand such limited-use pathway in accord-*  
13       *ance with such a determination. The approval of any drugs*  
14       *under any such expansion shall be subject to the consider-*  
15       *ations and requirements described in such section 505(z)*  
16       *for purposes of expansion to other serious or life-threatening*  
17       *diseases or conditions.*

18       *(g) MONITORING.—The Public Health Service Act is*  
19       *amended by inserting after section 317T (42 U.S.C. 247b–*  
20       *22) the following:*

21       **“SEC. 317U. MONITORING ANTIBACTERIAL AND**  
22       **ANTIFUNGAL DRUG USE AND RESISTANCE.**

23       *“(a) MONITORING.—The Secretary shall use an appro-*  
24       *priate monitoring system to monitor—*

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

5           “(2) *changes in bacterial and fungal resistance*  
6 *to drugs.*

7           “(b) *PUBLIC AVAILABILITY OF DATA.—The Secretary*  
8 *shall make summaries of the data derived from monitoring*  
9 *under this section publicly available for the purposes of—*

10           “(1) *improving the monitoring of important*  
11 *trends in antibacterial and antifungal resistance; and*

12           “(2) *ensuring appropriate stewardship of anti-*  
13 *bacterial and antifungal drugs, including those re-*  
14 *ceiving approval or licensure for a limited population*  
15 *pursuant to section 505(z) of the Federal Food, Drug,*  
16 *and Cosmetic Act.”.*

17 **SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
18 **FOR MICROORGANISMS.**

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

22 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**  
23 **TEST INTERPRETIVE CRITERIA FOR MICRO-**  
24 **ORGANISMS.**

25           “(a) *PURPOSE; IDENTIFICATION OF CRITERIA.—*

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

4                   “(A) *clearance or premarket approval of*  
5                   *antimicrobial susceptibility testing devices uti-*  
6                   *lizing updated, recognized susceptibility test in-*  
7                   *terpretive criteria to characterize the in vitro*  
8                   *susceptibility of particular bacteria, fungi, or*  
9                   *other microorganisms to antimicrobial drugs;*  
10                  *and*

11                  “(B) *providing public notice of the avail-*  
12                  *ability of recognized interpretive criteria to meet*  
13                  *premarket submission requirements or other re-*  
14                  *quirements under this Act for antimicrobial sus-*  
15                  *ceptibility testing devices.*

16           “(2) *IN GENERAL.*—*The Secretary shall identify*  
17           *appropriate susceptibility test interpretive criteria*  
18           *with respect to antimicrobial drugs—*

19                   “(A) *if such criteria are available on the*  
20                   *date of approval of the drug under section 505*  
21                   *of this Act or licensure of the drug under section*  
22                   *351 of the Public Health Service Act (as applica-*  
23                   *ble), upon such approval or licensure; or*

1           “(B) if such criteria are unavailable on  
2           such date, on the date on which such criteria are  
3           available for such drug.

4           “(3) *BASES FOR INITIAL IDENTIFICATION.*—The  
5           Secretary shall identify appropriate susceptibility test  
6           interpretive criteria under paragraph (2), based on  
7           the Secretary’s review of, to the extent available and  
8           relevant—

9                   “(A) preclinical and clinical data, includ-  
10                  ing pharmacokinetic, pharmacodynamic, and ep-  
11                  idemiological data;

12                   “(B) Bayesian and pharmacometric statis-  
13                  tical methodologies; and

14                   “(C) such other evidence and information as  
15                  the Secretary considers appropriate.

16           “(b) *SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA*  
17           *WEBSITE.*—

18                   “(1) *IN GENERAL.*—Not later than 1 year after  
19                  the date of the enactment of the 21st Century Cures  
20                  Act, the Secretary shall establish, and maintain there-  
21                  after, on the website of the Food and Drug Adminis-  
22                  tration, a dedicated website that contains a list of  
23                  any appropriate new or updated susceptibility test  
24                  interpretive criteria standards in accordance with

1 paragraph (2) (referred to in this section as the ‘In-  
2 terpretive Criteria Website’).

3 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-  
4 PRETIVE CRITERIA STANDARDS.—

5 “(A) IN GENERAL.—The list described in  
6 paragraph (1) shall consist of any new or up-  
7 dated susceptibility test interpretive criteria  
8 standards that are—

9 “(i) established by a nationally or  
10 internationally recognized standard devel-  
11 opment organization that—

12 “(I) establishes and maintains  
13 procedures to address potential con-  
14 flicts of interest and ensure trans-  
15 parent decisionmaking;

16 “(II) holds open meetings to en-  
17 sure that there is an opportunity for  
18 public input by interested parties, and  
19 establishes and maintains processes to  
20 ensure that such input is considered in  
21 decisionmaking; and

22 “(III) permits its standards to be  
23 made publicly available, through the  
24 National Library of Medicine or an-

1                    *other similar source acceptable to the*  
2                    *Secretary; and*

3                    *“(ii) recognized in whole, or in part,*  
4                    *by the Secretary under subsection (c).*

5                    *“(B) OTHER LIST.—The Interpretive Cri-*  
6                    *teria Website shall, in addition to the list de-*  
7                    *scribed in subparagraph (A), include a list of in-*  
8                    *terpretive criteria, if any, that the Secretary has*  
9                    *determined to be appropriate with respect to le-*  
10                    *gally marketed antimicrobial drugs, where—*

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

15                    *“(ii) the Secretary withdraws under*  
16                    *subsection (c)(1)(B) recognition of a stand-*  
17                    *ard, in whole or in part, otherwise applica-*  
18                    *ble to such a drug;*

19                    *“(iii) the Secretary approves an appli-*  
20                    *cation under section 505 of this Act or sec-*  
21                    *tion 351 of the Public Health Service Act,*  
22                    *as applicable, with respect to marketing of*  
23                    *such a drug for which there are no relevant*  
24                    *interpretive criteria included in a standard*

1           *recognized by the Secretary under sub-*  
2           *section (c); or*

3           *“(iv) because the characteristics of such*  
4           *a drug differ from other drugs with the*  
5           *same active ingredient, the interpretive cri-*  
6           *teria with respect to such drug—*

7                   *“(I) differ from otherwise applica-*  
8                   *ble interpretive criteria included in a*  
9                   *standard listed under subparagraph*  
10                   *(A) or interpretive criteria otherwise*  
11                   *listed under this subparagraph; and*

12                   *“(II) are determined by the Sec-*  
13                   *retary to be appropriate for the drug.*

14           *“(C) REQUIRED STATEMENTS OF LIMITA-*  
15           *TIONS OF INFORMATION.—The Interpretive Cri-*  
16           *teria Website shall include the following:*

17                   *“(i) A statement that—*

18                           *“(I) the website provides informa-*  
19                           *tion about the susceptibility of bac-*  
20                           *teria, fungi, or other microorganisms*  
21                           *to a certain drug (or drugs); and*

22                           *“(II) the safety and efficacy of the*  
23                           *drug in treating clinical infections due*  
24                           *to such bacteria, fungi, or other micro-*  
25                           *organisms may not have been estab-*



1                    *lished in adequate and well-controlled*  
2                    *clinical trials and the clinical signifi-*  
3                    *cance of such susceptibility informa-*  
4                    *tion in such trials is unknown.*

5                    *“(ii) A statement that directs health*  
6                    *care practitioners to consult the approved*  
7                    *product labeling for specific drugs to deter-*  
8                    *mine the uses for which the Food and Drug*  
9                    *Administration has approved the product.*

10                    *“(iii) Any other statement that the*  
11                    *Secretary determines appropriate to ade-*  
12                    *quately convey the limitations of the data*  
13                    *supporting susceptibility test interpretive*  
14                    *criteria standard listed on the website.*

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

19                    *“(4) INAPPLICABILITY OF MISBRANDING PROVI-*  
20                    *SION.—The inclusion in the approved labeling of an*  
21                    *antimicrobial drug of a reference or hyperlink to the*  
22                    *Interpretive Criteria Website, in and of itself, shall*  
23                    *not cause the drug to be misbranded in violation of*  
24                    *section 502, or the regulations promulgated there-*  
25                    *under.*

1           “(5) *TRADE SECRETS AND CONFIDENTIAL INFOR-*  
2           *MATION.—Nothing in this section shall be construed*  
3           *as authorizing the Secretary to disclose any informa-*  
4           *tion that is a trade secret or confidential information*  
5           *subject to section 552(b)(4) of title 5, United States*  
6           *Code.*

7           “(c) *RECOGNITION OF SUSCEPTIBILITY TEST INTER-*  
8           *PRETIVE CRITERIA FROM STANDARD DEVELOPMENT ORGA-*  
9           *NIZATIONS.—*

10           “(1) *IN GENERAL.—Beginning on the date of the*  
11           *establishment of the Interpretive Criteria Website, and*  
12           *at least every 6 months thereafter, the Secretary*  
13           *shall—*

14                   “(A) *evaluate any appropriate new or up-*  
15                   *dated susceptibility test interpretive criteria*  
16                   *standards established by a nationally or inter-*  
17                   *nationally recognized standard development or-*  
18                   *ganization described in subsection (b)(2)(A)(i);*  
19                   *and*

20                   “(B) *publish on the public website of the*  
21                   *Food and Drug Administration a notice—*

22                           “(i) *withdrawing recognition of any*  
23                           *different susceptibility test interpretive cri-*  
24                           *teria standard, in whole or in part;*

1                   “(ii) recognizing the new or updated  
2 standards;

3                   “(iii) recognizing one or more parts of  
4 the new or updated interpretive criteria  
5 specified in such a standard and declining  
6 to recognize the remainder of such standard;  
7 and

8                   “(iv) making any necessary updates to  
9 the lists under subsection (b)(2).

10                   “(2) *BASES FOR UPDATING INTERPRETIVE CRI-*  
11 *TERIA STANDARDS.—In evaluating new or updated*  
12 *susceptibility test interpretive criteria standards*  
13 *under paragraph (1)(A), the Secretary may con-*  
14 *sider—*

15                   “(A) *the Secretary’s determination that*  
16 *such a standard is not applicable to a particular*  
17 *drug because the characteristics of the drug differ*  
18 *from other drugs with the same active ingredient;*

19                   “(B) *information provided by interested*  
20 *third parties, including public comment on the*  
21 *annual compilation of notices published under*  
22 *paragraph (3);*

23                   “(C) *any bases used to identify suscepti-*  
24 *bility test interpretive criteria under subsection*  
25 *(a)(2); and*

1           “(D) such other information or factors as  
2           the Secretary determines appropriate.

3           “(3) ANNUAL COMPILATION OF NOTICES.—Each  
4           year, the Secretary shall compile the notices published  
5           under paragraph (1)(B) and publish such compila-  
6           tion in the Federal Register and provide for public  
7           comment. If the Secretary receives comments, the Sec-  
8           retary will review such comments and, if the Sec-  
9           retary determines appropriate, update pursuant to  
10          this subsection susceptibility test interpretive criteria  
11          standards—

12           “(A) recognized by the Secretary under this  
13          subsection; or

14           “(B) otherwise listed on the Interpretive  
15          Criteria Website under subsection (b)(2).

16           “(4) RELATION TO SECTION 514(c).—Any suscep-  
17          tibility test interpretive standard recognized under  
18          this subsection or any criteria otherwise listed under  
19          subsection (b)(2)(B) shall be deemed to be recognized  
20          as a standard by the Secretary under section  
21          514(c)(1).

22           “(5) VOLUNTARY USE OF INTERPRETIVE CRI-  
23          TERIA.—Nothing in this section prohibits a person  
24          from seeking approval or clearance of a drug or de-  
25          vice, or changes to the drug or the device, on the basis

1 *of susceptibility test interpretive criteria standards*  
2 *which differ from those recognized pursuant to para-*  
3 *graph (1).*

4 “(d) *ANTIMICROBIAL DRUG LABELING.*—

5 “(1) *DRUGS MARKETED PRIOR TO ESTABLISH-*  
6 *MENT OF INTERPRETIVE CRITERIA WEBSITE.*—*With*  
7 *respect to an antimicrobial drug lawfully introduced*  
8 *or delivered for introduction into interstate commerce*  
9 *for commercial distribution before the establishment of*  
10 *the Interpretive Criteria Website, a holder of an ap-*  
11 *proved application under section 505 of this Act or*  
12 *section 351 of the Public Health Service Act, as ap-*  
13 *plicable, for each such drug—*

14 “(A) *not later than 1 year after establish-*  
15 *ment of the Interpretive Criteria Website, shall*  
16 *submit to the Secretary a supplemental applica-*  
17 *tion for purposes of changing the drug’s labeling*  
18 *to substitute a reference or hyperlink to such*  
19 *Website for any susceptibility test interpretive*  
20 *criteria and related information; and*

21 “(B) *may begin distribution of the drug in-*  
22 *volved upon receipt by the Secretary of the sup-*  
23 *plemental application for such change.*

24 “(2) *DRUGS MARKETED SUBSEQUENT TO ESTAB-*  
25 *LISHMENT OF INTERPRETIVE CRITERIA WEBSITE.*—

1        *With respect to antimicrobial drugs lawfully intro-*  
2        *duced or delivered for introduction into interstate*  
3        *commerce for commercial distribution on or after the*  
4        *date of the establishment of the Interpretive Criteria*  
5        *Website, the labeling for such a drug shall include, in*  
6        *lieu of susceptibility test interpretive criteria and re-*  
7        *lated information, a reference to such Website.*

8        *“(e) SPECIAL CONDITION FOR MARKETING OF ANTI-*  
9        *MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—*

10            *“(1) IN GENERAL.—Notwithstanding sections*  
11            *501, 502, 510, 513, and 515, if the conditions speci-*  
12            *fied in paragraph (2) are met (in addition to other*  
13            *applicable provisions under this chapter) with respect*  
14            *to an antimicrobial susceptibility testing device de-*  
15            *scribed in subsection (f)(1), the Secretary may au-*  
16            *thorize the marketing of such device for a use de-*  
17            *scribed in such subsection.*

18            *“(2) CONDITIONS APPLICABLE TO ANTI-*  
19            *MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The*  
20            *conditions specified in this paragraph are the fol-*  
21            *lowing:*

22                    *“(A) The device is used to make a deter-*  
23                    *mination of susceptibility using susceptibility*  
24                    *test interpretive criteria that are—*

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

3           “(ii) otherwise listed on the Interpretive  
4           Criteria Website under subsection  
5           (b)(2).

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

7           “(i) includes a statement that—

8           “(I) the device provides information  
9           about the susceptibility of bacteria  
10           and fungi to certain drugs; and

11           “(II) the safety and efficacy of  
12           such drugs in treating clinical infections  
13           due to such bacteria or fungi  
14           may not have been established in adequate  
15           and well-controlled clinical trials  
16           and the clinical significance of such  
17           susceptibility information in those instances  
18           is unknown;

19           “(ii) includes a statement directing  
20           health care practitioners to consult the approved  
21           labeling for drugs tested using such  
22           a device, to determine the uses for which the  
23           Food and Drug Administration has approved  
24           such drugs; and  
25

1                   “(iii) includes any other statement the  
2                   Secretary determines appropriate to ade-  
3                   quately convey the limitations of the data  
4                   supporting the interpretive criteria de-  
5                   scribed in subparagraph (A).

6           “(f) DEFINITIONS.—In this section:

7                   “(1) The term ‘antimicrobial susceptibility test-  
8                   ing device’ means a device that utilizes susceptibility  
9                   test interpretive criteria to determine and report the  
10                  *in vitro* susceptibility of certain microorganisms to a  
11                  drug (or drugs).

12                  “(2) The term ‘qualified infectious disease prod-  
13                  uct’ means a qualified infectious disease product des-  
14                  ignated under section 505E(d).

15                  “(3) The term ‘susceptibility test interpretive cri-  
16                  teria’ means—

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

20                          “(B) related categorizations of such suscep-  
21                          tibility, including categorization of the drug as  
22                          susceptible, intermediate, resistant, or such other  
23                          term as the Secretary determines appropriate.



1           “(4)(A) *The term ‘antimicrobial drug’ means,*  
2           *subject to subparagraph (B), a systemic antibacterial*  
3           *or antifungal drug that—*

4                   “(i) *is intended for human use in the treat-*  
5                   *ment of a disease or condition caused by a bac-*  
6                   *terium or fungus;*

7                   “(ii) *may include a qualified infectious dis-*  
8                   *ease product designated under section 505E(d);*  
9                   *and*

10                   “(iii) *is subject to section 503(b)(1).*

11           “(B) *If provided by the Secretary through regu-*  
12           *lations, such term may include—*

13                   “(i) *drugs other than systemic antibacterial*  
14                   *and antifungal drugs; and*

15                   “(ii) *biological products (as such term is de-*  
16                   *fined in section 351 of the Public Health Service*  
17                   *Act) to the extent such products exhibit anti-*  
18                   *microbial activity.*

19           “(g) *RULE OF CONSTRUCTION.—Nothing in this sec-*  
20           *tion shall be construed—*

21                   “(1) *to alter the standards of evidence—*

22                   “(A) *under subsection (c) or (d) of section*  
23                   *505, including the substantial evidence standard*  
24                   *in section 505(d), or under section 351 of the*  
25                   *Public Health Service Act (as applicable); or*

1           “(B) with respect to marketing authoriza-  
2           tion for devices, under section 510, 513, or 515;

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

5           “(A) an antimicrobial drug; or

6           “(B) an antimicrobial susceptibility testing  
7           device that uses susceptibility test interpretive  
8           criteria to characterize and report the *in vitro*  
9           susceptibility of certain bacteria, fungi, or other  
10          microorganisms to antimicrobial drugs in ac-  
11          cordance with this section; or

12          “(3) unless specifically stated, to have any effect  
13          on authorities provided under other sections of this  
14          Act, including any regulations issued under such sec-  
15          tions.”.

16          (b) CONFORMING AMENDMENTS.—

17               (1) REPEAL OF RELATED AUTHORITY.—Section  
18               1111 of the Food and Drug Administration Amend-  
19               ments Act of 2007 (42 U.S.C. 247d–5a; relating to  
20               identification of clinically susceptible concentrations  
21               of antimicrobials) is repealed.

22               (2) CLERICAL AMENDMENT.—The table of con-  
23               tents in section 2 of the Food and Drug Administra-  
24               tion Amendments Act of 2007 is amended by striking  
25               the item relating to section 1111.

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

5           “(ee) *If it is an antimicrobial drug and its labeling*  
6           *fails to conform with the requirements under section*  
7           *511(d).”.*

8           (4) *RECOGNITION OF INTERPRETIVE CRITERIA AS*  
9           *DEVICE STANDARD.*—Section 514(c)(1)(A) of the Fed-  
10          *eral Food, Drug, and Cosmetic Act (21 U.S.C.*  
11          *360d(c)(1)(A)) is amended by inserting after “the*  
12          *Secretary shall, by publication in the Federal Reg-*  
13          *ister” the following: “(or, with respect to suscepti-*  
14          *bility test interpretive criteria or standards recog-*  
15          *nized or otherwise listed under section 511, by posting*  
16          *on the Interpretive Criteria Website in accordance*  
17          *with such section)”.*

18          (c) *REPORT TO CONGRESS.*—Not later than two years  
19          *after the date of enactment of this Act, the Secretary of*  
20          *Health and Human Services shall submit to the Committee*  
21          *on Energy and Commerce of the House of Representatives*  
22          *and the Committee on Health, Education, Labor and Pen-*  
23          *sions of the Senate a report on the progress made in imple-*  
24          *menting section 511 of the Federal Food, Drug, and Cos-*  
25          *metic Act (21 U.S.C. 360a), as amended by this section.*

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

9           (e) *NO EFFECT ON HEALTH CARE PRACTICE.*—Noth-  
10 ing in this subtitle (including the amendments made by this  
11 subtitle) shall be construed to restrict, in any manner, the  
12 prescribing or administering of antibiotics or other prod-  
13 ucts by health care practitioners, or to limit the practice  
14 of health care.

15 **SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF**  
16 **NEW ANTIMICROBIAL DRUGS.**

17           (a) *ADDITIONAL PAYMENT FOR NEW ANTIMICROBIAL*  
18 *DRUGS UNDER MEDICARE.*—

19                   (1) *IN GENERAL.*—Section 1886(d)(5) of the So-  
20 cial Security Act (42 U.S.C. 1395ww(d)(5)) is  
21 amended by adding at the end the following new sub-  
22 paragraph:

23                   “(M)(i) As part of the annual rulemaking under this  
24 subsection for payment for subsection (d) hospitals for each

1 *fiscal year beginning with fiscal year 2018, the Secretary*  
2 *shall—*

3           “(I) *include publication of a list of the new anti-*  
4 *microbial drugs for such fiscal year; and*

5           “(II) *with respect to discharges by eligible hos-*  
6 *pitals that involve a drug so published, provide for an*  
7 *additional payment to be made under this subsection*  
8 *in accordance with the provisions of this subpara-*  
9 *graph.*

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

12           “(I) *other than during the 5-fiscal-year period*  
13 *beginning with the fiscal year for which the drug is*  
14 *first included in the publication described in clause*  
15 *(i)(I); and*

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

18          “(iii) *For purposes of this subparagraph, the term*  
19 *‘new antimicrobial drug’ means a product that is approved*  
20 *for use, or a product for which an indication is first ap-*  
21 *proved for use, by the Food and Drug Administration on*  
22 *or after December 1, 2014, and that the Food and Drug*  
23 *Administration determines—*

24           “(I) *either—*

1           “(aa) is intended to treat an infection  
2           caused by, or likely to be caused by, a qualifying  
3           pathogen (as defined under section 505E(f) of the  
4           Federal Food, Drug, and Cosmetic Act); or

5           “(bb) meets the definition of a qualified in-  
6           fectious disease product under section 505E(g) of  
7           the Federal Food, Drug, and Cosmetic Act; and

8           “(II) is intended to treat an infection—

9           “(aa) for which there is an unmet medical  
10          need; and

11          “(bb) which is associated with high rates of  
12          mortality or significant patient morbidity, as  
13          determined in consultation with the Director of  
14          the Centers for Disease Control and Prevention  
15          and the infectious disease professional commu-  
16          nity.

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

20          “(iv) For purposes of this subparagraph, the term ‘eli-  
21          gible hospital’ means a subsection (d) hospital that partici-  
22          pates in the National Healthcare Safety Network of the Cen-  
23          ters for Disease Control and Prevention (or, to the extent  
24          a similar surveillance system reporting program that in-  
25          cludes reporting about antimicrobial drugs is determined

1 *by the Secretary to be available to such hospitals, such simi-*  
2 *lar surveillance system as the Secretary may specify).*

3       “(v)(I) *Subject to the succeeding provisions of this*  
4 *clause, the additional payment under this subparagraph,*  
5 *with respect to a drug, shall be in the amount provided*  
6 *for such drug under section 1847A.*

7       “(II) *The Secretary shall, as part of the rulemaking*  
8 *referred to in clause (i) for each fiscal year, estimate—*

9               “(aa) *the total amount of the additional pay-*  
10 *ments that will be made under this subsection pursu-*  
11 *ant to this subparagraph for discharges in such fiscal*  
12 *year without regard to the application of subclause*  
13 *(III); and*

14               “(bb) *the total program payments to be made*  
15 *under this subsection for all discharges in such fiscal*  
16 *year.*

17       “(III) *If the estimated total amount described in sub-*  
18 *clause (II)(aa) for a fiscal year exceeds the applicable per-*  
19 *centage of the estimated total program payments described*  
20 *in subclause (II)(bb) for such fiscal year, the Secretary shall*  
21 *reduce in a pro rata manner the amount of each additional*  
22 *payment under this subsection pursuant to this subpara-*  
23 *graph for such fiscal year in order to ensure that the total*  
24 *amount of the additional payments under this subsection*  
25 *pursuant to this subparagraph for such fiscal year do not*

1 *exceed the applicable percentage of the estimated total pro-*  
 2 *gram payments described in subclause (II)(bb) for such fis-*  
 3 *cal year.*

4 “(IV) *For purposes of subclause (III), the term ‘appli-*  
 5 *cable percentage’ means 0.03 percent.*”

6 (2) *CONFORMING AMENDMENTS.—*

7 (A) *NO DUPLICATIVE NTAP PAYMENTS.—*  
 8 *Section 1886(d)(5)(K)(vi) of the Social Security*  
 9 *Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended*  
 10 *by inserting “if additional payment has never*  
 11 *been made under this subsection pursuant to sub-*  
 12 *paragraph (M) with respect to the service or*  
 13 *technology” after “if the service or technology”.*

14 (B) *ACCESS TO PRICE INFORMATION.—**Sec-*  
 15 *tion 1927(b)(3)(A)(iii) of the Social Security Act*  
 16 *(42 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended—*

17 (i) *in subclause (II), by inserting “or*  
 18 *under section 1886(d) pursuant to para-*  
 19 *graph (5)(M) of such section,” after*  
 20 *“1847A,”; and*

21 (ii) *in the matter following subclause*  
 22 *(III), by inserting “or section*  
 23 *1886(d)(5)(M)” after “1881(b)(13)(A)(ii)”.*

24 (b) *STUDY AND REPORT ON REMOVING BARRIERS TO*  
 25 *DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—*



1           (1) *STUDY.*—*The Comptroller General of the*  
2           *United States shall, in consultation with the Director*  
3           *of the National Institutes of Health, the Commissioner*  
4           *of Food and Drugs, and the Director of the Centers*  
5           *for Disease Control and Prevention, conduct a study*  
6           *to—*

7                     (A) *identify and examine the barriers that*  
8                     *prevent the development of new antimicrobial*  
9                     *drugs, as defined in section 1886(d)(5)(M)(iii) of*  
10                    *the Social Security Act (42 U.S.C.*  
11                    *1395ww(d)(5)(M)(iii)), as added by subsection*  
12                    *(a)(1); and*

13                    (B) *develop recommendations for actions to*  
14                    *be taken in order to overcome any barriers iden-*  
15                    *tified under subparagraph (A).*

16           (2) *REPORT.*—*Not later than 1 year after the*  
17           *date of the enactment of this Act, the Comptroller*  
18           *General shall submit to Congress a report on the*  
19           *study conducted under paragraph (1).*

1           ***Subtitle H—Vaccine Access,***  
2           ***Certainty, and Innovation***

3   ***SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY***  
4                           ***COMMITTEE ON IMMUNIZATION PRACTICES.***

5           *Section 2102(a) of the Public Health Service Act (42*  
6   *U.S.C. 300aa-2(a)) is amended by adding at the end the*  
7   *following:*

8                   “(10) *ADVISORY COMMITTEE ON IMMUNIZATION*  
9           *PRACTICES.—*

10                   “(A) *STANDARD PERIODS OF TIME FOR*  
11           *MAKING RECOMMENDATIONS.—Upon the licen-*  
12           *sure of any vaccine or any new indication for a*  
13           *vaccine, the Director of the Program shall direct*  
14           *the Advisory Committee on Immunization Prac-*  
15           *tices, at its next regularly scheduled meeting, to*  
16           *consider the use of the vaccine.*

17                   “(B) *EXPEDITED REVIEW PURSUANT TO RE-*  
18           *QUEST BY SPONSOR OR MANUFACTURER.—If the*  
19           *Advisory Committee does not make recommenda-*  
20           *tions with respect to the use of a vaccine at the*  
21           *Advisory Committee’s first regularly scheduled*  
22           *meeting after the licensure of the vaccine or any*  
23           *new indication for the vaccine, the Advisory*  
24           *Committee, at the request of the sponsor of the*

1           *vaccine, shall make such recommendations on an*  
2           *expedited basis.*

3           “(C) *EXPEDITED REVIEW FOR BREAK-*  
4           *THROUGH THERAPIES AND FOR USE DURING*  
5           *PUBLIC HEALTH EMERGENCIES.—If a vaccine is*  
6           *designated as a breakthrough therapy under sec-*  
7           *tion 506 of the Federal Food, Drug, and Cos-*  
8           *metic Act and is licensed under section 351 of*  
9           *this Act, the Advisory Committee shall make rec-*  
10          *ommendations with respect to the use of the vac-*  
11          *cine on an expedited basis.*

12          “(D) *DEFINITION.—In this paragraph, the*  
13          *terms ‘Advisory Committee on Immunization*  
14          *Practices’ and ‘Advisory Committee’ mean the*  
15          *advisory committee on immunization practices*  
16          *established by the Secretary pursuant to section*  
17          *222, acting through the Director of the Centers*  
18          *for Disease Control and Prevention.”.*

19   **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**  
20            **ACIP RECOMMENDATIONS.**

21          “(a) *REVIEW.—The Director of the Centers for Disease*  
22          *Control and Prevention shall conduct a review of the process*  
23          *used by the Advisory Committee on Immunization Practices*  
24          *to evaluate consistency in formulating and issuing rec-*  
25          *ommendations pertaining to vaccines.*

1       (b) *CONSIDERATIONS.*—*The review under subsection*  
2 *(a) shall include assessment of—*

3           (1) *the criteria used to evaluate new and existing*  
4 *vaccines;*

5           (2) *the Grading of Recommendations, Assess-*  
6 *ment, Development, and Evaluation (GRADE) ap-*  
7 *proach to the review and analysis of scientific and*  
8 *economic data, including the scientific basis for such*  
9 *approach; and*

10          (3) *the extent to which the processes used by the*  
11 *working groups of the Advisory Committee on Immu-*  
12 *nization Practices are consistent among groups.*

13       (c) *STAKEHOLDERS.*—*In carrying out the review*  
14 *under subsection (a), the Director of the Centers for Disease*  
15 *Control and Prevention shall solicit input from vaccine*  
16 *stakeholders.*

17       (d) *REPORT.*—*Not later than 18 months after the date*  
18 *of enactment of this Act, the Director of the Centers for Dis-*  
19 *ease Control and Prevention shall submit to the appropriate*  
20 *committees of the Congress and make publicly available a*  
21 *report on the results of the review under subsection (a), in-*  
22 *cluding recommendations on improving the consistency of*  
23 *the process described in such subsection.*

24       (e) *DEFINITION.*—*In this section, the term “Advisory*  
25 *Committee on Immunization Practices” means the advisory*

1 *committee on immunization practices established by the*  
2 *Secretary of Health and Human Services pursuant to sec-*  
3 *tion 222 of the Public Health Service Act (42 U.S.C. 217a),*  
4 *acting through the Director of the Centers for Disease Con-*  
5 *trol and Prevention.*

6 **SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**  
7 **OPERS.**

8 *Section 310 of the Public Health Service Act (42*  
9 *U.S.C. 242o) is amended by adding at the end the following:*

10 *“(c)(1) In this subsection, the term ‘vaccine developer’*  
11 *means a nongovernmental entity engaged in—*

12 *“(A)(i) the development of a vaccine with the in-*  
13 *tent to pursue licensing of the vaccine by the Food*  
14 *and Drug Administration; or*

15 *“(ii) the production of a vaccine licensed by the*  
16 *Food and Drug Administration; and*

17 *“(B) vaccine research.*

18 *“(2)(A) Upon the submission of a written request for*  
19 *a meeting by a vaccine developer, that includes a justifica-*  
20 *tion for the meeting, the Secretary, acting through the Di-*  
21 *rector of the Centers for Disease Control and Prevention,*  
22 *shall convene a meeting of representatives of the vaccine de-*  
23 *veloper and experts from the Centers for Disease Control*  
24 *and Prevention in immunization programs, epidemiology,*  
25 *and other relevant areas at which the Director (or the Di-*

1 rector's designee), for the purpose of informing the vaccine  
2 developer's understanding of public health needs and prior-  
3 ities, shall provide the perspectives of the Centers for Dis-  
4 ease Control and Prevention and other relevant Federal  
5 agencies regarding—

6           “(i) public health needs, epidemiology, and im-  
7           plementation considerations with regard to a vaccine  
8           developer's potential vaccine profile; and

9           “(ii) potential implications of such perspectives  
10          for the vaccine developer's vaccine research and devel-  
11          opment planning.

12          “(B) In addition to the representatives specified in  
13          subparagraph (A), the Secretary may, with the agreement  
14          of the vaccine developer requesting a meeting under such  
15          subparagraph, include in such meeting representatives of—

16               “(i) the Food and Drug Administration; and

17               “(ii) the National Vaccine Program.

18          “(C) The Secretary shall convene a meeting requested  
19          under subparagraph (A) not later than 120 days after re-  
20          ceipt of the request for the meeting.

21          “(3)(A) Upon the submission of a written request by  
22          a vaccine developer, the Secretary, acting through the Direc-  
23          tor of the Centers for Disease Control and Prevention, shall  
24          provide to the vaccine developer any age-based or other de-

1 *mographically assessed disease epidemiological analyses or*  
2 *data that—*

3           “(i) *are specified in the request;*

4           “(ii) *have been published;*

5           “(iii) *have been performed by or are in the pos-*  
6 *session of the Centers;*

7           “(iv) *are not a trade secret or commercial or fi-*  
8 *nancial information that is privileged or confidential*  
9 *and subject to section 552(b)(4) of title 5, United*  
10 *States Code, or section 1905 of title 18, United States*  
11 *Code; and*

12           “(v) *do not contain individually identifiable in-*  
13 *formation.*

14           “(B) *The Secretary shall provide analyses requested by*  
15 *a vaccine manufacturer under subparagraph (A) not later*  
16 *than 120 calendar days after receipt of the request for the*  
17 *analyses.*

18           “(4) *The Secretary shall promptly notify a vaccine de-*  
19 *veloper if—*

20           “(A) *the Secretary becomes aware of any change*  
21 *to information that was—*

22           “(i) *shared by the Secretary with the vac-*  
23 *cine developer during a meeting under para-*  
24 *graph (2); or*

1           “(i) provided by the Secretary to the vac-  
 2           cine developer in one or more analyses under  
 3           paragraph (3); and

4           “(B) the change to such information may have  
 5           implications for the vaccine developer’s vaccine re-  
 6           search and development.”.

7 ***Subtitle I—Orphan Product Exten-***  
 8 ***sions Now; Incentives for Cer-***  
 9 ***tain Products for Limited Popu-***  
 10 ***lations***

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

14           (a) *IN GENERAL.*—Chapter V of the Federal Food,  
 15 Drug, and Cosmetic Act, as amended by sections 2062 and  
 16 2063, is further amended by inserting after section 505H  
 17 of such Act the following:

18 ***“SEC. 505I. EXTENSION OF EXCLUSIVITY PERIODS FOR A***  
 19 ***DRUG APPROVED FOR A NEW INDICATION***  
 20 ***FOR A RARE DISEASE OR CONDITION.***

21           “(a) *DESIGNATION.*—

22           “(1) *IN GENERAL.*—The Secretary shall des-  
 23           ignate a drug as a drug approved for a new indica-  
 24           tion to prevent, diagnose, or treat a rare disease or



1       *condition for purposes of granting the extensions*  
2       *under subsection (b) if—*

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

9               “(B)(i) *the sponsor of the approved or li-*  
10              *censed drug files an application or a supple-*  
11              *mental application for approval of the new indi-*  
12              *cation for use of the drug to prevent, diagnose,*  
13              *or treat the rare disease or condition; and*

14              “(i) *the Secretary approves the application*  
15              *or supplemental application; and*

16              “(C) *the application or supplemental appli-*  
17              *cation for the new indication contains the con-*  
18              *sent of the applicant to notice being given by the*  
19              *Secretary under paragraph (4) respecting the*  
20              *designation of the drug.*

21       “(2) *REVOCATION OF DESIGNATION.—*

22              “(A) *IN GENERAL.—Except as provided in*  
23              *subparagraph (B), a designation under para-*  
24              *graph (1) shall not be revoked for any reason.*

1           “(B) *EXCEPTION.*—*The Secretary may re-*  
2           *voke a designation of a drug under paragraph*  
3           *(1) if the Secretary finds that the application or*  
4           *supplemental application resulting in such des-*  
5           *ignation contained an untrue statement of mate-*  
6           *rial fact.*

7           “(3) *NOTIFICATION PRIOR TO DISCONTINUANCE*  
8           *OF PRODUCTION FOR SOLELY COMMERCIAL REA-*  
9           *SONS.*—*A designation of a drug under paragraph (1)*  
10          *shall be subject to the condition that the sponsor of the*  
11          *drug will notify the Secretary of any discontinuance*  
12          *of the production of the drug for solely commercial*  
13          *reasons at least one year before such discontinuance.*

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

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

20                 “(1)(A) *the 4-, 5-, and 7<sup>1</sup>/<sub>2</sub>-year periods de-*  
21                 *scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of*  
22                 *section 505, the 3-year periods described in clauses*  
23                 *(iii) and (iv) of subsection (c)(3)(E) and clauses (iii)*  
24                 *and (iv) of subsection (j)(5)(F) of section 505, and the*

1       7-year period described in section 527, as applicable,  
2       shall be extended by 6 months; or

3               “(B) the 4- and 12-year periods described in sub-  
4       paragraphs (A) and (B) of section 351(k)(7) of the  
5       Public Health Service Act and the 7-year period de-  
6       scribed in section 527, as applicable, shall be extended  
7       by 6 months; and

8               “(2)(A) if the drug is the subject of a listed pat-  
9       ent for which a certification has been submitted under  
10       subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section  
11       505 or a listed patent for which a certification has  
12       been submitted under subsections (b)(2)(A)(iii) or  
13       (j)(2)(A)(vii)(III) of section 505, the period during  
14       which an application may not be approved under sec-  
15       tion 505(c)(3) or section 505(j)(5)(B) shall be ex-  
16       tended by a period of 6 months after the date the pat-  
17       ent expires (including any patent extensions); or

18               “(B) if the drug is the subject of a listed patent  
19       for which a certification has been submitted under  
20       subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section  
21       505, and in the patent infringement litigation result-  
22       ing from the certification the court determines that  
23       the patent is valid and would be infringed, the period  
24       during which an application may not be approved  
25       under section 505(c)(3) or section 505(j)(5)(B) shall

1        *be extended by a period of 6 months after the date the*  
2        *patent expires (including any patent extensions).*

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

9        “(d) *LIMITATIONS.—The extension described in sub-*  
10        *section (b) shall not apply if the drug designated under sub-*  
11        *section (a)(1) has previously received an extension by oper-*  
12        *ation of subsection (b).*

13        “(e) *DEFINITION.—In this section, the term ‘rare dis-*  
14        *ease or condition’ has the meaning given to such term in*  
15        *section 526(a)(2).”.*

16        (b) *APPLICATION.—Section 505G of the Federal Food,*  
17        *Drug, and Cosmetic Act, as added by subsection (a), applies*  
18        *only with respect to a drug for which an application or*  
19        *supplemental application described in subsection*  
20        *(a)(1)(B)(i) of such section 505G is first approved under*  
21        *section 505(c) of such Act (21 U.S.C. 355(c)) or section*  
22        *351(a) of the Public Health Service Act (42 U.S.C. 262(a))*  
23        *on or after the date of the enactment of this Act.*

24        (c) *CONFORMING AMENDMENTS.—*

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

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

6           “(3) *RELATION TO EXCLUSIVITY FOR A DRUG AP-*  
7 *PROVED FOR A NEW INDICATION FOR A RARE DISEASE*  
8 *OR CONDITION.—Notwithstanding the references in*  
9 *paragraph (1) to the lengths of the exclusivity periods*  
10 *after application of pediatric exclusivity, the 6-month*  
11 *extensions described in paragraph (1) shall be in ad-*  
12 *dition to any extensions under section 505G.”; and*

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

15           “(3) *RELATION TO EXCLUSIVITY FOR A DRUG AP-*  
16 *PROVED FOR A NEW INDICATION FOR A RARE DISEASE*  
17 *OR CONDITION.—Notwithstanding the references in*  
18 *paragraph (1) to the lengths of the exclusivity periods*  
19 *after application of pediatric exclusivity, the 6-month*  
20 *extensions described in paragraph (1) shall be in ad-*  
21 *dition to any extensions under section 505G.”.*

22           (2) *RELATION TO EXCLUSIVITY FOR NEW QUALI-*  
23 *FIED INFECTIOUS DISEASE PRODUCTS THAT ARE*  
24 *DRUGS.—Subsection (b) of section 505E of the Fed-*

1 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 355f)*  
2 *is amended—*

3 *(A) by amending the subsection heading to*  
4 *read as follows: “RELATION TO PEDIATRIC EX-*  
5 *CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-*  
6 *PROVED FOR A NEW INDICATION FOR A RARE*  
7 *DISEASE OR CONDITION.—”; and*

8 *(B) by striking “any extension of the period*  
9 *under section 505A” and inserting “any exten-*  
10 *sion of the periods under sections 505A and*  
11 *505G, as applicable,”.*

12 *(3) RELATION TO PEDIATRIC EXCLUSIVITY FOR*  
13 *BIOLOGICAL PRODUCTS.—Section 351(m) of the Pub-*  
14 *lic Health Service Act (42 U.S.C. 262(m)) is amended*  
15 *by adding at the end the following:*

16 *“(5) RELATION TO EXCLUSIVITY FOR A BIOLOGI-*  
17 *CAL PRODUCT APPROVED FOR A NEW INDICATION FOR*  
18 *A RARE DISEASE OR CONDITION.—Notwithstanding*  
19 *the references in paragraphs (2)(A), (2)(B), (3)(A),*  
20 *and (3)(B) to the lengths of the exclusivity periods*  
21 *after application of pediatric exclusivity, the 6-month*  
22 *extensions described in such paragraphs shall be in*  
23 *addition to any extensions under section 505G.”.*

1 **SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**  
2 **EASE PRIORITY REVIEW VOUCHER INCENTIVE**  
3 **PROGRAM.**

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

6 (1) *in subsection (a)*—

7 (A) *in paragraph (3), by amending sub-*  
8 *paragraph (A) to read as follows:*

9 “(A) *The disease is a serious or life-threat-*  
10 *ening disease in which the serious or life-threat-*  
11 *ening manifestations primarily affect individ-*  
12 *uals aged from birth to 18 years, including age*  
13 *groups often called neonates, infants, children,*  
14 *and adolescents.”; and*

15 (B) *in paragraph (4)*—

16 (i) *in subparagraph (E), by striking*  
17 *“and” at the end;*

18 (ii) *in subparagraph (F), by striking*  
19 *the period at the end and inserting “; and”;*  
20 *and*

21 (iii) *by adding at the end the fol-*  
22 *lowing:*

23 “(G) *is for a drug or biological product for*  
24 *which a priority review voucher has not been*  
25 *issued under section 524 (relating to tropical*  
26 *disease products).”;* and

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

3           “(5) *TERMINATION OF AUTHORITY.—The Sec-*  
4 *retary may not award any priority review vouchers*  
5 *under paragraph (1) after December 31, 2018.”.*

6           ***(b) GAO STUDY AND REPORT.—***

7           ***(1) STUDY.—The Comptroller General of the***  
8 *United States shall conduct a study on the effective-*  
9 *ness of awarding priority review vouchers under sec-*  
10 *tion 529 of the Federal Food, Drug, and Cosmetic Act*  
11 *(21 U.S.C. 360ff) in providing incentives for the de-*  
12 *velopment of drugs that treat or prevent rare pedi-*  
13 *atric diseases (as defined in subsection (a)(3) of such*  
14 *section) that would not otherwise have been developed.*  
15 *In conducting such study, the Comptroller General*  
16 *shall examine the following:*

17                   ***(A) The indications for which each drug for***  
18 *which a priority review voucher was awarded*  
19 *under such section 529 was approved under sec-*  
20 *tion 505 of such Act (21 U.S.C. 355) or section*  
21 *351 of the Public Health Service Act (42 U.S.C.*  
22 *262).*

23                   ***(B) Whether the priority review voucher im-***  
24 *acted a sponsor’s decision to invest in devel-*



1            *oping a drug to treat or prevent a rare pediatric*  
2            *disease.*

3            *(C) An analysis of the drugs that utilized*  
4            *such priority review vouchers, which shall in-*  
5            *clude—*

6                    *(i) the indications for which such*  
7                    *drugs were approved under section 505 of*  
8                    *the Federal Food, Drug, and Cosmetic Act*  
9                    *(21 U.S.C. 355) or section 351 of the Public*  
10                   *Health Service Act (42 U.S.C. 262);*

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

14                            *(I) if an alternative therapy was*  
15                            *previously available to treat the indi-*  
16                            *cation; and*

17                            *(II) the benefit or advantage the*  
18                            *drug provided over another available*  
19                            *therapy;*

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

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

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

4                   (D) With respect to the priority review  
5                   voucher program under section 529 of the Fed-  
6                   eral Food, Drug, and Cosmetic Act (21 U.S.C.  
7                   360ff)—

8                   (i) the resources used by, and burden  
9                   placed on, the Food and Drug Administra-  
10                  tion in implementing such program, includ-  
11                  ing the effect of such program on the Food  
12                  and Drug Administration's review of drugs  
13                  for which a priority review voucher was not  
14                  awarded or used;

15                  (ii) the impact of the program on the  
16                  public health as a result of the expedited re-  
17                  view of applications for drugs that treat or  
18                  prevent non-serious indications that are  
19                  generally used by the broader public; and

20                  (iii) alternative approaches to improv-  
21                  ing such program so that the program is  
22                  appropriately targeted toward providing in-  
23                  centives for the development of clinically  
24                  important drugs that—

1                   (I) prevent or treat rare pediatric  
2                   diseases; and

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

6                   (2) *REPORT.*—Not later than December 31, 2017,  
7                   the Comptroller General of the United States shall  
8                   submit to the Committee on Energy and Commerce of  
9                   the House of Representatives and the Committee on  
10                  Health, Education, Labor and Pensions of the Senate  
11                  a report containing the results of the study of con-  
12                  ducted under paragraph (1).

13                  ***Subtitle J—Domestic Manufac-***  
14                  ***turing and Export Efficiencies***

15                  ***SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-***  
16                  ***TINUOUS DRUG MANUFACTURING.***

17                  (a) *IN GENERAL.*—The Commissioner of Food and  
18                  Drugs may award grants to institutions of higher education  
19                  and nonprofit organizations for the purpose of studying  
20                  and recommending improvements to the process of contin-  
21                  uous manufacturing of drugs and biological products and  
22                  similar innovative monitoring and control techniques.

23                  (b) *DEFINITIONS.*—In this section:

1           (1) *The term “drug” has the meaning given to*  
2 *such term in section 201 of the Federal Food, Drug,*  
3 *and Cosmetic Act (21 U.S.C. 321).*

4           (2) *The term “biological product” has the mean-*  
5 *ing given to such term in section 351(i) of the Public*  
6 *Health Service Act (42 U.S.C. 262(i)).*

7           (3) *The term “institution of higher education”*  
8 *has the meaning given to such term in section 101 of*  
9 *the Higher Education Act of 1965 (20 U.S.C. 1001).*

10       (c) *AUTHORIZATION OF APPROPRIATIONS.—There is*  
11 *authorized to be appropriated to carry out this section*  
12 *\$5,000,000 for each of fiscal years 2016 through 2020.*

13 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**  
14 **ROPEAN ECONOMIC AREA.**

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

17           (1) *in subsection (f)—*

18               (A) *in paragraph (5)—*

19                   (i) *by striking “(5)” and inserting*  
20 *“(5)(A)”;*

21                   (ii) *by inserting “, except that the con-*  
22 *trolled substance may be exported from the*  
23 *second country to another country that is a*  
24 *member of the European Economic Area”*  
25 *before the period at the end; and*

1                   (iii) by adding at the end the fol-  
2                   lowing:

3                   “(B) Subsequent to any re-exportation described  
4                   in subparagraph (A), a controlled substance may con-  
5                   tinue to be exported from any country that is a mem-  
6                   ber of the European Economic Area to any other such  
7                   country, provided that—

8                   “(i) the conditions applicable with respect  
9                   to the first country under paragraphs (1), (2),  
10                  (3), (4), (6), and (7) are met by each subsequent  
11                  country from which the controlled substance is  
12                  exported pursuant to this paragraph; and

13                  “(ii) the conditions applicable with respect  
14                  to the second country under such paragraphs are  
15                  met by each subsequent country to which the con-  
16                  trolled substance is exported pursuant to this  
17                  paragraph.”; and

18                  (B) in paragraph (6)—

19                         (i) by striking “(6)” and inserting  
20                         “(6)(A)”; and

21                         (ii) by adding at the end the following:

22                         “(B) In the case of re-exportation among mem-  
23                         bers of the European Economic Area, within 30 days  
24                         after each re-exportation, the person who exported the

1       *controlled substance from the United States delivers to*  
2       *the Attorney General—*

3               “(i) *documentation certifying that such re-*  
4               *exportation has occurred; and*

5               “(ii) *information concerning the consignee,*  
6               *country, and product.*”; and

7               (2) *by adding at the end the following:*

8               “(g) *LIMITATION.—The Attorney General shall not*  
9       *promulgate nor enforce any regulation, subregulatory guid-*  
10       *ance, or enforcement policy which impedes re-exportation*  
11       *among European Economic Area countries (as provided in*  
12       *subsection (f)(5)), including by promulgating or enforcing*  
13       *any requirement that—*

14               “(1) *re-exportation from the first country to the*  
15       *second country or re-exportation from the second*  
16       *country to another country (as such terms are used*  
17       *in subsection (f)) occur within a specified period of*  
18       *time; or*

19               “(2) *information concerning the consignee, coun-*  
20       *try, and product be provided prior to exportation of*  
21       *the controlled substance from the United States or*  
22       *prior to each re-exportation among members of the*  
23       *European Economic Area.*”.

1                   **Subtitle K—Enhancing**  
2                   **Combination Products Review**

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

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

7           “(iii) Not later than 18 months after the date of the  
8   enactment of the 21st Century Cures Act, the Secretary shall  
9   issue final guidance that describes the responsibilities of  
10 each agency center regarding its review of combination  
11 products. The Secretary shall, after soliciting public com-  
12 ment, review and update the guidance periodically.”.

13                   **Subtitle L—Priority Review for**  
14                   **Breakthrough Devices**

15   **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
16                   **VICES.**

17           (a) *IN GENERAL.*—Chapter V of the Federal Food,  
18 *Drug, and Cosmetic Act is amended—*

19                   (1) *in section 515(d)—*

20                           (A) *by striking paragraph (5); and*

21                           (B) *by redesignating paragraph (6) as*  
22                   *paragraph (5); and*

23                   (2) *by inserting after section 515A (21 U.S.C.*  
24                   *360e–1) the following:*

1 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
2 **VICES.**

3 *“(a) IN GENERAL.—In order to provide for more effec-*  
4 *tive treatment or diagnosis of life-threatening or irrevers-*  
5 *ibly debilitating human diseases or conditions, the Sec-*  
6 *retary shall establish a program to provide priority review*  
7 *for devices—*

8 *“(1) representing breakthrough technologies;*

9 *“(2) for which no approved alternatives exist;*

10 *“(3) offering significant advantages over existing*  
11 *approved or cleared alternatives, including the poten-*  
12 *tial to, compared to existing approved or cleared al-*  
13 *ternatives, reduce or eliminate the need for hos-*  
14 *pitalization, improve patient quality of life, facilitate*  
15 *patients’ ability to manage their own care (such as*  
16 *through self-directed personal assistance), or establish*  
17 *long-term clinical efficiencies; or*

18 *“(4) the availability of which is in the best inter-*  
19 *est of patients.*

20 *“(b) REQUEST FOR DESIGNATION.—A sponsor of a de-*  
21 *vice may request that the Secretary designate the device for*  
22 *priority review under this section. Any such request for des-*  
23 *ignation may be made at any time prior to the submission*  
24 *of an application under section 515(c), a petition for classi-*  
25 *fication under section 513(f)(2), or a notification under sec-*  
26 *tion 510(k).*



1       “(c) *DESIGNATION PROCESS.*—

2               “(1) *IN GENERAL.*—Not later than 60 calendar  
3 days after the receipt of a request under subsection  
4 (b), the Secretary shall determine whether the device  
5 that is the subject of the request meets the criteria de-  
6 scribed in subsection (a). If the Secretary determines  
7 that the device meets the criteria, the Secretary shall  
8 designate the device for priority review.

9               “(2) *REVIEW.*—Review of a request under sub-  
10 section (b) shall be undertaken by a team that is com-  
11 posed of experienced staff and managers of the Food  
12 and Drug Administration and is chaired by a senior  
13 manager.

14               “(3) *DESIGNATION DETERMINATION.*—A deter-  
15 mination approving or denying a request under sub-  
16 section (b) shall be considered a significant decision  
17 under section 517A and the Secretary shall provide a  
18 written, substantive summary of the basis for the de-  
19 termination in accordance with section 517A(a).

20               “(4) *RECONSIDERATION.*—

21                       “(A) *REQUEST FOR RECONSIDERATION.*—  
22 Any person whose request under subsection (b) is  
23 denied may, within 30 days of the denial, re-  
24 quest reconsideration of the denial in accordance  
25 with section 517A(b)—

1                   “(i) based upon the submission of doc-  
2                   uments by such person; or

3                   “(ii) based upon such documents and a  
4                   meeting or teleconference.

5                   “(B) RESPONSE.—Reconsideration of a des-  
6                   ignation determination under this paragraph  
7                   shall be conducted in accordance with section  
8                   517A(b).

9                   “(5) WITHDRAWAL.—If the Secretary approves a  
10                  priority review designation for a device under this  
11                  section, the Secretary may not withdraw the designa-  
12                  tion based on the fact that the criteria specified in  
13                  subsection (a) are no longer met because of the subse-  
14                  quent clearance or approval of another device that  
15                  was designated under—

16                         “(A) this section; or

17                         “(B) section 515(d)(5) (as in effect imme-  
18                         diately prior to the enactment of the 21st Cen-  
19                         tury Cures Act).

20                  “(d) PRIORITY REVIEW.—

21                         “(1) ACTIONS.—For purposes of expediting the  
22                         development and review of devices designated under  
23                         subsection (c), the Secretary shall—

24                                 “(A) assign a team of staff, including a  
25                                 team leader with appropriate subject matter ex-

1            *pertise and experience, for each device for which*  
2            *a request is submitted under subsection (b);*

3            *“(B) provide for oversight of the team by*  
4            *senior agency personnel to facilitate the efficient*  
5            *development of the device and the efficient review*  
6            *of any submission described in subsection (b) for*  
7            *the device;*

8            *“(C) adopt an efficient process for timely*  
9            *dispute resolution;*

10           *“(D) provide for interactive communication*  
11           *with the sponsor of the device during the review*  
12           *process;*

13           *“(E) expedite the Secretary’s review of*  
14           *manufacturing and quality systems compliance,*  
15           *as applicable;*

16           *“(F) disclose to the sponsor in advance the*  
17           *topics of any consultation concerning the spon-*  
18           *sor’s device that the Secretary intends to under-*  
19           *take with external experts or an advisory com-*  
20           *mittee and provide the sponsor an opportunity*  
21           *to recommend such external experts;*

22           *“(G) for applications submitted under sec-*  
23           *tion 515(c), provide for advisory committee*  
24           *input, as the Secretary determines appropriate*

1           *(including in response to the request of the spon-*  
2           *sor); and*

3           *“(H) assign staff to be available within a*  
4           *reasonable time to address questions posed by in-*  
5           *stitutional review committees concerning the con-*  
6           *ditions and clinical testing requirements appli-*  
7           *cable to the investigational use of the device pur-*  
8           *suant to an exemption under section 520(g).*

9           *“(2) ADDITIONAL ACTIONS.—In addition to the*  
10          *actions described in paragraph (1), for purposes of*  
11          *expediting the development and review of devices des-*  
12          *ignated under subsection (c), the Secretary, in col-*  
13          *laboration with the device sponsor, may, as appro-*  
14          *priate—*

15                 *“(A) coordinate with the sponsor regarding*  
16                 *early agreement on a data development plan;*

17                 *“(B) take steps to ensure that the design of*  
18                 *clinical trials is as efficient as practicable, such*  
19                 *as through adoption of shorter or smaller clinical*  
20                 *trials, application of surrogate endpoints, and*  
21                 *use of adaptive trial designs and Bayesian sta-*  
22                 *tistics, to the extent scientifically appropriate;*

23                 *“(C) facilitate, to the extent scientifically*  
24                 *appropriate, expedited and efficient development*  
25                 *and review of the device through utilization of*

1 *timely postmarket data collection, with regard to*  
2 *applications for approval under section 515(c);*  
3 *and*

4 *“(D) agree to clinical protocols that the Sec-*  
5 *retary will consider binding on the Secretary*  
6 *and the sponsor, subject to—*

7 *“(i) changes agreed to by the sponsor*  
8 *and the Secretary;*

9 *“(ii) changes that the Secretary deter-*  
10 *mines are required to prevent an unreason-*  
11 *able risk to the public health; or*

12 *“(iii) the identification of a substan-*  
13 *tial scientific issue determined by the Sec-*  
14 *retary to be essential to the safety or effec-*  
15 *tiveness of the device involved.*

16 *“(e) PRIORITY REVIEW GUIDANCE.—*

17 *“(1) CONTENT.—The Secretary shall issue guid-*  
18 *ance on the implementation of this section. Such*  
19 *guidance shall include the following:*

20 *“(A) The process for a person to seek a pri-*  
21 *ority review designation.*

22 *“(B) A template for requests under sub-*  
23 *section (b).*

24 *“(C) The criteria the Secretary will use in*  
25 *evaluating a request for priority review.*

1           “(D) *The standards the Secretary will use*  
2           *in assigning a team of staff, including team*  
3           *leaders, to review devices designated for priority*  
4           *review, including any training required for such*  
5           *personnel on effective and efficient review.*

6           “(2) *PROCESS.—Prior to finalizing the guidance*  
7           *under paragraph (1), the Secretary shall propose such*  
8           *guidance for public comment.*

9           “(f) *CONSTRUCTION.—*

10           “(1) *PURPOSE.—This section is intended to en-*  
11           *courage the Secretary and provide the Secretary suffi-*  
12           *cient authorities to apply efficient and flexible ap-*  
13           *proaches to expedite the development of, and prioritize*  
14           *the agency’s review of, devices that represent break-*  
15           *through technologies.*

16           “(2) *CONSTRUCTION.—Nothing in this section*  
17           *shall be construed to alter the criteria and standards*  
18           *for evaluating an application pursuant to section*  
19           *515(c), a report and request for classification under*  
20           *section 513(f)(2), or a report under section 510(k), in-*  
21           *cluding the recognition of valid scientific evidence as*  
22           *described in section 513(a)(3)(B), and consideration*  
23           *of the least burdensome means of evaluating device ef-*  
24           *fectiveness or demonstrating substantial equivalence*  
25           *between devices with differing technological character-*

1       istics, as applicable. Nothing in this section alters the  
 2       authority of the Secretary to act on an application  
 3       pursuant to section 515(d) before completion of an es-  
 4       tablishment inspection, as the Secretary deems appro-  
 5       priate.”.

6       (b) *CONFORMING AMENDMENT RELATED TO DESIGNA-*  
 7       *TION DETERMINATIONS.*—Section 517A(a)(1) of the Federal  
 8       Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is  
 9       amended by inserting “a request for designation under sec-  
 10      tion 515B,” after “an application under section 515,”.

11                   ***Subtitle M—Medical Device***  
 12                   ***Regulatory Process Improvements***

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

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

18      ***“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.***

19           ***“(a) ACCREDITATION AND ASSESSMENT.—***

20                   ***“(1) IN GENERAL; CERTIFICATION OF DEVICE***  
 21      ***QUALITY SYSTEM.—The Secretary shall, in accordance***  
 22      ***with this section, establish a third-party quality sys-***  
 23      ***tem assessment program—***

24                           ***“(A) to accredit persons to assess whether a***  
 25                           ***requestor’s quality system, including its design***

1           *controls, can reasonably assure the safety and ef-*  
2           *fectiveness of in-scope devices subject to device-re-*  
3           *lated changes;*

4           “(B) *under which accredited persons shall*  
5           *(as applicable) certify that a requestor’s quality*  
6           *system meets the criteria included in the guid-*  
7           *ance issued under paragraph (5) with respect to*  
8           *the in-scope devices at issue; and*

9           “(C) *under which the Secretary shall rely*  
10          *on such certifications for purposes of deter-*  
11          *mining the safety and effectiveness (or as appli-*  
12          *cable, substantial equivalence) of in-scope devices*  
13          *subject to the device-related changes involved, in*  
14          *lieu of compliance with the following submission*  
15          *requirements:*

16                   “(i) *A premarket notification.*

17                   “(ii) *A thirty-day notice.*

18                   “(iii) *A Special PMA supplement.*

19          “(2) *DEFINITIONS.—For purposes of this sec-*  
20          *tion—*

21                   “(A) *the term ‘device-related changes’ means*  
22                   *changes made by a requestor with respect to in-*  
23                   *scope devices, which are—*

24                           “(i) *changes to a device found to be*  
25                           *substantially equivalent under sections*



1                   513(i) and 510(k) to a predicate device,  
2                   that—

3                               “(I) would otherwise be subject to  
4                               a premarket notification; and

5                               “(II) do not alter—

6                                       “(aa) the intended use of the  
7                                       changed device; or

8                                       “(bb) the fundamental sci-  
9                                       entific technology of such device;

10                                      “(ii) manufacturing changes subject to  
11                                      a 30-day notice;

12                                      “(iii) changes that qualify for a Spe-  
13                                      cial PMA Supplement; and

14                                      “(iv) such other changes relating to the  
15                                      devices or the device manufacturing process  
16                                      as the Secretary determines appropriate;

17                                      “(B) the term ‘in-scope device’ means a de-  
18                                      vice within the scope of devices agreed to by the  
19                                      requestor and the accredited person for purposes  
20                                      of a request for certification under this section;

21                                      “(C) the term ‘premarket notification’  
22                                      means a premarket notification under section  
23                                      510(k);

24                                      “(D) the term ‘quality system’ means the  
25                                      methods used in, and the facilities and controls

1           *used for, the design, manufacture, packaging, la-*  
2           *beling, storage, installation, and servicing of de-*  
3           *VICES, as described in section 520(f);*

4           *“(E) the term ‘requestor’ means a device*  
5           *manufacturer that is seeking certification under*  
6           *this section of a quality system used by such*  
7           *manufacturer;*

8           *“(F) the term ‘Special PMA’ means a Spe-*  
9           *cial PMA supplement under section 814.39(d) of*  
10           *title 21, Code of Federal Regulations (or any*  
11           *successor regulations); and*

12           *“(G) the term ‘thirty-day notice’ means a*  
13           *notice described in section 515(d)(6).*

14           *“(3) ACCREDITATION PROCESS; ACCREDITATION*  
15           *RENEWAL.—Except as inconsistent with this section,*  
16           *the process and qualifications for accreditation of per-*  
17           *sons and renewal of such accreditation under section*  
18           *704(g) shall apply with respect to accreditation of*  
19           *persons and renewal of such accreditation under this*  
20           *section.*

21           *“(4) USE OF ACCREDITED PARTIES TO CONDUCT*  
22           *ASSESSMENTS.—*

23           *“(A) INITIATION OF ASSESSMENT SERV-*  
24           *ICES.—*

1           “(i) *DATE ASSESSMENTS AUTHORIZED.*—Beginning after the date on which  
2           the final guidance is issued under para-  
3           graph (5), an accredited person may con-  
4           duct an assessment under this section.  
5

6           “(ii) *INITIATION OF ASSESSMENTS.*—  
7           Use of one or more accredited persons to as-  
8           sess a requestor’s quality system under this  
9           section with respect to in-scope devices shall  
10          be at the initiation of the person who reg-  
11          isters and lists the devices at issue under  
12          section 510.

13          “(B) *COMPENSATION.*—Compensation for  
14          such accredited persons shall—

15                 “(i) be determined by agreement be-  
16                 tween the accredited person and the person  
17                 who engages the services of the accredited  
18                 person; and

19                 “(ii) be paid by the person who en-  
20                 gages such services.

21          “(C) *ACCREDITED PERSON SELECTION.*—  
22          Each person who chooses to use an accredited  
23          person to assess a requestor’s quality system, as  
24          described in this section, shall select the accred-  
25          ited person from a list of such persons published

1           *by the Secretary in accordance with section*  
2           *704(g)(4).*

3           “(5) *GUIDANCE; CRITERIA FOR CERTIFI-*  
4           *CATION.—*

5                   “(A) *IN GENERAL.—The criteria for certifi-*  
6                   *cation of a quality system under this section*  
7                   *shall be as specified by the Secretary in guidance*  
8                   *issued under this paragraph.*

9                   “(B) *CONTENTS; CERTIFICATION CRI-*  
10                   *TERIA.—The guidance under this paragraph*  
11                   *shall include specification of—*

12                           “(i) *evaluative criteria to be used by*  
13                           *an accredited person to assess and, as ap-*  
14                           *plicable, certify a requestor’s quality system*  
15                           *under this section with respect to in-scope*  
16                           *devices; and*

17                           “(ii) *criteria for accredited persons to*  
18                           *apply for a waiver of, and exemptions from,*  
19                           *the certification criteria under clause (i).*

20                   “(C) *TIMEFRAME FOR ISSUING GUID-*  
21                   *ANCE.—The Secretary shall issue under this*  
22                   *paragraph—*

23                           “(i) *draft guidance not later than 12*  
24                           *months after the enactment of the 21st Cen-*  
25                           *tury Cures Act; and*

1                   “(i) final guidance not later than 12  
2                   months after issuance of the draft guidance  
3                   under clause (i).

4                   “(b) USE OF THIRD-PARTY ASSESSMENT.—

5                   “(1) ASSESSMENT SUMMARY; CERTIFICATION.—

6                   “(A) SUBMISSION OF ASSESSMENT TO SEC-  
7                   RETARY.—An accredited person who assesses a  
8                   requestor’s quality system under subsection (a)  
9                   shall submit to the Secretary a summary of the  
10                  assessment—

11                  “(i) within 30 days of the assessment;

12                  and

13                  “(ii) which shall include (as applica-  
14                  ble)—

15                         “(I) the accredited person’s certifi-  
16                         cation that the requestor has satisfied  
17                         the criteria specified in the guidance  
18                         issued under subsection (a)(5) for qual-  
19                         ity system certification with respect to  
20                         the in-scope devices at issue; and

21                         “(II) any waivers or exemptions  
22                         from such criteria applied by the ac-  
23                         credited person.

24                   “(B) TREATMENT OF ASSESSMENTS.—Sub-  
25                   ject to action by the Secretary under subpara-

1 graph (C), with respect to assessments which in-  
2 clude a certification under this section—

3 “(i) the Secretary’s review of the as-  
4 sessment summary shall be deemed complete  
5 on the day that is 30 days after the date on  
6 which the Secretary receives the summary  
7 under subparagraph (A); and

8 “(ii) the assessment summary and cer-  
9 tification of the quality system of a re-  
10 questor shall be deemed accepted by the Sec-  
11 retary on such 30th day.

12 “(C) ACTIONS BY SECRETARY.—

13 “(i) *IN GENERAL.*—Within 30 days of  
14 receiving an assessment summary and cer-  
15 tification under subparagraph (A), the Sec-  
16 retary may, by written notice to the accred-  
17 ited person submitting such assessment cer-  
18 tification, deem any such certification to be  
19 provisional beyond such 30-day period, sus-  
20 pended pending further review by the Sec-  
21 retary, or otherwise qualified or cancelled,  
22 based on the Secretary’s determination that  
23 (as applicable)—

24 “(I) additional information is  
25 needed to support such certification;

1           “(II) such assessment or certifi-  
2           cation is unwarranted; or

3           “(III) such action with regard to  
4           the certification is otherwise justified  
5           according to such factors and criteria  
6           as the Secretary finds appropriate.

7           “(ii) ACCEPTANCE OF CERTIFI-  
8           CATION.—If following action by the Sec-  
9           retary under clause (i) with respect to a  
10          certification, the Secretary determines that  
11          such certification is acceptable, the Sec-  
12          retary shall issue written notice to the ap-  
13          plicable accredited person indicating such  
14          acceptance.

15          “(2) NOTIFICATIONS TO SECRETARY BY CER-  
16          TIFIED REQUESTORS OR ACCREDITED PERSONS FOR  
17          PROGRAM EVALUATION PURPOSES.—

18                 “(A) ANNUAL SUMMARY REPORT FOR DE-  
19                 VICE-RELATED CHANGES OTHERWISE SUBJECT  
20                 TO PREMARKET NOTIFICATION.—A requestor  
21                 whose quality system is certified under this sec-  
22                 tion that effectuates device-related changes with  
23                 respect to in-scope devices, without prior submis-  
24                 sion of a premarket notification, shall ensure

1           that an annual summary report is submitted to  
2           the Secretary by the accredited person which—

3                   “(i) describes the changes made to the  
4                   in-scope device; and

5                   “(ii) indicates the effective dates of  
6                   such changes.

7           “(B) *PERIODIC NOTIFICATION FOR MANU-*  
8           *FACTURING CHANGES OTHERWISE SUBJECT TO*  
9           *THIRTY-DAY NOTICE.*—A requestor whose quality  
10          system is certified under this section that effec-  
11          tuates device-related changes with respect to in-  
12          scope devices, without prior submission of a thir-  
13          ty-day notice, shall provide notification to the  
14          Secretary of such changes in the requestor’s next  
15          periodic report under section 814.84(b) of title  
16          21, Code of Federal Regulations (or any suc-  
17          cessor regulation). Such notification shall—

18                   “(i) describe the changes made; and

19                   “(ii) indicate the effective dates of such  
20                   changes.

21          “(C) *PERIODIC NOTIFICATION FOR DEVICE-*  
22          *RELATED CHANGES OTHERWISE SUBJECT TO*  
23          *SPECIAL PMA SUPPLEMENT.*—A requestor whose  
24          quality system is certified under this section that  
25          effectuates device-related changes with respect to



1 *in-scope devices, without prior submission of a*  
2 *Special PMA Supplement, shall provide notifica-*  
3 *tion to the Secretary of such changes in the re-*  
4 *questor's next periodic report under section*  
5 *814.84(b) of title 21, Code of Federal Regulations*  
6 *(or any successor regulation). Such notification*  
7 *shall—*

8 *“(i) describe the changes made, includ-*  
9 *ing a full explanation of the basis for the*  
10 *changes; and*

11 *“(ii) indicate the effective dates of such*  
12 *changes.*

13 *“(D) USE OF NOTIFICATIONS FOR PROGRAM*  
14 *EVALUATION PURPOSES.—Information submitted*  
15 *to the Secretary under subparagraphs (A)*  
16 *through (C) shall be used by the Secretary for*  
17 *purposes of the program evaluation under sub-*  
18 *section (d).*

19 *“(c) DURATION AND EFFECT OF CERTIFICATION.—A*  
20 *certification under this section—*

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

24 *“(2) may be renewed through the process de-*  
25 *scribed in subsection (a)(3);*

1           “(3) shall continue to apply with respect to de-  
2           vice-related changes made during such 2-year period,  
3           provided the certification remains in effect, irrespec-  
4           tive of whether such certification is renewed after such  
5           2-year period;

6           “(4) shall have no effect on the need to comply  
7           with applicable submission requirements specified in  
8           subsection (a)(1)(C) with respect to any change per-  
9           taining to in-scope devices which is not a device-re-  
10          lated change under subsection (a)(2);

11          “(5) shall have no effect on the authority of the  
12          Secretary to conduct an inspection or otherwise deter-  
13          mine whether the requestor has complied with the ap-  
14          plicable requirements of this Act; and

15          “(6) may be revoked by the Secretary upon a de-  
16          termination that the requestor’s quality system no  
17          longer meets the certification criteria specified in the  
18          guidance issued under subsection (a)(5) with respect  
19          to the in-scope devices at issue.

20          “(d) NOTICE OF REVOCATION.—The Secretary shall  
21          provide written notification to the requestor of a revocation  
22          pursuant to subsection (c)(6) not later than 10 business  
23          days after the determination described in such subsection.  
24          Upon receipt of the written notification, the requestor shall  
25          satisfy the applicable submission requirements specified in

1 *subsection (a)(1)(C) for any device-related changes effec-*  
2 *tuated after the date of such determination. After such rev-*  
3 *ocation, such requestor is eligible to seek re-certification*  
4 *under this section of its quality system.*

5 *“(e) PROGRAM EVALUATION; SUNSET.—*

6 *“(1) PROGRAM EVALUATION AND REPORT.—*

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

11 *“(i) analysis of information from a*  
12 *representative group of device manufactur-*  
13 *ers obtained from notifications provided by*  
14 *certified requestors or accredited persons*  
15 *under subsection (b)(2); and*

16 *“(ii) such other available information*  
17 *and data as the Secretary determines ap-*  
18 *propriate.*

19 *“(B) REPORT.—No later than 1 year after*  
20 *completing the evaluation under subparagraph*  
21 *(A), the Secretary shall issue a report of the eval-*  
22 *uation’s findings on the website of the Food and*  
23 *Drug Administration, which shall include the*  
24 *Secretary’s recommendations with respect to con-*

1           *tinuation and as applicable expansion of the*  
2           *program under this section to encompass—*

3                   “(i) *device submissions beyond those*  
4                   *identified in subsection (a)(1)(C); and*

5                   “(ii) *device changes beyond those de-*  
6                   *scribed in subsection (a)(2)(A).*

7           “(2) *SUNSET.—This section shall cease to be ef-*  
8           *fective October 1, 2022.*

9           “(f) *RULE OF CONSTRUCTION.—Nothing in this sec-*  
10          *tion shall be construed to limit the authority of the Sec-*  
11          *retary to request and review the complete assessment of a*  
12          *certified requestor under this section on a for-cause basis.”.*

13          (b) *CONFORMING AMENDMENTS.—*

14                  (1) *REQUIREMENTS FOR PREMARKET APPROVAL*  
15          *SUPPLEMENTS.—Section 515(d)(5)(A)(i) of the Fed-*  
16          *eral Food, Drug, and Cosmetic Act (21 U.S.C.*  
17          *360e(d)(5)(A)(i)), as redesignated by section 2201, is*  
18          *further amended by inserting “, subject to section*  
19          *524B” after “that affects safety or effectiveness”.*

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

1           (3) *REQUIREMENTS FOR PREMARKET NOTIFICA-*  
2           *TION; TECHNICAL CORRECTION TO REFERENCE TO*  
3           *SECTION 510(K).*—Section 510(l) of the Federal Food,  
4           Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amend-  
5           ed by striking “of this subsection under subsection  
6           (m)” and inserting “of subsection (k) under sub-  
7           section (m) or section 524B”.

8           (4) *MISBRANDED DEVICES.*—Section 502(t) of  
9           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10          352(t)) is amended by inserting “or 524B” after “sec-  
11          tion 519”.

12 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

13          Section 513(a)(3)(B) of the Federal Food, Drug, and  
14          Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

15                 (1) by redesignating clauses (i) and (ii) as sub-  
16                 clauses (I) and (II), respectively;

17                 (2) by striking “(B) If the Secretary” and insert-  
18                 ing “(B)(i) If the Secretary”; and

19                 (3) by adding at the end the following:

20                 “(ii) For purposes of clause (i), valid scientific evi-  
21                 dence may include—

22                         “(I) evidence described in well-documented case  
23                         histories, including registry data, that are collected  
24                         and monitored under an acceptable protocol;

1           “(II) studies published in peer-reviewed journals;  
2           and

3           “(III) data collected in countries other than the  
4           United States so long as such data otherwise meet the  
5           criteria specified in this subparagraph.

6           “(iii) In the case of a study published in a peer-re-  
7           viewed journal that is offered as valid scientific evidence  
8           for purposes of clause (i), the Secretary may request data  
9           underlying the study if—

10           “(I) the Secretary, in making such request, com-  
11           plies with the requirement of subparagraph (D)(ii) to  
12           consider the least burdensome appropriate means of  
13           evaluating device effectiveness or subsection (i)(1)(D)  
14           to consider the least burdensome means of deter-  
15           mining substantial equivalence, as applicable;

16           “(II) the Secretary furnishes a written rationale  
17           for so requesting the underlying data together with  
18           such request; and

19           “(III) if the requested underlying data for such  
20           a study are unavailable, the Secretary shall consider  
21           such study to be part of the totality of the evidence  
22           with respect to the device, as the Secretary determines  
23           appropriate.”.

1 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**  
2 **SOME APPROPRIATE MEANS CONCEPT.**

3 (a) *IN GENERAL.*—Section 513 of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by  
5 adding at the end the following:

6 “(j) *TRAINING AND OVERSIGHT IN LEAST BURDEN-*  
7 *SOME APPROPRIATE MEANS CONCEPT.*—

8 “(1) *TRAINING.*—Each employee of the Food and  
9 Drug Administration who is involved in the review of  
10 premarket submissions under section 515 or section  
11 510(k), including supervisors, shall receive training  
12 regarding the meaning and implementation of the  
13 least burdensome appropriate means concept in the  
14 context of the use of that term in subsections  
15 (a)(3)(D) and (i)(1)(D) of this section and in section  
16 515(c)(5).

17 “(2) *GUIDANCE DOCUMENTS.*—

18 “(A) *DRAFT UPDATED GUIDANCE.*—Not  
19 later than 12 months after the date of enactment  
20 of the 21st Century Cures Act, the Secretary  
21 shall issue a draft guidance document updating  
22 the October 4, 2002, guidance document entitled  
23 ‘The Least Burdensome Provision of the FDA  
24 Modernization Act of 1997: Concept and Prin-  
25 ciples; Final Guidance for FDA and Industry’.

1           “(B) *MEETING OF STAKEHOLDERS.*—*In de-*  
2           *veloping such draft guidance document, the Sec-*  
3           *retary shall convene a meeting of stakeholders to*  
4           *ensure a full record to support the publication of*  
5           *such document.*

6           “(3) *OMBUDSMAN AUDIT.*—*Not later than 18*  
7           *months after the date of issuance of final version of*  
8           *the draft guidance under paragraph (2), the ombuds-*  
9           *man for the organizational unit of the Food and*  
10          *Drug Administration responsible for the premarket*  
11          *review of devices shall—*

12                 “(A) *conduct, or have conducted, an audit*  
13                 *of the training described in paragraph (1); and*

14                 “(B) *include in such audit interviews with*  
15                 *a representative sample of persons from industry*  
16                 *regarding their experience in the device pre-*  
17                 *market review process.”.*

18          (b) *ADDITIONAL INFORMATION REGARDING PRE-*  
19          *MARKET APPLICATIONS.*—*Subsection (c) of section 515 of*  
20          *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*  
21          *is amended by adding at the end the following:*

22                 “(5)(A) *Whenever the Secretary requests additional in-*  
23                 *formation from an applicant regarding an application*  
24                 *under paragraph (1), the Secretary shall consider the least*  
25                 *burdensome appropriate means necessary to demonstrate*



1 *device safety and effectiveness, and request information ac-*  
2 *cordingly.*

3       “(B) *For purposes of subparagraph (A), the term ‘nec-*  
4 *essary’ means the minimum required information that*  
5 *would support a determination by the Secretary that an*  
6 *application provides a reasonable assurance of the safety*  
7 *and effectiveness of the device.*

8       “(C) *Nothing in this paragraph alters the standards*  
9 *for premarket approval of a device.’’.*

10 **SEC. 2224. RECOGNITION OF STANDARDS.**

11       *Section 514(c) of the Federal Food, Drug, and Cos-*  
12 *metic Act (21 U.S.C. 360d(c)) is amended—*

13             (1) *in paragraph (1), by inserting after subpara-*  
14 *graph (B) the following new subparagraphs:*

15       “(C)(i) *Any person may submit a request for recogni-*  
16 *tion under subparagraph (A) of all or part of an appro-*  
17 *priate standard established by a nationally or internation-*  
18 *ally recognized standard organization.*

19       “(ii) *Not later than 60 days after the Secretary re-*  
20 *ceives such a request, the Secretary shall—*

21             “(I) *make a determination to recognize all, part,*  
22 *or none of the standard that is the subject of the re-*  
23 *quest; and*

24             “(II) *issue to the person who submitted such re-*  
25 *quest a response in writing that states the Secretary’s*

1       *rationale for that determination, including the sci-*  
2       *entific, technical, regulatory, or other basis for such*  
3       *determination.*

4       “(iii) *The Secretary shall make a response issued*  
5       *under clause (ii)(II) publicly available, in such manner as*  
6       *the Secretary determines appropriate.*

7       “(iv) *The Secretary shall take such actions as may be*  
8       *necessary to implement all or part of a standard recognized*  
9       *under clause (i)(I), in accordance with subparagraph (A).*

10       “(D) *The Secretary shall make publicly available, in*  
11       *such manner as the Secretary determines appropriate, the*  
12       *rationale for recognition under subparagraph (A) of part*  
13       *of a standard, including the scientific, technical, regulatory,*  
14       *or other basis for such recognition.”; and*

15               (2) *by adding at the end the following new para-*  
16       *graphs:*

17               “(4) *TRAINING ON USE OF STANDARDS.—The*  
18       *Secretary shall provide to all employees of the Food*  
19       *and Drug Administration who review premarket sub-*  
20       *missions for devices periodic training on the concept*  
21       *and use of recognized standards for purposes of meet-*  
22       *ing a premarket submission requirement or other ap-*  
23       *plicable requirement under this Act, including stand-*  
24       *ards relevant to an employee’s area of device review.*

25               “(5) *GUIDANCE.—*

1           “(A) *DRAFT GUIDANCE.*—*The Secretary*  
2           *shall publish guidance identifying the principles*  
3           *for recognizing standards under this section. In*  
4           *publishing such guidance, the Secretary shall*  
5           *consider—*

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

9                     “(ii) *whether recognition of a standard*  
10                    *will promote harmonization among regu-*  
11                    *latory authorities in the regulation of de-*  
12                    *vices.*

13           “(B) *TIMING.*—*The Secretary shall pub-*  
14           *lish—*

15                    “(i) *draft guidance under subpara-*  
16                    *graph (A) not later than 12 months after*  
17                    *the date of the enactment of the 21st Cen-*  
18                    *ture Cures Act; and*

19                    “(ii) *final guidance not later than 12*  
20                    *months after the close of the public comment*  
21                    *period for the draft guidance under clause*  
22                    *(i).”.*

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

3 (a) *CLASS I DEVICES.*—Section 510(l) of the Federal  
4 *Food, Drug, and Cosmetic Act* (21 U.S.C. 360(l)) is amend-  
5 *ed—*

6 (1) *by striking “A report under subsection (k)”*  
7 *and inserting “(1) A report under subsection (k)”;*  
8 *and*

9 (2) *by adding at the end the following new para-*  
10 *graph:*

11 “(2) *Not later than 120 days after the date of the en-*  
12 *actment of the 21st Century Cures Act, the Secretary shall*  
13 *identify, through publication in the Federal Register, any*  
14 *type of class I device that the Secretary determines no*  
15 *longer requires a report under subsection (k) to provide rea-*  
16 *sonable assurance of safety and effectiveness. Upon such*  
17 *publication—*

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

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

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

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

3           “(A) not later than 60 days after the date of the  
4 enactment of the 21st Century Cures Act—

5           “(i) publish in the Federal Register a notice  
6 that contains a list of each type of class II device  
7 that the Secretary determines no longer requires  
8 a report under subsection (k) to provide reason-  
9 able assurance of safety and effectiveness; and

10           “(ii) provide for a period of not less than  
11 60 days for public comment beginning on the  
12 date of the publication of such notice; and

13           “(B) not later than 180 days after the date of the  
14 enactment of 21st Century Cures Act, publish in the  
15 Federal Register a list representing the Secretary’s  
16 final determination with respect to the devices in-  
17 cluded in the list published under subparagraph  
18 (A).”;

19           (2) in paragraph (2)—

20           (A) by striking “1 day after the date of the  
21 publication of a list under this subsection,” and  
22 inserting “1 day after the date of publication of  
23 the final list under paragraph (1)(B),”; and

24           (B) by striking “30-day period” and insert-  
25 ing “60-day period”; and

1           (3) by adding at the end the following new para-  
2 graph:

3           “(3) Upon the publication of the final list under para-  
4 graph (1)(B)—

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

8           “(B) the classification regulation applicable to  
9 each such type of device shall be deemed amended to  
10 incorporate such exemption.”.

11 **SEC. 2226. ADVISORY COMMITTEE PROCESS.**

12           (a) **CLASSIFICATION PANELS.**—Paragraph (5) of sec-  
13 tion 513(b) of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 360c(b)) is amended—

15           (1) by striking “(5)” and inserting “(5)(A)”;  
16 and

17           (2) by adding at the end the following:

18           “(B) When a device is specifically the subject of review  
19 by a classification panel, the Secretary shall—

20           “(i) ensure that adequate expertise is represented  
21 on the classification panel to assess—

22           “(I) the disease or condition which the de-  
23 vice is intended to cure, treat, mitigate, prevent,  
24 or diagnose; and

25           “(II) the technology of the device; and

1           “(ii) as part of the process to ensure adequate ex-  
2           pertise under clause (i), give due consideration to the  
3           recommendations of the person whose premarket sub-  
4           mission is subject to panel review on the expertise  
5           needed among the voting members of the panel.

6           “(C) For review by a classification panel of a pre-  
7           market submission for a device, the Secretary shall—

8           “(i) provide an opportunity for the person whose  
9           premarket submission is subject to panel review to  
10          provide recommendations on the expertise needed  
11          among the voting members of the panel; and

12          “(ii) give due consideration to such recommenda-  
13          tions and ensure that adequate expertise is rep-  
14          resented on advisory panels to assess—

15                  “(I) the disease or condition for which the  
16                  device is intended to cure, treat, mitigate, pre-  
17                  vent, or diagnose; and

18                  “(II) the technology of the device.

19          “(D) For purposes of subparagraph (B)(ii), the term  
20          ‘adequate expertise’ means, with respect to the membership  
21          of the classification panel reviewing a premarket submis-  
22          sion, that such membership includes—

23                  “(i) two or more voting members, with a spe-  
24                  cialty or other expertise clinically relevant to the de-  
25                  vice under review; and

1           “(ii) at least one voting member who is knowl-  
2           edgeable about the technology of the device.”.

3           (b) *PANEL REVIEW PROCESS*.—Section 513(b)(6) of  
4           the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.  
5           360c(b)(6)) is amended—

6           (1) in subparagraph (A)(iii), by inserting before  
7           the period at the end “, including by designating a  
8           representative who will be provided a time during the  
9           panel meeting to address the panel individually (or  
10           accompanied by experts selected by such representa-  
11           tive) for the purpose of correcting misstatements of  
12           fact or providing clarifying information, subject to  
13           the discretion of the panel chairperson”; and

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

16           “(B)(i) Any meeting of a classification panel for a de-  
17           vice that is specifically the subject of review shall—

18           “(I) provide adequate time for initial presen-  
19           tations by the person whose device is specifically the  
20           subject of a classification panel review and by the  
21           Secretary; and

22           “(II) encourage free and open participation by  
23           all interested persons.

24           “(ii) Following the initial presentations described in  
25           clause (i), the panel may—



1           “(I) pose questions to a designated representative  
2 described in subparagraph (A)(iii); and

3           “(II) consider the responses to such questions in  
4 the panel’s review of the device that is specifically the  
5 subject of review by the panel.”.

6 **SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICA-**  
7 **TION.**

8           (a) *IN GENERAL.*—Section 520(m) of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-  
10 ed—

11           (1) in paragraph (1) by striking “fewer than  
12 4,000” and inserting “not more than 8,000”;

13           (2) in paragraph (2)(A) by striking “fewer than  
14 4,000” and inserting “not more than 8,000”; and

15           (3) in paragraph (6)(A)(ii), by striking “4,000”  
16 and inserting “8,000”

17           (b) *GUIDANCE DOCUMENT ON PROBABLE BENEFIT.*—

18 Not later than 18 months after the date of enactment of  
19 this Act, the Secretary of Health and Human Services, act-  
20 ing through the Commissioner of Food and Drugs, shall  
21 publish a draft guidance document that defines the criteria  
22 for establishing “probable benefit” as that term is used in  
23 section 520(m)(2)(C) of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 360j(m)(2)(C)).

1 **SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**  
2 **VITRO DIAGNOSTICS.**

3 (a) *DRAFT REVISED GUIDANCE.*—Not later than 12  
4 months after the date of the enactment of this Act, the Sec-  
5 retary of Health and Human Services shall publish a draft  
6 guidance that—

7 (1) revises “Section V. Demonstrating Insignifi-  
8 cant Risk of an Erroneous Result—‘Accuracy’” of the  
9 guidance entitled “Recommendations for Clinical  
10 Laboratory Improvement Amendments of 1988  
11 (CLIA) Waiver Applications for Manufacturers of In  
12 Vitro Diagnostic Devices” and dated January 30,  
13 2008; and

14 (2) includes guidance on the appropriate use of  
15 comparable performance between a waived user and a  
16 moderately complex laboratory user to demonstrate  
17 accuracy.

18 (b) *FINAL REVISED GUIDANCE.*—The Secretary of  
19 Health and Human Services shall finalize the draft guid-  
20 ance published under subsection (a) not later than 12  
21 months after the comment period for such draft guidance  
22 closes.

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

4 **SEC. 2241. HEALTH SOFTWARE.**

5 *Section 201 of the Federal Food, Drug, and Cosmetic*  
6 *Act (21 U.S.C. 321) is amended by adding at the end the*  
7 *following:*

8 *“(ss)(1) The term ‘health software’ means software that*  
9 *does not, through use of an in vitro diagnostic device or*  
10 *signal acquisition system, acquire, process, or analyze an*  
11 *image or physiological signal, is not an accessory, is not*  
12 *an integral part of a device necessary to support the use*  
13 *of the device, is not used in the manufacture and trans-*  
14 *fusion of blood and blood components to assist in the pre-*  
15 *vention of disease in humans, and—*

16 *“(A) is intended for use for administrative or*  
17 *operational support or the processing and mainte-*  
18 *nance of financial records;*

19 *“(B) is intended for use in clinical, laboratory,*  
20 *or administrative workflow and related recordkeeping;*

21 *“(C)(i) is intended for use solely in the transfer,*  
22 *aggregation, conversion (in accordance with a present*  
23 *specification), storage, management, retrieval, or*  
24 *transmission of data or information;*

1           “(ii) utilizes a connectivity software platform,  
2           electronic or electrical hardware, or a physical com-  
3           munications infrastructure; and

4           “(iii) is not intended for use—

5                   “(I) in active patient monitoring; or

6                   “(II) in controlling or altering the functions  
7           or parameters of a device that is connected to  
8           such software;

9           “(D) is intended for use to organize and present  
10          information for health or wellness education or for  
11          use in maintaining a healthy lifestyle, including  
12          medication adherence and health management tools;

13          “(E) is intended for use to analyze information  
14          to provide general health information that does not  
15          include patient-specific recommended options to con-  
16          sider in the prevention, diagnosis, treatment, cure, or  
17          mitigation of a particular disease or condition; or

18          “(F) is intended for use to analyze information  
19          to provide patient-specific recommended options to  
20          consider in the prevention, diagnosis, treatment, cure,  
21          or mitigation of a particular disease or condition.

22          “(2) The term ‘accessory’ means a product that—

23                  “(A) is intended for use with one or more parent  
24                  devices;

1           “(B) is intended to support, supplement, or aug-  
2           ment the performance of one or more parent devices;  
3           and

4           “(C) shall be classified by the Secretary—

5                   “(i) according to its intended use; and

6                   “(ii) independently of any classification of  
7           any parent device with which it is used.”.

8   **SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGU-**  
9                   **LATION.**

10           Subchapter A of chapter V of the Federal Food, Drug,  
11           and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by  
12           section 2221(a), is further amended by adding at the end  
13           the following:

14   **“SEC. 524C. HEALTH SOFTWARE.**

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

18           “(b) *EXCEPTION.*—

19                   “(1) *IN GENERAL.*—Subsection (a) shall not  
20           apply with respect to a software product—

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

23                           “(B) that the Secretary determines poses a  
24           significant risk to patient safety.

1           “(2) *CONSIDERATIONS.*—*In making a deter-*  
2           *mination under subparagraph (B) of paragraph (1)*  
3           *with respect to a product to which such paragraph*  
4           *applies, the Secretary shall consider the following:*

5                   “(A) *The likelihood and severity of patient*  
6                   *harm if the product were to not perform as in-*  
7                   *tended.*

8                   “(B) *The extent to which the product is in-*  
9                   *tended to support the clinical judgment of a*  
10                   *medical professional.*

11                   “(C) *Whether there is a reasonable oppor-*  
12                   *tunity for a medical professional to review the*  
13                   *basis of the information or treatment rec-*  
14                   *ommendation provided by the product.*

15                   “(D) *The intended user and user environ-*  
16                   *ment, such as whether a medical professional*  
17                   *will use a software product of a type described*  
18                   *in subparagraph (F) of section 201(ss)(1).*

19           “(c) *DELEGATION.*—*The Secretary shall delegate pri-*  
20           *mary jurisdiction for regulating a software product deter-*  
21           *mined under subsection (b) to be subject to regulation under*  
22           *this Act to the center at the Food and Drug Administration*  
23           *charged with regulating devices.*

24           “(d) *REGULATION OF SOFTWARE.*—

1           “(1) *IN GENERAL.*—*The Secretary shall review*  
2           *existing regulations and guidance regarding the regu-*  
3           *lation of software under this Act. The Secretary may*  
4           *implement a new framework for the regulation of soft-*  
5           *ware and shall, as appropriate, modify such regula-*  
6           *tions and guidance or issue new regulations or guid-*  
7           *ance.*

8           “(2) *ISSUANCE BY ORDER.*—*Notwithstanding*  
9           *subchapter II of chapter 5 of title 5, United States*  
10          *Code, the Secretary may modify or issue regulations*  
11          *for the regulation of software under this Act by ad-*  
12          *ministrative order published in the Federal Register*  
13          *following the publication of a proposed order.*

14          “(3) *AREAS UNDER REVIEW.*—*The review of ex-*  
15          *isting regulations and guidance under paragraph (1)*  
16          *may include review of the following areas:*

17                  “(A) *Classification of software.*

18                  “(B) *Standards for development of software.*

19                  “(C) *Standards for validation and*  
20                  *verification of software.*

21                  “(D) *Review of software.*

22                  “(E) *Modifications to software.*

23                  “(F) *Manufacturing of software.*

24                  “(G) *Quality systems for software.*

25                  “(H) *Labeling requirements for software.*

1           “(I) *Postmarketing requirements for report-*  
2           *ing of adverse events.*”

3           “(4) *PROCESS FOR ISSUING PROPOSED REGULA-*  
4           *TIONS, ADMINISTRATIVE ORDER, AND GUIDANCE.—Not*  
5           *later than 18 months after the date of enactment of*  
6           *this section, the Secretary shall consult with external*  
7           *stakeholders (including patients, industry, health care*  
8           *providers, academia, and government) to gather input*  
9           *before issuing regulations, an administrative order,*  
10          *and guidance under this subsection.*”

11          “(e) *RULE OF CONSTRUCTION.—Nothing in this sec-*  
12          *tion shall be construed as providing the Secretary with the*  
13          *authority to regulate under this Act any health software*  
14          *product of the type described in subparagraph (F) of section*  
15          *201(ss)(1) unless and until the Secretary has made a deter-*  
16          *mination described in subsection (b)(1)(B) with respect to*  
17          *such product.*”

18          **SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.**

19          *Section 201(h) of the Federal Food, Drug, and Cos-*  
20          *metic Act (21 U.S.C. 321) is amended—*

21                  (1) *in subparagraph (2), by striking “or” after*  
22                  *“or other animals,”;*

23                  (2) *in subparagraph (3), by striking “and” and*  
24                  *inserting “or”; and*



1           (3) by inserting after subparagraph (3) the fol-  
2           lowing:

3           “(4) not health software (other than software de-  
4           termined to be a risk to patient safety under section  
5           524B(b)), and”.

6           **Subtitle O—Streamlining Clinical**  
7           **Trials**

8           **SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RE-**  
9           **SEARCH; APPLICABILITY OF RULES.**

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

18          (b) *AVOIDING REGULATORY DUPLICATION AND UN-*  
19 *NECESSARY DELAYS.*—

20               (1) *IN GENERAL.*—The Secretary shall—

21                       (A) make such modifications to the provi-  
22 sions of the HHS Human Subject Regulations,  
23 the FDA Human Subject Regulations, and the  
24 vulnerable-populations rules as may be nec-  
25 essary—

1                   (i) to reduce regulatory duplication  
2                   and unnecessary delays;

3                   (ii) to modernize such provisions in the  
4                   context of multisite and cooperative research  
5                   projects; and

6                   (iii) to incorporate local consider-  
7                   ations, community values, and mechanisms  
8                   to protect vulnerable populations; and

9                   (B) ensure that human subject research that  
10                  is subject to the HHS Human Subject Regula-  
11                  tions or to the FDA Human Subject Regulations  
12                  may—

13                         (i) use joint or shared review;

14                         (ii) rely upon the review of—

15                                 (I) an independent institutional  
16                                 review board; or

17                                 (II) an institutional review board  
18                                 of an entity other than the sponsor of  
19                                 the research; or

20                                 (iii) use similar arrangements to avoid  
21                                 duplication of effort.

22                   (2) *REGULATIONS AND GUIDANCE.*—Not later  
23                  than 36 months after the date of enactment of this  
24                  Act, the Secretary, acting through the relevant agen-  
25                  cies and offices of the Department of Health and

1        *Human Services, including the Office for Human Re-*  
2        *search Protections and relevant agencies and offices of*  
3        *the Food and Drug Administration, shall issue such*  
4        *regulations and guidance and take such other actions*  
5        *as may be necessary to implement this section and*  
6        *help to facilitate the broader use of single, central, or*  
7        *lead institutional review boards. Such regulations*  
8        *and guidance shall clarify the requirements and poli-*  
9        *cies relating to the following:*

10                *(A) Arrangements to avoid duplication de-*  
11                *scribed in paragraph (1)(A)(i), including—*

12                        *(i) delineating the roles of institutional*  
13                        *review boards in multisite or cooperative,*  
14                        *multisite studies where one or more local*  
15                        *institutional review boards are relied upon,*  
16                        *or similar arrangements are used;*

17                        *(ii) the risks and benefits to human*  
18                        *subjects;*

19                        *(iii) standardizing the informed con-*  
20                        *sent and other processes and legal docu-*  
21                        *ments; and*

22                        *(iv) incorporating community values*  
23                        *through the use of local institutional review*  
24                        *boards while continuing to use central or*  
25                        *lead institutional review boards.*

1                   (B) *Concerns about regulatory and legal li-*  
2                   *ability contributing to decisions by the sponsors*  
3                   *of research to rely on local institutional review*  
4                   *boards for multisite research.*

5                   (3) *CONSULTATION.*—*In issuing regulations or*  
6                   *guidance under paragraph (2), the Secretary shall*  
7                   *consult with stakeholders (including researchers, aca-*  
8                   *ademic organizations, hospitals, institutional research*  
9                   *boards, pharmaceutical, biotechnology and medical*  
10                   *device developers, clinical research organizations, pa-*  
11                   *tient groups, and others).*

12                   (c) *TIMING.*—*The Secretary shall complete the harmo-*  
13                   *nization described in subsection (a) not later than 36*  
14                   *months after the date of enactment of this Act.*

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

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

25                   (f) *DEFINITIONS.*—

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

3           (A) *FDA HUMAN SUBJECT REGULATIONS.*—  
4     *The term “FDA Human Subject Regulations”*  
5     *means the provisions of parts 50, 56, 312, and*  
6     *812 of title 21, Code of Federal Regulations (or*  
7     *any successor regulations).*

8           (B) *HHS HUMAN SUBJECT REGULA-*  
9     *TIONS.*—*The term “HHS Human Subject Regu-*  
10    *lations” means the provisions of subpart A of*  
11    *part 46 of title 45, Code of Federal Regulations*  
12    *(or any successor regulations).*

13          (C) *VULNERABLE-POPULATIONS RULES.*—  
14    *The term “vulnerable-populations rules”—*

15           (i) *subject to clause (ii), means the*  
16           *provisions of subparts B through D of such*  
17           *part 46 (or any successor regulations); or*

18           (ii) *as applicable to research that is*  
19           *subject to the FDA Human Subject Regula-*  
20           *tions, means the provisions applicable to*  
21           *vulnerable populations under part 56 of*  
22           *such title 21 (or any successor regulations)*  
23           *and subpart D of part 50 of such title 21*  
24           *(or any successor regulations).*

25          (2) *OTHER DEFINITIONS.*—*In this section:*

1           (A) *INSTITUTIONAL REVIEW BOARD.*—The  
 2 term “institutional review board” has the mean-  
 3 ing that applies to the term “institutional review  
 4 board” under the HHS Human Subject Regula-  
 5 tions.

6           (B) *LEAD INSTITUTIONAL REVIEW*  
 7 *BOARD.*—The term “lead institutional review  
 8 board” means an institutional review board that  
 9 otherwise meets the requirements of the HHS  
 10 Human Subject Regulations and enters into a  
 11 written agreement with an institution, another  
 12 institutional review board, a sponsor, or a prin-  
 13 cipal investigator to approve and oversee human  
 14 subject research that is conducted at multiple lo-  
 15 cations. References to an institutional review  
 16 board include an institutional review board that  
 17 serves a single institution as well as a lead insti-  
 18 tutional review board.

19 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**  
 20 **BOARDS FOR REVIEW OF INVESTIGATIONAL**  
 21 **DEVICE EXEMPTIONS AND HUMAN DEVICE**  
 22 **EXEMPTIONS.**

23           (a) *IN GENERAL.*—Section 520 of the Federal Food,  
 24 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

25           (1) in subsection (g)(3)—



1       *prescribe, the investigator” and inserting the fol-*  
2       *lowing: “except where, subject to such conditions as*  
3       *the Secretary may prescribe—*

4               *“(i) the proposed clinical testing poses no*  
5               *more than minimal risk to the human subject*  
6               *and includes appropriate safeguards to protect*  
7               *the rights, safety, and welfare of the human sub-*  
8               *ject; or*

9               *“(i) the investigator”; and*

10              *(2) in the matter following subparagraph (D), by*  
11              *striking “subparagraph (D)” and inserting “subpara-*  
12              *graph (D)(i)”.*

13        **(b) DRUGS.**—*Section 505(i)(4) of the Federal Food,*  
14        *Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended*  
15        *by striking “except where it is not feasible or it is contrary*  
16        *to the best interests of such human beings” and inserting*  
17        *“except where it is not feasible, it is contrary to the best*  
18        *interests of such human beings, or the proposed clinical test-*  
19        *ing poses no more than minimal risk to such human beings*  
20        *and includes appropriate safeguards as prescribed to pro-*  
21        *tect the rights, safety, and welfare of such human beings”.*



1     ***Subtitle P—Improving Scientific***  
2     ***Expertise and Outreach at FDA***

3     ***SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-***  
4             ***SEARCH SERVICE.***

5             *(a) HIRING AND RETENTION AUTHORITY.—Section*  
6     *228 of the Public Health Service Act (42 U.S.C. 237) is*  
7     *amended—*

8             *(1) in the section heading, by inserting “AND*  
9             *BIOMEDICAL PRODUCT ASSESSMENT” after “RE-*  
10            *SEARCH”;*

11            *(2) in subsection (a)(1), by striking “Silvio O.*  
12            *Conte Senior Biomedical Research Service, not to ex-*  
13            *ceed 500 members” and inserting “Silvio O. Conte*  
14            *Senior Biomedical Research and Biomedical Product*  
15            *Assessment Service (in this section referred to as the*  
16            *‘Service’), the purpose of which is to recruit and re-*  
17            *tain competitive and qualified scientific and technical*  
18            *experts outstanding in the field of biomedical re-*  
19            *search, clinical research evaluation, and biomedical*  
20            *product assessment”;*

21            *(3) by amending subsection (a)(2) to read as fol-*  
22            *lows:*

23            *“(2) The authority established in paragraph (1) may*  
24     *not be construed to require the Secretary to reduce the num-*  
25     *ber of employees serving under any other employment sys-*

1 *tem in order to offset the number of members serving in*  
2 *the Service.”;*

3 *(4) in subsection (b)—*

4 *(A) in the matter preceding paragraph (1),*  
5 *by striking “or clinical research evaluation” and*  
6 *inserting “, clinical research evaluation or bio-*  
7 *medical product assessment”; and*

8 *(B) in paragraph (1), by inserting “or a*  
9 *master’s level degree in engineering,*  
10 *bioinformatics, or a related or emerging field,”*  
11 *after the comma;*

12 *(5) in subsection (d)(2), by striking “and shall*  
13 *not exceed the rate payable for level I of the Executive*  
14 *Schedule unless approved by the President under sec-*  
15 *tion 5377(d)(2) of title 5, United States Code” and*  
16 *inserting “and shall not exceed the rate payable for*  
17 *the President”;*

18 *(6) by striking subsection (e); and*

19 *(7) by redesignating subsections (f) and (g) as*  
20 *subsections (e) and (f), respectively.*

21 *(b) REPORT.—Not later than 3 years after the date*  
22 *of the enactment of this Act, the Secretary of Health and*  
23 *Human Services shall submit, and publish on the website*  
24 *of the Department of Health and Human Services a report*  
25 *on the implementation of the amendments made by sub-*

1 *section (a), including whether the amendments have im-*  
 2 *proved the ability of the Food and Drug Administration*  
 3 *to hire and retain qualified experts to fulfill obligations*  
 4 *specified under user fee agreements.*

5 **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

6 *It is the sense of Congress that the participation in,*  
 7 *or sponsorship of, scientific conferences and meetings is es-*  
 8 *sential to the mission of the Food and Drug Administra-*  
 9 *tion.*

10 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**  
 11 **AND DRUG ADMINISTRATION.**

12 *(a) BOARD OF DIRECTORS.—*

13 *(1) COMPOSITION AND SIZE.—Section*  
 14 *770(d)(1)(C) of the Federal Food, Drug, and Cosmetic*  
 15 *Act (21 U.S.C. 379dd(d)(1)(C)) is amended—*

16 *(A) by redesignating clause (ii) as clause*  
 17 *(iii);*

18 *(B) by inserting after clause (i) the fol-*  
 19 *lowing:*

20 *“(ii) ADDITIONAL MEMBERS.—The*  
 21 *Board, through amendments to the bylaws*  
 22 *of the Foundation, may provide that the*  
 23 *number of voting members of the Board*  
 24 *shall be a number (to be specified in such*  
 25 *amendment) greater than 14. Any Board*

1           positions that are established by any such  
2           amendment shall be appointed (by majority  
3           vote) by the individuals who, as of the date  
4           of such amendment, are voting members of  
5           the Board and persons so appointed may  
6           represent any of the categories specified in  
7           subclauses (I) through (V) of clause (i), so  
8           long as no more than 30 percent of the total  
9           voting members of the Board (including  
10          members whose positions are established by  
11          such amendment) are representatives of the  
12          general pharmaceutical, device, food, cos-  
13          metic, and biotechnology industries.”; and

14          (C) in clause (iii)(I), as redesignated by  
15          subparagraph (A), by striking “The ex officio  
16          members shall ensure” and inserting “The ex  
17          officio members, acting pursuant to clause (i),  
18          and the Board, acting pursuant to clause (ii),  
19          shall ensure”.

20          (2) *FEDERAL EMPLOYEES ALLOWED TO SERVE*  
21          *ON BOARD.*—Clause (iii)(II) of section 770(d)(1)(C) of  
22          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
23          379dd(d)(1)(C)), as redesignated by paragraph  
24          (1)(A), is amended by adding at the end the fol-  
25          lowing: “For purposes of this section, the term ‘em-

1        *ployee of the Federal Government’ does not include a*  
2        *‘special Government employee’, as that term is de-*  
3        *fin ed in section 202(a) of title 18, United States*  
4        *Code.”.*

5            (3) *STAGGERED TERMS.*—*Subparagraph (A) of*  
6        *section 770(d)(3) of the Federal Food, Drug, and Cos-*  
7        *metic Act (21 U.S.C. 379dd(d)(3)) is amended to read*  
8        *as follows:*

9            “(A) *TERM.*—*The term of office of each*  
10        *member of the Board appointed under para-*  
11        *graph (1)(C)(i), and the term of office of any*  
12        *member of the Board whose position is estab-*  
13        *lished pursuant to paragraph (1)(C)(ii), shall be*  
14        *4 years, except that—*

15            “(i) *the terms of offices for the members*  
16        *of the Board initially appointed under*  
17        *paragraph (1)(C)(i) shall expire on a stag-*  
18        *gered basis as determined by the ex officio*  
19        *members; and*

20            “(ii) *the terms of office for the persons*  
21        *initially appointed to positions established*  
22        *pursuant to paragraph (1)(C)(ii) may be*  
23        *made to expire on a staggered basis, as de-*  
24        *termined by the individuals who, as of the*

1                    *date of the amendment establishing such po-*  
2                    *sitions, are members of the Board.”.*

3            (b) *EXECUTIVE DIRECTOR COMPENSATION.*—Section  
4 *770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21*  
5 *U.S.C. 379dd(g)(2)) is amended by striking “but shall not*  
6 *be greater than the compensation of the Commissioner”.*

7            (c) *SEPARATION OF FUNDS.*—Section 770(m) of the  
8 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
9 *379dd(m)) is amended by striking “are held in separate*  
10 *accounts from funds received from entities under subsection*  
11 *(i)” and inserting “are managed as individual pro-*  
12 *grammatic funds under subsection (i), according to best ac-*  
13 *counting practices”.*

14 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFORMA-**  
15 **TION EXEMPTED FROM PAPERWORK REDUC-**  
16 **TION ACT.**

17            *Chapter VII of the Federal Food, Drug, and Cosmetic*  
18 *Act is amended by inserting after section 708 of such Act*  
19 *(21 U.S.C. 379) the following:*

20 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
21 **MATION EXEMPTED FROM PAPERWORK RE-**  
22 **DUCTION ACT.**

23            *“Chapter 35 of title 44, United States Code, shall not*  
24 *apply to the collection from patients, industry, academia,*  
25 *and other stakeholders, of voluntary information such as*

1 *through voluntary surveys or questionnaires, initiated by*  
2 *the Secretary.”.*

3 **SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**  
4 **NICAL, AND PROFESSIONAL PERSONNEL.**

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

8 **“SEC. 714A. ADDITIONAL HIRING AUTHORITY.**

9 *“(a) IN GENERAL.—The Secretary may, without re-*  
10 *gard to the provisions of title 5, United States Code, gov-*  
11 *erning appointments in the competitive service, appoint*  
12 *qualified candidates to scientific, technical, or professional*  
13 *positions within the following centers of the Food and Drug*  
14 *Administration:*

15 *“(1) The Center for Drug Evaluation and Re-*  
16 *search.*

17 *“(2) The Center for Biologics Evaluation and*  
18 *Research.*

19 *“(3) The Center for Devices and Radiological*  
20 *Health.*

21 *Such positions shall be within the competitive service.*

22 *“(b) COMPENSATION.—*

23 *“(1) IN GENERAL.—Notwithstanding any other*  
24 *provision of law, including any requirement with re-*  
25 *spect to General Schedule pay rates under subchapter*

1 *III of chapter 53 of title 5, United States Code, and*  
2 *consistent with the requirements of paragraph (2), the*  
3 *Secretary may determine and fix—*

4 *“(A) the annual rate of pay of any indi-*  
5 *vidual appointed under subsection (a); and*

6 *“(B) for purposes of retaining qualified em-*  
7 *ployees, the annual rate of pay for any highly*  
8 *qualified scientific, technical, or professional per-*  
9 *sonnel appointed to a position at any of the cen-*  
10 *ters listed under subsection (a) before the date of*  
11 *enactment of this section.*

12 *“(2) LIMITATION.—The annual rate of pay es-*  
13 *tablished pursuant to paragraph (1) may not exceed*  
14 *the annual rate of pay of the President.*

15 *“(c) SUNSET.—The authority to appoint employees*  
16 *under this section shall terminate on September 30, 2022.*

17 *“(d) REPORT.—*

18 *“(1) IN GENERAL.—Not later than September 30,*  
19 *2021, the Secretary shall submit a report to Congress*  
20 *that examines the extent to which the authority to ap-*  
21 *point and retain personnel under this section en-*  
22 *hanced the Food and Drug Administration’s ability*  
23 *to meet the agency’s critical need for highly qualified*  
24 *individuals for scientific, technical, or professional*  
25 *positions.*



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

4                     “(A) *whether the authority to appoint per-*  
 5                     *sonnel under this section should be reauthorized;*  
 6                     *and*

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

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

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

18           ***SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN***  
 19                    ***USER FEES OF FOOD AND DRUG ADMINISTRA-***  
 20                    ***TION.***

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

23                    (1) *in section 255(g)(1)(A) (2 U.S.C.*  
 24                    *905(g)(1)(A)), by inserting after the item relating to*  
 25                    *“Financial Agent Services” the following new item:*

1           *“Food and Drug Administration, Salaries*  
 2           *and Expenses, but only the portion of appropria-*  
 3           *tions under such account corresponding to fees*  
 4           *collected under sections 736, 738, 740, 741,*  
 5           *744B, and 744H of the Federal Food, Drug, and*  
 6           *Cosmetic Act (75–9911–0–1–554).”;* and  
 7           *(2) in section 256(h) (2 U.S.C. 906(h)), by add-*  
 8           *ing at the end the following new paragraph:*

9           *“(5) Notwithstanding any other provision of law,*  
 10          *this subsection shall not apply with respect to the por-*  
 11          *tion of administrative expenses incurred by the Food*  
 12          *and Drug Administration that are funded through*  
 13          *fees collected under sections 736, 738, 740, 741, 744B,*  
 14          *and 744H of the Federal Food, Drug, and Cosmetic*  
 15          *Act.”.*

## 16                           **TITLE III—DELIVERY**

### 17                           **Subtitle A—Interoperability**

#### 18   **SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH IN-** 19                           **FORMATION TECHNOLOGY.**

20           *(a) INTEROPERABILITY STANDARDS.—*

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

1 **“SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH IN-**  
2 **FORMATION TECHNOLOGY.**

3 “(a) *INTEROPERABILITY.*—*In order for health infor-*  
4 *mation technology to be considered interoperable, such tech-*  
5 *nology must satisfy the following criteria:*

6 “(1) *SECURE TRANSFER.*—*The technology allows*  
7 *the secure transfer of the entirety of a patient’s data*  
8 *from any and all health information technology for*  
9 *authorized use under applicable law.*

10 “(2) *COMPLETE ACCESS TO HEALTH DATA.*—*The*  
11 *technology allows access to the entirety of a patient’s*  
12 *available data for authorized use under applicable*  
13 *law without special effort, as defined by recommenda-*  
14 *tions for interoperability standards adopted under*  
15 *section 3004, by the requestor of such data unless such*  
16 *data is not disclosable under applicable law.*

17 “(3) *NO INFORMATION BLOCKING.*—*The tech-*  
18 *nology is not configured, set up, or implemented to*  
19 *engage in information blocking, as defined in section*  
20 *3010A(f).*

21 “(b) *CATEGORIES FOR INTEROPERABILITY STAND-*  
22 *ARDS.*—*The categories described in this subsection, with re-*  
23 *spect to standards for determining if health information*  
24 *technology is interoperable, consistent with the criteria de-*  
25 *scribed in subsection (a), include the following categories*  
26 *of standards:*

1           “(1) *Standards with respect to vocabulary and*  
2           *terminology.*”

3           “(2) *Standards with respect to content and*  
4           *structure.*”

5           “(3) *Standards with respect to transport of in-*  
6           *formation.*”

7           “(4) *Security standards.*”

8           “(5) *Service standards.*”

9           (2) *GUIDANCE.—Not later than January 1,*  
10          *2017, the Secretary of Health and Human Services,*  
11          *through the National Coordinator of the Office of the*  
12          *National Coordinator for Health Information Tech-*  
13          *nology, shall issue guidance with respect to the imple-*  
14          *mentation of section 3010 of the Public Health Serv-*  
15          *ice Act, as added by paragraph (1), including with*  
16          *respect to defining and providing examples of author-*  
17          *ized use of health information technology, as described*  
18          *in such section.*

19          (b) *IMPROVEMENTS TO RECOMMENDATION PROC-*  
20          *ESS.—*

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

25                         (A) *in subsection (a)—*

1           (i) by striking “National Coordinator”  
2           and inserting “Secretary, in consultation  
3           with the National Coordinator,”; and

4           (ii) by adding at the end the following  
5           new sentence: “The HIT Policy Committee  
6           is authorized only to provide policy and  
7           priority recommendations to the Secretary  
8           and not authorized to otherwise affect the  
9           development or modification of any stand-  
10          ard, implementation specification, or cer-  
11          tification criterion under this title.”; and

12          (B) in subsection (b)(2)—

13                 (i) in subparagraph (A), in the first  
14                 sentence—

15                         (I) by striking “The HIT Policy  
16                         Committee” and inserting “Subject to  
17                         subparagraph (D), the HIT Policy  
18                         Committee”; and

19                         (II) by inserting “(including the  
20                         areas in which modifications and ad-  
21                         ditions to interoperability standards  
22                         under section 3010 are needed for the  
23                         electronic exchange and use of health  
24                         information for purposes of adoption of  
25                         such modifications and additions

1                   *under section 3004)*” after “*section*  
2                   *3004*”.

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

5                   “(D) *SPECIAL RULE RELATED TO INTER-*  
6                   *OPERABILITY.—Any recommendation made by*  
7                   *the HIT Policy Committee on or after the date*  
8                   *of the enactment of this subparagraph with re-*  
9                   *spect to interoperability of health information*  
10                   *technology shall be consistent with the criteria*  
11                   *described in subsection (a) of section 3010.*”.

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

16                   “(f) *TERMINATION.—The HIT Standards Committee*  
17                   *shall terminate on the date that is 90 days after the date*  
18                   *of the enactment of this subsection.*”.

19                   (3) *STANDARDS DEVELOPMENT ORGANIZA-*  
20                   *TIONS.—Title XXX of the Public Health Service Act*  
21                   *is amended by inserting after section 3003 the fol-*  
22                   *lowing new section:*

1 **“SEC. 3003A. RECOMMENDATIONS FOR STANDARDS**  
2 **THROUGH CONTRACTS WITH STANDARDS DE-**  
3 **VELOPMENT ORGANIZATIONS.**

4 “(a) *CONTRACTS.*—

5 “(1) *IN GENERAL.*—*For purposes of activities*  
6 *conducted under this title, the Secretary shall enter*  
7 *into contracts with health care standards development*  
8 *organizations accredited by the American National*  
9 *Standards Institute to carry out the duties described*  
10 *in subsection (b), as applicable.*

11 “(2) *TIMING FOR FIRST CONTRACT.*—*As soon as*  
12 *practicable after the date of the enactment of this sec-*  
13 *tion, the Secretary shall enter into the first contract*  
14 *under paragraph (1).*

15 “(3) *PERIOD OF CONTRACT.*—*Each contract*  
16 *under paragraph (1) shall be for a period determined*  
17 *necessary by the Secretary, in consultation with the*  
18 *National Coordinator, to carry out the applicable du-*  
19 *ties described in subsection (b).*

20 “(4) *APPROPRIATE ORGANIZATIONS.*—*The Sec-*  
21 *retary shall ensure the most appropriate organiza-*  
22 *tions described in paragraph (1) are selected for each*  
23 *contract under such paragraph.*

24 “(5) *ALLOWANCE FOR VARIATIONS.*—*Standards*  
25 *developed pursuant to a contract under this sub-*  
26 *section, and the methods to test such standards, shall*

1     *allow for variations on such standards as long as*  
2     *such variations are consistent with the standards so*  
3     *developed under this section.*

4     “(b) *DUTIES.*—

5             “(1) *INITIAL CONTRACT.*—*Under the initial con-*  
6     *tract under subsection (a)(1), the standards develop-*  
7     *ment organizations—*

8                     “(A) *shall provide to the Secretary, in con-*  
9     *sultation with the National Coordinator, for*  
10    *adoption under section 3004, recommendations,*  
11    *in accordance with section 3010, for interoper-*  
12    *ability standards, and methods to test such*  
13    *standards, consistent with the criteria described*  
14    *in subsection (a) of such section and with respect*  
15    *to the categories described in subsection (b)(1) of*  
16    *such section; and*

17                     “(B) *may provide to the Secretary rec-*  
18    *ommendations described in paragraph (2).*

19             “(2) *SUBSEQUENT CONTRACTS.*—*Under each*  
20    *subsequent contract, the organizations shall provide to*  
21    *the Secretary, in consultation with the National Coor-*  
22    *dinator, for adoption under section 3004 rec-*  
23    *ommendations for any standards (including inter-*  
24    *operability standards and methods to test such stand-*  
25    *ards), implementation specifications, and certifi-*



1     *ation criteria (and modifications, including addi-*  
2     *tions, to such standards, specifications, and criteria),*  
3     *which are in accordance with the policies and prior-*  
4     *ities developed by the Secretary, in consultation with*  
5     *the National Coordinator.*

6             “(3) *MULTIPLE METHODS TO TEST INTEROPER-*  
7     *ABILITY STANDARDS.—For the purposes of developing*  
8     *methods to test interoperability standards for adop-*  
9     *tion under section 3004, the Secretary shall ensure*  
10    *that contracts under this section allow for multiple*  
11    *methods to test such standards to account for vari-*  
12    *ations in the adoption of such standards that do not*  
13    *conflict with section 3010(a).*

14            “(c) *MODIFICATIONS AND SUBSEQUENT CONTRACTS.—*

15            “(1) *IN GENERAL.—The Secretary, in consulta-*  
16    *tion with the National Coordinator, shall periodically*  
17    *conduct hearings to evaluate and review the stand-*  
18    *ards, implementation specifications, and certification*  
19    *criteria adopted under section 3004 for purposes of*  
20    *determining if modifications, including any addi-*  
21    *tions, are needed with respect to such standards, spec-*  
22    *ifications, and criteria.*

23            “(2) *CONTRACT TRIGGER.—Based on the needs*  
24    *for standards, implementation specifications, and cer-*  
25    *tification criteria (and modifications, including addi-*

1        *tions, to such standards, specifications, and criteria)*  
2        *under this title, as determined by the Secretary, in*  
3        *consultation with the National Coordinator, the Sec-*  
4        *retary shall, as needed, enter into contracts under*  
5        *subsection (a) in addition to the initial contract.*

6        “(d) *AUTHORIZATION OF APPROPRIATIONS.—There is*  
7        *authorized to be appropriated \$10,000,000 for contracts*  
8        *under subsection (a), to remain available until expended.”.*

9                (4) *MODIFICATIONS TO ROLE OF ONCHIT.—Sec-*  
10        *tion 3001(c)(1)(A) of the Public Health Service Act*  
11        *(42 U.S.C. 300jj–11(c)(1)(A)) is amended by insert-*  
12        *ing “for recommendations made before the date of the*  
13        *enactment of the 21st Century Cures Act,” before “re-*  
14        *view and determine”.*

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

17                (1) *in subsection (a)—*

18                        (A) *in paragraph (1), by inserting after*  
19                        *“section 3001(c)” the following: “(or, subject to*  
20                        *subsection (c), in the case of a standard, speci-*  
21                        *fication, or criterion recommended on or after*  
22                        *the date of the enactment of the 21st Century*  
23                        *Cures Act, after the date of submission of the rec-*  
24                        *ommendation to the Secretary under section*  
25                        *3003A)”;* and

1                   (B) in paragraph (2)(B), by striking “and  
2                   the HIT Standards Committee”;

3                   (2) in subsection (b), by adding at the end the  
4                   following new paragraph:

5                   “(4) *LIMITATION.*—The Secretary may not adopt  
6                   any standards, implementation specifications, or cer-  
7                   tification criteria under this subsection or subsection  
8                   (a) that are inconsistent with or duplicative of an  
9                   interoperability standard adopted under this section,  
10                  in accordance with subsections (c) and (d). In the  
11                  case of a standard, specification, or criterion that has  
12                  been adopted under this section and is inconsistent or  
13                  duplicative of such an interoperability standard that  
14                  is subsequently adopted under this section, such inter-  
15                  operability standard shall supercede such other stand-  
16                  ard, specification, or criterion and such other stand-  
17                  ard, specification, or criterion shall no longer be con-  
18                  sidered adopted under this section beginning on the  
19                  date that such interoperability standard becomes effec-  
20                  tive.”; and

21                  (3) by adding at the end the following new sub-  
22                  sections:

23                  “(c) *ADOPTION OF INITIAL INTEROPERABILITY STAND-*  
24                  *ARDS.*—Notwithstanding the previous subsections of this  
25                  section, the following shall apply in the case of the initial

1 *set of interoperability standards recommended under sec-*  
2 *tion 3003A:*

3           “(1) *REVIEW OF STANDARDS.*—*Not later than 90*  
4 *days after the date of receipt of recommendations for*  
5 *such interoperability standards, the Secretary, in con-*  
6 *sultation with the National Coordinator and rep-*  
7 *resentatives of other relevant Federal agencies, shall*  
8 *jointly review such standards and shall determine*  
9 *whether or not to propose adoption of such standards.*

10           “(2) *DETERMINATION TO ADOPT.*—*If the Sec-*  
11 *retary determines—*

12                   “(A) *to propose adoption of such standards,*  
13 *the Secretary shall, by regulation under section*  
14 *553 of title 5, United States Code, determine*  
15 *whether or not to adopt such standards; or*

16                   “(B) *not to propose adoption of such stand-*  
17 *ards, the Secretary shall notify the applicable*  
18 *standards development organizations with a con-*  
19 *tract under section 3003A in writing of such de-*  
20 *termination and the reasons for not proposing*  
21 *the adoption of the recommendation for such*  
22 *standards.*

23           “(3) *PUBLICATION.*—*The Secretary shall provide*  
24 *for publication in the Federal Register of all deter-*

1        *minations made by the Secretary under paragraph*  
2        *(1).*

3            *“(4) APPLICATION.—Any standard adopted*  
4        *under this subsection shall be effective 12 months after*  
5        *the date of publication of the determination to adopt*  
6        *such standard.*

7            *“(d) RULES FOR ADOPTION.—In the case of a stand-*  
8        *ard (including interoperability standard), implementation*  
9        *specification, or certification criteria adopted under this*  
10       *section on or after the date of the enactment of the 21st*  
11       *Century Cures Act, the following shall apply:*

12            *“(1) IN GENERAL.—Except as provided in para-*  
13        *graph (2), any such standard (including interoper-*  
14        *ability standard), implementation specification, or*  
15        *certification criterion shall be a standard, specifica-*  
16        *tion, or criterion that has been recommended by the*  
17        *standards development organizations with which the*  
18        *Secretary has entered into a contract under section*  
19        *3003A.*

20            *“(2) SPECIAL RULE IF NO STANDARD, SPECIFICA-*  
21        *TION, OR CRITERION RECOMMENDED.—If no standard*  
22        *is recommended under paragraph (1)—*

23            *“(A) in the case of interoperability stand-*  
24        *ards, relating to a category described in section*  
25        *3010(b)—*

1                   “(i) paragraph (1) shall not apply;

2                   and

3                   “(ii) paragraph (4) shall apply; or

4                   “(B) in the case of any other standard, im-  
5                   plementation specification, or certification cri-  
6                   teria, relating to a policy or priority to carry  
7                   out this title, as determined by the Secretary, in  
8                   consultation with the National Coordinator—

9                   “(i) paragraph (1) shall not apply;

10                  and

11                  “(ii) paragraph (4) shall apply.

12                  “(3) *EFFECTIVE DATE.*—Any standard, imple-  
13                  mentation specification, or certification criterion  
14                  adopted under this section shall be effective 12 months  
15                  after the date of publication of the final rule to adopt  
16                  such standard, implementation specification, or cer-  
17                  tification criterion.

18                  “(4) *ASSISTANCE TO THE SECRETARY.*—In com-  
19                  plying with the requirements of this subsection, the  
20                  Secretary shall rely on the recommendations of the  
21                  National Committee on Vital and Health Statistics  
22                  established under section 306(k), and shall consult  
23                  with appropriate Federal and State agencies and pri-  
24                  vate organizations. The Secretary shall publish in the  
25                  Federal Register any recommendation of the National

1        *Committee on Vital and Health Statistics regarding*  
2        *the adoption of a standard, implementation specifica-*  
3        *tion, or certification criterion under this section. Any*  
4        *standard, implementation specification, or certifi-*  
5        *cation criterion adopted pursuant to this paragraph*  
6        *shall be promulgated in accordance with the rule-*  
7        *making procedures of subchapter III of chapter 5 of*  
8        *title 5, United States Code.”.*

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

13        *“(c) DISSEMINATION OF INFORMATION.—*

14                *“(1) INITIAL SUMMARY REPORT.—Not later than*  
15        *July 1, 2017, the Secretary, after consultation with*  
16        *relevant stakeholders, shall submit to Congress and*  
17        *provide for publication in the Federal Register and*  
18        *the posting on the Internet website of the Office of the*  
19        *National Coordinator for Health Information Tech-*  
20        *nology of a report on the following:*

21                *“(A) The initial set of interoperability*  
22        *standards adopted under section 3004(c).*

23                *“(B) The strategies for achieving wide-*  
24        *spread interoperability.*

1           “(C) *An overview of the extent to which*  
2           *electronic health records and health information*  
3           *technology offered as of such date satisfy such*  
4           *initial set.*

5           “(D) *Any barriers that are preventing wide-*  
6           *spread interoperability.*

7           “(E) *The plan and milestones, including*  
8           *specific steps, to achieve widespread interoper-*  
9           *ability.*

10          “(2) *FOLLOWUP DETERMINATION AND REPORT*  
11          *ON WIDESPREAD INTEROPERABILITY.—Not later than*  
12          *December 31, 2019, the Secretary shall provide for*  
13          *publication in the Federal Register and the posting*  
14          *on the Internet website of the Office of the National*  
15          *Coordinator for Health Information Technology of the*  
16          *following:*

17                 “(A) *A determination by the Secretary*  
18                 *whether the goal of widespread interoperability*  
19                 *has been achieved.*

20                 “(B) *A list identifying the vendors of, or*  
21                 *other entities offering, qualified electronic health*  
22                 *records, which categorizes such entities, with re-*  
23                 *spect to such records, as in compliance or not in*  
24                 *compliance with the certification criteria de-*  
25                 *scribed in section 3001(c)(5)(B)(ii) and with the*



1            *requirements under clause (i) of section*  
2            *3001(c)(5)(C) (including with the terms of the*  
3            *attestation and other requirements under such*  
4            *clause).*

5            *“(C) Actions that may be taken by entities*  
6            *identified under subparagraph (B) as not being*  
7            *in compliance with such criteria and require-*  
8            *ments in order for such entities to become in*  
9            *compliance with such criteria and requirements.*

10           *“(D) Penalties described in section*  
11           *3010A(d) to which entities, with respect to such*  
12           *qualified electronic health records, beginning*  
13           *January 1, 2019, are subject if such technology*  
14           *and entities are not in compliance with the cer-*  
15           *tification criteria described in section*  
16           *3001(c)(5)(B)(ii) and with the requirements*  
17           *under clause (i) of section 3001(c)(5)(C), respec-*  
18           *tively.*

19           *“(3) ONGOING PUBLICATION OF RECOMMENDA-*  
20           *TIONS.—The Secretary shall provide for publication*  
21           *in the Federal Register and the posting on the Inter-*  
22           *net website of the Office of the National Coordinator*  
23           *for Health Information Technology of all rec-*  
24           *ommendations made under this section.”.*

1           (e) *CERTIFICATION AND OTHER ENFORCEMENT PROVI-*  
2 *SIONS.—*

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

5           (A) *IN GENERAL.—Section 3007(b) of the*  
6 *Public Health Service Act (42 U.S.C. 300jj–*  
7 *17(b)) is amended by striking “under section*  
8 *3001(c)(3) to be in compliance with” and all*  
9 *that follows through the period at the end and*  
10 *inserting “under section 3001(c)(3)—*

11           *“(1) for certifications made before January 1,*  
12 *2018, to be in compliance with applicable standards*  
13 *adopted under subsections (a) and (b) of section 3004;*  
14 *and*

15           *“(2) for certifications made on or after January*  
16 *1, 2018, to be in compliance with applicable stand-*  
17 *ards adopted under subsections (a) and (b) of section*  
18 *3004 and to be interoperable in accordance with sec-*  
19 *tion 3010, including by being in compliance with*  
20 *interoperability standards adopted under section*  
21 *3004.”.*

22           (B) *REQUIREMENTS OF SECRETARY.—Sec-*  
23 *tion 3001(c)(5) of the Public Health Service Act*  
24 *(42 U.S.C. 300jj–11(c)(5)) is amended—*

1                   *(i) by amending subparagraph (B) of*  
2                   *such section to read as follows:*

3                   “*(B) CERTIFICATION CRITERIA DE-*  
4                   *SCRIBED.—In this title, the term ‘certification*  
5                   *criteria’ means, with respect to qualified elec-*  
6                   *tronic health records—*

7                   “*(i) for certifications made before Jan-*  
8                   *uary 1, 2018, criteria to establish that the*  
9                   *records meet standards and implementation*  
10                  *specifications adopted under subsections (a)*  
11                  *and (b) of section 3004 for qualified elec-*  
12                  *tronic health records; and*

13                  “*(ii) for certifications made on or after*  
14                  *January 1, 2018, criteria described in*  
15                  *clause (i) and criteria to establish that the*  
16                  *records are interoperable, in accordance*  
17                  *with section 3010, including by being in*  
18                  *compliance with interoperability standards*  
19                  *adopted under section 3004.”; and*

20                  “*(i) by adding at the end the following*  
21                  *new subparagraph:*

22                  “*(C) ENFORCEMENT; DECERTIFICATIONS.—*

23                  “*(i) REQUIREMENTS.—Under any pro-*  
24                  *gram kept or recognized under subpara-*  
25                  *graph (A), the Secretary shall ensure that*

1           *any vendor of or other entity offering quali-*  
2           *fied electronic health records seeking a cer-*  
3           *tification of such records under such pro-*  
4           *gram on or after January 1, 2018, shall, as*  
5           *a condition of certification (and mainte-*  
6           *nance of certification) of such a record*  
7           *under such program—*

8                     *“(I) provide to the Secretary an*  
9                     *attestation—*

10                             *“(aa) that the entity, unless*  
11                             *for a legitimate purpose specified*  
12                             *by the Secretary, has not taken*  
13                             *any action, including through*  
14                             *any financial, administrative, or*  
15                             *technological barrier, which the*  
16                             *entity knows or should know (as*  
17                             *defined in section 1128A(i)(7) of*  
18                             *the Social Security Act), is to*  
19                             *limit or restrict the exchange of*  
20                             *information or to prevent or*  
21                             *disincentivize widespread inter-*  
22                             *operability between any providers*  
23                             *using such records or other health*  
24                             *information technology in connec-*  
25                             *tion with such record;*

1                   “(bb) on the pricing informa-  
2                   tion described in clause (v) for  
3                   purposes of the portal created  
4                   under paragraph (9); that such  
5                   information will be available on a  
6                   public Web site of such entity and  
7                   in marketing materials, commu-  
8                   nications statements, and other  
9                   assertions of such entity related to  
10                  such record; and that the entity  
11                  will voluntarily provide such in-  
12                  formation to customers prior to  
13                  providing any qualified electronic  
14                  health records or related product  
15                  or service (including subsequent  
16                  updates, add-ons, or additional  
17                  products or services to be provided  
18                  during the course of an on-going  
19                  contract), prospective customers  
20                  (such as persons who request or  
21                  receive a quotation, estimate, or  
22                  other similar marketing or pro-  
23                  motional material), and other  
24                  persons who request such informa-  
25                  tion;

1           “(cc) that the software with  
2           respect to such records have pub-  
3           lished application programming  
4           interfaces for medical records  
5           data, search and indexing, seman-  
6           tic harmonization and vocabulary  
7           translation, and user interface ap-  
8           plications;

9           “(dd) that the entity has suc-  
10          cessfully tested the use of the  
11          record in the type of setting in  
12          which it would be marketed;

13          “(ee) the entity has in place  
14          implementation guidelines for  
15          such record that support inter-  
16          operability, consistent with sec-  
17          tion 3010; and

18          “(ff) that the entity has in  
19          place data sharing programs or  
20          capabilities based on common  
21          data elements through application  
22          programming interfaces without  
23          the requirement for vendor-specific  
24          interfaces;

1           “(II) publish application pro-  
2           gramming interfaces and associated  
3           documentation, with respect to such  
4           records, for medical records data,  
5           search and indexing, semantic harmo-  
6           nization and vocabulary translation,  
7           and user interface applications; and

8           “(III) demonstrate to the satisfac-  
9           tion of the Secretary that data from  
10          such records are able to be exchanged  
11          through the use of application pro-  
12          gramming interfaces and used in a  
13          manner that allows for exchange and  
14          everyday use, as authorized under ap-  
15          plicable law, of such records.

16          “(ii) *DECERTIFICATION*.—Under any  
17          program kept or recognized under subpara-  
18          graph (A), the Secretary shall ensure that  
19          beginning January 1, 2019, any qualified  
20          electronic health records that do not satisfy  
21          the certification criteria described in section  
22          3001(c)(5)(B)(ii) or with respect to which  
23          the vendor or other entity described in  
24          clause (i) does not satisfy the requirements  
25          under such clause (or is determined to be in

1            *violation of the terms of the attestation or*  
2            *other requirements under such clause) shall*  
3            *no longer be considered as certified under*  
4            *such program.*

5            *“(iii) ANNUAL PUBLICATION.—For*  
6            *2019 and each subsequent year, the Sec-*  
7            *retary shall post on the public Internet*  
8            *website of the Department of Health and*  
9            *Human Services a list of any vendors of or*  
10           *other entities offering qualified electronic*  
11           *health records with respect to which certifi-*  
12           *cation has been withdrawn under clause (ii)*  
13           *during such year.*

14           *“(iv) PERIODIC REVIEW.—The Sec-*  
15           *retary shall periodically review and confirm*  
16           *that vendors of and other entities offering*  
17           *qualified electronic health records have pub-*  
18           *licly published application programming*  
19           *interfaces and associated documentation as*  
20           *required by clause (i)(II) for purposes of*  
21           *certification and maintaining certification*  
22           *under any program kept or recognized*  
23           *under subparagraph (A).*

24           *“(v) PRICING INFORMATION.—For pur-*  
25           *poses of clause (i)(I)(bb), the pricing infor-*



1            *mation described in this clause, with respect*  
2            *to a vendor of or other entity offering a*  
3            *qualified electronic health record, is the fol-*  
4            *lowing:*

5                    *“(I) Additional types of costs or*  
6                    *fees (whether fixed, recurring, trans-*  
7                    *action based, or otherwise) imposed by*  
8                    *the entity (or any third-party from*  
9                    *whom the entity purchases, licenses, or*  
10                   *obtains any technology, products, or*  
11                   *services in connection with the quali-*  
12                   *fied electronic health record) to pur-*  
13                   *chase, license, implement, maintain,*  
14                   *upgrade, use, or otherwise enable and*  
15                   *support the use of capabilities to which*  
16                   *such record is to be certified under this*  
17                   *section; or in connection with any data*  
18                   *generated in the course of using any*  
19                   *capability to which the record is to be*  
20                   *so certified.*

21                   *“(II) Limitations, whether by*  
22                   *contract or otherwise, on the use of any*  
23                   *capability to which the record is to be*  
24                   *certified under this section for any*  
25                   *purpose within the scope of the record’s*

1                   *certification; or in connection with any*  
2                   *data generated in the course of using*  
3                   *any capability to which the record is*  
4                   *to be certified under this section.*

5                   “(III) *Limitations, including*  
6                   *technical or practical limitations of*  
7                   *technology or its capabilities, that*  
8                   *could prevent or impair the successful*  
9                   *implementation, configuration,*  
10                  *customization, maintenance, support,*  
11                  *or use of any capabilities to which the*  
12                  *record is to be certified under this sec-*  
13                  *tion; or that could prevent or limit the*  
14                  *use, exchange, or portability of any*  
15                  *data generated in the course of using*  
16                  *any capability to which the record is*  
17                  *to be so certified.”.*

18                  (2) *ADDITIONAL ENFORCEMENT PROVISIONS*  
19                  *UNDER THE PUBLIC HEALTH SERVICE ACT.—Subtitle*  
20                  *A of title XXX of the Public Health Service Act (42*  
21                  *U.S.C. 300jj–11 et seq.), as amended by subsections*  
22                  *(a)(1) and (d), is further amended by adding at the*  
23                  *end the following new section:*

1 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

2       “(a) *INSPECTOR GENERAL AUTHORITY.*—*The Inspec-*  
3 *tor General of the Department of Health and Human Serv-*  
4 *ices shall have the authority to investigate claims of—*

5               “(1) *vendors of, or other entities offering, quali-*  
6 *fied electronic health records—*

7                       “(A) *being in violation of an attestation*  
8 *made under section 3001(c)(5)(C)(i)(I), with re-*  
9 *spect to the use of such records by a health care*  
10 *provider under a specified meaningful use incen-*  
11 *tive program; and*

12                       “(B) *having engaged in information block-*  
13 *ing (as defined in subsection (f)), unless for a le-*  
14 *gitimate purpose specified by the Secretary, with*  
15 *respect to the use of such records by a health care*  
16 *provider under such a program;*

17               “(2) *health care providers, with respect to the use*  
18 *of such records under a specified meaningful use in-*  
19 *centive program, having, unless for a legitimate pur-*  
20 *pose specified by the Secretary, engaged in informa-*  
21 *tion blocking (as so defined);*

22               “(3) *health information system providers de-*  
23 *scribed in subsection (b) having engaged in informa-*  
24 *tion blocking (as so defined), unless for a legitimate*  
25 *purpose specified by the Secretary, with respect to the*

1        *use of such records under a specified meaningful use*  
2        *incentive program; and*

3            *“(4) vendors of, or other entities offering, health*  
4        *information technology (other than technology de-*  
5        *scribed in paragraph (1)), health care providers, with*  
6        *respect to the use of such technology, and health infor-*  
7        *mation system providers, with respect to such tech-*  
8        *nology, unless for a legitimate purpose specified by*  
9        *the Secretary, having engaged in information block-*  
10       *ing (as so defined).*

11        *“(b) HEALTH INFORMATION SYSTEM PROVIDERS.—*  
12       *The Inspector General of the Department of Health and*  
13       *Human Services shall, in coordination with the Federal*  
14       *Trade Commission, ensure that health information system*  
15       *providers (such as operators of health information ex-*  
16       *changes and other systems that facilitate the exchange of*  
17       *information) investigate claims of information blocking,*  
18       *with respect to the use of such records under a specified*  
19       *meaningful use incentive program.*

20        *“(c) INFORMATION SHARING PROVISIONS.—*

21            *“(1) IN GENERAL.—The National Coordinator*  
22        *may serve as a technical consultant to the Inspector*  
23        *General of the Department of Health and Human*  
24        *Services and the Federal Trade Commission for pur-*  
25        *poses of carrying out this section. As such technical*

1        *consultant, the National Coordinator may, notwith-*  
2        *standing any other provision of law, share informa-*  
3        *tion related to claims or investigations under sub-*  
4        *section (a) or (b) with the Federal Trade Commission*  
5        *for purposes of such investigations.*

6            *“(2) PROTECTION FROM DISCLOSURE OF INFOR-*  
7        *MATION.—Any information shared by the National*  
8        *Coordinator under paragraph (1) shall not be subject*  
9        *to the provisions of section 552 of title 5, United*  
10       *States Code (commonly referred to as the Freedom of*  
11       *Information Act). Any information acquired pursu-*  
12       *ant to paragraph (1) shall be held in confidence and*  
13       *shall not be disclosed to any person except as may be*  
14       *necessary to carry out the purposes of subsection (a).*

15           *“(3) NON-APPLICATION OF PAPERWORK REDUC-*  
16       *TION ACT.—Chapter 35 of title 44, United States*  
17       *Code (commonly referred to as the Paperwork Reduc-*  
18       *tion Act of 1995) shall not apply to the National Co-*  
19       *ordinator or to the Office of the National Coordinator*  
20       *for Health Information Technology with respect to the*  
21       *collection of complaints relating to claims described*  
22       *in subsection (a).*

23           *“(d) PENALTY.—Any person or entity determined to*  
24       *have committed an act described in paragraph (1), (2), or*  
25       *(3) of subsection (a), in connection with a specified mean-*

1 *ingful use incentive program, shall be subject to a civil mon-*  
2 *etary penalty of not more than \$10,000 for each such act.*  
3 *The provisions of section 1128A (other than subsections (a)*  
4 *and (b)) shall apply to a civil money penalty applied under*  
5 *this subsection in the same manner as they apply to a civil*  
6 *money penalty or proceeding under section 1128A(a).*

7       “(e) *SPECIFIED MEANINGFUL USE INCENTIVE PRO-*  
8 *GRAM.—For purposes of this section, the term ‘specified*  
9 *meaningful use incentive program’ includes the following:*

10           “(1) *The incentive payments under subsection*  
11 *(o) of section 1848 of the Social Security Act (42*  
12 *U.S.C. 1395w–4) and adjustments under subsection*  
13 *(a)(7) of such section.*

14           “(2) *The incentive payments under subsection*  
15 *(n) of section 1848 of such Act (42 U.S.C. 1395ww)*  
16 *and adjustments under subsection (b)(3)(B) of such*  
17 *section.*

18           “(3) *The incentive payments and adjustments*  
19 *made under subsections (l) and (m) of section 1853*  
20 *of such Act (42 U.S.C. 1395w–23).*

21           “(4) *The incentive payment under paragraph (3)*  
22 *of section 1814(l) of such Act (42 U.S.C. 1395f(l))*  
23 *and adjustment under paragraph (4) of such section.*

24           “(5) *The shared savings program under section*  
25 *1899 of such Act (42 U.S.C. 1395jjj).*

1           “(6) *The payments to Medicaid providers de-*  
2           *scribed in section 1903(t) of such Act (42 U.S.C.*  
3           *1396b(t)).*

4           “(f) *INFORMATION BLOCKING.—*

5           “(1) *IN GENERAL.—For purposes of this section*  
6           *and section 3010, the term ‘information blocking’*  
7           *means, with respect to the use of qualified electronic*  
8           *health records or other health information technology*  
9           *under a specified meaningful use incentive program,*  
10           *business, technical, and organizational practices, in-*  
11           *cluding practices described in paragraph (2), that—*

12                   “(A) *prevent or materially discourage the*  
13                   *exchange of electronic health information;*

14                   “(B) *the actor knows or should know (as de-*  
15                   *fined in section 1128A(i)(7) of the Social Secu-*  
16                   *rity Act) are likely to interfere with the exchange*  
17                   *or use of electronic health information; and*

18                   “(C) *do not serve to protect patient safety,*  
19                   *maintain the privacy and security of individ-*  
20                   *uals’ health information or promote competition*  
21                   *and consumer welfare.*

22           “(2) *PRACTICES DESCRIBED.—For purposes of*  
23           *paragraph (1), the practices described in this para-*  
24           *graph are the following:*

1           “(A) Contract terms, policies, or other busi-  
2           ness or organizational practices that restrict in-  
3           dividuals’ access to their electronic health infor-  
4           mation or restrict the exchange or use of that in-  
5           formation for treatment and other permitted  
6           purposes.

7           “(B) Charging prices or fees (such as for  
8           data exchange, portability, and interfaces) that  
9           make exchanging and using electronic health in-  
10          formation cost prohibitive.

11          “(C) Developing or implementing health in-  
12          formation technology in nonstandard ways that  
13          are likely to substantially increase the costs,  
14          complexity, or burden of sharing electronic  
15          health information, especially in cases in which  
16          relevant interoperability standards or methods to  
17          measure interoperability have been adopted by  
18          the Secretary.

19          “(D) Developing or implementing health in-  
20          formation technology in ways that are likely to  
21          lock in users or electronic health information,  
22          such as not allowing for the full export of data;  
23          lead to fraud, waste, or abuse; or impede innova-  
24          tions and advancements in health information



1           *exchange and health information technology-en-*  
2           *abled care delivery.*

3           “(g) *TREATMENT OF VENDORS WITH RESPECT TO PA-*  
4           *TIENT SAFETY ORGANIZATIONS.—In applying part C of*  
5           *title IX—*

6           “(1) *vendors shall be treated as a provider (as*  
7           *defined in section 921) for purposes of reporting re-*  
8           *quirements under such part, to the extent that such*  
9           *reports are related to attestation requirements under*  
10           *section 3001(c)(5)(C)(i)(I);*

11           “(2) *claims of information blocking described in*  
12           *subsection (a) shall be treated as a patient safety ac-*  
13           *tivity under such part for purposes of reporting re-*  
14           *quirements under such part; and*

15           “(3) *health care providers that are not members*  
16           *of patient safety organizations shall be treated in the*  
17           *same manner as health care providers that are such*  
18           *members for purposes of such reporting requirements*  
19           *with respect to claims of information blocking de-*  
20           *scribed in subsection (a).”.*

21           (3) *ONCHIT.—*

22           (A) *PORTAL.—Section 3001(c) of the Public*  
23           *Health Service Act (42 U.S.C. 300jj–11(c)) is*  
24           *amended by adding at the end the following new*  
25           *paragraph:*

1           “(9) *PORTAL*.—Not later than January 1, 2019,  
2           *the National Coordinator shall create a portal to*  
3           *make the information described in paragraph*  
4           *(5)(C)(I)(i)(bb) available to the public in a manner*  
5           *that allows for comparison of price information*  
6           *among health information technology products and*  
7           *that aids in making informed decisions for pur-*  
8           *chasing such a product.”.*

9           *(B) INFORMATION BLOCKING*.—Not later  
10           *than 12 months after the date of the enactment*  
11           *of this Act, the National Coordinator of the Of-*  
12           *fice of the National Coordinator of Health Infor-*  
13           *mation Technology shall, through rulemaking,*  
14           *implement the provisions of this section, and*  
15           *amendments made by this section, relating to in-*  
16           *formation blocking.*

17           *(C) HIPAA*.—Not later than January 1,  
18           *2017, the National Coordinator shall publish*  
19           *guidance to clarify the relationship of the*  
20           *HIPAA privacy and security law, as defined in*  
21           *section 3009(a)(2) of the Public Health Service*  
22           *Act (42 U.S.C. 300jj–19(a)(2)) as such provi-*  
23           *sions relate to information blocking (as defined*  
24           *in section 3010A(f) of such Act, as added by*

1 paragraph (2)), including examples of how such  
2 provisions may result in information blocking.

3 (4) *DEMONSTRATION REQUIRED FOR MEANING-*  
4 *FUL EHR USE INCENTIVES UNDER MEDICARE.—*

5 (A) *INCENTIVES FOR PROFESSIONALS.—*

6 (i) *IN GENERAL.—Section*  
7 *1848(o)(2)(C) of the Social Security Act (42*  
8 *U.S.C. 1395w-4(o)(2)(C)) is amended by*  
9 *adding at the end the following new clause:*

10 “(iii) *INTEROPERABILITY.—With re-*  
11 *spect to EHR reporting periods for pay-*  
12 *ment years beginning with 2018, the means*  
13 *described in clause (i) specified by the Sec-*  
14 *retary shall include a demonstration,*  
15 *through means such as an attestation, that*  
16 *the professional has not taken any action*  
17 *described in subsection (a)(2) of section*  
18 *3010A of the Public Health Service Act,*  
19 *with respect to the use of any certified EHR*  
20 *technology.”.*

21 (ii) *HARDSHIP EXEMPTION IN CASE OF*  
22 *DECERTIFIED EHR.—Subparagraph (B) of*  
23 *section 1848(a)(7) of the Social Security*  
24 *Act (42 U.S.C. 1395w-4(a)(7)) is amended*  
25 *to read as follows:*

1                   “(B) *SIGNIFICANT HARDSHIP EXCEPTION.*—

2                   “*(i) IN GENERAL.*—*The Secretary may,*  
3                   *on a case-by-case basis, exempt an eligible*  
4                   *professional from the application of the*  
5                   *payment adjustment under subparagraph*  
6                   *(A) if the Secretary determines, subject to*  
7                   *annual renewal, that compliance with the*  
8                   *requirement for being a meaningful EHR*  
9                   *user would result in a significant hardship,*  
10                   *such as in the case of an eligible profes-*  
11                   *sional who practices in a rural area with-*  
12                   *out sufficient Internet access.*

13                   “*(ii) DECERTIFICATION.*—

14                   “*(I) IN GENERAL.*—*The Secretary*  
15                   *may, on a case-by-case basis, exempt*  
16                   *an eligible professional from the appli-*  
17                   *cation of the payment adjustment*  
18                   *under subparagraph (A) if the Sec-*  
19                   *retary determines that such profes-*  
20                   *sional was determined to not be a*  
21                   *meaningful EHR user because the*  
22                   *qualified electronic health record used*  
23                   *by such professional was decertified*  
24                   *under section 3001(c)(5)(C) of the Pub-*  
25                   *lic Health Service Act. An exemption*

1            *under the previous sentence may be ap-*  
2            *plied to an eligible professional only,*  
3            *subject to subclause (II), during the*  
4            *first payment year with respect to the*  
5            *first EHR reporting period to which*  
6            *such decertification applies.*

7            “(II) DURATION.—

8                  “(aa) IN GENERAL.—*In no*  
9                  *case shall an exemption by reason*  
10                  *of this clause be for a period of*  
11                  *less than 12 months.*

12                  “(bb) EXTENSION.—*An ex-*  
13                  *emption under this clause may be*  
14                  *extended for a period of an addi-*  
15                  *tional 12 months subject to the*  
16                  *limitation described in clause (ii).*

17                  “(iii) LIMITATION.—*Subject to clause*  
18                  *(ii)(II)(aa), in no case may an eligible pro-*  
19                  *fessional be granted an exemption under*  
20                  *this subparagraph for more than 5 years.”.*

21            (B) INCENTIVES FOR HOSPITALS.—

22                  (i) IN GENERAL.—*Section 1886(o)(1)*  
23                  *of the Social Security Act (42 U.S.C.*  
24                  *1395ww(o)(1)) is amended—*

1                   (I) in subparagraph (A), by in-  
2                   serting before the period at the end the  
3                   following: “and, for performance peri-  
4                   ods for fiscal year 2018 or a subsequent  
5                   fiscal year, that provide a demonstra-  
6                   tion described in subparagraph (D) to  
7                   the Secretary”; and

8                   (II) by adding at the end the fol-  
9                   lowing new subparagraph:

10                   “(D) *DEMONSTRATION DESCRIBED.*—The  
11                   demonstration described in this subparagraph is  
12                   a demonstration, through means such as an at-  
13                   testation, that the hospital has not taken any ac-  
14                   tion described in subsection (a)(2) of section  
15                   3010A of the Public Health Service Act, with re-  
16                   spect to the use of any certified EHR tech-  
17                   nology.”.

18                   (ii) *HARDSHIP EXEMPTION IN CASE OF*  
19                   *DECERTIFIED EHR.*—Subclause (II) of sec-  
20                   tion 1886(b)(3)(B)(ix) of the Social Secu-  
21                   rity Act (42 U.S.C. 1395ww(b)(3)(B)(ix)) is  
22                   amended to read as follows:

23                   “(II)(aa) The Secretary may, on a case-by-case basis,  
24                   exempt a subsection (d) hospital from the application of  
25                   subclause (I) with respect to a fiscal year if the Secretary

1 *determines, subject to annual renewal, that requiring such*  
2 *hospital to be a meaningful EHR user during such fiscal*  
3 *year would result in a significant hardship, such as in the*  
4 *case of a hospital in a rural area without sufficient Internet*  
5 *access.*

6       “(bb) *The Secretary may, on a case-by-case basis, ex-*  
7 *empt a subsection (d) hospital from the application of sub-*  
8 *clause (I) with respect to a fiscal year if the Secretary deter-*  
9 *mines, subject to annual renewal, that such hospital was*  
10 *determined to not be a meaningful EHR user because the*  
11 *qualified electronic health record used by such hospital was*  
12 *decertified under section 3001(c)(5)(C) of the Public Health*  
13 *Service Act. An exemption under the previous sentence may*  
14 *be applied to a subsection (d) hospital only, subject to items*  
15 *(cc) and (dd), during the first payment year with respect*  
16 *to the first EHR reporting period to which such decertifica-*  
17 *tion applies.*

18       “(cc) *In no case shall an exemption by reason of item*  
19 *(bb) be for a period of less than 12 months.*

20       “(dd) *An exemption under item (bb) may be extended*  
21 *for a period of an additional 12 months subject to the limi-*  
22 *tation described in item (ee).*

23       “(ee) *Subject to item (cc), in no case may a hospital*  
24 *be granted an exemption under this subclause for more than*  
25 *5 years.”.*

1                   (C) *DEMONSTRATION REQUIRED FOR MEAN-*  
2                   *INGFUL EHR USE INCENTIVES UNDER MED-*  
3                   *ICAID.—Section 1903(t)(2) of the Social Security*  
4                   *Act (42 U.S.C. 1396b(t)(2)) is amended by add-*  
5                   *ing at the end the following: “An eligible profes-*  
6                   *sional shall not qualify as a Medicaid provider*  
7                   *under this subsection, with respect to a year be-*  
8                   *ginning with 2018, unless such provider dem-*  
9                   *onstrates to the Secretary, through means such as*  
10                   *an attestation, that the provider has not taken*  
11                   *any action described in subsection (a)(2) of sec-*  
12                   *tion 3010A of the Public Health Service Act with*  
13                   *respect to which the provider knows or should*  
14                   *know (as defined in section 1128A(i)(7) of the*  
15                   *Social Security Act) about, with respect to the*  
16                   *use of any certified EHR technology.”.*

17                   (f) *DEFINITIONS.—*

18                   (1) *CERTIFIED EHR TECHNOLOGY.—Paragraph*  
19                   *(1) of section 3000 of the Public Health Service Act*  
20                   *(42 U.S.C. 300jj) is amended to read as follows:*

21                   “(1) *CERTIFIED EHR TECHNOLOGY.—The term*  
22                   *‘certified EHR technology’ means a qualified elec-*  
23                   *tronic health record that is certified pursuant to sec-*  
24                   *tion 3001(c)(5) as meeting the certification criteria*  
25                   *defined in subparagraph (B) of such section that are*



1 applicable to the type of record involved (as deter-  
2 mined by the Secretary, such as an ambulatory elec-  
3 tronic health record for office-based physicians or an  
4 inpatient hospital electronic health record for hos-  
5 pitals) including, beginning January 1, 2018, with  
6 respect to which the vendor or other entity offering  
7 such technology is in compliance with the require-  
8 ments under section 3001(c)(5)(C)(i).”.

9 (2) *WIDESPREAD INTEROPERABILITY*.—Section  
10 3000 of the Public Health Service Act (42 U.S.C.  
11 300jj) is amended by adding at the end the following  
12 new paragraph:

13 “(15) *WIDESPREAD INTEROPERABILITY*.—The  
14 term ‘widespread interoperability’ means that, on a  
15 nationwide basis—

16 “(A) health information technology is inter-  
17 operable, in accordance with section 3010; and

18 “(B) such technology is employed by mean-  
19 ingful EHR users under the specified meaningful  
20 use incentive programs (as defined in section  
21 3010A(e)) and by other clinicians and health  
22 care providers.”.

23 (g) *CONFORMING AMENDMENTS*.—

1           (1) *VOLUNTARY USE OF STANDARDS.*—Section  
2           3006 of the Public Health Service Act (42 U.S.C.  
3           300jj–16) is amended—

4                   (A) in subsection (a)(1), by inserting “, in-  
5                   cluding an interoperability standard adopted  
6                   under such section” after “section 3004”.

7                   (B) in subsection (b), by inserting “, in-  
8                   cluding the interoperability standards adopted  
9                   under such section” after “section 3004”.

10           (2) *HIPAA PRIVACY AND SECURITY LAW DEFINI-*  
11           *TION CORRECTION.*—Section 3009(a)(2)(A) of the  
12           Public Health Service Act (42 U.S.C. 300jj–  
13           19(a)(2)(A)) is amended by striking “title IV” and  
14           inserting “title XIII”.

15           (3) *COORDINATION OF FEDERAL ACTIVITIES.*—  
16           Section 13111 of the HITECH Act is amended—

17                   (A) in subsection (a), by inserting before the  
18                   period at the end the following: “(and, beginning  
19                   on January 1, 2018, that are also interoperable  
20                   under section 3010 of such Act, including by  
21                   being in compliance with interoperability stand-  
22                   ards adopted under section 3004 of such Act)”;  
23                   and

24                   (B) in subsection (b), by inserting “(and,  
25                   beginning on January 1, 2018, including an

1           *interoperability standard adopted under section*  
2           *3004 of such Act)” before “the President”.*

3           (4) *APPLICATION TO PRIVATE ENTITIES.*—*Sec-*  
4           *tion 13112 of the HITECH Act is amended by insert-*  
5           *ing before the period at the end the following: “(and,*  
6           *beginning on January 1, 2018, that are also inter-*  
7           *operable under section 3010 of such Act, including by*  
8           *being in compliance with interoperability standards*  
9           *adopted under section 3004 of such Act)”.*

10           (5) *COORDINATION WITH RECOMMENDATIONS*  
11           *FOR ACHIEVING WIDESPREAD EHR INTEROPER-*  
12           *ABILITY.*—*Section 106 of the Medicare Access and*  
13           *CHIP Reauthorization Act of 2015 (Public Law 114-*  
14           *10) is amended by striking subsection (b).”.*

15           (h) *PATIENT EMPOWERMENT.*—*It is the sense of Con-*  
16           *gress that—*

17           (1) *patients have the right to the entirety of the*  
18           *health information of such patients, including such*  
19           *information contained in an electronic health record*  
20           *of such patients;*

21           (2) *such right extends to both structured and*  
22           *unstructured data; and*

23           (3) *to further facilitate patient ownership over*  
24           *health information of such patient—*

1           (A) health care providers should not have  
2           the ability to deny a patient's request for access  
3           to the entirety of such health information of such  
4           patient; and

5           (B) health care providers do not need the  
6           consent of their patients to share personal health  
7           information of such patients with other covered  
8           entities, in compliance with the HIPAA privacy  
9           regulations promulgated pursuant to section  
10          264(c) of the Health Insurance Portability and  
11          Accountability Act of 1996 for the purposes of  
12          supporting patient care, except in situations  
13          where consent is specifically required under such  
14          regulations, such as in cases related to the psy-  
15          chiatric records of the patient.

## 16           **Subtitle B—Telehealth**

### 17   **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE** 18           **PROGRAM.**

19          (a) *PROVISION OF INFORMATION BY CENTERS FOR*  
20          *MEDICARE & MEDICAID SERVICES.*—Not later than 1 year  
21          after the date of the enactment of this Act, the Adminis-  
22          trator of the Centers for Medicare & Medicaid Services shall  
23          provide to the committees of jurisdiction of the House of  
24          Representatives and the Senate information on the fol-  
25          lowing:

1           (1) *The populations of Medicare beneficiaries,*  
2           *such as those who are dually eligible for the Medicare*  
3           *program under title XVIII of the Social Security Act*  
4           *(42 U.S.C. 1395 et seq.) and the Medicaid program*  
5           *under title XIX of such Act (42 U.S.C. 1396 et seq.)*  
6           *and those with chronic conditions, whose care may be*  
7           *improved most in terms of quality and efficiency by*  
8           *the expansion, in a manner that meets or exceeds the*  
9           *existing in-person standard of care under the Medi-*  
10          *care program under title XVIII of such Act, of tele-*  
11          *health services under section 1834(m)(4) of such Act*  
12          *(42 U.S.C. 1395m(m)(4)).*

13           (2) *Activities by the Center for Medicare and*  
14          *Medicaid Innovation which examine the use of tele-*  
15          *health services in models, projects, or initiatives fund-*  
16          *ed through section 1115A of the Social Security Act*  
17          *(42 U.S.C. 1315a).*

18           (3) *The types of high volume procedures codes or*  
19          *diagnoses under such title XVIII which might be suit-*  
20          *able to the furnishing of services via telehealth.*

21           (4) *Barriers that might prevent the expansion of*  
22          *telehealth services under section 1834(m)(4) of the So-*  
23          *cial Security Act (42 U.S.C. 1395m(m)(4)) beyond*  
24          *such services that are in effect as of the date of the*  
25          *enactment of this Act.*

1           (b) *PROVISION OF INFORMATION BY MEDPAC.*—Not  
2 later than 1 year after the date of the enactment of this  
3 Act, the Medicare Payment Advisory Commission estab-  
4 lished under section 1805 of the Social Security Act (42  
5 U.S.C. 1395b–6) shall, using data from the Medicare Ad-  
6 vantage program under part C of title XVIII of such Act  
7 (42 U.S.C. 1395w–21 et seq.), provide information to the  
8 committees of jurisdiction of the House of Representatives  
9 and the Senate that identifies—

10           (1) services—

11                   (A) for which payment could not be made,  
12 as of the date of the enactment of this Act, under  
13 the fee-for-service program under parts A and B  
14 of such title by reason of any limitation imposed  
15 under section 1834(m) of such Act (42 U.S.C.  
16 1395m(m)); and

17                   (B) that are services that are recommended  
18 by the Commission to be included as telehealth  
19 services for which payment may be made under  
20 the fee-for-service program under parts A and B  
21 of such title; and

22           (2) barriers to furnishing telehealth services for  
23 which payment may be made under such title XVIII  
24 and solutions to address such barriers.

1       (c) *SENSE OF CONGRESS.—It is the sense of Congress*  
2 *that—*

3           (1) *States should collaborate, through the use of*  
4 *State health board compacts or other mechanisms, to*  
5 *create common licensure requirements services in*  
6 *order to facilitate multistate practices and allow for*  
7 *health care providers to provide such services across*  
8 *State lines;*

9           (2) *health care providers should be appropriately*  
10 *licensed in the physical location where the patient is*  
11 *receiving services;*

12           (3) *eligible originating sites should be expanded*  
13 *beyond those originating sites described in section*  
14 *1834(m)(4)(C) of the Social Security Act (42 U.S.C.*  
15 *1395m(m)(4)(C)); and*

16           (4) *any expansion of telehealth services under the*  
17 *Medicare program should—*

18           (A) *recognize that telemedicine is the deliv-*  
19 *ery of safe, effective, quality health care services,*  
20 *by a health care provider, using technology as*  
21 *the mode of care delivery;*

22           (B) *meet or exceed the conditions of cov-*  
23 *erage and payment with respect to the Medicare*  
24 *program under title XVIII unless specifically ad-*  
25 *dress in subsequent statute, of such Act if the*

1           service were furnished in person, including  
2           standards of care; and

3                   (C) involve clinically appropriate means to  
4           furnish such services.

5   **Subtitle    C—Encouraging    Con-**  
6   **tinuing    Medical    Education    for**  
7   **Physicians**

8   **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**  
9                   **PARENCY REPORTING CERTAIN TRANSFERS**  
10                   **USED FOR EDUCATIONAL PURPOSES.**

11           (a) *IN GENERAL.*—Section 1128G(e)(10)(B) of the So-  
12   cial Security Act (42 U.S.C. 1320a-7h(e)(10)(B)) is  
13   amended—

14                   (1) in clause (iii), by inserting “, including  
15           peer-reviewed journals, journal reprints, journal sup-  
16           plements, medical conference reports, and medical  
17           textbooks” after “patient use”; and

18                   (2) by adding at the end the following new  
19   clause:

20                                   “(xiii) In the case of a covered recipi-  
21           ent who is a physician, an indirect pay-  
22           ment or transfer of value to the covered re-  
23           cipient—

24   “(I) for speaking at, or preparing  
25           educational materials for, an edu-



1                    *ational event for physicians or other*  
2                    *health care professionals that does not*  
3                    *commercially promote a covered drug,*  
4                    *device, biological, or medical supply; or*  
5                    *“(II) that serves the sole purpose*  
6                    *of providing the covered recipient with*  
7                    *medical education, such as by pro-*  
8                    *viding the covered recipient with the*  
9                    *tuition required to attend an edu-*  
10                   *cational event or with materials pro-*  
11                   *vided to physicians at an educational*  
12                   *event.”.*

13                   *(b) EFFECTIVE DATE.—The amendments made by this*  
14 *section shall apply with respect to transfers of value made*  
15 *on or after the date of the enactment of this Act.*

16                   ***Subtitle D—Disposable Medical***  
17                   ***Technologies***

18                   ***SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.***

19                   *(a) IN GENERAL.—Section 1834 of the Social Security*  
20 *Act (42 U.S.C. 1395m) is amended by adding at the end*  
21 *the following new subsection:*

22                   *“(r) PAYMENT FOR CERTAIN DISPOSABLE DEVICES.—*  
23                   *“(1) IN GENERAL.—The Secretary shall make*  
24                   *separate payment in the amount established under*  
25                   *paragraph (3) to a home health agency for a device*

1 *described in paragraph (2) when furnished to an in-*  
2 *dividual who receives home health services for which*  
3 *payment is made under section 1895(b).*

4 “(2) *DEVICE DESCRIBED.*—For purposes of  
5 *paragraph (1), a device described in this paragraph*  
6 *is a disposable device for which, as of January 1,*  
7 *2015, there is—*

8 “(A) *a Level I Healthcare Common Proce-*  
9 *dure Coding System (HCPCS) code for which*  
10 *the description for a professional service includes*  
11 *the furnishing of such device; and*

12 “(B) *a separate Level I HCPCS code for a*  
13 *professional service that uses durable medical*  
14 *equipment instead of such device.*

15 “(3) *PAYMENT AMOUNT.*—The Secretary shall es-  
16 *tablish the separate payment amount for such a de-*  
17 *vice such that such amount does not exceed the pay-*  
18 *ment that would be made for the HCPCS code de-*  
19 *scribed in paragraph (2)(A) under section 1833(t)*  
20 *(relating to payment for covered OPD services).”.*

21 (b) *CONFORMING AMENDMENT.*—Section 1861(m)(5)  
22 *of the Social Security Act (42 U.S.C. 1395x(m)(5)) is*  
23 *amended by inserting “and devices described in section*  
24 *1834(r)(2)” after “durable medical equipment”.*

1           (c) *EFFECTIVE DATE.*—*The amendments made by this*  
2 *section shall apply to devices furnished on or after January*  
3 *1, 2017.*

4                           ***Subtitle E—Local Coverage***  
5                           ***Decision Reforms***

6 ***SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-***  
7 ***ERAGE DETERMINATION (LCD) PROCESS.***

8           (a) *IN GENERAL.*—*Section 1862(l)(5) of the Social Se-*  
9 *curity Act (42 U.S.C. 1395y(l)(5)) is amended by adding*  
10 *at the end the following new subparagraph:*

11                           “(D) *LOCAL COVERAGE DETERMINATIONS.*—  
12                           *The Secretary shall require each medicare ad-*  
13                           *ministrative contractor that develops a local cov-*  
14                           *erage determination to make available on the*  
15                           *website of such contractor and in the coverage*  
16                           *database on the Medicare website, at least 45*  
17                           *days before the effective date of such determina-*  
18                           *tion, the following information:*

19   “(i) *Such determination in its en-*  
20   *tirety.*

21   “(ii) *Where and when the proposed de-*  
22   *termination was first made public.*

23   “(iii) *Hyperlinks to the proposed deter-*  
24   *mination and a response to comments sub-*

1                   mitted to the contractor with respect to such  
2                   proposed determination.

3                   “(iv) A summary of evidence that was  
4                   considered by the contractor during the de-  
5                   velopment of such determination and a list  
6                   of the sources of such evidence.

7                   “(v) An explanation of the rationale  
8                   that supports such determination.”.

9                   (b) *EFFECTIVE DATE.*—The amendment made by sub-  
10                  section (a) shall apply with respect to local coverage deter-  
11                  minations that are proposed or revised on or after the date  
12                  that is 180 days after the date of the enactment of this Act.

13                  **Subtitle F—Medicare Pharma-**  
14                  **ceutical and Technology Om-**  
15                  **budsman**

16                  **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECHNOLOGY**  
17                  **OMBUDSMAN.**

18                  Section 1808(c) of the Social Security Act (42 U.S.C.  
19                  1395b–9(c)) is amended by adding at the end the following  
20                  new paragraph:

21                  “(4) *PHARMACEUTICAL AND TECHNOLOGY OM-*  
22                  *BUDSMAN.*—Not later than 12 months after the date  
23                  of the enactment of this paragraph, the Secretary  
24                  shall provide for a pharmaceutical and technology  
25                  ombudsman within the Centers for Medicare & Med-

1        *icaid Services who shall receive and respond to com-*  
 2        *plaints, grievances, and requests that—*

3                *“(A) are from entities that manufacture*  
 4                *pharmaceutical, biotechnology, medical device, or*  
 5                *diagnostic products that are covered or for which*  
 6                *coverage is being sought under this title; and*

7                *“(B) are with respect to coverage, coding, or*  
 8                *payment under this title for such products.”.*

9                ***Subtitle G—Medicare Site-of-***  
 10              ***Service Price Transparency***

11 ***SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-***  
 12                ***PARENCY.***

13        *Section 1834 of the Social Security Act (42 U.S.C.*  
 14 *1395m), as amended by section 3061, is further amended*  
 15 *by adding at the end the following new subsection:*

16        *“(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—*

17                *“(1) IN GENERAL.—In order to facilitate price*  
 18                *transparency with respect to items and services for*  
 19                *which payment may be made either to a hospital out-*  
 20                *patient department or to an ambulatory surgical cen-*  
 21                *ter under this title, the Secretary shall, for 2017 and*  
 22                *each year thereafter, make available to the public via*  
 23                *a searchable website, with respect to an appropriate*  
 24                *number of such items and services—*

1           “(A) the estimated payment amount for the  
2           item or service under the outpatient department  
3           fee schedule under subsection (t) of section 1833  
4           and the ambulatory surgical center payment sys-  
5           tem under subsection (i) of such section; and

6           “(B) the estimated amount of beneficiary li-  
7           ability applicable to the item or service.

8           “(2) *CALCULATION OF ESTIMATED BENEFICIARY*  
9           *LIABILITY.*—For purposes of paragraph (1)(B), the es-  
10          timated amount of beneficiary liability, with respect  
11          to an item or service, is the amount for such item or  
12          service for which an individual who does not have  
13          coverage under a medicare supplemental policy cer-  
14          tified under section 1882 or any other supplemental  
15          insurance coverage is responsible.

16          “(3) *IMPLEMENTATION.*—In carrying out this  
17          subsection, the Secretary—

18                 “(A) shall include in the notice described in  
19                 section 1804(a) a notification of the availability  
20                 of the estimated amounts made available under  
21                 paragraph (1); and

22                 “(B) may utilize mechanisms in existence  
23                 on the date of the enactment of this subsection,  
24                 such as the portion of the website of the Centers  
25                 for Medicare & Medicaid Services on which in-

1        *formation comparing physician performance is*  
 2        *posted (commonly referred to as the Physician*  
 3        *Compare website), to make available such esti-*  
 4        *mated amounts under such paragraph.*

5        “(4) *FUNDING.—For purposes of implementing*  
 6        *this subsection, the Secretary shall provide for the*  
 7        *transfer, from the Supplemental Medical Insurance*  
 8        *Trust Fund under section 1841 to the Centers for*  
 9        *Medicare & Medicaid Services Program Management*  
 10        *Account, of \$6,000,000 for fiscal year 2015, to remain*  
 11        *available until expended.”.*

12        ***Subtitle H—Medicare Part D Pa-***  
 13        ***tient Safety and Drug Abuse Pre-***  
 14        ***vention***

15        ***SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG***  
 16        ***ABUSE UNDER MEDICARE PARTS C AND D.***

17        (a) *DRUG MANAGEMENT PROGRAM FOR AT-RISK*  
 18        *BENEFICIARIES.—*

19        (1) *IN GENERAL.—Section 1860D–4(c) of the So-*  
 20        *cial Security Act (42 U.S.C. 1395w–10(c)) is amend-*  
 21        *ed by adding at the end the following:*

22        “(5) *DRUG MANAGEMENT PROGRAM FOR AT-RISK*  
 23        *BENEFICIARIES.—*

24        “(A) *AUTHORITY TO ESTABLISH.—A PDP*  
 25        *sponsor may establish a drug management pro-*

1           *gram for at-risk beneficiaries under which, sub-*  
2           *ject to subparagraph (B), the PDP sponsor may,*  
3           *in the case of an at-risk beneficiary for prescrip-*  
4           *tion drug abuse who is an enrollee in a prescrip-*  
5           *tion drug plan of such PDP sponsor, limit such*  
6           *beneficiary's access to coverage for frequently*  
7           *abused drugs under such plan to frequently*  
8           *abused drugs that are prescribed for such bene-*  
9           *ficiary by one or more prescribers selected under*  
10           *subparagraph (D), and dispensed for such bene-*  
11           *ficiary by one or more pharmacies selected under*  
12           *such subparagraph.*

13           “(B) *REQUIREMENT FOR NOTICES.*—

14           “(i) *IN GENERAL.*—A PDP sponsor  
15           *may not limit the access of an at-risk bene-*  
16           *ficiary for prescription drug abuse to cov-*  
17           *erage for frequently abused drugs under a*  
18           *prescription drug plan until such sponsor—*

19           “(I) *provides to the beneficiary an*  
20           *initial notice described in clause (ii)*  
21           *and a second notice described in clause*  
22           *(iii); and*

23           “(II) *verifies with the providers of*  
24           *the beneficiary that the beneficiary is*



1            *an at-risk beneficiary for prescription*  
2            *drug abuse.*

3            “(ii) *INITIAL NOTICE.—An initial no-*  
4            *tice described in this clause is a notice that*  
5            *provides to the beneficiary—*

6                    “(I) *notice that the PDP sponsor*  
7                    *has identified the beneficiary as poten-*  
8                    *tially being an at-risk beneficiary for*  
9                    *prescription drug abuse;*

10                   “(II) *information describing all*  
11                   *State and Federal public health re-*  
12                   *sources that are designed to address*  
13                   *prescription drug abuse to which the*  
14                   *beneficiary has access, including men-*  
15                   *tal health services and other counseling*  
16                   *services;*

17                   “(III) *notice of, and information*  
18                   *about, the right of the beneficiary to*  
19                   *appeal such identification under sub-*  
20                   *section (h) and the option of an auto-*  
21                   *matic escalation to external review;*

22                   “(IV) *a request for the beneficiary*  
23                   *to submit to the PDP sponsor pref-*  
24                   *erences for which prescribers and phar-*  
25                   *macies the beneficiary would prefer the*

1 *PDP sponsor to select under subpara-*  
2 *graph (D) in the case that the bene-*  
3 *ficiary is identified as an at-risk bene-*  
4 *ficiary for prescription drug abuse as*  
5 *described in clause (iii)(I);*

6 *“(V) an explanation of the mean-*  
7 *ing and consequences of the identifica-*  
8 *tion of the beneficiary as potentially*  
9 *being an at-risk beneficiary for pre-*  
10 *scription drug abuse, including an ex-*  
11 *planation of the drug management*  
12 *program established by the PDP spon-*  
13 *sor pursuant to subparagraph (A);*

14 *“(VI) clear instructions that ex-*  
15 *plain how the beneficiary can contact*  
16 *the PDP sponsor in order to submit to*  
17 *the PDP sponsor the preferences de-*  
18 *scribed in subclause (IV) and any*  
19 *other communications relating to the*  
20 *drug management program for at-risk*  
21 *beneficiaries established by the PDP*  
22 *sponsor; and*

23 *“(VII) contact information for*  
24 *other organizations that can provide*  
25 *the beneficiary with assistance regard-*

1            *ing such drug management program*  
2            *(similar to the information provided*  
3            *by the Secretary in other standardized*  
4            *notices provided to part D eligible in-*  
5            *dividuals enrolled in prescription drug*  
6            *plans under this part).*

7            *“(iii) SECOND NOTICE.—A second no-*  
8            *tice described in this clause is a notice that*  
9            *provides to the beneficiary notice—*

10            *“(I) that the PDP sponsor has*  
11            *identified the beneficiary as an at-risk*  
12            *beneficiary for prescription drug abuse;*

13            *“(II) that such beneficiary is sub-*  
14            *ject to the requirements of the drug*  
15            *management program for at-risk bene-*  
16            *ficiaries established by such PDP spon-*  
17            *sor for such plan;*

18            *“(III) of the prescriber (or pre-*  
19            *scribers) and pharmacy (or phar-*  
20            *macies) selected for such individual*  
21            *under subparagraph (D);*

22            *“(IV) of, and information about,*  
23            *the beneficiary’s right to appeal such*  
24            *identification under subsection (h) and*

1           *the option of an automatic escalation*  
2           *to external review;*

3           “(V) *that the beneficiary can, in*  
4           *the case that the beneficiary has not*  
5           *previously submitted to the PDP spon-*  
6           *sor preferences for which prescribers*  
7           *and pharmacies the beneficiary would*  
8           *prefer the PDP sponsor select under*  
9           *subparagraph (D), submit such pref-*  
10           *erences to the PDP sponsor; and*

11           “(VI) *that includes clear instruc-*  
12           *tions that explain how the beneficiary*  
13           *can contact the PDP sponsor.*

14           “(iv) *TIMING OF NOTICES.—*

15           “(I) *IN GENERAL.—Subject to*  
16           *subclause (II), a second notice de-*  
17           *scribed in clause (iii) shall be provided*  
18           *to the beneficiary on a date that is not*  
19           *less than 60 days after an initial no-*  
20           *tice described in clause (ii) is provided*  
21           *to the beneficiary.*

22           “(II) *EXCEPTION.—In the case*  
23           *that the PDP sponsor, in conjunction*  
24           *with the Secretary, determines that*  
25           *concerns identified through rulemaking*

1           by the Secretary regarding the health  
2           or safety of the beneficiary or regard-  
3           ing significant drug diversion activi-  
4           ties require the PDP sponsor to pro-  
5           vide a second notice described in clause  
6           (iii) to the beneficiary on a date that  
7           is earlier than the date described in  
8           subclause (I), the PDP sponsor may  
9           provide such second notice on such ear-  
10          lier date.

11                   “(C) *AT-RISK BENEFICIARY FOR PRESCRIP-*  
12                   *TION DRUG ABUSE.—*

13                   “(i) *IN GENERAL.—*For purposes of  
14                   this paragraph, the term ‘at-risk beneficiary  
15                   for prescription drug abuse’ means a part  
16                   D eligible individual who is not an exempt-  
17                   ed individual described in clause (ii) and—

18                   “(I) who is identified through the  
19                   use of clinical guidelines developed by  
20                   the Secretary in consultation with  
21                   PDP sponsors and other stakeholders  
22                   described in section 3141(f)(2)(A) of  
23                   the 21st Century Cures Act; or

24                   “(II) with respect to whom the  
25                   PDP sponsor of a prescription drug

1            *plan, upon enrolling such individual*  
2            *in such plan, received notice from the*  
3            *Secretary that such individual was*  
4            *identified under this paragraph to be*  
5            *an at-risk beneficiary for prescription*  
6            *drug abuse under the prescription drug*  
7            *plan in which such individual was*  
8            *most recently previously enrolled and*  
9            *such identification has not been termi-*  
10           *nated under subparagraph (F).*

11           *“(ii) EXEMPTED INDIVIDUAL DE-*  
12           *SCRIBED.—An exempted individual de-*  
13           *scribed in this clause is an individual*  
14           *who—*

15                    *“(I) receives hospice care under*  
16                    *this title;*

17                    *“(II) is a resident of a long-term*  
18                    *care facility, of an intermediate care*  
19                    *facility for the mentally retarded, or of*  
20                    *another facility for which frequently*  
21                    *abused drugs are dispensed for resi-*  
22                    *dents through a contract with a single*  
23                    *pharmacy; or*

1                   “(III) the Secretary elects to treat  
2                   as an exempted individual for purposes  
3                   of clause (i).

4                   “(D) SELECTION OF PRESCRIBERS AND  
5                   PHARMACIES.—

6                   “(i) IN GENERAL.—With respect to  
7                   each at-risk beneficiary for prescription  
8                   drug abuse enrolled in a prescription drug  
9                   plan offered by such sponsor, a PDP spon-  
10                  sor shall, based on the preferences submitted  
11                  to the PDP sponsor by the beneficiary pur-  
12                  suant to clauses (ii)(IV) and (iii)(V) of sub-  
13                  paragraph (B), select—

14                  “(I) one or more individuals who  
15                  are authorized to prescribe frequently  
16                  abused drugs (referred to in this para-  
17                  graph as ‘prescribers’) who may write  
18                  prescriptions for such drugs for such  
19                  beneficiary; and

20                  “(II) one or more pharmacies that  
21                  may dispense such drugs to such bene-  
22                  ficiary.

23                  “(ii) REASONABLE ACCESS.—In mak-  
24                  ing the selections under this subpara-  
25                  graph—

1           “(I) a PDP sponsor shall ensure  
2           that the beneficiary continues to have  
3           reasonable access to frequently abused  
4           drugs (as defined in subparagraph  
5           (G)), taking into account geographic  
6           location, beneficiary preference, impact  
7           on costsharing, and reasonable travel  
8           time; and

9           “(II) a PDP sponsor shall ensure  
10          such access (including access to pre-  
11          scribers and pharmacies with respect  
12          to frequently abused drugs) in the case  
13          of individuals with multiple residences  
14          and in the case of natural disasters  
15          and similar emergency situations.

16          “(iii) *BENEFICIARY PREFERENCES.*—

17                 “(I) *IN GENERAL.*—If an at-risk  
18                 beneficiary for prescription drug abuse  
19                 submits preferences for which in-net-  
20                 work prescribers and pharmacies the  
21                 beneficiary would prefer the PDP  
22                 sponsor select in response to a notice  
23                 under subparagraph (B), the PDP  
24                 sponsor shall—



1                   “(aa) review such pref-  
2                   erences;

3                   “(bb) select or change the se-  
4                   lection of prescribers and phar-  
5                   macies for the beneficiary based  
6                   on such preferences; and

7                   “(cc) inform the beneficiary  
8                   of such selection or change of se-  
9                   lection.

10                  “(II) EXCEPTION.—In the case  
11                  that the PDP sponsor determines that  
12                  a change to the selection of prescriber  
13                  or pharmacy under item (bb) by the  
14                  PDP sponsor is contributing or would  
15                  contribute to prescription drug abuse  
16                  or drug diversion by the beneficiary,  
17                  the PDP sponsor may change the selec-  
18                  tion of prescriber or pharmacy for the  
19                  beneficiary without regard to the pref-  
20                  erences of the beneficiary described in  
21                  subclause (I).

22                  “(iv) CONFIRMATION.—Before selecting  
23                  a prescriber (or prescribers) or pharmacy  
24                  (or pharmacies) under this subparagraph, a  
25                  PDP sponsor must request and receive con-

1           *firmation from such a prescriber or phar-*  
2           *macy acknowledging and accepting that the*  
3           *beneficiary involved is in the drug manage-*  
4           *ment program for at-risk beneficiaries.*

5           “(E) *TERMINATIONS AND APPEALS.—The*  
6           *identification of an individual as an at-risk ben-*  
7           *eficiary for prescription drug abuse under this*  
8           *paragraph, a coverage determination made*  
9           *under a drug management program for at-risk*  
10          *beneficiaries, and the selection of prescriber or*  
11          *pharmacy under subparagraph (D) with respect*  
12          *to such individual shall be subject to reconsider-*  
13          *ation and appeal under subsection (h) and the*  
14          *option of an automatic escalation to external re-*  
15          *view to the extent provided by the Secretary.*

16          “(F) *TERMINATION OF IDENTIFICATION.—*

17                 “(i) *IN GENERAL.—The Secretary shall*  
18                 *develop standards for the termination of*  
19                 *identification of an individual as an at-risk*  
20                 *beneficiary for prescription drug abuse*  
21                 *under this paragraph. Under such stand-*  
22                 *ards such identification shall terminate as*  
23                 *of the earlier of—*

24                         “(I) *the date the individual dem-*  
25                         *onstrates that the individual is no*

1 longer likely, in the absence of the re-  
2 strictions under this paragraph, to be  
3 an at-risk beneficiary for prescription  
4 drug abuse described in subparagraph  
5 (C)(i); and

6 “(II) the end of such maximum  
7 period of identification as the Sec-  
8 retary may specify.

9 “(ii) *RULE OF CONSTRUCTION.*—*Noth-*  
10 *ing in clause (i) shall be construed as pre-*  
11 *venting a plan from identifying an indi-*  
12 *vidual as an at-risk beneficiary for pre-*  
13 *scription drug abuse under subparagraph*  
14 *(C)(i) after such termination on the basis of*  
15 *additional information on drug use occur-*  
16 *ring after the date of notice of such termi-*  
17 *nation.*

18 “(G) *FREQUENTLY ABUSED DRUG.*—*For*  
19 *purposes of this subsection, the term ‘frequently*  
20 *abused drug’ means a drug that is a controlled*  
21 *substance that the Secretary determines to be fre-*  
22 *quently abused or diverted.*

23 “(H) *DATA DISCLOSURE.*—*In the case of an*  
24 *at-risk beneficiary for prescription drug abuse*  
25 *whose access to coverage for frequently abused*

1           *drugs under a prescription drug plan has been*  
2           *limited by a PDP sponsor under this paragraph,*  
3           *such PDP sponsor shall disclose data, including*  
4           *any necessary individually identifiable health*  
5           *information, in a form and manner specified by*  
6           *the Secretary, about the decision to impose such*  
7           *limitations and the limitations imposed by the*  
8           *sponsor under this part.*

9           “(I) *EDUCATION.*—*The Secretary shall pro-*  
10          *vide education to enrollees in prescription drug*  
11          *plans of PDP sponsors and providers regarding*  
12          *the drug management program for at-risk bene-*  
13          *ficiaries described in this paragraph, including*  
14          *education—*

15                “(i) *provided by medicare administra-*  
16                *tive contractors through the improper pay-*  
17                *ment outreach and education program de-*  
18                *scribed in section 1874A(h); and*

19                “(ii) *through current education efforts*  
20                *(such as State health insurance assistance*  
21                *programs described in subsection (a)(1)(A)*  
22                *of section 119 of the Medicare Improvements*  
23                *for Patients and Providers Act of 2008 (42*  
24                *U.S.C. 1395b–3 note)) and materials di-*  
25                *rected toward such enrollees.*

1           “(J) *APPLICATION UNDER MA–PD PLANS.*—  
2           *Pursuant to section 1860D—21(c)(1), the provi-*  
3           *sions of this paragraph apply under part D to*  
4           *MA organizations offering MA–PD plans to MA*  
5           *eligible individuals in the same manner as such*  
6           *provisions apply under this part to a PDP spon-*  
7           *sor offering a prescription drug plan to a part*  
8           *D eligible individual.”*

9           (2) *INFORMATION FOR CONSUMERS.*—*Section*  
10          *1860D–4(a)(1)(B) of the Social Security Act (42*  
11          *U.S.C. 1395w–104(a)(1)(B)) is amended by adding at*  
12          *the end the following:*

13                   “(v) *The drug management program*  
14                   *for at-risk beneficiaries under subsection*  
15                   *(c)(5).”*

16          (b) *UTILIZATION MANAGEMENT PROGRAMS.*—*Section*  
17          *1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–*  
18          *104(c)), as amended by subsection (a)(1), is further amend-*  
19          *ed—*

20                   (1) *in paragraph (1), by inserting after subpara-*  
21                   *graph (D) the following new subparagraph:*

22                           “(E) *A utilization management tool to pre-*  
23                           *vent drug abuse (as described in paragraph*  
24                           *(6)(A)).”*; and

1           (2) *by adding at the end the following new para-*  
2 *graph:*

3           “(6) *UTILIZATION MANAGEMENT TOOL TO PRE-*  
4 *VENT DRUG ABUSE.—*

5           “(A) *IN GENERAL.—A tool described in this*  
6 *paragraph is any of the following:*

7           “(i) *A utilization tool designed to pre-*  
8 *vent the abuse of frequently abused drugs by*  
9 *individuals and to prevent the diversion of*  
10 *such drugs at pharmacies.*

11           “(ii) *Retrospective utilization review to*  
12 *identify—*

13           “(I) *individuals that receive fre-*  
14 *quently abused drugs at a frequency or*  
15 *in amounts that are not clinically ap-*  
16 *propriate; and*

17           “(II) *providers of services or sup-*  
18 *pliers that may facilitate the abuse or*  
19 *diversion of frequently abused drugs by*  
20 *beneficiaries.*

21           “(iii) *Consultation with the contractor*  
22 *described in subparagraph (B) to verify if*  
23 *an individual enrolling in a prescription*  
24 *drug plan offered by a PDP sponsor has*  
25 *been previously identified by another PDP*

1                    sponsor as an individual described in clause  
2                    (ii)(I).

3                    “(B) *REPORTING.*—A PDP sponsor offering  
4                    a prescription drug plan (and an MA organiza-  
5                    tion offering an MA–PD plan) in a State shall  
6                    submit to the Secretary and the Medicare drug  
7                    integrity contractor with which the Secretary  
8                    has entered into a contract under section 1893  
9                    with respect to such State a report, on a monthly  
10                    basis, containing information on—

11                    “(i) any provider of services or sup-  
12                    plier described in subparagraph (A)(ii)(II)  
13                    that is identified by such plan sponsor (or  
14                    organization) during the 30-day period be-  
15                    fore such report is submitted; and

16                    “(ii) the name and prescription  
17                    records of individuals described in para-  
18                    graph (5)(C).”.

19                    (c) *EXPANDING ACTIVITIES OF MEDICARE DRUG IN-*  
20 *TEGRITY CONTRACTORS (MEDICS).*—

21                    (1) *IN GENERAL.*—Section 1893 of the Social Se-  
22                    curity Act (42 U.S.C. 1395ddd) is amended by add-  
23                    ing at the end the following new subsection:

24                    “(j) *EXPANDING ACTIVITIES OF MEDICARE DRUG IN-*  
25 *TEGRITY CONTRACTORS (MEDICS).*—

1           “(1) *ACCESS TO INFORMATION.*—*Under contracts*  
2           *entered into under this section with Medicare drug*  
3           *integrity contractors (including any successor entity*  
4           *to a Medicare drug integrity contractor), the Sec-*  
5           *retary shall authorize such contractors to directly ac-*  
6           *cept prescription and necessary medical records from*  
7           *entities such as pharmacies, prescription drug plans,*  
8           *MA–PD plans, and physicians with respect to an in-*  
9           *dividual in order for such contractors to provide in-*  
10           *formation relevant to the determination of whether*  
11           *such individual is an at-risk beneficiary for prescrip-*  
12           *tion drug abuse, as defined in section 1860D–*  
13           *4(c)(5)(C).*

14           “(2) *REQUIREMENT FOR ACKNOWLEDGMENT OF*  
15           *REFERRALS.*—*If a PDP sponsor or MA organization*  
16           *refers information to a contractor described in para-*  
17           *graph (1) in order for such contractor to assist in the*  
18           *determination described in such paragraph, the con-*  
19           *tractor shall—*

20                   “(A) *acknowledge to the sponsor or organi-*  
21                   *zation receipt of the referral; and*

22                   “(B) *in the case that any PDP sponsor or*  
23                   *MA organization contacts the contractor request-*  
24                   *ing to know the determination by the contractor*  
25                   *of whether or not an individual has been deter-*



1           *mined to be an individual described such para-*  
2           *graph, shall inform such sponsor or organization*  
3           *of such determination on a date that is not later*  
4           *than 15 days after the date on which the sponsor*  
5           *or organization contacts the contractor.*

6           “(3) *MAKING DATA AVAILABLE TO OTHER ENTI-*  
7           *TIES.—*

8                     “(A) *IN GENERAL.—For purposes of car-*  
9                     *rying out this subsection, subject to subpara-*  
10                    *graph (B), the Secretary shall authorize MED-*  
11                    *ICs to respond to requests for information from*  
12                    *PDP sponsors and MA organizations, State pre-*  
13                    *scription drug monitoring programs, and other*  
14                    *entities delegated by such sponsors or organiza-*  
15                    *tions using available programs and systems in*  
16                    *the effort to prevent fraud, waste, and abuse.*

17                    “(B) *HIPAA COMPLIANT INFORMATION*  
18                    *ONLY.—Information may only be disclosed by a*  
19                    *MEDIC under subparagraph (A) if the disclo-*  
20                    *sure of such information is permitted under the*  
21                    *Federal regulations (concerning the privacy of*  
22                    *individually identifiable health information)*  
23                    *promulgated under section 264(c) of the Health*  
24                    *Insurance Portability and Accountability Act of*  
25                    *1996 (42 U.S.C. 1320d–2 note).”.*

1           (2) *OIG STUDY AND REPORT ON EFFECTIVENESS*  
2           *OF MEDICS.*—

3                   (A) *STUDY.*—*The Inspector General of the*  
4                   *Department of Health and Human Services shall*  
5                   *conduct a study on the effectiveness of Medicare*  
6                   *drug integrity contractors with which the Sec-*  
7                   *retary of Health and Human Services has en-*  
8                   *tered into a contract under section 1893 of the*  
9                   *Social Security Act (42 U.S.C. 1395ddd) in*  
10                   *identifying, combating, and preventing fraud*  
11                   *under the Medicare program, including under*  
12                   *the authority provided under section 1893(j) of*  
13                   *the Social Security Act, added by paragraph (1).*

14                   (B) *REPORT.*—*Not later than 1 year after*  
15                   *the date of the enactment of this Act, the Inspec-*  
16                   *tor General shall submit to Congress a report on*  
17                   *the study conducted under subparagraph (A).*  
18                   *Such report shall include such recommendations*  
19                   *for improvements in the effectiveness of such con-*  
20                   *tractors as the Inspector General determines ap-*  
21                   *propriate.*

22           (d) *TREATMENT OF CERTAIN COMPLAINTS FOR PUR-*  
23           *POSES OF QUALITY OR PERFORMANCE ASSESSMENT.*—*Sec-*  
24           *tion 1860D-42 of the Social Security Act (42 U.S.C.*

1 1395w–152) is amended by adding at the end the following  
2 new subsection:

3       “(d) *TREATMENT OF CERTAIN COMPLAINTS FOR PUR-*  
4 *POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In*  
5 *conducting a quality or performance assessment of a PDP*  
6 *sponsor, the Secretary shall develop or utilize existing*  
7 *screening methods for reviewing and considering com-*  
8 *plaints that are received from enrollees in a prescription*  
9 *drug plan offered by such PDP sponsor and that are com-*  
10 *plaints regarding the lack of access by the individual to*  
11 *prescription drugs due to a drug management program for*  
12 *at-risk beneficiaries.”.*

13       “(e) *SENSE OF CONGRESS REGARDING USE OF TECH-*  
14 *NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of Con-*  
15 *gress that MA organizations and PDP sponsors should con-*  
16 *sider using e-prescribing and other health information tech-*  
17 *nology tools to support combating fraud under MA–PD*  
18 *plans and prescription drug plans under parts C and D*  
19 *of the Medicare program.*

20       “(f) *EFFECTIVE DATE.—*

21               “(1) *IN GENERAL.—The amendments made by*  
22 *this section shall apply to prescription drug plans*  
23 *(and MA–PD plans) for plan years beginning more*  
24 *than 1 year after the date of the enactment of this*  
25 *Act.*

1           (2) *STAKEHOLDER MEETINGS PRIOR TO EFFEC-*  
2           *TIVE DATE.—*

3                   (A) *IN GENERAL.—Not later than January*  
4                   *1, 2016, the Secretary of Health and Human*  
5                   *Services shall convene stakeholders, including in-*  
6                   *dividuals entitled to benefits under part A of*  
7                   *title XVIII of the Social Security Act or enrolled*  
8                   *under part B of such title of such Act, advocacy*  
9                   *groups representing such individuals, physicians,*  
10                   *pharmacists, and other clinicians, retail phar-*  
11                   *macies, plan sponsors, entities delegated by plan*  
12                   *sponsors, and biopharmaceutical manufacturers*  
13                   *for input regarding the topics described in sub-*  
14                   *paragraph (B).*

15                   (B) *TOPICS DESCRIBED.—The topics de-*  
16                   *scribed in this subparagraph are the topics of—*

17                           (i) *the impact on cost-sharing and en-*  
18                           *sureing accessibility to prescription drugs for*  
19                           *enrollees in prescription drug plans of PDP*  
20                           *sponsors, and enrollees in MA–PD plans,*  
21                           *who are at-risk beneficiaries for prescrip-*  
22                           *tion drug abuse (as defined in subpara-*  
23                           *graph (C) of paragraph (5) of section*  
24                           *1860D–4(c) of the Social Security Act (42*  
25                           *U.S.C. 1395w–104(c));*

1           (ii) the use of an expedited appeals  
2 process under which such an enrollee may  
3 appeal an identification of such enrollee as  
4 an at-risk beneficiary for prescription drug  
5 abuse under such paragraph (similar to the  
6 processes established under the Medicare Ad-  
7 vantage program under part C of title  
8 XVIII of the Social Security Act that allow  
9 an automatic escalation to external review  
10 of claims submitted under such part);

11           (iii) the types of enrollees that should  
12 be treated as exempted individuals, as de-  
13 scribed in subparagraph (C)(ii) of such  
14 paragraph;

15           (iv) the manner in which terms and  
16 definitions in such paragraph should be ap-  
17 plied, such as the use of clinical appro-  
18 priateness in determining whether an en-  
19 rollee is an at-risk beneficiary for prescrip-  
20 tion drug abuse as defined in subparagraph  
21 (C) of such paragraph;

22           (v) the information to be included in  
23 the notices described in subparagraph (B) of  
24 such paragraph and the standardization of  
25 such notices; and

1                   (vi) with respect to a PDP sponsor (or  
 2                   Medicare Advantage organization) that es-  
 3                   tablishes a drug management program for  
 4                   at-risk beneficiaries under such paragraph,  
 5                   the responsibilities of such PDP sponsor (or  
 6                   organization) with respect to the implemen-  
 7                   tation of such program.

8           (g) *RULEMAKING.*—The Secretary of Health and  
 9           Human Services shall promulgate regulations based on the  
 10          input gathered pursuant to subsection (f)(2)(A).

11          ***TITLE IV—MEDICAID, MEDICARE,***  
 12                                   ***AND OTHER REFORMS***

13          ***Subtitle A—Medicaid and Medicare***  
 14                                   ***Reforms***

15          ***SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT***  
 16                                   ***TO STATES FOR DURABLE MEDICAL EQUIP-***  
 17                                   ***MENT (DME) TO MEDICARE PAYMENT RATES.***

18          (a) *MEDICAID REIMBURSEMENT.*—

19                   (1) *IN GENERAL.*—Section 1903(i) of the Social  
 20          Security Act (42 U.S.C. 1396b(i)) is amended—

21                                   (A) in paragraph (25), by striking “or” at  
 22                                   the end;

23                                   (B) in paragraph (26), by striking the pe-  
 24                                   riod at the end and inserting “; or”; and

1           (C) by inserting after paragraph (26) the  
2           following new paragraph:

3           “(27) with respect to any amounts expended by  
4           the State on the basis of a fee schedule for items de-  
5           scribed in section 1861(n), as determined in the ag-  
6           gregate with respect to each class of such items as de-  
7           fined by the Secretary, in excess of the aggregate  
8           amount, if any, that would be paid for such items  
9           within such class on a fee-for-service basis under the  
10          program under part B of title XVIII, including, as  
11          applicable, under a competitive acquisition program  
12          under section 1847 in an area of the State.”.

13          (2) *EFFECTIVE DATE.*—The amendments made  
14          by this subsection shall be effective with respect to  
15          payments for items furnished on or after January 1,  
16          2020.

17          (b) *MEDICARE OMBUDSMAN.*—Section 1808(c) of the  
18          Social Security Act (42 U.S.C. 1395b(c)), as amended by  
19          section 3101, is further amended by adding at the end the  
20          following new paragraph:

21          “(5) *MONITORING DME REIMBURSEMENT UNDER*  
22          *MEDICAID.*—The ombudsmen under each of para-  
23          graphs (1) and (4) shall evaluate the impact of the  
24          competitive acquisition program under section 1847,

1       *including as applied under section 1903(i)(27), on*  
2       *beneficiary health status and health outcomes.”.*

3   **SEC. 4002. MEDICARE PAYMENT INCENTIVE FOR THE TRAN-**  
4                   **SITION FROM TRADITIONAL X-RAY IMAGING**  
5                   **TO DIGITAL RADIOGRAPHY AND OTHER MEDI-**  
6                   **CARE IMAGING PAYMENT PROVISION.**

7       *(a) PHYSICIAN FEE SCHEDULE.—*

8               *(1) PAYMENT INCENTIVE FOR TRANSITION.—*

9                   *(A) IN GENERAL.—Section 1848(b) of the*  
10                  *Social Security Act (42 U.S.C. 1395w-4(b)) is*  
11                  *amended by adding at the end the following new*  
12                  *paragraph:*

13                *“(9) SPECIAL RULE TO INCENTIVIZE TRANSITION*  
14                *FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADI-*  
15                *OGRAPHY.—*

16                    *“(A) LIMITATION ON PAYMENT FOR FILM X-*  
17                    *RAY IMAGING SERVICES.—In the case of imaging*  
18                    *services that are X rays taken using film and*  
19                    *that are furnished during 2017 or a subsequent*  
20                    *year, the payment amount for the technical com-*  
21                    *ponent (including the technical component por-*  
22                    *tion of a global fee) of such services that would*  
23                    *otherwise be determined under this section (with-*  
24                    *out application of this paragraph and before ap-*  
25                    *plication of any other adjustment under this sec-*



1           tion) for such year shall be reduced by 20 per-  
2           cent.

3           “(B) *PHASED-IN LIMITATION ON PAYMENT*  
4           *FOR COMPUTED RADIOGRAPHY IMAGING SERV-*  
5           *ICES.—In the case of imaging services that are*  
6           *X rays taken using computed radiography tech-*  
7           *nology—*

8                   “(i) *in the case of such services fur-*  
9                   *nished during 2018, 2019, 2020, 2021, or*  
10                  *2022 the payment amount for the technical*  
11                  *component (including the technical compo-*  
12                  *nent portion of a global fee) of such services*  
13                  *that would otherwise be determined under*  
14                  *this section (without application of this*  
15                  *paragraph and before application of any*  
16                  *other adjustment under this section) for*  
17                  *such year shall be reduced by 7 percent; and*

18                   “(ii) *in the case of such services fur-*  
19                   *nished during 2023 or a subsequent year,*  
20                   *the payment amount for the technical com-*  
21                   *ponent (including the technical component*  
22                   *portion of a global fee) of such services that*  
23                   *would otherwise be determined under this*  
24                   *section (without application of this para-*  
25                   *graph and before application of any other*

1                   *adjustment under this section) for such year*  
2                   *shall be reduced by 10 percent.*

3                   “(C) *COMPUTED RADIOGRAPHY TECH-*  
4                   *NOLOGY DEFINED.—For purposes of this para-*  
5                   *graph, the term ‘computed radiography tech-*  
6                   *nology’ means cassette-based imaging which uti-*  
7                   *lizes an imaging plate to create the image in-*  
8                   *volved.*”

9                   “(D) *IMPLEMENTATION.—In order to imple-*  
10                   *ment this paragraph, the Secretary shall adopt*  
11                   *appropriate mechanisms which may include use*  
12                   *of modifiers.”.*

13                   (B) *EXEMPTION FROM BUDGET NEU-*  
14                   *TRALITY.—Section 1848(c)(2)(B)(v) of the Social*  
15                   *Security Act (42 U.S.C. 1395w–4(c)(2)(B)(v)) is*  
16                   *amended by adding at the end the following new*  
17                   *subclause:*

18                                   “(X) *REDUCED EXPENDITURES*  
19                                   *ATTRIBUTABLE TO INCENTIVES TO*  
20                                   *TRANSITION TO DIGITAL RADIOG-*  
21                                   *RAPHY.—Effective for fee schedules es-*  
22                                   *tablished beginning with 2017, reduced*  
23                                   *expenditures attributable to subpara-*  
24                                   *graph (A) of subsection (b)(9) and ef-*  
25                                   *fective for fee schedules established be-*

1                    *ginning with 2018, reduced expendi-*  
 2                    *tures attributable to subparagraph (B)*  
 3                    *of such subsection.”.*

4                    (2) *ELIMINATION OF APPLICATION OF MULTIPLE*  
 5                    *PROCEDURE PAYMENT REDUCTION.—Section*  
 6                    *1848(b)(4) of the Social Security Act (42 U.S.C.*  
 7                    *1395w-4(b)(4)) is amended by adding at the end the*  
 8                    *following new subparagraph:*

9                    “(E) *ELIMINATION OF APPLICATION OF*  
 10                    *MULTIPLE PROCEDURE PAYMENT REDUCTION.—*

11                    “(i) *IN GENERAL.—Not later than Jan-*  
 12                    *uary 1, 2016, the Secretary shall not apply*  
 13                    *a multiple procedure payment reduction*  
 14                    *policy to the professional component of im-*  
 15                    *aging services furnished in any subsequent*  
 16                    *year that is prior to a year in which the*  
 17                    *Secretary conducts and publishes, as part of*  
 18                    *the Medicare Physician Fee Schedule Pro-*  
 19                    *posed Rule for a year, the empirical anal-*  
 20                    *ysis described in clause (ii).*

21                    “(ii) *EMPIRICAL ANALYSIS DE-*  
 22                    *SCRIBED.—The empirical analysis described*  
 23                    *in this clause is an analysis of the Re-*  
 24                    *source-Based Relative Value Scale (com-*  
 25                    *monly known as the ‘RBRVS’) Data Man-*

1            *ager information that is used to determine*  
2            *what, if any, efficiencies exist within the*  
3            *professional component of imaging services*  
4            *when two or more studies are performed on*  
5            *the same patient on the same day. Such em-*  
6            *pirical analysis shall include—*

7                    *“(I) work sheets and other infor-*  
8                    *mation detailing which physician work*  
9                    *activities performed given the typical*  
10                   *vignettes were assigned reduction per-*  
11                   *centages of 0, 25, 50, 75 and 100 per-*  
12                   *cent;*

13                   *“(II) a discussion of the clinical*  
14                   *aspects that informed the assignment of*  
15                   *the reduction percentages described in*  
16                   *subclause (I);*

17                   *“(III) an explanation of how the*  
18                   *percentage reductions for pre-, intra-,*  
19                   *and post-service work were determined*  
20                   *and calculated; and*

21                   *“(IV) a demonstration that the*  
22                   *Centers for Medicare & Medicaid Serv-*  
23                   *ices has consulted with practicing ra-*  
24                   *diologists to gain knowledge of how ra-*  
25                   *diologists interpret studies of multiple*

1                    *body parts on the same individual on*  
2                    *the same day.”.*

3            *(b) PAYMENT INCENTIVE FOR TRANSITION UNDER*  
4 *HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYS-*  
5 *TEM.—Section 1833(t)(16) of the Social Security Act (42*  
6 *U.S.C. 1395(t)(16)) is amended by adding at the end the*  
7 *following new subparagraph:*

8                    *“(F) PAYMENT INCENTIVE FOR THE TRANSI-*  
9                    *TION FROM TRADITIONAL X-RAY IMAGING TO DIG-*  
10                    *ITAL RADIOGRAPHY.—Notwithstanding the pre-*  
11                    *vious provisions of this subsection:*

12                    *“(i) LIMITATION ON PAYMENT FOR*  
13                    *FILM X-RAY IMAGING SERVICES.—In the*  
14                    *case of imaging services that are X rays*  
15                    *taken using film and that are furnished*  
16                    *during 2017 or a subsequent year, the pay-*  
17                    *ment amount for the technical component*  
18                    *(including the technical component portion*  
19                    *of a global fee) of such services that would*  
20                    *otherwise be determined under this section*  
21                    *(without application of this paragraph and*  
22                    *before application of any other adjustment*  
23                    *under this subsection) for such year shall be*  
24                    *reduced by 20 percent.*

1                   “(i) *PHASED-IN LIMITATION ON PAY-*  
2                   *MENT FOR COMPUTED RADIOGRAPHY IMAG-*  
3                   *ING SERVICES.—In the case of imaging*  
4                   *services that are X rays taken using com-*  
5                   *puted radiography technology (as defined in*  
6                   *section 1848(b)(9)(C))—*

7                   “(I) *in the case of such services*  
8                   *furnished during 2018, 2019, 2020,*  
9                   *2021, or 2022 the payment amount for*  
10                  *the technical component (including the*  
11                  *technical component portion of a global*  
12                  *fee) of such services that would other-*  
13                  *wise be determined under this section*  
14                  *(without application of this paragraph*  
15                  *and before application of any other ad-*  
16                  *justment under this subsection) for*  
17                  *such year shall be reduced by 7 per-*  
18                  *cent; and*

19                  “(II) *in the case of such services*  
20                  *furnished during 2023 or a subsequent*  
21                  *year, the payment amount for the tech-*  
22                  *nical component (including the tech-*  
23                  *nical component portion of a global*  
24                  *fee) of such services that would other-*  
25                  *wise be determined under this section*

1                   *(without application of this paragraph*  
2                   *and before application of any other ad-*  
3                   *justment under this subsection) for*  
4                   *such year shall be reduced by 10 per-*  
5                   *cent.*

6                   “(iii) *APPLICATION WITHOUT REGARD*  
7                   *TO BUDGET NEUTRALITY.—The reductions*  
8                   *made under this paragraph—*

9                   *“(I) shall not be considered an ad-*  
10                  *justment under paragraph (2)(E); and*

11                  *“(II) shall not be implemented in*  
12                  *a budget neutral manner.”.*

13 **SEC. 4003. IMPLEMENTATION OF OFFICE OF INSPECTOR**  
14                   **GENERAL RECOMMENDATION TO DELAY CER-**  
15                   **TAIN MEDICARE PRESCRIPTION DRUG PLAN**  
16                   **PREPAYMENTS.**

17                  *Section 1860D–15(d) of the Social Security Act (42*  
18                  *U.S.C. 1395w–115(d)) is amended by adding at the end the*  
19                  *following:*

20                  “(5) *TIMING OF PAYMENTS.—With respect to*  
21                  *monthly reinsurance payment amounts under this*  
22                  *section to a PDP sponsor for months in a year (be-*  
23                  *ginning with 2020), such payment amounts for a*  
24                  *month shall be made on the first business day occur-*  
25                  *ring on or after the following date for that month:*

1                   “(A) *For the month of January, January*  
2                   *2nd.*

3                   “(B) *For the month of February, February*  
4                   *5th.*

5                   “(C) *For the month of March, March 10th.*

6                   “(D) *For the month of April, April 15th.*

7                   “(E) *For the month of May, May 20th.*

8                   “(F) *For the month of June, June 25th.*

9                   “(G) *For the month of July and each suc-*  
10                  *ceeding month (other than December) in a year,*  
11                  *the first day of the next month.*

12                  “(H) *For the month of December, December*  
13                  *24th.”.*

## 14    ***Subtitle B—Cures Innovation Fund***

### 15    ***SEC. 4041. CURES INNOVATION FUND.***

16            (a) *ESTABLISHMENT.—There is hereby established in*  
17            *the Treasury of the United States a fund to be known as*  
18            *the Cures Innovation Fund (in this section referred to as*  
19            *the “Fund”).*

20            (b) *APPROPRIATIONS.—There is hereby appropriated*  
21            *to the Fund, out of any funds in the Treasury not otherwise*  
22            *appropriated, \$110,000,000 for each of fiscal years 2016*  
23            *through 2020.*



1       (c) *EXPENDITURES.*—Amounts in the Fund shall be  
2 available, as provided by appropriation Acts, for making  
3 expenditures for carrying out the following:

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

7           (2) *Part E of title II of the Public Health Serv-*  
8 *ice Act, as added by section 1141 (relating to Council*  
9 *for 21st Century Cures).*

10          (3) *Section 2001 and the amendments made by*  
11 *such section (relating to development and use of pa-*  
12 *tient experience data to enhance structured risk-ben-*  
13 *efit assessment framework).*

14          (4) *Section 2021 and the amendments made by*  
15 *such section (relating to qualification of drug develop-*  
16 *ment tools).*

17          (5) *Section 2062 and the amendments made by*  
18 *such section (relating to utilizing evidence from clin-*  
19 *ical experience).*

20          (6) *Section 2161 (relating to grants for studying*  
21 *the process of continuous drug manufacturing).*

22       (d) *SUPPLEMENT, NOT SUPPLANT; PROHIBITION*  
23 *AGAINST TRANSFER.*—Funds appropriated by subsection  
24 (b)—

1           (1) shall be used to supplement, not supplant,  
2           amounts otherwise made available to the National In-  
3           stitutes of Health and the Food and Drug Adminis-  
4           tration; and

5           (2) notwithstanding any transfer authority in  
6           any appropriation Act, shall not be used for any pur-  
7           pose other than the expenditures listed in subsection  
8           (c).

### 9           **Subtitle C—Other Reforms**

#### 10       **SEC. 4061. SPR DRAWDOWN.**

11       (a) *DRAWDOWN AND SALE.*—Notwithstanding section  
12       161 of the Energy Policy and Conservation Act (42 U.S.C.  
13       6241), the Secretary of Energy shall draw down and sell  
14       8,000,000 barrels of crude oil from the Strategic Petroleum  
15       Reserve during each of the fiscal years 2018 through 2025,  
16       except as provided in subsection (b). Amounts received for  
17       a sale under this subsection shall be deposited in the general  
18       fund of the Treasury during the fiscal year in which the  
19       sale occurs.

20       (b) *EMERGENCY PROTECTION.*—The Secretary shall  
21       not draw down and sell crude oil under this section in  
22       amounts that would result in a Strategic Petroleum Reserve  
23       that contains an inventory of petroleum products rep-  
24       resenting less than 90 days of emergency reserves, based on

1 *the average daily level of net imports of crude oil and petro-*  
 2 *leum products in the previous calendar year.*

3 (c) *PROCEEDS.*—*Proceeds from a sale under this sec-*  
 4 *tion shall be deposited into the general fund of the Treasury*  
 5 *of the United States.*

6 ***Subtitle D—Miscellaneous***

7 ***SEC. 4081. LYME DISEASE AND OTHER TICK-BORNE DIS-***  
 8 ***EASES.***

9 (a) *IN GENERAL.*—*Title III of the Public Health Serv-*  
 10 *ice Act (42 U.S.C. 241 et seq.) is amended by adding at*  
 11 *the end the following new part:*

12 ***“PART W—LYME DISEASE AND OTHER TICK-***  
 13 ***BORNE DISEASES***

14 ***“SEC. 3990O. RESEARCH.***

15 *“(a) IN GENERAL.*—*The Secretary shall conduct or*  
 16 *support epidemiological, basic, translational, and clinical*  
 17 *research regarding Lyme disease and other tick-borne dis-*  
 18 *eases.*

19 *“(b) BIENNIAL REPORTS.*—*The Secretary shall ensure*  
 20 *that each biennial report under section 403 includes infor-*  
 21 *mation on actions undertaken by the National Institutes*  
 22 *of Health to carry out subsection (a) with respect to Lyme*  
 23 *disease and other tick-borne diseases, including an assess-*  
 24 *ment of the progress made in improving the outcomes of*  
 25 *Lyme disease and such other tick-borne diseases.*

1 **“SEC. 39900–1. WORKING GROUP.**

2       “(a) *ESTABLISHMENT.*—*The Secretary shall establish*  
3 *a permanent working group, to be known as the Interagency*  
4 *Lyme and Tick-Borne Disease Working Group (in this sec-*  
5 *tion and section 39900–2 referred to as the ‘Working*  
6 *Group’), to review all efforts within the Department of*  
7 *Health and Human Services concerning Lyme disease and*  
8 *other tick-borne diseases to ensure interagency coordination,*  
9 *minimize overlap, and examine research priorities.*

10       “(b) *RESPONSIBILITIES.*—*The Working Group shall—*

11               “(1) *not later than 24 months after the date of*  
12 *enactment of this part, and every 24 months there-*  
13 *after, develop or update a summary of—*

14                       “(A) *ongoing Lyme disease and other tick-*  
15 *borne disease research related to causes, preven-*  
16 *tion, treatment, surveillance, diagnosis,*  
17 *diagnostics, duration of illness, intervention, and*  
18 *access to services and supports for individuals*  
19 *with Lyme disease or other tick-borne diseases;*

20                       “(B) *advances made pursuant to such re-*  
21 *search;*

22                       “(C) *the engagement of the Department of*  
23 *Health and Human Services with persons that*  
24 *participate at the public meetings required by*  
25 *paragraph (5); and*

1           “(D) the comments received by the Working  
2           Group at such public meetings and the Sec-  
3           retary’s response to such comments;

4           “(2) ensure that a broad spectrum of scientific  
5           viewpoints is represented in each such summary;

6           “(3) monitor Federal activities with respect to  
7           Lyme disease and other tick-borne diseases;

8           “(4) make recommendations to the Secretary re-  
9           garding any appropriate changes to such activities;  
10          and

11          “(5) ensure public input by holding annual pub-  
12          lic meetings that address scientific advances, research  
13          questions, surveillance activities, and emerging  
14          strains in species of pathogenic organisms.

15          “(c) MEMBERSHIP.—

16                 “(1) IN GENERAL.—The Working Group shall be  
17                 composed of a total of 14 members as follows:

18                         “(A) FEDERAL MEMBERS.—Seven Federal  
19                         members, consisting of one or more representa-  
20                         tives of each of—

21                                 “(i) the Office of the Assistant Sec-  
22                                 retary for Health;

23                                 “(ii) the Food and Drug Administra-  
24                                 tion;

1                   “(iii) the Centers for Disease Control  
2                   and Prevention;

3                   “(iv) the National Institutes of Health;  
4                   and

5                   “(v) such other agencies and offices of  
6                   the Department of Health and Human  
7                   Services as the Secretary determines appro-  
8                   priate.

9                   “(B) NON-FEDERAL PUBLIC MEMBERS.—  
10                  Seven non-Federal public members, consisting of  
11                  representatives of the following categories:

12                   “(i) Physicians and other medical pro-  
13                   viders with experience in diagnosing and  
14                   treating Lyme disease and other tick-borne  
15                   diseases.

16                   “(ii) Scientists or researchers with ex-  
17                   pertise.

18                   “(iii) Patients and their family mem-  
19                   bers.

20                   “(iv) Nonprofit organizations that ad-  
21                   vocate for patients with respect to Lyme  
22                   disease and other tick-borne diseases.

23                   “(v) Other individuals whose expertise  
24                   is determined by the Secretary to be bene-

1                   *ficial to the functioning of the Working*  
2                   *Group.*

3                   “(2) *APPOINTMENT.*—*The members of the Work-*  
4                   *ing Group shall be appointed by the Secretary, except*  
5                   *that of the non-Federal public members under para-*  
6                   *graph (1)(B)—*

7                   “(A) *one shall be appointed by the Speaker*  
8                   *of the House of Representatives; and*

9                   “(B) *one shall be appointed by the majority*  
10                  *leader of the Senate.*

11                  “(3) *DIVERSITY OF SCIENTIFIC PERSPECTIVES.*—  
12                  *In making appointments under paragraph (2), the*  
13                  *Secretary, the Speaker of the House of Representa-*  
14                  *tives, and the majority leader of the Senate shall en-*  
15                  *sure that the non-Federal public members of the*  
16                  *Working Group represent a diversity of scientific per-*  
17                  *spectives.*

18                  “(4) *TERMS.*—*The non-Federal public members*  
19                  *of the Working Group shall each be appointed to serve*  
20                  *a 4-year term and may be reappointed at the end of*  
21                  *such term.*

22                  “(d) *MEETINGS.*—*The Working Group shall meet as*  
23                  *often as necessary, as determined by the Secretary, but not*  
24                  *less than twice each year.*

1       “(e) *APPLICABILITY OF FACA.*—*The Working Group*  
2 *shall be treated as an advisory committee subject to the Fed-*  
3 *eral Advisory Committee Act.*

4       “(f) *REPORTING.*—*Not later than 24 months after the*  
5 *date of enactment of this part, and every 24 months there-*  
6 *after, the Working Group—*

7               “(1) *shall submit a report on its activities, in-*  
8 *cluding an up-to-date summary under subsection*  
9 *(b)(1) and any recommendations under subsection*  
10 *(b)(4), to the Secretary, the Committee on Energy and*  
11 *Commerce of the House of Representatives, and the*  
12 *Committee on Health, Education, Labor and Pen-*  
13 *sions of the Senate;*

14               “(2) *shall make each such report publicly avail-*  
15 *able on the website of the Department of Health and*  
16 *Human Services; and*

17               “(3) *shall allow any member of the Working*  
18 *Group to include in any such report minority views.*

19 **“SEC. 39900–2. STRATEGIC PLAN.**

20       “*Not later than 3 years after the date of enactment*  
21 *of this section, and every 5 years thereafter, the Secretary*  
22 *shall submit to the Congress a strategic plan, informed by*  
23 *the most recent summary under section 39900–1(b)(1), for*  
24 *the conduct and support of Lyme disease and tick-borne dis-*  
25 *ease research, including—*



1           “(1) proposed budgetary requirements;

2           “(2) a plan for improving outcomes of Lyme dis-  
3           ease and other tick-borne diseases, including progress  
4           related to chronic or persistent symptoms and chronic  
5           or persistent infection and co-infections;

6           “(3) a plan for improving diagnosis, treatment,  
7           and prevention;

8           “(4) appropriate benchmarks to measure  
9           progress on achieving the improvements described in  
10          paragraphs (2) and (3); and

11          “(5) a plan to disseminate each summary under  
12          section 39900–1(b)(1) and other relevant information  
13          developed by the Working Group to the public, includ-  
14          ing health care providers, public health departments,  
15          and other relevant medical groups.”.

16          (b) *NO ADDITIONAL AUTHORIZATION OF APPROPRIA-*  
17          *TIONS.—No additional funds are authorized to be appro-*  
18          *priated for the purpose of carrying out this section and the*  
19          *amendment made by this section, and this section and such*  
20          *amendment shall be carried out using amounts otherwise*  
21          *available for such purpose.*

**Union Calendar No. 142**

114<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**H. R. 6**

[Report No. 114-190, Part I]

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**A BILL**

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

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JULY 7, 2015

Reported from the Committee on Energy and Commerce  
with an amendment

JULY 7, 2015

The Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed