

[DISCUSSION DOCUMENT]

114TH CONGRESS  
1ST SESSION

H. R. \_\_\_\_\_

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

IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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.**

4 This Act may be cited as the “21st Century Cures  
5 Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

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1 **TITLE I—PUTTING PATIENTS**  
 2 **FIRST BY INCORPORATING**  
 3 **THEIR PERSPECTIVES INTO**  
 4 **THE REGULATORY PROCESS**  
 5 **AND ADDRESSING UNMET**  
 6 **NEEDS**

7 **Subtitle A—Patient-Focused Drug**  
 8 **Development**

9 **SEC. 1001. 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—



1 (1) in subsection (d), by striking “The Sec-  
2 retary shall implement” and all that follows through  
3 “premarket approval of a drug.”; and

4 (2) by adding at the end the following new sub-  
5 sections:

6 “(x) STRUCTURED RISK-BENEFIT ASSESSMENT  
7 FRAMEWORK.—

8 “(1) IN GENERAL.—The Secretary shall imple-  
9 ment a structured risk-benefit assessment frame-  
10 work in the new drug approval process—

11 “(A) to facilitate the balanced consider-  
12 ation of benefits and risks; and

13 “(B) to develop and implement a con-  
14 sistent and systematic approach to the discus-  
15 sion of, regulatory decisionmaking with respect  
16 to, and the communication of, the benefits and  
17 risks of new drugs.

18 “(2) RULE OF CONSTRUCTION.—Nothing in  
19 paragraph (1) shall alter the criteria for evaluating  
20 an application for premarket approval of a drug.

21 “(y) DEVELOPMENT AND USE OF PATIENT EXPERI-  
22 ENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT  
23 ASSESSMENT FRAMEWORK.—

24 “(1) IN GENERAL.—Not later than two years  
25 after the date of the enactment of this subsection,

1 the Secretary shall establish and implement proc-  
2 esses under which—

3 “(A) an entity seeking to develop patient  
4 experience data may submit to the Secretary—

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

7 “(ii) with respect to patient experience  
8 data collected by the entity, draft guidance  
9 documents, completed data, and sum-  
10 maries and analyses of such data;

11 “(B) the Secretary may request such an  
12 entity to submit such documents and sum-  
13 maries; and

14 “(C) patient experience data may be devel-  
15 oped and used to enhance the structured risk-  
16 benefit assessment framework under subsection  
17 (x).

18 “(2) PATIENT EXPERIENCE DATA.—In this sub-  
19 section, the term ‘patient experience data’ means  
20 data collected by patients, parents, caregivers, pa-  
21 tient advocacy organizations, disease research foun-  
22 dations, or medical researchers that is intended to  
23 provide information about the experience of patients  
24 with a disease, or the impact a disease and manage-

1           ment of the disease has on the lives of patients or  
2           their caregivers.”.

3           (b) GUIDANCE.—

4                   (1) IN GENERAL.—The Secretary of Health and  
5           Human Services shall publish guidance on the imple-  
6           mentation of subsection (y) of section 505 of the  
7           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8           355), as added by subsection (a). Such guidance  
9           shall include—

10                           (A) with respect to draft guidance docu-  
11                           ments or data submitted to the Secretary under  
12                           paragraph (1)(A) of such subsection, guid-  
13                           ance—

14                                   (i) specifying the timelines for the re-  
15                                   view of such documents and data by the  
16                                   Secretary; and

17                                   (ii) on how the Secretary will use such  
18                                   documents and data to update any guid-  
19                                   ance documents published under this sub-  
20                                   section or publish new guidance;

21                           (B) with respect to the collection and anal-  
22                           ysis of patient experience data (as defined in  
23                           paragraph (2) of such subsection (y)), guidance  
24                           on—

1 (i) methodological considerations for  
2 the collection of patient experience data,  
3 which may include structured approaches  
4 to gathering information on—

5 (I) the experience of a patient liv-  
6 ing with a particular disease;

7 (II) the burden of living with or  
8 managing the disease;

9 (III) the impact of the disease on  
10 daily life and long-term functioning;  
11 and

12 (IV) the effect of current thera-  
13 peutic options on different aspects of  
14 the disease; and

15 (ii) the establishment and mainte-  
16 nance of registries designed to increase un-  
17 derstanding of the natural history of a dis-  
18 ease;

19 (C) methodological approaches that may be  
20 used to assess patients' beliefs with respect to  
21 such benefits and risks in the management of  
22 the patient's disease; and

23 (D) methodologies, standards, and poten-  
24 tial experimental designs for patient-reported  
25 outcomes.

1           (2) TIMING.—Not later than two years after  
2 the date of the enactment of this Act, the Secretary  
3 shall issue draft guidance on the implementation of  
4 subsection (y) of section 505 of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 355), as added  
6 by subsection (a). The Secretary shall issue final  
7 guidance on the implementation of such subsection  
8 not later than one year after the date on which the  
9 comment period for the draft guidance closes.

10           (3) WORKSHOPS.—

11           (A) IN GENERAL.—Not later than 6  
12 months after the date of the enactment of this  
13 Act and once every 6 months during the fol-  
14 lowing 12-month period, the Secretary of  
15 Health and Human Services shall convene a  
16 workshop to obtain input regarding methodolo-  
17 gies for developing the guidance under para-  
18 graph (1), including the collection of patient ex-  
19 perience data.

20           (B) ATTENDEES.—A workshop under this  
21 paragraph shall include—

22                   (i) patients;

23                   (ii) representatives from patient advo-  
24 cacy organizations and disease research  
25 foundations;

1 (iii) representatives of the reviewing  
2 divisions of the Food and Drug Adminis-  
3 tration; and

4 (iv) methodological experts with sig-  
5 nificant expertise in patient experience  
6 data.

7 (4) PUBLIC MEETING.—Not later than 90 days  
8 after the date on which the draft guidance is pub-  
9 lished under this subsection, the Secretary shall con-  
10 vene a public meeting to solicit input on the guid-  
11 ance.

12 (5) REPORT.—Not later than 5 years after the  
13 date of the enactment of this Act, the Secretary  
14 shall submit to the Committee on Energy and Com-  
15 merce of the House of Representatives and the Com-  
16 mittee on Health, Education, Labor and Pensions of  
17 the Senate, and make publicly available on the  
18 website of the Food and Drug Administration, a re-  
19 port. Such report shall include, with respect to the  
20 use to date of patient experience data in benefit and  
21 risk assessments, information on—

22 (A) potential improvements to processes  
23 for developing and submitting such data; and

1 (B) proposed enhancements for future use  
2 of patient experience data in systematic benefit  
3 and risk assessments.

4 **Subtitle B—Surrogate Endpoint**  
5 **Qualification and Utilization**

6 **SEC. 1021. EVIDENTIARY STANDARDS FOR THE REVIEW OF**  
7 **REQUESTS FOR THE QUALIFICATION OF SUR-**  
8 **ROGATE ENDPOINTS; BIOMARKERS PART-**  
9 **NERSHIP.**

10 Chapter V of the Federal Food, Drug, and Cosmetic  
11 Act is amended by inserting after section 506F (21 U.S.C.  
12 356f) the following new section:

13 **“SEC. 507. EVIDENTIARY STANDARDS FOR THE REVIEW OF**  
14 **REQUESTS FOR THE QUALIFICATION OF SUR-**  
15 **ROGATE ENDPOINTS; BIOMARKERS PART-**  
16 **NERSHIP.**

17 “(a) IN GENERAL.—The Secretary shall develop, and  
18 revise as appropriate, evidentiary standards for making  
19 determinations on whether surrogate endpoints are quali-  
20 fied under section 507A for the context of use specified  
21 by a requestor (as defined in section 507A(g)). Such  
22 standards shall include—

23 “(1) the type of data and studies generally re-  
24 quired for such qualification;

1           “(2) the information required to be included in  
2           a context of use statement submitted with a request  
3           under section 507A, including a comprehensive and  
4           clear description of the appropriate manner and con-  
5           ditions for the surrogate endpoint to be used for reg-  
6           ulatory purposes;

7           “(3) the information required to be included in  
8           a qualification plan submitted with a request under  
9           section 507A; and

10           “(4) the format in which data and information  
11           are required to be submitted in a request under sec-  
12           tion 507A.

13           “(b) GUIDANCE.—

14           “(1) DRAFT GUIDANCE.—Not later than 12  
15           months after the date of enactment of the 21st Cen-  
16           tury Cures Act, the Secretary shall, in consultation  
17           with stakeholders (including patients, industry,  
18           health care providers, academia, and government)  
19           issue draft guidance containing proposed evidentiary  
20           standards under subsection (a).

21           “(2) FINAL GUIDANCE.—Not later than 18  
22           months after the date of enactment of the 21st Cen-  
23           tury Cures Act, the Secretary shall issue final guid-  
24           ance containing the final evidentiary standards  
25           under subsection (a).



1           “(3) UPDATES.—The Secretary shall periodi-  
2 cally review, and, as appropriate, update the guid-  
3 ance under paragraph (2).

4           “(c) DETERMINATIONS PRIOR TO FINALIZATION OF  
5 STANDARDS.—Nothing in this section shall be construed  
6 as precluding the Secretary from making a determination  
7 under this section before the finalization of standards  
8 under subsection (b)(2) with respect to whether a specific  
9 surrogate endpoint is qualified for the context of use speci-  
10 fied by the requestor.

11          “(d) PUBLIC-PRIVATE PARTNERSHIP.—The Sec-  
12 retary may enter into a public-private partnership with  
13 one or more private entities for purposes of—

14           “(1) the review of requests for the qualification  
15 of biomarkers for use other than as surrogate  
16 endpoints (as defined in section 507A(g));

17           “(2) the development of evidentiary standards  
18 for such review; and

19           “(3) the qualification of biomarkers for use  
20 other than as a surrogate endpoint.

21          “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
22 tion or section 507A shall be construed as having any im-  
23 pact on confidential discussions between the Secretary and  
24 any person (including a requestor) regarding the consider-  
25 ation of a surrogate endpoint that has or has not been

1 qualified under section 507A for purposes of supporting  
2 or obtaining approval, clearance, or licensure of the speci-  
3 fied drug, device, or biological product under section 505,  
4 515, or 510(k) of this Act, or section 351(a) of the Public  
5 Health Service Act, respectively, for purposes of sup-  
6 porting investigational use of a drug under section 505(i)  
7 of this Act, a device under section 520(g) of this Act, or  
8 a biological product under section 351(a) of the Public  
9 Health Service Act, or for any other regulatory purpose.”.

10 **SEC. 1022. ENHANCING THE PROCESS FOR QUALIFICATION**  
11 **OF SURROGATE ENDPOINTS.**

12 Chapter V of the Federal Food, Drug, and Cosmetic  
13 Act, as amended by section 1021, is further amended by  
14 inserting after section 507 the following new section:

15 **“SEC. 507A. ENHANCING THE PROCESS FOR QUALIFICA-**  
16 **TION OF SURROGATE ENDPOINTS.**

17 “(a) IN GENERAL.—

18 “(1) REQUEST.—Beginning not later than 90  
19 days after the date on which the final guidance is  
20 issued under section 507, upon the submission of a  
21 request to the Secretary for the qualification of a  
22 surrogate endpoint for the context of use specified in  
23 the request, the Secretary shall initiate the qualifica-  
24 tion process under this section for purposes of deter-  
25 mining whether the surrogate endpoint is qualified

1 for such use. The decision as to whether to submit  
2 a request for qualification of a surrogate endpoint  
3 under this section is committed to the sole discretion  
4 of the requestor.

5 “(2) CONTENTS OF REQUEST.—A request  
6 under paragraph (1) shall include, with respect to  
7 the surrogate endpoint involved, a context of use  
8 statement and a qualification plan that contain the  
9 information required under section 507(a).

10 “(3) FILING OF REQUEST.—Not later than 30  
11 days after the submission of a request under sub-  
12 section (a), the Secretary shall—

13 “(A)(i) issue a written notification to the  
14 requestor determining that the request is in the  
15 correct format and sufficiently complete to con-  
16 duct a substantive review and make such notifi-  
17 cation publicly available; and

18 “(ii) file the request; or

19 “(B) issue a written notification to the re-  
20 questor stating the reasons for the refusal and  
21 make such notification publicly available.

22 “(b) CONSULTATION WITH SCIENTIFIC EXPERTS.—

23 “(1) IN GENERAL.—In reviewing a request sub-  
24 mitted under subsection (a), the Secretary may con-

1           sult with or include external scientific experts, so  
2           long as the Secretary obtains—

3                   “(A) a signed, written instrument from  
4                   each such expert under which the expert agrees  
5                   to protect the confidentiality of information  
6                   shared with the expert by the Secretary;

7                   “(B) the written consent of the requestor  
8                   before sharing any confidential commercial or  
9                   trade secret information publicly or with any  
10                  such expert who is not otherwise a special Gov-  
11                  ernment employee (as defined in section 202 of  
12                  title 18, United States Code); and

13                  “(C) shall, only upon written request of a  
14                  requestor made at the time of the submission of  
15                  data described in subsection (c)(1), consult with  
16                  such external scientific experts in a public  
17                  forum that—

18                           “(i) is in accordance with paragraph  
19                           (2); and

20                           “(ii) may include additional scientific  
21                           experts identified by the requestor as hav-  
22                           ing relevant scientific expertise.

23                  “(2) PUBLIC FORUM.—

24                           “(A) IN GENERAL.—In the case of a re-  
25                           quest under paragraph (1)(C) for consultation

1 with external scientific experts in a public  
2 forum, the Secretary shall—

3 “(i) not later than 90 days after the  
4 date on which the Secretary receives such  
5 request, convene the forum; and

6 “(ii) not later than 30 days before the  
7 date on which the forum will be held, pub-  
8 lish a notice in the Federal Register an-  
9 nouncing such date.

10 “(B) FORUM REQUIREMENTS.—A public  
11 forum convened under this paragraph shall—

12 “(i) be convened for the purpose of  
13 evaluating data described in subsection  
14 (c)(1);

15 “(ii) be open to the public and accept  
16 oral and written submissions on the sub-  
17 ject matter from any person;

18 “(iii) include testimony or public com-  
19 ments from—

20 “(I) one or more individuals  
21 knowledgeable in the fields of bio-  
22 statistics, pharmacogenomics, and  
23 quantitative biology;

1                   “(II) one or more physician sci-  
2                   entists with direct expertise in the rel-  
3                   evant therapeutic areas;

4                   “(III) one or more representa-  
5                   tives recommended by one or more  
6                   relevant patient-oriented organiza-  
7                   tions; and

8                   “(IV) one or more individuals  
9                   representing the interests of sponsors  
10                  of new drugs; and

11                  “(iv) be exempt from the Federal Ad-  
12                  visory Committee Act (5 U.S.C. App.).

13                  “(c) QUALIFICATION PROCESS.—For purposes of the  
14                  review of a request submitted under subsection (a)—

15                   “(1) not later than 90 days after the date of  
16                   the submission of the request, the requestor and the  
17                   Secretary shall agree on a surrogate endpoint quali-  
18                   fication plan that includes a description of data that  
19                   would be sufficient, applying the evidentiary stand-  
20                   ards under section 507, to qualify the surrogate end-  
21                   point for the context of use specified in the request;

22                   “(2) not later than 60 days after the requestor  
23                   submits the data described in paragraph (1) (or in  
24                   the case of a request for a public forum under sub-

1 section (b)(2), not later than 30 days after the date  
2 of such public forum), the Secretary shall—

3 “(A) make a final determination on wheth-  
4 er to qualify the surrogate endpoint for the con-  
5 text of use as specified in the request;

6 “(B) provide a written notification of such  
7 determination to the requestor; and

8 “(C) in the case of a determination to not  
9 qualify the surrogate endpoint, include in such  
10 notification an explanation of the reasons for  
11 the determination, including any evidentiary  
12 gaps in the data submitted to support the re-  
13 quest;

14 “(3) a requestor may appeal a determination to  
15 not qualify a surrogate endpoint under paragraph  
16 (2); and

17 “(4) in the case of an appeal under paragraph  
18 (3), not later than 30 days after the date on which  
19 such appeal is submitted to the Secretary, the Sec-  
20 retary shall—

21 “(A) review the appeal;

22 “(B) make a determination to reverse or  
23 uphold the determination that is the subject of  
24 the appeal; and

1                   “(C) notify the requestor who made such  
2                   appeal of such determination.

3                   “(d) EFFECT OF QUALIFICATION.—A surrogate end-  
4 point determined under this section to be qualified for the  
5 specified context of use may be so used by any person for  
6 purposes of supporting or obtaining approval, clearance,  
7 or licensure of a drug, device, or biological product under  
8 section 505, 515, or 510(k) of this Act, or section 351(a)  
9 of the Public Health Service Act, respectively, for purposes  
10 of supporting investigational use of a drug under section  
11 505(i) of this Act, a device under section 520(g) of this  
12 Act, or a biological product under section 351(a) of the  
13 Public Health Service Act, or for any other regulatory pur-  
14 pose, provided that such determination remains in effect.

15                   “(f) PUBLIC AVAILABILITY OF INFORMATION.—

16                   “(1) IN GENERAL.—If a requestor provides a  
17 statement of consent with respect to a request sub-  
18 mitted under subsection (a), the Secretary shall  
19 make publicly available—

20                   “(A) information on surrogate endpoints  
21 with respect to which such request was sub-  
22 mitted and a summary of the data that have  
23 been submitted to support such request; and

24                   “(B) information on surrogate endpoints  
25 that have been determined under this section to



1 be qualified for use and the context of use for  
2 which the surrogate endpoints are so qualified.

3 “(2) INTERNET PAGE.—The Secretary shall  
4 maintain and update, no less frequently than quar-  
5 terly, on the Internet site of the Food and Drug Ad-  
6 ministration, a dedicated Internet page that contains  
7 summary statistics regarding—

8 “(A) the number of requests received by  
9 the Secretary under subsection (a);

10 “(B) the number of surrogate endpoints  
11 qualified under subsection (c); and

12 “(C) the number of such requests that  
13 have been withdrawn by the requestor.

14 “(3) CONSTRUCTION.—Nothing in this sub-  
15 section shall be construed as authorizing the Sec-  
16 retary to disclose any information that is a trade se-  
17 cret or confidential information subject to section  
18 552(b)(4) of title 5, United States Code, without the  
19 requestor’s consent.

20 “(g) DEFINITIONS.—In this section:

21 “(1) BIOMARKER.—The terms ‘biomarker’  
22 mean a characteristic (such as a physiologic,  
23 pathologic, or anatomic characteristic or measure-  
24 ment) that is objectively measured and evaluated as  
25 an indicator of normal biologic processes, pathologic

1 processes, or biological responses to a therapeutic  
2 intervention.

3 “(2) QUALIFICATION.—The terms ‘qualifica-  
4 tion’, ‘qualified’, and ‘qualify’ refer to a conclusion  
5 that, within the stated context of use, a surrogate  
6 endpoint can be relied on to have a specific interpre-  
7 tation and application in drug, device, or biological  
8 product development and regulatory review.

9 “(3) REQUESTOR.—The term ‘requestor’ means  
10 the person submitting the request under subsection  
11 (a) that is at issue.

12 “(4) SURROGATE ENDPOINT.—The term ‘surro-  
13 gate endpoint’ means a biomarker that is intended  
14 to substitute for a clinical endpoint.”.

15 **SEC. 1023. TRANSITIONAL PROVISIONS FOR PREVIOUS SUB-**  
16 **MISSIONS FOR QUALIFICATION OF BIOMARK-**  
17 **ERS AS SURROGATE ENDPOINTS.**

18 (a) IN GENERAL.—Any person who submitted a  
19 pending biomarker request to the Secretary of Health and  
20 Human Services before the date of enactment of this Act  
21 may submit to the Secretary a request to review the pend-  
22 ing biomarker request under section 507A of the Federal  
23 Food, Drug, and Cosmetic Act (as applicable), as added  
24 by this Act. The decision as to whether to submit a request  
25 for the review of a pending biomarker request under such

1 section 507A is committed to the sole discretion of the  
2 requestor.

3 (b) CONTENTS OF REQUEST.—A request under sub-  
4 section (a) shall—

5 (1) include the pending biomarker request, in-  
6 cluding a description of the context of use of the bio-  
7 marker that is the subject of such pending bio-  
8 marker request and any other documentation or  
9 data submitted in support of the pending biomarker  
10 request;

11 (2) specify the stage of the process of the re-  
12 view of the pending biomarker request as of the date  
13 of the enactment of this Act; and

14 (3) with respect to the review of the pending  
15 biomarker request under section 507A of the Fed-  
16 eral Food, Drug, and Cosmetic Act (as added by  
17 this Act), what stage of the review under such re-  
18 spective section the person submitting such request  
19 anticipates the Secretary of Health and Human  
20 Services should begin such review of such pending  
21 biomarker request.

22 (c) EFFECT OF SPECIFICATION OF STAGE.—Unless  
23 the Secretary determines the stage specified in subsection  
24 (b)(3) is clearly erroneous, the Secretary shall begin the  
25 review under section 507A of the Federal Food, Drug, and

1 Cosmetic Act (as added by this Act) of a pending bio-  
2 marker request, at the stage of such review specified pur-  
3 suant to such subsection.

4 (d) DETERMINATIONS PRIOR TO FINALIZATION OF  
5 STANDARDS.—Nothing in this section shall be construed  
6 as precluding the Secretary from making a determination  
7 on whether any biomarker is qualified for use as a surro-  
8 gate endpoint, prior to the finalization of evidentiary  
9 standards under section 507A(a) of the Federal Food,  
10 Drug, and Cosmetic Act, as added by this Act.

11 (e) DEFINITION.—In this section, the term “pending  
12 biomarker request” means a request submitted to the Sec-  
13 retary before the date of the enactment of this Act for  
14 the qualification of a biomarker as a surrogate endpoint  
15 with respect to which, as of such date of enactment, the  
16 Secretary has not made a determination.

17 **SEC. 1024. BIENNIAL REPORTS TO CONGRESS.**

18 Not later than 18 months after the issuance of the  
19 final guidance under section 507(b)(2), and biannually  
20 thereafter, the Secretary shall submit to Congress a report  
21 that includes—

22 (1) the number and type of surrogate endpoints  
23 requested for review under section 507A; and

24 (2) the number of surrogate endpoints qualified  
25 under section 507A.

1                   **Subtitle C—Approval of**  
2                   **Breakthrough Therapies**

3   **SEC. 1041. APPROVAL OF BREAKTHROUGH THERAPIES.**

4           (a) IN GENERAL.—Section 506 of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

6                   (1) by moving subsection (f) (relating to aware-  
7 ness efforts) so that such subsection follows sub-  
8 section (e); and

9                   (2) by adding at the end the following:

10           “(g) APPROVAL OF BREAKTHROUGH THERAPIES.—

11                   “(1) IN GENERAL.—

12                           “(A) APPROVAL.—At the request of the  
13 sponsor of a drug that has received designation  
14 as a breakthrough therapy under subsection (a)  
15 for a serious or life-threatening disease or con-  
16 dition, and for which an application is sub-  
17 mitted under section 505(b) of this Act or sec-  
18 tion 351 of the Public Health Service Act, the  
19 Secretary may grant approval of such applica-  
20 tion upon a determination that the sponsor has  
21 submitted the evidence described in subpara-  
22 graph (B).

23                           “(B) EVIDENCE.—The evidence described  
24 in this subparagraph consists of early stage  
25 clinical safety and effectiveness data that pro-

1           vide sufficient evidence for approval of the drug  
2           as safe and effective under subsections (c) and  
3           (d) of section 505 of this Act or for licensure  
4           of the drug as safe, pure, and potent under sec-  
5           tion 351(a) of the Public Health Service Act for  
6           such disease or condition, considering the risks  
7           and benefits of the drug and the risks associ-  
8           ated with such disease or condition for which  
9           unmet medical needs exist.

10           “(C) DEFINITION.—In this paragraph, the  
11           term ‘early stage clinical safety and effective-  
12           ness data’ includes clinical safety and effective-  
13           ness data derived from one or more phase 2  
14           studies, as defined in section 312.21 of title 21,  
15           Code of Federal Regulations (or any successor  
16           regulation).

17           “(2) LIMITATION.—The Secretary may make  
18           approval of a drug under this subsection subject to  
19           a requirement that the sponsor will assess the safety  
20           and effectiveness of the drug through a postmarket  
21           assessment plan. Such a plan shall be based on an  
22           agreement between the Secretary and the sponsor of  
23           the drug and shall consist of one of, or a combina-  
24           tion of, the following:

1           “(A) One or more clinical trials after ap-  
2           proval or licensure of the drug.

3           “(B) One or more studies on the drug  
4           after its approval or licensure using data about  
5           the usage, benefits, or risks of the drug derived  
6           from sources other than randomized clinical  
7           trials, including from observational studies and  
8           registries.

9           “(3) WITHDRAWAL OF APPROVAL.—

10           “(A) IN GENERAL.—The Secretary may  
11           withdraw the approval of a drug pursuant to  
12           this subsection if—

13                   “(i) the sponsor of the drug fails to  
14                   execute, with due diligence, any  
15                   postmarket assessment plan required  
16                   under paragraph (2);

17                   “(ii) other evidence demonstrates that  
18                   the drug is not safe or effective under the  
19                   conditions of use for which the drug is ap-  
20                   proved under this subsection; or

21                   “(iii) the sponsor of the drug dissemi-  
22                   nates false or misleading promotional ma-  
23                   terials with respect to the drug.

1           “(B) PROCEDURES.—In so withdrawing  
2 approval of a drug, the Secretary shall use pro-  
3 cedures that—

4                   “(i) are prescribed by the Secretary in  
5 regulations; and

6                   “(ii) include an opportunity for an in-  
7 formal hearing.”.

8           (b)       CONFORMING        AMENDMENT.—Section  
9 506(a)(3)(B) of the Federal Food, Drug, and Cosmetic  
10 Act (21 U.S.C. 356(a)(3)(B)) is amended—

11           (1) in clause (iv), by striking “and” at the end;

12           (2) in clause (v), by striking the period at the  
13 end and inserting “; and”; and

14           (3) by adding at the end the following:

15                   “(vi) providing priority review with re-  
16 spect to, and granting approval of, such an  
17 application pursuant to subsection (g).”.

18           (c) RULES OF CONSTRUCTION.—Nothing in this sec-  
19 tion or the amendments made by this section shall be con-  
20 strued—

21           (1) to replace the Food and Drug Administra-  
22 tion’s program for breakthrough therapies under  
23 section 506(a) of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 356(a)); or



1 (2) to limit the rule of construction in sub-  
2 section (e)(2) of section 506 of such Act (21 U.S.C.  
3 356), which provides that nothing in such section  
4 506 (including section 506(g), as added by this sec-  
5 tion) shall be construed to alter the standards of evi-  
6 dence under—

7 (A) subsection (c) or (d) of section 505 of  
8 the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 355) including the substantial evidence  
10 standard in section 505(d) of such Act (21  
11 U.S.C. 355(d)); or

12 (B) section 351(a) of the Public Health  
13 Service Act (42 U.S.C. 262(a)).

14 (d) GUIDANCE.—

15 (1) IN GENERAL.—The Secretary shall publish  
16 guidance that specifies—

17 (A) the policies and procedures for obtain-  
18 ing approval of breakthrough therapies under  
19 section 506(g) of the Federal Food, Drug, and  
20 Cosmetic Act (21 U.S.C. 356(g)); and

21 (B) the circumstances under which a spon-  
22 sor of a drug should consider the drug as a po-  
23 tential candidate for such approval, including  
24 when a substantial portion of the population

1 with the disease or condition is not eligible for  
2 existing clinical trials.

3 (2) TIMING.—The Secretary shall—

4 (A) issue draft guidance under paragraph  
5 (1) not later than 12 months after the date of  
6 enactment of this Act; and

7 (B) after providing notice of the draft  
8 guidance and an opportunity for public com-  
9 ment, finalize such guidance not later than 18  
10 months after the date of publication of the  
11 draft guidance.

12 (3) CONSULTATION.—In developing guidance  
13 under this subsection, the Secretary shall consult  
14 with the regulated industry, academia, representa-  
15 tives of patient advocacy organizations and disease  
16 research foundations, and other interested parties  
17 through a public process.

18 **Subtitle D—Antibiotic Drug**  
19 **Development**

20 **SEC. 1061. APPROVAL OF CERTAIN DRUGS FOR USE IN A**  
21 **LIMITED POPULATION OF PATIENTS.**

22 (a) APPROVAL OF CERTAIN ANTIBACTERIAL AND  
23 ANTIFUNGAL DRUGS.—

24 (1) IN GENERAL.—Section 505 of the Federal  
25 Food, Drug, and Cosmetic Act (21 U.S.C. 355), as

1 amended by section 1001, is further amended by  
2 adding at the end the following:

3 “(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND  
4 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-  
5 LATION OF PATIENTS.—

6 “(1) PROCESS.—At the request of the sponsor  
7 of an antibacterial or antifungal drug that is in-  
8 tended to treat a serious or life-threatening disease  
9 or condition, the Secretary—

10 “(A) shall provide the sponsor with an op-  
11 portunity to request meetings under paragraph  
12 (2); and

13 “(B) may, consistent with an agreement  
14 between the sponsor and the Secretary, if any  
15 such agreement is reached, approve the drug  
16 under subsection (c) for such treatment in a  
17 limited population of patients for which there is  
18 an unmet medical need.

19 “(2) FORMAL MEETINGS.—

20 “(A) IN GENERAL.—In the case of any  
21 drug subject to an agreement under paragraph  
22 (1) for approval for use in a limited population,  
23 the sponsor of the drug may request, and the  
24 Secretary shall agree to conduct, any or all of  
25 the following types of meetings:

1 “(i) A clinical development planning  
2 meeting.

3 “(ii) An assessment meeting.

4 “(iii) A postapproval meeting.

5 “(B) RELATION TO COMPARABLE FORMAL  
6 MEETINGS.—A meeting conducted pursuant to  
7 a request described in subparagraph (A) shall  
8 not replace any meeting with the Secretary to  
9 which the sponsor of the drug is otherwise enti-  
10 tled, but may be conducted as part of a com-  
11 parable formal meeting.

12 “(C) TIMING.—The Secretary shall meet  
13 with the sponsor of a drug pursuant to a re-  
14 quest described in subparagraph (A) not later  
15 than 60 days after the date of the Secretary’s  
16 receipt of the request.

17 “(D) DEFINITIONS.—In this paragraph:

18 “(i) The term ‘assessment meeting’  
19 means a meeting, other than a clinical de-  
20 velopment planning meeting, held prior to  
21 submission of an application for a drug  
22 under section 505(b) of this Act or section  
23 351(a) of the Public Health Service Act, at  
24 which the sponsor of the drug and the Sec-  
25 retary meet—

1                   “(I) to assess progress in imple-  
2                   menting the clinical development pro-  
3                   gram agreed to under paragraph (1);

4                   “(II) to discuss the necessity of,  
5                   and reach agreement with respect to,  
6                   any postapproval commitments; and

7                   “(III) to reach agreement on the  
8                   efficacy or safety data necessary to  
9                   support expansion of the approval or  
10                  licensure of the drug beyond use in  
11                  the limited population.

12                  “(ii) The term ‘clinical development  
13                  planning meeting’ means a meeting, other  
14                  than an assessment meeting, at which the  
15                  sponsor of the drug and the Secretary  
16                  meet to discuss and reach an initial agree-  
17                  ment with respect to the content of the  
18                  clinical development program (including  
19                  the matters described in paragraph (1)(B))  
20                  that is necessary to support approval or li-  
21                  censure of the drug for use in a limited  
22                  population.

23                  “(iii) The term ‘comparable formal  
24                  meeting’—

1                   “(I) means a formal meeting that  
2                   is typically held during the drug devel-  
3                   opment or approval process; and

4                   “(II) includes any such meeting  
5                   that is described in applicable guid-  
6                   ance documents of the Food and Drug  
7                   Administration that are in effect.

8                   “(iv) The term ‘postapproval meeting’  
9                   means a meeting, held following initial ap-  
10                  proval or licensure of the drug for use in  
11                  a limited population, to discuss any issues  
12                  regarding postapproval commitments or ex-  
13                  pansion of approved uses agreed to under  
14                  paragraph (1).

15                  “(3) AGREEMENTS.—

16                  “(A) FORM.—Any agreement that is  
17                  reached between the Secretary and a sponsor of  
18                  a drug under paragraph (1), including an  
19                  agreement with respect to the design or size of  
20                  clinical trials, shall be reduced to writing and  
21                  made part of the administrative record by the  
22                  Secretary.

23                  “(B) EVIDENCE.—An agreement under  
24                  paragraph (1) may provide for reliance on tra-  
25                  ditional endpoints, alternative endpoints, or a

1 combination of traditional and alternative  
2 endpoints; datasets of limited size; pharmaco-  
3 logic or pathophysiologic data; data from phase  
4 2 clinical studies; data obtained in real-world  
5 settings; and such other confirmatory evidence  
6 as the Secretary deems necessary to approve  
7 the drug, as described in paragraph (1).

8 “(C) LABELING STATEMENT.—An agree-  
9 ment under paragraph (1) shall require the  
10 drug’s labeling, upon approval pursuant to the  
11 agreement, to prominently include in the pre-  
12 scribing information required by section 201.57  
13 of title 21, Code of Federal Regulations (or any  
14 successor regulation) the following statement:  
15 ‘This drug is indicated for use in a limited and  
16 specific population of patients.’.

17 “(D) CHANGES.—An agreement described  
18 in subparagraph (A) shall not be changed after  
19 the development of such data begins, except—

20 “(i) with the written agreement of the  
21 sponsor of the drug; or

22 “(ii) pursuant to a decision by the di-  
23 rector of the division responsible for re-  
24 viewing the drug that a substantial sci-  
25 entific issue essential to determining the

1 safety or effectiveness of the drug was  
2 identified after data development began.

3 “(E) DECISION BY DIRECTOR.—A decision  
4 under subparagraph (D)(ii) shall be in writing.  
5 Before any such decision is made final, the Sec-  
6 retary shall provide to the sponsor of the drug  
7 an opportunity for a meeting at which—

8 “(i) the director of the division re-  
9 sponsible for reviewing the drug and the  
10 sponsor will be present; and

11 “(ii) the director will document the  
12 scientific issues involved.

13 “(4) PROMOTIONAL MATERIALS.—The provi-  
14 sions of section 506(c)(2)(B) shall apply with re-  
15 spect to approval under this subsection to the same  
16 extent and in the same manner as such provisions  
17 apply with respect to accelerated approval under sec-  
18 tion 506(c)(1).

19 “(5) WITHDRAWAL OF LIMITED POPULATION  
20 APPROVAL REQUIREMENTS.—If a drug is approved  
21 pursuant to this subsection for treatment in a lim-  
22 ited population of patients and is subsequently ap-  
23 proved or licensed under this section or section 351  
24 of the Public Health Service Act, respectively, with-  
25 out such a limitation, the Secretary shall remove any



1 labeling requirements or postmarketing conditions  
2 that were made applicable to the drug on the basis  
3 of such limitation.

4 “(6) RELATION TO OTHER PROVISIONS.—Noth-  
5 ing in this subsection shall be construed to prohibit  
6 designation and expedited review of a drug as a  
7 breakthrough therapy under section 506(a), approval  
8 of such a drug under section 506(g), designation  
9 and treatment of a drug as a fast track product  
10 under section 506(b), or accelerated approval of a  
11 drug under section 506(c), in combination with ap-  
12 proval of the drug for use in a limited population of  
13 patients under this subsection.

14 “(7) RULE OF CONSTRUCTION.—Nothing in  
15 this subsection shall be construed to alter the stand-  
16 ards of evidence under subsection (c) or (d) (includ-  
17 ing the substantial evidence standard in subsection  
18 (d)). Subsections (c) and (d) and such standards of  
19 evidence apply to the review and approval of drugs  
20 under this subsection, including whether a drug is  
21 safe and effective. Nothing in this subsection shall  
22 be construed to limit the authority of the Secretary  
23 to approve products pursuant to this Act and the  
24 Public Health Service Act as authorized prior to the  
25 date of enactment of this subsection.

1           “(8) EFFECTIVE IMMEDIATELY.—The Sec-  
2           retary shall have the authorities vested in the Sec-  
3           retary by this subsection beginning on the date of  
4           enactment of this subsection, irrespective of when  
5           and whether the Secretary promulgates final regula-  
6           tions or guidance.”.

7           (2) GUIDANCE.—Not later than 12 months  
8           after the date of enactment of this Act, the Sec-  
9           retary of Health and Human Services, acting  
10          through the Commissioner of Food and Drugs, shall  
11          issue draft guidance describing criteria, processes,  
12          and other general considerations for demonstrating  
13          the safety and effectiveness of antibacterial and  
14          antifungal drugs to be approved for use in a limited  
15          population under section 505(z) of the Federal  
16          Food, Drug, and Cosmetic Act, as added by para-  
17          graph (1).

18          (b) LICENSURE OF CERTAIN BIOLOGICAL PROD-  
19          UCTS.—Section 351(j) of the Public Health Service Act  
20          (42 U.S.C. 262(j)) is amended—

- 21                   (1) by striking “(j)” and inserting “(j)(1)”;
- 22                   (2) by inserting “505(z),” after “505(p),”; and
- 23                   (3) by adding at the end the following:

1           “(2) In applying section 505(z) of the Federal  
2 Food, Drug, and Cosmetic Act to the licensure of bi-  
3 ological products under this section—

4           “(A) references to an antibacterial or  
5 antifungal drug that is intended to treat a seri-  
6 ous or life-threatening disease or condition shall  
7 be construed to refer to biological products in-  
8 tended to treat a bacterial or fungal infection  
9 associated with a serious or life-threatening dis-  
10 ease; and

11           “(B) references to approval of a drug  
12 under section 505(c) of such Act shall be con-  
13 strued to refer to licensure of a biological prod-  
14 uct under subsection (a) of this section.”.

15       (c) MONITORING.—Title III of the Public Health  
16 Service Act is amended by inserting after section 317T  
17 (42 U.S.C. 247b–22) the following:

18 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**  
19 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

20       “(a) MONITORING.—The Secretary, acting through  
21 the Director of the Centers for Disease Control and Pre-  
22 vention, shall use the National Healthcare Safety Network  
23 or another appropriate monitoring system to monitor—

24           “(1) the use of antibacterial and antifungal  
25 drugs, including those receiving approval or licensure

1 for a limited population pursuant to section 505(z)  
2 of the Federal Food, Drug, and Cosmetic Act; and

3 “(2) changes in bacterial and fungal resistance  
4 to drugs.

5 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-  
6 retary, acting through the Director of the Centers for Dis-  
7 ease Control and Prevention, shall make the data derived  
8 from monitoring under this section publicly available for  
9 the purposes of—

10 “(1) improving the monitoring of important  
11 trends in antibacterial and antifungal resistance;  
12 and

13 “(2) ensuring appropriate stewardship of anti-  
14 bacterial and antifungal drugs, including those re-  
15 ceiving approval or licensure for a limited population  
16 pursuant to section 505(z) of the Federal Food,  
17 Drug, and Cosmetic Act.”.

18 **SEC. 1062. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
19 **FOR MICROBIAL ORGANISMS.**

20 (a) IN GENERAL.—Section 511 of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to  
22 read as follows:

1 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**  
2 **TEST INTERPRETIVE CRITERIA FOR MICRO-**  
3 **BIAL ORGANISMS.**

4 “(a) IDENTIFICATION OF CRITERIA.—

5 “(1) IN GENERAL.—The Secretary shall iden-  
6 tify appropriate susceptibility test interpretive cri-  
7 teria for systemic antibacterial or antifungal  
8 drugs—

9 “(A) if such criteria are available on the  
10 date of approval of the drug under section 505  
11 of this Act or licensure of the drug under sec-  
12 tion 351 of the Public Health Service Act (as  
13 applicable), upon such approval or licensure; or

14 “(B) if such criteria are unavailable on  
15 such date, on the date on which such criteria  
16 are available for such drug.

17 “(2) BASES FOR INITIAL IDENTIFICATION.—

18 The Secretary shall, in identifying susceptibility test  
19 interpretive criteria under subsection (a), rely upon,  
20 to the extent available and relevant—

21 “(A) preclinical and clinical data, including  
22 pharmacokinetic, pharmacodynamic, and epide-  
23 miological data;

24 “(B) Bayesian and pharmacometric statis-  
25 tical methodologies; and

1                   “(C) such other evidence and information  
2                   as the Secretary considers appropriate.

3                   “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA  
4 WEBSITE.—

5                   “(1) IN GENERAL.—Not later than one year  
6                   after the date of the enactment of the 21st Century  
7                   Cures Act, the Secretary shall establish, and main-  
8                   tain thereafter, on the website of the Food and Drug  
9                   Administration, a dedicated website that contains a  
10                  list of any appropriate new or updated susceptibility  
11                  test interpretive criteria standards in accordance  
12                  with paragraph (2) (referred to in this section as the  
13                  ‘Interpretive Criteria Website’).

14                  “(2) LISTING OF SUSCEPTIBILITY TEST INTER-  
15                  PRETIVE CRITERIA STANDARDS.—

16                  “(A) IN GENERAL.—The list described in  
17                  paragraph (1) shall consist of any new or up-  
18                  dated susceptibility test interpretive criteria  
19                  standards that are—

20                         “(i) established by a nationally or  
21                         internationally recognized standard devel-  
22                         opment organization that—

23                                 “(I) establishes and maintains  
24                                 procedures to address potential con-

1                   flicts of interest and ensure trans-  
2                   parent decisionmaking;

3                   “(II) holds open meetings to en-  
4                   sure that there is an opportunity for  
5                   public input by interested parties, and  
6                   establishes and maintains processes to  
7                   ensure that such input is considered  
8                   in decisionmaking; and

9                   “(III) permits its standards to be  
10                  made publicly available, through the  
11                  National Library of Medicine or an-  
12                  other similar source acceptable to the  
13                  Secretary; and

14                  “(ii) recognized in whole, or in part,  
15                  by the Secretary under subsection (c).

16                  “(B) OTHER LISTS.—The Interpretive Cri-  
17                  teria Website shall, in addition to the list de-  
18                  scribed in subparagraph (A), include the fol-  
19                  lowing lists:

20                  “(i) A list of each susceptibility test  
21                  interpretive criteria standard described in  
22                  subparagraph (A) that is applicable to a  
23                  systemic antibicrobial or antifungal drug  
24                  that the Secretary does not recognize, in  
25                  whole or in part.

1           “(ii) A list of each susceptibility test  
2           interpretive criteria standard, the recogni-  
3           tion of which, the Secretary has withdrawn  
4           under paragraph (3).

5           “(iii) A list of each susceptibility test  
6           interpretive criteria standard applicable to  
7           such a drug that differs from the standard  
8           described in subparagraph (A) that applies  
9           with respect to other drugs with the same  
10          active ingredient.

11          “(iv) A list of each drug for which the  
12          Secretary approves an application under  
13          section 505(b) of this Act or section  
14          351(a) of the Public Health Service Act, as  
15          applicable, for which there are no relevant  
16          susceptibility test interpretive criteria in-  
17          cluded in a standard recognized by the  
18          Secretary.

19          “(C) REQUIRED STATEMENTS ON LIMITA-  
20          TIONS OF INFORMATION.—The Interpretive Cri-  
21          teria Website shall include the following state-  
22          ments:

23                 “(i) A statement that—



1                   “(I) the Website provides infor-  
2                   mation about the susceptibility of bac-  
3                   teria and fungi to a certain drug; and

4                   “(II) the safety and efficacy of  
5                   the drug in treating clinical infections  
6                   due to such bacteria or fungi may not  
7                   have been established in adequate and  
8                   well-controlled clinical trials and the  
9                   clinical significance of such suscepti-  
10                  bility information in such trials is un-  
11                  known.

12                  “(ii) A statement that directs health  
13                  care practitioners to consult the approved  
14                  product labeling for specific drugs to deter-  
15                  mine the uses for which the Secretary has  
16                  approved the product.

17                  “(iii) Any other statement that the  
18                  Secretary determines appropriate to ade-  
19                  quately convey the limitations of the data  
20                  supporting susceptibility test interpretive  
21                  criteria standard listed on the Website.

22                  “(3) NOTICE.—Not later than the date on  
23                  which the Interpretive Criteria Website is published,  
24                  the Secretary shall publish a notice of that publica-  
25                  tion in the Federal Register.

1           “(4) INAPPLICABILITY OF MISBRANDING PROVI-  
2           SIONS.—The inclusion in the approved labeling of a  
3           systemic antibacterial or antifungal drug of a ref-  
4           erence or hyperlink to the Interpretive Criteria  
5           Website shall not cause the drug to be misbranded  
6           in violation of section 502.

7           “(5) TRADE SECRETS AND CONFIDENTIAL IN-  
8           FORMATION.—Nothing in this section shall be con-  
9           strued as authorizing the Secretary to disclose any  
10          information that is a trade secret or confidential in-  
11          formation subject to section 552(b)(4) of title 5,  
12          United States Code.

13          “(c) RESPONDING TO SUSCEPTIBILITY TEST INTER-  
14          PRETIVE CRITERIA IDENTIFIED OR UPDATED BY PRI-  
15          VATE ENTITIES.—

16          “(1) IN GENERAL.—Beginning on the date of  
17          the establishment of the Interpretive Criteria  
18          Website, and every 6 months thereafter, the Sec-  
19          retary shall—

20                  “(A) evaluate any appropriate new or up-  
21                  dated susceptibility test interpretive criteria  
22                  standards established by a nationally or inter-  
23                  nationally recognized standard development or-  
24                  ganization described in subsection (b)(2)(A)(i);  
25                  and

1                   “(B) publish on the public website of the  
2                   Food and Drug Administration a notice—

3                   “(i) withdrawing recognition of any  
4                   different susceptibility test interpretive cri-  
5                   teria standard, in whole or in part;

6                   “(ii) adopting the new or updated  
7                   standards;

8                   “(iii) adopting one or more parts of  
9                   the new or updated interpretive criteria  
10                  specified in such a standard, declining to  
11                  adopt the remainder of such criteria, and  
12                  explaining the reason for so declining; and

13                  “(iv) making any necessary updates to  
14                  a list under subsection (b)(2).

15                  “(2) BASES FOR UPDATING INTERPRETIVE CRI-  
16                  TERIA STANDARDS.—In evaluating new or updated  
17                  susceptibility test interpretive criteria standards  
18                  under paragraph (1)(A), the Secretary may con-  
19                  sider—

20                  “(A) the Secretary’s determination that  
21                  such a standard is not applicable to a particular  
22                  drug because the characteristics of the drug dif-  
23                  fer from other drugs with the same active in-  
24                  gredient;

1           “(B) information provided by interested  
2           third parties, including public comment on the  
3           annual compilation of notices published under  
4           paragraph (5);

5           “(C) any bases used to identify suscepti-  
6           bility test interpretive criteria under subsection  
7           (a)(1)(B); and

8           “(D) such other information or factors as  
9           the Secretary determines appropriate.

10          “(3) ANNUAL COMPILATION OF NOTICES.—

11          Each year, the Secretary shall compile the notices  
12          published under paragraph (1)(B) and publish such  
13          compilation in the Federal Register and provide for  
14          public comment. If the Secretary receives comments,  
15          the Secretary will review such comments and, if the  
16          Secretary determines appropriate, update pursuant  
17          to such subsection, susceptibility test interpretive  
18          criteria standards—

19                 “(A) recognized by the Secretary under  
20                 this subsection; or

21                 “(B) otherwise listed on the Interpretive  
22                 Criteria Website under subsection (b)(2).

23          “(4) RELATION TO SECTION 514(c).—Any sus-  
24          ceptibility test interpretive criterion for which an ap-  
25          proval is in effect under paragraph (1) shall be rec-

1           ognized as a standard by the Secretary under sec-  
2           tion 514(c)(1).

3           “(5) VOLUNTARY USE OF NONADOPTED CRI-  
4           TERIA.—Nothing in this section prohibits the spon-  
5           sor of a drug or device from seeking approval or  
6           clearance of the drug or device, or changes to the  
7           drug, the device, or its labeling, on the basis of sus-  
8           ceptibility test interpretive criteria which differ from  
9           those adopted pursuant to paragraph (1).

10          “(d) SYSTEMIC ANTIBACTERIAL AND ANTIFUNGAL  
11         DRUG LABELING.—

12                 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-  
13                 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With  
14                 respect to a systemic antibacterial or antifungal  
15                 drug lawfully introduced or delivered for introduc-  
16                 tion into interstate commerce for commercial dis-  
17                 tribution before the establishment of the Internet  
18                 site under subsection (b)(1), a holder of an approved  
19                 application under section 505 or section 351 of the  
20                 Public Health Service Act, as applicable, for each  
21                 such drug—

22                         “(A) not later than 1 year after establish-  
23                         ment of the Interpretive Criteria Website, shall  
24                         submit to the Secretary a supplemental applica-  
25                         tion for purposes of changing the drug’s label-

1 ing to substitute a reference or hyperlink to  
2 such Website for any susceptibility test inter-  
3 preitive criteria and related information; and

4 “(B) may begin distribution of the drug in-  
5 volved upon receipt by the Secretary of the sup-  
6 plemental application for such change.

7 “(2) DRUGS MARKETED SUBSEQUENT TO ES-  
8 TABLISHMENT OF INTERPRETIVE CRITERIA  
9 WEBSITE.—With respect to systemic antibacterial  
10 and antifungal drugs lawfully introduced or delivered  
11 for introduction into interstate commerce for com-  
12 mercial distribution on or after the date of the es-  
13 tablishment of the Interpretive Criteria Website, the  
14 labeling for such a drug shall include, in lieu of sus-  
15 ceptibility test interpretive criteria and related infor-  
16 mation, a reference to such Website.

17 “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-  
18 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—Not-  
19 withstanding sections 502, 505, 513, 514, and 515, a de-  
20 vice for use to test the susceptibility of bacteria and fungi  
21 to drugs may be lawfully marketed under this Act if—

22 “(1) the device is used to make a determination  
23 of susceptibility using susceptibility test interpretive  
24 criteria that are—

1           “(A) included in a standard recognized by  
2           the Secretary under subsection (c); or

3           “(B) otherwise listed on the Interpretive  
4           Criteria Website under subsection (b)(2); and

5           “(2) the labeling of such device prominently  
6           and conspicuously—

7           “(A) includes a statement that—

8                   “(i) the device provides information  
9                   about the susceptibility of bacteria and  
10                  fungi to certain drugs; and

11                   “(ii) the safety and efficacy of such  
12                  drugs in treating clinical infections due to  
13                  such bacteria or fungi may not have been  
14                  established in adequate and well-controlled  
15                  clinical trials and the clinical significance  
16                  of such susceptibility information in those  
17                  instances is unknown;

18           “(B) includes a statement directing health  
19           care practitioners to consult the approved label-  
20           ing for drugs tested using such a device, to de-  
21           termine the uses for which the Secretary has  
22           approved such drugs; and

23           “(C) includes any other statement the Sec-  
24           retary determines appropriate to adequately  
25           convey the limitations of the data supporting

1 the interpretive criteria described in paragraph  
2 (1).

3 “(f) DEFINITIONS.—In this section:

4 “(1) The term ‘antimicrobial testing device’  
5 means, in the case of a drug, the efficacy of which  
6 in treating clinical infections due to certain bacteria  
7 or fungi has not been established in adequate and  
8 well-controlled clinical trials, a device that utilizes  
9 susceptibility test interpretive criteria to determine  
10 and report the susceptibility of such bacteria or  
11 fungi to such drug.

12 “(2) The term ‘qualified infectious disease  
13 product’ means a qualified infectious disease product  
14 designated under section 505E(d).

15 “(3) The term ‘susceptibility test interpretive  
16 criteria’ 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 sus-  
21 ceptibility, including categorization of the drug  
22 as susceptible, intermediate, resistant, or such  
23 other term as the Secretary determines appro-  
24 priate.



1           “(4)(A) The term ‘systemic antibacterial or  
2           antifungal drug’ means a drug that—

3                   “(i) is intended for human use in the treat-  
4                   ment of a disease or condition caused by a bac-  
5                   terium or fungus; and

6                   “(ii) is subject to section 503(b)(1).

7           “(B) Such term includes a qualified infectious  
8           disease product.

9           “(C) Unless otherwise specified by the Sec-  
10           retary through regulations, such term does not in-  
11           clude—

12                   “(i) antimicrobial drugs other than anti-  
13                   bacterial and antifungal drugs; and

14                   “(ii) biological products (as such term is  
15                   defined in section 351 of the Public Health  
16                   Service Act).

17           “(g) RULE OF CONSTRUCTION.—Nothing in this sec-  
18           tion shall be construed to alter the standards of evidence  
19           under subsection (c) or (d) of section 505.”.

20           (b) CONFORMING AMENDMENTS.—

21                   (1) REPEAL OF RELATED AUTHORITY.—Section  
22                   1111 of the Food and Drug Administration Amend-  
23                   ments Act of 2007 (42 U.S.C. 247d–5a; relating to  
24                   identification of clinically susceptible concentrations  
25                   of antimicrobials) is repealed.

1           (2) MISBRANDING.—Section 502 of the Federal  
2           Food, Drug, and Cosmetic Act (28 U.S.C. 352) is  
3           amended by adding at the end the following:

4           “(dd) If it is a systemic antibacterial or antifungal  
5           drug and its labeling fails to conform with the require-  
6           ments under section 511(d).”.

7           (3) RECOGNITION FOR PURPOSES OF DEVICE  
8           CLASSIFICATION.—Section 514(c)(1)(A) of the Fed-  
9           eral Food, Drug, and Cosmetic Act (21 U.S.C.  
10          360d(e)(1)(A)) is amended by inserting after “the  
11          Secretary shall, by publication in the Federal Reg-  
12          ister” the following: “(or, with respect to the ap-  
13          proval of an antimicrobial testing device under sec-  
14          tion 511(e), by posting on the Interpretive Criteria  
15          Website established under subsection (b) of such sec-  
16          tion the applicable susceptibility test interpretive cri-  
17          teria standards in accordance with section 511)”.

18          (c) REPORT TO CONGRESS.—Not later than two  
19          years after the date of enactment of this Act, the Sec-  
20          retary of Health and Human Services shall submit to the  
21          Committee on Energy and Commerce of the House of  
22          Representatives and the Committee on Health, Education,  
23          Labor, and Pensions of the Senate a report on the  
24          progress made in implementing section 511 of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as  
2 amended by this section.

3 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-  
4 TERIA WEBSITE.—Chapter 35 of title 44, United States  
5 Code, shall not apply to the collection of information from  
6 interested parties regarding the updating of lists under  
7 paragraph (2) of subsection (b) section 511 of the Federal  
8 Food, Drug, and Cosmetic Act, as amended by subsection  
9 (a), and posted on the Interpretive Criteria Website estab-  
10 lished under paragraph (1) of such subsection.

11 (e) RULE OF CONSTRUCTION.—Nothing in this Act  
12 (including the amendments made by this Act) shall be con-  
13 strued to restrict, in any manner, the prescribing of anti-  
14 biotics or other products by health care professionals, or  
15 to limit the practice of health care.

16 **SEC. 1063. ELECTION TO CONVEY A PORTION OF EXTENDED**  
17 **EXCLUSIVITY PERIOD APPLICABLE TO**  
18 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

19 Section 505E of the Federal Food, Drug, and Cos-  
20 metic Act (21 U.S.C. 355f) is amended—

21 (1) in subsection (a), by inserting “, subject to  
22 subsection (h),” before “be extended by 5 years”;  
23 and

24 (2) by adding at the end the following new sub-  
25 section:

1           “(h) ELECTION TO CONVEY A PORTION OF EXCLU-  
2 SIVITY.—

3           “(1) IN GENERAL.—Subject to the succeeding  
4 provisions of this subsection, the holder of an ap-  
5 proved application for a qualified infectious disease  
6 product may elect to convey up to [12] months of  
7 the 5-year extension of exclusivity described in sub-  
8 section (a) so as to apply such extension of exclu-  
9 sivity with respect to one or more other drugs.

10           “(2) NOTICE TO SECRETARY.—Upon making a  
11 conveyance under paragraph (1), the holder of the  
12 approved application for the qualified infectious dis-  
13 ease product involved shall submit a notice to the  
14 Secretary including—

15           “(A) the name of the qualified infectious  
16 disease product;

17           “(B) the name of the recipient drug; and

18           “(C) the duration of the conveyed exclu-  
19 sivity period.

20           “(3) EFFECT OF CONVEYANCE.—

21           “(A) EXTENSION OF OTHER APPLICABLE  
22 EXCLUSIVITY PERIODS.—Immediately upon the  
23 Secretary’s receipt of a notice under paragraph  
24 (2), with respect to the recipient drug, the fol-  
25 lowing exclusivity periods (as applicable) are

1 each extended by the conveyed exclusivity pe-  
2 riod:

3 “(i) The 4- and 5-year periods de-  
4 scribed in subsections (c)(3)(E)(ii) and  
5 (j)(5)(F)(ii) of section 505.

6 “(ii) The 3-year periods described in  
7 clauses (iii) and (iv) of subsection  
8 (c)(3)(E) and clauses (iii) and (iv) of sub-  
9 section (j)(5)(F) of section 505.

10 “(iii) The 7-year period described in  
11 section 527.

12 “(iv) The 12-year period referred to in  
13 section 351(k)(7)(A) of the Public Health  
14 Service Act and the 4-year period referred  
15 to in section 351(k)(7)(B) of such Act.

16 “(B) DRUGS SUBJECT TO LISTED PAT-  
17 ENTS.—Immediately upon the Secretary’s re-  
18 ceipt of a notice under paragraph (2), the pe-  
19 riod during which an approval of an application  
20 may not be made effective by operation of sub-  
21 section (c)(3) or (j)(5)(B) of section 505, as ap-  
22 plicable, shall be extended after the date the  
23 patent expires (including any patent extensions)  
24 for a period equal to the conveyed exclusivity

1 period in the case of a recipient drug that is the  
2 subject of—

3 “(i) a listed patent for which a certifi-  
4 cation has been submitted under sub-  
5 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of  
6 section 505;

7 “(ii) a listed patent for which a cer-  
8 tification has been submitted under sub-  
9 section (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)  
10 of section 505; or

11 “(iii) a listed patent for which a cer-  
12 tification has been submitted under sub-  
13 section (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)  
14 of section 505 and the patent infringement  
15 litigation resulting from the certification  
16 the court determines that the patent is  
17 valid and would be infringed.

18 “(4) LIMITATION ON AMOUNT OF CONVEYED  
19 EXCLUSIVITY.—In no case may the aggregate  
20 amount of time conveyed pursuant to paragraph (2)  
21 from a 5-year extension of exclusivity described in  
22 subsection (a) exceed **[12]** months.

23 “(5) PERIOD FOR ELECTIONS.—An election  
24 under paragraph (2) with respect to a qualified in-  
25 fectionous disease product may not be made later than

1 the date that is the last day of the fourth year of  
2 the 5-year extension of exclusivity described in sub-  
3 section (a) applicable with respect to such product.

4 “(6) RULE OF CONSTRUCTION.—Nothing in  
5 this Act shall be construed as prohibiting the sale of  
6 any conveyed exclusivity period.

7 “(7) REDUCTION OF EXTENSION OF EXCLU-  
8 SIVITY PERIOD FOR QUALIFIED INFECTIOUS DISEASE  
9 PRODUCT.—Immediately upon the Secretary’s re-  
10 ceipt of a notice under paragraph (2), the 5-year ex-  
11 tension of exclusivity described in subsection (a) ap-  
12 plicable with respect to a qualified infectious disease  
13 product shall be reduced by the conveyed exclusivity  
14 period.

15 “(8) EXCEPTION.—The periods referred to in  
16 subparagraphs (A) and (B) of paragraph (3) shall  
17 not be extended pursuant to such paragraph if, with  
18 respect to the proposed recipient drug, less than 4  
19 years remain of—

20 “(A) an exclusivity period described in  
21 clause (i), (ii), (iii), or (iv) of subparagraph (A),  
22 as applicable; or

23 “(B) the patent terms for all patents listed  
24 in the publication entitled ‘Approved Drug  
25 Products with Therapeutic Equivalence Evalua-

1 tions’ (commonly referred to as the ‘Orange  
2 Book’).

3 “(9) RELATION TO PEDIATRIC EXCLUSIVITY.—  
4 Any extension of a period under paragraph (3) shall  
5 be in addition to any extension of the period under  
6 section 505A of this Act or section 351(m) of the  
7 Public Health Service Act, and any reference to a  
8 period in paragraph (8) is deemed to be a reference  
9 to the period as extended under such section 505A  
10 or 351(m), if applicable.

11 “(10) DONATION TO THE NATIONAL INSTI-  
12 TUTES OF HEALTH.—As a condition on receipt of a  
13 conveyed exclusivity period, the holder of the ap-  
14 proved application for the recipient drug shall make  
15 a donation to the National Institutes of Health as  
16 follows:

17 “(A) Except as expressly specified in this  
18 paragraph, the donation shall be unconditional.

19 “(B) The donation amount shall equal  
20 **[\_\_\_\_\_]** percent (not to exceed 5 percent) of  
21 sales of the recipient drug in the United States  
22 for the period—

23 “(i) beginning on the first day of the  
24 conveyed exclusivity period; and



1 “(ii) ending on the date of market  
2 entry of a drug approved pursuant to an  
3 application filed under subsection (b)(2) or  
4 (j) of section 505 of this Act that ref-  
5 erences the recipient drug as the listed  
6 drug or of a biological product licensed  
7 pursuant to section 351(k) of the Public  
8 Health Service Act that references the re-  
9 cipient drug as the reference product.

10 “(C) The donation shall be made not later  
11 than 60 days after the end of the marketing pe-  
12 riod described in subparagraph (B).

13 “(D) In no event shall the total donation  
14 required under this paragraph with respect to a  
15 recipient drug exceed **【\$\_\_\_\_\_】** dollars.

16 “(E) The holder of the approved applica-  
17 tion for the recipient drug, when making a do-  
18 nation pursuant to this paragraph, shall specify  
19 that the donation is to be used for making  
20 grants to fund antimicrobial resistance re-  
21 search.

22 “(11) DONATIONS TO PATIENT ASSISTANCE  
23 PROGRAMS.—As a condition on receipt of a conveyed  
24 exclusivity period, in addition to the donation re-  
25 quired by paragraph (10), the holder of the ap-

1 proved application for the recipient drug shall make  
2 a donation to a bona fide, independent patient as-  
3 sistance program as follows:

4 “(A) The donation amount shall equal  
5 **【\_\_\_\_\_】** percent (not to exceed 5 percent) of  
6 sales of the recipient drug in the United States  
7 for the period—

8 “(i) beginning on the first day of the  
9 conveyed exclusivity period; and

10 “(ii) ending on the date of market  
11 entry of a drug approved pursuant to an  
12 application filed under subsection (b)(2) or  
13 (j) of section 505 of this Act that ref-  
14 erences the recipient drug as the listed  
15 drug or of a biological product licensed  
16 pursuant to section 351(k) of the Public  
17 Health Service Act that references the re-  
18 cipient drug as the reference product.

19 “(B) The donation shall be made not later  
20 than 60 days after the end of the marketing pe-  
21 riod described in subparagraph (A).

22 “(C) In no event shall the total donations  
23 required under this paragraph with respect to a  
24 recipient drug exceed **【\$\_\_\_\_\_】** dollars.

1           “(D) The patient assistance program must  
2           have received a favorable advisory opinion from  
3           the Inspector General of the Food and Drug  
4           Administration with respect the program’s ar-  
5           rangement to provide cost-sharing assistance  
6           for prescription drugs.

7           “(E) The donation shall be earmarked by  
8           the patient assistance program for one or more  
9           broadly defined disease funds that—

10                   “(i) include the diseases or conditions  
11                   for which the recipient drug is intended to  
12                   treat; and

13                   “(ii) do not limit assistance to a sub-  
14                   set of available products approved to treat  
15                   such diseases or conditions.

16           “(F) In the event that no patient assist-  
17           ance program described in subparagraph (D) is  
18           available to receive the donation, the holder of  
19           the approved application for the recipient drug  
20           shall instead contribute the amount calculated  
21           under subparagraph (A) (in addition to the  
22           amount calculated under paragraph (9)(B)) to  
23           the National Institutes of Health in accordance  
24           with paragraph (9).

25           “(12) DEFINITIONS.—In this subsection:

1           “(A) The term ‘conveyed exclusivity period’  
2           means the amount of time conveyed pursuant to  
3           an election made under paragraph (2).

4           “(B) The term ‘recipient drug’ means a  
5           drug receiving a conveyed exclusivity period.”.

6   **SEC. 1064. ENCOURAGING THE DEVELOPMENT AND USE OF**  
7           **NEW ANTIMICROBIAL DRUGS.**

8           (a) ADDITIONAL PAYMENT FOR NEW ANTI-  
9   MICROBIAL DRUGS UNDER MEDICARE.—Section  
10 1886(d)(5) of the Social Security Act (42 U.S.C.  
11 1395ww(d)(5)) is amended by adding at the end the fol-  
12 lowing new subparagraph:

13           “(M)(i) Effective for discharges beginning  
14           on or after October 1, 2015, the Secretary  
15           shall, after notice and opportunity for public  
16           comment (in the publications required by sub-  
17           section (e)(5) for a fiscal year or otherwise),  
18           recognize the costs of new antimicrobial drugs  
19           under the payment system established under  
20           this subparagraph.

21           “(ii) Pursuant to clause (i), the Secretary  
22           shall provide for additional payment to be made  
23           under this subsection with respect to discharges  
24           involving new antimicrobial drugs in the  
25           amount provided for under section A for drugs

1 and biological products that are described in  
2 section 1842(o)(1)(C).

3 “(iii) For purposes of this subparagraph,  
4 the term ‘new antimicrobial drug’ means a  
5 product that is approved for use, or a product  
6 for which an indication is first approved for  
7 use, by the Food and Drug Administration on  
8 or after January 1, 2015, and—

9 “(I)(aa) is intended to treat an infec-  
10 tion caused by, or likely to be caused by,  
11 a qualifying pathogen (as defined under  
12 section 505E(f) of the Federal Food,  
13 Drug, and Cosmetic Act); or

14 “(bb) meets the definition of a quali-  
15 fied infectious disease product under sec-  
16 tion 505E(g) of the Federal Food, Drug,  
17 and Cosmetic Act;

18 “(II) for which there is an ‘unmet  
19 medical need’ as determined by the Food  
20 and Drug Administration;

21 “(III) which is associated with high  
22 rates of mortality or significant patient  
23 morbidity, as determined by the Secretary,  
24 in consultation with the Director of the  
25 Centers for Disease Control and Preven-

1                   tion and the infectious disease professional  
2                   community; and

3                   “(IV) is used in facilities that partici-  
4                   pate in the National Healthcare Safety  
5                   Network of the Centers for Disease Con-  
6                   trol and Prevention (or, to the extent a  
7                   similar reporting program relating to anti-  
8                   microbial drugs is determined by the Sec-  
9                   retary to be available to such facilities,  
10                  such similar reporting program as the Sec-  
11                  retary may specify).

12                  “(iv)(I) The manufacturer or sponsor of a  
13                  drug may request the Secretary to designate a  
14                  drug as a new antimicrobial drug at any time  
15                  before or after the submission of an application  
16                  under section 505(b) of the Federal Food,  
17                  Drug, and Cosmetic Act or section 351(a) of  
18                  the Public Health Service Act for such drug.  
19                  The Secretary shall, not later than 60 days  
20                  after the submission of such a request, deter-  
21                  mine whether the drug is a new antimicrobial  
22                  drug.

23                  “(II) Except as provided in subclause (III),  
24                  a designation under this subsection shall not be  
25                  withdrawn for any reason.

1           “(III) The Secretary may revoke a des-  
2           ignation of a drug as a new antimicrobial drug  
3           product if the Secretary finds that the request  
4           for such designation contained an untrue state-  
5           ment of material fact.

6           “(v) Not later than July 1, 2015, the Sec-  
7           retary shall first publish in the Federal Register  
8           a list of the new antimicrobial drugs.”.

9           (b) STUDY AND REPORT ON REMOVING BARRIERS TO  
10          DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

11           (1) STUDY.—The Comptroller General of the  
12           United States shall, in consultation with the Direc-  
13           tor of the National Institutes of Health, the Com-  
14           missioner of Food and Drugs, and the Director of  
15           the Centers for Disease Control and Prevention, con-  
16           duct a study to—

17                   (A) identify and examine the barriers that  
18                   prevent the development of new antimicrobial  
19                   drugs, as defined in section 1886(d)(5)(M)(iii)  
20                   of the Social Security Act (42 U.S.C.  
21                   1395ww(d)(5)(M)(iii)); and

22                   (B) develop recommendations for actions  
23                   to be taken in order to overcome any barriers  
24                   identified under subparagraph (A).

1           (2) REPORT.—Not later than 1 year after the  
2           date of the enactment of this Act, the Comptroller  
3           General shall submit to Congress a report on the  
4           study conducted under paragraph (1).

5           **Subtitle E—Priority Review for**  
6           **Breakthrough Devices**

7           **SEC. 1081. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
8           **VICES.**

9           Chapter V of the Federal Food, Drug, and Cosmetic  
10          Act is amended—

11           (1) in section 515(d)—

12                   (A) by striking paragraph (5); and

13                   (B) by redesignating paragraph (6) as  
14           paragraph (5); and

15           (2) by inserting after section 515A (21 U.S.C.  
16          360e–1) the following:

17          **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
18          **VICES.**

19           “(a) IN GENERAL.—In order to provide for more ef-  
20          fective treatment or diagnosis of life-threatening or irre-  
21          versibly debilitating human diseases or conditions, the  
22          Secretary shall establish a program to provide priority re-  
23          view for devices—

24                   “(1) representing breakthrough technologies;

25                   “(2) for which no approved alternatives exist;



1           “(3) offering significant advantages over exist-  
2           ing approved or cleared alternatives; or

3           “(4) the availability of which—

4                   “(A) has the potential to, compared to ex-  
5                   isting approved alternatives, reduce or eliminate  
6                   the need for hospitalization, improve patient  
7                   quality of life, facilitate patients’ ability to man-  
8                   age their own care (such as through self-di-  
9                   rected personal assistance), or establish long-  
10                  term clinical efficiencies; or

11                  “(B) is otherwise in the best interest of pa-  
12                  tients.

13           “(b) REQUEST FOR DESIGNATION.—A sponsor of a  
14           device may request that the Secretary designate the device  
15           for priority review under this section. Any such request  
16           for designation may be made at any time prior to, concur-  
17           rently with, or subsequent to, the submission of an appli-  
18           cation under section 515(c), a petition for classification  
19           under section 513(f)(2), or a notification under section  
20           510(k).

21           “(c) DESIGNATION PROCESS.—

22                   “(1) IN GENERAL.—Not later than 60 calendar  
23                   days after the receipt of a request under subsection  
24                   (b), the Secretary shall determine whether the device  
25                   that is the subject of the request meets the criteria

1 described in subsection (a). If the Secretary deter-  
2 mines that the device meets the criteria, the Sec-  
3 retary shall designate the device for priority review.

4 “(2) REVIEW.—Review of a request under sub-  
5 section (b) shall be undertaken by a team that is  
6 composed of experienced staff and managers of the  
7 Food and Drug Administration and is chaired by a  
8 senior manager.

9 “(3) DESIGNATION DETERMINATION.—In  
10 issuing a determination approving or denying a re-  
11 quest under subsection (b), the Secretary shall pro-  
12 vide a written, substantive summary of the basis for  
13 the determination.

14 “(4) RECONSIDERATION BY DIRECTOR OF CEN-  
15 TER FOR DEVICES AND RADIOLOGICAL HEALTH.—

16 “(A) REQUEST FOR RECONSIDERATION.—  
17 Any person whose request under subsection (b)  
18 is denied may, within 30 days of the denial, re-  
19 quest reconsideration of the denial by the Di-  
20 rector of the Center for Devices and Radio-  
21 logical Health—

22 “(i) based upon the submission of  
23 documents by such person; or

24 “(ii) based upon such documents and  
25 a meeting or teleconference.

1           “(B) DIRECTOR’S RESPONSE.—The Direc-  
2           tor of the Center for Devices and Radiological  
3           Health shall respond to a request under sub-  
4           paragraph (A)—

5                   “(i) in the case of a request for recon-  
6                   sideration described in subparagraph  
7                   (A)(i), not later than 30 days after the  
8                   date on which the Director receives the re-  
9                   quest; or

10                   “(ii) in the case of a request for re-  
11                   consideration described in subparagraph  
12                   (A)(ii), not later than 30 days after the  
13                   date of the meeting or teleconference.

14           “(5) WITHDRAWAL.—If the Secretary approves  
15           a priority review designation for a device under this  
16           section, the Secretary may not withdraw the des-  
17           ignation based on the fact that the criteria specified  
18           in subsection (a) are no longer met because of the  
19           subsequent clearance or approval of another device  
20           that was previously approved for such designation  
21           under this section or section 515(d)(5) (as in effect  
22           on the day before the date of the enactment of the  
23           21st Century Cures Act).

24           “(d) PRIORITY REVIEW.—

1           “(1) ACTIONS.—For purposes of expediting the  
2 development and review of devices designated under  
3 subsection (c), the Secretary shall—

4           “(A) assign a team of staff, including a  
5 team leader with appropriate subject matter ex-  
6 pertise and experience, for each device for  
7 which a request is submitted under subsection  
8 (b);

9           “(B) provide for oversight of the team by  
10 senior agency personnel to facilitate the effi-  
11 cient development of the device and the efficient  
12 review of any submission described in sub-  
13 section (b) for the device;

14           “(C) adopt an efficient process for timely  
15 dispute resolution;

16           “(D) provide for interactive communication  
17 with the sponsor of the device during the review  
18 process;

19           “(E) expedite the Secretary’s review of  
20 manufacturing and quality systems compliance,  
21 as applicable;

22           “(F) if the Secretary intends to consult  
23 with external experts or an advisory committee  
24 concerning the sponsor’s device—

1 “(i) disclose to the sponsor of the de-  
2 vice in advance the topics of any such con-  
3 sultation; and

4 “(ii) provide an opportunity for the  
5 sponsor to recommend such external ex-  
6 perts;

7 “(G) for applications submitted under sec-  
8 tion 515(c), provide for advisory committee  
9 input, as determined by the Secretary or at the  
10 request of the sponsor; and

11 “(H) assign staff to communicate with in-  
12 stitutional review committees concerning the  
13 conditions and clinical testing requirements ap-  
14 plicable to the investigational use of the device  
15 pursuant to an exemption under section 520(g).

16 “(2) ADDITIONAL ACTIONS.—In addition to the  
17 actions described in paragraph (1), for purposes of  
18 expediting the development and review of devices  
19 designated under subsection (c), the Secretary, in  
20 collaboration with the device sponsor, may, as appro-  
21 priate—

22 “(A) coordinate with the sponsor regarding  
23 early agreement on a data development plan;

24 “(B) take steps to ensure that the design  
25 of clinical trials is as efficient as practicable,

1 such as through adoption of shorter or smaller  
2 clinical trials, application of surrogate  
3 endpoints, and use of adaptive trial designs and  
4 Bayesian statistics, to the extent scientifically  
5 appropriate;

6 “(C) facilitate, to the extent scientifically  
7 appropriate, expedited and efficient develop-  
8 ment and review of the device through utiliza-  
9 tion of postmarket data collection, with regard  
10 to applications for approval under section  
11 515(c) and petitions for classification under  
12 section 513(f)(2); and

13 “(D) agree to clinical protocols that the  
14 Secretary will consider binding on the Sec-  
15 retary, subject to changes agreed to by the  
16 sponsor and the Secretary or other changes  
17 that the Secretary determines are required to  
18 prevent an unreasonable risk to the public  
19 health.

20 “(e) PRIORITY REVIEW GUIDANCE.—

21 “(1) CONTENT.—The Secretary shall issue  
22 guidance on the implementation of this section. Such  
23 guidance shall include the following:

24 “(A) The process for a person to seek a  
25 priority review designation.

1           “(B) A template for requests under sub-  
2           section (b).

3           “(C) The criteria the Secretary will use in  
4           evaluating a request for priority review.

5           “(D) The standards the Secretary will use  
6           in assigning a team of staff, including team  
7           leaders, to review devices designated for priority  
8           review, including any training required for such  
9           personnel on effective and efficient review.

10          “(2) PROCESS.—Prior to finalizing the guid-  
11          ance under paragraph (1), the Secretary shall pro-  
12          pose such guidance for public comment.

13          “(f) PREDICATE DEVICES.—If a device has been clas-  
14          sified in response to a petition for classification under sec-  
15          tion 513(f)(2) pursuant to priority review under this sec-  
16          tion, and such classification and review includes the use  
17          of postmarket data collection pursuant to subsection  
18          (d)(2)(C), the device may not be cited as a predicate device  
19          for purposes of determining substantial equivalence under  
20          section 513(f) unless such postmarket data collection has  
21          been completed.

22          “(g) CONSTRUCTION.—

23          “(1) PURPOSE.—This section is intended to en-  
24          courage the Secretary and provide the Secretary suf-  
25          ficient authorities to apply efficient and flexible ap-

1 proaches to expedite the development of, and  
2 prioritize the agency’s review of, devices that rep-  
3 resent breakthrough technologies.

4 “(2) CONSTRUCTION.—Nothing in this section  
5 shall be construed to alter the criteria and standards  
6 for evaluating an application pursuant to section  
7 515(c), a report and request for classification under  
8 section 513(f)(2), or a report under section 510(k),  
9 including the recognition of valid scientific evidence  
10 as described in section 513(a)(3)(B), and consider-  
11 ation of the least burdensome means of evaluating  
12 device effectiveness or demonstrating substantial  
13 equivalence between devices with differing techno-  
14 logical characteristics, as applicable. Nothing in this  
15 section alters the authority of the Secretary to act  
16 on an application pursuant to section 515(d) before  
17 completion of an establishment inspection, as the  
18 Secretary deems appropriate.”.

19 **SEC. 1082. CMS COVERAGE OF BREAKTHROUGH DEVICES**

20 **[TO BE SUPPLIED].**

21 **[To be supplied.]**



1     **Subtitle F—Accelerated Approval**  
2             **for Breakthrough Devices**

3     **SEC. 1101. ACCELERATED APPROVAL FOR BREAKTHROUGH**  
4             **DEVICES.**

5             Chapter V of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
7 section 515B, as inserted by section 1081, the following:

8     **“SEC. 515C. ACCELERATED APPROVAL FOR BREAK-**  
9             **THROUGH DEVICES.**

10            “(a) IN GENERAL.—The Secretary may approve a de-  
11 vice that meets the criteria under section 515B(a) upon  
12 a determination that the device has an effect on a surro-  
13 gate endpoint that is reasonably likely to predict clinical  
14 benefit, or on a clinical endpoint that can be measured  
15 earlier than irreversible morbidity or mortality, that is rea-  
16 sonably likely to predict an effect on irreversible morbidity  
17 or mortality or other clinical benefit.

18            “(b) LIMITATIONS.—Approval of a device under this  
19 section may be subject to a requirement that the sponsor  
20 of the device conduct appropriate postapproval studies to  
21 verify clinical benefit or effectiveness.”.

1           **Subtitle G—Expanded Access**

2   **SEC. 1121. EXPANDED ACCESS POLICY AS CONDITION OF**  
3           **EXPEDITED APPROVAL.**

4           Section 561 of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 360bbb) is amended—

6                   (1) by redesignating subsections (d) and (e) as  
7 subsections (e) and (f), respectively; and

8                   (2) by inserting after subsection (c) the fol-  
9 lowing new subsection:

10           “(d) **EXPANDED ACCESS POLICY REQUIRED FOR**  
11 **COVERED INVESTIGATIONAL DRUGS.—**

12                   “(1) **IN GENERAL.—**With respect to a covered  
13 investigational drug, not later than 30 days after the  
14 date on which the drug meets the definition of a cov-  
15 ered investigational drug (as specified in paragraph  
16 (2)), the sponsor of the covered investigational drug  
17 shall submit to the Secretary and make publicly  
18 available the policy of the sponsor with respect to re-  
19 quests submitted under subsection (b). In the case  
20 of such a policy under which the sponsor accepts  
21 such requests, such policy shall include—

22                           “(A) a single point of contact who receives  
23 and processes such requests;

24                           “(B) procedures for making such requests;

1           “(C) the general criteria for the sponsor’s  
2           consideration or approval of such requests; and

3           “(D) the amount of time the sponsor an-  
4           ticipates will be necessary to respond to such  
5           requests.

6           “(2) COVERED INVESTIGATIONAL DRUG.—In  
7           this subsection, the term ‘covered investigational  
8           drug’ means a drug that—

9           “(A) is designated as a breakthrough ther-  
10          apy or as a fast track product;

11          “(B) is designated under section 505E(d)  
12          as a qualified infectious disease product; or

13          “(C) is designated an orphan drug under  
14          section 526.”.

15 **SEC. 1122. NOTIFICATION OF SUBMITTERS OF EXPANDED**  
16 **ACCESS REQUESTS.**

17          Section 561 of the Federal Food, Drug, and Cosmetic  
18          Act (21 U.S.C. 360bbb), as amended by section 1121, is  
19          further amended—

20                 (1) by redesignating subsections (e) and (f) (as  
21                 redesignated by section 1121(1)) as subsections (f)  
22                 and (g), respectively; and

23                 (2) by inserting after subsection (d) (as in-  
24                 serted by section 1121(2)) the following new sub-  
25                 section:

1           “(e) NOTIFICATION OF SUBMITTERS OF RE-  
2 QUESTS.—In the case of the denial by a manufacturer or  
3 distributor of a request under subsection (b), not later  
4 than 5 days after the date of such denial, the manufac-  
5 turer or distributor, as applicable, shall submit to the per-  
6 son (or physician) who made the request written notice  
7 of the denial, including an explanation for the denial.”.

8 **SEC. 1123. GAO QUALITATIVE ANALYSIS ON INDIVIDUAL PA-**  
9                                   **TIENT ACCESS TO UNAPPROVED THERAPIES**  
10                                   **AND DIAGNOSTICS.**

11           Not later than 180 days after the date of the enact-  
12 ment of this Act and every two years thereafter through  
13 2023, the Comptroller General of the United States shall  
14 submit to the Committee on Energy and Commerce of the  
15 House of Representatives and the Committee on Health,  
16 Education, Labor and Pensions of the Senate a report  
17 containing a qualitative analysis of the extent to which in-  
18 dividual patients have access to investigational drugs pur-  
19 suant to subsection (b) of section 561 of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 360bbb) and rec-  
21 ommendations for improving such access. In preparing  
22 such report, the Comptroller General shall conduct a qual-  
23 itative analysis of the following:

24                           (1) Whether there are any identifiable patterns  
25                           in requests submitted under subsection (b) of such

1 section, such as the types of indications for which  
2 requests for individual patient access are sought or  
3 the reasons for the denial of such requests.

4 (2) What the primary barriers are to drug  
5 sponsors granting requests for individual patient ac-  
6 cess.

7 (3) How the Secretary evaluates safety and effi-  
8 cacy data submitted in connection with such re-  
9 quests.

10 (4) The amount of time that—

11 (A) a physician typically takes to complete  
12 the paperwork necessary to make such a re-  
13 quest;

14 (B) a drug sponsor takes to process such  
15 a request and to issue a decision with respect  
16 to the request; and

17 (C) the Secretary takes to process such a  
18 request and to issue a decision with respect to  
19 the request.

20 (5) How regulations, guidance, policies, or prac-  
21 tices may be modified, streamlined, expanded, or dis-  
22 continued to reduce or prevent delays in approving  
23 such requests.

24 (6) The number of such requests that, for the  
25 period covered by the report—

1 (A) were approved by drug sponsors and  
2 the Food and Drug Administration;

3 (B) were approved by drug sponsors but  
4 denied by the Food and Drug Administration;  
5 and

6 (C) were denied by drug sponsors.

7 (7) How to encourage drug sponsors to grant  
8 requests for expanded access under such section  
9 561, including requests for emergency use, inter-  
10 mediate-size patient populations, and large patient  
11 populations under a specified indication.

12 (8) Whether and to what extent adverse events  
13 reported to the Secretary as a result of individual  
14 use of an investigational drug or investigational de-  
15 vice under such section 561 affected the development  
16 or approval of any drug or device.

17 **SEC. 1124. EXPANDED ACCESS TASK FORCE.**

18 (a) ESTABLISHMENT.—The Secretary of Health and  
19 Human Services shall establish a task force within the De-  
20 partment of Health and Human Services to explore mech-  
21 anisms for improving the access individual patients have  
22 to investigational drugs pursuant to subsection (b) of sec-  
23 tion 561 of the Federal Food, Drug, and Cosmetic Act  
24 (21 U.S.C. 360bbb), to be known as the “Expanded Ac-  
25 cess Task Force” (in this section referred to as the “Task

1 Force”). Not later than 90 days after the date on which  
2 the Comptroller General of the United States submits the  
3 first report required under section 1123, the Task Force  
4 shall be convened.

5 (b) MEMBERSHIP.—

6 (1) COMPOSITION.—The Task Force shall be  
7 composed of not more than 13 voting members ap-  
8 pointed as follows:

9 (A) One member to serve as Chairman of  
10 the Task Force, appointed by the Speaker of  
11 the House of Representatives.

12 (B) One representative from the Depart-  
13 ment of Health and Human Services, appointed  
14 by the Secretary of Health and Human Serv-  
15 ices.

16 (C) Six representatives appointed by the  
17 majority leader of the House of Representa-  
18 tives, in consultation with the minority leader of  
19 the House of Representatives, and the chairman  
20 and the ranking member of the Committee on  
21 Energy and Commerce of the House of Rep-  
22 resentatives, including—

23 (i) one current or former representa-  
24 tive of the biopharmaceutical industry of  
25 not less than 250 full-time employees;

1 (ii) one representative of a biopharma-  
2 ceutical company of less than 250 full-time  
3 employees;

4 (iii) one representative of the patient  
5 community;

6 (iv) one representative of the rare dis-  
7 ease patient community;

8 (v) one representative of the health  
9 care provider community; and

10 (vi) one bioethicist.

11 (D) Five representatives appointed by ma-  
12 jority leader of the Senate, in consultation with  
13 the minority leader of the Senate, and the  
14 chairman and the ranking member of the Com-  
15 mittee on Health, Education, Labor and Pen-  
16 sions of the Senate, including—

17 (i) one representative of the bio-  
18 pharmaceutical industry of not less than  
19 250 full-time employees;

20 (ii) one current or former representa-  
21 tive of a biopharmaceutical company of  
22 less than 250 full-time employees;

23 (iii) one representative of the patient  
24 community;



1 (iv) one representative of the rare dis-  
2 ease patient community; and

3 (v) one representative of the health  
4 care payor community.

5 (2) COMPENSATION.—Members of the Task  
6 Force shall serve without compensation.

7 (c) DUTIES.—The Task Force shall comprehensively  
8 evaluate the access individual patients have to investiga-  
9 tional drugs pursuant to subsection (b) of section 561 of  
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 360bbb), taking into account—

12 (1) the unique challenges faced by children with  
13 likely fatal diseases for which there is not a com-  
14 parable or satisfactory alternative therapy available;

15 (2) possible incentives for biopharmaceutical  
16 companies and providers to approve requests sub-  
17 mitted under such subsection;

18 (3) ways to improve followup reporting of ad-  
19 verse event data and compliance with such reporting  
20 requirements;

21 (4) how the Secretary of Health and Human  
22 Services interprets and takes into consideration ad-  
23 verse event data reported in the case of data from  
24 use under a request submitted under such sub-  
25 section;

1 (5) ways to streamline and standardize the  
2 process for submitting requests under such sub-  
3 section; and

4 (6) the costs incurred by biopharmaceutical  
5 companies for the time, effort, and delivery of inves-  
6 tigational drugs to patients for the diagnosis, moni-  
7 toring, or treatment of a serious disease or condition  
8 under such subsection.

9 (d) REPORT.—Not later than 180 days after the date  
10 on which the Task Force is convened, the Task Force shall  
11 submit to the Committee on Energy and Commerce of the  
12 House of Representatives and the Committee on Health,  
13 Education, Labor and Pensions of the Senate a report in  
14 an electronic format describing the specific recommenda-  
15 tions of the Task Force for improving the access individual  
16 patients have to investigational drugs pursuant to sub-  
17 section (b) of section 561 of the Federal Food, Drug, and  
18 Cosmetic Act (21 U.S.C. 360bbb).

19 (e) TERMINATION.—The task force shall terminate  
20 upon submission of the report required under subsection  
21 (d).

22 **SEC. 1125. FINALIZING DRAFT GUIDANCE ON EXPANDED**  
23 **ACCESS.**

24 (a) IN GENERAL.—Not later than 180 days after the  
25 date on which the Expanded Access Task Force estab-

1 lished under section 1124 submits the report under sub-  
2 section (d) of such section, the Secretary of Health and  
3 Human Services shall finalize the draft guidance entitled  
4 “Expanded Access to Investigational Drugs for Treatment  
5 Use—Qs & As” and dated May 2013.

6 (b) CONTENTS.—The final guidance referred to in  
7 subsection (a) shall—

8 (1) clearly define how the Secretary interprets  
9 and uses adverse drug event data reported by inves-  
10 tigators in the case of data reported from use under  
11 a request submitted under section 561(b) of the  
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 360bbb(b)); and

14 (2) take into account the report of the Ex-  
15 panded Access Task Force submitted under section  
16 1124(d) and the first report of the Comptroller Gen-  
17 eral of the United States submitted under section  
18 1123.

1 **Subtitle H—Facilitating Respon-**  
2 **sible Communication of Sci-**  
3 **entific and Medical Develop-**  
4 **ments**

5 **SEC. 1141. [TO BE SUPPLIED].**

6 **Subtitle I—Modernizing the**  
7 **Regulation of Social Media**

8 **SEC. 1161. DISSEMINATION OF INFORMATION ABOUT MED-**  
9 **ICAL PRODUCTS USING THE INTERNET.**

10 (a) IN GENERAL.—Chapter VII of the Federal, Food,  
11 Drug, and Cosmetic Act is amended by inserting after sec-  
12 tion 715 of such Act (21 U.S.C. 379d–4) the following:

13 **“SEC. 716. DISSEMINATION OF INFORMATION ABOUT MED-**  
14 **ICAL PRODUCTS USING THE INTERNET.**

15 “(a) PROPOSED REVISIONS.—Not later than 12  
16 months after the date of enactment of this section, the  
17 Secretary shall—

18 “(1) review each regulation and guidance that  
19 applies to the dissemination by means of the Inter-  
20 net (including social media platforms and character-  
21 limited applications) of information about medical  
22 products; and

23 “(2) propose revisions to such regulations and  
24 guidance (in the form of proposed amended regula-  
25 tions and draft guidance, respectively) that—

1           “(A) facilitate meaningful use, by the  
2 sponsors of medical products, of the Internet,  
3 including Internet applications and social  
4 media, for dissemination of truthful, nonmis-  
5 leading information about medical products;

6           “(B) recognize that such sponsors may use  
7 the Internet—

8                   “(i) to disseminate, in character-lim-  
9 ited applications, truthful, introductory in-  
10 formation about medical products, includ-  
11 ing the name of such products and their  
12 approved uses; and

13                   “(ii) to provide additional information  
14 about the safety and effectiveness of the  
15 medical products using information that is  
16 hyperlinked to such introductory informa-  
17 tion; and

18           “(C) for regulatory purposes, treat  
19 hyperlinked information described in subpara-  
20 graph (B)(ii) as if the information appeared in  
21 introductory information described in subpara-  
22 graph (B)(i).

23           “(b) FINAL REGULATIONS AND GUIDANCE; UP-  
24 DATES.—The Secretary shall, after providing notice and  
25 an opportunity for public comment—



1 may, to support the approval of the use of a drug that  
2 is the subject of the application for a new qualified indica-  
3 tion, submit qualified data summaries.

4 “(b) ELIGIBILITY.—In carrying out the streamlined  
5 data review program under subsection (a), the Secretary  
6 may authorize the sponsor of a drug to include one or  
7 more summaries described in subsection (a) in a supple-  
8 mental application if—

9 “(1) the drug has been approved or licensed  
10 under section 505(c) of this Act or section 351(a) of  
11 the Public Health Service Act for one or more indi-  
12 cations, and such approval or licensure remains in  
13 effect;

14 “(2) the supplemental application is for ap-  
15 proval of the use of the drug for a new qualified in-  
16 dication under such section 505(c) or 351(a);

17 “(3) there is an existing database on the safety  
18 of the drug developed for one or more indications of  
19 the drug under such section 505(c) or 351(a);

20 “(4) the supplemental application incorporates  
21 or supplements the data submitted in the application  
22 for approval or licensure referred to in paragraph  
23 (1); and

24 “(5) the full data sets used to develop the quali-  
25 fied data summaries are submitted, unless the Sec-

1       retary determines that the full data sets are not re-  
2       quired.

3       “(c) DEFINITIONS.—In this section:

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

5                 “(A) an indication for the detection, diag-  
6                 nosis, prevention, treatment, or cure of cancer;  
7                 or

8                 “(B) such other types of indications as the  
9                 Secretary determines to be subject to the  
10                streamlined data review program under this  
11                section.

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

16       (b) GUIDANCE; REPORT; REGULATIONS.—

17            (1) GUIDANCE; REGULATIONS.—The Commis-  
18            sioner of Food and Drugs—

19                 (A) shall—

20                     (i) issue final guidance for implemen-  
21                     tation of the streamlined data review pro-  
22                     gram established under section 505F of  
23                     the Federal Food, Drug, and Cosmetic  
24                     Act, as added by subsection (a), not later



1           than 18 months after the date of enact-  
2           ment of this Act; and

3                   (ii) include in such guidance the proc-  
4           ess for expanding the types of indications  
5           to be subject to the streamlined data re-  
6           view program, as authorized by section  
7           505F(c)(1)(B) of such Act; and

8                   (B) in addition to issuing guidance under  
9           subparagraph (A), may issue such regulations  
10          as may be necessary for implementation of the  
11          program.

12           (2) REPORT.—The Commissioner of Food and  
13          Drugs shall submit to the Committee on Energy and  
14          Commerce of the House of Representatives and the  
15          Committee on Health, Education, Labor, and Pen-  
16          sions of the Senate, and make publicly available, 2  
17          reports on the implementation of the streamlined  
18          data review program. The first such report shall be  
19          not later than 2 years after the date of enactment  
20          of this Act. The second such report shall be not later  
21          than 5 years after the date of enactment of this Act.

22          Each such report shall—

23                   (A) address—

1 (i) the processes for submission and  
2 review of summaries pursuant to the  
3 streamlined data review program; and

4 (ii) any improvements to the regu-  
5 latory process achieved through the use of  
6 such summaries; and

7 (B) include recommendations on the future  
8 use of such summaries in the review of applica-  
9 tions and supplemental applications submitted  
10 under section 505(b) of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 355(b))  
12 and section 351(a) of the Public Health Service  
13 Act (42 U.S.C. 262(a)), including with respect  
14 to—

15 (i) the components of full data sets  
16 that will not need to be submitted, as de-  
17 scribed in section 505F(b)(7) of the Fed-  
18 eral Food, Drug, and Cosmetic Act, as  
19 added by subsection (a); and

20 (ii) the expansion of the types of indi-  
21 cations to be subject to the streamlined  
22 data review program, as authorized under  
23 section 505F(c)(2) of the Federal Food,  
24 Drug, and Cosmetic Act, as added by sub-  
25 section (a).



1 2016 through 2020. Funds appropriated under this  
2 section shall be available until expended.

3 “(2) AUTHORITY TO TRANSFER ADDITIONAL  
4 FUNDS.—The Director of the Center may transfer  
5 any funds appropriated to the Center, other than  
6 under paragraph (1), for purposes of the Cures Ac-  
7 celeration Network.”.

8 **SEC. 1202. REPURPOSING DRUGS.**

9 Section 480 of the Public Health Service Act (42  
10 U.S.C. 287a), as amended by section 1201, is further  
11 amended—

12 (1) in subsection (c)—

13 (A) by redesignating paragraphs (3), (4),  
14 and (5) as paragraphs (4), (5), and (6), respec-  
15 tively; and

16 (B) by inserting after paragraph (2) the  
17 following new paragraph:

18 “(3) award grants and contracts for research  
19 on, and development of, high-need cures based upon  
20 new indications for drugs and biological products—

21 “(A) that have been previously approved or  
22 licensed by the Food and Drug Administration  
23 for other indications; and

1 “(B) with respect to which all applicable  
2 patents and exclusivity periods have expired;”;  
3 and  
4 (2) in subsection (f)(1), as redesignated by sec-  
5 tion 1201, by inserting after the first sentence the  
6 following: “For each of fiscal years 2016 through  
7 2018, in addition to the amount authorized to be ap-  
8 propriated to carry out this section pursuant to the  
9 first sentence of this paragraph, [§ \_\_\_\_] is author-  
10 ized to be appropriated for the function described in  
11 subsection (c)(3).”.

## 12 **Subtitle L—Dormant Therapies**

### 13 **SEC. 1221. DEFINITIONS.**

14 In this subtitle:

15 (1) The term “biological product” has the  
16 meaning given to that term in section 351 of the  
17 Public Health Service Act (42 U.S.C. 262).

18 (2) The term “Director” means the Under Sec-  
19 retary of Commerce for Intellectual Property and  
20 Director of the United States Patent and Trade-  
21 mark Office.

22 (3) The term “dormant therapy” means a med-  
23 icine designated as a dormant therapy under section  
24 1222(a).

1           (4) The term “drug” has the meaning given to  
2           that term in section 201 of the Federal Food, Drug,  
3           and Cosmetic Act (21 U.S.C. 321).

4           (5) The term “medicine” means a biological  
5           product or a drug.

6           (6) The term “protection period”, with respect  
7           to a dormant therapy, means the period that—

8                   (A) begins on the date on which the Sec-  
9                   retary first approves an application under sec-  
10                   tion 505(b) of the Federal Food, Drug, and  
11                   Cosmetic Act (21 U.S.C. 355(b)) or section  
12                   351(a) of the Public Health Service Act (42  
13                   U.S.C. 262(a)) for the dormant therapy for any  
14                   indication; and

15                   (B) ends on the date that is 15 years after  
16                   the date of such approval.

17           (7) The term “Secretary” means the Secretary  
18           of Health and Human Services.

19           (8) The term “sponsor”, with respect to a dor-  
20           mant therapy, is the person who takes responsibility  
21           for the designation and development of the dormant  
22           therapy. The sponsor may be a single entity or an  
23           entity collaborating with one or more other entities.

1 **SEC. 1222. CAPTURING LOST OPPORTUNITIES AND CRE-**  
2 **ATING NEW CURES FOR PATIENTS.**

3 (a) DESIGNATION AS A DORMANT THERAPY.—The  
4 Secretary shall designate a medicine as a dormant therapy  
5 if—

6 (1) the sponsor of the medicine submits a re-  
7 quest for such designation meeting the requirements  
8 under subsection (b), and the request has not been  
9 withdrawn under subsection (d)(1); and

10 (2) the Secretary determines that—

11 (A) the medicine is being investigated or is  
12 intended to be investigated for an indication to  
13 address one or more unmet medical needs;

14 (B) a suitable clinical plan for such inves-  
15 tigation of the medicine has been developed by  
16 the sponsor;

17 (C) the sponsor intends to file an applica-  
18 tion pursuant to section 505(b) of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C.  
20 355(b)) or section 351(a) of the Public Health  
21 Service Act (42 U.S.C. 262(a)) for approval or  
22 licensing of the medicine for an indication de-  
23 scribed in subparagraph (A); and

24 (D) at the time the request for designation  
25 is made, the medicine for which designation is  
26 being requested contains, in the case of a drug

1 an active moiety that is not the same as, and  
2 in the case of a biological product an active  
3 moiety that is not highly similar to, an active  
4 moiety in a medicine for which an application  
5 under section 505 of the Federal Food, Drug,  
6 and Cosmetic Act (21 U.S.C. 355) or section  
7 351 of the Public Health Service Act (42  
8 U.S.C. 262) has been submitted.

9 (b) REQUIREMENTS FOR REQUEST FOR DESIGNA-  
10 TION AS DORMANT THERAPY.—A request under sub-  
11 section (a)(1) with respect to a medicine may be made only  
12 by the sponsor of the medicine and shall contain each of  
13 the following:

14 (1) A listing of all United States patents and  
15 applications for patents under which the sponsor has  
16 rights and that may be reasonably construed to pro-  
17 vide protection for the medicine.

18 (2) A waiver of patent rights to the extent re-  
19 quired under subsection (c) to take effect, if at all,  
20 as provided under subsection (c)(3).

21 (3) Such additional information as the Sec-  
22 retary may require by regulation in order to deter-  
23 mine eligibility for designation under subsection (a).

24 (c) WAIVER OF PATENT RIGHTS EXPIRING AFTER  
25 THE PROTECTION PERIOD ENDS.—



1 (1) PATENT WAIVER.—

2 (A) IN GENERAL.—Subject to subpara-  
3 graph (B), the request under this subsection  
4 shall include a waiver of the right to enforce or  
5 otherwise assert any patent described in sub-  
6 section (b)(1) (or any patent issued on the basis  
7 of an application described in subsection  
8 (b)(1)), which may expire after the end of the  
9 protection period for the dormant therapy,  
10 against any applicable product described in  
11 paragraph (2). The waiver shall be made by the  
12 owner of the patent or application for patent,  
13 as the case may be.

14 (B) LIMITATIONS ON PATENT WAIVER.—  
15 Any patent waiver provided pursuant to this  
16 section, should it become effective—

17 (i) shall have no effect during the pro-  
18 tection period for the medicine to which  
19 the waiver relates; and

20 (ii) shall have no effect with respect to  
21 the subject matter of a claimed invention  
22 in a patent that does not provide any pro-  
23 tection for such medicine with respect to  
24 an applicable product described in para-  
25 graph (2).

1           (2) APPLICABLE PRODUCTS DESCRIBED.—An  
2 applicable product is described in this paragraph  
3 only if—

4           (A) it is approved or licensed pursuant to  
5 an application that—

6           (i) is filed under section 505(b)(2) or  
7 505(j) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or  
9 section 351(k) of the Public Health Service  
10 Act (42 U.S.C. 262(k)); and

11           (ii) references or otherwise relies upon  
12 the approval or licensure of the dormant  
13 therapy to which the waiver relates; and

14           (B) the approval or licensure of the prod-  
15 uct occurs after the expiration of the protection  
16 period applicable to the medicine to which the  
17 request under subsection (a)(1) relates.

18           (3) EFFECTIVE DATE OF WAIVER.—A waiver  
19 under subsection (b)(2) with respect to a patent  
20 shall take effect, if at all, on the date the Director  
21 publishes the notice required under subsection  
22 (e)(2)(F) relating to the patent.

23           (d) WITHDRAWAL OF REQUEST FOR DESIGNATION,  
24 REVOCATION BY THE SECRETARY.—

1           (1) IN GENERAL.—The sponsor of a medicine  
2           may withdraw a request for designation under sub-  
3           section (a)(1) with respect to a medicine unless the  
4           medicine has been approved or licensed under sec-  
5           tion 505 of the Federal Food, Drug, and Cosmetic  
6           Act (21 U.S.C. 355) or section 351 of the Public  
7           Health Service Act (42 U.S.C. 262). The Secretary  
8           shall deny a designation request or revoke any des-  
9           ignation granted if at any time the Secretary finds  
10          that the sponsor is not in compliance with subsection  
11          (c)(1) or (g)(1).

12          (2) EFFECTS OF WITHDRAWAL OF REQUEST OR  
13          REVOCAION OF DESIGNATION.—If the sponsor of a  
14          medicine withdraws a request under subsection (b)  
15          or the Secretary denies a designation request or re-  
16          vokes a designation with respect to the medicine—

17                (A) any patent waiver submitted under  
18                this section with respect to the medicine, but  
19                not yet effective, is canceled and deemed a nul-  
20                lity;

21                (B) any patent waiver that has taken ef-  
22                fect under this section with respect to the medi-  
23                cine shall remain in effect;

24                (C) any patent term extension granted by  
25                the Director under subsection (e)(2) with re-

1           spect to the medicine shall be canceled, except  
2           that the Director shall maintain the patent  
3           term extension for one patent, to be selected by  
4           the sponsor of the medicine, for the period of  
5           extension that would have been applicable under  
6           section 156 of title 35, United States Code; and

7                   (D) the designation, if made, otherwise  
8           shall be treated as never having been requested  
9           or made or having effect.

10           (3) BASIS FOR REVOCATION.—The Secretary  
11           may revoke a designation made under subsection  
12           (a), but only based upon a finding by the Secretary  
13           under paragraph (1).

14           (e) GUARANTEED PROTECTIONS FOR DORMANT  
15           THERAPIES.—

16                   (1) APPLICATIONS FILED DURING THE PROTEC-  
17           TION PERIOD.—During the protection period for a  
18           dormant therapy, notwithstanding any other provi-  
19           sion of the Federal Food, Drug, and Cosmetic Act  
20           (21 U.S.C. 301 et seq.) or the Public Health Service  
21           Act (42 U.S.C. 201 et seq.)—

22                   (A) absent a right of reference from the  
23           holder of such approved application for the dor-  
24           mant therapy, the Secretary shall not approve  
25           an application filed pursuant to section

1 505(b)(2) or section 505(j) of the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C.  
3 355(b)(2), (j)) or section 351(k) of the Public  
4 Health Service Act (42 U.S.C. 262(k)) ref-  
5 erencing or otherwise relying on the approval of  
6 the dormant therapy;

7 (B) the Secretary shall not approve—

8 (i) an application filed pursuant to  
9 such section 505(b)(2) or 505(j) that ref-  
10 erences or otherwise relies on the approval  
11 of a medicine that is not the dormant ther-  
12 apy, was approved subsequent to the ap-  
13 proval of the dormant therapy, and con-  
14 tains the same active moiety as the active  
15 moiety in the dormant therapy (or if the  
16 dormant therapy contains more than one  
17 active moiety, all of the active moieties are  
18 the same); or

19 (ii) an application filed pursuant to  
20 such section 351(k) that references or oth-  
21 erwise relies on the licensure of a medicine  
22 that is not the dormant therapy, was li-  
23 censed subsequent to the licensure of the  
24 dormant therapy, and contains an active  
25 moiety that is highly similar to the active

1 moiety in the dormant therapy (or if the  
2 dormant therapy contains more than one  
3 active moiety, all of the active moieties are  
4 highly similar); and

5 (C) the Secretary shall not approve an ap-  
6 plication filed pursuant to section 505(b)(1) of  
7 the Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 355(b)(1)) for a drug that contains the  
9 same active moiety as the active moiety in the  
10 qualifying medicine (or if the qualifying medi-  
11 cine contains more than one active moiety, all  
12 of the active moieties are the same), or an ap-  
13 plication filed pursuant to section 351(a) of the  
14 Public Health Service Act (42 U.S.C. 262(a))  
15 for a biological product that contains an active  
16 moiety that is highly similar to the active moi-  
17 ety in the qualifying medicine (or if the quali-  
18 fying medicine contains more than one active  
19 moiety, all of the active moieties are highly  
20 similar), unless the information provided to  
21 support approval of such application is com-  
22 parable in scope and extent, including with re-  
23 spect to design and extent of preclinical and  
24 clinical testing, to the information provided to  
25 support approval of the application for the

1           qualifying medicine under section 505(b) of the  
2           Federal Food, Drug, and Cosmetic Act (21  
3           U.S.C. 355(b)) or section 351(a) of the Public  
4           Health Service Act (42 U.S.C. 262(a)).

5           (2) PATENT TERM ALIGNMENT WITH DATA  
6           PACKAGE PROTECTION PERIOD.—

7                   (A) IN GENERAL.—Notwithstanding any  
8                   provision of title 35, United States Code, a  
9                   sponsor of a medicine designated as a dormant  
10                  therapy under subsection (a)(1), upon the ap-  
11                  proval or licensure thereof under section 505 of  
12                  the Federal Food, Drug, and Cosmetic Act (21  
13                  U.S.C. 355) or section 351 of the Public Health  
14                  Service Act (42 U.S.C. 262), and in lieu of fil-  
15                  ing a patent term extension application under  
16                  section 156(d) of such title 35, shall be entitled  
17                  to patent term extensions in accordance with  
18                  this paragraph.

19                  (B) SUBMISSION OF FINAL LISTING OF  
20                  PATENTS AND APPLICATIONS FOR PATENTS  
21                  FOLLOWING APPROVAL OR LICENSURE.—

22                          (i) SUBMISSION.—The sponsor of the  
23                          dormant therapy, within a period to be set  
24                          by the Director of not less than 2 months  
25                          beginning on the date the Secretary ap-

1 proves or licenses the dormant therapy,  
2 shall submit to the Director—

3 (I) the listing of patents and ap-  
4 plications for patents provided to the  
5 Secretary under subsection (b)(1);

6 (II) any revisions to such listing  
7 as may be required for compliance  
8 with subsection (b)(1); and

9 (III) any documentation the Di-  
10 rector may require from the patentee  
11 or patent applicant (as the case may  
12 be) of the waiver of patent rights re-  
13 quired under subsection (b)(2).

14 (ii) FAILURE TO PROVIDE SUFFICIENT  
15 DOCUMENTATION OF WAIVER.—If the Di-  
16 rector determines that the sponsor has not  
17 complied with the waiver requirements  
18 under subsection (c), after providing the  
19 sponsor the opportunity to remedy any in-  
20 sufficiency, the Director shall so notify the  
21 Secretary that the patent waiver require-  
22 ments for designation have not been satis-  
23 fied.

24 (C) EXTENSION OF PATENTS.—



1 (i) IN GENERAL.—Unless the Director  
2 has notified the Secretary of a determina-  
3 tion under subparagraph (B)(ii), for each  
4 patent identified in a submission pursuant  
5 to subparagraph (B)(i), and for each pat-  
6 ent issuing based upon an application for  
7 patent so identified, the Director shall,  
8 within the 3-month period beginning on  
9 the date of the submission, extend the pat-  
10 ent to expire at the end of the protection  
11 period for the dormant therapy, if the pat-  
12 ent would otherwise expire before the end  
13 of the protection period. If the Director  
14 has so notified the Secretary under sub-  
15 paragraph (B)(ii), the Director shall ex-  
16 tend one such patent, selected by the spon-  
17 sor, for the period that would have been  
18 applicable had an application for extension  
19 been filed under section 156 of title 35,  
20 United States Code, with respect to such  
21 patent.

22 (ii) APPLICATION OF CERTAIN PROVI-  
23 SIONS.—During the period of an extension  
24 under clause (i)—

1 (I) the rights under the patent  
2 shall be limited in the manner pro-  
3 vided under section 156(b) of title 35,  
4 United States Code; and

5 (II) the terms “product” and  
6 “approved product” in such section  
7 156(b) shall be deemed to include  
8 forms of the active moiety of the dor-  
9 mant therapy and highly similar ac-  
10 tive moieties that might be approved  
11 or licensed by the Secretary based  
12 upon an application filed under sec-  
13 tion 505(b)(2) or 505(j) of the Fed-  
14 eral Food, Drug, and Cosmetic Act  
15 (21 U.S.C. 355(b)(2), (j)) or under  
16 section 351(k) of the Public Health  
17 Service Act (42 U.S.C. 262(k)) that  
18 references or otherwise relies upon the  
19 dormant therapy.

20 (D) INTERIM PATENT EXTENSIONS.—Not-  
21 withstanding any provision of title 35, United  
22 States Code, with respect to any patent listed  
23 (or patent issuing on an application listed)  
24 under subsection (b)(1) that would otherwise  
25 expire before the sponsor could make a submis-

1           sion under subparagraph (B), the Director,  
2           upon application of the patentee, shall grant to  
3           the patentee an interim extension of such pat-  
4           ent, subject to the limitations in section  
5           156(d)(5)(F) of such title 35, for such period  
6           as may be necessary to permit the sponsor to  
7           submit the listing under subparagraph (B) and,  
8           if the patent is therein listed, to extend the pat-  
9           ent as provided under subparagraph (C). The  
10          Director may require, for any patent extended  
11          under this subparagraph, that the sponsor of  
12          the dormant therapy to which the patent relates  
13          provide periodic certifications that development  
14          of the dormant therapy is continuing. The Di-  
15          rector may terminate any interim extension for  
16          which a required certification has not been  
17          made.

18               (E) NOTICE OF EXTENSION.—For each  
19          patent that is extended under this paragraph,  
20          the Director shall publish a notice of such ex-  
21          tension and issue a certificate of extension de-  
22          scribed in section 156(e)(1) of title 35, United  
23          States Code.

24               (F) NOTICE OF WAIVER.—For each patent  
25          identified in a submission under subparagraph

1 (B)(i), and each patent issuing based upon an  
2 application for patent so identified, that expires  
3 after the end of the protection period for the  
4 dormant therapy, the Director shall publish a  
5 notice that the patent is subject to the limited  
6 waiver of the right to enforce described in sub-  
7 section (c)(1).

8 (f) CERTAIN FDA PROTECTIONS INAPPLICABLE.—If  
9 a medicine has been designated as a dormant therapy  
10 under subsection (a), the protections otherwise applicable  
11 with respect to such medicine under sections 505A, 505E,  
12 and 527 of the Federal Food, Drug, and Cosmetic Act  
13 (21 U.S.C. 355a, 355f, 360cc) shall not apply. The pre-  
14 ceding sentence shall not be construed to affect any pro-  
15 tections applicable with respect to a medicine, including  
16 a medicine designated under section 526 of such Act (21  
17 U.S.C. 360bb) for a rare disease or condition, under provi-  
18 sions other than such sections 505A, 505E, and 527.

19 (g) DEVELOPMENT CERTIFICATIONS.—

20 (1) IN GENERAL.—The Secretary shall require  
21 that the sponsor of a dormant therapy provide a cer-  
22 tification that the clinical plan under subsection  
23 (a)(2)(B) has been completed, and, that the initial  
24 marketing approval or licensure for the qualifying  
25 medicine was based on the investigations set forth in

1 such clinical plan (including modifications to the ini-  
2 tial plan approved by the Food and Drug Adminis-  
3 tration). Prior to receiving such certifications, the  
4 Secretary shall require periodic certifications that  
5 the clinical plan under subsection (a)(2)(B) is con-  
6 tinuing.

7 (2) DETERMINATION OF NONCOMPLIANCE.—If  
8 the Secretary concludes that the sponsor has not  
9 complied with paragraph (1), after providing the  
10 sponsor the opportunity to remedy any insufficiency,  
11 the Secretary shall, for purposes of subsection  
12 (d)(1), determine that the sponsor is not in compli-  
13 ance with the certification requirement under para-  
14 graph (1).

15 (h) COLLABORATION.—Nothing in this section shall  
16 be construed as preventing a sponsor from collaborating  
17 with other entities in developing a dormant therapy or ap-  
18 plying for a dormant therapy designation.

19 **SEC. 1223. IMPLEMENTATION AND EFFECT.**

20 (a) EFFECTIVE DATE.—Subject to the provisions of  
21 this section, this subtitle shall take effect on the date of  
22 enactment.

23 (b) IMPLEMENTING REGULATIONS.—The Secretary,  
24 in consultation with the Secretary of Commerce, shall pro-  
25 mulgate such regulations and finalize such guidance as

1 necessary to implement the provisions of section 1222.  
2 Such regulations or guidance shall take effect 18 months  
3 after the date of enactment of this Act.

4 (c) LIMITATION ON DETERMINATIONS AND DESIGNA-  
5 TIONS.—Notwithstanding any provision of section 1222,  
6 the Secretary may not make a determination on a request  
7 for designation by a manufacturer or sponsor under sec-  
8 tion 1222(a) prior to the effective date of the regulations  
9 under subsection (b) or 30 months after the date of enact-  
10 ment of this Act, whichever occurs first, and the Secretary  
11 may not designate a medicine under section 1222(a) un-  
12 less the requirement under section 1222(a)(2)(D) is met  
13 for such medicine as of the effective date of the regulations  
14 under subsection (b) or 30 months after the date of enact-  
15 ment of this Act, whichever occurs first.

## 16 **Subtitle M—New Therapeutic** 17 **Entities**

### 18 **SEC. 1241. EXTENDED EXCLUSIVITY PERIOD FOR CERTAIN** 19 **NEW DRUG APPLICATIONS AND ABBRE-** 20 **VIATED NEW DRUG APPLICATIONS.**

21 (a) NEW DRUG APPLICATIONS.—Section  
22 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic  
23 Act (21 U.S.C. 355(c)(3)(E)) is amended by adding at  
24 the end the following new clause:

1           “(vi) With respect to an application described  
2           in clause (iii) or a supplement to an application de-  
3           scribed in clause (iv), the three-year period specified  
4           in such clause shall be extended for an additional pe-  
5           riod of not more than two years if the person sub-  
6           mitting such application or supplement provides doc-  
7           umentation to the Secretary demonstrating that—

8                   “(I) the new clinical investigations essen-  
9                   tial to the approval of the application or supple-  
10                  ment and conducted or sponsored by the person  
11                  submitting the application or supplement sup-  
12                  port the approval of a new indication or use for  
13                  the drug that is the subject of the application  
14                  or supplement; or

15                  “(II) the drug that is the subject of the  
16                  application or supplement has been reformu-  
17                  lated or redesigned so that the drug can reason-  
18                  ably (as determined by the Secretary in con-  
19                  sultation with the person submitting such appli-  
20                  cation or supplement) be expected—

21                   “(aa) to promote greater patient ad-  
22                   herence to an approved treatment regime  
23                   relative to the previously approved formu-  
24                   lation or design of the drug;

1 “(bb) to reduce the public-health risks  
2 associated with the drug relative to the  
3 previously approved formulation or design  
4 of the drug;

5 “(cc) to reduce the manner or extent  
6 of side effects or adverse events associated  
7 with the previously approved formulation  
8 or design of the drug;

9 “(dd) to provide systemic benefits to  
10 the health care system relative to the pre-  
11 viously approved formulation or design of  
12 the drug; or

13 “(ee) to provide other patient benefits  
14 that are comparable to the benefits de-  
15 scribed in items (aa) through (dd).”.

16 (b) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-  
17 tion 505(j)(5)(F) of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 355(j)(5)(F)) is amended by adding  
19 at the end the following new clause:

20 “(vi) With respect to an application described in  
21 clause (iii) or a supplement to an application described  
22 in clause (iv), the three-year period specified in such  
23 clause shall be extended for an additional period of not  
24 more than 24 months if the person submitting such appli-



1 cation or supplement provides documentation to the Sec-  
2 retary demonstrating that—

3 “(I) the new clinical investigations essential to  
4 the approval of the application or supplement and  
5 conducted or sponsored by the person submitting the  
6 application or supplement support the approval of a  
7 new indication or use for the drug that is the subject  
8 of the application or supplement; or

9 “(II) the drug that is the subject of the applica-  
10 tion or supplement has been reformulated or rede-  
11 signed so that the drug may reasonably (as deter-  
12 mined by the Secretary in consultation with the per-  
13 son submitting such application or supplement) be  
14 expected—

15 “(aa) to promote greater patient adherence  
16 to an approved treatment regime relative to the  
17 previously approved formulation or design of  
18 the drug;

19 “(bb) to reduce the public-health risks as-  
20 sociated with the drug relative to the previously  
21 approved formulation or design of the drug;

22 “(cc) to reduce the manner or extent of  
23 side effects or adverse events associated with  
24 the previously approved formulation or design  
25 of the drug;

1           “(dd) to provide systemic benefits to the  
2           health care system relative to the previously ap-  
3           proved formulation or design of the drug; or

4           “(ee) to provide other patient benefits that  
5           are comparable to the benefits described in  
6           items (aa) through (dd).”.

7           (c) REGULATIONS.—Not later than 180 days after  
8           the date of the enactment of this Act, the Secretary of  
9           Health and Human Services shall promulgate final regula-  
10          tions to carry out the amendments made by this section,  
11          including regulations establishing a process under which  
12          the Secretary consults with persons submitting applica-  
13          tions or supplements for approval of a drug under sub-  
14          section (b) of section 505 of the Federal Food, Drug, and  
15          Cosmetic Act (21 U.S.C. 355) on how such drug may rea-  
16          sonably be expected to provide the benefits described in  
17          items (aa) through (ee) of (as applicable)—

18               (1) clause (vi)(II) of subsection (c)(3)(E) of  
19               such section, as added by subsection (a); or

20               (2) clause (vi)(II) of subsection (j)(5)(F) of  
21               such section, as added by subsection (b).

1           **Subtitle N—Orphan Product**  
2                           **Extensions Now**

3   **SEC. 1261. EXTENSION OF EXCLUSIVITY PERIODS FOR A**  
4                           **DRUG APPROVED FOR A NEW INDICATION**  
5                           **FOR A RARE DISEASE OR CONDITION.**

6           (a) IN GENERAL.—Chapter V of the Federal Food,  
7 Drug, and Cosmetic Act, as amended by section 1181, is  
8 further amended by inserting after section 505F of such  
9 Act the following:

10   **“SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A**  
11                           **DRUG APPROVED FOR A NEW INDICATION**  
12                           **FOR A RARE DISEASE OR CONDITION.**

13           “(a) DESIGNATION.—

14                   “(1) IN GENERAL.—The Secretary shall des-  
15 ignate a drug as a drug approved for a new indica-  
16 tion to prevent, diagnose, or treat a rare disease or  
17 condition for purposes of granting the extensions  
18 under subsection (b) if—

19                           “(A) prior to approval of an application or  
20 supplemental application for the new indication,  
21 the drug was approved or licensed for mar-  
22 keting under section 505(c) of this Act or sec-  
23 tion 351(a) of the Public Health Service Act,  
24 but was not so approved or licensed for the new  
25 indication;

1           “(B)(i) the sponsor of the approved or li-  
2           censed drug files an application or a supple-  
3           mental application for approval of the new indi-  
4           cation for use of the drug to prevent, diagnose,  
5           or treat the rare disease or condition; and

6           “(ii) the Secretary approves the application  
7           or supplemental application; and

8           “(C) the application or supplemental appli-  
9           cation for the new indication contains the con-  
10          sent of the applicant to notice being given by  
11          the Secretary under paragraph (4) respecting  
12          the designation of the drug.

13          “(2) REVOCATION OF DESIGNATION.—

14                 “(A) IN GENERAL.—Except as provided in  
15                 subparagraph (B), a designation under this  
16                 subsection shall not be revoked for any reason.

17                 “(B) EXCEPTION.—The Secretary may re-  
18                 voke a designation of a drug under paragraph  
19                 (1) if the Secretary finds that the application or  
20                 supplemental application resulting in such des-  
21                 ignation contained an untrue statement of ma-  
22                 terial fact.

23                 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE  
24                 OF PRODUCTION FOR SOLELY COMMERCIAL REA-  
25                 SONS.—A designation of a drug under paragraph (1)

1 shall be subject to the condition that the sponsor of  
2 the drug will notify the Secretary of any discontinu-  
3 ance of the production of the drug for solely com-  
4 mercial reasons at least one year before such dis-  
5 continuance.

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

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

12 “(1)(A) the 4-, 5-, and seven and one-half year  
13 periods described in subsections (c)(3)(E)(ii) and  
14 (j)(5)(F)(ii) of section 505, the 3-year periods de-  
15 scribed in clauses (iii) and (iv) of subsection  
16 (c)(3)(E) and clauses (iii) and (iv) of subsection  
17 (j)(5)(F) of section 505, and the 7-year period de-  
18 scribed in section 527, as applicable, shall be ex-  
19 tended by 6 months; or

20 “(B) the 4- and 12-year periods described in  
21 subparagraphs (A) and (B) of section 351(k)(7) of  
22 the Public Health Service Act and the 7-year period  
23 described in section 527, as applicable, shall be ex-  
24 tended by 6 months; and

1           “(2) if, at the time a drug is designated under  
2 subsection (a)(1)—

3           “(A) the drug is the subject of a listed pat-  
4 ent for which a certification has been submitted  
5 under subsection (b)(2)(A)(ii) or  
6 (j)(2)(A)(vii)(II) of section 505 or a listed pat-  
7 ent for which a certification has been submitted  
8 under subsections (b)(2)(A)(iii) or  
9 (j)(2)(A)(vii)(III) of section 505, the period  
10 during which an application may not be ap-  
11 proved under section 505(c)(3) or section  
12 505(j)(5)(B) shall be extended by a period of 6  
13 months after the date the patent expires (in-  
14 cluding any patent extensions); or

15           “(B) the drug is the subject of a listed  
16 patent for which a certification has been sub-  
17 mitted under subsection (b)(2)(A)(iv) or  
18 (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
19 ent infringement litigation resulting from the  
20 certification the court determines that the pat-  
21 ent is valid and would be infringed, the period  
22 during which an application may not be ap-  
23 proved under section 505(c)(3) or section  
24 505(j)(5)(B) shall be extended by a period of 6

1 months after the date the patent expires (in-  
2 cluding any patent extensions).

3 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-  
4 FECTIONOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-  
5 sion under subsection (b) of a period shall be in addition  
6 to any extension of the periods under sections 505A and  
7 505E of this Act and section 351(m) of the Public Health  
8 Service 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  
11 subsection (a)(1) has previously received an extension by  
12 operation of subsection (b).

13 “(e) REGULATIONS.—

14 “(1) IN GENERAL.—Not later than 2 years  
15 after the date of enactment of this section, the Sec-  
16 retary shall adopt final regulations implementing  
17 this section.

18 “(2) PROCEDURE.—In promulgating a regula-  
19 tion implementing this section, the Secretary shall—

20 “(A) issue a notice of proposed rulemaking  
21 that includes the proposed regulation;

22 “(B) provide a period of not less than 60  
23 days for comments on the proposed regulation;  
24 and

1           “(C) publish the final regulation not less  
2           than 30 days before the effective date of the  
3           regulation.

4           “(3) RESTRICTIONS.—Notwithstanding any  
5           other provision of law, the Secretary shall promul-  
6           gate regulations implementing this section only as  
7           described in paragraph (2), except that the Sec-  
8           retary may issue interim guidance for sponsors seek-  
9           ing to submit an application or supplemental appli-  
10          cation described in subsection (a) prior to the pro-  
11          mulgation of such regulations.

12          “(4) DESIGNATION PRIOR TO REGULATIONS.—  
13          The Secretary shall designate drugs under sub-  
14          section (a) prior to the promulgation of regulations  
15          under this subsection, if such drugs meet the criteria  
16          described in subsection (a).

17          “(f) DEFINITION.—In this section, the term ‘rare dis-  
18          ease or condition’ has the meaning given to such term in  
19          section 526(a)(2).”.

20          (b) APPLICATION.—Section 505G of the Federal  
21          Food, Drug, and Cosmetic Act, as added by subsection  
22          (a), applies only with respect to a drug for which an appli-  
23          cation or supplemental application described in subsection  
24          (a)(1)(B)(i) of such section 505G is first approved under  
25          section 505(c) of such Act (21 U.S.C. 355(c)) or section



1 351(a) of the Public Health Service Act (42 U.S.C.  
2 262(a)) on or after the date of the enactment of this Act.

3 (c) CONFORMING AMENDMENTS.—

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

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

9 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
10 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
11 EASE OR CONDITION.—Notwithstanding the ref-  
12 erences in subsection (b)(1) to the lengths of the ex-  
13 clusivity periods after application of pediatric exclu-  
14 sivity, the 6-month extensions described in sub-  
15 section (b)(1) shall be in addition to any extensions  
16 under section 505G.”; and

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

19 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
20 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
21 EASE OR CONDITION.—Notwithstanding the ref-  
22 erences in subsection (c)(1) to the lengths of the ex-  
23 clusivity periods after application of pediatric exclu-  
24 sivity, the 6-month extensions described in sub-

1 section (c)(1) shall be in addition to any extensions  
2 under section 505G.”.

3 (2) RELATION TO EXCLUSIVITY FOR NEW  
4 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT  
5 ARE DRUGS.—Subsection (b) of section 505E of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 355f) is amended—

8 (A) by amending the subsection heading to  
9 read as follows: “RELATION TO PEDIATRIC EX-  
10 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-  
11 PROVED FOR A NEW INDICATION FOR A RARE  
12 DISEASE OR CONDITION”; and

13 (B) by striking “any extension of the pe-  
14 riod under section 505A” and inserting “any  
15 extension of the periods under sections 505A  
16 and 505G, as applicable.”.

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

21 “(5) RELATION TO EXCLUSIVITY FOR A BIO-  
22 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-  
23 TION FOR A RARE DISEASE OR CONDITION.—Not-  
24 withstanding the references in paragraphs (2)(A),  
25 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-

1 exclusivity periods after application of pediatric exclu-  
2 sivity, the 6-month extensions described in such  
3 paragraphs shall be in addition to any extensions  
4 under section 505G.”.

5 **TITLE II—BUILDING THE FOUN-**  
6 **DATION FOR 21ST CENTURY**  
7 **MEDICINE, INCLUDING HELP-**  
8 **ING YOUNG SCIENTISTS**

9 **Subtitle A—21st Century Cures**  
10 **Consortium Act**

11 **SEC. 2001. INNOVATIVE CURES CONSORTIUM.**

12 Title II of the Public Health Service Act (42 U.S.C.  
13 202 et seq.) is amended by adding at the end the fol-  
14 lowing:

15 **“PART E—INNOVATIVE CURES CONSORTIUM**

16 **“SEC. 281. ESTABLISHMENT.**

17 “A nonprofit corporation to be known as the 21st  
18 Century Cures Consortium (referred to in this part as the  
19 ‘Consortium’) shall be established in accordance with this  
20 section. The Consortium shall be a public-private partner-  
21 ship headed by an Executive Director (referred to in this  
22 part as the ‘Executive Director’), appointed by the mem-  
23 bers of the Board of Directors. The Consortium shall not  
24 be an agency or instrumentality of the United States Gov-  
25 ernment.

1 **“SEC. 281A. PURPOSE.**

2 “The purpose of the Consortium is to accelerate the  
3 discovery, development, and delivery in the United States  
4 of innovative cures, treatments, and preventive measures  
5 for patients.

6 **“SEC. 281B. DUTIES.**

7 “For the purpose described in section 281A, the Con-  
8 sortium shall—

9 “(1) foster collaboration among the Consor-  
10 tium, academia, government agencies, industry,  
11 health care payors and providers, patient advocates,  
12 and others engaged in the cycle of discovery, devel-  
13 opment, and delivery of life-saving and health-en-  
14 hancing innovative interventions;

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

17 “(3) publish information on the activities fund-  
18 ed under section 281D;

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

23 “(5) identify gaps and opportunities within and  
24 across the discovery, development, and delivery cycle  
25 that are best addressed by consortia; and

1           “(6) facilitate the interoperability of the compo-  
2           nents of the discovery, development, and delivery  
3           cycle.

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

5           “(a) BOARD OF DIRECTORS.—

6           “(1) ESTABLISHMENT.—

7                   “(A) IN GENERAL.—The Consortium shall  
8           have a Board of Directors (in this part referred  
9           to as the ‘Board of Directors’), which shall be  
10          composed of the ex officio members under sub-  
11          paragraph (B) and the appointed members  
12          under subparagraph (C). All members of the  
13          Board shall be voting members.

14                   “(B) EX OFFICIO MEMBERS.—The ex offi-  
15          cio members of the Board shall be the following  
16          individuals or their designees:

17                           “(i) The Director of the National In-  
18                           stitutes of Health.

19                           “(ii) The Commissioner of Food and  
20                           Drugs.

21                           “(iii) The Administrator of the Cen-  
22                           ters for Medicare & Medicaid Services.

23                   “(C) APPOINTED MEMBERS.—The ap-  
24          pointed members of the Board shall consist of  
25          22 individuals, of whom—

1           “(i) 5 shall be representatives of Fed-  
2           eral agencies, to be appointed by the ex  
3           officio members of the Board under sub-  
4           paragraph (B);

5           “(ii) 8 shall be representatives of the  
6           biopharmaceutical and medical device in-  
7           dustries, to be appointed by the Comp-  
8           troller General of the United States from  
9           a list of nominations submitted by leading  
10          trade associations; and

11          “(iii) 9 shall be representatives of aca-  
12          demic researchers, patients, health care  
13          providers, and health care plans and insur-  
14          ers, to be appointed by the Comptroller  
15          General of the United States, after solici-  
16          ting nominations.

17          “(D) CHAIR.—The Chair of the Board  
18          shall be selected by the members of the Board  
19          by majority vote from among the members of  
20          the Board.

21          “(2) TERMS AND VACANCIES.—

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

1                   “(B) VACANCY.—Any vacancy in the mem-  
2                   bership of the Board—

3                   “(i) shall not affect the power of the  
4                   remaining members to execute the duties  
5                   of the Board; and

6                   “(ii) shall be filled by appointment by  
7                   the appointed members described in para-  
8                   graph (1)(C) by majority vote.

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

16                  “(3) RESPONSIBILITIES.—The Board of Direc-  
17                  tors shall establish bylaws and policies for the Con-  
18                  sortium that—

19                  “(A) are published in the Federal Register  
20                  and available for public comment;

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

23                  “(i) the officers, employees, agents,  
24                  and contractors of the Consortium; and

1                   “(ii) the members of any committees  
2                   of the Consortium;

3                   “(C) establish policies, including ethical  
4                   standards, for the award of grants, contracts,  
5                   and other assistance under section 281D; and

6                   “(D) establish specific duties of the Execu-  
7                   tive Director.

8                   “(4) AGENDA.—The Board of Directors shall—

9                   “(A) not later than 3 months after the in-  
10                  corporation of the Consortium, issue an agenda  
11                  (in this part referred to as the ‘agenda’) out-  
12                  lining how the Consortium will achieve the pur-  
13                  pose described in section 281A; and

14                  “(B) annually thereafter, in consultation  
15                  with the Executive Director, review and update  
16                  such agenda.

17                  “(b) INCORPORATION.—The ex officio members of  
18                  the Board of Directors shall serve as incorporators and  
19                  shall take whatever actions necessary to incorporate the  
20                  Consortium by not later than January 1, 2016.

21                  “(c) NONPROFIT STATUS.—In carrying out this part,  
22                  the Board of Directors shall establish such policies and  
23                  bylaws, and the Executive Director shall carry out such  
24                  activities, as may be necessary to ensure that the Consor-  
25                  tium maintains status as an organization that—



1           “(1) is described in subsection (c)(3) of section  
2           501 of the Internal Revenue Code of 1986; and

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

5           “(d) EXECUTIVE DIRECTOR.—The Executive Direc-  
6           tor shall—

7           “(1) be the chief executive officer of the Con-  
8           sortium; and

9           “(2) subject to the oversight of the Board of  
10          Directors, be responsible for the day-to-day manage-  
11          ment of the Consortium.

12       **“SEC. 281D. GRANTS, CONTRACTS, AND OTHER ASSIST-**  
13               **ANCE.**

14          “(a) IN GENERAL.—The Consortium shall, on a com-  
15          petitive basis, award grants, contracts, and provide other  
16          assistance to eligible entities for activities to accelerate the  
17          discovery, development, and delivery in the United States  
18          of innovative cures, treatments, and preventive measures  
19          for patients. Any financial assistance provided by the Con-  
20          sortium under this part for such activities shall be pro-  
21          vided in accordance with this section.

22          “(b) PRIVATE SECTOR MATCHING FUNDS.—As a  
23          condition of participation in a program or initiative spon-  
24          sored by the Consortium or receipt of a grant, contract,  
25          or other assistance from the Consortium, the entity so par-

1 participating or receiving such grant, contract, or other as-  
2 sistance shall provide funds, in-kind contributions, or a  
3 combination of both that—

4 “(1) are derived from sources other than the  
5 Federal Government; and

6 “(2) are in an amount that is, as determined by  
7 the Board, proportional to the assistance that is de-  
8 rived from payments by the Secretary under section  
9 281F.

10 “(c) ELIGIBLE ENTITIES.—An entity is eligible to re-  
11 ceive a grant or other assistance under subsection (a) only  
12 if the entity is—

13 “(1) a small business; or

14 “(2) a nonprofit organization.

15 “(d) AGREEMENT OR CONTRACT.—A grant agree-  
16 ment or other contract providing for assistance under this  
17 section shall—

18 “(1) set up appropriate arrangements for imple-  
19 mentation of the activities;

20 “(2) set up appropriate financial arrangements  
21 and rules relating to intellectual property rights;

22 “(3) govern the relationship between the Con-  
23 sortium, the recipients of the grant or contract, and  
24 any one or more other entities that is working in col-

1 laboration with such recipients to carry out the ac-  
2 tivities; and

3 “(4) provide for reporting to the Consortium on  
4 the activities funded through the grant agreement or  
5 other contract.

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

7 “(a) IN GENERAL.—The Consortium shall terminate  
8 on September 30, 2021.

9 “(b) REPORT.—Not later than one year after the  
10 date on which the Consortium is established and each year  
11 thereafter, the Executive Director shall submit to the ap-  
12 propriate congressional committees a report on the per-  
13 formance of the Consortium. In preparing such report, the  
14 Consortium shall consult with a nongovernmental consult-  
15 ant with appropriate expertise.

16 **“SEC. 281F. FUNDING.**

17 “For the period of fiscal years 2016 through 2021,  
18 the Secretary shall make a payment to the Consortium  
19 for purposes of carrying out the duties of the Consortium  
20 under this part in an amount of not less than  
21 **【\$\_\_\_\_\_】.**”.

1           **Subtitle B—Medical Product**  
2           **Innovation Advisory Commission**

3   **SEC. 2021. MEDICAL PRODUCT INNOVATION ADVISORY**  
4                           **COMMISSION.**

5           Part A of title II of the Public Health Service Act  
6 is amended by inserting after section 229 (42 U.S.C.  
7 237a) the following new section:

8   **“SEC. 229A. MEDICAL PRODUCT INNOVATION ADVISORY**  
9                           **COMMISSION.**

10           “(a) ESTABLISHMENT.—There is hereby established  
11 as an agency of Congress the Medical Product Innovation  
12 Advisory Commission (in this section referred to as the  
13 ‘Commission’). The purpose of the Commission shall be  
14 to analyze medical product innovation in the United States  
15 and recommend policies to accelerate the discovery, devel-  
16 opment, and delivery of new medical products.

17           “(b) DUTIES.—

18                           “(1) REVIEW OF MEDICAL PRODUCT INNOVA-  
19           TION POLICIES AND ANNUAL REPORTS.—The Com-  
20           mission shall—

21                                   “(A) review medical product innovation  
22                           policies, including the topics described in para-  
23                           graph (2);

24                                   “(B) make recommendations to Congress  
25                           concerning such policies;

1           “(C) by not later than March 15 of each  
2 year, submit a report to Congress containing  
3 the results of the reviews under subparagraph  
4 (A); and

5           “(D) by not later than June 15 of each  
6 year, submit a report to Congress containing an  
7 examination of issues affecting medical product  
8 innovation and the recommendations of the  
9 Commission with respect to medical product in-  
10 novation policies reviewed under subparagraph  
11 (A).

12           “(2) SPECIFIC TOPICS TO BE REVIEWED.—

13           “(A) DISCOVERY, DEVELOPMENT, AND DE-  
14 LIVERY.—Specifically, the Commission shall re-  
15 view Federal policies (including policies of the  
16 National Institutes of Health, the Food and  
17 Drug Administration, and the Centers for  
18 Medicare & Medicaid Services) relating to the  
19 discovery, development, and delivery of new  
20 medical products.

21           “(B) INTERACTION OF THE AGENCIES.—  
22 Specifically, the Commission shall review the  
23 interaction of Federal agencies with respect to  
24 the discovery, development, and delivery of new

1 medical products and how such interactions in-  
2 fluence medical product innovation.

3 “(C) THE CYCLE OF DISCOVERY, DEVEL-  
4 OPMENT, AND DELIVERY OF MEDICAL PROD-  
5 UCTS AND INNOVATION.—Specifically, the Com-  
6 mission shall assess—

7 “(i) the cycle of discovery, develop-  
8 ment, and delivery of new medical products  
9 in the United States, and the policies af-  
10 fecting such cycle; and

11 “(ii) what steps may be taken to ac-  
12 celerate the cycle and facilitate the transi-  
13 tion between the phases of the cycle.

14 “(3) AGENDA AND ADDITIONAL REVIEWS.—The  
15 Commission shall consult periodically with the chair-  
16 men and ranking minority members of the appro-  
17 priate committees of Congress regarding the Com-  
18 mission’s agenda and progress toward achieving the  
19 agenda. The Commission may conduct additional re-  
20 views, and submit additional reports to the appro-  
21 priate committees of Congress, from time to time on  
22 such topics relating to medical product innovation as  
23 may be requested by such chairmen and ranking  
24 members and as the Commission determines appro-  
25 priate.

1           “(4) AVAILABILITY OF REPORTS.—The Com-  
2 mission shall transmit to the Secretary a copy of  
3 each report submitted under this subsection and  
4 shall make such reports available to the public.

5           “(5) VOTING AND REPORTING REQUIRE-  
6 MENTS.—With respect to each recommendation con-  
7 tained in a report submitted under paragraph (1),  
8 each member of the Commission shall vote on the  
9 recommendation, and the Commission shall include,  
10 by member, the results of that vote in the report  
11 containing the recommendation.

12           “(c) MEMBERSHIP.—

13           “(1) NUMBER AND APPOINTMENT.—The Com-  
14 mission shall be composed of 17 members appointed  
15 by the Comptroller General of the United States.

16           “(2) QUALIFICATIONS.—

17           “(A) IN GENERAL.—The membership of  
18 the Commission shall include academic re-  
19 searchers, physicians and other health profes-  
20 sionals, experts in the research and develop-  
21 ment of medical products for prevention, detec-  
22 tion, prediction, elimination, or modulation of  
23 disease, experts in the areas of biostatistics,  
24 clinical pharmacology, pharmacoeconomics, or

1 prescription drug benefit programs, employers,  
2 health plans, and third party payors.

3 “(B) ETHICAL DISCLOSURE.—The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members. Members of the Commission shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).  
10  
11

12 “(3) TERMS.—

13 “(A) IN GENERAL.—The terms of members of the Commission shall be for 3 years except that the Comptroller General shall designate staggered terms for the members first appointed.  
16  
17

18 “(B) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member’s term until a successor has taken office. A vacancy in the  
21  
22  
23  
24



1 Commission shall be filled in the manner in  
2 which the original appointment was made.

3 “(4) COMPENSATION.—While serving on the  
4 business of the Commission (including traveltime), a  
5 member of the Commission shall be entitled to com-  
6 pensation at the per diem equivalent of the rate pro-  
7 vided for level IV of the Executive Schedule under  
8 section 5315 of title 5, United States Code. While  
9 so serving away from home and the member’s reg-  
10 ular place of business, a member may be allowed  
11 travel expenses, as authorized by the Chairman of  
12 the Commission. Physicians serving as personnel of  
13 the Commission may be provided a physician com-  
14 parability allowance by the Commission in the same  
15 manner as Government physicians may be provided  
16 such an allowance by an agency under section 5948  
17 of title 5, United States Code, and for such purpose  
18 subsection (i) of such section shall apply to the Com-  
19 mission in the same manner as it applies to the Ten-  
20 nessee Valley Authority. For purposes of pay (other  
21 than pay of members of the Commission) and em-  
22 ployment benefits, rights, and privileges, all per-  
23 sonnel of the Commission shall be treated as if they  
24 were employees of the United States Senate.

1           “(5) CHAIRMAN; VICE CHAIRMAN.—The Comp-  
2           troller General shall designate two members of the  
3           Commission, at the time of appointment of the mem-  
4           bers, as Chairman and Vice Chairman for that term  
5           of appointment, except that in the case of vacancy  
6           of the Chairmanship or Vice Chairmanship, the  
7           Comptroller General may designate another member  
8           for the remainder of that member’s term.

9           “(6) MEETINGS.—The Commission shall meet  
10          at the call of the Chairman.

11          “(d) DIRECTOR AND STAFF; EXPERTS AND CON-  
12          SULTANTS.—Subject to such review as the Comptroller  
13          General determines necessary to ensure the efficient ad-  
14          ministration of the Commission, the Commission may—

15                 “(1) employ and fix the compensation of an Ex-  
16                 ecutive Director (subject to the approval of the  
17                 Comptroller General) and such other personnel as  
18                 may be necessary to carry out its duties (without re-  
19                 gard to the provisions of title 5, United States Code,  
20                 governing appointments in the competitive service);

21                 “(2) seek such assistance and support as may  
22                 be required in the performance of its duties from ap-  
23                 propriate Federal departments and agencies;

24                 “(3) enter into contracts or make other ar-  
25                 rangements, as may be necessary for the conduct of

1 the work of the Commission (without regard to sec-  
2 tion 3709 of the Revised Statutes (41 U.S.C. 5));

3 “(4) make advance, progress, and other pay-  
4 ments which relate to the work of the Commission;

5 “(5) provide transportation and subsistence for  
6 persons serving without compensation; and

7 “(6) prescribe such rules and regulations as it  
8 determines necessary with respect to the internal or-  
9 ganization and operation of the Commission.

10 “(e) POWERS.—

11 “(1) OBTAINING OFFICIAL DATA.—The Com-  
12 mission may secure directly from any department or  
13 agency of the United States any information nec-  
14 essary to enable it to carry out this section. Upon  
15 request of the Chairman, the head of that depart-  
16 ment or agency shall furnish that information to the  
17 Commission on an agreed upon schedule.

18 “(2) DATA COLLECTION.—In order to carry out  
19 its functions, the Commission shall—

20 “(A) utilize existing information, both pub-  
21 lished and unpublished, where possible, collected  
22 and assessed either by its own staff or under  
23 other arrangements made in accordance with  
24 this section;

1           “(B) carry out, or award grants or con-  
2           tracts for, original research and experimen-  
3           tation, where existing information is inad-  
4           equate; and

5           “(C) adopt procedures allowing any inter-  
6           ested party to submit information for the Com-  
7           mission’s use in making reports and rec-  
8           ommendations.

9           “(3) ACCESS OF GAO TO INFORMATION.—The  
10          Comptroller General shall have unrestricted access  
11          to all deliberations, records, and nonproprietary data  
12          of the Commission, immediately upon request.

13          “(4) PERIODIC AUDIT.—The Commission shall  
14          be subject to periodic audit by the Comptroller Gen-  
15          eral.

16          “(f) AUTHORIZATION OF APPROPRIATIONS.—

17          “(1) REQUEST FOR APPROPRIATIONS.—The  
18          Commission shall submit requests for appropriations  
19          in the same manner as the Comptroller General sub-  
20          mits requests for appropriations, but amounts ap-  
21          propriated for the Commission shall be separate  
22          from amounts appropriated for the Comptroller Gen-  
23          eral.

1           “(2) AUTHORIZATION.—There are authorized to  
2           be appropriated [ \_\_\_\_\_ ] to carry out this sec-  
3           tion.”.

## 4   **Subtitle C—Regenerative Medicine**

### 5   **SEC. 2041. ISSUANCE OF GUIDANCE ON SURROGATE AND** 6                           **INTERMEDIATE ENDPOINTS FOR ACCELER-** 7                           **ATED APPROVAL OF REGENERATIVE MEDI-** 8                           **CINE PRODUCTS.**

9           (a) GUIDANCE.—The Secretary of Health and  
10          Human Services, acting through the Commissioner of  
11          Food and Drugs (in this section referred to as the “Sec-  
12          retary”) shall issue guidance on the use of surrogate and  
13          intermediate endpoints for accelerated approval of regen-  
14          erative medicine products under section 506(c) of the Fed-  
15          eral Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)).

16          (b) PROCESS.—In issuing guidance under subsection  
17          (a), the Secretary—

18                 (1) not later than 1 year after date of enact-  
19                 ment of this Act, shall consult with stakeholders;

20                 (2) may, for purposes of such consultation, con-  
21                 duct public hearings;

22                 (3) not later than 2 years after the date of en-  
23                 actment of this Act, shall issue proposed guidance  
24                 under subsection (a); and

1 (4) not later than 1 year after the issuance of  
2 such proposed guidance, and after an opportunity  
3 for public comment, shall issue final guidance under  
4 subsection (a).

5 **Subtitle D—Genetically Targeted**  
6 **Platform Technologies for Rare**  
7 **Diseases**

8 **SEC. 2051. GENETICALLY TARGETED PLATFORM TECH-**  
9 **NOLOGIES FOR RARE DISEASES.**

10 Paragraph (1) of section 506(c) of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended  
12 to read as follows:

13 “(1) IN GENERAL.—

14 “(A) ACCELERATED APPROVAL.—

15 “(i) IN GENERAL.—The Secretary  
16 may approve an application for approval of  
17 a product (in this section referred to as  
18 ‘accelerated approval’) for a serious or life-  
19 threatening disease or condition, including  
20 a fast track product, under section 505(c)  
21 of this Act or section 351(a) of the Public  
22 Health Service Act upon a determination  
23 that, taking into account the severity, rar-  
24 ity, or prevalence of the condition and the

1 availability or lack of alternative treat-  
2 ments—

3 “(I) the product has an effect on  
4 a surrogate endpoint that is reason-  
5 ably likely to predict clinical benefit,  
6 or on a clinical endpoint that can be  
7 measured earlier than irreversible  
8 morbidity or mortality, that is reason-  
9 ably likely to predict an effect on irre-  
10 versible morbidity or mortality or  
11 other clinical benefit; or

12 “(II) the extrapolation of evi-  
13 dence is reasonably likely to predict  
14 clinical benefit of the product.

15 “(ii) BASIS FOR CERTAIN DETERMINA-  
16 TION.—A determination under clause (i)  
17 shall be based on the totality of the evi-  
18 dence.

19 “(B) EVIDENCE.—The evidence to support  
20 that an endpoint is reasonably likely to predict  
21 clinical benefit, or that a product is reasonably  
22 likely to have a clinical benefit under subpara-  
23 graph (A) may include—

24 “(i) epidemiological,  
25 pathophysiological, therapeutic, pharmaco-

1 logic, or other evidence, such as evidence  
2 from the use of biomarkers; or

3 “(ii) evidence derived from extrapola-  
4 tion from adequate and well-controlled  
5 trials that have formed the basis for inves-  
6 tigation on other products—

7 “(I) that utilize the same or a  
8 very similar underlying genetically-  
9 targeted therapeutic platform tech-  
10 nology as the product involved;

11 “(II) for which disease genomics  
12 are known; and

13 “(III) that possess the same or  
14 very similar drug-like characteristics  
15 as the product involved, including  
16 with respect to safety, distribution,  
17 and metabolism; or

18 “(iii) other scientific methods or tools.

19 “(C) DEFINITIONS.—In this subsection:

20 “(i) The term ‘extrapolation’ includes  
21 extending a sponsor’s information and con-  
22 clusions available from studies in one or  
23 more subgroups of the patient population,  
24 with respect to related conditions or re-  
25 lated medicinal products, to make infer-



1 ences for another subgroup of the popu-  
2 lation, condition, or medicinal product,  
3 thus reducing the need to generate addi-  
4 tional information to reach conclusions for  
5 the target subgroup, condition, or medie-  
6 inal product.

7 “(ii) The term ‘genetically-targeted  
8 therapeutic platform technology’ means a  
9 therapy based on a nucleic acid or an anal-  
10 ogous compound with a common or highly-  
11 similar chemistry that—

12 “(I) may be applied across mul-  
13 tiple products; and

14 “(II) can result in the modula-  
15 tion (including suppression,  
16 upregulation, or activation) of the  
17 function of a gene or its associated  
18 gene product, causing an altered dis-  
19 ease state.”.

1 **Subtitle E—Sensible Oversight for**  
2 **Technology Which Advances**  
3 **Regulatory Efficiency**

4 **SEC. 2061. MEDICAL AND HEALTH SOFTWARE DEFINED.**

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 ‘software’ means a coded or oper-  
9 ational product that contains programs, procedures, and  
10 rules that act upon data to process, store, transmit, ana-  
11 lyze, present, or operationalize information.

12 “(2) The term ‘medical software’ means software  
13 that—

14 “(A) is not a component;

15 “(B) is not intended to provide a diagnosis; and

16 “(C) is intended to analyze patient-specific in-  
17 formation and other information to recommend to  
18 health care professionals a single treatment or  
19 course of action—

20 “(i) without the need for such profes-  
21 sionals to perform additional interpretation of,  
22 or to independently confirm the means for, such  
23 recommendation; and

24 “(ii) for the purpose of informing or influ-  
25 encing health care decisions in the prevention,

1 diagnosis, prognosis, treatment, cure, or disease  
2 management related to any disease or condition  
3 in humans.

4 “(3) The term ‘health software’ means software that  
5 is not medical software, is not a component, is intended  
6 to be used for or in support of a health care purpose, and  
7 *【How do we ensure that products that have features that  
8 should be regulated as medical software or medical devices  
9 or components thereof are not exempted from regulation as  
10 such products?】*—

11 “(A) is intended for use for administrative or  
12 operational support or the processing and mainte-  
13 nance of financial records;

14 “(B) is intended for use for clinical, laboratory,  
15 or administrative workflow and related record-  
16 keeping, including electronic health records;

17 “(C) is intended for use for aggregation, con-  
18 version, storage, management, retrieval, or trans-  
19 mission of data from a device or other thing;

20 “(D) is intended for use as a platform for a  
21 secondary software—

22 “(i) to run or act as a mechanism for  
23 connectivity; or

24 “(ii) to store data;

1           “(E) is intended for use to organize and  
2 present medical information for consumer health and  
3 wellness education or for use for maintaining health  
4 or wellness;

5           “(F) is intended for use by patients for self-  
6 management or self-monitoring of a disease or con-  
7 dition, including management of medications;

8           “(G) is intended for use to collect patient re-  
9 ported outcomes data for use by a health care prac-  
10 titioner;

11           “(H) is intended for use to analyze patient-spe-  
12 cific information or other information for purposes  
13 of presenting patient-specific recommended treat-  
14 ments or courses of action to inform health care pro-  
15 fessionals’ decisions with respect to the prevention,  
16 diagnosis, prognosis, treatment, cure, or manage-  
17 ment of a particular disease or condition, with the  
18 opportunity for additional interpretation or an inde-  
19 pendent confirmation of the means for such treat-  
20 ments or courses of action; or

21           “(I) is intended for use to analyze patient-spe-  
22 cific information or other medical information for  
23 the purpose of providing general information related  
24 to the prevention, diagnosis, prognosis, treatment,

1 cure, monitoring, or management of a disease or  
2 condition.

3 “(4) The term ‘accessory’ means a product that—

4 “(A) is intended by its manufacturer to be used  
5 together with a particular device or software product  
6 to extend that device’s or software product’s in-  
7 tended use or functionality;

8 “(B) is not a component and could, based on  
9 the intended use of the product, be considered med-  
10 ical software, health software, or a device; and

11 “(C) is a product in its own right and should  
12 be classified based on its own intended use,  
13 functionality, and risk, and not the product in con-  
14 junction with which it is used.

15 “(5) The term ‘component’ means a product that is  
16 an integral part of a device necessary to support the in-  
17 tended use of the device.”.

18 **SEC. 2062. APPLICABILITY AND INAPPLICABILITY OF REGU-**  
19 **LATION.**

20 Subchapter A of chapter V of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
22 ed by adding at the end the following:

23 **“SEC. 524B. MEDICAL AND HEALTH SOFTWARE.**

24 **“(a) REGULATION OF MEDICAL SOFTWARE.—**

1           “(1) IN GENERAL.—Not later than 24 months  
2 after the date of enactment of this section, the Sec-  
3 retary shall promulgate final regulations to establish  
4 standards, policies, and procedures for—

5                   “(A) classifying medical software;

6                   “(B) standards for the development of  
7 medical software;

8                   “(C) standards for the validation and  
9 verification of medical software;

10                  “(D) review of medical software;

11                  “(E) modifications to medical software;

12                  “(F) manufacturing of medical software;

13                  “(G) quality systems for medical software;

14                  “(H) labeling requirements for medical  
15 software; and

16                  “(I) postmarketing requirements for re-  
17 porting networks and the reporting of adverse  
18 events.

19           “(2) RELATION TO OTHER PROVISIONS.—

20                   “(A) IN GENERAL.—The provisions of this  
21 Act shall continue to apply to medical software  
22 subject to the regulations under paragraph (1),  
23 except that—

24                           “(i) medical software that is classified  
25 and reviewed under the regulations under

1 paragraph (1) shall not be required to be  
2 classified and cleared or approved under  
3 sections 513, 510(k), and 515; and

4 “(ii) medical software shall not be  
5 subject to provisions under this Act to the  
6 extent such provisions are superseded by  
7 the regulations under paragraph (1).

8 “(B) ADULTERATION, MISBRANDING.—  
9 Medical software shall be treated as—

10 “(i) adulterated under section 501 if  
11 such software is manufactured, distributed,  
12 sold, or offered for sale in violation of the  
13 regulations under paragraph (1); and

14 “(ii) misbranded under section 502 if  
15 the labeling of such software is in violation  
16 of the regulations under paragraph (1).

17 “(C) PREVIOUS SUBMISSIONS.—If, before  
18 the effective date of the regulations under para-  
19 graph (1), the sponsor of medical software initi-  
20 ates the process for classification and clearance  
21 or approval of the medical software as a device  
22 under sections 513 and 510(k) or 515, as appli-  
23 cable—

24 “(i) the sponsor of the medical soft-  
25 ware may choose to proceed with such

1 process rather than seeking classification  
2 and review of the medical software under  
3 the regulations under paragraph (1); and  
4 “(ii) the sponsor of the medical soft-  
5 ware may rely on classification and clear-  
6 ance or approval pursuant to sections 513,  
7 510(k), and 515, if granted, and may not  
8 be required by the Secretary to seek review  
9 of the medical software under the regula-  
10 tions under paragraph (1) in lieu of such  
11 reliance.

12 “(3) PROCESS FOR PROMULGATING REGULA-  
13 TIONS.—

14 “(A) CONVENING WORKSHOPS.—Not later  
15 than 6 months after the date of enactment of  
16 this section, and once every 6 months during  
17 the following 12-month period, the Secretary  
18 shall convene a workshop to obtain input re-  
19 garding the regulation to be promulgated under  
20 paragraph (1).

21 “(B) PARTICIPANTS AT WORKSHOPS.—The  
22 Secretary shall invite representatives of the fol-  
23 lowing categories to participate in each work-  
24 shop under this paragraph:

25 “(i) Patients.



1 “(ii) The Food and Drug Administra-  
2 tion.

3 “(iii) Individuals and organizations  
4 with significant expertise in standards for  
5 software development.

6 “(iv) Individuals and organizations  
7 with significant expertise in the develop-  
8 ment of health care software products.

9 “(C) PROPOSED REGULATIONS.—Not later  
10 than 18 months after the date of enactment of  
11 this section, the Secretary shall, in consultation  
12 with stakeholders (including patients, industry,  
13 health care providers, academia, and govern-  
14 ment) issue proposed regulations under para-  
15 graph (1).

16 “(4) DELEGATION.—The Secretary shall dele-  
17 gate primary jurisdiction for regulating medical soft-  
18 ware to the center at the Food and Drug Adminis-  
19 tration charged with regulating devices.

20 “(b) INAPPLICABILITY OF REGULATION TO HEALTH  
21 SOFTWARE.—Health software shall not be subject to regu-  
22 lation under this Act.”

23 **SEC. 2063. EXCLUSION FROM DEFINITION OF DEVICE.**

24 Section 201(h) of the Federal Food, Drug, and Cos-  
25 metic Act (21 U.S.C. 321) is amended—

1 (1) in subparagraph (2), by striking “or” after  
2 “or other animals,”;

3 (2) in subparagraph (3), by striking “and” and  
4 inserting “or”; and

5 (3) by inserting after subparagraph (3) the fol-  
6 lowing:

7 “(4) is not health software, and”.

8 **Subtitle F—Building a 21st**  
9 **Century Data Sharing Framework**

10 **PART 1—IMPROVING CLINICAL TRIAL DATA**

11 **OPPORTUNITIES FOR PATIENTS**

12 **SEC. 2081. STANDARDIZATION OF DATA IN CLINICAL TRIAL**

13 **REGISTRY DATA BANK ON ELIGIBILITY FOR**

14 **CLINICAL TRIALS.**

15 (a) STANDARDIZATION.—

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

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

20 (B) by inserting after paragraph (6) the  
21 following:

22 “(7) STANDARDIZATION.—The Director of NIH  
23 shall ensure that—

24 “(A) the registry and results data bank is  
25 easily used by the public;

1 “(B) entries in the registry and results  
2 data bank are easily compared; and

3 “(C) information required to be submitted  
4 to the registry and results data bank, including  
5 recruitment information under paragraph  
6 (2)(A)(ii)(II), is submitted by persons and post-  
7 ed by the Director of NIH in a standardized  
8 format employing comprehensive health care  
9 terminology that includes clinical trial inclusion  
10 and exclusion criteria, including—

11 “(i) such criteria for the primary dis-  
12 ease or condition being studied; and

13 “(ii) eligibility criteria that allow—

14 “(I) electronic matching to diag-  
15 noses or procedure coding systems  
16 such as the International Classifica-  
17 tion of Diseases or the Current Proce-  
18 dural Terminology; and

19 “(II) integration into electronic  
20 health records.”.

21 (2) CONFORMING AMENDMENT.—Clause (iv) of  
22 section 402(j)(2)(B) of the Public Health Service  
23 Act (42 U.S.C. 282(j)(2)(B)) is hereby stricken.

24 (b) CONSULTATION.—Not later than 90 days after  
25 the date of enactment of this Act, the Secretary of Health

1 and Human Services shall convene a meeting of stake-  
2 holders (including patients, researchers, physicians, indus-  
3 try representatives, health information technology pro-  
4 viders, and the Food and Drug Administration) to provide  
5 advice to the Secretary on enhancements to the clinical  
6 trial registry data bank under section 402(j) of the Public  
7 Health Service Act (42 U.S.C. 282(j)) (including enhance-  
8 ments to usability, functionality, and search capability)  
9 that are necessary to implement paragraph (7) of section  
10 402(j) of such Act, as added by subsection (a).

11 (c) APPLICABILITY.—Not later than one year after  
12 the date of enactment of this Act, the Secretary of Health  
13 and Human Services shall begin implementation of para-  
14 graph (7) of section 402(j) of the Public Health Service  
15 Act, as added by subsection (a).

16 **SEC. 2082. CLINICAL TRIAL DATA SYSTEM.**

17 (a) ESTABLISHMENT.—The Secretary, acting  
18 through the Commissioner of Food and Drugs and the Di-  
19 rector of the National Institutes of Health, shall enter into  
20 a collaborative agreement, to be known as the Clinical  
21 Trial Data System Agreement, with one or more eligible  
22 entities to implement a system to make de-identified clin-  
23 ical trial data from qualified clinical trials available for  
24 purposes of conducting further research.

1 (b) APPLICATION.—Eligible entities seeking to enter  
2 into a cooperative agreement with the Secretary under this  
3 section shall submit to the Secretary an application in  
4 such time and manner, and containing such information,  
5 as the Secretary may require. Any such application shall  
6 include the following:

7 (1) A certification that each applicant 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 pur-  
11 poses of sponsoring, operating, or participating in a  
12 clinical trial.

13 (2) A description of how each applicant will  
14 compile clinical trial data in standardized formats  
15 using terminologies and standards that have been  
16 developed by recognized standards developing orga-  
17 nizations with input from diverse stakeholder  
18 groups, and a description of the methodologies to be  
19 used to de-identify clinical trial data consistent with  
20 the requirements of section 164.514 of title 45, Code  
21 of Federal Regulations (or successor regulations).

22 (3) Documentation establishing that each appli-  
23 cant has a plan in place to allow registered users to  
24 access and use de-identified clinical trial data, gath-  
25 ered from qualified clinical trials, available under

1 carefully controlled contractual terms as defined by  
2 the Secretary.

3 (4) Evidence demonstrating the ability to en-  
4 sure dissemination of the results of the research to  
5 interested parties to serve as a guide to future med-  
6 ical product development or scientific research.

7 (5) The plan of each applicant for securing  
8 funding for the partnership described in paragraph  
9 (2) from governmental sources and private founda-  
10 tions, entities, and individuals.

11 (6) Evidence demonstrating a proven track  
12 record of—

13 (A) being a neutral third party in working  
14 with medical product manufacturers, academic  
15 institutions, and the Food and Drug Adminis-  
16 tration; and

17 (B) having the ability to protect confiden-  
18 tial data.

19 (c) DEFINITIONS.—In this section:

20 (1) The term “eligible entity” means an entity  
21 that has experienced personnel with clinical and  
22 other technical expertise in the biomedical sciences  
23 and biomedical ethics and that is—

24 (A) an institution of higher education (as  
25 such term is defined in section 1001 of the

1 Higher Education Act of 1965 (20 U.S.C.  
2 1001)) or a consortium of such institutions; or

3 (B) an organization described in section  
4 501(c)(3) of title 26 of the Internal Revenue  
5 Code of 1986 and exempt from tax under sec-  
6 tion 501(a) of such title.

7 (2) The term “medical product” means a drug  
8 (as defined in subsection (g) of section 201 of the  
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10 331), a device (as defined in subsection (h) of such  
11 section), a biological product (as defined in section  
12 351 of the Public Health Service Act (42 U.S.C.  
13 262), or any combination thereof.

14 (3) The term “qualified clinical trial” means a  
15 clinical trial sponsored solely by an agency of the  
16 Department of Health and Human Services with re-  
17 spect to a medical product—

18 (A) that was—

19 (i) approved or cleared under section  
20 505, 510(k), or 515, or has an exemption  
21 for investigational use in effect under sec-  
22 tion 505 or 520(m), of the Federal Food,  
23 Drug, and Cosmetic Act (42 U.S.C. 301 et  
24 seq.); or

1 (ii) licensed under section 351 of the  
2 Public Health Service Act (42 U.S.C. 262)  
3 or has an exemption for investigational use  
4 in effect under such section 351; or

5 (B) that is an investigational product for  
6 which the original development was discon-  
7 tinued and with respect to which—

8 (i) no additional work to support ap-  
9 proval, licensure, or clearance of such med-  
10 ical product is being or is planned to be  
11 undertaken by the sponsor of the original  
12 development program, its successors, as-  
13 signs, or collaborators; and

14 (ii) the sponsor of the original inves-  
15 tigational development program has pro-  
16 vided its consent to the Secretary for inclu-  
17 sion of data regarding such product in the  
18 system established under this section.

19 **PART 2—IMPROVING CLINICAL OUTCOMES FOR**  
20 **PATIENTS AND PROGRAM INTEGRITY**  
21 **THROUGH CMS DATA**

22 **SEC. 2085. EXPANDING AVAILABILITY OF MEDICARE DATA.**

23 (a) EXPANDING USES OF MEDICARE DATA BY  
24 QUALIFIED ENTITIES.—

25 (1) ADDITIONAL ANALYSES.—



1 (A) IN GENERAL.—Subject to subpara-  
2 graph (B), to the extent consistent with appli-  
3 cable information, privacy, security, and diselo-  
4 sure laws (including paragraph (3)), notwith-  
5 standing paragraph (4)(B) of section 1874(e) of  
6 the Social Security Act (42 U.S.C. 1395kk(e))  
7 and the second sentence of paragraph (4)(D) of  
8 such section, beginning July 1, 2015, a quali-  
9 fied entity may use the combined data described  
10 in paragraph (4)(B)(iii) of such section received  
11 by such entity under such section, and informa-  
12 tion derived from the evaluation described in  
13 such paragraph (4)(D), to conduct additional  
14 nonpublic analyses (as determined appropriate  
15 by the Secretary) and provide or sell such anal-  
16 yses to authorized users for nonpublic use (in-  
17 cluding for the purposes of assisting providers  
18 of services and suppliers to develop and partici-  
19 pate in quality and patient care improvement  
20 activities, including developing new models of  
21 care).

22 (B) LIMITATIONS WITH RESPECT TO ANAL-  
23 YSES.—

24 (i) EMPLOYERS.—Any analyses pro-  
25 vided or sold under subparagraph (A) to

1 an employer described in paragraph  
2 (9)(A)(iii) may only be used by such em-  
3 ployer for purposes of providing health in-  
4 surance to employees and retirees of the  
5 employer.

6 (ii) HEALTH INSURANCE ISSUERS.—A  
7 qualified entity may not provide or sell an  
8 analysis to a health insurance issuer de-  
9 scribed in paragraph (9)(A)(iv) unless the  
10 issuer is providing the qualified entity with  
11 data under section 1874(e)(4)(B)(iii) of  
12 the Social Security Act (42 U.S.C.  
13 1395kk(e)(4)(B)(iii)).

14 (2) ACCESS TO CERTAIN DATA.—

15 (A) ACCESS.—To the extent consistent  
16 with applicable information, privacy, security,  
17 and disclosure laws (including paragraph (3)),  
18 notwithstanding paragraph (4)(B) of section  
19 1874(e) of the Social Security Act (42 U.S.C.  
20 1395kk(e)) and the second sentence of para-  
21 graph (4)(D) of such section, beginning July 1,  
22 2015, a qualified entity may—

23 (i) provide or sell the combined data  
24 described in paragraph (4)(B)(iii) of such  
25 section to authorized users described in

1 clauses (i), (ii), and (v) of paragraph  
2 (9)(A) for nonpublic use, including for the  
3 purposes described in subparagraph (B);  
4 or

5 (ii) subject to subparagraph (C), pro-  
6 vide Medicare claims data to authorized  
7 users described in clauses (i), (ii), and (v),  
8 of paragraph (9)(A) for nonpublic use, in-  
9 cluding for the purposes described in sub-  
10 paragraph (B).

11 (B) PURPOSES DESCRIBED.—The purposes  
12 described in this subparagraph are assisting  
13 providers of services and suppliers in developing  
14 and participating in quality and patient care  
15 improvement activities, including developing  
16 new models of care.

17 (C) MEDICARE CLAIMS DATA MUST BE  
18 PROVIDED AT NO COST.—A qualified entity may  
19 not charge a fee for providing the data under  
20 subparagraph (A)(ii).

21 (3) PROTECTION OF INFORMATION.—

22 (A) IN GENERAL.—Except as provided in  
23 subparagraph (B), an analysis that is or data  
24 that are provided or sold under paragraph (1)

1 or (2) shall not contain information that indi-  
2 vidually identifies a patient.

3 (B) INFORMATION ON PATIENTS OF THE  
4 PROVIDER OF SERVICES OR SUPPLIER.—To the  
5 extent consistent with applicable information,  
6 privacy, security, and disclosure laws, an anal-  
7 ysis that is or data that are provided or sold to  
8 a provider of services or supplier under para-  
9 graph (1) or (2) may contain information that  
10 individually identifies a patient of such provider  
11 or supplier, including with respect to items and  
12 services furnished to the patient by other pro-  
13 viders of services or suppliers.

14 (C) PROHIBITION ON USING ANALYSES OR  
15 DATA FOR MARKETING PURPOSES.—An author-  
16 ized user shall not use any analysis or data pro-  
17 vided or sold under paragraph (1) or (2) for  
18 marketing purposes.

19 (4) DATA USE AGREEMENT.—A qualified entity  
20 and an authorized user described in clauses (i), (ii),  
21 and (v) of paragraph (9)(A) shall enter into an  
22 agreement regarding the use of any data that the  
23 qualified entity is providing or selling to the author-  
24 ized user under paragraph (2). Such agreement shall  
25 describe the requirements for privacy and security of

1 the data and, as determined appropriate by the Sec-  
2 retary, any prohibitions on using such data to link  
3 to other individually identifiable sources of informa-  
4 tion. If the authorized user is not a covered entity  
5 under the rules promulgated pursuant to the Health  
6 Insurance Portability and Accountability Act of  
7 1996, the agreement shall identify the relevant regu-  
8 lations, as determined by the Secretary, that the  
9 user shall comply with as if it were acting in the ca-  
10 pacity of such a covered entity.

11 (5) NO REDISCLOSURE OF ANALYSES OR  
12 DATA.—

13 (A) IN GENERAL.—Except as provided in  
14 subparagraph (B), an authorized user that is  
15 provided or sold an analysis or data under  
16 paragraph (1) or (2) shall not redisclose or  
17 make public such analysis or data or any anal-  
18 ysis using such data.

19 (B) PERMITTED REDISCLOSURE.—A pro-  
20 vider of services or supplier that is provided or  
21 sold an analysis or data under paragraph (1) or  
22 (2) may, as determined by the Secretary, redis-  
23 close such analysis or data for the purposes of  
24 performance improvement and care coordination

1 activities but shall not make public such anal-  
2 ysis or data or any analysis using such data.

3 (6) OPPORTUNITY FOR PROVIDERS OF SERV-  
4 ICES AND SUPPLIERS TO REVIEW.—Prior to a quali-  
5 fied entity providing or selling an analysis to an au-  
6 thorized user under paragraph (1), to the extent  
7 that such analysis would individually identify a pro-  
8 vider of services or supplier who is not being pro-  
9 vided or sold such analysis, such qualified entity  
10 shall provide such provider or supplier with the op-  
11 portunity to appeal and correct errors in the manner  
12 described in section 1874(e)(4)(C)(ii) of the Social  
13 Security Act (42 U.S.C. 1395kk(e)(4)(C)(ii)).

14 (7) ASSESSMENT FOR A BREACH.—

15 (A) IN GENERAL.—In the case of a breach  
16 of a data use agreement under this section or  
17 section 1874(e) of the Social Security Act (42  
18 U.S.C. 1395kk(e)), the Secretary shall impose  
19 an assessment on the qualified entity both in  
20 the case of—

21 (i) an agreement between the Sec-  
22 retary and a qualified entity; and

23 (ii) an agreement between a qualified  
24 entity and an authorized user.

1 (B) ASSESSMENT.—The assessment under  
2 subparagraph (A) shall be an amount up to  
3 \$100 for each individual entitled to, or enrolled  
4 for, benefits under part A of title XVIII of the  
5 Social Security Act or enrolled for benefits  
6 under part B of such title—

7 (i) in the case of an agreement de-  
8 scribed in subparagraph (A)(i), for whom  
9 the Secretary provided data to the quali-  
10 fied entity under paragraph (2); and

11 (ii) in the case of an agreement de-  
12 scribed in subparagraph (A)(ii), for whom  
13 the qualified entity provided data to the  
14 authorized user under paragraph (2).

15 (C) DEPOSIT OF AMOUNTS COLLECTED.—  
16 Any amounts collected pursuant to this para-  
17 graph shall be deposited in the Federal Supple-  
18 mentary Medical Insurance Trust Fund under  
19 section 1841 of the Social Security Act (42  
20 U.S.C. 1395t).

21 (8) ANNUAL REPORTS.—Any qualified entity  
22 that provides or sells an analysis or data under  
23 paragraph (1) or (2) shall annually submit to the  
24 Secretary a report that includes—

1 (A) a summary of the analyses provided or  
2 sold, including the number of such analyses, the  
3 number of purchasers of such analyses, and the  
4 total amount of fees received for such analyses;

5 (B) a description of the topics and pur-  
6 poses of such analyses;

7 (C) information on the entities who re-  
8 ceived the data under paragraph (2), the uses  
9 of the data, and the total amount of fees re-  
10 ceived for providing, selling, or sharing the  
11 data; and

12 (D) other information determined appro-  
13 priate by the Secretary.

14 (9) DEFINITIONS.—In this subsection and sub-  
15 section (b):

16 (A) AUTHORIZED USER.—The term “au-  
17 thorized user” means the following:

18 (i) A provider of services.

19 (ii) A supplier.

20 (iii) An employer (as defined in sec-  
21 tion 3(5) of the Employee Retirement In-  
22 surance Security Act of 1974).

23 (iv) A health insurance issuer (as de-  
24 fined in section 2791 of the Public Health  
25 Service Act).



1 (v) A medical society or hospital asso-  
2 ciation.

3 (vi) Any entity not described in  
4 clauses (i) through (v) that is approved by  
5 the Secretary (other than an employer or  
6 health insurance issuer not described in  
7 clauses (iii) and (iv), respectively, as deter-  
8 mined by the Secretary).

9 (B) PROVIDER OF SERVICES.—The term  
10 “provider of services” has the meaning given  
11 such term in section 1861(u) of the Social Se-  
12 curity Act (42 U.S.C. 1395x(u)).

13 (C) QUALIFIED ENTITY.—The term “quali-  
14 fied entity” has the meaning given such term in  
15 section 1874(e)(2) of the Social Security Act  
16 (42 U.S.C. 1395kk(e)).

17 (D) SECRETARY.—The term “Secretary”  
18 means the Secretary of Health and Human  
19 Services.

20 (E) SUPPLIER.—The term “supplier” has  
21 the meaning given such term in section 1861(d)  
22 of the Social Security Act (42 U.S.C.  
23 1395x(d)).

1 (b) ACCESS TO MEDICARE DATA BY QUALIFIED  
2 CLINICAL DATA REGISTRIES TO FACILITATE QUALITY  
3 IMPROVEMENT.—

4 (1) ACCESS.—

5 (A) IN GENERAL.—To the extent con-  
6 sistent with applicable information, privacy, se-  
7 curity, and disclosure laws, beginning July 1,  
8 2015, the Secretary shall, at the request of a  
9 qualified clinical data registry under section  
10 1848(m)(3)(E) of the Social Security Act (42  
11 U.S.C. 1395w-4(m)(3)(E)), provide the data  
12 described in subparagraph (B) (in a form and  
13 manner determined to be appropriate) to such  
14 qualified clinical data registry for purposes of  
15 linking such data with clinical outcomes data  
16 and performing risk-adjusted, scientifically valid  
17 analyses and research to support quality im-  
18 provement or patient safety, provided that any  
19 public reporting of such analyses or research  
20 that identifies a provider of services or supplier  
21 shall only be conducted with the opportunity of  
22 such provider or supplier to appeal and correct  
23 errors in the manner described in subsection  
24 (a)(6).

1 (B) DATA DESCRIBED.—The data de-  
2 scribed in this subparagraph is—

3 (i) claims data under the Medicare  
4 program under title XVIII of the Social  
5 Security Act; and

6 (ii) if the Secretary determines appro-  
7 priate, claims data under the Medicaid  
8 program under title XIX of such Act and  
9 the State Children’s Health Insurance Pro-  
10 gram under title XXI of such Act.

11 (2) FEE.—Data described in paragraph (1)(B)  
12 shall be provided to a qualified clinical data registry  
13 under paragraph (1) at a fee equal to the cost of  
14 providing such data. Any fee collected pursuant to  
15 the preceding sentence shall be deposited in the Cen-  
16 ters for Medicare & Medicaid Services Program  
17 Management Account.

18 (c) EXPANSION OF DATA AVAILABLE TO QUALIFIED  
19 ENTITIES.—Section 1874(e) of the Social Security Act  
20 (42 U.S.C. 1395kk(e)) is amended—

21 (1) in the subsection heading, by striking  
22 “MEDICARE”; and

23 (2) in paragraph (3)—

24 (A) by inserting after the first sentence the  
25 following new sentence: “Beginning July 1,

1           2015, if the Secretary determines appropriate,  
2           the data described in this paragraph may also  
3           include standardized extracts (as determined by  
4           the Secretary) of claims data under titles XIX  
5           and XXI for assistance provided under such ti-  
6           tles for one or more specified geographic areas  
7           and time periods requested by a qualified enti-  
8           ty.”; and

9                       (B) in the last sentence, by inserting “or  
10           under titles XIX or XXI” before the period at  
11           the end.

12           (d) REVISION OF PLACEMENT OF FEES.—Section  
13   1874(e)(4)(A) of the Social Security Act (42 U.S.C.  
14   1395kk(e)(4)(A)) is amended, in the second sentence—

15                       (1) by inserting “, for periods prior to July 1,  
16           2015,” after “deposited”; and

17                       (2) by inserting the following before the period  
18           at the end: “, and, beginning July 1, 2015, into the  
19           Centers for Medicare & Medicaid Services Program  
20           Management Account”.

21   **SEC. 2086. EMPOWERING PATIENT RESEARCH AND BETTER**  
22                       **OUTCOMES THROUGH CMS DATA.**

23           (a) IN GENERAL.—Not later than 60 days after the  
24           date of the enactment of this section, the Secretary of  
25           Health and Human Services shall promulgate interim final

1 regulations that permit an entity described in subsection  
2 (b) to obtain from the Secretary the data described in sub-  
3 section (c).

4 (b) ENTITIES DESCRIBED.—An entity described in  
5 this subsection is an entity that—

6 (1) is a State or a qualified researcher; and

7 (2) submits to the Secretary an application that  
8 includes—

9 (A) a description of the purposes for which  
10 the entity intends to use the data that the enti-  
11 ty seeks to obtain under subsection (a);

12 (B) a demonstration that the entity is  
13 qualified to perform the tasks necessary to  
14 achieve the purposes described by the entity  
15 pursuant to subparagraph (A); and

16 (C) an attestation by the entity that the  
17 entity will adhere to all requirements promul-  
18 gated by the Secretary with respect to the use  
19 of the data.

20 (c) DATA DESCRIBED.—The data described in this  
21 subsection, with respect to an entity described in sub-  
22 section (b), is data that—

23 (1) do not contain individually identifiable  
24 health information;

1           (2) are the minimum amount of data that are  
2           necessary for the entity to accomplish the purposes  
3           described by the entity pursuant to subparagraph  
4           (A) of paragraph (2) of such subsection in the attes-  
5           tation submitted by the entity under such para-  
6           graph; and

7           (3) relate to files designated by the Centers for  
8           Medicare & Medicaid Services as research-identifi-  
9           able files.

10          (d) DATA RELEASE PROCEDURES.—The Secretary of  
11          Health and Human Services shall ensure that any data  
12          made available to an entity described in subsection (b)  
13          pursuant to subsection (a) are made available in a manner  
14          that is in accordance with applicable data release proce-  
15          dures specified in Federal law and in regulations promul-  
16          gated by the Secretary relating to data privacy.

17          (e) DEFINITION.—In this section, the term “qualified  
18          researcher” means an individual with the education and  
19          experience necessary to design and conduct research prop-  
20          erly, as determined by the Secretary, regardless of the in-  
21          dividual’s commercial or institutional affiliation.

1 **SEC. 2087. ALLOWING CLINICAL DATA REGISTRIES TO COM-**  
2 **PLY WITH HIPAA PRIVACY AND SECURITY**  
3 **LAW IN LIEU OF COMPLYING WITH THE PRI-**  
4 **VACY AND SECURITY PROVISIONS OF THE**  
5 **COMMON RULE.**

6 (a) IN GENERAL.—The HITECH Act (title XIII of  
7 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  
9 et seq.) the following:

10 **“PART 3—COMPLIANCE BY CLINICAL DATA REG-**  
11 **ISTRIES WITH HIPAA PRIVACY AND SECU-**  
12 **RITY LAW**

13 **“SEC. 13431. RELATION TO PRIVACY AND SECURITY PROVI-**  
14 **SIONS OF THE COMMON RULE.**

15 “The Secretary shall—

16 “(1) identify the privacy and security provisions  
17 of—

18 “(A) subpart A of part 46 of title 45, Code  
19 of Federal Regulations (commonly referred to  
20 as the ‘Common Rule’); and

21 “(B) parts 50, 56, 312, and 812 of title  
22 21, Code of Federal Regulations; and

23 “(2) establish an exception to such provisions  
24 (or any successor provisions) under which a clinical  
25 data registry may, in lieu of complying with such  
26 provisions, choose to comply with the privacy and se-

1 security provisions of HIPAA privacy and security law  
2 (as such term is defined in section 3009 of the Pub-  
3 lic Health Service Act).”.

4 (b) REVISION OF REGULATIONS.—Not later than 12  
5 months after the date of enactment of this Act, the Sec-  
6 retary of Health and Human Services shall propose such  
7 guidance and regulations as may be necessary to imple-  
8 ment section 13431 of the HITECH Act, as added by sub-  
9 section (a).

10 **SEC. 2088. ACCESS TO CMS CLAIMS DATA FOR PURPOSES**  
11 **OF FRAUD ANALYTICS.**

12 Notwithstanding any other provision of law, the Sec-  
13 retary of Health and Human Services and the Commis-  
14 sioner of Social Security may allow access in real time to  
15 claims data under title XVIII of the Social Security Act  
16 (42 U.S.C. 1395 et seq.) by third parties certified by the  
17 Secretary or the Commissioner, as applicable, for purposes  
18 of fraud prevention.

19 **PART 3—BUILDING A 21ST CENTURY CLINICAL**  
20 **DATA SHARING SYSTEM**

21 **SEC. 2091. COMMISSION ON DATA SHARING FOR RESEARCH**  
22 **AND DEVELOPMENT.**

23 (a) ESTABLISHMENT.—The Secretary of Health and  
24 Human Services shall establish within the Department of  
25 Health and Human Services a commission to be known



1 as the “Commission on Data Sharing for Research and  
2 Development” (in this section referred to as the “Commis-  
3 sion”). The Commission shall be headed by a Director of  
4 Data Sharing for Research and Development (in this sec-  
5 tion referred to as the “Director”) appointed by the  
6 Speaker of the House of Representatives.

7 (b) DUTIES.—The duties of the Commission shall be  
8 to—

9 (1) with respect to the collection and dissemina-  
10 tion of clinical data, develop—

11 (A) methods to enable data obtained from  
12 individuals participating in a public health pro-  
13 gram, including the Medicare program under  
14 title XVIII of the Social Security Act, the Med-  
15 icaid program under title XIX of such Act, the  
16 Children’s Health Insurance Program under  
17 title XXI of such Act, and an Exchange estab-  
18 lished under title I of the Patient Protection  
19 and Affordable Care Act (Public Law 111–  
20 148), to be shared with a qualified entity (as  
21 defined in section 1874(e) of the Social Security  
22 Act (42 U.S.C. 1395kk(e)));

23 (B) uniform standards for the sharing by  
24 such a qualified entity or other entity of data  
25 so obtained; and

1 (C) other recommendations for the collec-  
2 tion and dissemination of such data, as appro-  
3 priate;

4 (2) with respect to the collection and dissemina-  
5 tion of clinical data in a clinical data registry, de-  
6 velop—

7 (A) processes and procedures to ensure  
8 that only valid data are entered into a clinical  
9 data registry, including processes and proce-  
10 dures for the development of standardized data  
11 definitions for use by health care providers  
12 (specific to each specialty) to enable real-time  
13 data migration between electronic health  
14 records used by such providers and such a reg-  
15 istry;

16 (B) appropriate data integrity and security  
17 standards to ensure that the validity of the data  
18 in a clinical data registry is maintained both  
19 during the active phase of the clinical data reg-  
20 istry and after closure of any special activities  
21 carried out by the registry;

22 (C) appropriate processes for adverse event  
23 adjudication with respect to the use of data  
24 from a clinical data registry;

1 (D) best practices to support audit prac-  
2 tices necessary to ensure the integrity of the  
3 data in a clinical data registry; and

4 (E) rules governing the review and access  
5 to data in such a registry, including rules estab-  
6 lishing—

7 (i) the review and acceptance process  
8 for requests and analysis of such data, tak-  
9 ing into consideration informed consent re-  
10 strictions, if any, and the objective of the  
11 initial clinical data registry activity;

12 (ii) controlled processes for the access  
13 and release of such data that take into ac-  
14 count—

15 (I) data privacy, data integrity  
16 and traceability concerns; and

17 (II) the effect that such access  
18 and release has on the market approv-  
19 als and patent exclusivity periods for  
20 drugs, biological products, and devices  
21 and patent exclusivity periods;

22 (iii) guidelines for data transparency;

23 (iv) a process for the sharing of such  
24 data that relates to a specific drug, biologi-  
25 cal product, or device, including how such

1 data are shared with the sponsor of the  
2 drug, biological product, or device; and

3 (v) a process for sharing such data  
4 with qualified scientific and medical re-  
5 searchers for purposes benefitting public  
6 health or patient care; and

7 (3) develop, for purposes of clinical research  
8 and clinical development and with respect to, a proc-  
9 ess to enable such a qualified entity or another enti-  
10 ty approved by the Secretary of Health and Human  
11 Services under paragraph (1) to—

12 (A) search across databases maintaining  
13 such data for de-identified information satis-  
14 fying characteristics specified by such entity;  
15 and

16 (B) receive such de-identified information  
17 satisfying such characteristics, whether or not  
18 data relating to such characteristics were in-  
19 cluded or specified in such a database using  
20 standardized or uniform terminology.

21 (c) MEMBERSHIP.—

22 (1) COMPOSITION.—The Commission shall be  
23 composed of 15 members appointed as follows:

1 (A) 5 individuals appointed by the Sec-  
2 retary, from among individuals who are officers  
3 and employees of the Federal Government;

4 (B) 5 individuals appointed by the Speaker  
5 of the House of Representatives.

6 (C) 5 individuals appointed by the majority  
7 leader of the Senate.

8 (2) REPRESENTATION OF STAKEHOLDERS.—  
9 Members appointed to the Commission shall include  
10 stakeholders including patients and experts in their  
11 field of expertise, including researchers, physicians,  
12 industry representatives, and health information  
13 technology providers.

14 (3) TERMS.—Each member shall be appointed  
15 for the life of the Commission.

16 (4) VACANCIES.—A vacancy in the Commission  
17 shall be filled in the manner in which the original  
18 appointment was made.

19 (d) MEETING.—Not later than one year after the  
20 date of the enactment of this Act, the Secretary shall con-  
21 vene a meeting of the Commission to carry out the duties  
22 of the Commission specified in subsection (b).

23 (e) REPORT.—Not later than one year after the date  
24 on which the meeting described in subsection (d) is held,  
25 the Commission shall submit to the Committee on Energy

1 and Commerce of the House of Representatives and the  
2 Committee on Health, Education, Labor, and Pensions of  
3 the Senate a report on the findings and conclusions of the  
4 Commission, together with its recommendations for legis-  
5 lation the Commission considers appropriate.

6 (f) DEFINITION.—In this section, the term “clinical  
7 data registry” means **【How should “clinical data registry”**  
8 *be defined?*】

9 (g) TERMINATION.—The Commission shall terminate  
10 on the date the report is submitted under subsection (e).

11 **SEC. 2092. RECOMMENDATIONS FOR DEVELOPMENT AND**  
12 **USE OF CLINICAL DATA REGISTRIES.**

13 (a) IN GENERAL.—Not later than one year after the  
14 date of the enactment of this Act, the Secretary of Health  
15 and Human Services shall make recommendations for the  
16 development and use, when appropriate, of clinical data  
17 registries that are integrated with clinical practice guide-  
18 lines and best practices or standards of care, including  
19 registries designed to minimize duplication and burden on  
20 those operating or reporting to such registries, for the im-  
21 provement of patient care. The Secretary shall make such  
22 recommendations available to the public by posting them  
23 on a public website of the Department of Health and  
24 Human Services.

1 (b) SPECIFIC RECOMMENDATIONS.—Such rec-  
2 ommendations, with respect to such registries, shall in-  
3 clude the following:

4 (1) Recommendations for a set of standards  
5 that, if adopted by such registries, would allow for  
6 the bidirectional, interoperable exchange of informa-  
7 tion between the electronic health records of the re-  
8 porting clinicians and such registries.

9 (2) Recommendations on how clinical registries,  
10 including outcomes-based registries, may be devel-  
11 oped and then used to evaluate various care models  
12 and methods, including improved clinical care co-  
13 ordination, and the impact of such models and meth-  
14 ods on the management of diseases as measured by  
15 appropriate care parameters based on clinical prac-  
16 tice guidelines and best practices (such as A1C,  
17 blood pressure, and cholesterol levels in the case of  
18 diabetes).

19 (3) Recommendations on how such registries  
20 should be structured to facilitate the recording and  
21 reporting of postmarket data for the purposes of  
22 monitoring safety and efficacy of FDA-approved de-  
23 vices and drugs, reporting relevant clinical data to  
24 satisfy attestation requirements for coverage of pre-  
25 scribed devices and drugs, and better defining appro-

1        appropriate clinical use in support of evidence develop-  
2        ment for the Medicare program (such as improving  
3        patient access to safe and effective glucose moni-  
4        toring systems and future glucose monitoring tech-  
5        nologies).

6            (4) Recommendations on how data from such  
7        registries may be used to inform physicians and  
8        other health care professionals regarding clinical  
9        practices for the prevention of diseases (such as dia-  
10       betes and the precursor conditions of diabetes) and  
11       appropriate methods for the dissemination of clinical  
12       practice support tools and other educational re-  
13       sources that may be derived from registry data.

14           (5) Recommendations for how registries can be  
15        used to promote preventive health benefits such as  
16        screenings and the Medicare annual wellness visits  
17        that may reduce the risk of chronic diseases (such  
18        as obesity, osteoporosis, cardiovascular disease, can-  
19        cer, diabetes, and their complications).

20        (c) CONSULTATION WITH CLINICAL EXPERTS.—The  
21        Secretary shall consult with national medical specialty so-  
22        cieties and with manufacturers of drugs and medical de-  
23        vices in the development of such recommendations as they  
24        relate to the diseases that they (or their manufactured  
25        drugs or devices) manage and treat (such as with



1 endocrinologists with respect to recommendations relating  
2 to diabetes and prediabetes conditions). **[Note on this sub-**  
3 *title: Are there other ideas for supporting the use of data*  
4 *to support new cures and increase the quality of patient*  
5 *care?]*

## 6 **Subtitle G—Utilizing Real-World** 7 **Evidence**

### 8 **SEC. 2101. UTILIZING REAL-WORLD EVIDENCE.**

9 Chapter V of the Federal Food, Drug, and Cosmetic  
10 Act, as amended by section 1261, is further amended by  
11 inserting after section 505G of such Act the following:

#### 12 **“SEC. 505H. UTILIZING REAL-WORLD EVIDENCE.**

13 “(a) IN GENERAL.—The Secretary shall establish a  
14 program under which a sponsor may submit real-world  
15 evidence for purposes including—

16 “(1) to support the approval of the use of a  
17 drug for a new indication; and

18 “(2) to support or satisfy post-approval study  
19 requirements.

20 “(b) REAL-WORLD EVIDENCE DEFINED.—In this  
21 section, the term ‘real-world evidence’ means data about  
22 the usage, benefits, or risks of a drug derived from sources  
23 other than randomized clinical trials, including from ob-  
24 servational studies and registries, used to establish safety  
25 or effectiveness under section 505(d).

1 “(c) GUIDANCE.—

2 “(1) IN GENERAL.—The Secretary shall—

3 “(A) not later than 12 months after the  
4 date of enactment of this section, issue draft  
5 guidance for implementation of the program  
6 under this section; and

7 “(B) not later 18 months after the date of  
8 enactment of this section, after providing an op-  
9 portunity for public comment on the draft guid-  
10 ance, issue final guidance for implementation of  
11 the program under this section.

12 “(2) CONTENTS OF GUIDANCE.—The guidance  
13 under paragraph (1) shall include guidance describ-  
14 ing—

15 “(A) the appropriate standards and meth-  
16 odologies for the collection and analysis of real-  
17 world evidence submitted for the purposes de-  
18 scribed in paragraphs (1) and (2) of subsection  
19 (a); and

20 “(B) the circumstances under which spon-  
21 sors of drugs and the Secretary may rely on  
22 real-world evidence for such purposes.

23 “(3) CONSULTATION.—In developing guidance  
24 under paragraph (1), the Secretary shall consult  
25 with the regulated industry, academia, organized

1 medicine, representatives of patient advocacy organi-  
2 zations and disease research foundations, and other  
3 interested parties through a public process.

4 “(d) REPORTS.—Not later than 2 years after the  
5 date of enactment of this section, and not later than 4  
6 years after such date of enactment, the Secretary shall  
7 submit to the Committee on Energy and Commerce of the  
8 House of Representatives and the Committee on Health,  
9 Education, Labor, and Pensions of the Senate, and make  
10 publicly available, a report on the implementation of the  
11 real-world evidence program under this section. The re-  
12 ports required by this subsection shall address the fol-  
13 lowing:

14 “(1) How the program under this section has  
15 been utilized by sponsors of drugs.

16 “(2) How the program under this section has  
17 impacted regulatory decisionmaking, including ‘sub-  
18 stantial evidence’ determinations under section  
19 505(d).

20 “(3) How the program under this section could  
21 be expanded for the use of real-world evidence for  
22 additional purposes.

23 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
24 tion prohibits the Secretary from using real-world evidence  
25 for purposes not specified in this section.”.

1                   **Subtitle H—Coverage With**  
2                   **Evidence Development**

3   **SEC. 2121. AUTHORITY FOR COVERAGE WITH EVIDENCE**  
4                   **DEVELOPMENT FOR MEDICAL DEVICES**  
5                   **UNDER THE MEDICARE PROGRAM.**

6           (a) EXCEPTION TO REASONABLE AND NECESSARY  
7 REQUIREMENT.—Section 1862(a)(1)(A) of the Social Se-  
8 curity Act (42 U.S.C. 1395y(a)(1)(A)) is amended by in-  
9 serting “or a CED item or service (as described in section  
10 1861(iii))” after “(as described in section 1861(ddd)(1))”.

11          (b) DEFINITION OF CED ITEM OR SERVICE.—Sec-  
12 tion 1861 of the Social Security Act (42 U.S.C. 1395x)  
13 is amended by adding at the end the following new sub-  
14 section:

15           “(iii) CED ITEM OR SERVICE.—

16                   “(1) IN GENERAL.—The term ‘CED item or  
17 service’ means an item or service that is for coverage  
18 with evidence development (as described in para-  
19 graph (2)).

20                   “(2) COVERAGE WITH EVIDENCE DEVELOP-  
21 MENT.—For purposes of paragraph (1), an item or  
22 service is for coverage with evidence development  
23 if—

24                           “(A) the item or service is furnished to in-  
25 dividuals as part of a clinical study performed

1 to determine whether the furnishing of such  
2 item or service improves the health outcomes of  
3 such individuals, as determined under para-  
4 graph (3); and

5 “(B) the furnishing of the item or service  
6 to the individual is determined by the Secretary  
7 to be reasonable and necessary to the carrying  
8 out of such clinical study.

9 “(3) DETERMINATION OF IMPROVED HEALTH  
10 OUTCOMES.—For purposes of paragraph (2)(A), a  
11 determination of whether the furnishing to individ-  
12 uals of items or services improves the health out-  
13 comes of such individuals shall be determined by as-  
14 sessing whether the furnishing of such items or serv-  
15 ices improves the—

16 “(A) diagnosis or treatment of illnesses or  
17 injuries of such individuals (as compared to the  
18 diagnosis or treatment of illnesses or injuries of  
19 comparable individuals who are not so furnished  
20 such items or services); or

21 “(B) functioning of malformed body mem-  
22 bers of such individuals (as compared to the  
23 functioning of malformed body members of  
24 comparable individuals who are not so furnished  
25 such items or services).”.

1 (c) LOCAL COVERAGE DETERMINATIONS.—Section  
2 1869(f)(2)(B) of the Social Security Act (42 U.S.C.  
3 1395ff(f)(2)(B)) is amended by adding at the end the fol-  
4 lowing new sentence: “For purposes of the preceding sen-  
5 tence, a determination of whether a particular item or  
6 service is subject to the exception for CED items and serv-  
7 ices described in section 1862(a)(1)(A) shall be considered  
8 to be a determination respecting whether such item or  
9 service is so covered in accordance with such section.”

## 10 **Subtitle I—Combination Products**

### 11 **SEC. 2141. REGULATION OF COMBINATION PRODUCTS BY** 12 **THE FOOD AND DRUG ADMINISTRATION.**

13 Section 503(g) of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 353(g)) is amended—

15 (1) in paragraph (4)(C), by adding at the end  
16 the following:

17 “(iii) The Office shall ensure that the agency center  
18 with primary jurisdiction for the premarket review of a  
19 combination product shall be the sole point of contact for  
20 the sponsor of the product. The Office shall also coordi-  
21 nate communications to and from any consulting agency  
22 center involved in such premarket review. Agency commu-  
23 nications and commitments from the center with primary  
24 jurisdiction shall be binding on all other centers involved  
25 in the review.

1           “(iv) The Office shall, with respect to the premarket  
2 review of a combination product—

3                   “(I) ensure that any meeting between the Food  
4 and Drug Administration and the sponsor of the  
5 product is attended by each agency center involved  
6 in the review;

7                   “(II) require that each consulting agency center  
8 has completed its premarket review and provided the  
9 results of such review to the agency center with pri-  
10 mary jurisdiction within timeframes that allow the  
11 agency center with primary jurisdiction to meet the  
12 review goals established pursuant to the most recent  
13 authorization or reauthorization of parts 2, 3, 7, and  
14 8, as applicable, of subchapter C of title VII; and

15                   “(III) ensure that each consulting agency cen-  
16 ter complies with the guidance described in clause  
17 (vi) and other relevant regulations, guidances, and  
18 policies.

19           “(v) Not later than 10 days after the receipt by an  
20 agency center of an application under section 505, 510(k),  
21 or 520 of this Act, or under section 351 of the Public  
22 Health Service Act, for a combination product or an appli-  
23 cation for investigational use of a combination product  
24 under section 505(i) or 520(g), the agency center shall  
25 inform the Office of such receipt.

1           “(vi) Not later than 1 year after the date of enact-  
2 ment of the 21st Century Cures Act, the Secretary shall  
3 issue final guidance that describes the responsibilities of  
4 each agency center regarding its review of combination  
5 products, including each center’s role in evaluating label-  
6 ing, product usability assessments, and human factors  
7 testing. The Office shall, after soliciting public comment,  
8 review and update the guidance at least biannually and  
9 specify in such updated guidance the reasons for updates.

10           “(vii) Before finalizing any guidance developed by an  
11 agency center or centers under this subparagraph the Of-  
12 fice shall review the guidance to determine its applicability  
13 to combination products. If applicable, the Office shall en-  
14 sure that such guidance is consistent with the require-  
15 ments of subparagraph (F).”;

16           (2) in paragraph (4)(G)—

17                   (A) in clause (ii), by striking “and” at the  
18 end;

19                   (B) in clause (iii), by striking the period at  
20 the end and inserting a semicolon; and

21                   (C) by adding at the end the following:

22                   “(iv) identifying the percentage of combination  
23 products for which a dispute resolution, with respect  
24 to premarket review, was requested by the combina-  
25 tion product’s sponsor; and



1           “(v) identifying the percentage of meetings be-  
2           tween the Food and Drug Administration and the  
3           sponsor of a combination product at which all of the  
4           centers participating in the review of the combina-  
5           tion product were in attendance, as required by sub-  
6           paragraph (C)(iv)(I).”; and

7           (3) in paragraph (5), by adding at the end the  
8           following:

9           “(D) The terms ‘premarket review’ and ‘re-  
10          views’ include all activities of the Food and Drug  
11          Administration conducted prior to approval or clear-  
12          ance of an application or notification submitted  
13          under section 505, 510(k), 515, or 520 of this Act  
14          or under section 351 of the Public Health Service  
15          Act, including with respect to investigational use of  
16          the product.”.

17 **SEC. 2142. GAO REPORT ON FDA REGULATION OF COM-**  
18 **BINATION PRODUCTS.**

19          (a) IN GENERAL.—Not later than 1 year after the  
20          date of enactment of this Act, the Comptroller General  
21          of the United States shall submit to the Congress a report  
22          on the regulation by the Food and Drug Administration  
23          (in this section referred to as the “FDA”) of combination  
24          products.

1 (b) ISSUES TO BE ADDRESSED.—The report under  
2 subsection (a) shall provide information on the following:

3 (1) The number of letters of request (as defined  
4 in section 3.2(j) of title 21, Code of Federal Regula-  
5 tions) the Food and Drug Administration received  
6 each year during the period beginning with 2003  
7 and ending with 2013 (in this subsection referred to  
8 as the “applicable 11-year period”) that were sent to  
9 the Office of Combination Products.

10 (2) How do the designations made by the Food  
11 and Drug Administration, pursuant to such letters,  
12 compare to the sponsor’s requested designation (in-  
13 cluding both formal and informal requests)?

14 (3) How many combination product applica-  
15 tions (including new drug applications, biological  
16 products license applications, and premarket clear-  
17 ance notifications) have been received annually by  
18 the FDA during the applicable 11-year period?

19 (4) For informal requests for designation, as  
20 described in paragraph (1), how often did sponsors  
21 submit in accordance with the advice received (with  
22 respect to the lead center)? How many times annu-  
23 ally in the applicable 11-year period did a sponsor  
24 submit an application to one center and have it reas-  
25 signed to another center?

1 (5) Is there a formal internal process that docu-  
2 ments the inter-center consultation and review and  
3 ensures the feedback from both centers is sent to the  
4 sponsor? If so, what is the process and how often is  
5 it followed (or was it followed during the applicable  
6 11-year period)? How do sponsors have access to  
7 those inter-center consulting reviews? How many  
8 times during the applicable 11-year period did a  
9 sponsor request consulting center participation and  
10 not have it occur? How far into the review process  
11 does one center bring the other centers for con-  
12 sulting reviews, including whether other centers are  
13 included during presubmission consulting reviews?

14 (6) Is there a well-established process across  
15 the centers determining when simulated use (such as  
16 human factor studies and labeling comprehension  
17 studies)(HF) versus use in clinical trials are re-  
18 quired for instructions for use (IFU)? Is there a  
19 consistent unit that reviews HF studies, independent  
20 of the lead center? If not, is there a process for de-  
21 termining who reviews HF studies?

22 (7) How many products types are regulated as  
23 combination products that were previously regulated  
24 by a single center (such as drug-coated devices and  
25 drug-delivery devices? How many products annually

1 during the applicable 11-year period were impacted  
2 by these changes in categorizations? What types of  
3 products (such as integral, co-labeled, kitted prod-  
4 ucts) constitute the increase in the number of com-  
5 bination products during the applicable 11-year pe-  
6 riod? How did the FDA make the decision to change  
7 the regulation of these products?

8 (8) Does the Office of the Commissioner of  
9 Food and Drugs have a process to collect metrics re-  
10 garding the management of the combination product  
11 review process, including the following:

12 (A) Are there dedicated project managers  
13 or team leaders assigned with accountability for  
14 oversight of—

15 (i) the metrics for review meetings  
16 with required joint center review teams  
17 and transparent review reports and meet-  
18 ings; and

19 (ii) decision timelines, authorities, and  
20 milestones built into the application and  
21 review process?

22 (B) Does the Office ensure the Office's in-  
23 volvement in any guidance of the Food and  
24 Drug Administration that addresses combina-  
25 tion products, such as in the development of the

1 draft Guidance for Industry on Rheumatoid Ar-  
2 thritis: Developing Drug Products for Treat-  
3 ment?

4 (C) Does the Office play a role in estab-  
5 lishing cross-center expert committees or cen-  
6 ters of excellence to uniformly review scientific  
7 aspects that span the centers (such as single  
8 Human Factor review committee)?

9 (9) What training does FDA staff receive on  
10 combination product review and regulation? Has the  
11 FDA developed training on methodologies and in-  
12 spection approaches, such as quality by design, crit-  
13 ical or risk-based inspection and review practices,  
14 patient-focused reviews, human factor testing, bio-  
15 compatibility testing, bridging study designs, and  
16 endpoints for device design or drug/biological prod-  
17 uct formulation changes before and after marketing?

18 (10) What are the experience and expertise of  
19 the staff of the Office of Combination Products (es-  
20 tablished under section 503(g)(4)(A) of the Federal  
21 Food, Drug, and Cosmetic Act (21 U.S.C.  
22 353(g)(4)(A))?

23 (c) RECOMMENDATIONS.—The report under sub-  
24 section (a) shall include such recommendations as the  
25 Comptroller General may have to improve the process for

1 the timely and efficient development and review of com-  
2 bination products.

3 (d) COMBINATION PRODUCT DEFINED.—In this sec-  
4 tion, the term “combination product” means a combina-  
5 tion product as such term is used in section 503(g) of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 353(g)).

8 **Subtitle J—Modernizing**  
9 **Regulation of Diagnostics**

10 **SEC. 2161. [TO BE SUPPLIED].**

11 **Subtitle K—Interoperability**

12 **SEC. 2181. [TO BE SUPPLIED].**

13 **Subtitle L—NIH—Federal Data**  
14 **Sharing**

15 **SEC. 2201. SHARING OF DATA GENERATED THROUGH NIH-**  
16 **FUNDED RESEARCH.**

17 Part H of title IV of the Public Health Service Act  
18 (42 U.S.C. 289 et seq.) is amended by adding at the end  
19 the following:

20 **“SEC. 498E. SHARING OF DATA GENERATED THROUGH NIH-**  
21 **FUNDED RESEARCH.**

22 “(a) AUTHORITY.—As a condition on the award of  
23 a grant or the provision of other financial support for re-  
24 search, irrespective of whether the research is fully or only  
25 partially funded through such grant or other support, the

1 Director of NIH may require the recipient of such grant  
2 or other support to agree to share with the public data  
3 generated through such research.

4 “(b) LIMITATION.—Subsection (a) does not authorize  
5 the Director of NIH to require the sharing of—

6 “(1) any individually identifiable information  
7 with respect to a human subject participating in the  
8 research; or

9 “(2) any trade secret or commercial or financial  
10 information that is privileged or confidential.”.

11 **Subtitle M—Accessing, Sharing,**  
12 **and Using Health Data for Re-**  
13 **search Purposes**

14 **SEC. 2221. ACCESSING, SHARING, AND USING HEALTH DATA**  
15 **FOR RESEARCH PURPOSES.**

16 (a) IN GENERAL.—The HITECH Act (title XIII of  
17 division A of Public Law 111–5), as amended by section  
18 2087, is further amended by adding at the end of subtitle  
19 D of such Act (42 U.S.C. 17921 et seq.) the following:

20 **“PART 4—ACCESSING, SHARING, AND USING**  
21 **HEALTH DATA FOR RESEARCH PURPOSES**

22 **“SEC. 13441. DEFINING HEALTH DATA RESEARCH AS PART**  
23 **OF HEALTH CARE OPERATIONS.**

24 “(a) IN GENERAL.—Subject to subsection (b), the  
25 Secretary shall allow the use and disclosure of protected

1 health information by a covered entity for research pur-  
2 poses, including studies whose purpose is to obtain gener-  
3 alizable knowledge, to be treated as the use and disclosure  
4 of such information for health care operations described  
5 in subparagraph (1) of the definition of health care oper-  
6 ations in section 164.501 of title 45, Code of Federal Reg-  
7 ulations (or any successor regulations).

8 “(b) MODIFICATIONS TO RULES FOR DISCLOSURES  
9 FOR HEALTH CARE OPERATIONS.—In applying section  
10 164.506, of title 45, Code of Federal Regulations (or any  
11 successor regulation), to the disclosure of protected health  
12 information described in subsection (a)—

13 “(1) the Secretary shall require that the disclo-  
14 sure be made by the covered entity to—

15 “(A) another covered entity for health care  
16 operations (as defined in such section 164.501  
17 of such title);

18 “(B) a business associate that has entered  
19 into a contract with the disclosing covered enti-  
20 ty to perform health care operations; or

21 “(C) a business associate for the purpose  
22 of data aggregation (as defined in such section  
23 164.501); and



1           “(2) the disclosure shall not be subject to the  
2           limitation described in section 164.506(c)(4) of such  
3           title (or any successor regulation).

4   **“SEC. 13442. TREATING DISCLOSURES OF PROTECTED**  
5                   **HEALTH INFORMATION FOR RESEARCH SIMI-**  
6                   **LARLY TO DISCLOSURES OF SUCH INFORMA-**  
7                   **TION FOR PUBLIC HEALTH PURPOSES.**

8           “(a) REMUNERATION.—The Secretary shall authorize  
9           the disclosure of protected health information for research  
10          purposes pursuant to section 164.502(a)(5)(ii)(B)(2)(ii)  
11          of title 45, Code of Federal Regulations (or any successor  
12          regulation), without applying the limitation on remunera-  
13          tion described in such section.

14          “(b) PERMITTED USES AND DISCLOSURES.—The  
15          public health activities and purposes for which a covered  
16          entity may disclose protected health information to a per-  
17          son subject to the jurisdiction of the Food and Drug Ad-  
18          ministration with respect to a product or activity regulated  
19          by such Administration for which that person has respon-  
20          sibility, as described in section 164.512(b)(1)(iii) of title  
21          45, Code of Federal Regulations (or any successor regula-  
22          tion), shall include research activities, including compara-  
23          tive effectiveness research activities.

1 **“SEC. 13443. PERMITTING REMOTE ACCESS TO PROTECTED**  
2 **HEALTH INFORMATION BY RESEARCHERS.**

3 “Subparagraph (B) of section 164.512(i)(1)(ii) of  
4 title 45, Code of Federal Regulations (prohibiting the re-  
5 moval of protected health information by a researcher) (or  
6 any successor regulation) shall not prohibit remote access  
7 to health information by a researcher from a portal or  
8 other access point outside of the covered entity so long  
9 as—

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

12 “(2) the protected health information is not  
13 copied or otherwise retained by the researcher.

14 **“SEC. 13444. ALLOWING ONE-TIME AUTHORIZATION OF USE**  
15 **AND DISCLOSURE OF PROTECTED HEALTH**  
16 **INFORMATION FOR RESEARCH PURPOSES.**

17 “(a) IN GENERAL.—In applying section 164.508(c)  
18 of title 45, Code of Federal Regulations, with respect to  
19 the use or disclosure of protected health information of  
20 an individual for research purposes, the individual may  
21 submit a one-time valid authorization for the use or dislo-  
22 sure of protected health information of the individual with  
23 respect to all future research purposes, including the use  
24 and disclosure of protected health information of the indi-  
25 vidual that is collected after the date of such authoriza-  
26 tion, and such one-time authorization shall satisfy the re-

1 quirement under paragraph (1)(iv) of such section with  
2 respect to such future research if such authorization—

3 “(1) sufficiently explains that the information  
4 will be used and disclosed for future research;

5 “(2) states that the authorization will remain  
6 valid unless and until it is withdrawn by the indi-  
7 vidual; and

8 “(3) permits the individual, and provides in-  
9 struction to the individual on how to opt-out of, or  
10 otherwise withdraw, such authorization at any time.

11 “(b) WITHDRAWAL OF AUTHORIZATION.—A with-  
12 drawal pursuant to subsection (a) of a valid authorization  
13 with respect to the use or disclosure of protected health  
14 information of an individual for research purposes shall  
15 terminate such authorization for any use or disclosure  
16 after the date of such withdrawal, provided that a reason-  
17 able period of time for implementation of such termination  
18 of authorization shall be specified by the Secretary, not  
19 to exceed 60 days. Such withdrawal shall not affect re-  
20 search using the protected health information of the indi-  
21 vidual that has been undertaken before such implementa-  
22 tion date in reliance on the valid authorization.

1 **“SEC. 13445. STRENGTHENING PRIVACY AND SECURITY**  
2 **PROTECTION OF HEALTH DATA USED FOR**  
3 **RESEARCH.**

4 “(a) IN GENERAL.—In applying paragraph (e)(1) of  
5 section 164.514 of title 45, Code of Federal Regulations,  
6 a covered entity may use or disclose a limited data set  
7 for research purposes, without a data use agreement as  
8 required by paragraph (e)(4) of such section 164.514 only  
9 if the requirements described in subsection (b) are satis-  
10 fied.

11 “(b) REQUIREMENTS.—For purposes of subsection  
12 (a), the requirements described in this subsection, with re-  
13 spect to the use or disclosure of a limited data set for  
14 research purposes, are the following:

15 “(1) The specific use of such limited data set  
16 has been reviewed and approved by an institutional  
17 review board that is registered with the Department  
18 of Health and Human Services.

19 “(2) The recipient of such limited data set pro-  
20 tects the limited data set with safeguards that con-  
21 form to the required and addressable standards and  
22 implementation specifications set forth in sections  
23 164.308, 164.310, 164.312, and 164.316 of title 45,  
24 Code of Federal Regulations.

25 “(c) NO RE-IDENTIFICATION OF HEALTH INFORMA-  
26 TION USED OR DISCLOSED FOR RESEARCH.—

1           “(1) IN GENERAL.—Subject to paragraph (2),  
2           no person who has received or been granted access  
3           to a limited data set or health information that has  
4           been de-identified, in accordance with paragraphs  
5           (a) through (c) of section 164.514 of title 45, Code  
6           of Federal Regulations, may:

7                   “(A) knowingly identify or contact, or at-  
8                   tempt to identify or contact, individuals whose  
9                   data are included in the limited data set or de-  
10                  identified health information; or

11                  “(B) knowingly permit or authorize a third  
12                  party to knowingly identify or contact, or at-  
13                  tempt to identify or contact, individuals whose  
14                  data are included in the limited data set or de-  
15                  identified health information.

16           “(2) EXCEPTION.—The prohibition under para-  
17           graph (1) shall not apply to a person who has re-  
18           ceived or been granted access to a limited data set  
19           or health information that has been de-identified if  
20           the person performs the functions of identifying or  
21           contacting individuals whose data are included in the  
22           limited data set or de-identified health information  
23           on behalf of a covered entity pursuant to a business  
24           associate agreement in compliance with the require-

1       ments under section 164.504(e) of title 45, Code of  
2       Federal Regulations.

3           “(3) PENALTY.—The provisions of subsections  
4       (a) and (b) of section 1176 of the Social Security  
5       Act (42 U.S.C. 1320d–5) shall apply to a violation  
6       of paragraph (1) in the same manner as such provi-  
7       sions apply to a violation of a provision of part C  
8       of title XI of such Act. Any person or entity receiv-  
9       ing a limited data set or de-identified health infor-  
10      mation pursuant to this section who is in violation  
11      of paragraph (1) shall be criminally punishable  
12      under subsections (a) and (b) of section 1176 of the  
13      Social Security Act (42 U.S.C. 1320d–5) or other  
14      relevant Federal criminal statutes.

15          “(d) LIMITED DATA SET DEFINED.—For purposes  
16      of this section, the term ‘limited data set’ means a limited  
17      data set described in section 164.514(e)(2) of title 45,  
18      Code of Federal Regulations.”.

19          (b) REVISION OF REGULATIONS.—Not later than 12  
20      months after the date of the enactment of this Act, the  
21      Secretary of Health and Human Services shall revise the  
22      provisions of title 45, Code of Federal Regulations, for  
23      consistency with part 4 of subtitle D of the HITECH Act,  
24      as added by subsection (a).

1     **Subtitle N—21st Century Chronic**  
2                    **Disease Initiative Act**

3     **SEC. 2241. PLAN FOR LONGITUDINAL STUDY ON OUTCOMES**  
4                    **OF PATIENTS WITH A CHRONIC DISEASE.**

5           (a) DEVELOPMENT AND SUBMISSION.—Not later  
6 than 1 year after the date of enactment of this Act, the  
7 Secretary of Health and Human Services, in consultation  
8 with the Director of the National Institutes of Health,  
9 shall develop and submit to the appropriate committees  
10 of the Congress a plan to carry out a longitudinal study  
11 designed to improve the outcomes of patients with a  
12 chronic disease through better understanding of risk, tran-  
13 sition from wellness to disease, disease progression, diag-  
14 nosis, and other factors related to chronic disease, includ-  
15 ing by identifying potential targets for preventive or thera-  
16 peutic intervention.

17          (b) CONTENTS.—The plan developed under sub-  
18 section (a) shall—

19               (1) ensure that the longitudinal study’s design  
20               and execution can support the goal of improving the  
21               outcomes of patients with a chronic disease;

22               (2) address the roles of the following types of  
23               people in developing the plan and implementing the  
24               longitudinal study: scientific and medical research-  
25               ers, patient representatives, experts in the design

1 and implementation of longitudinal studies related to  
2 chronic disease, health care providers with expertise  
3 in chronic disease, ethicists, academic researchers,  
4 government researchers, representatives of clinical  
5 research organizations, and scientific or medical  
6 staff from biopharmaceutical manufacturers and de-  
7 velopers;

8 (3) identify existing and ongoing studies that  
9 are relevant to informing and developing the longitu-  
10 dinal study;

11 (4) include in the plan a description of how pa-  
12 tient cohorts will be utilized, coordinated, and ex-  
13 panded in support of the longitudinal study to en-  
14 sure sufficient enrollment; and

15 (5) include a description of how the efforts of  
16 researchers and investigators participating in the  
17 longitudinal study will interact and be coordinated  
18 with other chronic disease research efforts, including  
19 research under the National Alzheimer's Project Act.

## 20 **Subtitle O—Helping Young** 21 **Emerging Scientists**

### 22 **SEC. 2261. FUNDING RESEARCH BY EMERGING SCIENTISTS** 23 **THROUGH COMMON FUND.**

24 (a) USE OF FUNDS.—Section 402(b)(7)(B) of the  
25 Public Health Service Act (42 U.S.C. 282) is amended—



1 (1) in clause (i), by striking “and” at the end;

2 (2) by redesignating clause (ii) as clause (iii);

3 and

4 (3) by inserting after clause (i) the following:

5 “(ii) shall, with respect to funds reserved under  
6 section 402A(e)(1)(C) for the Common Fund, allo-  
7 cate such funds to the national research institutes  
8 and national centers for conducting and supporting  
9 research that is identified under subparagraph (A)  
10 and is carried out by one or more emerging sci-  
11 entists (as defined in section 402A(e)(1)(C)(iv));  
12 and”.

13 (b) RESERVATION OF FUNDS.—Section 402A(e)(1)  
14 of the Public Health Service Act (42 U.S.C. 282a(e)(1))  
15 is amended—

16 (1) by redesignating subparagraphs (C) and  
17 (D) as subparagraphs (D) and (E), respectively; and

18 (2) by inserting after subparagraph (B) the fol-  
19 lowing:

20 “(C) ADDITIONAL RESERVATION FOR RE-  
21 SEARCH BY EMERGING SCIENTISTS.—

22 “(i) INAPPLICABILITY OF TAP FOR  
23 EVALUATION ACTIVITIES.—Beginning with  
24 fiscal year 2015, funds appropriated to the

1 National Institutes of Health shall not be  
2 subject to section 241.

3 “(ii) RESERVATION.—In addition to  
4 the amounts reserved for the Common  
5 Fund under subparagraph (B) and  
6 amounts appropriated to the Common  
7 Fund under subsection (a)(2), the Director  
8 of NIH shall reserve an amount for the  
9 Common Fund for fiscal year 2015 and  
10 each subsequent fiscal year that is equal to  
11 the amount that, but for clause (i), would  
12 be made available under section 241 for  
13 evaluation activities for such fiscal year.

14 “(iii) PURPOSE OF RESERVATION.—  
15 Amounts reserved under clause (ii) shall be  
16 used for the purpose of carrying out sec-  
17 tion 402(b)(7)(B)(ii) (relating to the con-  
18 duct and support of research that is identi-  
19 fied under section 402A(b)(7)(A) and is  
20 carried out by one or more emerging sci-  
21 entists).

22 “(iv) DEFINITION.—In this subpara-  
23 graph, the term ‘emerging scientist’ means  
24 an investigator who—

1 “(I) will be the principal investi-  
2 gator or the program director of the  
3 proposed research;

4 “(II) has never been awarded, or  
5 has been awarded only once, a sub-  
6 stantial, competing grant by the Na-  
7 tional Institutes of Health for inde-  
8 pendent research; and

9 “(III) is within 15 years of hav-  
10 ing completed—

11 “(aa) the investigator’s ter-  
12 minal degree; or

13 “(bb) a medical residency  
14 (or the equivalent).”.

15 (c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION  
16 AGAINST TRANSFER.—Funds reserved pursuant to sec-  
17 tion 402A(c)(1)(C) of the Public Health Service Act, as  
18 added by subsection (b)—

19 (1) shall be used to supplement, not supplant,  
20 the funds otherwise allocated by the National Insti-  
21 tutes of Health for young investigators; and

22 (2) notwithstanding any transfer authority in  
23 any appropriation Act, shall not be used for any  
24 purpose other than allocating funds as described in

1 section 402(b)(7)(B)(ii) of the Public Health Service  
2 Act, as added by subsection (a).

3 (d) CONFORMING AMENDMENTS.—

4 (1) Section 241(a) of the Public Health Service  
5 Act (42 U.S.C. 238j(a)) is amended by striking  
6 “Such portion” and inserting “Subject to section  
7 402A(c)(1)(C)(i), such portion”.

8 (2) Section 402A(a)(2) of the Public Health  
9 Service Act is amended—

10 (A) by striking “402(b)(7)(B)(ii)” and in-  
11 serting “402(b)(7)(B)(iii)”; and

12 (B) by striking “reserved under subsection  
13 (c)(1)(B)(i)” and inserting “reserved under  
14 subparagraph (B)(i) or (C)(ii) of subsection  
15 (c)(1)”.

16 (3) Section 3(c)(2) of the Gabriella Miller Kids  
17 First Research Act (Public Law 113–94) is amended  
18 by striking “402(b)(7)(B)(ii) of the Public Health  
19 Service Act, as added by subsection (a)” and insert-  
20 ing “402(b)(7)(B)(iii) of the Public Health Service  
21 Act, as added by subsection (a) and redesignated by  
22 section 2(a) of the YES to Cures Act of 2014”.

23 (e) RULE OF CONSTRUCTION.—Nothing in this Act  
24 (and the amendments made by this Act) is intended to

1 affect the amount of funds authorized to be appropriated  
2 to the Agency for Healthcare Research and Quality.

3 **SEC. 2262. REPORT ON TRENDS IN AGE OF RECIPIENTS OF**  
4 **NIH-FUNDED MAJOR RESEARCH GRANTS.**

5 Not later than six months after the date of enactment  
6 of this Act, the Director of the National Institutes of  
7 Health shall submit a report to the Congress—

8 (1) explaining why, over the 30-year period pre-  
9 ceding the enactment of this Act—

10 (A) there has been a substantial increase  
11 in the age of investigators receiving their first  
12 major research grant from the National Insti-  
13 tutes of Health;

14 (B) there has been a substantial increase  
15 in the average age of all recipients of major re-  
16 search grants from the National Institutes of  
17 Health; and

18 (C) there has been a dramatic drop in the  
19 number of investigators under 40 years of age  
20 receiving major research grants from the Na-  
21 tional Institutes of Health; and

22 (2) describing—

23 (A) the steps taken by the National Insti-  
24 tutes of Health in recent years to address the  
25 trends identified in paragraph (1); and

1 (B) the impact of taking such steps.

2 **Subtitle P—Fostering High-Risk,**  
3 **High-Reward Science**

4 **SEC. 2281. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**  
5 **GRAM.**

6 Part B of title IV of the Public Health Service Act  
7 (42 U.S.C. 284 et seq.) is amended by adding at the end  
8 the following:

9 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**  
10 **GRAM.**

11 “The director of each national research institute, in  
12 collaboration with other scientists, shall—

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

18 “(2) set aside a specific percentage of funding,  
19 to be determined by the Director of NIH for each  
20 national research institute, for such projects.”.

1       **Subtitle Q—Precision Medicine**

2       **SEC. 2301. [TO BE SUPPLIED].**

3               **TITLE III—MODERNIZING**  
4               **CLINICAL TRIALS**

5               **Subtitle A—Clinical Research**  
6               **Modernization**

7       **SEC. 3001. PROTECTION OF HUMAN SUBJECTS IN RE-**  
8               **SEARCH; APPLICABILITY OF RULES.**

9               Part H of title IV of the Public Health Service Act  
10       (42 U.S.C. 289 et seq.) is amended by inserting after sec-  
11       tion 491 the following section:

12       **“SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RE-**  
13               **SEARCH; APPLICABILITY OF RULES.**

14               “(a) PROTECTION OF HUMAN SUBJECTS.—

15                       “(1) IN GENERAL.—All human subject research  
16       described in paragraph (2)(A) shall be conducted in  
17       accordance with the HHS Human Subject Regula-  
18       tions, and as applicable to the human subjects in-  
19       volved in such research, with the vulnerable-popu-  
20       lations rules.

21                       “(2) APPLICABILITY.—

22                               “(A) IN GENERAL.—This section applies to  
23       human subject research that is—

1 “(i) conducted or supported by the  
2 Department of Health and Human Serv-  
3 ices; or

4 “(ii) otherwise subject to regulation  
5 by the Department under a provision of  
6 Federal law (other than this section).

7 “(B) OTHER FEDERAL DEPARTMENTS AND  
8 AGENCIES.—The Secretary shall make available  
9 assistance to any Federal department or agency  
10 seeking—

11 “(i) to improve the regulation or over-  
12 sight of human subject research; or

13 “(ii) to apply the HHS Human Sub-  
14 ject Regulations or the vulnerable-popu-  
15 lations rules to human subject research  
16 that is conducted, supported, or regulated  
17 by such department or agency.

18 “(b) HHS HUMAN SUBJECT REGULATIONS; OTHER  
19 DEFINITIONS.—

20 “(1) HHS HUMAN SUBJECT REGULATIONS;  
21 VULNERABLE-POPULATIONS RULES.—For purposes  
22 of this section:

23 “(A) The term ‘HHS Human Subject Reg-  
24 ulations’—



1 “(i) subject to clause (ii), means the  
2 provisions of subpart A of part 46 of title  
3 45, Code of Federal Regulations (or any  
4 successor regulations); and

5 “(ii) in the case of human subject re-  
6 search that is subject to the Federal Food,  
7 Drug, and Cosmetic Act or to section 351  
8 of this Act, means the provisions of parts  
9 50, 56, 312, and 812 of title 21, Code of  
10 Federal Regulations (or any successor reg-  
11 ulations).

12 “(B) The term ‘vulnerable-populations  
13 rules’—

14 “(i) subject to clause (ii), means the  
15 provisions of subparts B through D of  
16 such part 46 (or any successor regula-  
17 tions); and

18 “(ii) as applicable to the human sub-  
19 jects involved in research described in sub-  
20 paragraph (A), means the provisions appli-  
21 cable to vulnerable populations under part  
22 56 of such title 21 (or any successor regu-  
23 lations) and subpart D of part 50 of such  
24 title 21 (or any successor regulations).

1           “(2) HUMAN SUBJECT RESEARCH.—For pur-  
2           poses of this section:

3                   “(A) Except as provided in subparagraph  
4                   (B), the term ‘human subject research’ means  
5                   research, as defined in subpart A of part 46 of  
6                   title 45, Code of Federal Regulations (or any  
7                   successor regulations), that involves a human  
8                   subject, as defined in such subpart A (or any  
9                   successor regulations).

10                   “(B) In the case of an investigation that is  
11                   subject to the provisions of part 50 of title 21,  
12                   Code of Federal Regulations (or any successor  
13                   regulations), the term ‘human subject’ has the  
14                   meaning given such term in such part 50, and  
15                   the term ‘human subject research’ means a clin-  
16                   ical investigation as defined in such part 50.

17           “(3) OTHER DEFINITIONS.—For purposes of  
18           this section:

19                   “(A) The term ‘institutional review board’  
20                   has the meaning that applies to the term ‘insti-  
21                   tutional review board’ under the HHS Human  
22                   Subject Regulations.

23                   “(B) The term ‘lead institutional review  
24                   board’ means an institutional review board that  
25                   otherwise meets the requirements of the HHS

1 Human Subject Regulations and enters into a  
2 written agreement with an institution, another  
3 institutional review board, a sponsor, or a prin-  
4 cipal investigator to approve and oversee human  
5 subject research that is conducted at multiple  
6 locations. References to an institutional review  
7 board include an institutional review board that  
8 serves a single institution as well as a lead in-  
9 stitutional review board.

10 “(c) SCOPE OF AUTHORITY OF SECRETARY.—

11 “(1) IN GENERAL.—The HHS Human Subject  
12 Regulations (including provisions regarding exemp-  
13 tions) and the vulnerable-populations rules, as in ef-  
14 fect on the day before the date of the enactment of  
15 the 21st Century Cures Act, continue to be in effect  
16 on and after such date, subject to paragraph (2).

17 “(2) MODIFICATIONS.—

18 “(A) COMPLIANCE WITH LAW.—Promptly  
19 after the date of the enactment of the Act re-  
20 ferred to in paragraph (1), the Secretary shall  
21 promulgate regulations to make such modifica-  
22 tions to the provisions of the HHS Human  
23 Subject Regulations as may be necessary to en-  
24 sure that such provisions implement, and do not  
25 conflict with, this section.

1           “(B) OTHER MODIFICATIONS.—This sec-  
2           tion may not be construed as affecting the au-  
3           thority of the Secretary to modify the provisions  
4           of the HHS Human Subject Regulations or the  
5           vulnerable-populations rules, except to the ex-  
6           tent that any such modification is in conflict  
7           with this section. Any such modification shall  
8           be made by regulation or guidance, as applica-  
9           ble.

10          “(d) AVOIDING REGULATORY DUPLICATION AND UN-  
11          NECESSARY DELAYS.—

12                 “(1) IN GENERAL.—The Secretary shall—

13                         “(A) make such modifications to the provi-  
14                         sions of the HHS Human Subject Regulations  
15                         and the vulnerable-populations rules as may be  
16                         necessary—

17                                 “(i) to reduce regulatory duplication  
18                                 and unnecessary delays;

19                                 “(ii) to modernize such provisions in  
20                                 the context of multisite and cooperative re-  
21                                 search projects; and

22                                 “(iii) to incorporate local consider-  
23                                 ations, community values, and mechanisms  
24                                 to protect vulnerable populations;

1           “(B) ensure that human subject research  
2           that is subject to the Federal Food, Drug, and  
3           Cosmetic Act or to section 351 of this Act, and  
4           is therefore subject to parts 50, 56, 312, and  
5           812 of title 21, Code of Federal Regulations (or  
6           any successor regulations), is not subject to  
7           subpart A of part 46 of title 45, Code of Fed-  
8           eral Regulations (or any successor regulations);  
9           and

10           “(C) ensure that human subject research  
11           that is described in subparagraph (B), and is  
12           cooperative research as such term is defined in  
13           section 46.114 of title 45, Code of Federal Reg-  
14           ulations (or any successor regulations), may—

15                   “(i) use joint or shared review;

16                   “(ii) rely upon the review of—

17                           “(I) an independent institutional  
18                           review board; or

19                           “(II) an institutional review  
20                           board of an entity other than the  
21                           sponsor of the research; or

22                   “(iii) use similar arrangements to  
23                   avoid duplication of effort.

24           “(2) REGULATIONS AND GUIDANCE.—Not later  
25           than 12 months after the date of enactment of the

1 21st Century Cures Act, the Secretary, acting  
2 through the relevant agencies and offices of the De-  
3 partment of Health and Human Services, including  
4 the Office for Human Research Protections and rel-  
5 evant agencies and offices of the Food and Drug Ad-  
6 ministration, shall issue such regulations and guid-  
7 ance and take such other actions as may be nec-  
8 essary to implement this subsection. Such regula-  
9 tions and guidance shall include clarification of re-  
10 quirements and policies relating to the following:

11 “(A) Arrangements to avoid duplication  
12 described in paragraph (1)(C), including—

13 “(i) delineating the roles of institu-  
14 tional review boards in multisite or cooper-  
15 ative, multisite studies where one or more  
16 local institutional review boards are relied  
17 upon, or similar arrangements are used;

18 “(ii) the risks and benefits to human  
19 subjects;

20 “(iii) standardization of informed con-  
21 sent and other processes and legal docu-  
22 ments; and

23 “(iv) incorporating community values  
24 through the use of local institutional re-

1 view boards while continuing to use central  
2 or lead institutional review boards.

3 “(B) Concerns about regulatory and legal  
4 liability contributing to decisions by the spon-  
5 sors of research to rely on local institutional re-  
6 view boards for multisite research.

7 “(3) CONSULTATION.—In issuing regulations or  
8 guidance pursuant to paragraph (2), the Secretary  
9 shall consult with stakeholders (including research-  
10 ers, academic organizations, hospitals, institutional  
11 research boards, pharmaceutical, biotechnology and  
12 medical device developers, clinical research organiza-  
13 tions, patient groups, and others).”.

14 **SEC. 3002. USE OF INSTITUTIONAL REVIEW BOARDS FOR**  
15 **REVIEW OF INVESTIGATIONAL DEVICE EX-**  
16 **EMPTIONS.**

17 (a) IN GENERAL.—Section 520(g)(3) of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is  
19 amended by striking “local” each place it appears in sub-  
20 paragraphs (A)(i) and (B).

21 (b) REGULATIONS.—Not later than 6 months after  
22 the date of the enactment of this Act, the Secretary of  
23 Health and Human Services shall revise or issue such reg-  
24 ulations or guidance as may be necessary to carry out the  
25 amendments made by subsection (a).

1 **Subtitle B—Broader Application of**  
2 **Bayesian Statistics and Adapt-**  
3 **ive Trial Designs**

4 **SEC. 3021. CLINICAL TRIAL MODERNIZATION.**

5 (a) PROPOSALS FOR USE OF INNOVATIVE STATIS-  
6 TICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS,  
7 BIOLOGICAL PRODUCTS, AND DEVICES.—Chapter V of  
8 the Federal Food, Drug, and Cosmetic Act is amended  
9 by inserting after section 507A of such Act, as added by  
10 section 1022 of this Act, the following new section:

11 **“SEC. 507B. CLINICAL TRIAL MODERNIZATION.**

12 “To promote the efficiency of the development and  
13 regulatory review and approval, licensure, or clearance of  
14 drugs, biological products, and devices and the timely  
15 availability of innovative treatments, the Secretary shall,  
16 after providing notice and an opportunity for public com-  
17 ment, establish and implement a framework through  
18 which sponsors of drugs, biological products, or devices  
19 may submit to the Secretary a proposal for the incorpora-  
20 tion of adaptive trial designs, Bayesian methods, or other  
21 alternative statistical methods into proposed clinical proto-  
22 cols and marketing applications for drugs, biological prod-  
23 ucts, or devices.”.

24 (b) GUIDANCE ADDRESSING USE OF ADAPTIVE  
25 TRIAL DESIGNS AND BAYESIAN METHODS.—



1 (1) IN GENERAL.—The Secretary of Health and  
2 Human Services, acting through the Commissioner  
3 of Food and Drugs (in this subsection referred to as  
4 the “Secretary”), shall—

5 (A) update and finalize the draft guidance  
6 addressing the use of adaptive trial design for  
7 drugs and biological products; and

8 (B) issue draft guidance on the use of  
9 Bayesian methods in the development and regu-  
10 latory review and approval, licensure, or clear-  
11 ance of drugs, biological products, and devices.

12 (2) CONTENTS.—The guidances under para-  
13 graph (1) shall—

14 (A) establish or clarify standards for using  
15 adaptive trial designs and Bayesian methods in  
16 clinical trials, including clinical trials that form  
17 the primary basis for approval, clearance, or li-  
18 censure of the products involved (such as trials  
19 that provide substantial evidence for the ap-  
20 proval of drugs);

21 (B) establish a mechanism for sponsors to  
22 obtain feedback from the Secretary under sec-  
23 tion 507B, as added by subsection (a), on tech-  
24 nical issues related to modeling and simulations  
25 prior to—

1 (i) completion of such modeling or  
2 simulations; or

3 (ii) the submission of resulting infor-  
4 mation to the Secretary;

5 (C) specify the types of quantitative and  
6 qualitative information required for review; and

7 (D) specify the recommended analysis  
8 methodology.

9 (3) PUBLIC MEETING.—Prior to updating or  
10 developing the guidances required by paragraph (1),  
11 the Secretary shall consult, through a public meeting  
12 to be held no later than 1 year after the date of en-  
13 actment of this Act, with stakeholders including rep-  
14 resentatives of regulated industry, academia, patient  
15 advocacy organizations, and disease research founda-  
16 tions.

17 (4) SCHEDULE.—The Secretary shall, after pro-  
18 viding notice and opportunity for public comment,  
19 publish—

20 (A) the final guidance required by para-  
21 graph (1)(A) not later than 6 months after the  
22 date of the public meeting required by para-  
23 graph (3); and

24 (B) the guidance required by paragraph  
25 (1)(B) not later than 12 months after the date

1 of the public meeting required by paragraph  
2 (3).

3 (5) REVIEW AND REVISION OF GUIDANCE DOC-  
4 UMENTS.—Not later than 48 months after the date  
5 of enactment of this Act, the Secretary shall review  
6 and, as appropriate, revise the guidance documents  
7 required by subparagraphs (A) and (B) of para-  
8 graph (1) to reflect developments in statistical meth-  
9 ods that could be appropriate for use in clinical  
10 trials, including clinical trials that—

11 (A) form the primary basis for approval,  
12 clearance, or licensure of drugs, biological prod-  
13 ucts or devices; or

14 (B) provide substantial evidence for the  
15 approval of drugs.

16 **Subtitle C—Postapproval Studies**  
17 **and Clinical Trials**

18 **SEC. 3031. EVALUATIONS OF REQUIRED POSTAPPROVAL**  
19 **STUDIES AND CLINICAL TRIALS.**

20 (a) IN GENERAL.—Section 505(o)(3) of the Federal  
21 Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is  
22 amended by adding at the end the following new subpara-  
23 graph:

24 “(G) EVALUATIONS OF REQUIRED POST-  
25 APPROVAL STUDIES AND CLINICAL TRIALS.—

1                   “(i) IN GENERAL.—The Secretary  
2                   shall establish a process under which the  
3                   Secretary, on the initiative of the Secretary  
4                   or at the request of a responsible person,  
5                   shall periodically evaluate a postapproval  
6                   study or clinical trial required to be con-  
7                   ducted under this paragraph to determine  
8                   whether—

9                                 “(I) the trial or study is no  
10                                longer scientifically warranted; or

11                               “(II) the design, or the timelines  
12                               applicable to the completion of, the  
13                               study or trial should be renegotiated  
14                               because of changes in medical practice  
15                               or the standard of care.

16                   “(ii) NOT SCIENTIFICALLY WAR-  
17                   RANTED.—In the case of a determination  
18                   under clause (i)(I) that a postapproval  
19                   study or clinical trial required to be con-  
20                   ducted under this paragraph is no longer  
21                   scientifically warranted, the Secretary shall  
22                   no longer require the responsible person to  
23                   conduct the study or trial.

24                   “(iii) RENEGOTIATION.—In the case  
25                   of a determination under clause (i)(II) that

1 the design, or the timelines applicable to  
2 the completion of, a postapproval study or  
3 clinical trial required to be conducted  
4 under this paragraph should be renegoti-  
5 ated, the Secretary shall enter into nego-  
6 tiations with the responsible person to  
7 make such changes as may be necessary to  
8 such design or timelines as the Secretary  
9 determines are necessary.”.

10 (b) GUIDANCE.—Not later than one year after the  
11 date of the enactment of this Act, the Secretary shall issue  
12 draft guidance on the implementation of subparagraph  
13 (G) of section 505(o)(3) of the Federal Food, Drug, and  
14 Cosmetic Act (21 U.S.C. 355(o)(3), as added by sub-  
15 section (a). Not later than two years after such date of  
16 enactment, the Secretary shall issue final guidance on  
17 such implementation.

## 18 **Subtitle D—Pediatric Research**

### 19 **Network Improvement**

#### 20 **SEC. 3041. NATIONAL PEDIATRIC RESEARCH NETWORK.**

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

23 (1) in paragraph (1)—

24 (A) by striking “in consultation with the  
25 Director of the Eunice Kennedy Shriver Na-

1           tional Institute of Child Health and Human  
2           Development and in collaboration with other  
3           appropriate national research institutes and na-  
4           tional centers that carry out activities involving  
5           pediatric research” and inserting “in collabora-  
6           tion with the national research institutes and  
7           national centers that carry out activities involv-  
8           ing pediatric research”;

9           (B) by striking subparagraph (B);

10           (C) by striking “may be comprised of, as  
11           appropriate” and all that follows through “the  
12           pediatric research consortia” and inserting  
13           “may be comprised of, as appropriate, the pedi-  
14           atric research consortia”; and

15           (D) by striking “; or” at the end and in-  
16           serting a period; and

17           (2) in paragraph (1), paragraph (2)(A), the  
18           first sentence of paragraph (2)(E), and paragraph  
19           (4), by striking “may” each place it appears and in-  
20           serting “shall”.

## 21           **Subtitle E—Global Pediatric** 22           **Clinical Trial**

### 23           **SEC. 3061. SENSE OF CONGRESS.**

24           It is the sense of Congress that—

1           (1) the National Institutes of Health should  
2 support a global pediatric clinical trial network  
3 through the allocation of grants to supplement the  
4 salaries of young researchers who participate in the  
5 global pediatric clinical trial network;

6           (2) National Institutes of Health grants should  
7 be awarded, solely for the purpose of supplementing  
8 the salaries of young researchers, to entities that  
9 participate in the global pediatric clinical trial net-  
10 work;

11           (3) the Food and Drug Administration should  
12 engage the European Medicines Agency and other  
13 foreign regulatory entities during the formation of  
14 the global pediatric clinical trials network to encour-  
15 age their participation; and

16           (4) once a global pediatric clinical trial network  
17 is established and becomes operational, the Food  
18 and Drug Administration should continue to engage  
19 the European Medicines Agency and other foreign  
20 regulatory entities to encourage and facilitate their  
21 participation in the network with the goal of enhanc-  
22 ing the global reach of the network.

1 **TITLE IV—ACCELERATING THE**  
2 **DISCOVERY, DEVELOPMENT,**  
3 **AND DELIVERY CYCLE AND**  
4 **CONTINUING 21ST CENTURY**  
5 **INNOVATION AT NIH, FDA,**  
6 **CDC, AND CMS**

7 **Subtitle A—National Institutes of**  
8 **Health**

9 **SEC. 4001. NIH RESEARCH STRATEGIC INVESTMENT PLAN.**

10 Section 402 of the Public Health Service Act (42  
11 U.S.C. 282) is amended—

12 (1) in subsection (b), by amending paragraph  
13 (5) to read as follows:

14 “(5) shall ensure that scientifically based stra-  
15 tegic planning is implemented in support of research  
16 priorities as determined by the agencies of the Na-  
17 tional Institutes of Health, including through devel-  
18 opment, use, and updating of the research strategic  
19 investment plan under subsection (m);” and

20 (2) by adding at the end the following:

21 “(m) RESEARCH STRATEGIC INVESTMENT PLAN.—

22 “(1) IN GENERAL.—For fiscal year 2016 and  
23 each subsequent fiscal year, the Director of NIH, in  
24 consultation with the directors of the national re-  
25 search institutes and national centers, researchers,



1 patient advocacy groups, and industry leaders, shall  
2 develop and maintain a 5-year biomedical research  
3 strategic investment plan (in this subsection referred  
4 to as the ‘strategic investment plan’) that—

5 “(A) is designed to increase the efficient  
6 and effective focus of biomedical research in a  
7 manner that leverages the best scientific oppor-  
8 tunities through a deliberative planning process;

9 “(B) identifies areas, to be known as stra-  
10 tegic focus areas, in which the resources of the  
11 National Institutes of Health can best con-  
12 tribute to the goal of expanding knowledge on  
13 human health in the United States through bio-  
14 medical research; and

15 “(C) includes measurable objectives for  
16 each such strategic focus area.

17 “(2) USE OF PLAN.—The Director of NIH and  
18 the directors of the national research institutes and  
19 national centers shall use the strategic investment  
20 plan—

21 “(A) to make resource allocation decisions;  
22 and

23 “(B) to develop individual strategic invest-  
24 ment plans for the research activities of each of

1 the national research institutes and national  
2 centers that—

3 “(i) have a common format; and

4 “(ii) identify strategic focus areas in  
5 which the resources of the national re-  
6 search institutes and national centers can  
7 best contribute to the goal described in  
8 paragraph (1)(B).

9 “(3) CONTENTS OF PLANS.—

10 “(A) FUNDING PRIORITY FOR NIH OVER-  
11 ALL.—In developing and maintaining a stra-  
12 tegic investment plan under this subsection, the  
13 Director of NIH shall ensure that at least 55  
14 percent of the funds that are used by the Na-  
15 tional Institutes of Health to support extra-  
16 mural research for any fiscal year are used to  
17 support basic biomedical extramural research.

18 “(B) STRATEGIC FOCUS AREAS.—The stra-  
19 tegic focus areas identified pursuant to para-  
20 graphs (1)(B) and (2)(B) shall—

21 “(i) be identified in a manner that—

22 “(I) maximizes the return on in-  
23 vestment to the United States public  
24 through the investments of the Na-

1                    tional Institutes of Health in bio-  
2                    medical research; 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 up to 10 strategic focus  
8                    areas, to be known as Mission Priority  
9                    Focus Areas, which best serve the goals of  
10                   preventing or eliminating the burden of a  
11                   disease or condition and scientifically merit  
12                   an enhanced and focused research engage-  
13                   ment campaign over the next 5 years.

14                   “(C) RARE AND PEDIATRIC DISEASES AND  
15                   CONDITIONS.—In developing and maintaining a  
16                   strategic investment plan under this subsection,  
17                   the Director of NIH shall ensure that rare and  
18                   pediatric diseases and conditions remain a pri-  
19                   ority.

20                   “(4) INITIAL PLAN.—Not later than 270 days  
21                   after the date of enactment of this subsection, the  
22                   Director of NIH and the directors of the national re-  
23                   search institutes and national centers shall—

1           “(A) complete the initial strategic invest-  
2           ment plans required by paragraphs (1) and (2);  
3           and

4           “(B) make such initial strategic investment  
5           plans publicly available on the website of the  
6           National Institutes of Health.

7           “(5) REVIEW; UPDATES.—

8           “(A) METRICS REVIEWS.—Not less than  
9           biannually, the Director of the NIH, in con-  
10          sultation with the directors of the national re-  
11          search institutes and national centers, shall  
12          conduct metrics reviews for each strategic focus  
13          area identified under paragraph (1)(B).

14          “(B) UPDATES.—Not later than the end of  
15          the 5-year period covered by the initial strategic  
16          investment plan under this subsection, and  
17          every 5 years thereafter, the Director of NIH,  
18          in consultation with the directors of the na-  
19          tional research institutes and national centers,  
20          stakeholders in the scientific field, advocates,  
21          and the public at large, shall—

22                  “(i) conduct a review of the plan, in-  
23                  cluding each strategic focus area identified  
24                  under paragraph (1)(B); and

1                   “(ii) update such plan in accordance  
2                   with this section.”.

3 **SEC. 4002. BIOMEDICAL RESEARCH WORKING GROUP TO**  
4                   **REDUCE ADMINISTRATIVE BURDEN ON RE-**  
5                   **SEARCHERS.**

6           (a) ESTABLISHMENT.—There is established a work-  
7 ing group, to be known as the “Biomedical Research  
8 Working Group”. The Director of the National Institutes  
9 of Health shall serve as the Chairperson of such working  
10 group.

11          (b) DUTIES.—The Biomedical Research Working  
12 Group shall—

13               (1) review literature and reports on—

14                   (A) administrative burdens of researchers  
15 funded by the National Institutes of Health;  
16 and

17                   (B) improving replicability of research  
18 funded by the National Institutes of Health;

19               (2) provide recommendations to the Director of  
20 the National Institutes of Health to—

21                   (A) reduce such administrative burdens,  
22 including with respect to the extent to which  
23 (and how) the grant proposal submission and  
24 progress report requirements of the National

1 Institutes of Health should be restructured,  
2 streamlined, and simplified; and

3 (B) improve replicability of research fund-  
4 ed by the National Institutes of Health;

5 (3) evaluate and provide recommendations on  
6 the extent to which it is required for Congress to  
7 provide any statutory authority to implement any  
8 recommendation proposed pursuant to paragraph  
9 (2); and

10 (4) prepare a plan, including timeframes, for  
11 implementing recommendations proposed pursuant  
12 to paragraph (2) [for which congressional action is  
13 not required].

14 (c) MEMBERSHIP.—The Biomedical Research Work-  
15 ing Group shall be composed of the following members:

16 (1) FEDERAL MEMBERS.—

17 (A) The Director of the National Institutes  
18 of Health.

19 (B) The Director of the Division of Pro-  
20 gram Coordination, Planning, and Strategic  
21 Initiatives within the Office of the Director of  
22 the National Institutes of Health.

23 (C) The Director of Extramural Programs  
24 of the National Institutes of Health.

1 (D) The Director of Intramural Programs  
2 of the National Institutes of Health.

3 (2) NON-FEDERAL MEMBERS.—Seven non-Fed-  
4 eral members representing physicians, health practi-  
5 tioners, academics, scientists, and entrepreneurs  
6 whose work, research specialization, or professional  
7 expertise includes a significant focus on basic and  
8 clinical research that is funded by the National In-  
9 stitutes of Health—

10 (A) three of whom shall be appointed by  
11 the Secretary of Health and Human Services,  
12 in consultation with the Director of the Na-  
13 tional Institutes of Health;

14 (B) one of whom shall be appointed by the  
15 Speaker of the House of Representatives;

16 (C) one of whom shall be appointed by the  
17 minority leader of the House of Representa-  
18 tives;

19 (D) one of whom shall be appointed by the  
20 majority leader of the Senate; and

21 (E) one of whom shall be appointed by the  
22 minority leader of the Senate.

23 (d) IMPLEMENTATION OF MEASURES TO REDUCE  
24 ADMINISTRATIVE BURDENS.—The Director of the Na-  
25 tional Institutes of Health, taking into account the rec-

1 ommendations, evaluations, and plan described in sub-  
2 section (b), shall implement measures to—

3 (1) reduce the administrative burdens of re-  
4 searchers funded by the National Institutes of  
5 Health; and

6 (2) improve replicability of research funded by  
7 the National Institutes of Health.

8 (e) REPORTS.—

9 (1) REPORT BY WORKING GROUP ON REC-  
10 OMMENDATIONS AND PLAN.—Not later than one  
11 year after the date of the enactment of this Act, the  
12 Biomedical Research Working Group shall submit to  
13 Congress a report including the recommendations,  
14 evaluations, and plan described in subsection (b).

15 (2) PERIODIC REPORTS BY DIRECTOR OF NIH  
16 ON IMPLEMENTATION OF MEASURES TO REDUCE AD-  
17 MINISTRATIVE BURDENS.—Not later than six  
18 months after the date of the submission of the re-  
19 port under paragraph (1) and every six months  
20 thereafter, the Director of the National Institutes of  
21 Health shall submit to Congress a report on the ex-  
22 tent to which the Director has implemented meas-  
23 ures pursuant to subsection (d).



1 (f) TERMINATION.—The Biomedical Research Work-  
2 ing Group shall terminate 30 days after the date of the  
3 submission of the report under subsection (e)(1).

4 **[SEC. 4003. NIH TRAVEL.**

5 **[TO BE SUPPLIED]]**

6 **SEC. 4004. INCREASING ACCOUNTABILITY AT THE NA-**  
7 **TIONAL INSTITUTES OF HEALTH.**

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

12 “(a) APPOINTMENT; TERMS.—

13 “(1) APPOINTMENT.—The Director of the Na-  
14 tional Cancer Institute shall be appointed by the  
15 President and the directors of the other national re-  
16 search institutes and national centers shall be ap-  
17 pointed by the Director of NIH. The directors of the  
18 national research institutes and national centers  
19 shall report directly to the Director of NIH.

20 “(2) TERMS.—

21 “(A) IN GENERAL.—The term of office of  
22 a director of a national research institute or na-  
23 tional center shall be 4 years.

24 “(B) REMOVAL.—The director of a na-  
25 tional research institute or national center may

1 be removed from office by the Director of NIH  
2 prior to the expiration of such director's 4-year  
3 term.

4 “(C) REAPPOINTMENT.—At the end of the  
5 term of a director of a national research insti-  
6 tute or national center, the director may be re-  
7 appointed. There is no limit on the number of  
8 terms a director may serve.

9 “(D) VACANCIES.—If the office of a direc-  
10 tor of a national research institute or national  
11 center becomes vacant before the end of such  
12 director's term, the director appointed to fill the  
13 vacancy shall be appointed for a 4-year term  
14 starting on the date of such appointment.

15 “(E) TRANSITIONAL PROVISION.—Each di-  
16 rector of a national research institute or na-  
17 tional center serving on the date of enactment  
18 of the \_\_\_\_\_ Act of 2014 is deemed  
19 to be appointed for a 4-year term under this  
20 subsection starting on such date of enact-  
21 ment.”.

22 (b) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—  
23 Section 405(b) of the Public Health Service Act (42  
24 U.S.C. 284(b)) is amended by adding at the end the fol-  
25 lowing:

1 “(3) Before an award is made by a national research  
2 institute or national center for a grant for a research pro-  
3 gram or project (commonly referred to as an ‘R-series  
4 grant’), other than an award constituting a renewal of  
5 such a grant, the director of such national research insti-  
6 tute or national center—

7 “(A) shall personally review and approve the  
8 award; and

9 “(B) shall take into consideration—

10 “(i) whether the goals of the research pro-  
11 gram or project are a national priority and have  
12 public support;

13 “(ii) whether other agencies are funding  
14 programs or projects to accomplish the same  
15 goal; and

16 “(iii) whether the monetary investment is  
17 worth the potential scientific discovery.”.

18 (c) GAO STUDY ON DUPLICATION IN FEDERAL BIO-  
19 MEDICAL RESEARCH.—Not later than 270 days after the  
20 date of enactment of this Act, the Comptroller General  
21 of the United States shall—

22 (1) complete a study on the extent to which bio-  
23 medical research conducted or supported by Federal  
24 agencies is duplicative; and

1           (2) submit a report to the Congress on the re-  
2           sults of such study, including recommendations on  
3           how to prevent such duplication.

4           (d) GAO STUDY ON WASTE, FRAUD, AND LACK OF  
5           CONSISTENCY WITH THE NIH MISSION.—Not later than  
6           270 days after the date of enactment of this Act, the  
7           Comptroller General of the United States shall—

8           (1) complete a study on the extent to which  
9           there is waste, fraud, and lack of consistency with  
10          the mission of the National Institutes of Health in  
11          the conduct and support of research by the National  
12          Institutes of Health; and

13          (2) submit a report to the Congress on the re-  
14          sults of such study.

15   **SEC. 4005. GAO REPORT ON COMMON FUND.**

16          (a) IN GENERAL.—Not later than 270 days after the  
17          date of enactment of this Act, the Comptroller General  
18          of the United States shall submit to Congress a report  
19          on the Common Fund established under section 402A(c)  
20          of the Public Health Service Act (42 U.S.C. 282a(c)).

21          (b) CONTENTS.—The report under subsection (a)  
22          shall include an analysis of how amounts reserved under  
23          such section have been used and the impact of that fund-  
24          ing on the each of the areas that received funding.

1 **SEC. 4006. EXEMPTION FOR THE NATIONAL INSTITUTES OF**  
2 **HEALTH FROM THE PAPERWORK REDUCTION**  
3 **ACT REQUIREMENTS.**

4 Section 3518(c)(1) of title 44, United States Code,  
5 is amended—

6 (1) in subparagraph (C), by striking “; or” and  
7 inserting a semicolon;

8 (2) in subparagraph (D), by striking the period  
9 at the end and inserting “; or”; and

10 (3) by inserting at the end the following new  
11 subparagraph:

12 “(E) during the conduct of research by the  
13 National Institutes of Health.”.

14 **SEC. 4007. ADDITIONAL FUNDING FOR NIH COMMON FUND.**

15 Section 402A(a) of the Public Health Service Act (42  
16 U.S.C. 282a(a)) is amended by adding at the end the fol-  
17 lowing:

18 “(3) ADDITIONAL AMOUNT FOR COMMON  
19 FUND.—For the purpose of carrying out section  
20 402(b)(7)(B), there is authorized to be appropriated  
21 to the Common Fund **【\$\_\_\_\_\_】** for each of fis-  
22 cal years 2016 through 2020. Amounts made avail-  
23 able pursuant to the preceding sentence shall be in  
24 addition to amounts otherwise made available under  
25 paragraph (1), (2), or (4) of this subsection and in

1 addition to amounts reserved under subsection  
2 (c)(1)(B).”.

3 **SEC. 4008. ADDITIONAL FUNDING FOR NIH BRAIN RE-**  
4 **SEARCH.**

5 Section 402A(a) of the Public Health Service Act (42  
6 U.S.C. 282a(a)), as amended by section 1, is further  
7 amended by adding at the end the following:

8 “(4) ADDITIONAL FUNDING FOR BRAIN RE-  
9 SEARCH.—For the purpose of conducting or sup-  
10 porting brain research under this title, including  
11 through the Brain Research through Advancing In-  
12 novative Neurotechnologies (BRAIN) initiative,  
13 there is authorized to be appropriated **【\$\_\_\_\_\_】**  
14 for each of fiscal years 2016 through 2020.  
15 Amounts made available pursuant to the preceding  
16 sentence shall be in addition to amounts otherwise  
17 made available under paragraph (1), (2), or (3) and  
18 shall not be subject to reservation under subsection  
19 (c)(1)(B).”.

20 **SEC. 4009. NCATS PHASE IIB RESTRICTION.**

21 Section 479 of the Public Health Service Act (42  
22 U.S.C. 287) is amended—

23 (1) prior to making the amendments under  
24 paragraph (2), by striking “IIB” each place it ap-  
25 pears and inserting “III”; and

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

3 **Subtitle B—Advancing Research**  
4 **for Neurological Diseases**

5 **SEC. 4021. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**  
6 **LANCE SYSTEM.**

7 Part P of title III of the Public Health Service Act  
8 (42 U.S.C. 280g et seq.) is amended by adding at the end  
9 the following:

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

11 “(a) IN GENERAL.—The Secretary, acting through  
12 the Director of the Centers for Disease Control and Pre-  
13 vention, shall—

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

18 “(2) incorporate information obtained through  
19 such activities into a statistically sound, scientifically  
20 credible, integrated surveillance system, to be known  
21 as the National Neurological Diseases Surveillance  
22 System.

23 “(b) RESEARCH.—The Secretary shall ensure that  
24 the National Neurological Diseases Surveillance System is

1 designed in a manner that facilitates further research on  
2 neurological diseases.

3 “(c) CONTENT.—In carrying out subsection (a), the  
4 Secretary—

5 “(1) shall provide for the collection and storage  
6 of information on the incidence and prevalence of  
7 neurological diseases in the United States;

8 “(2) to the extent practicable, shall provide for  
9 the collection and storage of other available informa-  
10 tion on neurological diseases, such as information  
11 concerning—

12 “(A) demographics and other information  
13 associated or possibly associated with neuro-  
14 logical diseases, such as age, race, ethnicity,  
15 sex, geographic location, and family history;

16 “(B) risk factors associated or possibly as-  
17 sociated with neurological diseases, including  
18 genetic and environmental risk factors; and

19 “(C) diagnosis and progression markers;

20 “(3) may provide for the collection and storage  
21 of information relevant to analysis on neurological  
22 diseases, such as information concerning—

23 “(A) the epidemiology of the diseases;

24 “(B) the natural history of the diseases;

25 “(C) the prevention of the diseases;



1           “(D) the detection, management, and  
2           treatment approaches for the diseases; and

3           “(E) the development of outcomes meas-  
4           ures; and

5           “(4) may address issues identified during the  
6           consultation process under subsection (d).

7           “(d) CONSULTATION.—In carrying out this section,  
8           the Secretary shall consult with individuals with appro-  
9           priate expertise, including—

10           “(1) epidemiologists with experience in disease  
11           surveillance or registries;

12           “(2) representatives of national voluntary  
13           health associations that—

14           “(A) focus on neurological diseases, includ-  
15           ing multiple sclerosis and Parkinson’s disease;  
16           and

17           “(B) have demonstrated experience in re-  
18           search, care, or patient services;

19           “(3) health information technology experts or  
20           other information management specialists;

21           “(4) clinicians with expertise in neurological  
22           diseases; and

23           “(5) research scientists with experience con-  
24           ducting translational research or utilizing surveil-  
25           lance systems for scientific research purposes.

1           “(e) GRANTS.—The Secretary may award grants to,  
2 or enter into contracts or cooperative agreements with,  
3 public or private nonprofit entities to carry out activities  
4 under this section.

5           “(f) COORDINATION WITH OTHER FEDERAL AGEN-  
6 CIES.—Subject to subsection (h), the Secretary shall make  
7 information and analysis in the National Neurological Dis-  
8 eases Surveillance System available, as appropriate, to  
9 Federal departments and agencies, such as the National  
10 Institutes of Health, the Food and Drug Administration,  
11 the Centers for Medicare & Medicaid Services, the Agency  
12 for Healthcare Research and Quality, the Department of  
13 Veterans Affairs, and the Department of Defense.

14           “(g) PUBLIC ACCESS.—Subject to subsection (h), the  
15 Secretary shall make information and analysis in the Na-  
16 tional Neurological Diseases Surveillance System avail-  
17 able, as appropriate, to the public, including researchers.

18           “(h) PRIVACY.—The Secretary shall ensure that pri-  
19 vacy and security protections applicable to the National  
20 Neurological Diseases Surveillance System are at least as  
21 stringent as the privacy and security protections under  
22 HIPAA privacy and security law (as defined in section  
23 3009(a)(2)).

24           “(i) REPORT.—Not later than 4 years after the date  
25 of the enactment of this section, the Secretary shall sub-

1 mit a report to the Congress concerning the implementa-  
2 tion of this section. Such report shall include information  
3 on—

4 “(1) the development and maintenance of the  
5 National Neurological Diseases Surveillance System;

6 “(2) the type of information collected and  
7 stored in the System;

8 “(3) the use and availability of such informa-  
9 tion, including guidelines for such use; and

10 “(4) the use and coordination of databases that  
11 collect or maintain information on neurological dis-  
12 eases.

13 “(j) DEFINITION.—In this section, the term ‘national  
14 voluntary health association’ means a national nonprofit  
15 organization with chapters, other affiliated organizations,  
16 or networks in States throughout the United States.

17 “(k) AUTHORIZATION OF APPROPRIATIONS.—To  
18 carry out this section, there is authorized to be appro-  
19 priated **【\$\_\_\_\_\_】** for each of fiscal years 2015 through  
20 2019.”.

1                   **Subtitle C—Vaccine Access,**  
2                   **Certainty, and Innovation**  
3                   **PART 1—DEVELOPMENT, LICENSURE, AND**  
4                   **RECOMMENDATIONS**

5                   **SEC. 4041. PROMPT REVIEW OF VACCINES BY THE ADVI-**  
6                   **SORY COMMITTEE ON IMMUNIZATION PRAC-**  
7                   **TICES.**

8                   Section 2102(a) of the Public Health Service Act (42  
9                   U.S.C. 300aa–2(a)) is amended by adding at the end the  
10                  following:

11                  “(10) ADVISORY COMMITTEE ON IMMUNIZATION  
12                  PRACTICES.—

13                  “(A) STANDARD PERIODS OF TIME FOR  
14                  MAKING RECOMMENDATIONS.—The Director of  
15                  the Program shall establish standard timelines  
16                  during which the Advisory Committee on Im-  
17                  munization Practices should consider and make  
18                  recommendations with respect to the route of  
19                  administration, dosage, and frequency of ad-  
20                  ministration of vaccines for specified popu-  
21                  lations.

22                  “(B) EXPEDITED REVIEW PURSUANT TO  
23                  REQUEST BY SPONSOR OR MANUFACTURER.—If  
24                  the Advisory Committee does not make the rec-  
25                  ommendations described in subparagraph (A)

1 for a vaccine by the date that is 120 calendar  
2 days after the licensure of the vaccine under  
3 section 351, the Advisory Committee, at the re-  
4 quest of the sponsor of the vaccine, shall make  
5 such recommendations within 60 calendar days  
6 of the Advisory Committee's receipt of the re-  
7 quest.

8 “(C) EXPEDITED REVIEW FOR BREAK-  
9 THROUGH THERAPIES AND FOR USE DURING  
10 PUBLIC HEALTH EMERGENCIES.—If a vaccine  
11 is designated as a breakthrough therapy under  
12 section 506 of the Federal Food, Drug, and  
13 Cosmetic Act, the Advisory Committee shall  
14 make the recommendations described in sub-  
15 paragraph (A) on an expedited basis.

16 “(D) DEFINITION.—In this paragraph, the  
17 terms ‘Advisory Committee on Immunization  
18 Practices’ and ‘Advisory Committee’ mean the  
19 advisory committee on immunization practices  
20 established by the Secretary pursuant to section  
21 222, acting through the Director of the Centers  
22 for Disease Control and Prevention.”.

1 **SEC. 4042. REVIEW OF TRANSPARENCY AND CONSISTENCY**  
2 **OF ACIP RECOMMENDATION PROCESS.**

3 (a) REVIEW.—The Director of the Centers for Dis-  
4 ease Control and Prevention shall conduct a review of the  
5 transparency and consistency of the process used by the  
6 Advisory Committee on Immunization Practices in formu-  
7 lating and issuing recommendations pertaining to vac-  
8 cines.

9 (b) CONSIDERATIONS.—The review under subsection  
10 (a) shall include assessment of—

11 (1) the criteria used to evaluate new and exist-  
12 ing vaccines;

13 (2) the Grading of Recommendations, Assess-  
14 ment, Development, and Evaluation (GRADE) ap-  
15 proach to the review and analysis of scientific and  
16 economic data, including the scientific basis for such  
17 approach; and

18 (3) the extent to which the processes used by  
19 the working groups of the Advisory Committee on  
20 Immunization Practices are transparent and con-  
21 sistent.

22 (c) STAKEHOLDERS.—In carrying out the review  
23 under subsection (a), the Director of the Centers for Dis-  
24 ease Control and Prevention shall solicit input from vac-  
25 cine stakeholders.

1 (d) REPORT.—Not later than 1 year after the date  
2 of enactment of this Act, the Director of the Centers for  
3 Disease Control and Prevention shall submit to the appro-  
4 priate committees of the Congress and make publicly  
5 available a report on the results of the review under sub-  
6 section (a), including recommendations on improving the  
7 transparency and consistency of the process described in  
8 such subsection.

9 (e) DEFINITION.—In this section, the term “Advisory  
10 Committee on Immunization Practices” means the advi-  
11 sory committee on immunization practices established by  
12 the Secretary of Health and Human Services pursuant to  
13 section 222 of the Public Health Service Act (42 U.S.C.  
14 217a), acting through the Director of the Centers for Dis-  
15 ease Control and Prevention.

16 **SEC. 4043. GUIDANCE ON VACCINE DEVELOPMENT.**

17 (a) ISSUANCE.—Not later than 2 years after the date  
18 of enactment of this Act, the Secretary of Health and  
19 Human Services shall issue final guidance to facilitate the  
20 use of accelerated and expedited pathways for the develop-  
21 ment and licensure of vaccines to prevent—

22 (1) emerging, re-emerging, or rare infectious  
23 diseases with respect to which the low prevalence or  
24 nature of the disease may render the existence or

1 collection of clinical outcome data unlikely or im-  
2 practical; and

3 (2) infectious diseases with respect to which  
4 currently available vaccines are not addressing the  
5 full scope of public health needs.

6 (b) CONSIDERATIONS.—In developing the guidance  
7 required by this section, the Secretary of Health and  
8 Human Services shall consider issues relating to clinical  
9 development strategies for diseases described in subsection  
10 (a), including the development and acceptability of novel  
11 clinical and surrogate endpoints, the use of novel or accel-  
12 erated study designs, the use of observational real-world  
13 data, the use of novel adjuvants, the use of new tech-  
14 nologies or approaches to collecting and monitoring pa-  
15 tient-level data, and the demonstration of efficacy through  
16 studies in healthy volunteers for the purpose of licensure.

17 **SEC. 4044. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**  
18 **OPERS.**

19 Section 310 of the Public Health Service Act (42  
20 U.S.C. 242o) is amended by adding at the end the fol-  
21 lowing:

22 “(c)(1) In this subsection, the term ‘vaccine devel-  
23 oper’ means a nongovernmental entity engaged in—

24 “(A) the development or production of a vac-  
25 cine; and



1           “(B) vaccine research.

2           “(2)(A) Upon the submission of a written request by  
3 a vaccine developer, the Secretary, acting through the Di-  
4 rector of the Centers for Disease Control and Prevention,  
5 shall convene a meeting of representatives of the vaccine  
6 developer and experts in immunization programs, epidemi-  
7 ology, and other relevant areas, including such experts  
8 from the Food and Drug Administration and the National  
9 Vaccine Program, at which the Director (or the Director’s  
10 designee), for the purpose of informing the vaccine devel-  
11 oper’s understanding of public health needs and priorities,  
12 shall provide the perspectives of the Centers for Disease  
13 Control and Prevention and other relevant Federal agen-  
14 cies regarding—

15           “(i) public health needs, epidemiology, and im-  
16 plementation considerations with regard to a vaccine  
17 developer’s potential vaccine profile; and

18           “(ii) potential implications of such perspectives  
19 for the vaccine developer’s vaccine research and de-  
20 velopment planning.

21           “(B) The Director of the Centers for Disease Control  
22 and Prevention (or the Director’s designee) shall convene  
23 a meeting requested under subparagraph (A) not later  
24 than 90 calendar days after receipt of the request for the  
25 meeting.

1           “(3)(A) Upon the submission of a written request by  
2 a vaccine developer, the Secretary, acting through the Di-  
3 rector of the Centers for Disease Control and Prevention,  
4 shall provide to the vaccine developer any age-based dis-  
5 ease epidemiological analyses or data that—

6                   “(i) are specified in the request;

7                   “(ii) have been published;

8                   “(iii) have been performed by or are in the pos-  
9 session of the Centers; and

10                   “(iv) are not a trade secret or otherwise con-  
11 fidential information subject to section 552(b)(4) of  
12 title 5, United States Code, or section 1905 of title  
13 18, United States Code.

14           “(B) The Secretary shall provide analyses requested  
15 by a vaccine manufacturer under subparagraph (A) not  
16 later than 90 calendar days after receipt of the request  
17 for the analyses.

18           “(4) The Secretary shall promptly notify a vaccine  
19 developer if—

20                   “(A) the Secretary becomes aware of any  
21 change 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           “(ii) provided by the Secretary to the vac-  
2           cine developer in one or more analyses under  
3           paragraph (3); and

4           “(B) the change may have implications for the  
5           vaccine developer’s vaccine research and develop-  
6           ment.”.

7   **SEC. 4045. MODIFICATIONS TO PRIORITY REVIEW VOUCHER**  
8           **PROGRAM FOR TROPICAL DISEASES.**

9           Section 524 of the Federal Food, Drug, and Cosmetic  
10          Act (21 U.S. Code 360n) is amended—

11                  (1) in subsection (a)—

12                          (A) in paragraph (3)—

13                                  (i) in the matter before subparagraph  
14                                  (A), by striking “This term” and inserting  
15                                  “In this section, this term”;

16                                  (ii) in subparagraph (R), by striking  
17                                  “designated by order of the Secretary” and  
18                                  inserting “designated by the Secretary pur-  
19                                  suant to paragraph (4)”;

20                          (B) by redesignating paragraph (4) as  
21                          paragraph (5); and

22                          (C) by inserting after paragraph (3) the  
23                          following:

24                          “(4) DESIGNATION OF OTHER INFECTIOUS DIS-  
25                          EASES AS TROPICAL DISEASES.—

1                   “(A) IN GENERAL.—The Secretary shall  
2                   establish a process under which the Secretary—

3                   “(i) using a methodology that is made  
4                   available to the public on the Website of  
5                   the Food and Drug Administration, des-  
6                   ignates infectious diseases other than the  
7                   diseases specified in subparagraphs (A)  
8                   through (Q) of paragraph (3) to be trop-  
9                   ical diseases for purposes of this section;  
10                  and

11                  “(ii) publishes on such Website a com-  
12                  plete, updated list of the diseases that are  
13                  tropical diseases for purposes of this sec-  
14                  tion.

15                  “(B) CONSIDERATIONS.—In designating  
16                  an infectious disease as a tropical disease under  
17                  subparagraph (A), the Secretary shall—

18                  “(i) consider the potential impact of  
19                  the disease on the public health due to—

20                          “(I) the potential rate of spread  
21                          of the disease; and

22                          “(II) the potential severity of the  
23                          disease in terms of human morbidity  
24                          and mortality; and

1                   “(ii) consult with experts in tropical  
2                   infectious diseases, including the Centers  
3                   for Disease Control and Prevention, the  
4                   Food and Drug Administration, medical  
5                   professionals, the clinical research commu-  
6                   nity, and the World Health Organization.

7                   “(C) REVIEW.—Every 5 years, or more  
8                   frequently as determined necessary by the Sec-  
9                   retary, the Secretary shall review, provide modi-  
10                  fications to, and republish the list published  
11                  under subparagraph (A) and any revisions  
12                  made to the methodology for designation of dis-  
13                  eases under such subparagraph.”;

14                  (2) in subsection (b)—

15                         (A) in paragraph (2), by striking “The  
16                         sponsor of a tropical disease” and inserting:

17                                 “(A) IN GENERAL.—The sponsor of a trop-  
18                                 ical disease”;

19                                 (B) by inserting after such paragraph  
20                                 (2)(A) the following:

21                                         “(B) NOTIFICATION OF TRANSFER.—Each  
22                                         person to whom a priority review voucher is  
23                                         transferred shall notify the Secretary of such  
24                                         change in ownership of the voucher not later  
25                                         than 30 calendar days after such transfer.”;

1 (C) in paragraph (4), by striking “The  
2 sponsor of a human drug application” and in-  
3 serting:

4 “(A) IN GENERAL.—The sponsor of a  
5 human drug application”; and

6 (D) by inserting after paragraph (4)(A), as  
7 designated by subparagraph (D), the following:

8 “(B) TRANSFER AFTER NOTICE.—The  
9 sponsor of a human drug application that pro-  
10 vides notification of intent under subparagraph  
11 (A) may transfer the voucher after such notifi-  
12 cation is provided, if such sponsor has not yet  
13 submitted the human drug application de-  
14 scribed in the notification. Upon such a trans-  
15 fer, notwithstanding subparagraph (A), such  
16 sponsor shall not remain legally committed to  
17 pay a user fee because of the sponsor’s notifica-  
18 tion of intent under such subparagraph.”; and

19 (3) in subsection (c), by amending paragraph  
20 (2) to read as follows:

21 “(2) FEE AMOUNT.—The amount of the pri-  
22 ority review user fee shall be determined each fiscal  
23 year by the Secretary based on the difference be-  
24 tween—

1           “(A) the average cost incurred by the  
2           agency in the review of a human drug applica-  
3           tion subject to priority review in the previous  
4           fiscal year; and

5           “(B) the average cost incurred by the  
6           Food and Drug Administration in the review of  
7           a human drug application that is not subject to  
8           priority review in the previous fiscal year.”.

9   **SEC. 4046. GUIDANCE ON CHANGES TO AN APPROVED AP-**  
10                           **PLICATION FOR BIOLOGICAL PRODUCTS.**

11           Not later than 2 years after the date of enactment  
12           of this Act, the Secretary of Health and Human Services  
13           shall issue final guidance that—

14           (1) addresses changes in a licensed biological  
15           product or the labeling, production process, quality  
16           controls, equipment, facilities, or responsible per-  
17           sonnel for such a product established in the applica-  
18           tion for the product that was approved under section  
19           351 of the Public Health Service Act (42 U.S.C.  
20           262);

21           (2) does not address such changes for specified  
22           biotechnology or specified synthetic biological prod-  
23           ucts listed in section 601.2(c) of title 21 of the Code  
24           of Federal Regulation; and

1 (3) updates and supersedes the guidance enti-  
2 tled “Changes to an Approved Application: Biologi-  
3 cal Products,” that was issued by the Food and  
4 Drug Administration in July 1997.

5 **SEC. 4047. EXPEDITING THE PROCESS FOR EXPORT CER-**  
6 **TIFICATIONS FOR VACCINES.**

7 Section 801(e)(4) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

9 (1) in the matter following clause (ii) in sub-  
10 paragraph (A), by striking “within 20 days of the  
11 receipt of a request for such certification” and in-  
12 serting “within **[20 calendar days]** of the receipt of  
13 a request for such certification, except that in the  
14 case of a vaccine the Secretary shall issue such cer-  
15 tification within **[10 business days]** of the receipt of  
16 a request for such certification”; and

17 (2) in subparagraph (B), by striking “within  
18 the 20 days prescribed by subparagraph (A)” and  
19 inserting “within the period prescribed by subpara-  
20 graph (A)”.

21 **SEC. 4048. NIH VACCINE RESEARCH.**

22 (a) IN GENERAL.—Subpart 6 of part C of title IV  
23 of the Public Health Service Act (42 U.S.C. 285f et seq.)  
24 is amended by adding at the end the following:



1 **“SEC. 447D. ADVANCEMENT OF VACCINE DEVELOPMENT.**

2 “In carrying out the general purpose described in sec-  
3 tion 446, the Director of the Institute shall conduct or  
4 support translational science, research, and research train-  
5 ing to advance the development of vaccines for the preven-  
6 tion of diseases, including the advancement of vaccine de-  
7 velopment programs into clinical trials.”.

8 (b) REVIEW OF NIH VACCINE RESEARCH.—

9 (1) IN GENERAL.—Not later than one year  
10 after the date of enactment of this Act, the Director  
11 of the National Institutes of Health shall—

12 (A) conduct a review on vaccine research  
13 being conducted or supported by the Institutes;  
14 and

15 (B) publish a report on the results of such  
16 review.

17 (2) CONTENTS.—At a minimum, the report  
18 under paragraph (1)(B) shall—

19 (A) describe intramural and extramural  
20 vaccine research and development programs  
21 that are being conducted or supported by the  
22 National Institutes of Health, including those  
23 that are translational or clinical phase studies;

24 (B) provide a summary of funding alloca-  
25 tions made to conduct or support the matters  
26 described in section 447D of the Public Health

1 Service Act, as added by subsection (a), and  
2 identify projected funding needs with regard to  
3 future research or support with regard to these  
4 matters; and

5 (C) identify funding and collaborations  
6 with the private sector through—

7 (i) the Small Business Innovation Re-  
8 search and Small Business Technology  
9 Transfer programs; and

10 (ii) cooperative research and develop-  
11 ment agreements.

12 **PART 2—MEDICARE, MEDICAID, AND OTHER**  
13 **PROVISIONS**

14 **SEC. 4061. REQUIRING PROMPT UPDATES TO MEDICARE**  
15 **PROGRAM UPON ISSUANCE OF ACIP REC-**  
16 **COMMENDATIONS.**

17 In the case that the Advisory Committee on Immuni-  
18 zation Practices (as defined in paragraph (10)(D) of sec-  
19 tion 2102(a) of the Public Health Service Act (42 U.S.C.  
20 300aa-2(a))) issues a recommendation for a vaccine or an  
21 update to a recommendation for a vaccine that the Sec-  
22 retary of Health and Human Services is using under title  
23 XVIII of the Social Security Act (42 U.S.C. 1395 et seq.)  
24 with respect to coverage of vaccines or immunizations  
25 under such title, the Secretary shall determine whether or

1 not to update policies under such title with respect to such  
2 coverage on a date that is not later than 60 calendar days  
3 after the date on which such Advisory Committee issues  
4 such recommendation or update.

5 **SEC. 4062. ENCOURAGING HEALTH PLANS TO ESTABLISH**  
6 **PROGRAMS TO INCREASE ADULT IMMUNIZA-**  
7 **TION.**

8 (a) PRIVATE HEALTH PLANS.—Section 2718 of the  
9 Public Health Service Act (42 U.S.C. 300gg–18) is  
10 amended by adding at the end the following new sub-  
11 section:

12 “(f) PROGRAMS TO INCREASE ADULT IMMUNIZA-  
13 TION.—

14 “(1) IN GENERAL.—For purposes of this sec-  
15 tion, for plan years beginning on or after the date  
16 of enactment of the Vaccine Access, Certainty, and  
17 Innovation Act of 2015, activities that improve  
18 health care quality described in subsection (a)(2)  
19 shall include programs to increase adult immuniza-  
20 tion.

21 “(2) ADMINISTRATION.—Not later than Decem-  
22 ber 31, 2016, the Secretary shall establish standard-  
23 ized methodologies, including definitions, for which  
24 activities, and in what regard such activities, con-  
25 stitute programs to increase adult immunization in

1 accordance with this subsection. The Secretary shall  
2 consult with relevant stakeholders in establishing  
3 such methodologies.”.

4 (b) MEDICARE ADVANTAGE AND PART D PLANS.—  
5 Section 1857(e) of the Social Security Act (42 U.S.C.  
6 1395w–27(e)) is amended by adding at the end the fol-  
7 lowing new paragraph:

8 “(5) INCLUSION OF EXPENDITURES ON PRO-  
9 GRAMS TO INCREASE ADULT IMMUNIZATION IN MIN-  
10 IMUM MEDICAL LOSS RATIO CALCULATION.—For  
11 purposes of calculating the minimum medical loss  
12 ratio under paragraph (4), for plan years beginning  
13 at least 12 months after the date of enactment of  
14 this Act, the numerator shall include any expendi-  
15 tures on programs to increase adult immunization.”.

16 **Subtitle D—Reagan-Udall**  
17 **Improvements Bill**

18 **SEC. 4081. REAGAN-UDALL FOUNDATION FOR THE FOOD**  
19 **AND DRUG ADMINISTRATION.**

20 (a) BOARD OF DIRECTORS.—

21 (1) COMPOSITION AND SIZE.—Section  
22 770(d)(1)(C) of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

24 (A) by redesignating clause (ii) as clause  
25 (iii);

1 (B) by inserting after clause (i) the fol-  
2 lowing:

3 “(ii) ADDITIONAL MEMBERS.—The  
4 Board, through amendments to the bylaws  
5 of the Foundation, may provide that the  
6 number of voting members of the Board  
7 shall be a number (to be specified in such  
8 amendment) greater than 14. Any Board  
9 positions that are established by any such  
10 amendment shall be appointed (by majority  
11 vote) by the individuals who, as of the date  
12 of such amendment, are voting members of  
13 the Board and persons so appointed may  
14 represent any of the categories specified in  
15 subclauses (I) through (V) of clause (i), so  
16 long as no more than 30 percent of the  
17 total voting members of the Board (includ-  
18 ing members whose positions are estab-  
19 lished by such amendment) are representa-  
20 tives of the general pharmaceutical, device,  
21 food, cosmetic, and biotechnology indus-  
22 tries.”; and

23 (C) in clause (iii)(I), as redesignated by  
24 subparagraph (A), by striking “The ex officio  
25 members shall ensure” and inserting “The ex

1 officio members, acting pursuant to clause (i),  
2 and the Board, acting pursuant to clause (ii),  
3 shall ensure”.

4 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE  
5 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)  
6 of the Federal Food, Drug, and Cosmetic Act (21  
7 U.S.C. 379dd(d)(1)(C)), as redesignated by para-  
8 graph (1)(A), is amended by adding at the end the  
9 following: “For purposes of this section, the term  
10 ‘employee of the Federal Government’ does not in-  
11 clude a ‘special Government employee’, as that term  
12 is defined in section 202(a) of title 18, United  
13 States Code.”.

14 (3) STAGGERED TERMS.—Subparagraph (A) of  
15 section 770(d)(3) of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended  
17 to read as follows:

18 “(A) TERM.—The term of office of each  
19 member of the Board appointed under para-  
20 graph (1)(C)(i), and the term of office of any  
21 member of the Board whose position is estab-  
22 lished pursuant to paragraph (1)(C)(ii), shall be  
23 4 years, except that—

24 “(i) the terms of offices for the mem-  
25 bers of the Board initially appointed under

1 paragraph (1)(C)(i) shall expire on a stag-  
2 gered basis as determined by the ex officio  
3 members; and

4 “(ii) the terms of office for the per-  
5 sons initially appointed to positions estab-  
6 lished pursuant to paragraph (1)(C)(ii)  
7 may be made to expire on a staggered  
8 basis, as determined by the individuals  
9 who, as of the date of the amendment es-  
10 tablishing such positions, are members of  
11 the Board.”.

12 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section  
13 770(g)(2) of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall  
15 not be greater than the compensation of the Commis-  
16 sioner”.

17 (c) SEPARATION OF FUNDS.—Section 770(m) of the  
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 379dd(m)) is amended by striking “are held in separate  
20 accounts from funds received from entities under sub-  
21 section (i)” and inserting “are managed as individual pro-  
22 grammatic funds under subsection (i), according to best  
23 accounting practices”.





1 the goal of enhancing professional development, as  
2 described in subsection (a); and

3 “(2) responsibility for such procedures is dele-  
4 gated to the relevant supervising officials and em-  
5 ployees of the Food and Drug Administration.”.

6 (b) REPORT.—Not later than 1 year after the date  
7 of enactment of this Act, the Commissioner of Food and  
8 Drugs shall submit to the Congress a report on the actions  
9 taken to carry out section 746A of the Federal Food,  
10 Drug, and Cosmetic Act, as added by subsection (a).

11 **SEC. 4122. FDA MANAGEMENT SUCCESSION PLANNING.**

12 (a) IN GENERAL.—Section 1003 of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 393) is amend-  
14 ed by adding at the end the following:

15 “(j) MANAGEMENT SUCCESSION PLANNING.—The  
16 Secretary shall—

17 “(1) develop and implement a formal succession  
18 plan for management positions within the Food and  
19 Drug Administration at or higher than the level of  
20 a director of a center; and

21 “(2) include in such plan staffing contingency  
22 planning, internal and external recruitment strate-  
23 gies, training and professional development for man-  
24 agement candidates, and considerations regarding

1 any need for special or direct hiring or compensation  
2 flexibility.”.

3 (b) INITIAL PLAN.—Not later than 180 days after  
4 the date of enactment of this Act, the Commissioner of  
5 Food and Drugs shall complete the development of the ini-  
6 tial succession plan required by section 1003(j) of the Fed-  
7 eral Food, Drug, and Cosmetic Act, as added by sub-  
8 section (a).

## 9 **Subtitle G—Disposable Medical** 10 **Technologies**

### 11 **SEC. 4141. COVERAGE OF CERTAIN DISPOSABLE MEDICAL** 12 **TECHNOLOGIES UNDER THE MEDICARE PRO-** 13 **GRAM.**

14 (a) COVERAGE.—Section 1861 of the Social Security  
15 Act (42 U.S.C. 1395x), as amended by section 2121, is  
16 further amended, by adding at the end the following new  
17 subsection:

18 “Substitute Disposable Medical Technology

19 “(jjj) The term ‘substitute disposable medical tech-  
20 nology’ means medical equipment that—

21 “(1) is primarily and customarily used to serve  
22 a medical purpose;

23 “(2) would otherwise be covered as durable  
24 medical equipment under this title but for the fact  
25 that such equipment is not durable (as defined by

1 the Secretary for purposes of coverage of durable  
2 medical equipment under this title); and

3 “(3) the Secretary determines substitutes for  
4 durable medical equipment.”.

5 (b) PAYMENT PROVISIONS.—Section 1834(a) of the  
6 Social Security Act (42 U.S.C. 1395m(a)) is amended by  
7 adding at the end the following new paragraph:

8 “(23) SPECIAL PAYMENT RULE FOR SUB-  
9 STITUTE DISPOSABLE MEDICAL TECHNOLOGIES.—  
10 Notwithstanding the preceding provisions of this  
11 subsection, the Secretary shall determine the pay-  
12 ment amount under this subsection for a substitute  
13 disposable medical technology (as defined in section  
14 1861(jjj)), and for any services and supplies used in  
15 conjunction with such technology, in accordance with  
16 the following:

17 “(A) SINGLE PAYMENT AMOUNT.—The  
18 Secretary shall determine a single payment  
19 amount that shall be paid for a substitute dis-  
20 posable medical technology and for any services  
21 and supplies used in conjunction with such  
22 technology. A payment for such a technology  
23 and for any such services and supplies that is  
24 made in the amount of such single payment  
25 amount shall constitute full payment under this

1 title for such technology and such services and  
2 supplies.

3 “(B) CALCULATION OF PAYMENT  
4 AMOUNT.—The single payment amount de-  
5 scribed in subparagraph (A) for a substitute  
6 disposable medical technology and for any serv-  
7 ices and supplies used in conjunction with such  
8 technology shall be calculated by—

9 “(i) calculating the sum of the  
10 amounts of payment that otherwise would  
11 be made under this section for—

12 “(I) the item of durable medical  
13 equipment for which the Secretary de-  
14 termines, pursuant to section  
15 1861(jjj)(3), that such substitute dis-  
16 posable medical technology sub-  
17 stitutes; and

18 “(II) all services and supplies  
19 used in conjunction with such item of  
20 durable medical equipment;

21 “(ii) calculating the amount that is 95  
22 percent of the sum calculated under clause  
23 (i); and

24 “(iii) calculating the single payment  
25 amount for the substitute disposable med-

1           ical technology and for any services and  
2           supplies used in conjunction with such  
3           technology such that the sum of the pay-  
4           ments under this subsection for—

5                   “(I) all substitute disposable  
6                   medical technologies that the Sec-  
7                   retary determines, pursuant to section  
8                   1861(jjj)(3), will be necessary to pro-  
9                   vide a substitute for the item of dura-  
10                  ble medical equipment described in  
11                  clause (i)(I); and

12                   “(II) any services and supplies  
13                   used in conjunction with such tech-  
14                   nologies;

15                  is equal to the amount calculated under  
16                  clause (ii).

17                   “(C) LUMP-SUM PAYMENT.—The single  
18                  payment amount described in subparagraph (A)  
19                  for a substitute disposable medical technology  
20                  and for any services and supplies used in con-  
21                  junction with such technology shall be made in  
22                  a lump-sum amount.”.

23           (c) NONAPPLICATION OF COMPETITIVE ACQUI-  
24           TION.—Section 1847(a)(7)(B) of the Social Security Act  
25           (42 U.S.C. 1395w-3(a)(7)(B)) is amended—

1 (1) in clause (i), by striking “and” at the end;

2 (2) in clause (ii), by striking the period at the  
3 end and inserting “; and”; and

4 (3) by adding at the end the following new  
5 clause:

6 “(iii) that are substitute disposable  
7 medical technologies (as defined in section  
8 1861(n)(2)(B)).”.

9 (d) EFFECTIVE DATE.—The amendments made by  
10 this section shall apply with respect to items and services  
11 furnished on or after the date that is one year after the  
12 date of the enactment of this section.

13 **Subtitle H—Local and National**  
14 **Coverage Decision Reforms**

15 **SEC. 4161. IMPROVEMENTS IN THE MEDICARE LOCAL COV-**  
16 **ERAGE DETERMINATION (LCD) PROCESS.**

*【Are there ways in which the NCD/LCD process can  
work better for both the administration and those seeking  
coverage under the Medicare program?】*

17 (a) IN GENERAL.—Section 1862(l)(5) of the Social  
18 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-  
19 ing at the end the following subparagraph:

20 “(D) REQUIREMENTS FOR LOCAL COV-  
21 ERAGE DETERMINATION PROCESS FOR MEDI-  
22 CARE ADMINISTRATIVE CONTRACTORS.—

1                   “(i) IN GENERAL.—The Secretary  
2                   shall require each medicare administrative  
3                   contractor to establish a timely process for  
4                   development of local coverage determina-  
5                   tions that provides for opportunities for  
6                   public comment and for disclosure of infor-  
7                   mation to the public regarding such deter-  
8                   minations.

9                   “(ii) PROCESS.—Before releasing a  
10                  new or significantly revised local coverage  
11                  determination, a medicare administrative  
12                  contractor shall—

13                         “(I) issue a proposed local cov-  
14                         erage determination and provide a pe-  
15                         riod for public comment of at least 45  
16                         days (or 60 days in the case described  
17                         in clause (iii));

18                         “(II) upon request of individuals  
19                         (including providers or representatives  
20                         of Medicare beneficiaries) within the  
21                         jurisdiction of the contractor, convene  
22                         an open, public meeting to review the  
23                         proposed local coverage determination  
24                         and to receive comments from  
25                         attendees; and

1                   “(III) meet upon request with in-  
2                   dividuals (including providers or rep-  
3                   resentatives of Medicare beneficiaries)  
4                   within such jurisdiction and manufac-  
5                   turers or sponsors of items affected by  
6                   the proposed local coverage deter-  
7                   mination.

8                   “(iii) PROCESS FOR LIMITATIONS.—If  
9                   a medicare administrative contractor pro-  
10                  poses a local coverage determination that  
11                  would limit or preclude coverage of an item  
12                  or service, the contractor shall convene a  
13                  meeting of its Carrier Advisory Committee  
14                  as required under chapter 13 of the Medi-  
15                  care Program Integrity Manual to secure  
16                  its advice on the proposed determination  
17                  and shall provide a period for public com-  
18                  ment on the proposed determination of at  
19                  least 60 days.

20                  “(iv) RESPONDING TO COMMENTS.—A  
21                  medicare administrative contractor shall  
22                  include with any public release of a final  
23                  local coverage determination—



1                   “(I) the contractor’s response to  
2                   comments on the proposed local cov-  
3                   erage determination; and

4                   “(II) a description of the evi-  
5                   dence the contractor considered in  
6                   making the determination and the ra-  
7                   tionale for the policy adopted.

8                   “(v) ADOPTING DETERMINATIONS IN  
9                   OTHER JURISDICTIONS.—A medicare ad-  
10                  ministrative contractor may adopt for its  
11                  jurisdiction a local coverage determination  
12                  proposed or adopted for another jurisdic-  
13                  tion only if it undertakes the process as de-  
14                  scribed in this subparagraph in its jurisdic-  
15                  tion with respect to such determination, in-  
16                  cluding providing an opportunity for com-  
17                  ment and meetings in its jurisdiction on  
18                  such determination.

19                  “(vi) TREATMENT OF REVISIONS.—A  
20                  medicare administrative contractor may  
21                  issue a revised local coverage determina-  
22                  tion without regard to clauses (ii), (iii),  
23                  and (iv) if the determination is—

24                  “(I) a clarification that does not  
25                  restrict coverage;

1                   “(II) a change for a compelling  
2                   clinical, safety, or technical reason,  
3                   such as prevention of harm to individ-  
4                   uals (subject to the approval of the  
5                   Secretary);

6                   “(III) a change for coding, cov-  
7                   erage, or payment updates over which  
8                   the medicare administrative con-  
9                   tractor does not have discretion;

10                   “(IV) a discretionary coding up-  
11                   date that does not restrict coverage;

12                   “(V) a change to effectuate a de-  
13                   cision of an administrative law judge  
14                   on a challenge under section 1869(f);  
15                   or

16                   “(VI) another type of change  
17                   that the Secretary may specify in reg-  
18                   ulations.”.

19           (b) EFFECTIVE DATE.—The amendment made by  
20           subsection (a) shall be effective with respect to local cov-  
21           erage determinations proposed or revised on or after the  
22           date that is 90 days after the date of the enactment of  
23           this Act.

1                   **Subtitle I—Telemedicine**

2   **SEC. 4181. ADVANCING TELEHEALTH OPPORTUNITIES IN**  
3                   **MEDICARE.**

4           (a) PAYMENT FOR SELECTED TELEHEALTH SERV-  
5 ICES.—

6                   (1) IN GENERAL.—Title XVIII of the Social Se-  
7           curity Act (42 U.S.C. 1395 et seq.) is amended by  
8           adding at the end the following new section:

9   **“SEC. 1899C. PAYMENT FOR SELECTED TELEHEALTH SERV-**  
10                   **ICES.**

11           “(a) IN GENERAL.—Subject to subsections (b)(1)  
12 and (d)(2), beginning not later than 4 years after the date  
13 of the enactment of this section, the Secretary shall imple-  
14 ment a methodology to provide for coverage and payment  
15 for a telehealth service (or episodes of such services) in-  
16 cluded on the list published under subsection (c) and fur-  
17 nished via a telecommunications system to an individual  
18 entitled to benefits under part A or enrolled under part  
19 B to the same extent and in the same amount as would  
20 be provided under this part if the supplier furnishing such  
21 service were at the same location as the individual. In de-  
22 veloping the methodology under the previous sentence, the  
23 provisions of section 1834(m) shall apply, except the Sec-  
24 retary may, subject to subsections (b)(1) and (d)(2), waive  
25 any provision of such section that applies a limitation on

1 what qualifies as an originating site, any geographic limi-  
2 tation, or any limitation on the type of health care pro-  
3 vider who may furnish such services.

4 “(b) LIMITATION AND CONSIDERATIONS.—

5 “(1) LIMITATION.—In no case may the applica-  
6 tion of the methodology under subsection (a) result  
7 in expenditures under this title for a year being  
8 greater than projected expenditures under this title  
9 without application of such methodology for such  
10 year.

11 “(2) CONSIDERATIONS.—In developing the  
12 methodology under subsection (a), the Secretary  
13 shall take into account, with respect to telehealth  
14 services (or episodes of such services) proposed to be  
15 included on the list under subsection (c), the fol-  
16 lowing:

17 “(A) The extent to which, and how, fully  
18 capitated rates and bundled payments under  
19 this title, with respect to such services or epi-  
20 sodes, may achieve reduced expenditures under  
21 this title.

22 “(B) The extent to which, and how, de-  
23 fined episodes, with respect to such services,  
24 may help facilitate such reduced expenditures.

1           “(C) How the methodology might be used  
2           to utilize cost-effective sites of service, with re-  
3           spect to such services or episodes, that may re-  
4           sult in savings to individuals entitled to benefits  
5           under part A or enrolled under part B and re-  
6           duced expenditures under this title.

7           “(D) Proposals for reforms to the original  
8           Medicare fee-for-service program under parts A  
9           and B, including safe harbors from any limita-  
10          tions under section 1834(m), that would be  
11          needed to enable the methodology with respect  
12          to such services or episodes to result in such  
13          savings and reduced expenditures.

14          “(c) SELECTION OF SERVICES.—

15                 “(1) INITIAL LIST.—

16                         “(A) PROPOSED LIST.—Not later than  
17                         [\_\_\_\_], the Secretary shall, through notice of  
18                         proposed rulemaking, select telehealth services  
19                         and episodes of such services, if any, to be in-  
20                         cluded on a proposed initial list of such services  
21                         and episodes for which payment may be made  
22                         under the methodology under subsection (a).

23                         “(B) PUBLISHED LIST.—If the Chief Actua-  
24                         ry of the Centers for Medicare & Medicaid  
25                         Services certifies under subsection (d)(2) that

1 the methodology under subsection (a), with re-  
2 spect to the telehealth services and episodes in-  
3 cluded in the proposed list under subparagraph  
4 (A), would reduce (or would not result in any  
5 increase in) net program spending under this  
6 title, the Secretary shall, through rulemaking,  
7 publish such list in the Federal Register.

8 “(2) MODIFICATIONS.—The Secretary may pe-  
9 riodically, subject to subsection (b)(1) and through  
10 rulemaking, make modifications to the list under  
11 paragraph (1).

12 “(3) CONSIDERATIONS.—The Secretary shall  
13 consider for inclusion on the list published under  
14 paragraph (1), as may be modified under paragraph  
15 (2), the following:

16 “(A) Telehealth services that meet unmet  
17 service needs, as defined by the Secretary.

18 “(B) Telehealth services that are substi-  
19 tutions for an in-person visit.

20 “(C) Telehealth services that are proven to  
21 reduce readmissions (or other costly services),  
22 as defined by the Secretary.

23 “(D) Telehealth services that, without the  
24 provision of such a service, would not allow a

1 patient to be moved to a lower level of care (in-  
2 cluding home health care).

3 “(d) CONTINGENT IMPLEMENTATION.—

4 “(1) CERTIFICATION.—Not later than [\_\_\_\_],  
5 the Chief Actuary of the Centers for Medicare &  
6 Medicaid Services shall certify whether or not the  
7 methodology under subsection (a), with respect to  
8 the telehealth services (and episodes of such serv-  
9 ices) proposed to be included in the initial list pub-  
10 lished under subsection (c), would reduce (or would  
11 not result in any increase in) net program spending  
12 under this title.

13 “(2) IMPLEMENTATION.—The Secretary shall,  
14 through rulemaking, implement the methodology  
15 under subsection (a), with respect to the initial list  
16 of services and episodes to be published under sub-  
17 section (c), if the Chief Actuary of the Centers for  
18 Medicare & Medicaid Services certifies under para-  
19 graph (1) that such methodology, with respect to  
20 such initial list, would reduce (or would not result in  
21 any increase in) net program spending under this  
22 title.

23 “(3) REPORT.—If the Chief Actuary of the  
24 Centers for Medicare & Medicaid Services does not  
25 certify under paragraph (1) that the methodology

1 under subsection (a) would reduce (or would not re-  
2 sult in any increase in) net program spending under  
3 this title, then the Secretary—

4 “(A) shall not publish the initial list under  
5 subsection (c) and shall not implement such  
6 methodology; and

7 “(B) not later than [\_\_\_\_], shall submit  
8 to Congress a report containing the proposed  
9 methodology under subsection (a), the proposed  
10 initial list of telehealth services (and episodes of  
11 services) under subsection (c), and the analysis  
12 of the Chief Actuary of the Centers for Medi-  
13 care & Medicaid Services from which the certifi-  
14 cation under paragraph (1) was made.

15 “(e) TELEHEALTH SERVICES DEFINED.—For pur-  
16 poses of this section, the term ‘telehealth services’ has the  
17 meaning given such term under section 1834(m)(4)(F).”.

18 (2) CONFORMING AMENDMENTS.—Section  
19 1834(m) of the Social Security Act (42 U.S.C.  
20 1395m(m)) is amended in the subsection heading, by  
21 striking “SERVICES.—” and inserting “SERVICES.—  
22 Subject to subsection (r), the following shall apply:”.

23 (b) ENCOURAGING GREATER ACCESS TO TELE-  
24 HEALTH SERVICES IN BUNDLED PAYMENT MODELS.—



1           (1) WAIVER OF CERTAIN MEDICARE TELE-  
2 HEALTH LIMITATIONS FOR PURPOSES OF DEM-  
3 ONSTRATIONS AND MODELS.—Notwithstanding any  
4 other provision of law, the Secretary of Health and  
5 Human Services shall permit any demonstration  
6 project or model that is carried out with respect to  
7 the Medicare program under title XVIII of the So-  
8 cial Security Act, under section 1115A of the such  
9 Act (42 U.S.C. 1315a) or otherwise, to include  
10 under such project or model, with respect to individ-  
11 uals entitled to benefits under part A of such title  
12 or enrolled under part B of such title participating  
13 in such project or model, telehealth services (as de-  
14 fined in paragraph (4)(F) of section 1834(m) of  
15 such Act (42 U.S.C. 1395m(m)) furnished to such  
16 individuals and for which payment may otherwise be  
17 made under such title without application of any  
18 provision under such section 1834(m) that applies a  
19 limitation on what qualifies as an originating site,  
20 any geographic limitation, or any limitation on the  
21 type of health care provider who may furnish such  
22 services. In no case shall the application of the pre-  
23 vious sentence, with respect to individuals entitled to  
24 benefits under part A of such title or enrolled under  
25 part B of such title who are participating in such

1 project or model, result in expenditures under the  
2 respective demonstration project or model, with re-  
3 spect to a period, that are greater than the amount  
4 of expenditures that would have resulted under such  
5 project or model during such period without applica-  
6 tion of such sentence.

7 (2) TELEHEALTH SERVICES DEFINITION.—Sec-  
8 tion 1834(m)(4)(F) of the Social Security Act (42  
9 U.S.C. 1395m(m)(4)(F)) is amended by adding at  
10 the end the following new clause:

11 “(iii) STORE-AND-FORWARD TECH-  
12 NOLOGY.—***How should ‘store-and-forward’***  
13 ***be defined?*** The term ‘telehealth service’  
14 shall include, for purposes of application  
15 with respect to any demonstration project  
16 or model conducted with respect to the  
17 program under this title, store-and-forward  
18 technologies. For purposes of the previous  
19 sentence, the term ‘store-and-forward tech-  
20 nology’ means technologies that allow for  
21 the electronic transmission of medical in-  
22 formation, such as digital images, docu-  
23 ments, and prerecorded videos through se-  
24 cure email transmission.”.

1 (c) SENSE OF CONGRESS REGARDING STATE MED-  
2 ICAL BOARD COMPACTS.—It is the sense of Congress that  
3 States should collaborate, through the use of State med-  
4 ical board compacts, to create common licensure require-  
5 ments for providing telehealth services in order to facili-  
6 tate multistate practices and allow for health care pro-  
7 viders to provide such services across State lines.

8 (d) CONSTRUCTION.—Nothing in this section shall be  
9 construed to change the application of the HIPAA privacy  
10 regulations (as defined in section 1180(b)(3) of the Social  
11 Security Act (42 U.S.C. 1320d–9(b)(3))) with respect to  
12 a health care professional’s provision of telehealth services  
13 (as defined in section 1834(m)(4)(F) of the Social Secu-  
14 rity Act (42 U.S.C. 1395m(m)(4)(F))).

15 **Subtitle J—Revise IPPS New Tech-**  
16 **nology Add-On Payment (NTAP)**  
17 **Reimbursement Amounts**

18 **SEC. 4201. CODING AND REIMBURSEMENT REFORMS.**

19 (a) PERMITTING APPEALS OF NTAP DETERMINA-  
20 TIONS UNDER PART A.—Section 1886(d) of the Social Se-  
21 curity Act (42 U.S.C. 1395ww(d)) is amended—

22 (1) in paragraph (5)(K), by adding at the end  
23 the following new clause:

24 “(x) Administrative review of an ap-  
25 plication for additional payment under this

1           subparagraph with respect to a discharge  
2           occurring on or after the date of the enact-  
3           ment of the 21st Century Cures Act shall  
4           be conducted in an expedited manner and  
5           shall be completed not later than 90 days  
6           after the date on which the appeal is filed  
7           with the Secretary.”; and

8           (2) in paragraph (7)(B), by inserting “but not  
9           including a denial by the Secretary of an application  
10          for additional payment under paragraph (5)(K) with  
11          respect to a discharge occurring on or after the date  
12          of the date of the enactment of the 21st Century  
13          Cures Act” after “paragraph (4)(D)”.

14          (b) REPLACING HCPCS CODES WITH NDC CODES  
15          FOR PURPOSES OF PART B CODING.—

16               (1) IN GENERAL.—Section 1847A(b) of the So-  
17          cial Security Act (42 U.S.C. 1395w-3a(b)) is  
18          amended by adding at the end the following new  
19          paragraph:

20               “(9) USE OF NDC CODES.—Not later than two  
21          years after the date of the enactment of this para-  
22          graph, the Secretary shall—

23                       “(A) eliminate the use of HCPCS Level II  
24                       codes for drugs and biologicals for purposes of

1 coverage, coding, and reimbursement under this  
2 part; and

3 “(B) replace such codes with National  
4 Drug Codes for such drugs and biologicals.”.

5 (2) CONFORMING AMENDMENTS.—Section  
6 1847A(b) of such Act (42 U.S.C. 1395w-3a(b)), as  
7 amended by paragraph (1), is further amended—

8 (A) in paragraph (3), by inserting “, sub-  
9 ject to paragraph (10),” after “products in-  
10 cluded”;

11 (B) in paragraph (6)—

12 (i) in subparagraph (A), by inserting  
13 “, subject to paragraph (10),” after “prod-  
14 ucts included”; and

15 (ii) in subparagraph (B), by inserting  
16 “, subject to paragraph (10),” after “asso-  
17 ciated”; and

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

20 “(10) APPLICATION OF BILLING AND PAYMENT  
21 CODE REFERENCES.—

22 “(A) IN GENERAL.—In applying—

23 “(i) paragraph (3) and subparagraphs  
24 (A), (A)(i)(I), and (A)(ii)(II) of paragraph  
25 (6) on a date that is after the date de-

1           scribed in subparagraph (B), the Secretary  
2           shall treat each reference to all drug prod-  
3           ucts included within the same multiple  
4           source drug billing and payment code (in-  
5           cluding each reference to ‘the billing and  
6           payment code’ in such subparagraphs  
7           (A)(i)(I) and (A)(ii)(II)) as a reference to  
8           all drug products that are within National  
9           Drug Codes qualified as therapeutically  
10          equivalent by the Food and Drug Adminis-  
11          tration in the Approved Drug Products  
12          with Therapeutic Equivalence Evaluations  
13          list; and

14                   “(ii) paragraph (6)(B) on a date that  
15                   is after the date described in subparagraph  
16                   (B), the Secretary shall treat the reference  
17                   to a billing and payment code as a ref-  
18                   erence to National Drug Codes so qualified  
19                   as therapeutically equivalent.

20                   “(B) DATE DESCRIBED.—The date de-  
21                   scribed in this paragraph is the date on which  
22                   the Secretary, pursuant to paragraph (9), elimi-  
23                   nates the use of HCPCS Level II codes for  
24                   drugs and biologicals for purposes described in  
25                   such paragraph and replaces such codes with

1 National Drug Codes for such drugs and  
2 biologicals.”.

3 (3) NOTICE IN FEDERAL REGISTER.—The Sec-  
4 retary of Health and Human Services shall, on a  
5 date that is not later than 90 days before the date  
6 on which the Secretary, pursuant to paragraph (9)  
7 of section 1847A(b) of the Social Security Act (42  
8 U.S.C. 1395w–3a(b)), eliminates the use of HCPCS  
9 Level II codes for drugs and biologicals for purposes  
10 described in such paragraph and replaces such codes  
11 with National Drug Codes for such drugs and  
12 biologicals, publish in the Federal Register a notifi-  
13 cation of the HCPCS Level II codes that will be so  
14 eliminated and replaced, and of the National Drug  
15 Codes that will provide such replacement.

16 (c) SENSE OF CONGRESS.—It is the sense of the Con-  
17 gress that novel emerging therapies will offer a major step  
18 forward in the treatment and curing of diseases, as many  
19 of these new and emerging therapies, such as regenerative  
20 medicines, novel gene therapies, and new stem cell thera-  
21 pies, will be used across multiple sites of care. The Centers  
22 for Medicare & Medicaid Services are urged to begin the  
23 development of appropriate billing and payment coding re-  
24 games to anticipate the use of these and other new tech-  
25 nologies for the treatment and curing of disease.

1           **Subtitle K—Lowering Medicare**  
2                           **Patients OOP Costs**

3   **SEC. 4221. MEDICARE SITE-OF-SERVICE PRICE TRANS-**  
4                           **PARENCY.**

5           (a) IN GENERAL.—Beginning not later than [\_\_\_\_],  
6 the Director of the National Institute for Standards and  
7 Technology, in consultation with the Secretary of Health  
8 and Human Services, shall establish and periodically up-  
9 date a searchable public website to disclose to individuals  
10 entitled to benefits under part A of title XVIII of the So-  
11 cial Security Act and enrolled for benefits under part B  
12 of such title the information described in subsection (b).  
13 Such information shall be provided for each payment area  
14 involved and shall be accessible by any zip code included  
15 in such area, by item or service specified pursuant to sub-  
16 section (b)(1), and by applicable type of Medicare Advan-  
17 tage plan offered under part C of such title.

18           (b) INFORMATION.—For purposes of subsection (a),  
19 the information described in this subsection, with respect  
20 to a payment area, zip code included in such area, and,  
21 as applicable, Medicare Advantage plan, is the following:

22                   (1) A list of at [least \_\_\_\_] the items and serv-  
23                   ices specified by the Secretary, which may be fur-  
24                   nished at different types of sites of service and for



1       which payment may be made under such title at  
2       each of such types of sites.

3               (2) With respect to each item and service so  
4       listed—

5                       (A) each type of site of service described in  
6       paragraph (1) at which such item or service  
7       may be furnished;

8                       (B) a list of providers (and contact infor-  
9       mation for such providers) within such area  
10      and, as applicable, participating in the network  
11      of such plan, that furnishes such item and serv-  
12      ice; and

13                      (C) for each type of site of service specified  
14      pursuant to subparagraph (A)—

15                               (i) any criteria required to be satisfied  
16      for payment to be made under such title if  
17      such item or service were furnished at such  
18      a site;

19                              (ii) the maximum out-of-pocket cost,  
20      including deductible and cost sharing, re-  
21      sponsibility applicable to such an individual  
22      if such item or service were furnished at  
23      such a site; and

24                              (iii) the rate of payment for such item  
25      or service applicable to such a site under

1                   such title, without regard to any deductible  
2                   or cost sharing.

3           (c) ASSISTANCE.—The Secretary of Health and  
4 Human Services shall provide to the Director of the Na-  
5 tional Institute for Standards and Technology such assist-  
6 ance as may be necessary for the Director to carry out  
7 subsection (a).

8           (d) CONTRACT AUTHORITY.—The Director may  
9 enter into an agreement with an appropriate entity to  
10 carry out subsection (a).

11          (e) CLAIMS DATA.—The Director of the National In-  
12 stitute for Standards and Technology, in collaboration  
13 with the Secretary of Health and Human Services, shall  
14 determine the extent to which it is feasible for the Director  
15 to have access to the claims database of the Centers for  
16 Medicare & Medicaid Services to assess individualized  
17 (and in real time) the extent to which (and amount by  
18 which) an individual described in subsection (a) is subject  
19 to a deductible or out-of-pocket cost limitation with re-  
20 spect to items and services specified pursuant to sub-  
21 section (b)(1) and types of sites of services described in  
22 subsection (b)(2)(A) for purposes of enabling such indi-  
23 vidual to access such information through the database es-  
24 tablished under subsection (a).

1                   **Subtitle L—Global Surgery**  
2                   **Services Rule**

3 **SEC. 4241. TREATMENT OF GLOBAL SURGERY SERVICES**  
4                   **RULE.**

5           Notwithstanding any other provision of law, the Sec-  
6 retary of Health and Human Services shall not implement  
7 or enforce any provision of the final rule published on No-  
8 vember 13, 2014 (79 Federal Register 67582 through  
9 67591), relating to transitioning and revaluing 10-day and  
10 90-day global surgery services with 0-day global periods.

11 **Subtitle M—Providers Consolida-**  
12 **tion and Medicare Payments Ex-**  
13 **amined Through Evaluation**

14 **SEC. 4261. RULEMAKING THAT IMPLEMENTS CERTAIN**  
15 **MEDICARE PAYMENT CHANGES TO CONSIDER**  
16 **EFFECTS ON PROVIDER CONSOLIDATION.**

17           (a) IN GENERAL.—Beginning for 2016, as part of  
18 any annual notice and comment rulemaking process to im-  
19 plement changes to payment systems under title XVIII of  
20 the Social Security Act (42 U.S.C. 1395 et seq.) for items  
21 and services under title XVIII of the Social Security Act  
22 (including those for inpatient and outpatient hospital serv-  
23 ices, physicians’ services, and services furnished by other  
24 providers of services and suppliers), the Secretary of  
25 Health and Human Services shall seek public comment on

1 and evaluate the extent to which, and how, such a change  
2 is projected to affect provider consolidation.

3 (b) COORDINATION AND CONSULTATION.—

4 (1) INTERNAL COORDINATION.—For purposes  
5 of conducting the evaluations under subsection (a),  
6 the Secretary of Health and Human Services shall  
7 ensure appropriate coordination within the Centers  
8 for Medicare & Medicaid Services such that experts  
9 with respect to the applicable payment system under  
10 title XVIII of the Social Security Act work collabo-  
11 ratively for purposes of such evaluations.

12 (2) CONSULTATION.—For purposes of con-  
13 ducting the evaluations under subsection (a), the  
14 Secretary of Health and Human Services may con-  
15 sult with the Medicare Payment Advisory Commis-  
16 sion established under section 1805 of the Social Se-  
17 curity Act (42 U.S.C. 1395b–6), the Federal Trade  
18 Commission, other governmental agencies, and pri-  
19 vate sector entities.

20 (c) PROVIDER CONSOLIDATION DEFINED.—For pur-  
21 poses of this section, the term “provider consolidation” in-  
22 cludes the vertical integration among providers of services  
23 and suppliers, including professional practices, health care  
24 settings, and ancillary services by any entity (such as a  
25 health system, group practice, or health insurer).

1 **Subtitle N—Medicare Part D Pa-**  
2 **tient Safety and Drug Abuse**  
3 **Prevention**

4 **SEC. 4281. ESTABLISHING PDP SAFETY PROGRAM TO PRE-**  
5 **VENT FRAUD AND ABUSE IN MEDICARE PRE-**  
6 **SCRIPTION DRUG PLANS.**

7 (a) PDP SAFETY PROGRAM.—Section 1860D–4(c) of  
8 the Social Security Act (42 U.S.C. 1395w–104(c)) is  
9 amended—

10 (1) in paragraph (1)(D)—

11 (A) by inserting “, designed to” after  
12 “program”; and

13 (B) by inserting “, that includes the proce-  
14 dures described in paragraph (4)” after  
15 “waste”; and

16 (2) by adding at the end the following:

17 “(4) SAFE PHARMACY ACCESS PROGRAM.—

18 “(A) PDP SPONSOR PROCEDURES.—A  
19 PDP sponsor (or an MA organization offering  
20 an MA–PD plan) shall have in place procedures  
21 designed—

22 “(i) to identify an individual who has  
23 obtained coverage for a covered part D  
24 drug that is a frequently abused schedule  
25 II, III, IV, or V controlled substance, as

1 determined in accordance with utilization  
2 guidelines established by the Secretary and  
3 the sponsor (or MA organization), and to  
4 notify such individuals that they have been  
5 so identified;

6 “(ii) to contract with pharmacies au-  
7 thorized to dispense such controlled sub-  
8 stances to create a safe pharmacy network  
9 that meets the criteria specified in sub-  
10 paragraph (C);

11 “(iii) taking into account the location  
12 of the individual’s residence (or resi-  
13 dences), work site, mobility, and other rel-  
14 evant factors, to limit coverage to schedule  
15 II, III, IV, or V controlled substances for  
16 some or all classes of covered part D drugs  
17 for an individual identified under clause (i)  
18 (or under subparagraph (B)) to drugs dis-  
19 pensed by one or more pharmacies con-  
20 tracted with under clause (ii);

21 “(iv) to provide to the Secretary the  
22 name, and other information that the Sec-  
23 retary may require, of individuals so iden-  
24 tified and of the fact of such individual’s  
25 disenrollment (if any) from the plan of the

1 sponsor (or the MA–PD plan offered by  
2 the MA organization);

3 “(v) to provide for an appeals process  
4 whereby an individual so identified may  
5 appeal such identification on the basis that  
6 the identification was not appropriate;

7 “(vi) to provide for a process whereby  
8 an individual so identified may petition for  
9 the termination of such identification on  
10 the basis that the limitation on coverage is  
11 no longer necessary to prevent fraud and  
12 abuse by the individual; and

13 “(vii) to provide that coverage shall be  
14 provided for a schedule II, III, IV, or V  
15 controlled substance only if it is prescribed  
16 in accordance with an electronic pre-  
17 scribing program under subsection (e), ex-  
18 cept in such exceptional circumstances as  
19 the Secretary may permit.

20 “(B) SHARING INFORMATION FOR SUBSE-  
21 QUENT PLAN ENROLLMENTS.—The Secretary  
22 shall share information, with respect to the  
23 identity of an individual identified under sub-  
24 paragraph (A)(i) who disenrolls from a plan  
25 under subparagraph (A)(iv), with a PDP spon-

1 sor (or MA organization) that subsequently en-  
2 rolls such individual under another plan in  
3 order that the provisions of subparagraph  
4 (A)(iii) would apply under such subsequent en-  
5 rollment.

6 “(C) SAFE PHARMACY NETWORK CRI-  
7 TERIA.—The criteria specified in this subpara-  
8 graph for a safe pharmacy network are the fol-  
9 lowing:

10 “(i) The pharmacies in the network  
11 are able to properly monitor the usage of  
12 schedule II, III, IV, and V controlled sub-  
13 stances.

14 “(ii) Such pharmacies and network  
15 meet such other drug safety criteria as the  
16 Secretary or the PDP sponsor (or MA or-  
17 ganization) determines to be appropriate,  
18 such as use of a State prescription drug  
19 monitoring program, if such a program is  
20 available in the State.”.

21 (b) DUAL ELIGIBLES.—Section 1860D–1(b)(3)(D) of  
22 the Social Security Act (42 U.S.C. 1395w–101(b)(3)(D))  
23 is amended by inserting “, subject to such limits as the  
24 Secretary may establish for individuals identified pursuant  
25 to section 1860D–4(c)(4)(A)(i)” after “the Secretary”.



1 (c) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply with respect to plan years begin-  
3 ning after the date that is 8 months after the date of the  
4 enactment of this Act.

5 **SEC. 4282. PART D SUSPENSION OF CLAIMS PAYMENT.**

6 Section 1860D–12(b)(4) of the Social Security Act  
7 (42 U.S.C. 1395w–112(b)(4)) is amended by adding at  
8 the end the following new subparagraph:

9 “(H) SUSPENSION OF PAYMENTS PENDING  
10 INVESTIGATION OF CREDIBLE ALLEGATIONS OF  
11 FRAUD BY PHARMACIES.—

12 “(i) IN GENERAL.—A PDP sponsor  
13 may suspend payments and clean claim no-  
14 tifications to a pharmacy pending an inves-  
15 tigation of a credible allegation of fraud  
16 (as defined in clause (ii)) against the phar-  
17 macy, unless the Secretary determines  
18 there is a good cause not to suspend pay-  
19 ments.

20 “(ii) CREDIBLE ALLEGATION OF  
21 FRAUD DEFINED.—In this subparagraph,  
22 the term ‘credible allegation of fraud’ in-  
23 cludes—

24 “(I) a complaint made on the  
25 Medicare fraud hotline;

1 “(II) detection of potential fraud  
2 through the analysis of claims data;

3 “(III) detection of potential fraud  
4 through identification of inappropriate  
5 dispensing through audits, civil false  
6 claims cases, and law enforcement in-  
7 vestigations; and

8 “(IV) claims referred to Medicare  
9 drug integrity contractors (MEDICs).

10 “(iii) RULE OF CONSTRUCTION.—  
11 Nothing in this subparagraph shall be con-  
12 strued as limited the authority of a PDP  
13 sponsor to conduct postclaim payment re-  
14 view.”.

15 **SEC. 4283. IMPROVING ACTIVITIES OF MEDICARE DRUG IN-**  
16 **TEGRITY CONTRACTORS (MEDICS).**

17 (a) IN GENERAL.—Section 1893 of the Social Secu-  
18 rity Act (42 U.S.C. 1395ddd) is amended by adding at  
19 the end the following new subsection:

20 “(j) IMPROVING ACTIVITIES OF MEDICARE DRUG IN-  
21 TEGRITY CONTRACTORS (MEDICS).—

22 “(1) IN GENERAL.—Under contracts entered  
23 into under this section (each in this subsection re-  
24 ferred to as a ‘MEDIC contract’) with Medicare  
25 drug integrity contractors (each in this subsection

1 referred to as a ‘MEDIC’), the Secretary shall au-  
2 thorize MEDICs to directly obtain prescription and  
3 medical records from entities such as pharmacies,  
4 PDP and physicians.

5 “(2) REQUIREMENT FOR ACKNOWLEDGMENT  
6 OF REFERRALS.—If a PDP sponsor refers informa-  
7 tion to a MEDIC for investigation, under the  
8 MEDIC contract the MEDIC must acknowledge re-  
9 ceipt of the referral and must report back to the  
10 sponsor the result of the MEDIC’s investigation  
11 within 45 days of the date of the referral and share  
12 such results with appropriate agencies, such as law  
13 enforcement officials and State licensing authority.

14 “(3) UNIFORM ANNUAL REPORT CRITERIA.—In  
15 order to assess the performance of MEDICs, the  
16 Secretary shall develop a uniform reporting criteria  
17 for the annual reporting of the results of investiga-  
18 tions by MEDICs to the Secretary and to Congress.  
19 Each such annual report shall include information  
20 on the number of referrals for investigation made to  
21 a MEDIC, the average time required for investiga-  
22 tion, the results of the investigation, and the number  
23 of results that were referred to the Inspector Gen-  
24 eral of the Department of Health and Human Serv-

1       ices and to State licensing officials for further inves-  
2       tigations.”.

3       (b) **EFFECTIVE DATE.**—The amendment made by  
4       subsection (a) shall take effect on the date of the enact-  
5       ment of this Act and shall apply as quickly as possible  
6       to MEDIC contracts, including MEDIC contracts entered  
7       into before such date of enactment.

8       **SEC. 4284. REQUIRING E-PRESCRIBING FOR COVERAGE OF**  
9                   **COVERED PART D CONTROLLED SUB-**  
10                  **STANCES.**

11       (a) **IN GENERAL.**—Section 1860D–4(e) of the Social  
12       Security Act (42 U.S.C. 1395w–104(e)) is amended by  
13       adding at the end the following:

14               “(7) **REQUIREMENT OF E-PRESCRIBING FOR**  
15               **CONTROLLED SUBSTANCES.**—Except in such emer-  
16               gent circumstances as the Secretary may specify,  
17               coverage shall not be provided for a covered part D  
18               drug under a prescription drug plan (or under an  
19               MA–PD plan) for a schedule II, III, IV, or V con-  
20               trolled substance unless the prescription for the drug  
21               has been transmitted electronically in accordance  
22               with an electronic prescription drug program that  
23               meets the requirements of paragraph (2).”.

1 (b) EFFECTIVE DATE.—The amendment made by  
2 subsection (a) shall apply to coverage of drugs prescribed  
3 on or after January 1, 2015.

4 **Subtitle O—Accelerating**  
5 **Innovation in Medicine**

6 **SEC. 4301. ESTABLISHMENT OF MANUFACTURER OPT-OUT**  
7 **PROGRAM FOR MEDICAL DEVICES.**

8 (a) IN GENERAL.—Section 1862 of the Social Secu-  
9 rity Act (42 U.S.C. 1395y) is amended by adding at the  
10 end the following new subsection:

11 “(p) ESTABLISHMENT OF ACCELERATING INNOVA-  
12 TION IN MEDICINE (AIM) LIST OF MEDICAL DEVICES  
13 VOLUNTARILY EXCLUDED FROM COVERAGE.—

14 “(1) IN GENERAL.—Not later than 90 days  
15 after the date of the enactment of this subsection,  
16 the Secretary shall develop and maintain a listing  
17 (in this section referred to as the ‘AIM list’) of med-  
18 ical devices for which, because of their inclusion in  
19 such listing, no insurance benefit and no payment  
20 may be made for such a device under this title either  
21 directly or on a capitated basis such that no claim  
22 for payment may be submitted under this title for  
23 such a device and an individual who consents to re-  
24 ceive such a device is responsible for payment for

1 the device and services related to furnishing the de-  
2 vice.

3 “(2) PROCEDURES FOR INCLUSION IN AIM  
4 LIST.—

5 “(A) REQUIREMENT FOR WRITTEN CON-  
6 SENT OF MANUFACTURER.—No medical device  
7 may be included in the AIM list without the  
8 written consent of the manufacturer of the de-  
9 vice.

10 “(B) SUBMISSION PROCESS.—A manufac-  
11 turer seeking to have a medical device included  
12 in the AIM list shall submit to the Secretary a  
13 request for inclusion of the device in the AIM  
14 list. In the case of such a device for which—

15 “(i) there is a request for approval or  
16 clearance for marketing and sale of the de-  
17 vice by the Food and Drug Administration  
18 pursuant to authority granted by the Fed-  
19 eral Food, Drug, and Cosmetic Act (21  
20 U.S.C. 301 et seq.), including pursuant to  
21 section 510(k) or 515(c) of such Act (21  
22 U.S.C. 360(k), 360e(c)), the request for  
23 inclusion of the device in the AIM list may  
24 not be submitted earlier than the date of  
25 the request for such approval or clearance

1 and no later than the first business day of  
2 the month beginning at least 30 days after  
3 the date of such approval or clearance; or  
4 “(ii) the device is exempt from such  
5 approval and clearance requirements, the  
6 request may be submitted at a time that is  
7 not later than the first business day of the  
8 month beginning at least 30 days after the  
9 date of the first sale of the device by its  
10 manufacturer.

11 “(3) LISTING PERIODS; REMOVAL FROM LIST.—

12 “(A) 3-YEAR LISTING PERIODS.—A med-  
13 ical device included in the AIM list shall be ini-  
14 tially listed for a period of 3 years and shall re-  
15 main so listed for subsequent 3-year periods  
16 subject to subparagraphs (B) and (C).

17 “(B) REMOVAL AT REQUEST OF MANUFAC-  
18 Turer.—At any time a device of a manufac-  
19 turer included in the AIM list shall be removed  
20 from the AIM list upon the written request of  
21 the manufacturer. Subject to subparagraph (C),  
22 such a device of a manufacturer may not be re-  
23 moved from the AIM list except upon the writ-  
24 ten request of the manufacturer.

1           “(C) PROVISION OF DATA ON CLINICAL  
2           STUDIES AS A CONDITION FOR CONTINUED  
3           LISTING.—As a condition for the continued in-  
4           clusion of the device of a manufacturer in the  
5           AIM list for a subsequent 3-year listing period  
6           under subparagraph (A), the manufacturer  
7           shall provide the Secretary with published or  
8           publicly available data on clinical studies com-  
9           pleted for the device at the end of the previous  
10          3-year listing period. If the Secretary deter-  
11          mines that a manufacturer of a device has ma-  
12          terially failed to provide such data for the de-  
13          vice, the Secretary may remove the device from  
14          the AIM list or not renew the listing for the de-  
15          vice or both.

16          “(4) MEDICAL DEVICE DEFINED.—In this sub-  
17          section, the term ‘medical device’ has the meaning  
18          given the term ‘device’ in section 201(h) of the Fed-  
19          eral Food, Drug, and Cosmetic Act (21 U.S.C.  
20          321(h)).

21          “(5) POSTING OF LISTED DEVICES ON  
22          WEBSITE.—The Secretary shall post on a public  
23          website of the Department of Health and Human  
24          Services or other publicly accessible manner a list of  
25          the medical devices included in the AIM list and



1 shall provide for updating the website on a real-time  
2 basis (but no less frequently than monthly) to reflect  
3 changes in the medical devices in the AIM list.

4 “(6) REGULATIONS NOT REQUIRED.—Nothing  
5 in this subsection shall be construed as requiring the  
6 Secretary to promulgate regulations to carry out this  
7 subsection.

8 “(7) REQUIREMENT FOR INFORMED CONSENT  
9 IN ORDER FOR PROVIDER TO CHARGE FOR DE-  
10 VICE.—If a physician or other entity furnishes a  
11 medical device included in the AIM list to an indi-  
12 vidual under this title and failed to obtain, before  
13 furnishing the device, an appropriate informed con-  
14 sent under which the individual is informed of and  
15 accepts liability under paragraph (1) for payment  
16 for the device (and related services), the physician or  
17 other entity is deemed to have agreed not to impose  
18 any charge under this title for such device (and for  
19 services related to furnishing the device).”.

20 (b) CONFORMING AMENDMENT.—Section 1862(a) of  
21 the Social Security Act (42 U.S.C. 1395y(a)) is amend-  
22 ed—

23 (1) in paragraph (24), by striking “or” at the  
24 end;

1 (2) in paragraph (25), by striking the period at  
2 the end and inserting “; or”; and

3 (3) by inserting after paragraph (25) the fol-  
4 lowing new paragraph:

5 “(26) where such expenses are for a medical de-  
6 vice included in the AIM list under section 1862(p)  
7 or for items and services related to furnishing such  
8 device.”.

9 **Subtitle P—Medicare Pharma-**  
10 **ceutical and Technology Om-**  
11 **budsman**

12 **SEC. 4321. MEDICARE PHARMACEUTICAL AND TECH-**  
13 **NOLOGY OMBUDSMAN.**

14 Section 1808(c) of the Social Security Act (42 U.S.C.  
15 1395b–9(c)) is amended by adding at the end the fol-  
16 lowing new paragraph:

17 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-  
18 BUDSMAN.—Not later than 12 months after the date  
19 of the enactment of this paragraph, the Secretary  
20 shall provide for a pharmaceutical and technology  
21 ombudsman within the Centers for Medicare & Med-  
22 icaid Services who shall receive and respond to com-  
23 plaints, grievances, and requests that—

24 “(A) are from entities that manufacture  
25 pharmaceutical, biotechnology, medical device,

1 or diagnostic products that are covered or for  
2 which coverage is being sought under this title;  
3 and

4 “(B) regard coverage, coding, or payment  
5 under this title for such products.

6 The ombudsman shall submit to Congress an annual  
7 report on the activities carried out under this para-  
8 graph”.

9 **Subtitle Q—Ensuring Local Medi-**  
10 **care Administrative Contractors**  
11 **Evaluate Data Related to Cat-**  
12 **egory III Codes**

13 **SEC. 4341. ENSURING LOCAL MEDICARE ADMINISTRATIVE**  
14 **CONTRACTORS EVALUATE DATA RELATED TO**  
15 **CATEGORY III CODES.**

16 Section 1874A of the Social Security Act (42 U.S.C.  
17 1395kk–1) is amended—

18 (1) in subsection (a)(4), by inserting “, subject  
19 to subsection (b)(3)(D),” after “(including”;

20 (2) in subsection (b)(3), by adding at the end  
21 the following new subparagraph:

22 “(D) DATA EVALUATION REQUIREMENT  
23 FOR LOCAL COVERAGE DETERMINATIONS.—The  
24 Secretary shall include, as one of the require-  
25 ments developed under subparagraph (A), a re-

1           requirement that a medicare administrative con-  
2           tractor performing the function of developing  
3           local coverage determinations (as described in  
4           subsection (a)(4)) with respect to an item or  
5           service included as a Current Procedural Ter-  
6           minology Code that is a Category III Code  
7           shall, prior to developing such a determination  
8           with respect to such an item or service, evaluate  
9           all data related to such code.”.

## 10           **Subtitle R—Advancing Care for** 11           **Exceptional Kids**

### 12           **SEC. 4361. FINDINGS.**

13           Congress finds the following:

14           (1) Approximately 3,000,000 children in the  
15           United States suffer from medically complex condi-  
16           tions and approximately 2,000,000 of such children  
17           are enrolled in State plans under the Medicaid pro-  
18           gram under title XIX of the Social Security Act.

19           (2) Such children account for an estimated 6  
20           percent of Medicaid enrollees and approximately 40  
21           percent of children’s Medicaid spending is due to the  
22           severity of the illnesses of such children.

23           (3) The creation of nationally designated chil-  
24           dren’s hospital networks focused upon better coordi-  
25           nation and integration of care for such pediatric

1 population will result in improved health outcomes  
2 and savings under the Medicaid program and the  
3 Children’s Health Insurance Program under title  
4 XXI of the Social Security Act.

5 **SEC. 4362. ESTABLISHMENT OF MEDICAID AND CHIP CARE**  
6 **COORDINATION PROGRAM FOR CHILDREN**  
7 **WITH MEDICALLY COMPLEX CONDITIONS AS**  
8 **MEDICAID STATE OPTION.**

9 (a) MEDICAID.—Title XIX of the Social Security Act  
10 (42 U.S.C. 1396 et seq.) is amended—

11 (1) in section 1905(a) (42 U.S.C. 1396d(a))—

12 (A) by striking “and” at the end of para-  
13 graph (27);

14 (B) by redesignating paragraph (29) as  
15 paragraph (30); and

16 (C) by inserting after paragraph (28) the  
17 following new paragraph:

18 “(29) items and services furnished under an  
19 MCCC program under section 1947 to eligible chil-  
20 dren enrolled in an MCCC program under such sec-  
21 tion.”; and

22 (2) by adding at the end the following new sec-  
23 tion:

1 **“SEC. 1947. MEDICAID CHILDREN’S CARE COORDINATION**  
2 **PROGRAMS FOR CHILDREN WITH COMPLEX**  
3 **MEDICAL CONDITIONS.**

4 “(a) IN GENERAL.—Beginning January 1, 2015, a  
5 State, at its option as a State plan amendment, may elect  
6 to provide medical assistance for items and services fur-  
7 nished to eligible children enrolled in an MCCC program  
8 that meets the requirements of this section. As a condition  
9 on an eligible child’s receipt of medical assistance under  
10 this title, the State shall require, under such an amend-  
11 ment, that the eligible child be enrolled in an MCCC pro-  
12 gram that meets the requirements of this section.

13 “(b) MCCC PROGRAM REQUIREMENTS.—An MCCC  
14 program meets the requirements of this section if the  
15 MCCC program—

16 “(1) coordinates, integrates, and provides for  
17 the furnishing of the full range of MCCC program  
18 services to eligible children enrolled in the program;

19 “(2) enrolls eligible children in accordance with  
20 subsection (c);

21 “(3) is operating under a program agreement  
22 that meets the requirements of subsection (d); and

23 “(4) meets the pediatric network adequacy  
24 standards developed under subsection (e).

25 “(c) ELIGIBILITY DETERMINATIONS; ASSIGN-  
26 MENT.—

1           “(1) ENROLLMENT.—Subject to the assignment  
2 requirements of paragraph (2), the enrollment and  
3 disenrollment of eligible children in an MCCC pro-  
4 gram shall be carried out in accordance with regula-  
5 tions issued by the Secretary and the applicable pro-  
6 gram agreement.

7           “(2) NETWORK ASSIGNMENT.—

8           “(A) IN GENERAL.—Eligible children shall  
9 be prospectively enrolled in an MCCC program  
10 by initially assigning such eligible children to a  
11 nationally designated children’s hospital net-  
12 work for a period of not less than 90 days be-  
13 ginning on the date on which the child is ini-  
14 tially assigned to such hospital network.

15           “(B) BASIS FOR INITIAL ASSIGNMENT.—  
16 Such an assignment shall be based upon any of  
17 the following factors (or a combination thereof):

18           “(i) The prevalence of visits by the  
19 child to a pediatrician or other specialist  
20 who is participating in the nationally des-  
21 ignated children’s hospital network.

22           “(ii) The selection of the child’s fam-  
23 ily.

24           “(iii) The location of the primary resi-  
25 dence of the child.

1                   “(iv) The proximity of the child to re-  
2                   gional referral networks established by the  
3                   nationally designated children’s hospital  
4                   network.

5                   “(C) LIMITATION ON CERTAIN ASSIGN-  
6                   MENTS.—An assignment of a child under clause  
7                   (iii) or (iv) of subparagraph (B) may only be  
8                   made in the case of a nationally designated chil-  
9                   dren’s hospital network that offers medical  
10                  home access within 30 miles of the primary res-  
11                  idence of the child.

12                  “(D) REASSIGNMENT.—Following the 90-  
13                  day period referred to in subparagraph (A), the  
14                  child may elect—

15                       “(i) to be assigned to the nationally  
16                       designated children’s hospital network of  
17                       their choice that has an MCCC program  
18                       agreement in effect with respect to an  
19                       MCCC program in which the child is eligi-  
20                       ble to enroll; or

21                       “(ii) to not participate in any MCCC  
22                       program and receive care through enroll-  
23                       ment in the State plan under this title or  
24                       the State child health plan under title  
25                       XXI.



1 “(d) PROGRAM AGREEMENTS.—

2 “(1) IN GENERAL.—The Secretary, in close co-  
3 operation with the State administering agencies  
4 electing to provide the medical assistance described  
5 in subsection (a), shall establish procedures for en-  
6 tering into, extending, and terminating program  
7 agreements under this section.

8 “(2) TERMS.—

9 “(A) IN GENERAL.—A program agreement  
10 entered into under this section by the Sec-  
11 retary, a State administering agency, and a na-  
12 tionally designated children’s hospital network  
13 shall provide for each of the following terms:

14 “(i) The agreement shall designate  
15 the service area of the MCCC program  
16 that is the subject of the agreement.

17 “(ii) The agreement shall be effective  
18 for a contract year, but may be extended  
19 for additional contract years in the absence  
20 of a notice by a party to terminate, and is  
21 subject to termination by the Secretary  
22 and the State administering agency at any  
23 time for cause (as provided under the  
24 agreement).

1           “(iii) The agreement shall require  
2           that the nationally designated children’s  
3           hospital network submit care management  
4           network and coverage plans to the Sec-  
5           retary that are centered around medical  
6           home models and that describe the govern-  
7           ance of the network.

8           “(iv) The agreement shall require the  
9           hospital network to meet all applicable re-  
10          quirements imposed by State and local  
11          laws.

12          “(v) The agreement shall require such  
13          State, in the case of eligible children who  
14          are residents of the State, to make pay-  
15          ments to the hospital network, regardless  
16          of whether MCCC program services are  
17          furnished to such eligible children in an-  
18          other State.

19          “(vi) The agreement shall require that  
20          the standards and measures developed  
21          under subsection (e) be applied to the hos-  
22          pital network, including measures requir-  
23          ing, with respect to network adequacy  
24          standards, that the hospital network estab-  
25          lish such provider networks for primary,

1 secondary, and tertiary care as are nec-  
2 essary to ensure the adequate furnishing of  
3 MCCC program services to eligible children  
4 enrolled in the MCCC program that is the  
5 subject of the agreement.

6 “(vii) The agreement shall require the  
7 hospital network to comply with the data  
8 collection and recordkeeping requirements  
9 of subparagraph (C).

10 “(viii) The agreement shall require  
11 the hospital network to accept as payment  
12 any payment made using the risk-based  
13 methodology developed under subsection  
14 (g).

15 “(ix) The agreement shall contain  
16 such additional terms and conditions as  
17 the parties may agree to, so long as such  
18 terms and conditions are consistent with  
19 this section.

20 “(B) SERVICE AREA OVERLAP.—In desig-  
21 nating a service area under subparagraph  
22 (A)(i), the Secretary (in consultation with the  
23 relevant State administering agency) shall con-  
24 sider the impacts of designating an area that is  
25 already covered under another program agree-

1           ment, for purposes of avoiding the unnecessary  
2           duplication of services and the impairment of  
3           the financial and service viability of another  
4           MCCC program.

5           “(C) DATA AND RECORDKEEPING RE-  
6           QUIREMENTS.—The data collection and record-  
7           keeping requirements under this subparagraph,  
8           with respect to a nationally designated chil-  
9           dren’s hospital network, are as follows:

10                   “(i) The hospital network shall collect  
11                   claims data on claims submitted with re-  
12                   spect to eligible children who are furnished  
13                   MCCC program services under an MCCC  
14                   program. Such data shall be reported in a  
15                   standardized format and made available to  
16                   the public for purposes of establishing a  
17                   national database on such claims.

18                   “(ii) The hospital network shall main-  
19                   tain, and provide the Secretary and the  
20                   State administering agency access to, the  
21                   records relating to the MCCC program op-  
22                   erated by the hospital network, including  
23                   pertinent financial, medical, and personnel  
24                   records.

1                   “(iii) The hospital network shall sub-  
2                   mit to the Secretary and the State admin-  
3                   istering agency such reports as the Sec-  
4                   retary finds (in consultation with the State  
5                   administering agency) necessary to monitor  
6                   the operation, cost, and effectiveness of the  
7                   MCCC program operated by the hospital  
8                   network.

9                   “(3) TERMINATION OF AGREEMENTS.—The  
10                  Secretary shall issue regulations establishing the cir-  
11                  cumstances under which—

12                   “(A) the Secretary or a State admin-  
13                   istering agency may terminate an MCCC pro-  
14                   gram agreement for cause; and

15                   “(B) a nationally designated children’s  
16                   hospital network may terminate such an agree-  
17                   ment after appropriate notice to the Secretary,  
18                   the State administering agency, and enrollees.

19                  “(e) QUALITY ASSURANCE.—

20                   “(1) DEVELOPMENT OF STANDARDS AND MEAS-  
21                   URES.—The Secretary shall, in consultation with na-  
22                   tionally designated children’s hospital networks and  
23                   national pediatric policy organizations (such as the  
24                   Children’s Hospital Association and the American  
25                   Academy of Pediatrics)—

1           “(A) establish a national set of quality as-  
2           surance and improvement protocols and proce-  
3           dures to apply under MCCC programs;

4           “(B) develop pediatric quality measures;

5           “(C) develop pediatric network adequacy  
6           standards for access by eligible children to  
7           MCCC program services; and

8           “(D) develop criteria for national pediatric-  
9           focused care coordination for eligible children.

10          “(2) USE OF PQMP MEASURES.—In carrying  
11          out subparagraph (A), the Secretary shall apply, to  
12          the extent applicable, child health quality measures  
13          and measures for centers of excellence for children  
14          with complex needs developed under this title, title  
15          XXI, and section 1139A and take into account  
16          HEDIS quality measures as required under section  
17          1852(e)(3) and other quality measures.

18          “(f) STANDARD MEDICAID DATA SET.—

19                 “(1) IN GENERAL.—The Secretary, the States,  
20                 and the nationally designated children’s hospital net-  
21                 works shall collaborate to obtain consistent and  
22                 verifiable Medicaid Analytic Extract data or a com-  
23                 parable data set and shall establish data-sharing  
24                 agreements to further support collaborative planning

1 and care coordination for medically complex chil-  
2 dren.

3 “(2) CLAIMS ANALYSIS.—The Secretary shall—

4 “(A) perform claims analysis on the data  
5 set developed under paragraph (1) to determine  
6 the utilization of items and services furnished  
7 under an MCCC program to eligible children;  
8 and

9 “(B) submit to Congress and make pub-  
10 licly available on the Website of the Centers for  
11 Medicare & Medicaid services, a report on such  
12 claims in a standardized format for purposes of  
13 building a national database.

14 “(3) PAYMENT FOR REPORTING INCENTIVES.—

15 The Secretary may provide for pay-for-reporting in-  
16 centives during the first two years of any MCCC  
17 program agreement entered into under this section  
18 to ensure participation and analysis of consistent  
19 data under this paragraph to enable the development  
20 of an appropriate risk-based payment methodology  
21 under subsection (g).

22 “(g) PAYMENTS TO NATIONALLY DESIGNATED CHIL-  
23 DREN’S HOSPITAL NETWORKS.—

24 “(1) IN GENERAL.—The State plan shall pro-  
25 vide for payment to nationally designated children’s

1 hospital networks pursuant to the terms of an  
2 MCCC program agreement using a risk-based pay-  
3 ment methodology (or methodologies) established by  
4 the Secretary in accordance with this subsection.

5 “(2) TRANSITION FROM FEE-FOR-SERVICE TO  
6 RISK-BASED PAYMENT MODEL.—

7 “(A) IN GENERAL.—Payment to nationally  
8 designated children’s hospital networks under  
9 this subsection shall be based initially on a fee-  
10 for-service payment model and shall gradually  
11 transition, over a 5-year period, to an equitable,  
12 risk-based payment model using a methodology  
13 developed under paragraph (3). For the first  
14 two years of such period, a nationally des-  
15 ignated children’s hospital network may receive,  
16 in addition to any fee-for-service payments  
17 made to such hospital network, per capita care  
18 coordination payments with respect to expendi-  
19 tures for items and services furnished to eligible  
20 children enrolled in the MCCC program oper-  
21 ated by the hospital network through medical  
22 home programs and other care coordination ac-  
23 tivities for which an all-inclusive payment model  
24 is more suitable than fee-for-service reimburse-  
25 ment.



1           “(B) DATA ANALYSIS DURING INITIAL PE-  
2           RIOD.—During the first two years of the imple-  
3           mentation of an MCCC program, the Secretary  
4           shall analyze data collected under subsection (f)  
5           for purposes of developing a risk-based payment  
6           methodology that would be implemented begin-  
7           ning with the third year of implementation of  
8           the MCCC program.

9           “(3) DEVELOPMENT OF RISK-BASED PAYMENT  
10          METHODOLOGY.—The Secretary shall develop pay-  
11          ment methodologies under this subsection in coordi-  
12          nation with the Medicaid and CHIP Payment and  
13          Access Commission and the pediatric health care  
14          provider community that—

15                 “(A) take into account the data analyzed  
16                 under paragraph (2)(B);

17                 “(B) are actuarially sound, as determined  
18                 by the Secretary and the relevant State admin-  
19                 istering agency, in coordination with National  
20                 Association of Insurance Commissioners, using  
21                 an actuarial methodology that is adopted using  
22                 historic pediatric claims data;

23                 “(C) include—

24                         “(i) a risk adjustment method, re-in-  
25                         surance system, and risk-corridor proce-

1                   dure to account for variations in acuity of  
2                   the eligible children enrolled in MCCC pro-  
3                   grams; and

4                   “(ii) a shared-savings component; and

5                   “(D) may provide for a model for making  
6                   payments other than payments made on a per-  
7                   member, per-month basis.

8                   “(h) WAIVERS OF REQUIREMENTS.—With respect to  
9 carrying out an MCCC program under this section, the  
10 following provisions of law shall not apply:

11                   “(1) Section 1902(a)(1), relating to  
12                   statewideness.

13                   “(2) Section 1902(a)(10), insofar as such sec-  
14                   tion relates to comparability of services among dif-  
15                   ferent population groups.

16                   “(3) Sections 1902(a)(23) and 1915(b)(4), re-  
17                   lating to freedom of choice of providers.

18                   “(4) Section 1903(m)(2)(A), insofar as such  
19                   section would prohibit a nationally designated chil-  
20                   dren’s hospital network from receiving certain pay-  
21                   ments.

22                   “(5) Such other provisions of this title, title  
23                   XVIII, sections 1128A and 1128B, and any provi-  
24                   sions of the Federal antitrust laws as the Secretary  
25                   determines are inapplicable or the waiver of which

1 are necessary for purposes of carrying out an MCCC  
2 program under this section.

3 “(i) PREEMPTION OF STATE LAW.—A State may not  
4 impose any requirement on the nationally qualified chil-  
5 dren’s hospital network’s operation of an MCCC program  
6 under a program agreement that meets the requirements  
7 of this section that is inconsistent with or would otherwise  
8 impede the satisfaction by such hospital network of the  
9 requirements of this section (including the requirements  
10 of such program agreement).

11 “(j) DEFINITIONS.—In this section:

12 “(1) ELIGIBLE CHILD.—The term ‘eligible  
13 child’ means, with respect to an MCCC program, an  
14 individual who is under the age of 18 and who—

15 “(A) is eligible for medical assistance  
16 under the State plan under this title or child  
17 health assistance under the State child health  
18 plan under title XXI; and

19 “(B) has, or is at a heightened risk of de-  
20 veloping, a chronic, physical, developmental, be-  
21 havioral, or emotional condition that—

22 “(i) affects two or more body systems;

23 “(ii) requires intensive care coordina-  
24 tion to avoid excessive hospitalizations or  
25 emergency department visits; or

1                   “(iii) meets the criteria for medical  
2                   complexity using risk adjustment meth-  
3                   odologies (such as Clinical Risk Groups)  
4                   agreed upon by the Secretary in coordina-  
5                   tion with a national panel of pediatric ex-  
6                   perts.

7                   “(2) MCCC PROGRAM.—The term ‘MCCC pro-  
8                   gram’ means a Medicaid coordinated care program  
9                   that provides eligible children with MCCC program  
10                  services through a nationally designated children’s  
11                  hospital network in accordance with a program  
12                  agreement that meets the requirements of subsection  
13                  (d).

14                  “(3) MCCC PROGRAM SERVICES.—The term  
15                  ‘MCCC program services’ means the full range of  
16                  items and services for which medical assistance is  
17                  available under a State plan for children, including  
18                  pediatric care management services and pediatric-fo-  
19                  cused care coordination and health promotion, as  
20                  specified in the program agreement.

21                  “(4) QUALIFIED CHILDREN’S HOSPITAL.—The  
22                  term ‘qualified children’s hospital’ means a chil-  
23                  dren’s hospital that—

24                         “(A) qualifies to receive payment under  
25                         section 340E of the Public Health Service Act

1 (relating to children’s hospitals that operate  
2 graduate medical education programs); or

3 “(B) meets 3 or more of the following cri-  
4 teria:

5 “(i) MINIMUM PEDIATRIC DIS-  
6 CHARGES.—The hospital has at least 5,000  
7 annual pediatric discharges (including neo-  
8 nates, but excluding obstetrics and normal  
9 newborns) for the most recent cost report-  
10 ing period for which data are available.

11 “(ii) MINIMUM NUMBER OF BEDS.—  
12 The hospital has 100 licensed pediatric  
13 beds, not including beds in neonatal inten-  
14 sive care units but including beds in pedi-  
15 atric intensive care units and other acute  
16 care beds.

17 “(iii) ACCESS TO PEDIATRIC EMER-  
18 GENCY SERVICES.—The hospital has access  
19 (through ownership or otherwise) to pedi-  
20 atric emergency services.

21 “(iv) MEDICAID RELIANT.—At least  
22 30 percent of the pediatric discharges or  
23 inpatient days (excluding observation days)  
24 in the hospital for the most recent cost re-  
25 porting period for which data are available

1                   were children eligible for medical assist-  
2                   ance under this title or for children’s  
3                   health assistance under title XXI.

4                   “(v) AFFILIATION WITH ACCREDITED  
5                   PEDIATRIC RESIDENCY TRAINING PRO-  
6                   GRAM.—The hospital sponsors or is affili-  
7                   ated with a pediatric residency program  
8                   that is accredited by the Accreditation  
9                   Council for Graduate Medical Education.

10                  “(vi) PEDIATRIC MEDICAL HOME PRO-  
11                  GRAMS.—The hospital has established and  
12                  implemented demonstrable pediatric med-  
13                  ical home programs dedicated to medically  
14                  complex children.

15                  “(5) NATIONALLY DESIGNATED CHILDREN’S  
16                  HOSPITAL NETWORK.—The term ‘nationally des-  
17                  ignated children’s hospital network’ means a net-  
18                  work of hospitals and health care providers—

19                  “(A) anchored by a qualified children’s  
20                  hospital or hospitals with principal governance  
21                  responsibility over the hospital network;

22                  “(B) in which the full complement of  
23                  health care providers needed to provide the best  
24                  care for children in the network participate; and

1           “(C) that represents the interests of physi-  
2           cians, other health care providers, parents of  
3           medically complex children, and other relatives  
4           of such children.

5           “(6) PROGRAM AGREEMENT.—The term ‘pro-  
6           gram agreement’ means, with respect to a nationally  
7           designated children’s hospital network, an agree-  
8           ment, between the hospital network, the Secretary,  
9           and a State administering agency for the operation  
10          of an MCCC program by the hospital network in the  
11          State that meets the requirements of this section.

12          “(7) STATE ADMINISTERING AGENCY.—The  
13          term ‘State administering agency’ means, with re-  
14          spect to the operation of an MCCC program in a  
15          State, the agency of that State (which may be the  
16          single agency responsible for administration of the  
17          State plan under this title in the State) responsible  
18          for administering program agreements under this  
19          section.”.

20          (b) APPLICATION UNDER CHIP.—Section  
21          2107(e)(1) of the Social Security Act (42 U.S.C.  
22          1397gg(e)(1)) is amended by adding at the end the fol-  
23          lowing new subparagraph:

1           “(P) Section 1947 (relating to Medicaid  
2           children’s care coordination programs for chil-  
3           dren with complex medical conditions).”.

4           (c) REGULATIONS.—Not later than 120 days after  
5 the date of the enactment of this Act, the Secretary of  
6 Health and Human Services shall make rules on the  
7 record, after opportunity for an agency hearing to carry  
8 out the amendments made by this section in accordance  
9 with sections 556 and 557 of title 5, United States Code.

10           **Subtitle S—Continuing Medical**  
11           **Education Sunshine Exemption**

12           **SEC. 4381. EXEMPTING FROM MANUFACTURER TRANS-**  
13                           **PARENCY REPORTING CERTAIN TRANSFERS**  
14                           **USED FOR EDUCATIONAL PURPOSES.**

15           (a) IN GENERAL.—Section 1128G(e)(10)(B) of the  
16 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is  
17 amended—

18                   (1) in clause (iii), by inserting “, including  
19                   peer-reviewed journals, journal reprints, journal sup-  
20                   plements, and medical textbooks” after “patient  
21                   use”; and

22                   (2) by adding at the end the following new  
23                   clause:

24                                   “(xiii) A transfer of anything of value  
25                                   to a covered recipient who is a physician if



1 the thing of value is intended solely for  
2 purposes of providing continuing medical  
3 education to the physician.”.

4 (b) EFFECTIVE DATE.—The amendments made by  
5 this section shall apply with respect to transfers of value  
6 made on or after the date of the enactment of this Act.

7 **Subtitle T—Medical Testing**  
8 **Availability**

9 **SEC. 4401. CLARIFICATION REGARDING RESEARCH USE**  
10 **ONLY PRODUCTS.**

11 Section 520 of the Federal Food, Drug, and Cosmetic  
12 Act (21 U.S.C. 360j) is amended by adding at the end  
13 the following subsection:

14 “(o) PRODUCTS WITH RESEARCH USE ONLY LABEL-  
15 ING.—

16 “(1) IN GENERAL.—A product whose labeling  
17 bears the statement described in section  
18 809.10(c)(2)(i) of title 21, Code of Federal Regula-  
19 tions, as in effect on the date of the enactment of  
20 this subsection, may not be deemed to be adulter-  
21 ated or misbranded under this Act on the basis that  
22 the manufacturer or distributor of the product—

23 “(A) sells the product to an end user who  
24 uses the product in a manner inconsistent with  
25 such statement; or

1           “(B) engages in business communications  
2           regarding the product with an end user of the  
3           product.

4           “(2) BUSINESS COMMUNICATIONS DEFINED.—  
5           In this subsection, the term ‘business communica-  
6           tions’, with respect to a product with labeling de-  
7           scribed in paragraph (1)—

8           “(A) means oral, written, or electronic con-  
9           tact between a manufacturer or distributor of  
10          such product and an end user regarding the  
11          functioning of such product; and

12          “(B) includes any such contact consisting  
13          of technical support, customer service, assist-  
14          ance with the installation of such product, com-  
15          munication relating to ensuring the perform-  
16          ance of the product, and other similar contacts.

17          “(3) SUNSET.—This subsection shall cease to  
18          be effective on the last day of the five-year period  
19          beginning on the date of enactment of this section.”.

1 **TITLE V—MODERNIZING MED-**  
2 **ICAL PRODUCT REGULATION**  
3 **Subtitle A—Manufacturing**  
4 **Incentives**

5 **SEC. 5001. EXTENSION OF EXCLUSIVITY PERIOD FOR AMER-**  
6 **ICAN-MANUFACTURED GENERIC DRUGS AND**  
7 **BIOSIMILARS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,  
9 Drug, and Cosmetic Act, as amended by section 2101, is  
10 further amended by inserting after section 505H of such  
11 Act (21 U.S.C. 355f) the following:

12 **“SEC. 505I. EXTENSION OF EXCLUSIVITY PERIOD FOR**  
13 **AMERICAN-MANUFACTURED GENERIC DRUGS**  
14 **AND BIOSIMILARS.**

15 “(a) DESIGNATION.—The Secretary shall designate a  
16 drug (including a biological product) as an American-man-  
17 ufactured drug for purposes of granting the extensions  
18 under subsection (b) if—

19 “(1) an application is submitted for approval or  
20 licensure of such drug under section 505(j) of this  
21 Act or section 351(k) of the Public Health Service  
22 Act;

23 “(2) the manufacturer or the sponsor of the  
24 drug includes in such application a request for des-  
25 ignation of the drug as an American-manufactured

1 drug **[What additional or different requirements (rel-**  
2 *ative to those set forth in paragraph (3)) should a*  
3 *manufacturer have to meet in order to receive the des-*  
4 *ignation as an American-manufactured drug?]; and*

5 “(3) the request demonstrates to the Sec-  
6 retary’s satisfaction that all quantities of the drug  
7 intended to be marketed in the United States will be  
8 manufactured, prepared, propagated, compounded,  
9 and processed, as applicable, in the United States.

10 “(b) EXTENSION.—If the Secretary designates a  
11 drug as an American-manufactured drug, as described in  
12 subsection (a)—

13 “(1) the 180-day period described in clause (iv)  
14 of section 505(j)(5)(B) shall be extended by  
15 **[\_\_\_\_\_]**; or

16 “(2) the period of 1 year, 18 months, or 42  
17 months, as applicable, described in section 351(k) of  
18 the Public Health Service Act shall be extended by  
19 **[\_\_\_\_\_]**.

20 “(c) LIMITATIONS.—Subsection (b) does not apply to  
21 the approval of—

22 “(1) a supplement to an application under sec-  
23 tion 505(j) of this Act for a drug or under section  
24 351(k) of the Public Health Service Act for a bio-

1 logical product for which an extension described in  
2 subsection (b) is in effect or has expired; or

3 “(2) a subsequent application filed with respect  
4 to a drug approved under section 505(j) or a biological  
5 product licensed under section 351(k) for a  
6 change that results in a new route of administration,  
7 dosing schedule, dosage form, delivery system, delivery  
8 device, or strength.”.

9 (b) APPLICATION.—Section 505I of the Federal  
10 Food, Drug, and Cosmetic Act, as added by subsection  
11 (a), applies only with respect to a drug that is first ap-  
12 proved or licensed under section 505(j) of such Act (21  
13 U.S.C. 355(j)) or section 351(k) of the Public Health  
14 Service Act (42 U.S.C. 262(k)) on or after the date of  
15 the enactment of this Act.

## 16 **Subtitle B—21st Century** 17 **Manufacturing**

### 18 **SEC. 5021. UPDATING REGULATIONS AND GUIDANCE ON** 19 **CURRENT GOOD MANUFACTURING PRACTICE** 20 **REQUIREMENTS.**

21 Not later than 1 year after the date of enactment  
22 of this Act, the Secretary of Health and Human Services,  
23 acting through the Commissioner of Food and Drugs, and  
24 taking into consideration modern manufacturing tech-  
25 niques, shall issue final regulations and guidance, as appli-

1 cable, updating the regulations and guidance for ensuring  
2 that drugs are manufactured, processed, packed, and held  
3 in conformity with current good manufacturing practice  
4 requirements, including the requirements under section  
5 501(a)(1) of the Federal Food, Drug, and Cosmetic Act  
6 (21 U.S.C. 351(a)(1)).

7 **Subtitle C—Controlled Substance**  
8 **Manufacturing and Exports**

9 **SEC. 5041. RE-EXPORTATION AMONG MEMBERS OF THE EU-**  
10 **ROPEAN ECONOMIC AREA.**

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

13 (1) in paragraph (5)—

14 (A) by striking “(5)” and inserting  
15 “(5)(A)”;

16 (B) by inserting “, except that the con-  
17 trolled substance may be exported from the sec-  
18 ond country to another country that is a mem-  
19 ber of the European Economic Area” before the  
20 period at the end; and

21 (C) by adding at the end the following:

22 “(B) Subsequent to any re-exportation de-  
23 scribed in subparagraph (A), a controlled substance  
24 may continue to be exported from any country that

1 is a member of the European Economic Area to any  
2 other such country, provided that—

3 “(i) the conditions applicable with respect  
4 to the first country under paragraphs (1), (2),  
5 (3), (4), (6), and (7) are met by each subse-  
6 quent country from which the controlled sub-  
7 stances is exported pursuant to this paragraph;  
8 and

9 “(ii) the conditions applicable with respect  
10 to the second country under such paragraphs  
11 are met by each subsequent country to which  
12 the controlled substance is exported pursuant to  
13 this paragraph.”; and

14 (2) by adding at the end the following:

15 “(g) LIMITATION.—The Attorney General shall not  
16 promulgate nor enforce any regulation, subregulatory  
17 guidance, or enforcement policy which impedes re-expor-  
18 tation among European Economic Area countries (as pro-  
19 vided in subsection (f)(5)), including by promulgating or  
20 enforcing any requirement that—

21 “(1) re-exportation from the first country to the  
22 second country or re-exportation from the second  
23 country to another country (as such terms are used  
24 in subsection (f)) occur within a specified period of  
25 time; or

1           “(2) information concerning the consignee,  
2           country, and product be provided prior to expor-  
3           tation of the controlled substance from the United  
4           States.”.

## 5           **Subtitle D—Medical Device** 6           **Reforms**

### 7   **SEC. 5061. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

8           Chapter V of the Federal Food, Drug, and Cosmetic  
9   Act is amended by inserting after section 524A of such  
10   Act (21 U.S.C. 360n–1) the following:

### 11   **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

12           “(a) ACCREDITATION AND ASSESSMENT.—

13           “(1) RELIANCE ON ACCREDITED PERSONS.—

14           *【need more specificity. what types of changes: tech-*  
15           *nology, manufacturing, modifications that do not*  
16           *alter a device’s fundamental technology, and labeling*  
17           *– are appropriate for this type of certification, if*  
18           *any? What types of changes are not appropriate, if*

19           *any?】*The Secretary shall rely on persons accredited  
20           under section 523 or under this section to assess  
21           and certify a facility’s capability to evaluate and im-  
22           plement—

23           “(A) technology changes to devices that  
24           were found to be substantially equivalent to a



1 predicate device for purposes of classification  
2 under section 513(f);

3 “(B) changes in the manufacturing of a  
4 device;

5 “(C) changes that do not alter a device’s  
6 fundamental technology; and

7 “(D) labeling changes described in section  
8 814.39(d) of title 21, Code of Federal Regula-  
9 tions (or any successor regulations).

10 “(2) ASSESSMENTS.—An assessment pursuant  
11 to paragraph (1) shall assess the facility in which a  
12 device is manufactured or designed and determine  
13 whether the facility’s quality system, including the  
14 facility’s design controls, is capable of evaluating, on  
15 a continuing basis, the types of changes listed in  
16 paragraph (1) so as to provide a reasonable assur-  
17 ance of safety and effectiveness.

18 “(3) ACCREDITATION PROCESS.—

19 “(A) IN GENERAL.—Except as inconsistent  
20 with this section, the process and qualifications  
21 for accreditation of persons, and renewal of  
22 such accreditation, under section 523 shall  
23 apply with respect to accreditation of persons,  
24 and renewal of such accreditation, under this  
25 section.

1           “(B) EXCEPTIONS.—The provisions of  
2 subsections (a)(2), (a)(3), and (c) of section  
3 523 shall not apply for purposes of this section.

4           “(4) USE OF ACCREDITED PARTIES TO CON-  
5 DUCT ASSESSMENTS.—

6           “(A) INITIATION OF SERVICES.—Use of  
7 one or more accredited persons to assess  
8 changes listed in paragraph (1), with respect to  
9 a device, shall be at the initiation of the person  
10 who registers and lists the device under section  
11 510.

12           “(B) COMPENSATION.—Compensation for  
13 such accredited persons shall—

14           “(i) be determined by agreement be-  
15 tween the accredited person and the person  
16 who engages the services of the accredited  
17 person; and

18           “(ii) be paid by the person who en-  
19 gages such services.

20           “(C) ACCREDITED PERSON SELECTION.—  
21 Each person who chooses to use an accredited  
22 person to assess a facility’s quality system, as  
23 described in paragraphs (1) and (2), shall select  
24 the accredited person from a list of such per-

1           sons published by the Secretary in the Federal  
2           register for purposes of this section.

3           “(b) EFFECT OF THIRD-PARTY ASSESSMENT.—

4           “(1) DETERMINATION EFFECT.—If a facility is  
5           determined by an accredited person to have a quality  
6           system, as described in subsection (a)(2), then the  
7           facility need not submit a premarket notification  
8           under section 510(k) nor a supplement under section  
9           515(d)(6) with respect to any change listed in sub-  
10          section (a)(1), so long as the accredited person de-  
11          termines, in writing, that the change is in compli-  
12          ance with the requirements of this Act and the regu-  
13          lations thereunder, including part 820 of title 21,  
14          Code of Federal Regulations (or any successor regu-  
15          lations).

16          “(2) DURATION.—A determination under para-  
17          graph (1)—

18                 “(A) shall remain in effect for a period of  
19                 two years from the date of such determination,  
20                 and may be renewed through the process de-  
21                 scribed in this section; and

22                 “(B) shall continue to apply with respect  
23                 to changes made during such two-year period,  
24                 irrespective of whether such determination is  
25                 renewed after such two-year period.”.

1 **SEC. 5062. VALID SCIENTIFIC EVIDENCE.**

2 Section 513(a)(3)(B) of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

4 (1) by redesignating clauses (i) and (ii) as sub-  
5 clauses (I) and (II), respectively;

6 (2) by striking “(B) If the Secretary” and in-  
7 serting “(B)(i) If the Secretary”; and

8 (3) by adding at the end the following:

9 “(ii)(I) Valid scientific evidence for purposes of clause  
10 (i) means evidence described in well-documented case his-  
11 tories, including registry data, that are collected and mon-  
12 itored under an acceptable protocol, and studies published  
13 in peer-reviewed journals that are internationally recog-  
14 nized as authoritative sources of information.

15 “(II) The data from studies published in a journal  
16 described in subclause (I) shall be presumed valid based  
17 on the peer-review process that supports publication of the  
18 studies, and the Secretary may not require submission of  
19 the data for the Secretary’s review.

20 “(III) Valid scientific evidence may include data col-  
21 lected in countries other than the United States so long  
22 as such data otherwise meets the criteria specified in sub-  
23 clause (I).”.

1 **SEC. 5063. TRAINING AND OVERSIGHT IN LEAST BURDEN-**  
2 **SOME MEANS CONCEPT.**

3 Section 513 of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 360c) is amended by inserting after sub-  
5 section (i) the following:

6 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-  
7 SOME MEANS CONCEPT.—

8 “(1) TRAINING.—Each employee of the Food  
9 and Drug Administration who is involved in the re-  
10 view of premarket submissions under section 515 or  
11 section 510(k), including supervisors, shall receive  
12 training regarding the meaning and implementation  
13 of the least burdensome means concept in the con-  
14 text of the use of that term in subsections (a)(3)(D)  
15 and (i)(1)(D). Such training shall include consider-  
16 ation of when advisory panels are appropriate and  
17 necessary to review premarket submissions under  
18 section 515 or section 510(k). The Secretary shall  
19 require that each such employee receive re-training  
20 on an annual basis to reinforce the initial training  
21 received by such employee under this paragraph re-  
22 garding the meaning and implementation of such  
23 concept.

24 “(2) GUIDANCE DOCUMENTS.—

25 “(A) IN GENERAL.—The Secretary shall  
26 ensure that adequate guidance documents de-

1           scribing the least burdensome means concept  
2           set forth in subsections (a)(3)(D) and (i)(1)(D)  
3           and its implementation are available to the per-  
4           sons involved in the review of premarket sub-  
5           missions under section 515 or 510(k). Such  
6           guidance documents shall include tools that  
7           such persons may use to ensure adherence to  
8           the least burdensome means concept, such as  
9           an evidentiary matrix based on a device type’s  
10          benefits and risks.

11           “(B) PUBLICATION.—The Secretary shall  
12          publish updated guidance documents, as re-  
13          quired by subparagraph (A), not later than 12  
14          months after the date of enactment of this sub-  
15          section. In developing such guidance documents,  
16          the Secretary shall convene a meeting of stake-  
17          holders to ensure a full record to support the  
18          publication of such guidance.

19           “(3) OMBUDSMAN AUDIT.—The ombudsman for  
20          the organizational unit of the Food and Drug Ad-  
21          ministration responsible for the premarket review of  
22          devices shall conduct, or have conducted, an audit of  
23          such organizational unit to determine the unit’s per-  
24          formance in implementing the least burdensome  
25          means concept set forth in subsections (a)(3)(D) and

1 (i)(1)(D). Such ombudsman shall include in such  
2 audit interviews with a representative sample of per-  
3 sons from industry regarding their experience in the  
4 device premarket review process.”.

5 **SEC. 5064. RECOGNITION OF STANDARDS.**

6 Section 514 of the Federal Food, Drug, and Cosmetic  
7 Act (21 U.S.C. 360d) is amended—

8 (1) in subsection (c)(1)—

9 (A) in subparagraph (A)—

10 (i) by striking “shall” and inserting  
11 “may”; and

12 (ii) by striking “all or part of an ap-  
13 propriate standard” and inserting “any  
14 standard applicable to devices that is”; and

15 (B) by striking subparagraph (B) and in-  
16 serting the following new subparagraph:

17 “(B) The publication under subparagraph (A)  
18 with respect to the Secretary’s recognition of a  
19 standard described in such subparagraph shall be  
20 made not later than 60 days after the date on which  
21 the applicable standard development organization  
22 makes such standard available. If the Secretary  
23 chooses not to recognize a standard described in  
24 such subparagraph, the Secretary shall publish in

1 the Federal Register the basis for refusing to recog-  
2 nize the standard.”; and

3 (2) by adding at the end the following:

4 “(d) TRAINING ON USE OF STANDARDS.—The Sec-  
5 retary shall provide to all employees of the Food and Drug  
6 Administration who review premarket submissions for de-  
7 vices training on the concept and use of recognized stand-  
8 ards to facilitate the premarket review of devices and to  
9 provide reasonable assurance of safety and effectiveness,  
10 including standards relevant to an employee’s area of de-  
11 vice review. Such training shall be provided—

12 “(1) to all new employees of the Food and  
13 Drug Administration who are involved in such re-  
14 view, not later than 30 days of the commencement  
15 of their employment; and

16 “(2) to other employees of the Administration  
17 involved in such review, on an annual basis.”.

18 **SEC. 5065. NOTIFICATION OF MARKETING OF CERTAIN**  
19 **CLASS I DEVICES.**

20 Subsection (l) of section 510 of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 360) is amended by  
22 adding at the end the following: “For a class I device de-  
23 scribed in the preceding sentence, the requirement for a  
24 report under subsection (k) may be satisfied by the sub-  
25 mission to the Secretary of a notification that contains a



1 written determination by a person accredited under sec-  
2 tion 523 that the methods used in, or the facilities and  
3 controls used for, the manufacture, processing, packing,  
4 or installation of such device conforms with the require-  
5 ments of section 520(f) and that is received by the Sec-  
6 retary not less than 5 business days before the class I de-  
7 vice is introduced, or delivered for introduction, into inter-  
8 state commerce.”.

9 **SEC. 5066. GENERAL AND SPECIFIC USES.**

10 Subparagraph (E) of section 513(i)(1) is amended by  
11 adding at the end the following:

12 “(iv) In the context of a report for a device under  
13 section 510(k), the Secretary may not—

14 “(I) refuse to accept an indication for use state-  
15 ment for a device to the extent the predicate for  
16 such device has the same indication statement; or

17 “(II) require from the person submitting the re-  
18 port information or data related to an indication  
19 other than the proposed indication in the report.”.

20 **SEC. 5067. HUMANITARIAN DEVICE EXEMPTION APPLICA-**  
21 **TION TO IN VITRO DIAGNOSTICS.**

22 (a) IN GENERAL.—Section 520(m) of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is  
24 amended—

25 (1) in paragraph (1)—

1 (A) by striking “it is the purpose of this  
2 subsection to encourage” and inserting the fol-  
3 lowing: “it is the purpose of this subsection—  
4 “(A) to encourage”;

5 (B) by striking the period at the end and  
6 inserting “; or”; and

7 (C) by adding at the end the following:

8 “(B) to benefit patients in the treatment and  
9 diagnosis of diseases or conditions that affect great-  
10 er than 4,000 individuals in the United States annu-  
11 ally, when the applicant demonstrates that the sever-  
12 ity of the disease or condition is such that—

13 “(i) the public health requires a greater  
14 availability of the device to treat or diagnose  
15 such patients; and

16 “(ii) no satisfactory alternative is available  
17 for such treatment or diagnosis.”; and

18 (2) in paragraph (2)—

19 (A) in subparagraph (A), by inserting “or  
20 the device is designed to treat a disease or con-  
21 dition that affects greater than 4,000 individ-  
22 uals in the United States annually upon a  
23 showing that the criteria identified in para-  
24 graph (1)(B) are met” after “in the United  
25 States”; and

1 (B) in the continuation text following para-  
2 graph (3), by adding at the end the following:  
3 “An order granting a request for an exemption  
4 under this subsection shall not in any way limit  
5 the number of devices that are subject to the  
6 exemption if such devices are determined by the  
7 Secretary to be medically necessary to treat, di-  
8 agnose, or monitor individuals with diseases or  
9 conditions described in subparagraph (A) or  
10 (B) of paragraph (1).”.

11 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-  
12 EFIT.—Not later than 6 months after the date of enact-  
13 ment of this Act, the Secretary of Health and Human  
14 Services, acting through the Commissioner of Food and  
15 Drugs, shall publish a guidance document that defines the  
16 criteria for establishing “probable benefit” as that term  
17 is used in section 520(m)(2)(C) of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)).

19 **SEC. 5068. ADVISORY COMMITTEE PROCESS.**

20 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-  
21 tion 513(b) of the Federal Food, Drug, and Cosmetic Act  
22 (21 U.S.C. 360c(b)) is amended—

23 (1) by striking “(5)” and inserting “(5)(A)”;

24 and

25 (2) by adding at the end the following:

1           “(B) The Secretary shall convene such a meeting not  
2 later than 60 days after the matters to be considered by  
3 the panel during such meeting are ready, as determined  
4 by the Secretary, for panel review.

5           “(C) Not later than 30 calendar days before the date  
6 on which such a meeting is to be convened, the Secretary  
7 shall make available to the panel and the person whose  
8 device is subject to review by the panel during such meet-  
9 ing any material on the matters to be considered during  
10 such meeting. Not later than 14 calendar days before the  
11 date on which such a meeting is to be convened, the Sec-  
12 retary shall make any material that is made available to  
13 the members of the panel under the preceding sentence  
14 available to the public in a format that provides for appro-  
15 priate redactions of any information that is a trade secret  
16 or confidential information subject to section 552(b)(4) of  
17 title 5, United States Code, or section 1905 of title 18,  
18 United States Code.

19           “(D) For review by a classification panel of a submis-  
20 sion for a device, the Secretary shall—

21                   “(i) consult with the person whose submission  
22 is subject to panel review regarding the person’s rec-  
23 ommendations on the expertise needed among the  
24 voting members of the panel;

1           “(ii) give due consideration to such rec-  
2           ommendations and ensure that adequate expertise is  
3           represented on advisory panels to assess—

4                   “(I) the disease or condition for which the  
5           device is intended to cure, treat, mitigate, pre-  
6           vent, or diagnose; and

7                   “(II) the technology of the device.

8           “(E) For purposes of subparagraph (D)(ii), the term  
9           ‘adequate expertise’ means that the membership of the  
10          classification panel includes—

11                   “(i) two or more voting members who are spe-  
12          cialists or have other expertise in the disease or con-  
13          dition for which the device is under review; and

14                   “(ii) an equal number of voting members who  
15          are knowledgeable about the technology of the de-  
16          vice.”.

17          (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of  
18          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19          360c(b)(6)) is amended—

20                   (1) in subparagraph (A)(iii), by inserting before  
21          the period at the end “, including by being seated  
22          at a location that is the same distance from the  
23          panel chairperson as the Secretary is from the chair-  
24          person”; and

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

3           “(B)(i) Any meeting of a classification panel  
4           with respect to the review of a device shall provide  
5           adequate time for initial presentations by the person  
6           whose device is specifically the subject of such re-  
7           view, the Secretary, or any other interested party,  
8           and for a response to any differing views by such  
9           person, and shall encourage free and open participa-  
10          tion by all interested persons. Any initial presen-  
11          tation made by the person whose device is specifi-  
12          cally the subject of such review shall be made before  
13          the Secretary’s initial presentation. Such a meeting  
14          shall provide such person with adequate time to re-  
15          spond to the Secretary’s initial presentation.

16          “(ii) Following the initial presentations and re-  
17          sponses described in clause (i), the panel shall have  
18          a period of time the panel considers appropriate to  
19          pose to the person whose device is the subject of the  
20          review questions that—

21                  “(I) have been provided by the Secretary  
22                  to the panel for purposes of the panel’s review  
23                  of the device; and

24                  “(II) have been agreed upon by the Sec-  
25                  retary and such person for such purposes.

1           “(iii) The panel shall consider the responses to  
2           such questions in the panel’s review of the device.”.

3           **Subtitle E—Supply Chain Security**  
4           **for Devices**

5           **SEC. 5081. SHORT TITLE.**

6           This subtitle may be cited as the “Device Distribu-  
7           tion Licensing Act of 2015”.

8           **SEC. 5082. DEVICE DISTRIBUTION SUPPLY CHAIN.**

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

12           **“Subchapter I—Device Supply Chain**  
13           **Licensing**

14          **“SEC. 586. DEFINITIONS.**

15          “In this subchapter:

16           “(1) **AFFILIATE.**—The term ‘affiliate’ means a  
17           business entity that has a relationship with a second  
18           business entity if, directly or indirectly—

19           “(A) one business entity controls, or has  
20           the power to control, the other business entity;  
21           or

22           “(B) a third party controls, or has the  
23           power to control, both of the business entities.

24           “(2) **AUTHORIZED.**—The term ‘authorized’  
25           means—

1           “(A) in the case of a manufacturer, having  
2           a valid registration in accordance with section  
3           510, as applicable;

4           “(B) in the case of a wholesale distributor,  
5           having a valid license under State law or sec-  
6           tion 586B;

7           “(C) in the case of a third-party logistics  
8           provider, having a valid license under State law  
9           or section 586C; and

10           “(D) in the case of a dispenser, having a  
11           valid license under State law, as applicable.

12           “(3) DEVICE.—The term ‘device’ means a de-  
13           vice as defined in section 201(h).

14           “(4) DISPENSER.—The term ‘dispenser’ means  
15           any person who makes final delivery or sale of a pre-  
16           scription device to the ultimate user, but who does  
17           not repackage or otherwise change the container,  
18           wrapper, or labeling, including—

19           “(A) a retail pharmacy, hospital pharmacy,  
20           or group of chain pharmacies under common  
21           ownership and control that do not act as a  
22           wholesale distributor;

23           “(B) a hospital, ambulatory surgical facil-  
24           ity, nursing home, outpatient diagnostic facility,  
25           or outpatient treatment facility; and



1           “(C) a physician or other health care pro-  
2           vider authorized by applicable law to prescribe  
3           and administer prescription devices.

4           “(5) IMPORTER.—The term ‘importer’ means  
5           any person who imports a prescription device into  
6           the United States and who furthers the marketing  
7           of the prescription device from the original place of  
8           manufacture to the person who makes final delivery  
9           or sale to the ultimate user, but who does not re-  
10          package or otherwise change the container, wrapper,  
11          or labeling of the prescription device or prescription  
12          device package.

13          “(6) MANUFACTURER.—The term ‘manufac-  
14          turer’ means the person who manufactures, pre-  
15          pares, propagates, compounds, assembles, or proc-  
16          esses a prescription device by chemical, physical, bio-  
17          logical, or other procedure. The term includes any  
18          person who—

19                 “(A) repackages or otherwise changes the  
20                 container, wrapper, or labeling of a prescription  
21                 device in furtherance of the distribution of the  
22                 prescription device from the original place of  
23                 manufacture;

24                 “(B) initiates specifications for prescrip-  
25                 tion devices that are manufactured by a second

1 party for subsequent distribution by the person  
2 initiating the specifications;

3 “(C) manufactures components or acces-  
4 sories that are prescription devices that are  
5 ready to be used and are intended to be com-  
6 mercially distributed and intended to be used as  
7 is, or are processed by a licensed practitioner or  
8 other qualified person to meet the needs of a  
9 particular patient;

10 “(D) reprocesses a single-use prescription  
11 device that has previously been used on a pa-  
12 tient;

13 “(E) is an importer; or

14 “(F) is the United States agent of a for-  
15 eign manufacturer.

16 **【“(7) PRESCRIPTION DEVICE.—The term ‘pre-**  
17 **scription device’ means a restricted device, as de-**  
18 **defined in section 520(e)(1)—】**

19 **【“(A) that is intended for use by hu-**  
20 **mans;】**

21 **【“(B) which, because of any potentiality**  
22 **for harmful effect, the method of its use, or the**  
23 **collateral measures necessary to its use is not**  
24 **safe except under the supervision of a practi-**

1           tioner licensed by law to direct the use of such  
2           device;】

3           【“(C) for which the Secretary has deter-  
4           mined adequate directions for use cannot be  
5           prepared; and】

6           【“(D) that is required to carry on its label  
7           ‘Rx’, ‘Rx only’, a designation for physician-use  
8           or dentist-use only, or a statement that Federal  
9           law restricts the device to sale by or on the  
10          order of a licensed health care practitioner.】

11          “(8) SINGLE-USE PRESCRIPTION DEVICE.—The  
12          term ‘single-use prescription device’ means a pre-  
13          scription device that is a single-use device.

14          “(9) SPECIFIC PATIENT NEED.—The term ‘spe-  
15          cific patient need’—

16                 “(A) refers to the transfer of a prescrip-  
17                 tion device from one dispenser to another to fill  
18                 a prescription or order for an identified patient;  
19                 and

20                 “(B) does not include the transfer of a  
21                 prescription device from one dispenser to an-  
22                 other for the purpose of increasing or replen-  
23                 ishing stock in anticipation of a potential need.

24          “(10) THIRD-PARTY LOGISTICS PROVIDER.—  
25          The term ‘third-party logistics provider’ means an

1       entity that provides or coordinates warehousing of,  
2       or other logistics services with respect to, a prescrip-  
3       tion device in interstate commerce on behalf of a  
4       manufacturer, wholesale distributor, or dispenser of  
5       a prescription device, but does not take ownership of  
6       the prescription device, nor have responsibility to di-  
7       rect the sale or disposition of the prescription device.

8               “(11) TRADING PARTNER.—The term ‘trading  
9       partner’ means—

10               “(A) a manufacturer, wholesale distributor,  
11               or dispenser from whom a manufacturer, whole-  
12               sale distributor, or dispenser accepts direct  
13               ownership of a prescription device or to whom  
14               a manufacturer, wholesale distributor, or dis-  
15               penser transfers direct ownership of a prescrip-  
16               tion device; or

17               “(B) a third-party logistics provider from  
18               whom a manufacturer, wholesale distributor, or  
19               dispenser accepts direct possession of a pre-  
20               scription device or to whom a manufacturer,  
21               wholesale distributor, or dispenser transfers di-  
22               rect possession of a prescription device.

23               “(12) WHOLESALE DISTRIBUTION.—The term  
24       ‘wholesale distribution’—

25               “(A) means—

1           “(i) the distribution or sale of a pre-  
2           scription device to a person other than a  
3           consumer or patient, including  
4           warehouseurs, repackagers, own-label dis-  
5           tributors, and retail pharmacy  
6           warehouseurs; or

7           “(ii) receipt of a prescription device  
8           by a person other than the consumer or  
9           patient; and

10          “(B) does not include—

11           “(i) intracompany distribution of any  
12           prescription device within a manufacturer  
13           or between a manufacturer and an affiliate  
14           of such manufacturer;

15           “(ii) the dispensing of a prescription  
16           device pursuant to a prescription or order;

17           “(iii) the purchase or other acquisition  
18           by a dispenser of a prescription device for  
19           use by such dispenser;

20           “(iv) the distribution of a prescription  
21           device by the manufacturer of such pre-  
22           scription device;

23           “(v) the receipt or transfer of a pre-  
24           scription device by an authorized third-  
25           party logistics provider, provided that such

1 third-party logistics provider does not take  
2 ownership of the prescription device;

3 “(vi) the receipt or transfer of a pre-  
4 scription device by a common carrier that  
5 transports such prescription device, pro-  
6 vided that the common carrier does not  
7 take ownership of the prescription device;

8 “(vii) the distribution of a prescrip-  
9 tion device, or an offer to distribute a pre-  
10 scription device among hospitals or other  
11 health care entities which are under com-  
12 mon control;

13 “(viii) the distribution of a prescrip-  
14 tion device or an offer to distribute a pre-  
15 scription device for emergency medical rea-  
16 sons, including a public health emergency  
17 declaration pursuant to section 319 of the  
18 Public Health Service Act;

19 “(ix) the receipt of a single-use pre-  
20 scription device by, or the transfer of a  
21 single-use prescription device to, a repro-  
22 cessor of such single-use prescription device;

23 “(x) salable return of a prescription  
24 device when conducted by a dispenser; or

1                   “(xi) facilitating the distribution of a  
2                   prescription device by providing solely ad-  
3                   ministrative services, including processing  
4                   of orders and payments.

5                   “(13) WHOLESALE DISTRIBUTOR.—The term  
6                   ‘wholesale distributor’ means a person engaged in  
7                   wholesale distribution.”.

8   **SEC. 5083. AUTHORIZED TRADING PARTNERS.**

9                   Subchapter I of chapter V of the Federal Food, Drug,  
10                  and Cosmetic Act, as added by section 5082, is further  
11                  amended by adding at the end the following:

12   **“SEC. 586A. AUTHORIZED TRADING PARTNER REQUIRE-**  
13                  **MENTS.**

14                  “(a) MANUFACTURER.—Beginning not later than  
15                  January 1, 2016, the trading partners of a manufacturer  
16                  may only be authorized trading partners.

17                  “(b) WHOLESALE DISTRIBUTOR.—Beginning not  
18                  later than January 1, 2016, the trading partners of a  
19                  wholesale distributor may only be authorized trading part-  
20                  ners.

21                  “(c) THIRD-PARTY LOGISTICS PROVIDER.—Begin-  
22                  ning not later than January 1, 2016, the trading partners  
23                  of a third-party logistics provider may only be authorized  
24                  trading partners.

1 “(d) DISPENSER.—Beginning not later than January  
2 1, 2016, the trading partners of a dispenser may only be  
3 authorized trading partners.”.

4 **SEC. 5084. NATIONAL LICENSING STANDARDS FOR WHOLE-**  
5 **SALE DEVICE DISTRIBUTORS.**

6 Subchapter I of chapter V of the Federal Food, Drug,  
7 and Cosmetic Act, as amended, is further amended by  
8 adding at the end the following:

9 **“SEC. 586B. NATIONAL LICENSING STANDARDS FOR**  
10 **WHOLESALE DEVICE DISTRIBUTORS.**

11 “(a) REQUIREMENT.—No person may engage in  
12 wholesale distribution of a prescription device in any State  
13 unless such person has a valid license under section 583  
14 or, if not required to be licensed under section 583—

15 “(1)(A) is licensed by the State from which the  
16 prescription device is distributed; or

17 “(B) if the State from which the prescription  
18 device is distributed has not established a licensure  
19 requirement, is licensed by the Secretary; and

20 “(2) if the prescription device is distributed  
21 interstate, is licensed by the State into which the  
22 prescription device is distributed if the State into  
23 which the prescription device is distributed requires  
24 the licensure of a person that distributes prescrip-  
25 tion devices into the State.



1 “(b) COSTS.—

2 “(1) AUTHORIZED FEES OF SECRETARY.—If a  
3 State does not establish a licensing program for per-  
4 sons engaged in the wholesale distribution of a pre-  
5 scription device, the Secretary shall license a person  
6 engaged in wholesale distribution located in such  
7 State and may collect a reasonable fee in such  
8 amount as may be necessary to reimburse the Sec-  
9 retary for costs associated with establishing and ad-  
10 ministering the licensure program and conducting  
11 periodic inspections under this section. The Sec-  
12 retary shall adjust fee rates as needed on an annual  
13 basis to generate only the amount of revenue needed  
14 to perform this service. Fees authorized under this  
15 paragraph shall be collected and available for obliga-  
16 tion only to the extent and in the amounts provided  
17 in advance in appropriations Acts. Such fees are au-  
18 thorized to remain available until expended. Such  
19 sums as may be necessary may be transferred from  
20 the Food and Drug Administration salaries and ex-  
21 penses appropriation account without fiscal year lim-  
22 itation to such appropriation account for salaries  
23 and expenses with such fiscal year limitation.

24 “(2) STATE LICENSING FEES.—Nothing in this  
25 Act shall prohibit States from collecting fees from

1 wholesale distributors in connection with State li-  
2 censing of such distributors.

3 “(c) THIRD-PARTY LOGISTICS PROVIDERS.—Not-  
4 withstanding subsections (a) and (b), each entity that  
5 meets the definition of a third-party logistics provider  
6 under section 586—

7 “(1) shall obtain a license as a third-party lo-  
8 gistics provider as described in section 586C(a); and

9 “(2) is not required to obtain a license as a  
10 wholesale distributor if the entity never assumes an  
11 ownership interest in the prescription device it han-  
12 dles.

13 “(d) REGULATIONS.—

14 “(1) IN GENERAL.—The Secretary shall, not  
15 later than 1 year after the date of enactment of the  
16 Device Distribution Licensing Act of 2015, establish  
17 by regulation standards for the licensing of persons  
18 under subsection (a), including the revocation,  
19 reissuance, and renewal of such license.

20 “(2) CONTENT.—For the purpose of ensuring  
21 uniformity with respect to standards set forth in this  
22 section, the standards established under paragraph  
23 (1) shall apply without variation to all State and  
24 Federal licenses described under subsection (a) and  
25 shall include standards for the following:

1           “(A) The receipt, storage, and handling of  
2           prescription devices, including facility require-  
3           ments.

4           “(B) Notification to the relevant State li-  
5           censing authority or the Food and Drug Ad-  
6           ministration of any known contraband, counter-  
7           feit, or misbranded nonconforming device in its  
8           possession or control.

9           “(C) The furnishing of a bond or other  
10          equivalent means of security, as follows:

11           “(i)(I) For the issuance or renewal of  
12           a wholesale distributor license, an appli-  
13           cant that is not a government owned and  
14           operated wholesale distributor shall submit  
15           a surety bond of \$100,000 or other equiva-  
16           lent means of security acceptable to the  
17           State.

18           “(II) For purposes of subclause (I),  
19           the State or other applicable authority may  
20           accept a surety bond in the amount of  
21           \$25,000 if the annual gross receipts of the  
22           previous tax year for the wholesaler is  
23           \$10,000,000 or less.

24           “(ii) If a wholesale distributor can  
25           provide evidence that it possesses the re-

1           required bond in a State, the requirement for  
2           a bond in another State shall be waived.

3           “(D) Mandatory background checks and  
4           fingerprinting of facility managers or des-  
5           ignated representatives.

6           “(E) The establishment and implementa-  
7           tion of qualifications for key personnel.

8           “(F) The mandatory physical inspection of  
9           any facility to be used in wholesale distribution  
10          within a reasonable timeframe from the initial  
11          application of the facility and to be conducted  
12          by the licensing authority or by the State, con-  
13          sistent with paragraph (3).

14          “(G) In accordance with paragraph (4),  
15          the prohibition of certain persons from receiving  
16          or maintaining licensure for wholesale distribu-  
17          tion.

18          “(3) INSPECTIONS.—To satisfy the inspection  
19          requirement under paragraph (2)(F), the Federal or  
20          State licensing authority may conduct the inspection  
21          or may accept an inspection by the State in which  
22          the facility is located, or by a third-party accredita-  
23          tion or inspection service approved by the Secretary  
24          or the State licensing such wholesale distributor.

1           “(4) PROHIBITED PERSONS.—The standards  
2 established under paragraph (1) shall include re-  
3 quirements to prohibit a person from receiving or  
4 maintaining licensure for wholesale distribution if  
5 the person—

6           “(A) has been convicted of any felony for  
7 conduct relating to wholesale distribution, any  
8 felony violation of subsection (i), (k), or (r) of  
9 section 301, or any felony violation of section  
10 1365 of title 18, United States Code, relating  
11 to product tampering; or

12           “(B) has engaged in a pattern of violating  
13 the requirements of this section, or State re-  
14 quirements for licensure, that presents a threat  
15 of serious adverse health consequences or death  
16 to humans.

17           “(5) REQUIREMENTS.—The Secretary, in pro-  
18 mulgating any regulation pursuant to this section,  
19 shall, notwithstanding section 553 of title 5, United  
20 States Code—

21           “(A) issue a notice of proposed rulemaking  
22 that includes a copy of the proposed regulation;

23           “(B) provide a period of not less than 60  
24 days for comments on the proposed regulation;  
25 and

1           “(C) provide that the final regulation take  
2           effect on the date that is 1 year after the date  
3           such final regulation is published.”.

4 **SEC. 5085. NATIONAL LICENSING STANDARDS FOR THIRD-**  
5 **PARTY LOGISTICS PROVIDERS.**

6           Subchapter I of chapter V of the Federal Food, Drug,  
7 and Cosmetic Act, as amended, is further amended by  
8 adding at the end the following:

9 **“SEC. 586C. NATIONAL LICENSING STANDARDS FOR THIRD-**  
10 **PARTY LOGISTICS PROVIDERS.**

11           “(a) REQUIREMENTS.—No third-party logistics pro-  
12 vider in any State may conduct activities in any State un-  
13 less each facility of such third-party logistics provider has  
14 a valid license under section 584 or, if not required to  
15 be licensed under section 584—

16           “(1)(A) is licensed by the State from which the  
17 prescription device is distributed by the third-party  
18 logistics provider, in accordance with the regulations  
19 promulgated under subsection (c); or

20           “(B) if the State from which the prescription  
21 device distributed by the third-party logistics pro-  
22 vider has not established a licensure requirement, is  
23 licensed by the Secretary, in accordance with the  
24 regulations promulgated under subsection (c); and

1           “(2) if the prescription device is distributed  
2 interstate, is licensed by the State into which the  
3 prescription device is distributed by the third-party  
4 logistics provider if such State licenses third-party  
5 logistics providers that distribute prescription de-  
6 vices into the State and the third-party logistics pro-  
7 vider is not licensed by the Secretary as described in  
8 paragraph (1)(B).

9           “(b) COSTS.—

10           “(1) AUTHORIZED FEES OF SECRETARY.—If a  
11 State does not establish a licensing program for a  
12 third-party logistics provider, the Secretary shall li-  
13 cense the third-party logistics providers located in  
14 such State and may collect a reasonable fee in such  
15 amount as may be necessary to reimburse the Sec-  
16 retary for costs associated with establishing and ad-  
17 ministering the licensure program and conducting  
18 periodic inspections under this section. The Sec-  
19 retary shall adjust fee rates as needed on an annual  
20 basis to generate only the amount of revenue needed  
21 to perform this service. Fees authorized under this  
22 paragraph shall be collected and available for obliga-  
23 tion only to the extent and in the amount provided  
24 in advance in appropriations Acts. Such fees are au-  
25 thorized to remain available until expended. Such

1        sums as may be necessary may be transferred from  
2        the Food and Drug Administration salaries and ex-  
3        penses appropriation account without fiscal year lim-  
4        itation to such appropriation account for salaries  
5        and expenses with such fiscal year limitation.

6            “(2) STATE LICENSING FEES.—

7            “(A) STATE ESTABLISHED PROGRAM.—  
8        Nothing in this Act shall prohibit a State that  
9        has established a program to license a third-  
10       party logistics provider from collecting fees  
11       from a third-party logistics provider for such a  
12       license.

13           “(B) NO STATE ESTABLISHED PRO-  
14       GRAM.—A State that does not establish a pro-  
15       gram to license a third-party logistics provider  
16       in accordance with this section shall be prohib-  
17       ited from collecting a State licensing fee from  
18       a third-party logistics provider.

19           “(c) REGULATIONS.—

20           “(1) IN GENERAL.—Not later than 1 year after  
21       the date of enactment of the Device Distribution Li-  
22       censing Act of 2015, the Secretary shall issue regu-  
23       lations regarding the standards for licensing under  
24       subsection (a), including the revocation and



1 reissuance of such a license, to third-party logistics  
2 providers under this section.

3 “(2) CONTENT.—For the purpose of ensuring  
4 uniformity with respect to standards set forth in this  
5 section, the standards established under paragraph  
6 (1) shall apply without variation to all State and  
7 Federal licenses described under subsection (a) and  
8 shall include standards for the following:

9 “(A) Establish a process by which a third-  
10 party accreditation program approved by the  
11 Secretary shall, upon request by a third-party  
12 logistics provider, issue a license to each third-  
13 party logistics provider that meets the require-  
14 ments set forth in this section.

15 “(B) Establish a process by which the Sec-  
16 retary shall issue a license to each third-party  
17 logistics provider that meets the requirements  
18 set forth in this section if the Secretary is not  
19 able to approve a third-party accreditation pro-  
20 gram because no such program meets the Sec-  
21 retary’s requirements necessary for approval of  
22 such a third-party accreditation program.

23 “(C) Require that the third-party logistics  
24 provider complies with storage practices, as de-

1           terminated by the Secretary for such facility, in-  
2           cluding—

3                   “(i) maintaining access to warehouse  
4                   space of suitable size to facilitate safe op-  
5                   erations, including a suitable area to quar-  
6                   antine prescription devices unfit, or be-  
7                   lieved to be unfit, for distribution;

8                   “(ii) maintaining adequate security;  
9                   and

10                   “(iii) having written policies and pro-  
11                   cedures to—

12                           “(I) address receipt, security,  
13                           storage, inventory, shipment, and dis-  
14                           tribution of a prescription device;

15                           “(II) identify, record, and report  
16                           confirmed losses or thefts in the  
17                           United States;

18                           “(III) correct errors and inac-  
19                           curacies in inventories;

20                           “(IV) provide support for manu-  
21                           facturer recalls;

22                           “(V) prepare for, protect against,  
23                           and address any reasonably foresee-  
24                           able crisis that affects security or op-

1                   eration at the facility, such as a  
2                   strike, fire, or flood;

3                   “(VI) ensure that any outdated  
4                   prescription device is segregated from  
5                   other prescription devices and re-  
6                   turned to the manufacturer or de-  
7                   stroyed;

8                   “(VII) notify the relevant State  
9                   licensing authority or the Secretary of  
10                  any known contraband, counterfeit, or  
11                  misbranded nonconforming device in  
12                  its possession or control; and

13                  “(VIII) quarantine or destroy a  
14                  prescription device unfit for distribu-  
15                  tion if directed to do so by the respec-  
16                  tive manufacturer, wholesale dis-  
17                  tributor, dispenser, or an authorized  
18                  government agency.

19                  “(D) Provide for periodic inspection by the  
20                  licensing authority, as determined by the Sec-  
21                  retary, of such facility warehouse space to en-  
22                  sure compliance with this section.

23                  “(E) Prohibit a facility from having as a  
24                  manager or designated representative anyone  
25                  who has been convicted of any felony violation

1 of subsection (i), (k), or (r) of section 301, or  
2 any violation of section 1365 of title 18, United  
3 States Code relating to product tampering.

4 “(F) Provide for mandatory background  
5 checks of a facility manager or a designated  
6 representative of such manager.

7 “(G) Require a third-party logistics pro-  
8 vider to provide the applicable licensing author-  
9 ity, upon a request by such authority, a list of  
10 all prescription device manufacturers, wholesale  
11 distributors, and dispensers for whom the third-  
12 party logistics provider provides services at such  
13 facility.

14 “(H) Include procedures under which any  
15 third-party logistics provider license—

16 “(i) expires on the date that is 3  
17 years after issuance of the license; and

18 “(ii) may be renewed for additional 3-  
19 year periods.

20 “(3) PROCEDURE.—In promulgating the regula-  
21 tions under this subsection, the Secretary shall, not-  
22 withstanding section 553 of title 5, United States  
23 Code—

24 “(A) issue a notice of proposed rulemaking  
25 that includes a copy of the proposed regulation;

1           “(B) provide a period of not less than 60  
2           days for comments on the proposed regulation;  
3           and

4           “(C) provide that the final regulation takes  
5           effect upon the expiration of 1 year after the  
6           date that such final regulation is issued.

7           “(d) VALIDITY.—A license issued under this section  
8           shall remain valid as long as the third-party logistics pro-  
9           vider remains licensed consistent with this section. If the  
10          Secretary finds that the third-party accreditation program  
11          demonstrates that all applicable requirements for licensure  
12          under this section are met, the Secretary shall issue a li-  
13          cense under this section to a third-party logistics pro-  
14          vider.”.

15          **SEC. 5086. WAIVERS AND EXEMPTIONS.**

16          Subchapter I of chapter V of the Federal Food, Drug,  
17          and Cosmetic Act, as amended, is further amended by  
18          adding at the end the following:

19          **“SEC. 586D. WAIVERS AND EXEMPTIONS.**

20          “(a) IN GENERAL.—Not later than 1 year after the  
21          date of enactment of the Device Distribution Licensing  
22          Act of 2015, the Secretary shall, by guidance—

23                  “(1) establish a process—

24                          “(A) by which a wholesale distributor or  
25                          third-party logistics provider may request a

1 waiver from any of the requirements set forth  
2 in section 586B or 586C; and

3 “(B) under which the Secretary may grant  
4 the waiver—

5 “(i) if the Secretary determines that  
6 such requirements would result in an  
7 undue economic hardship; or

8 “(ii) for emergency medical reasons,  
9 including a public health emergency de-  
10 clared pursuant to section 319 of the Pub-  
11 lic Health Service Act; and

12 “(2) establish a process by which the Secretary  
13 may determine certain types or categories of whole-  
14 sale distributors, third-party logistics providers, or  
15 prescription devices to be exempt from the require-  
16 ments of section 586B or 586C.

17 “(3) CONTENT.—The guidance issued under  
18 subsection (a)(1) shall include a process for the bi-  
19 ennial review and renewal of any waiver.”.

20 **SEC. 5087. UNIFORM NATIONAL POLICY.**

21 Subchapter I of chapter V of the Federal Food, Drug,  
22 and Cosmetic Act, as amended, is further amended by  
23 adding at the end the following:

1 **“SEC. 586E. UNIFORM NATIONAL POLICY.**

2 “(a) IN GENERAL.—Beginning on the date of enact-  
3 ment of the Device Distribution Licensing Act of 2015,  
4 no State or political subdivision of a State may establish  
5 or continue any standards, requirements, or regulations  
6 with respect to device distribution or third-party logistics  
7 provider licensure that are inconsistent with, different  
8 than, or in addition to the standards and requirements  
9 applicable under section 586B, in the case of device dis-  
10 tribution, or section 586C, in the case of a third-party lo-  
11 gistics provider.

12 “(b) STATE REGULATION OF THIRD-PARTY LOGIS-  
13 TICS PROVIDERS.—No State shall regulate third-party lo-  
14 gistics providers as wholesale distributors.

15 “(c) STATE REGULATION OF OTHER ACTIVITY.—No  
16 State shall require licensure as a wholesale device dis-  
17 tributor or third-party logistics provider by any person or  
18 for any activity related to the manufacture, distribution,  
19 delivery, or dispensing of a device for which licensure is  
20 not required under section 586B or 586C, including the  
21 distribution of a device which is not a prescription device.

22 “(d) WHOLESALE DISTRIBUTOR LICENSING PRIOR  
23 TO EFFECTIVE DATE OF STANDARDS.—Until the effective  
24 date of the wholesale distributor licensing regulations  
25 under section 586B, a State may continue in force a State  
26 requirement for wholesale distributor licensing provided

1 such requirement is limited solely to wholesale distribution  
2 of prescription devices.

3 “(e) THIRD-PARTY LOGISTICS PROVIDER LICENSING  
4 PRIOR TO EFFECTIVE DATE OF STANDARDS.—Until the  
5 effective date of the third-party logistics provider licensing  
6 regulations under section 586C, a State may continue in  
7 force a State requirement for third-party logistics provider  
8 licensing provided such requirement is limited solely to  
9 third-party logistics provider activities related to prescrip-  
10 tion devices.

11 “(f) ADMINISTRATION FEES.—Notwithstanding  
12 paragraph (1), a State may administer fee collections for  
13 effectuating the wholesale prescription device distributor  
14 and third-party logistics provider licensure requirements  
15 under sections 586B and 586C.

16 “(g) ENFORCEMENT, SUSPENSION, AND REVOCA-  
17 TION.—Notwithstanding paragraph (1), a State—

18 “(1) may take administrative action, including  
19 fines, to enforce a requirement promulgated by the  
20 State in accordance with section 586B or 586C;

21 “(2) may provide for the suspension or revoca-  
22 tion of licenses issued by the State for violations of  
23 the laws of such State; and



1           “(3) upon conviction of violations of Federal,  
2           State, or local device laws or regulations, may pro-  
3           vide for fines, imprisonment, or civil penalties.”.

4 **SEC. 5088. PENALTIES.**

5           Section 301 of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 331), is amended by adding at the end  
7 the following:

8           “(ddd) Failure to comply with any requirement under  
9 section 586A, 586B, or 586C.”.