[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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''21st Century Cures Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 2. Table of contents.

TITLE I—PUTTING PATIENTS FIRST BY INCORPORATING THEIR PERSPECTIVES INTO THE REGULATORY PROCESS AND ADDRESSING UNMET NEEDS

Subtitle A—Patient-Focused Drug Development

SEC. 1001. DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.

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

(1) in subsection (d), by striking ''The Secretary shall implement'' and all that follows through ''premarket approval of a drug.''; and

(2) by adding at the end the following new subsections:

''(x) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

''(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process—

''(A) to facilitate the balanced consideration of benefits and risks; and

''(B) to develop and implement a consistent and systematic approach to the discussion of, regulatory decisionmaking with respect to, and the communication of, the benefits and risks of new drugs.

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

''(y) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

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

the Secretary shall establish and implement processes under which—

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

"(i) initial research concepts for feedback from the Secretary; and

"(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;

"(B) the Secretary may request such an entity to submit such documents and summaries; and

"(C) patient experience data may be developed and used to enhance the structured risk-benefit assessment framework under subsection (x).

"(2) PATIENT EXPERIENCE DATA.—In this subsection, the term 'patient experience data' means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, or medical researchers that is intended to provide information about the experience of patients with a disease, or the impact a disease and manage-

ment of the disease has on the lives of patients or their caregivers.''.

(b) GUIDANCE.—

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

(A) with respect to draft guidance documents or data submitted to the Secretary under paragraph (1)(A) of such subsection, guidance—

(i) specifying the timelines for the review of such documents and data by the Secretary; and

(ii) on how the Secretary will use such documents and data to update any guidance documents published under this subsection or publish new guidance;

(B) with respect to the collection and analysis of patient experience data (as defined in paragraph (2) of such subsection (y)), guidance on—

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

(I) the experience of a patient living with a particular disease;

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

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

(IV) the effect of current therapeutic options on different aspects of the disease; and

(ii) the establishment and maintenance of registries designed to increase understanding of the natural history of a disease;

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

(D) methodologies, standards, and potential experimental designs for patient-reported outcomes.

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

(3) WORKSHOPS.—

(A) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act and once every 6 months during the following 12-month period, the Secretary of Health and Human Services shall convene a workshop to obtain input regarding methodologies for developing the guidance under paragraph (1), including the collection of patient experience data.

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

(i) patients;

(ii) representatives from patient advocacy organizations and disease research foundations;

(iii) representatives of the reviewing divisions of the Food and Drug Administration; and

(iv) methodological experts with significant expertise in patient experience data.

(4) PUBLIC MEETING.—Not later than 90 days after the date on which the draft guidance is published under this subsection, the Secretary shall convene a public meeting to solicit input on the guidance.

(5) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, and make publicly available on the website of the Food and Drug Administration, a report. Such report shall include, with respect to the use to date of patient experience data in benefit and risk assessments, information on—

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

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

Subtitle B—Surrogate Endpoint Qualification and Utilization

SEC. 1021. EVIDENTIARY STANDARDS FOR THE REVIEW OF REQUESTS FOR THE QUALIFICATION OF SURROGATE ENDPOINTS; BIOMARKERS PARTNERSHIP.

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

"SEC. 507. EVIDENTIARY STANDARDS FOR THE REVIEW OF REQUESTS FOR THE QUALIFICATION OF SURROGATE ENDPOINTS; BIOMARKERS PARTNERSHIP.

''(a) IN GENERAL.—The Secretary shall develop, and revise as appropriate, evidentiary standards for making determinations on whether surrogate endpoints are qualified under section 507A for the context of use specified by a requestor (as defined in section 507A(g)). Such standards shall include—

''(1) the type of data and studies generally required for such qualification;

''(2) the information required to be included in a context of use statement submitted with a request under section 507A, including a comprehensive and clear description of the appropriate manner and conditions for the surrogate endpoint to be used for regulatory purposes;

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

''(4) the format in which data and information are required to be submitted in a request under section 507A.

''(b) GUIDANCE.—

''(1) DRAFT GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary shall, in consultation with stakeholders (including patients, industry, health care providers, academia, and government) issue draft guidance containing proposed evidentiary standards under subsection (a).

''(2) FINAL GUIDANCE.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue final guidance containing the final evidentiary standards under subsection (a).

''(3) UPDATES.—The Secretary shall periodically review, and, as appropriate, update the guidance under paragraph (2).

''(c) DETERMINATIONS PRIOR TO FINALIZATION OF STANDARDS.—Nothing in this section shall be construed as precluding the Secretary from making a determination under this section before the finalization of standards under subsection (b)(2) with respect to whether a specific surrogate endpoint is qualified for the context of use specified by the requestor.

''(d) PUBLIC-PRIVATE PARTNERSHIP.—The Secretary may enter into a public-private partnership with one or more private entities for purposes of—

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

''(2) the development of evidentiary standards for such review; and

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

''(e) RULE OF CONSTRUCTION.—Nothing in this section or section 507A shall be construed as having any impact on confidential discussions between the Secretary and any person (including a requestor) regarding the consideration of a surrogate endpoint that has or has not been

qualified under section 507A for purposes of supporting or obtaining approval, clearance, or licensure of the specified drug, device, or biological product under section 505, 515, or 510(k) of this Act, or section 351(a) of the Public Health Service Act, respectively, for purposes of supporting investigational use of a drug under section 505(i) of this Act, a device under section 520(g) of this Act, or a biological product under section 351(a) of the Public Health Service Act, or for any other regulatory purpose.''.

SEC. 1022. ENHANCING THE PROCESS FOR QUALIFICATION OF SURROGATE ENDPOINTS.

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

''SEC. 507A. ENHANCING THE PROCESS FOR QUALIFICATION OF SURROGATE ENDPOINTS.

''(a) IN GENERAL.—

''(1) REQUEST.—Beginning not later than 90 days after the date on which the final guidance is issued under section 507, upon the submission of a request to the Secretary for the qualification of a surrogate endpoint for the context of use specified in the request, the Secretary shall initiate the qualification process under this section for purposes of determining whether the surrogate endpoint is qualified

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

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

''(3) FILING OF REQUEST.—Not later than 30 days after the submission of a request under subsection (a), the Secretary shall—

''(A)(i) issue a written notification to the requestor determining that the request is in the correct format and sufficiently complete to conduct a substantive review and make such notification publicly available; and

''(ii) file the request; or

''(B) issue a written notification to the requestor stating the reasons for the refusal and make such notification publicly available.

''(b) CONSULTATION WITH SCIENTIFIC EXPERTS.—

''(1) IN GENERAL.—In reviewing a request submitted under subsection (a), the Secretary may con-

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

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

"(B) the written consent of the requestor before sharing any confidential commercial or trade secret information publicly or with any such expert who is not otherwise a special Government employee (as defined in section 202 of title 18, United States Code); and

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

"(i) is in accordance with paragraph (2); and

"(ii) may include additional scientific experts identified by the requestor as having relevant scientific expertise.

"(2) PUBLIC FORUM.—

"(A) IN GENERAL.—In the case of a request under paragraph (1)(C) for consultation

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

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

"(ii) not later than 30 days before the date on which the forum will be held, publish a notice in the Federal Register announcing such date.

"(B) FORUM REQUIREMENTS.—A public forum convened under this paragraph shall—

"(i) be convened for the purpose of evaluating data described in subsection (c)(1);

"(ii) be open to the public and accept oral and written submissions on the subject matter from any person;

"(iii) include testimony or public comments from—

"(I) one or more individuals knowledgeable in the fields of biostatistics, pharmacogenomics, and quantitative biology;

''(II) one or more physician scientists with direct expertise in the relevant therapeutic areas;

''(III) one or more representatives recommended by one or more relevant patient-oriented organizations; and

''(IV) one or more individuals representing the interests of sponsors of new drugs; and

''(iv) be exempt from the Federal Advisory Committee Act (5 U.S.C. App.).

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

''(1) not later than 90 days after the date of the submission of the request, the requestor and the Secretary shall agree on a surrogate endpoint qualification plan that includes a description of data that would be sufficient, applying the evidentiary standards under section 507, to qualify the surrogate endpoint for the context of use specified in the request;

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

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

"(A) make a final determination on whether to qualify the surrogate endpoint for the context of use as specified in the request;

"(B) provide a written notification of such determination to the requestor; and

"(C) in the case of a determination to not qualify the surrogate endpoint, include in such notification an explanation of the reasons for the determination, including any evidentiary gaps in the data submitted to support the request;

"(3) a requestor may appeal a determination to not qualify a surrogate endpoint under paragraph (2); and

"(4) in the case of an appeal under paragraph (3), not later than 30 days after the date on which such appeal is submitted to the Secretary, the Secretary shall—

"(A) review the appeal;

"(B) make a determination to reverse or uphold the determination that is the subject of the appeal; and

''(C) notify the requestor who made such appeal of such determination.

''(d) EFFECT OF QUALIFICATION.—A surrogate endpoint determined under this section to be qualified for the specified context of use may be so used by any person for purposes of supporting or obtaining approval, clearance, or licensure of a drug, device, or biological product under section 505, 515, or 510(k) of this Act, or section 351(a) of the Public Health Service Act, respectively, for purposes of supporting investigational use of a drug under section 505(i) of this Act, a device under section 520(g) of this Act, or a biological product under section 351(a) of the Public Health Service Act, or for any other regulatory purpose, provided that such determination remains in effect.

''(f) PUBLIC AVAILABILITY OF INFORMATION.—

''(1) IN GENERAL.—If a requestor provides a statement of consent with respect to a request submitted under subsection (a), the Secretary shall make publicly available—

''(A) information on surrogate endpoints with respect to which such request was submitted and a summary of the data that have been submitted to support such request; and

''(B) information on surrogate endpoints that have been determined under this section to

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

"(2) INTERNET PAGE.—The Secretary shall maintain and update, no less frequently than quarterly, on the Internet site of the Food and Drug Administration, a dedicated Internet page that contains summary statistics regarding—

"(A) the number of requests received by the Secretary under subsection (a);

"(B) the number of surrogate endpoints qualified under subsection (c); and

"(C) the number of such requests that have been withdrawn by the requestor.

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, without the requestor's consent.

"(g) DEFINITIONS.—In this section:

"(1) BIOMARKER.—The terms 'biomarker' mean a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic

processes, or biological responses to a therapeutic intervention.

''(2) QUALIFICATION.—The terms 'qualification', 'qualified', and 'qualify' refer to a conclusion that, within the stated context of use, a surrogate endpoint can be relied on to have a specific interpretation and application in drug, device, or biological product development and regulatory review.

''(3) REQUESTOR.—The term 'requestor' means the person submitting the request under subsection (a) that is at issue.

''(4) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a biomarker that is intended to substitute for a clinical endpoint.''.

SEC. 1023. TRANSITIONAL PROVISIONS FOR PREVIOUS SUBMISSIONS FOR QUALIFICATION OF BIOMARKERS AS SURROGATE ENDPOINTS.

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

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

(b) CONTENTS OF REQUEST.—A request under subsection (a) shall—

(1) include the pending biomarker request, including a description of the context of use of the biomarker that is the subject of such pending biomarker request and any other documentation or data submitted in support of the pending biomarker request;

(2) specify the stage of the process of the review of the pending biomarker request as of the date of the enactment of this Act; and

(3) with respect to the review of the pending biomarker request under section 507A of the Federal Food, Drug, and Cosmetic Act (as added by this Act), what stage of the review under such respective section the person submitting such request anticipates the Secretary of Health and Human Services should begin such review of such pending biomarker request.

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

Cosmetic Act (as added by this Act) of a pending biomarker request, at the stage of such review specified pursuant to such subsection.

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

(e) DEFINITION.—In this section, the term ''pending biomarker request'' means a request submitted to the Secretary before the date of the enactment of this Act for the qualification of a biomarker as a surrogate endpoint with respect to which, as of such date of enactment, the Secretary has not made a determination.

SEC. 1024. BIANNUAL REPORTS TO CONGRESS.

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

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

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

Subtitle C—Approval of Breakthrough Therapies

SEC. 1041. APPROVAL OF BREAKTHROUGH THERAPIES.

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

(1) by moving subsection (f) (relating to awareness efforts) so that such subsection follows subsection (e); and

(2) by adding at the end the following:

''(g) APPROVAL OF BREAKTHROUGH THERAPIES.—

''(1) IN GENERAL.—

''(A) APPROVAL.—At the request of the sponsor of a drug that has received designation as a breakthrough therapy under subsection (a) for a serious or life-threatening disease or condition, and for which an application is submitted under section 505(b) of this Act or section 351 of the Public Health Service Act, the Secretary may grant approval of such application upon a determination that the sponsor has submitted the evidence described in subparagraph (B).

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

vide sufficient evidence for approval of the drug as safe and effective under subsections (c) and (d) of section 505 of this Act or for licensure of the drug as safe, pure, and potent under section 351(a) of the Public Health Service Act for such disease or condition, considering the risks and benefits of the drug and the risks associated with such disease or condition for which unmet medical needs exist.

''(C) DEFINITION.—In this paragraph, the term 'early stage clinical safety and effectiveness data' includes clinical safety and effectiveness data derived from one or more phase 2 studies, as defined in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

''(2) LIMITATION.—The Secretary may make approval of a drug under this subsection subject to a requirement that the sponsor will assess the safety and effectiveness of the drug through a postmarket assessment plan. Such a plan shall be based on an agreement between the Secretary and the sponsor of the drug and shall consist of one of, or a combination of, the following:

''(A) One or more clinical trials after approval or licensure of the drug.

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

''(3) WITHDRAWAL OF APPROVAL.—

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

''(i) the sponsor of the drug fails to execute, with due diligence, any postmarket assessment plan required under paragraph (2);

''(ii) other evidence demonstrates that the drug is not safe or effective under the conditions of use for which the drug is approved under this subsection; or

''(iii) the sponsor of the drug disseminates false or misleading promotional materials with respect to the drug.

''(B) PROCEDURES.—In so withdrawing approval of a drug, the Secretary shall use procedures that—

''(i) are prescribed by the Secretary in regulations; and

''(ii) include an opportunity for an informal hearing.''.

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

(1) in clause (iv), by striking ''and'' at the end;

(2) in clause (v), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(vi) providing priority review with respect to, and granting approval of, such an application pursuant to subsection (g).''.

(c) RULES OF CONSTRUCTION.—Nothing in this section or the amendments made by this section shall be construed—

(1) to replace the Food and Drug Administration's program for breakthrough therapies under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)); or

(2) to limit the rule of construction in subsection (e)(2) of section 506 of such Act (21 U.S.C. 356), which provides that nothing in such section 506 (including section 506(g), as added by this section) shall be construed to alter the standards of evidence under—

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

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

(d) GUIDANCE.—

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

(A) the policies and procedures for obtaining approval of breakthrough therapies under section 506(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(g)); and

(B) the circumstances under which a sponsor of a drug should consider the drug as a potential candidate for such approval, including when a substantial portion of the population

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

(2) TIMING.—The Secretary shall—

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

(B) after providing notice of the draft guidance and an opportunity for public comment, finalize such guidance not later than 18 months after the date of publication of the draft guidance.

(3) CONSULTATION.—In developing guidance under this subsection, the Secretary shall consult with the regulated industry, academia, representatives of patient advocacy organizations and disease research foundations, and other interested parties through a public process.

Subtitle D—Antibiotic Drug Development

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

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

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

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

"(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—

"(1) PROCESS.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition, the Secretary—

"(A) shall provide the sponsor with an opportunity to request meetings under paragraph (2); and

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

"(2) FORMAL MEETINGS.—

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

''(i) A clinical development planning meeting.

''(ii) An assessment meeting.

''(iii) A postapproval meeting.

''(B) RELATION TO COMPARABLE FORMAL MEETINGS.—A meeting conducted pursuant to a request described in subparagraph (A) shall not replace any meeting with the Secretary to which the sponsor of the drug is otherwise entitled, but may be conducted as part of a comparable formal meeting.

''(C) TIMING.—The Secretary shall meet with the sponsor of a drug pursuant to a request described in subparagraph (A) not later than 60 days after the date of the Secretary's receipt of the request.

''(D) DEFINITIONS.—In this paragraph:

''(i) The term 'assessment meeting' means a meeting, other than a clinical development planning meeting, held prior to submission of an application for a drug under section 505(b) of this Act of section 351(a) of the Public Health Service Act, at which the sponsor of the drug and the Secretary meet—

''(I) to assess progress in implementing the clinical development program agreed to under paragraph (1);

''(II) to discuss the necessity of, and reach agreement with respect to, any postapproval commitments; and

''(III) to reach agreement on the efficacy or safety data necessary to support expansion of the approval or licensure of the drug beyond use in the limited population.

''(ii) The term 'clinical development planning meeting' means a meeting, other than an assessment meeting, at which the sponsor of the drug and the Secretary meet to discuss and reach an initial agreement with respect to the content of the clinical development program (including the matters described in paragraph (1)(B)) that is necessary to support approval or licensure of the drug for use in a limited population.

''(iii) The term 'comparable formal meeting'—

''(I) means a formal meeting that is typically held during the drug development or approval process; and

''(II) includes any such meeting that is described in applicable guidance documents of the Food and Drug Administration that are in effect.

''(iv) The term 'postapproval meeting' means a meeting, held following initial approval or licensure of the drug for use in a limited population, to discuss any issues regarding postapproval commitments or expansion of approved uses agreed to under paragraph (1).

''(3) AGREEMENTS.—

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

''(B) EVIDENCE.—An agreement under paragraph (1) may provide for reliance on traditional endpoints, alternative endpoints, or a

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

''(C) LABELING STATEMENT.—An agreement under paragraph (1) shall require the drug's labeling, upon approval pursuant to the agreement, to prominently include in the prescribing information required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

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

''(i) with the written agreement of the sponsor of the drug; or

''(ii) pursuant to a decision by the director of the division responsible for reviewing the drug that a substantial scientific issue essential to determining the

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

''(E) DECISION BY DIRECTOR.—A decision under subparagraph (D)(ii) shall be in writing. Before any such decision is made final, the Secretary shall provide to the sponsor of the drug an opportunity for a meeting at which—

''(i) the director of the division responsible for reviewing the drug and the sponsor will be present; and

''(ii) the director will document the scientific issues involved.

''(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval under this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval under section 506(c)(1).

''(5) WITHDRAWAL OF LIMITED POPULATION APPROVAL REQUIREMENTS.—If a drug is approved pursuant to this subsection for treatment in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, respectively, without such a limitation, the Secretary shall remove any

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

''(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit designation and expedited review of a drug as a breakthrough therapy under section 506(a), approval of such a drug under section 506(g), designation and treatment of a drug as a fast track product under section 506(b), or accelerated approval of a drug under section 506(c), in combination with approval of the drug for use in a limited population of patients under this subsection.

''(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d)). Subsections (c) and (d) and such standards of evidence apply to the review and approval of drugs under this subsection, including whether a drug is safe and effective. Nothing in this subsection shall be construed to limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this subsection.

''(8) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when and whether the Secretary promulgates final regulations or guidance.''.

(2) GUIDANCE.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1).

(b) LICENSURE OF CERTAIN BIOLOGICAL PRODUCTS.—Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended—

(1) by striking ''(j)'' and inserting ''(j)(1)'';

(2) by inserting ''505(z),'' after ''505(p),''; and

(3) by adding at the end the following:

''(2) In applying section 505(z) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—

''(A) references to an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition shall be construed to refer to biological products intended to treat a bacterial or fungal infection associated with a serious or life-threatening disease; and

''(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to licensure of a biological product under subsection (a) of this section.''.

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

''SEC. 317U. MONITORING ANTIBACTERIAL AND ANTIFUNGAL DRUG USE AND RESISTANCE.

''(a) MONITORING.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall use the National Healthcare Safety Network or another appropriate monitoring system to monitor—

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

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

''(2) changes in bacterial and fungal resistance to drugs.

''(b) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make the data derived from monitoring under this section publicly available for the purposes of—

''(1) improving the monitoring of important trends in antibacterial and antifungal resistance; and

''(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 1062. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROBIAL ORGANISMS.

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

"SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROBIAL ORGANISMS.

"(a) IDENTIFICATION OF CRITERIA.—

"(1) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria for systemic antibacterial or antifungal drugs—

"(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

"(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

"(2) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall, in identifying susceptibility test interpretive criteria under subsection (a), rely upon, to the extent available and relevant—

"(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

"(B) Bayesian and pharmacometric statistical methodologies; and

''(C) such other evidence and information as the Secretary considers appropriate.

''(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

''(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

''(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

''(i) established by a nationally or internationally recognized standard development organization that—

''(I) establishes and maintains procedures to address potential con-

flicts of interest and ensure transparent decisionmaking;

"(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

"(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

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

"(B) OTHER LISTS.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include the following lists:

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

"(ii) A list of each susceptibility test interpretive criteria standard, the recognition of which, the Secretary has withdrawn under paragraph (3).

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

"(iv) A list of each drug for which the Secretary approves an application under section 505(b) of this Act or section 351(a) of the Public Health Service Act, as applicable, for which there are no relevant susceptibility test interpretive criteria included in a standard recognized by the Secretary.

"(C) REQUIRED STATEMENTS ON LIMITATIONS OF INFORMATION.—The Interpretive Criteria Website shall include the following statements:

"(i) A statement that—

''(I) the Website provides information about the susceptibility of bacteria and fungi to a certain drug; and

''(II) the safety and efficacy of the drug in treating clinical infections due to such bacteria or fungi may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in such trials is unknown.

''(ii) A statement that directs health care practitioners to consult the approved product labeling for specific drugs to determine the uses for which the Secretary has approved the product.

''(iii) Any other statement that the Secretary determines appropriate to adequately convey the limitations of the data supporting susceptibility test interpretive criteria standard listed on the Website.

''(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is published, the Secretary shall publish a notice of that publication in the Federal Register.

''(4) INAPPLICABILITY OF MISBRANDING PROVISIONS.—The inclusion in the approved labeling of a systemic antibacterial or antifungal drug of a reference or hyperlink to the Interpretive Criteria Website shall not cause the drug to be misbranded in violation of section 502.

''(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

''(c) RESPONDING TO SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA IDENTIFIED OR UPDATED BY PRIVATE ENTITIES.—

''(1) IN GENERAL.—Beginning on the date of the establishment of the Interpretive Criteria Website, and every 6 months thereafter, the Secretary shall—

''(A) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

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

''(i) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

''(ii) adopting the new or updated standards;

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

''(iv) making any necessary updates to a list under subsection (b)(2).

''(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

''(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

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

''(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(1)(B); and

''(D) such other information or factors as the Secretary determines appropriate.

''(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(B) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary will review such comments and, if the Secretary determines appropriate, update pursuant to such subsection, susceptibility test interpretive criteria standards—

''(A) recognized by the Secretary under this subsection; or

''(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

''(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive criterion for which an approval is in effect under paragraph (1) shall be rec-

ognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF NONADOPTED CRITERIA.—Nothing in this section prohibits the sponsor of a drug or device from seeking approval or clearance of the drug or device, or changes to the drug, the device, or its labeling, on the basis of susceptibility test interpretive criteria which differ from those adopted pursuant to paragraph (1).

"(d) SYSTEMIC ANTIBACTERIAL AND ANTIFUNGAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to a systemic antibacterial or antifungal drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Internet site under subsection (b)(1), a holder of an approved application under section 505 or section 351 of the Public Health Service Act, as applicable, for each such drug—

"(A) not later than 1 year after establishment of the Interpretive Criteria Website, shall submit to the Secretary a supplemental application for purposes of changing the drug's label-

ing to substitute a reference or hyperlink to such Website for any susceptibility test interpretive criteria and related information; and

"(B) may begin distribution of the drug involved upon receipt by the Secretary of the supplemental application for such change.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to systemic antibacterial and antifungal drugs lawfully introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of the establishment of the Interpretive Criteria Website, the labeling for such a drug shall include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

"(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—Notwithstanding sections 502, 505, 513, 514, and 515, a device for use to test the susceptibility of bacteria and fungi to drugs may be lawfully marketed under this Act if—

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

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

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

''(2) the labeling of such device prominently and conspicuously—

''(A) includes a statement that—

''(i) the device provides information about the susceptibility of bacteria and fungi to certain drugs; and

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

''(B) includes a statement directing health care practitioners to consult the approved labeling for drugs tested using such a device, to determine the uses for which the Secretary has approved such drugs; and

''(C) includes any other statement the Secretary determines appropriate to adequately convey the limitations of the data supporting

the interpretive criteria described in paragraph (1).

''(f) DEFINITIONS.—In this section:

''(1) The term 'antimicrobial testing device' means, in the case of a drug, the efficacy of which in treating clinical infections due to certain bacteria or fungi has not been established in adequate and well-controlled clinical trials, a device that utilizes susceptibility test interpretive criteria to determine and report the susceptibility of such bacteria or fungi to such drug.

''(2) The term 'qualified infectious disease product' means a qualified infectious disease product designated under section 505E(d).

''(3) The term 'susceptibility test interpretive criteria' means—

''(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

''(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

"(4)(A) The term 'systemic antibacterial or antifungal drug' means a drug that—

"(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus; and

"(ii) is subject to section 503(b)(1).

"(B) Such term includes a qualified infectious disease product.

"(C) Unless otherwise specified by the Secretary through regulations, such term does not include—

"(i) antimicrobial drugs other than antibacterial and antifungal drugs; and

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

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505.".

(b) CONFORMING AMENDMENTS.—

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

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

''(dd) If it is a systemic antibacterial or antifungal drug and its labeling fails to conform with the requirements under section 511(d).''.

(3) RECOGNITION FOR PURPOSES OF DEVICE CLASSIFICATION.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after ''the Secretary shall, by publication in the Federal Register'' the following: ''(or, with respect to the approval of an antimicrobial testing device under section 511(e), by posting on the Interpretive Criteria Website established under subsection (b) of such section the applicable susceptibility test interpretive criteria standards in accordance with section 511)''.

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

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

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding the updating of lists under paragraph (2) of subsection (b) section 511 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), and posted on the Interpretive Criteria Website established under paragraph (1) of such subsection.

(e) RULE OF CONSTRUCTION.—Nothing in this Act (including the amendments made by this Act) shall be construed to restrict, in any manner, the prescribing of antibiotics or other products by health care professionals, or to limit the practice of health care.

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

Section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(1) in subsection (a), by inserting ", subject to subsection (h)," before "be extended by 5 years"; and

(2) by adding at the end the following new subsection:

''(h) ELECTION TO CONVEY A PORTION OF EXCLUSIVITY.—

''(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, the holder of an approved application for a qualified infectious disease product may elect to convey up to [12] months of the 5-year extension of exclusivity described in subsection (a) so as to apply such extension of exclusivity with respect to one or more other drugs.

''(2) NOTICE TO SECRETARY.—Upon making a conveyance under paragraph (1), the holder of the approved application for the qualified infectious disease product involved shall submit a notice to the Secretary including—

''(A) the name of the qualified infectious disease product;

''(B) the name of the recipient drug; and

''(C) the duration of the conveyed exclusivity period.

''(3) EFFECT OF CONVEYANCE.—

''(A) EXTENSION OF OTHER APPLICABLE EXCLUSIVITY PERIODS.—Immediately upon the Secretary's receipt of a notice under paragraph (2), with respect to the recipient drug, the following exclusivity periods (as applicable) are

each extended by the conveyed exclusivity period:

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

"(ii) The 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505.

"(iii) The 7-year period described in section 527.

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

"(B) DRUGS SUBJECT TO LISTED PATENTS.—Immediately upon the Secretary's receipt of a notice under paragraph (2), the period during which an approval of an application may not be made effective by operation of subsection (c)(3) or (j)(5)(B) of section 505, as applicable, shall be extended after the date the patent expires (including any patent extensions) for a period equal to the conveyed exclusivity

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

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505;

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505; or

"(iii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 and the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed.

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

"(5) PERIOD FOR ELECTIONS.—An election under paragraph (2) with respect to a qualified infectious disease product may not be made later than

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

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

''(7) REDUCTION OF EXTENSION OF EXCLUSIVITY PERIOD FOR QUALIFIED INFECTIOUS DISEASE PRODUCT.—Immediately upon the Secretary's receipt of a notice under paragraph (2), the 5-year extension of exclusivity described in subsection (a) applicable with respect to a qualified infectious disease product shall be reduced by the conveyed exclusivity period.

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

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

''(B) the patent terms for all patents listed in the publication entitled 'Approved Drug Products with Therapeutic Equivalence Evalua-

tions' (commonly referred to as the 'Orange Book').

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

''(10) DONATION TO THE NATIONAL INSTITUTES OF HEALTH.—As a condition on receipt of a conveyed exclusivity period, the holder of the approved application for the recipient drug shall make a donation to the National Institutes of Health as follows:

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

''(B) The donation amount shall equal **[**_____**]** percent (not to exceed 5 percent) of sales of the recipient drug in the United States for the period—

''(i) beginning on the first day of the conveyed exclusivity period; and

''(ii) ending on the date of market entry of a drug approved pursuant to an application filed under subsection (b)(2) or (j) of section 505 of this Act that references the recipient drug as the listed drug or of a biological product licensed pursuant to section 351(k) of the Public Health Service Act that references the recipient drug as the reference product.

''(C) The donation shall be made not later than 60 days after the end of the marketing period described in subparagraph (B).

''(D) In no event shall the total donation required under this paragraph with respect to a recipient drug exceed [$_____] dollars.

''(E) The holder of the approved application for the recipient drug, when making a donation pursuant to this paragraph, shall specify that the donation is to be used for making grants to fund antimicrobial resistance research.

''(11) DONATIONS TO PATIENT ASSISTANCE PROGRAMS.—As a condition on receipt of a conveyed exclusivity period, in addition to the donation required by paragraph (10), the holder of the ap-

proved application for the recipient drug shall make a donation to a bona fide, independent patient assistance program as follows:

"(A) The donation amount shall equal [_____] percent (not to exceed 5 percent) of sales of the recipient drug in the United States for the period—

"(i) beginning on the first day of the conveyed exclusivity period; and

"(ii) ending on the date of market entry of a drug approved pursuant to an application filed under subsection (b)(2) or (j) of section 505 of this Act that references the recipient drug as the listed drug or of a biological product licensed pursuant to section 351(k) of the Public Health Service Act that references the recipient drug as the reference product.

"(B) The donation shall be made not later than 60 days after the end of the marketing period described in subparagraph (A).

"(C) In no event shall the total donations required under this paragraph with respect to a recipient drug exceed [$_____] dollars.

''(D) The patient assistance program must have received a favorable advisory opinion from the Inspector General of the Food and Drug Administration with respect the program's arrangement to provide cost-sharing assistance for prescription drugs.

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

''(i) include the diseases or conditions for which the recipient drug is intended to treat; and

''(ii) do not limit assistance to a subset of available products approved to treat such diseases or conditions.

''(F) In the event that no patient assistance program described in subparagraph (D) is available to receive the donation, the holder of the approved application for the recipient drug shall instead contribute the amount calculated under subparagraph (A) (in addition to the amount calculated under paragraph (9)(B)) to the National Institutes of Health in accordance with paragraph (9).

''(12) DEFINITIONS.—In this subsection:

''(A) The term 'conveyed exclusivity period' means the amount of time conveyed pursuant to an election made under paragraph (2).

''(B) The term 'recipient drug' means a drug receiving a conveyed exclusivity period.''.

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

(a) ADDITIONAL PAYMENT FOR NEW ANTIMICROBIAL DRUGS UNDER MEDICARE.—Section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:

''(M)(i) Effective for discharges beginning on or after October 1, 2015, the Secretary shall, after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise), recognize the costs of new antimicrobial drugs under the payment system established under this subparagraph.

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

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

"(iii) For purposes of this subparagraph, the term 'new antimicrobial drug' means a product that is approved for use, or a product for which an indication is first approved for use, by the Food and Drug Administration on or after January 1, 2015, and—

"(I)(aa) is intended to treat an infection caused by, or likely to be caused by, a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); or

"(bb) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act;

"(II) for which there is an 'unmet medical need' as determined by the Food and Drug Administration;

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

tion and the infectious disease professional community; and

''(IV) is used in facilities that participate in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar reporting program relating to antimicrobial drugs is determined by the Secretary to be available to such facilities, such similar reporting program as the Secretary may specify).

''(iv)(I) The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a new antimicrobial drug at any time before or after the submission of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a new antimicrobial drug.

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

''(III) The Secretary may revoke a designation of a drug as a new antimicrobial drug product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

''(v) Not later than July 1, 2015, the Secretary shall first publish in the Federal Register a list of the new antimicrobial drugs.''.

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

(1) STUDY.—The Comptroller General of the United States shall, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention, conduct a study to—

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

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

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

Subtitle E—Priority Review for Breakthrough Devices

SEC. 1081. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

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

(1) in section 515(d)—

(A) by striking paragraph (5); and

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

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

"SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

''(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

''(1) representing breakthrough technologies;

''(2) for which no approved alternatives exist;

''(3) offering significant advantages over existing approved or cleared alternatives; or

''(4) the availability of which—

''(A) has the potential to, compared to existing approved alternatives, reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

''(B) is otherwise in the best interest of patients.

''(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to, concurrently with, or subsequent to, the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

''(c) DESIGNATION PROCESS.—

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

described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

''(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the Food and Drug Administration and is chaired by a senior manager.

''(3) DESIGNATION DETERMINATION.—In issuing a determination approving or denying a request under subsection (b), the Secretary shall provide a written, substantive summary of the basis for the determination.

''(4) RECONSIDERATION BY DIRECTOR OF CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.—

''(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial by the Director of the Center for Devices and Radiological Health—

''(i) based upon the submission of documents by such person; or

''(ii) based upon such documents and a meeting or teleconference.

''(B) DIRECTOR'S RESPONSE.—The Director of the Center for Devices and Radiological Health shall respond to a request under subparagraph (A)—

''(i) in the case of a request for reconsideration described in subparagraph (A)(i), not later than 30 days after the date on which the Director receives the request; or

''(ii) in the case of a request for reconsideration described in subparagraph (A)(ii), not later than 30 days after the date of the meeting or teleconference.

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

''(d) PRIORITY REVIEW.—

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

''(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (b);

''(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

''(C) adopt an efficient process for timely dispute resolution;

''(D) provide for interactive communication with the sponsor of the device during the review process;

''(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

''(F) if the Secretary intends to consult with external experts or an advisory committee concerning the sponsor's device—

''(i) disclose to the sponsor of the device in advance the topics of any such consultation; and

''(ii) provide an opportunity for the sponsor to recommend such external experts;

''(G) for applications submitted under section 515(c), provide for advisory committee input, as determined by the Secretary or at the request of the sponsor; and

''(H) assign staff to communicate with institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

''(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

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

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

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

"(C) facilitate, to the extent scientifically appropriate, expedited and efficient development and review of the device through utilization of postmarket data collection, with regard to applications for approval under section 515(c) and petitions for classification under section 513(f)(2); and

"(D) agree to clinical protocols that the Secretary will consider binding on the Secretary, subject to changes agreed to by the sponsor and the Secretary or other changes that the Secretary determines are required to prevent an unreasonable risk to the public health.

"(e) PRIORITY REVIEW GUIDANCE.—

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

"(A) The process for a person to seek a priority review designation.

''(B) A template for requests under subsection (b).

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

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

''(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

''(f) PREDICATE DEVICES.—If a device has been classified in response to a petition for classification under section 513(f)(2) pursuant to priority review under this section, and such classification and review includes the use of postmarket data collection pursuant to subsection (d)(2)(C), the device may not be cited as a predicate device for purposes of determining substantial equivalence under section 513(f) unless such postmarket data collection has been completed.

''(g) CONSTRUCTION.—

''(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible ap-

proaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.''.

SEC. 1082. CMS COVERAGE OF BREAKTHROUGH DEVICES [TO BE SUPPLIED].

[To be supplied.]

Subtitle F—Accelerated Approval for Breakthrough Devices

SEC. 1101. ACCELERATED APPROVAL FOR BREAKTHROUGH DEVICES.

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

"SEC. 515C. ACCELERATED APPROVAL FOR BREAKTHROUGH DEVICES.

''(a) IN GENERAL.—The Secretary may approve a device that meets the criteria under section 515B(a) upon a determination that the device has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

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

Subtitle G—Expanded Access

SEC. 1121. EXPANDED ACCESS POLICY AS CONDITION OF EXPEDITED APPROVAL.

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

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

(2) by inserting after subsection (c) the following new subsection:

''(d) EXPANDED ACCESS POLICY REQUIRED FOR COVERED INVESTIGATIONAL DRUGS.—

''(1) IN GENERAL.—With respect to a covered investigational drug, not later than 30 days after the date on which the drug meets the definition of a covered investigational drug (as specified in paragraph (2)), the sponsor of the covered investigational drug shall submit to the Secretary and make publicly available the policy of the sponsor with respect to requests submitted under subsection (b). In the case of such a policy under which the sponsor accepts such requests, such policy shall include—

''(A) a single point of contact who receives and processes such requests;

''(B) procedures for making such requests;

"(C) the general criteria for the sponsor's consideration or approval of such requests; and

"(D) the amount of time the sponsor anticipates will be necessary to respond to such requests.

"(2) COVERED INVESTIGATIONAL DRUG.—In this subsection, the term 'covered investigational drug' means a drug that—

"(A) is designated as a breakthrough therapy or as a fast track product;

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

"(C) is designated an orphan drug under section 526.".

SEC. 1122. NOTIFICATION OF SUBMITTERS OF EXPANDED ACCESS REQUESTS.

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

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

(2) by inserting after subsection (d) (as inserted by section 1121(2)) the following new subsection:

''(e) NOTIFICATION OF SUBMITTERS OF REQUESTS.—In the case of the denial by a manufacturer or distributor of a request under subsection (b), not later than 5 days after the date of such denial, the manufacturer or distributor, as applicable, shall submit to the person (or physician) who made the request written notice of the denial, including an explanation for the denial.''.

SEC. 1123. GAO QUALITATIVE ANALYSIS ON INDIVIDUAL PATIENT ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

Not later than 180 days after the date of the enactment of this Act and every two years thereafter through 2023, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a qualitative analysis of the extent to which individual patients have access to investigational drugs pursuant to subsection (b) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) and recommendations for improving such access. In preparing such report, the Comptroller General shall conduct a qualitative analysis of the following:

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

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

(2) What the primary barriers are to drug sponsors granting requests for individual patient access.

(3) How the Secretary evaluates safety and efficacy data submitted in connection with such requests.

(4) The amount of time that—

(A) a physician typically takes to complete the paperwork necessary to make such a request;

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

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

(5) How regulations, guidance, policies, or practices may be modified, streamlined, expanded, or discontinued to reduce or prevent delays in approving such requests.

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

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

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

(C) were denied by drug sponsors.

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

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

SEC. 1124. EXPANDED ACCESS TASK FORCE.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish a task force within the Department of Health and Human Services to explore mechanisms for improving the access individual patients have to investigational drugs pursuant to subsection (b) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb), to be known as the ''Expanded Access Task Force'' (in this section referred to as the ''Task

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

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Task Force shall be composed of not more than 13 voting members appointed as follows:

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

(B) One representative from the Department of Health and Human Services, appointed by the Secretary of Health and Human Services.

(C) Six representatives appointed by the majority leader of the House of Representatives, in consultation with the minority leader of the House of Representatives, and the chairman and the ranking member of the Committee on Energy and Commerce of the House of Representatives, including—

(i) one current or former representative of the biopharmaceutical industry of not less than 250 full-time employees;

(ii) one representative of a biopharmaceutical company of less than 250 full-time employees;

(iii) one representative of the patient community;

(iv) one representative of the rare disease patient community;

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

(vi) one bioethicist.

(D) Five representatives appointed by majority leader of the Senate, in consultation with the minority leader of the Senate, and the chairman and the ranking member of the Committee on Health, Education, Labor and Pensions of the Senate, including—

(i) one representative of the biopharmaceutical industry of not less than 250 full-time employees;

(ii) one current or former representative of a biopharmaceutical company of less than 250 full-time employees;

(iii) one representative of the patient community;

(iv) one representative of the rare disease patient community; and

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

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

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

(1) the unique challenges faced by children with likely fatal diseases for which there is not a comparable or satisfactory alternative therapy available;

(2) possible incentives for biopharmaceutical companies and providers to approve requests submitted under such subsection;

(3) ways to improve followup reporting of adverse event data and compliance with such reporting requirements;

(4) how the Secretary of Health and Human Services interprets and takes into consideration adverse event data reported in the case of data from use under a request submitted under such subsection;

(5) ways to streamline and standardize the process for submitting requests under such subsection; and

(6) the costs incurred by biopharmaceutical companies for the time, effort, and delivery of investigational drugs to patients for the diagnosis, monitoring, or treatment of a serious disease or condition under such subsection.

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

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

SEC. 1125. FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS.

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

lished under section 1124 submits the report under subsection (d) of such section, the Secretary of Health and Human Services shall finalize the draft guidance entitled ''Expanded Access to Investigational Drugs for Treatment Use—Qs & As'' and dated May 2013.

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

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

(2) take into account the report of the Expanded Access Task Force submitted under section 1124(d) and the first report of the Comptroller General of the United States submitted under section 1123.

Subtitle H—Facilitating Responsible Communication of Scientific and Medical Developments

SEC. 1141. [TO BE SUPPLIED].

Subtitle I—Modernizing the Regulation of Social Media

SEC. 1161. DISSEMINATION OF INFORMATION ABOUT MEDICAL PRODUCTS USING THE INTERNET.

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

"SEC. 716. DISSEMINATION OF INFORMATION ABOUT MEDICAL PRODUCTS USING THE INTERNET.

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

''(1) review each regulation and guidance that applies to the dissemination by means of the Internet (including social media platforms and character-limited applications) of information about medical products; and

''(2) propose revisions to such regulations and guidance (in the form of proposed amended regulations and draft guidance, respectively) that—

"(A) facilitate meaningful use, by the sponsors of medical products, of the Internet, including Internet applications and social media, for dissemination of truthful, nonmisleading information about medical products;

"(B) recognize that such sponsors may use the Internet—

"(i) to disseminate, in character-limited applications, truthful, introductory information about medical products, including the name of such products and their approved uses; and

"(ii) to provide additional information about the safety and effectiveness of the medical products using information that is hyperlinked to such introductory information; and

"(C) for regulatory purposes, treat hyperlinked information described in subparagraph (B)(ii) as if the information appeared in introductory information described in subparagraph (B)(i).

"(b) FINAL REGULATIONS AND GUIDANCE; UPDATES.—The Secretary shall, after providing notice and an opportunity for public comment—

''(1) not later than 6 months after publication of proposed regulations and guidance pursuant to subsection (a), publish final regulations and guidance addressing the matters described in subsection (a); and

''(2) periodically thereafter, review and, as appropriate, update such regulations and guidance.

''(c) MEDICAL PRODUCT DEFINED.—In this section, the term 'medical product' means a drug, biological product, or device.''.

(b) CONFORMING REPEAL.—Section 1121 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 21 U.S.C. 379d–5) is repealed.

Subtitle J—Streamlined Data Review

SEC. 1181. STREAMLINED DATA REVIEW PROGRAM.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is further amended by inserting after section 505E of such Act (21 U.S.C. 355f) the following:

''SEC. 505F. STREAMLINED DATA REVIEW PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a program under which a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351(a) of the Public Health Service Act

may, to support the approval of the use of a drug that is the subject of the application for a new qualified indication, submit qualified data summaries.

''(b) ELIGIBILITY.—In carrying out the streamlined data review program under subsection (a), the Secretary may authorize the sponsor of a drug to include one or more summaries described in subsection (a) in a supplemental application if—

''(1) the drug has been approved or licensed under section 505(c) of this Act or section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

''(2) the supplemental application is for approval of the use of the drug for a new qualified indication under such section 505(c) or 351(a);

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

''(4) the supplemental application incorporates or supplements the data submitted in the application for approval or licensure referred to in paragraph (1); and

''(5) the full data sets used to develop the qualified data summaries are submitted, unless the Sec-

retary determines that the full data sets are not required.

''(c) DEFINITIONS.—In this section:

''(1) The term 'qualified indication' means—

''(A) an indication for the detection, diagnosis, prevention, treatment, or cure of cancer; or

''(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

''(2) The term 'qualified data summary' means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.''.

(b) GUIDANCE; REPORT; REGULATIONS.—

(1) GUIDANCE; REGULATIONS.—The Commissioner of Food and Drugs—

(A) shall—

(i) issue final guidance for implementation of the streamlined data review program established under section 505F of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), not later

than 18 months after the date of enactment of this Act; and

(ii) include in such guidance the process for expanding the types of indications to be subject to the streamlined data review program, as authorized by section 505F(c)(1)(B) of such Act; and

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

(2) REPORT.—The Commissioner of Food and Drugs shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and make publicly available, 2 reports on the implementation of the streamlined data review program. The first such report shall be not later than 2 years after the date of enactment of this Act. The second such report shall be not later than 5 years after the date of enactment of this Act. Each such report shall—

(A) address—

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

(ii) any improvements to the regulatory process achieved through the use of such summaries; and

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

(i) the components of full data sets that will not need to be submitted, as described in section 505F(b)(7) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a); and

(ii) the expansion of the types of indications to be subject to the streamlined data review program, as authorized under section 505F(c)(2) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

Subtitle K—Cures Acceleration Network

SEC. 1201. FLEXIBLE RESEARCH AUTHORITY.

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

(1) in subsection (b), by striking ''the appropriation of funds as described in subsection (g)'' and inserting ''the availability of funds as described in subsection (f)'';

(2) in subsection (e)(3), by amending subparagraph (C) to read as follows:

''(C) FLEXIBLE RESEARCH AUTHORITY.—The Director of the Center shall have flexible research authority in entering into transactions to fund projects in accordance with the terms and conditions of this section.'';

(3) by striking subsection (f); and

(4) by redesignating subsection (g) as subsection (f) and amending such subsection, as so redesignated, to read as follows:

''(f) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For purposes of carrying out this section, there are authorized to be appropriated [$_____] for each of fiscal years

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

''(2) AUTHORITY TO TRANSFER ADDITIONAL FUNDS.—The Director of the Center may transfer any funds appropriated to the Center, other than under paragraph (1), for purposes of the Cures Acceleration Network.''.

SEC. 1202. REPURPOSING DRUGS.

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

(1) in subsection (c)—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

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

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

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

''(B) with respect to which all applicable patents and exclusivity periods have expired;''; and

(2) in subsection (f)(1), as redesignated by section 1201, by inserting after the first sentence the following: ''For each of fiscal years 2016 through 2018, in addition to the amount authorized to be appropriated to carry out this section pursuant to the first sentence of this paragraph, [$____] is authorized to be appropriated for the function described in subsection (c)(3).''.

Subtitle L—Dormant Therapies

SEC. 1221. DEFINITIONS.

In this subtitle:

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

(2) The term ''Director'' means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

(3) The term ''dormant therapy'' means a medicine designated as a dormant therapy under section 1222(a).

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

(5) The term ''medicine'' means a biological product or a drug.

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

(A) begins on the date on which the Secretary first approves an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for the dormant therapy for any indication; and

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

(7) The term ''Secretary'' means the Secretary of Health and Human Services.

(8) The term ''sponsor'', with respect to a dormant therapy, is the person who takes responsibility for the designation and development of the dormant therapy. The sponsor may be a single entity or an entity collaborating with one or more other entities.

SEC. 1222. CAPTURING LOST OPPORTUNITIES AND CREATING NEW CURES FOR PATIENTS.

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

(1) the sponsor of the medicine submits a request for such designation meeting the requirements under subsection (b), and the request has not been withdrawn under subsection (d)(1); and

(2) the Secretary determines that—

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

(B) a suitable clinical plan for such investigations of the medicine has been developed by the sponsor;

(C) the sponsor intends to file an application pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for approval or licensing of the medicine for an indication described in subparagraph (A); and

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

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

(b) REQUIREMENTS FOR REQUEST FOR DESIGNATION AS DORMANT THERAPY.—A request under subsection (a)(1) with respect to a medicine may be made only by the sponsor of the medicine and shall contain each of the following:

(1) A listing of all United States patents and applications for patents under which the sponsor has rights and that may be reasonably construed to provide protection for the medicine.

(2) A waiver of patent rights to the extent required under subsection (c) to take effect, if at all, as provided under subsection (c)(3).

(3) Such additional information as the Secretary may require by regulation in order to determine eligibility for designation under subsection (a).

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

(1) PATENT WAIVER.—

(A) IN GENERAL.—Subject to subparagraph (B), the request under this subsection shall include a waiver of the right to enforce or otherwise assert any patent described in subsection (b)(1) (or any patent issued on the basis of an application described in subsection (b)(1)), which may expire after the end of the protection period for the dormant therapy, against any applicable product described in paragraph (2). The waiver shall be made by the owner of the patent or application for patent, as the case may be.

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

(i) shall have no effect during the protection period for the medicine to which the waiver relates; and

(ii) shall have no effect with respect to the subject matter of a claimed invention in a patent that does not provide any protection for such medicine with respect to an applicable product described in paragraph (2).

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

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

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

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

(B) the approval or licensure of the product occurs after the expiration of the protection period applicable to the medicine to which the request under subsection (a)(1) relates.

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

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

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

(2) EFFECTS OF WITHDRAWAL OF REQUEST OR REVOCATION OF DESIGNATION.—If the sponsor of a medicine withdraws a request under subsection (b) or the Secretary denies a designation request or revokes a designation with respect to the medicine—

(A) any patent waiver submitted under this section with respect to the medicine, but not yet effective, is canceled and deemed a nullity;

(B) any patent waiver that has taken effect under this section with respect to the medicine shall remain in effect;

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

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

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

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

(e) GUARANTEED PROTECTIONS FOR DORMANT THERAPIES.—

(1) APPLICATIONS FILED DURING THE PROTECTION PERIOD.—During the protection period for a dormant therapy, notwithstanding any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.)—

(A) absent a right of reference from the holder of such approved application for the dormant therapy, the Secretary shall not approve an application filed pursuant to section

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

(B) the Secretary shall not approve—

(i) an application filed pursuant to such section 505(b)(2) or 505(j) that references or otherwise relies on the approval of a medicine that is not the dormant therapy, was approved subsequent to the approval of the dormant therapy, and contains the same active moiety as the active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are the same); or

(ii) an application filed pursuant to such section 351(k) that references or otherwise relies on the licensure of a medicine that is not the dormant therapy, was licensed subsequent to the licensure of the dormant therapy, and contains an active moiety that is highly similar to the active

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

(C) the Secretary shall not approve an application filed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a drug that contains the same active moiety as the active moiety in the qualifying medicine (or if the qualifying medicine contains more than one active moiety, all of the active moieties are the same), or an application filed pursuant to section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a biological product that contains an active moiety that is highly similar to the active moiety in the qualifying medicine (or if the qualifying medicine contains more than one active moiety, all of the active moieties are highly similar), unless the information provided to support approval of such application is comparable in scope and extent, including with respect to design and extent of preclinical and clinical testing, to the information provided to support approval of the application for the

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

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

(A) IN GENERAL.—Notwithstanding any provision of title 35, United States Code, a sponsor of a medicine designated as a dormant therapy under subsection (a)(1), upon the approval or licensure thereof under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262), and in lieu of filing a patent term extension application under section 156(d) of such title 35, shall be entitled to patent term extensions in accordance with this paragraph.

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

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

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

(I) the listing of patents and applications for patents provided to the Secretary under subsection (b)(1);

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

(III) any documentation the Director may require from the patentee or patent applicant (as the case may be) of the waiver of patent rights required under subsection (b)(2).

(ii) FAILURE TO PROVIDE SUFFICIENT DOCUMENTATION OF WAIVER.—If the Director determines that the sponsor has not complied with the waiver requirements under subsection (c), after providing the sponsor the opportunity to remedy any insufficiency, the Director shall so notify the Secretary that the patent waiver requirements for designation have not been satisfied.

(C) EXTENSION OF PATENTS.—

(i) IN GENERAL.—Unless the Director has notified the Secretary of a determination under subparagraph (B)(ii), for each patent identified in a submission pursuant to subparagraph (B)(i), and for each patent issuing based upon an application for patent so identified, the Director shall, within the 3-month period beginning on the date of the submission, extend the patent to expire at the end of the protection period for the dormant therapy, if the patent would otherwise expire before the end of the protection period. If the Director has so notified the Secretary under subparagraph (B)(ii), the Director shall extend one such patent, selected by the sponsor, for the period that would have been applicable had an application for extension been filed under section 156 of title 35, United States Code, with respect to such patent.

(ii) APPLICATION OF CERTAIN PROVISIONS.—During the period of an extension under clause (i)—

(I) the rights under the patent shall be limited in the manner provided under section 156(b) of title 35, United States Code; and

(II) the terms ''product'' and ''approved product'' in such section 156(b) shall be deemed to include forms of the active moiety of the dormant therapy and highly similar active moieties that might be approved or licensed by the Secretary based upon an application filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that references or otherwise relies upon the dormant therapy.

(D) INTERIM PATENT EXTENSIONS.—Notwithstanding any provision of title 35, United States Code, with respect to any patent listed (or patent issuing on an application listed) under subsection (b)(1) that would otherwise expire before the sponsor could make a submis-

sion under subparagraph (B), the Director, upon application of the patentee, shall grant to the patentee an interim extension of such patent, subject to the limitations in section 156(d)(5)(F) of such title 35, for such period as may be necessary to permit the sponsor to submit the listing under subparagraph (B) and, if the patent is therein listed, to extend the patent as provided under subparagraph (C). The Director may require, for any patent extended under this subparagraph, that the sponsor of the dormant therapy to which the patent relates provide periodic certifications that development of the dormant therapy is continuing. The Director may terminate any interim extension for which a required certification has not been made.

(E) NOTICE OF EXTENSION.—For each patent that is extended under this paragraph, the Director shall publish a notice of such extension and issue a certificate of extension described in section 156(e)(1) of title 35, United States Code.

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

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

(f) CERTAIN FDA PROTECTIONS INAPPLICABLE.—If a medicine has been designated as a dormant therapy under subsection (a), the protections otherwise applicable with respect to such medicine under sections 505A, 505E, and 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355f, 360cc) shall not apply. The preceding sentence shall not be construed to affect any protections applicable with respect to a medicine, including a medicine designated under section 526 of such Act (21 U.S.C. 360bb) for a rare disease or condition, under provisions other than such sections 505A, 505E, and 527.

(g) DEVELOPMENT CERTIFICATIONS.—

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

such clinical plan (including modifications to the initial plan approved by the Food and Drug Administration). Prior to receiving such certifications, the Secretary shall require periodic certifications that the clinical plan under subsection (a)(2)(B) is continuing.

(2) DETERMINATION OF NONCOMPLIANCE.—If the Secretary concludes that the sponsor has not complied with paragraph (1), after providing the sponsor the opportunity to remedy any insufficiency, the Secretary shall, for purposes of subsection (d)(1), determine that the sponsor is not in compliance with the certification requirement under paragraph (1).

(h) COLLABORATION.—Nothing in this section shall be construed as preventing a sponsor from collaborating with other entities in developing a dormant therapy or applying for a dormant therapy designation.

SEC. 1223. IMPLEMENTATION AND EFFECT.

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

(b) IMPLEMENTING REGULATIONS.—The Secretary, in consultation with the Secretary of Commerce, shall promulgate such regulations and finalize such guidance as

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

(c) LIMITATION ON DETERMINATIONS AND DESIGNATIONS.—Notwithstanding any provision of section 1222, the Secretary may not make a determination on a request for designation by a manufacturer or sponsor under section 1222(a) prior to the effective date of the regulations under subsection (b) or 30 months after the date of enactment of this Act, whichever occurs first, and the Secretary may not designate a medicine under section 1222(a) unless the requirement under section 1222(a)(2)(D) is met for such medicine as of the effective date of the regulations under subsection (b) or 30 months after the date of enactment of this Act, whichever occurs first.

Subtitle M—New Therapeutic Entities

SEC. 1241. EXTENDED EXCLUSIVITY PERIOD FOR CERTAIN NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.

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

''(vi) With respect to an application described in clause (iii) or a supplement to an application described in clause (iv), the three-year period specified in such clause shall be extended for an additional period of not more than two years if the person submitting such application or supplement provides documentation to the Secretary demonstrating that—

''(I) the new clinical investigations essential to the approval of the application or supplement and conducted or sponsored by the person submitting the application or supplement support the approval of a new indication or use for the drug that is the subject of the application or supplement; or

''(II) the drug that is the subject of the application or supplement has been reformulated or redesigned so that the drug can reasonably (as determined by the Secretary in consultation with the person submitting such application or supplement) be expected—

''(aa) to promote greater patient adherence to an approved treatment regime relative to the previously approved formulation or design of the drug;

''(bb) to reduce the public-health risks associated with the drug relative to the previously approved formulation or design of the drug;

''(cc) to reduce the manner or extent of side effects or adverse events associated with the previously approved formulation or design of the drug;

''(dd) to provide systemic benefits to the health care system relative to the previously approved formulation or design of the drug; or

''(ee) to provide other patient benefits that are comparable to the benefits described in items (aa) through (dd).''.

(b) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(F)) is amended by adding at the end the following new clause:

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

cation or supplement provides documentation to the Secretary demonstrating that—

"(I) the new clinical investigations essential to the approval of the application or supplement and conducted or sponsored by the person submitting the application or supplement support the approval of a new indication or use for the drug that is the subject of the application or supplement; or

"(II) the drug that is the subject of the application or supplement has been reformulated or redesigned so that the drug may reasonably (as determined by the Secretary in consultation with the person submitting such application or supplement) be expected—

"(aa) to promote greater patient adherence to an approved treatment regime relative to the previously approved formulation or design of the drug;

"(bb) to reduce the public-health risks associated with the drug relative to the previously approved formulation or design of the drug;

"(cc) to reduce the manner or extent of side effects or adverse events associated with the previously approved formulation or design of the drug;

"(dd) to provide systemic benefits to the health care system relative to the previously approved formulation or design of the drug; or

"(ee) to provide other patient benefits that are comparable to the benefits described in items (aa) through (dd).".

(c) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations to carry out the amendments made by this section, including regulations establishing a process under which the Secretary consults with persons submitting applications or supplements for approval of a drug under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) on how such drug may reasonably be expected to provide the benefits described in items (aa) through (ee) of (as applicable)—

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

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

Subtitle N—Orphan Product Extensions Now

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

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

"SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

''(a) DESIGNATION.—

''(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

''(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed for marketing under section 505(c) of this Act or section 351(a) of the Public Health Service Act, but was not so approved or licensed for the new indication;

''(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and

''(ii) the Secretary approves the application or supplemental application; and

''(C) the application or supplemental application for the new indication contains the consent of the applicant to notice being given by the Secretary under paragraph (4) respecting the designation of the drug.

''(2) REVOCATION OF DESIGNATION.—

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

''(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

''(3) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1)

shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.

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

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

''(1)(A) the 4-, 5-, and seven and one-half year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, and the 7-year period described in section 527, as applicable, shall be extended by 6 months; or

''(B) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act and the 7-year period described in section 527, as applicable, shall be extended by 6 months; and

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

''(A) the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

''(B) the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6

months after the date the patent expires (including any patent extensions).

''(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

''(d) LIMITATIONS.—The extension described in subsection (b) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b).

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

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

"(C) publish the final regulation not less than 30 days before the effective date of the regulation.

"(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking to submit an application or supplemental application described in subsection (a) prior to the promulgation of such regulations.

"(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs under subsection (a) prior to the promulgation of regulations under this subsection, if such drugs meet the criteria described in subsection (a).

"(f) DEFINITION.—In this section, the term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).".

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

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

(c) CONFORMING AMENDMENTS.—

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

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

"(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (b)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in subsection (b)(1) shall be in addition to any extensions under section 505G."; and

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

"(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (c)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in sub-

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

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

(A) by amending the subsection heading to read as follows: ''RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION''; and

(B) by striking ''any extension of the period under section 505A'' and inserting ''any extension of the periods under sections 505A and 505G, as applicable,''.

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

''(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the ex-

clusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.''.

TITLE II—BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE, INCLUDING HELPING YOUNG SCIENTISTS

Subtitle A—21st Century Cures Consortium Act

SEC. 2001. INNOVATIVE CURES CONSORTIUM.

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

''PART E—INNOVATIVE CURES CONSORTIUM

''SEC. 281. ESTABLISHMENT.

''A nonprofit corporation to be known as the 21st Century Cures Consortium (referred to in this part as the 'Consortium') shall be established in accordance with this section. The Consortium shall be a public-private partnership headed by an Executive Director (referred to in this part as the 'Executive Director'), appointed by the members of the Board of Directors. The Consortium shall not be an agency or instrumentality of the United States Government.

"SEC. 281A. PURPOSE.

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

"SEC. 281B. DUTIES.

"For the purpose described in section 281A, the Consortium shall—

"(1) foster collaboration among the Consortium, academia, government agencies, industry, health care payors and providers, patient advocates, and others engaged in the cycle of discovery, development, and delivery of life-saving and health-enhancing innovative interventions;

"(2) undertake communication and dissemination activities;

"(3) publish information on the activities funded under section 281D;

"(4) establish a strategic agenda for accelerating the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients;

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

''(6) facilitate the interoperability of the components of the discovery, development, and delivery cycle.

"SEC. 281C. ORGANIZATION; ADMINISTRATION.

''(a) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Consortium shall have a Board of Directors (in this part referred to as the 'Board of Directors'), which shall be composed of the ex officio members under subparagraph (B) and the appointed members under subparagraph (C). All members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Director of the National Institutes of Health.

''(ii) The Commissioner of Food and Drugs.

''(iii) The Administrator of the Centers for Medicare & Medicaid Services.

''(C) APPOINTED MEMBERS.—The appointed members of the Board shall consist of 22 individuals, of whom—

''(i) 5 shall be representatives of Federal agencies, to be appointed by the ex officio members of the Board under subparagraph (B);

''(ii) 8 shall be representatives of the biopharmaceutical and medical device industries, to be appointed by the Comptroller General of the United States from a list of nominations submitted by leading trade associations; and

''(iii) 9 shall be representatives of academic researchers, patients, health care providers, and health care plans and insurers, to be appointed by the Comptroller General of the United States, after soliciting nominations.

''(D) CHAIR.—The Chair of the Board shall be selected by the members of the Board by majority vote from among the members of the Board.

''(2) TERMS AND VACANCIES.—

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

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(3) RESPONSIBILITIES.—The Board of Directors shall establish bylaws and policies for the Consortium that—

''(A) are published in the Federal Register and available for public comment;

''(B) establish policies for the selection and, as applicable, appointment of—

''(i) the officers, employees, agents, and contractors of the Consortium; and

"(ii) the members of any committees of the Consortium;

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

"(D) establish specific duties of the Executive Director.

"(4) AGENDA.—The Board of Directors shall—

"(A) not later than 3 months after the incorporation of the Consortium, issue an agenda (in this part referred to as the 'agenda') outlining how the Consortium will achieve the purpose described in section 281A; and

"(B) annually thereafter, in consultation with the Executive Director, review and update such agenda.

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

"(c) NONPROFIT STATUS.—In carrying out this part, the Board of Directors shall establish such policies and bylaws, and the Executive Director shall carry out such activities, as may be necessary to ensure that the Consortium maintains status as an organization that—

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

''(2) is, under subsection (a) of such section, exempt from taxation.

''(d) EXECUTIVE DIRECTOR.—The Executive Director shall—

''(1) be the chief executive officer of the Consortium; and

''(2) subject to the oversight of the Board of Directors, be responsible for the day-to-day management of the Consortium.

''SEC. 281D. GRANTS, CONTRACTS, AND OTHER ASSISTANCE.

''(a) IN GENERAL.—The Consortium shall, on a competitive basis, award grants, contracts, and provide other assistance to eligible entities for activities to accelerate the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients. Any financial assistance provided by the Consortium under this part for such activities shall be provided in accordance with this section.

''(b) PRIVATE SECTOR MATCHING FUNDS.—As a condition of participation in a program or initiative sponsored by the Consortium or receipt of a grant, contract, or other assistance from the Consortium, the entity so par-

ticipating or receiving such grant, contract, or other assistance shall provide funds, in-kind contributions, or a combination of both that—

''(1) are derived from sources other than the Federal Government; and

''(2) are in an amount that is, as determined by the Board, proportional to the assistance that is derived from payments by the Secretary under section 281F.

''(c) ELIGIBLE ENTITIES.—An entity is eligible to receive a grant or other assistance under subsection (a) only if the entity is—

''(1) a small business; or

''(2) a nonprofit organization.

''(d) AGREEMENT OR CONTRACT.—A grant agreement or other contract providing for assistance under this section shall—

''(1) set up appropriate arrangements for implementation of the activities;

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

''(3) govern the relationship between the Consortium, the recipients of the grant or contract, and any one or more other entities that is working in col-

laboration with such recipients to carry out the activities; and

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

''SEC. 281E. TERMINATION; REPORT.

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

''(b) REPORT.—Not later than one year after the date on which the Consortium is established and each year thereafter, the Executive Director shall submit to the appropriate congressional committees a report on the performance of the Consortium. In preparing such report, the Consortium shall consult with a nongovernmental consultant with appropriate expertise.

''SEC. 281F. FUNDING.

''For the period of fiscal years 2016 through 2021, the Secretary shall make a payment to the Consortium for purposes of carrying out the duties of the Consortium under this part in an amount of not less than [$_____].''.

Subtitle B—Medical Product Innovation Advisory Commission

SEC. 2021. MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION.

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

"SEC. 229A. MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION.

''(a) ESTABLISHMENT.—There is hereby established as an agency of Congress the Medical Product Innovation Advisory Commission (in this section referred to as the 'Commission'). The purpose of the Commission shall be to analyze medical product innovation in the United States and recommend policies to accelerate the discovery, development, and delivery of new medical products.

''(b) DUTIES.—

''(1) REVIEW OF MEDICAL PRODUCT INNOVATION POLICIES AND ANNUAL REPORTS.—The Commission shall—

''(A) review medical product innovation policies, including the topics described in paragraph (2);

''(B) make recommendations to Congress concerning such policies;

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

"(D) by not later than June 15 of each year, submit a report to Congress containing an examination of issues affecting medical product innovation and the recommendations of the Commission with respect to medical product innovation policies reviewed under subparagraph (A).

"(2) SPECIFIC TOPICS TO BE REVIEWED.—

"(A) DISCOVERY, DEVELOPMENT, AND DELIVERY.—Specifically, the Commission shall review Federal policies (including policies of the National Institutes of Health, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services) relating to the discovery, development, and delivery of new medical products.

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

medical products and how such interactions influence medical product innovation.

''(C) THE CYCLE OF DISCOVERY, DEVELOPMENT, AND DELIVERY OF MEDICAL PRODUCTS AND INNOVATION.—Specifically, the Commission shall assess—

''(i) the cycle of discovery, development, and delivery of new medical products in the United States, and the policies affecting such cycle; and

''(ii) what steps may be taken to accelerate the cycle and facilitate the transition between the phases of the cycle.

''(3) AGENDA AND ADDITIONAL REVIEWS.—The Commission shall consult periodically with the chairmen and ranking minority members of the appropriate committees of Congress regarding the Commission's agenda and progress toward achieving the agenda. The Commission may conduct additional reviews, and submit additional reports to the appropriate committees of Congress, from time to time on such topics relating to medical product innovation as may be requested by such chairmen and ranking members and as the Commission determines appropriate.

"(4) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

"(5) VOTING AND REPORTING REQUIREMENTS.—With respect to each recommendation contained in a report submitted under paragraph (1), each member of the Commission shall vote on the recommendation, and the Commission shall include, by member, the results of that vote in the report containing the recommendation.

"(c) MEMBERSHIP.—

"(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 17 members appointed by the Comptroller General of the United States.

"(2) QUALIFICATIONS.—

"(A) IN GENERAL.—The membership of the Commission shall include academic researchers, physicians and other health professionals, experts in the research and development of medical products for prevention, detection, prediction, elimination, or modulation of disease, experts in the areas of biostatistics, clinical pharmacology, pharmacoeconomics, or

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

"(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).

"(3) TERMS.—

"(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.

"(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

Commission shall be filled in the manner in which the original appointment was made.

''(4) COMPENSATION.—While serving on the business of the Commission (including traveltime), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code. While so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of the Commission. Physicians serving as personnel of the Commission may be provided a physician comparability allowance by the Commission in the same manner as Government physicians may be provided such an allowance by an agency under section 5948 of title 5, United States Code, and for such purpose subsection (i) of such section shall apply to the Commission in the same manner as it applies to the Tennessee Valley Authority. For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate.

''(5) CHAIRMAN; VICE CHAIRMAN.—The Comptroller General shall designate two members of the Commission, at the time of appointment of the members, as Chairman and Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Comptroller General may designate another member for the remainder of that member's term.

''(6) MEETINGS.—The Commission shall meet at the call of the Chairman.

''(d) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—Subject to such review as the Comptroller General determines necessary to ensure the efficient administration of the Commission, the Commission may—

''(1) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General) and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

''(2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

''(3) enter into contracts or make other arrangements, as may be necessary for the conduct of

the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

''(4) make advance, progress, and other payments which relate to the work of the Commission;

''(5) provide transportation and subsistence for persons serving without compensation; and

''(6) prescribe such rules and regulations as it determines necessary with respect to the internal organization and operation of the Commission.

''(e) POWERS.—

''(1) OBTAINING OFFICIAL DATA.—The Commission may secure directly from any department or agency of the United States any information necessary to enable it to carry out this section. Upon request of the Chairman, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.

''(2) DATA COLLECTION.—In order to carry out its functions, the Commission shall—

''(A) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section;

''(B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate; and

''(C) adopt procedures allowing any interested party to submit information for the Commission's use in making reports and recommendations.

''(3) ACCESS OF GAO TO INFORMATION.—The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data of the Commission, immediately upon request.

''(4) PERIODIC AUDIT.—The Commission shall be subject to periodic audit by the Comptroller General.

''(f) AUTHORIZATION OF APPROPRIATIONS.—

''(1) REQUEST FOR APPROPRIATIONS.—The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

''(2) AUTHORIZATION.—There are authorized to be appropriated [_____] to carry out this section.''.

Subtitle C—Regenerative Medicine

SEC. 2041. ISSUANCE OF GUIDANCE ON SURROGATE AND INTERMEDIATE ENDPOINTS FOR ACCELERATED APPROVAL OF REGENERATIVE MEDICINE PRODUCTS.

(a) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (in this section referred to as the ''Secretary'') shall issue guidance on the use of surrogate and intermediate endpoints for accelerated approval of regenerative medicine products under section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)).

(b) PROCESS.—In issuing guidance under subsection (a), the Secretary—

(1) not later than 1 year after date of enactment of this Act, shall consult with stakeholders;

(2) may, for purposes of such consultation, conduct public hearings;

(3) not later than 2 years after the date of enactment of this Act, shall issue proposed guidance under subsection (a); and

(4) not later than 1 year after the issuance of such proposed guidance, and after an opportunity for public comment, shall issue final guidance under subsection (a).

Subtitle D—Genetically Targeted Platform Technologies for Rare Diseases

SEC. 2051. GENETICALLY TARGETED PLATFORM TECHNOLOGIES FOR RARE DISEASES.

Paragraph (1) of section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended to read as follows:

''(1) IN GENERAL.—

''(A) ACCELERATED APPROVAL.—

''(i) IN GENERAL.—The Secretary may approve an application for approval of a product (in this section referred to as 'accelerated approval') for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) of this Act or section 351(a) of the Public Health Service Act upon a determination that, taking into account the severity, rarity, or prevalence of the condition and the

availability or lack of alternative treatments—

"(I) the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit; or

"(II) the extrapolation of evidence is reasonably likely to predict clinical benefit of the product.

"(ii) BASIS FOR CERTAIN DETERMINATION.—A determination under clause (i) shall be based on the totality of the evidence.

"(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit, or that a product is reasonably likely to have a clinical benefit under subparagraph (A) may include—

"(i) epidemiological, pathophysiological, therapeutic, pharmaco-

logic, or other evidence, such as evidence from the use of biomarkers; or

"(ii) evidence derived from extrapolation from adequate and well-controlled trials that have formed the basis for investigation on other products—

"(I) that utilize the same or a very similar underlying genetically-targeted therapeutic platform technology as the product involved;

"(II) for which disease genomics are known; and

"(III) that possess the same or very similar drug-like characteristics as the product involved, including with respect to safety, distribution, and metabolism; or

"(iii) other scientific methods or tools.

"(C) DEFINITIONS.—In this subsection:

"(i) The term 'extrapolation' includes extending a sponsor's information and conclusions available from studies in one or more subgroups of the patient population, with respect to related conditions or related medicinal products, to make infer-

ences for another subgroup of the population, condition, or medicinal product, thus reducing the need to generate additional information to reach conclusions for the target subgroup, condition, or medicinal product.

"(ii) The term 'genetically-targeted therapeutic platform technology' means a therapy based on a nucleic acid or an analogous compound with a common or highly-similar chemistry that—

"(I) may be applied across multiple products; and

"(II) can result in the modulation (including suppression, upregulation, or activation) of the function of a gene or its associated gene product, causing an altered disease state.".

Subtitle E—Sensible Oversight for Technology Which Advances Regulatory Efficiency

SEC. 2061. MEDICAL AND HEALTH SOFTWARE DEFINED.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss)(1) The term 'software' means a coded or operational product that contains programs, procedures, and rules that act upon data to process, store, transmit, analyze, present, or operationalize information.

''(2) The term 'medical software' means software that—

''(A) is not a component;

''(B) is not intended to provide a diagnosis; and

''(C) is intended to analyze patient-specific information and other information to recommend to health care professionals a single treatment or course of action—

''(i) without the need for such professionals to perform additional interpretation of, or to independently confirm the means for, such recommendation; and

''(ii) for the purpose of informing or influencing health care decisions in the prevention,

diagnosis, prognosis, treatment, cure, or disease management related to any disease or condition in humans.

''(3) The term 'health software' means software that is not medical software, is not a component, is intended to be used for or in support of a health care purpose, and **[***How do we ensure that products that have features that should be regulated as medical software or medical devices or components thereof are not exempted from regulation as such products?***]**—

''(A) is intended for use for administrative or operational support or the processing and maintenance of financial records;

''(B) is intended for use for clinical, laboratory, or administrative workflow and related record-keeping, including electronic health records;

''(C) is intended for use for aggregation, conversion, storage, management, retrieval, or transmission of data from a device or other thing;

''(D) is intended for use as a platform for a secondary software—

''(i) to run or act as a mechanism for connectivity; or

''(ii) to store data;

''(E) is intended for use to organize and present medical information for consumer health and wellness education or for use for maintaining health or wellness;

''(F) is intended for use by patients for self-management or self-monitoring of a disease or condition, including management of medications;

''(G) is intended for use to collect patient reported outcomes data for use by a health care practitioner;

''(H) is intended for use to analyze patient-specific information or other information for purposes of presenting patient-specific recommended treatments or courses of action to inform health care professionals' decisions with respect to the prevention, diagnosis, prognosis, treatment, cure, or management of a particular disease or condition, with the opportunity for additional interpretation or an independent confirmation of the means for such treatments or courses of action; or

''(I) is intended for use to analyze patient-specific information or other medical information for the purpose of providing general information related to the prevention, diagnosis, prognosis, treatment,

cure, monitoring, or management of a disease or condition.

''(4) The term 'accessory' means a product that—

''(A) is intended by its manufacturer to be used together with a particular device or software product to extend that device's or software product's intended use or functionality;

''(B) is not a component and could, based on the intended use of the product, be considered medical software, health software, or a device; and

''(C) is a product in its own right and should be classified based on its own intended use, functionality, and risk, and not the product in conjunction with which it is used.

''(5) The term 'component' means a product that is an integral part of a device necessary to support the intended use of the device.''.

SEC. 2062. APPLICABILITY AND INAPPLICABILITY OF REGULATION.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524B. MEDICAL AND HEALTH SOFTWARE.

''(a) REGULATION OF MEDICAL SOFTWARE.—

''(1) IN GENERAL.—Not later than 24 months after the date of enactment of this section, the Secretary shall promulgate final regulations to establish standards, policies, and procedures for—

''(A) classifying medical software;

''(B) standards for the development of medical software;

''(C) standards for the validation and verification of medical software;

''(D) review of medical software;

''(E) modifications to medical software;

''(F) manufacturing of medical software;

''(G) quality systems for medical software;

''(H) labeling requirements for medical software; and

''(I) postmarketing requirements for reporting networks and the reporting of adverse events.

''(2) RELATION TO OTHER PROVISIONS.—

''(A) IN GENERAL.—The provisions of this Act shall continue to apply to medical software subject to the regulations under paragraph (1), except that—

''(i) medical software that is classified and reviewed under the regulations under

paragraph (1) shall not be required to be classified and cleared or approved under sections 513, 510(k), and 515; and

"(ii) medical software shall not be subject to provisions under this Act to the extent such provisions are superseded by the regulations under paragraph (1).

"(B) ADULTERATION, MISBRANDING.—Medical software shall be treated as—

"(i) adulterated under section 501 if such software is manufactured, distributed, sold, or offered for sale in violation of the regulations under paragraph (1); and

"(ii) misbranded under section 502 if the labeling of such software is in violation of the regulations under paragraph (1).

"(C) PREVIOUS SUBMISSIONS.—If, before the effective date of the regulations under paragraph (1), the sponsor of medical software initiates the process for classification and clearance or approval of the medical software as a device under sections 513 and 510(k) or 515, as applicable—

"(i) the sponsor of the medical software may choose to proceed with such

process rather than seeking classification and review of the medical software under the regulations under paragraph (1); and

"(ii) the sponsor of the medical software may rely on classification and clearance or approval pursuant to sections 513, 510(k), and 515, if granted, and may not be required by the Secretary to seek review of the medical software under the regulations under paragraph (1) in lieu of such reliance.

"(3) PROCESS FOR PROMULGATING REGULATIONS.—

"(A) CONVENING WORKSHOPS.—Not later than 6 months after the date of enactment of this section, and once every 6 months during the following 12-month period, the Secretary shall convene a workshop to obtain input regarding the regulation to be promulgated under paragraph (1).

"(B) PARTICIPANTS AT WORKSHOPS.—The Secretary shall invite representatives of the following categories to participate in each workshop under this paragraph:

"(i) Patients.

"(ii) The Food and Drug Administration.

"(iii) Individuals and organizations with significant expertise in standards for software development.

"(iv) Individuals and organizations with significant expertise in the development of health care software products.

"(C) PROPOSED REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, in consultation with stakeholders (including patients, industry, health care providers, academia, and government) issue proposed regulations under paragraph (1).

"(4) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating medical software to the center at the Food and Drug Administration charged with regulating devices.

"(b) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Health software shall not be subject to regulation under this Act.".

SEC. 2063. EXCLUSION FROM DEFINITION OF DEVICE.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in subparagraph (2), by striking ''or'' after ''or other animals,'';

(2) in subparagraph (3), by striking ''and'' and inserting ''or''; and

(3) by inserting after subparagraph (3) the following:

''(4) is not health software, and''.

Subtitle F—Building a 21st Century Data Sharing Framework

PART 1—IMPROVING CLINICAL TRIAL DATA OPPORTUNITIES FOR PATIENTS

SEC. 2081. STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS.

(a) STANDARDIZATION.—

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

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

(B) by inserting after paragraph (6) the following:

''(7) STANDARDIZATION.—The Director of NIH shall ensure that—

''(A) the registry and results data bank is easily used by the public;

''(B) entries in the registry and results data bank are easily compared; and

''(C) information required to be submitted to the registry and results data bank, including recruitment information under paragraph (2)(A)(ii)(II), is submitted by persons and posted by the Director of NIH in a standardized format employing comprehensive health care terminology that includes clinical trial inclusion and exclusion criteria, including—

''(i) such criteria for the primary disease or condition being studied; and

''(ii) eligibility criteria that allow—

''(I) electronic matching to diagnoses or procedure coding systems such as the International Classification of Diseases or the Current Procedural Terminology; and

''(II) integration into electronic health records.''.

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

(b) CONSULTATION.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health

and Human Services shall convene a meeting of stakeholders (including patients, researchers, physicians, industry representatives, health information technology providers, and the Food and Drug Administration) to provide advice to the Secretary on enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (including enhancements to usability, functionality, and search capability) that are necessary to implement paragraph (7) of section 402(j) of such Act, as added by subsection (a).

(c) APPLICABILITY.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall begin implementation of paragraph (7) of section 402(j) of the Public Health Service Act, as added by subsection (a).

SEC. 2082. CLINICAL TRIAL DATA SYSTEM.

(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs and the Director of the National Institutes of Health, shall enter into a collaborative agreement, to be known as the Clinical Trial Data System Agreement, with one or more eligible entities to implement a system to make de-identified clinical trial data from qualified clinical trials available for purposes of conducting further research.

(b) APPLICATION.—Eligible entities seeking to enter into a cooperative agreement with the Secretary under this section shall submit to the Secretary an application in such time and manner, and containing such information, as the Secretary may require. Any such application shall include the following:

(1) A certification that each applicant is not currently and does not plan to be involved in sponsoring, operating, or participating in a clinical trial nor collaborating with another entity for the purposes of sponsoring, operating, or participating in a clinical trial.

(2) A description of how each applicant will compile clinical trial data in standardized formats using terminologies and standards that have been developed by recognized standards developing organizations with input from diverse stakeholder groups, and a description of the methodologies to be used to de-identify clinical trial data consistent with the requirements of section 164.514 of title 45, Code of Federal Regulations (or successor regulations).

(3) Documentation establishing that each applicant has a plan in place to allow registered users to access and use de-identified clinical trial data, gathered from qualified clinical trials, available under

carefully controlled contractual terms as defined by the Secretary.

(4) Evidence demonstrating the ability to ensure dissemination of the results of the research to interested parties to serve as a guide to future medical product development or scientific research.

(5) The plan of each applicant for securing funding for the partnership described in paragraph (2) from governmental sources and private foundations, entities, and individuals.

(6) Evidence demonstrating a proven track record of—

(A) being a neutral third party in working with medical product manufacturers, academic institutions, and the Food and Drug Administration; and

(B) having the ability to protect confidential data.

(c) DEFINITIONS.—In this section:

(1) The term ''eligible entity'' means an entity that has experienced personnel with clinical and other technical expertise in the biomedical sciences and biomedical ethics and that is—

(A) an institution of higher education (as such term is defined in section 1001 of the

Higher Education Act of 1965 (20 U.S.C. 1001)) or a consortium of such institutions; or

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

(2) The term ''medical product'' means a drug (as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), a device (as defined in subsection (h) of such section), a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), or any combination thereof.

(3) The term ''qualified clinical trial'' means a clinical trial sponsored solely by an agency of the Department of Health and Human Services with respect to a medical product—

(A) that was—

(i) approved or cleared under section 505, 510(k), or 515, or has an exemption for investigational use in effect under section 505 or 520(m), of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 301 et seq.); or

(ii) licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or has an exemption for investigational use in effect under such section 351; or

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

(i) no additional work to support approval, licensure, or clearance of such medical product is being or is planned to be undertaken by the sponsor of the original development program, its successors, assigns, or collaborators; and

(ii) the sponsor of the original investigational development program has provided its consent to the Secretary for inclusion of data regarding such product in the system established under this section.

PART 2—IMPROVING CLINICAL OUTCOMES FOR PATIENTS AND PROGRAM INTEGRITY THROUGH CMS DATA

SEC. 2085. EXPANDING AVAILABILITY OF MEDICARE DATA.

(a) EXPANDING USES OF MEDICARE DATA BY QUALIFIED ENTITIES.—

(1) ADDITIONAL ANALYSES.—

(A) IN GENERAL.—Subject to subparagraph (B), to the extent consistent with applicable information, privacy, security, and disclosure laws (including paragraph (3)), notwithstanding paragraph (4)(B) of section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)) and the second sentence of paragraph (4)(D) of such section, beginning July 1, 2015, a qualified entity may use the combined data described in paragraph (4)(B)(iii) of such section received by such entity under such section, and information derived from the evaluation described in such paragraph (4)(D), to conduct additional nonpublic analyses (as determined appropriate by the Secretary) and provide or sell such analyses to authorized users for nonpublic use (including for the purposes of assisting providers of services and suppliers to develop and participate in quality and patient care improvement activities, including developing new models of care).

(B) LIMITATIONS WITH RESPECT TO ANALYSES.—

(i) EMPLOYERS.—Any analyses provided or sold under subparagraph (A) to

an employer described in paragraph (9)(A)(iii) may only be used by such employer for purposes of providing health insurance to employees and retirees of the employer.

(ii) HEALTH INSURANCE ISSUERS.—A qualified entity may not provide or sell an analysis to a health insurance issuer described in paragraph (9)(A)(iv) unless the issuer is providing the qualified entity with data under section 1874(e)(4)(B)(iii) of the Social Security Act (42 U.S.C. 1395kk(e)(4)(B)(iii)).

(2) ACCESS TO CERTAIN DATA.—

(A) ACCESS.—To the extent consistent with applicable information, privacy, security, and disclosure laws (including paragraph (3)), notwithstanding paragraph (4)(B) of section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)) and the second sentence of paragraph (4)(D) of such section, beginning July 1, 2015, a qualified entity may—

(i) provide or sell the combined data described in paragraph (4)(B)(iii) of such section to authorized users described in

clauses (i), (ii), and (v) of paragraph (9)(A) for nonpublic use, including for the purposes described in subparagraph (B); or

(ii) subject to subparagraph (C), provide Medicare claims data to authorized users described in clauses (i), (ii), and (v), of paragraph (9)(A) for nonpublic use, including for the purposes described in subparagraph (B).

(B) PURPOSES DESCRIBED.—The purposes described in this subparagraph are assisting providers of services and suppliers in developing and participating in quality and patient care improvement activities, including developing new models of care.

(C) MEDICARE CLAIMS DATA MUST BE PROVIDED AT NO COST.—A qualified entity may not charge a fee for providing the data under subparagraph (A)(ii).

(3) PROTECTION OF INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), an analysis that is or data that are provided or sold under paragraph (1)

or (2) shall not contain information that individually identifies a patient.

(B) INFORMATION ON PATIENTS OF THE PROVIDER OF SERVICES OR SUPPLIER.—To the extent consistent with applicable information, privacy, security, and disclosure laws, an analysis that is or data that are provided or sold to a provider of services or supplier under paragraph (1) or (2) may contain information that individually identifies a patient of such provider or supplier, including with respect to items and services furnished to the patient by other providers of services or suppliers.

(C) PROHIBITION ON USING ANALYSES OR DATA FOR MARKETING PURPOSES.—An authorized user shall not use any analysis or data provided or sold under paragraph (1) or (2) for marketing purposes.

(4) DATA USE AGREEMENT.—A qualified entity and an authorized user described in clauses (i), (ii), and (v) of paragraph (9)(A) shall enter into an agreement regarding the use of any data that the qualified entity is providing or selling to the authorized user under paragraph (2). Such agreement shall describe the requirements for privacy and security of

the data and, as determined appropriate by the Secretary, any prohibitions on using such data to link to other individually identifiable sources of information. If the authorized user is not a covered entity under the rules promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, the agreement shall identify the relevant regulations, as determined by the Secretary, that the user shall comply with as if it were acting in the capacity of such a covered entity.

(5) NO REDISCLOSURE OF ANALYSES OR DATA.—

(A) IN GENERAL.—Except as provided in subparagraph (B), an authorized user that is provided or sold an analysis or data under paragraph (1) or (2) shall not redisclose or make public such analysis or data or any analysis using such data.

(B) PERMITTED REDISCLOSURE.—A provider of services or supplier that is provided or sold an analysis or data under paragraph (1) or (2) may, as determined by the Secretary, redisclose such analysis or data for the purposes of performance improvement and care coordination

activities but shall not make public such analysis or data or any analysis using such data.

(6) OPPORTUNITY FOR PROVIDERS OF SERVICES AND SUPPLIERS TO REVIEW.—Prior to a qualified entity providing or selling an analysis to an authorized user under paragraph (1), to the extent that such analysis would individually identify a provider of services or supplier who is not being provided or sold such analysis, such qualified entity shall provide such provider or supplier with the opportunity to appeal and correct errors in the manner described in section 1874(e)(4)(C)(ii) of the Social Security Act (42 U.S.C. 1395kk(e)(4)(C)(ii)).

(7) ASSESSMENT FOR A BREACH.—

(A) IN GENERAL.—In the case of a breach of a data use agreement under this section or section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)), the Secretary shall impose an assessment on the qualified entity both in the case of—

(i) an agreement between the Secretary and a qualified entity; and

(ii) an agreement between a qualified entity and an authorized user.

(B) ASSESSMENT.—The assessment under subparagraph (A) shall be an amount up to $100 for each individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under part B of such title—

(i) in the case of an agreement described in subparagraph (A)(i), for whom the Secretary provided data to the qualified entity under paragraph (2); and

(ii) in the case of an agreement described in subparagraph (A)(ii), for whom the qualified entity provided data to the authorized user under paragraph (2).

(C) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to this paragraph shall be deposited in the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

(8) ANNUAL REPORTS.—Any qualified entity that provides or sells an analysis or data under paragraph (1) or (2) shall annually submit to the Secretary a report that includes—

(A) a summary of the analyses provided or sold, including the number of such analyses, the number of purchasers of such analyses, and the total amount of fees received for such analyses;

(B) a description of the topics and purposes of such analyses;

(C) information on the entities who received the data under paragraph (2), the uses of the data, and the total amount of fees received for providing, selling, or sharing the data; and

(D) other information determined appropriate by the Secretary.

(9) DEFINITIONS.—In this subsection and subsection (b):

(A) AUTHORIZED USER.—The term ''authorized user'' means the following:

(i) A provider of services.

(ii) A supplier.

(iii) An employer (as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974).

(iv) A health insurance issuer (as defined in section 2791 of the Public Health Service Act).

(v) A medical society or hospital association.

(vi) Any entity not described in clauses (i) through (v) that is approved by the Secretary (other than an employer or health insurance issuer not described in clauses (iii) and (iv), respectively, as determined by the Secretary).

(B) PROVIDER OF SERVICES.—The term ''provider of services'' has the meaning given such term in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)).

(C) QUALIFIED ENTITY.—The term ''qualified entity'' has the meaning given such term in section 1874(e)(2) of the Social Security Act (42 U.S.C. 1395kk(e)).

(D) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(E) SUPPLIER.—The term ''supplier'' has the meaning given such term in section 1861(d) of the Social Security Act (42 U.S.C. 1395x(d)).

(b) ACCESS TO MEDICARE DATA BY QUALIFIED CLINICAL DATA REGISTRIES TO FACILITATE QUALITY IMPROVEMENT.—

(1) ACCESS.—

(A) IN GENERAL.—To the extent consistent with applicable information, privacy, security, and disclosure laws, beginning July 1, 2015, the Secretary shall, at the request of a qualified clinical data registry under section 1848(m)(3)(E) of the Social Security Act (42 U.S.C. 1395w–4(m)(3)(E)), provide the data described in subparagraph (B) (in a form and manner determined to be appropriate) to such qualified clinical data registry for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety, provided that any public reporting of such analyses or research that identifies a provider of services or supplier shall only be conducted with the opportunity of such provider or supplier to appeal and correct errors in the manner described in subsection (a)(6).

(B) DATA DESCRIBED.—The data described in this subparagraph is—

(i) claims data under the Medicare program under title XVIII of the Social Security Act; and

(ii) if the Secretary determines appropriate, claims data under the Medicaid program under title XIX of such Act and the State Children's Health Insurance Program under title XXI of such Act.

(2) FEE.—Data described in paragraph (1)(B) shall be provided to a qualified clinical data registry under paragraph (1) at a fee equal to the cost of providing such data. Any fee collected pursuant to the preceding sentence shall be deposited in the Centers for Medicare & Medicaid Services Program Management Account.

(c) EXPANSION OF DATA AVAILABLE TO QUALIFIED ENTITIES.—Section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)) is amended—

(1) in the subsection heading, by striking ''MEDICARE''; and

(2) in paragraph (3)—

(A) by inserting after the first sentence the following new sentence: ''Beginning July 1,

2015, if the Secretary determines appropriate, the data described in this paragraph may also include standardized extracts (as determined by the Secretary) of claims data under titles XIX and XXI for assistance provided under such titles for one or more specified geographic areas and time periods requested by a qualified entity.''; and

(B) in the last sentence, by inserting ''or under titles XIX or XXI'' before the period at the end.

(d) REVISION OF PLACEMENT OF FEES.—Section 1874(e)(4)(A) of the Social Security Act (42 U.S.C. 1395kk(e)(4)(A)) is amended, in the second sentence—

(1) by inserting '', for periods prior to July 1, 2015,'' after ''deposited''; and

(2) by inserting the following before the period at the end: '', and, beginning July 1, 2015, into the Centers for Medicare & Medicaid Services Program Management Account''.

SEC. 2086. EMPOWERING PATIENT RESEARCH AND BETTER OUTCOMES THROUGH CMS DATA.

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of this section, the Secretary of Health and Human Services shall promulgate interim final

regulations that permit an entity described in subsection (b) to obtain from the Secretary the data described in subsection (c).

(b) ENTITIES DESCRIBED.—An entity described in this subsection is an entity that—

(1) is a State or a qualified researcher; and

(2) submits to the Secretary an application that includes—

(A) a description of the purposes for which the entity intends to use the data that the entity seeks to obtain under subsection (a);

(B) a demonstration that the entity is qualified to perform the tasks necessary to achieve the purposes described by the entity pursuant to subparagraph (A); and

(C) an attestation by the entity that the entity will adhere to all requirements promulgated by the Secretary with respect to the use of the data.

(c) DATA DESCRIBED.—The data described in this subsection, with respect to an entity described in subsection (b), is data that—

(1) do not contain individually identifiable health information;

(2) are the minimum amount of data that are necessary for the entity to accomplish the purposes described by the entity pursuant to subparagraph (A) of paragraph (2) of such subsection in the attestation submitted by the entity under such paragraph; and

(3) relate to files designated by the Centers for Medicare & Medicaid Services as research-identifiable files.

(d) DATA RELEASE PROCEDURES.—The Secretary of Health and Human Services shall ensure that any data made available to an entity described in subsection (b) pursuant to subsection (a) are made available in a manner that is in accordance with applicable data release procedures specified in Federal law and in regulations promulgated by the Secretary relating to data privacy.

(e) DEFINITION.—In this section, the term ''qualified researcher'' means an individual with the education and experience necessary to design and conduct research properly, as determined by the Secretary, regardless of the individual's commercial or institutional affiliation.

SEC. 2087. ALLOWING CLINICAL DATA REGISTRIES TO COMPLY WITH HIPAA PRIVACY AND SECURITY LAW IN LIEU OF COMPLYING WITH THE PRIVACY AND SECURITY PROVISIONS OF THE COMMON RULE.

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

"PART 3—COMPLIANCE BY CLINICAL DATA REGISTRIES WITH HIPAA PRIVACY AND SECURITY LAW

"SEC. 13431. RELATION TO PRIVACY AND SECURITY PROVISIONS OF THE COMMON RULE.

''The Secretary shall—

''(1) identify the privacy and security provisions of—

''(A) subpart A of part 46 of title 45, Code of Federal Regulations (commonly referred to as the 'Common Rule'); and

''(B) parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations; and

''(2) establish an exception to such provisions (or any successor provisions) under which a clinical data registry may, in lieu of complying with such provisions, choose to comply with the privacy and se-

curity provisions of HIPAA privacy and security law (as such term is defined in section 3009 of the Public Health Service Act).''.

(b) REVISION OF REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall propose such guidance and regulations as may be necessary to implement section 13431 of the HITECH Act, as added by subsection (a).

SEC. 2088. ACCESS TO CMS CLAIMS DATA FOR PURPOSES OF FRAUD ANALYTICS.

Notwithstanding any other provision of law, the Secretary of Health and Human Services and the Commissioner of Social Security may allow access in real time to claims data under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) by third parties certified by the Secretary or the Commissioner, as applicable, for purposes of fraud prevention.

PART 3—BUILDING A 21ST CENTURY CLINICAL DATA SHARING SYSTEM

SEC. 2091. COMMISSION ON DATA SHARING FOR RESEARCH AND DEVELOPMENT.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services a commission to be known

as the ''Commission on Data Sharing for Research and Development'' (in this section referred to as the ''Commission''). The Commission shall be headed by a Director of Data Sharing for Research and Development (in this section referred to as the ''Director'') appointed by the Speaker of the House of Representatives.

(b) DUTIES.—The duties of the Commission shall be to—

(1) with respect to the collection and dissemination of clinical data, develop—

(A) methods to enable data obtained from individuals participating in a public health program, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Children's Health Insurance Program under title XXI of such Act, and an Exchange established under title I of the Patient Protection and Affordable Care Act (Public Law 111–148), to be shared with a qualified entity (as defined in section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)));

(B) uniform standards for the sharing by such a qualified entity or other entity of data so obtained; and

(C) other recommendations for the collection and dissemination of such data, as appropriate;

(2) with respect to the collection and dissemination of clinical data in a clinical data registry, develop—

(A) processes and procedures to ensure that only valid data are entered into a clinical data registry, including processes and procedures for the development of standardized data definitions for use by health care providers (specific to each specialty) to enable real-time data migration between electronic health records used by such providers and such a registry;

(B) appropriate data integrity and security standards to ensure that the validity of the data in a clinical data registry is maintained both during the active phase of the clinical data registry and after closure of any special activities carried out by the registry;

(C) appropriate processes for adverse event adjudication with respect to the use of data from a clinical data registry;

(D) best practices to support audit practices necessary to ensure the integrity of the data in a clinical data registry; and

(E) rules governing the review and access to data in such a registry, including rules establishing—

(i) the review and acceptance process for requests and analysis of such data, taking into consideration informed consent restrictions, if any, and the objective of the initial clinical data registry activity;

(ii) controlled processes for the access and release of such data that take into account—

(I) data privacy, data integrity and traceability concerns; and

(II) the effect that such access and release has on the market approvals and patent exclusivity periods for drugs, biological products, and devices and patent exclusivity periods;

(iii) guidelines for data transparency;

(iv) a process for the sharing of such data that relates to a specific drug, biological product, or device, including how such

data are shared with the sponsor of the drug, biological product, or device; and

(v) a process for sharing such data with qualified scientific and medical researchers for purposes benefitting public health or patient care; and

(3) develop, for purposes of clinical research and clinical development and with respect to, a process to enable such a qualified entity or another entity approved by the Secretary of Health and Human Services under paragraph (1) to—

(A) search across databases maintaining such data for de-identified information satisfying characteristics specified by such entity; and

(B) receive such de-identified information satisfying such characteristics, whether or not data relating to such characteristics were included or specified in such a database using standardized or uniform terminology.

(c) MEMBERSHIP.—

(1) COMPOSITION.—The Commission shall be composed of 15 members appointed as follows:

(A) 5 individuals appointed by the Secretary, from among individuals who are officers and employees of the Federal Government;

(B) 5 individuals appointed by the Speaker of the House of Representatives.

(C) 5 individuals appointed by the majority leader of the Senate.

(2) REPRESENTATION OF STAKEHOLDERS.—Members appointed to the Commission shall include stakeholders including patients and experts in their field of expertise, including researchers, physicians, industry representatives, and health information technology providers.

(3) TERMS.—Each member shall be appointed for the life of the Commission.

(4) VACANCIES.—A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(d) MEETING.—Not later than one year after the date of the enactment of this Act, the Secretary shall convene a meeting of the Commission to carry out the duties of the Commission specified in subsection (b).

(e) REPORT.—Not later than one year after the date on which the meeting described in subsection (d) is held, the Commission shall submit to the Committee on Energy

and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the findings and conclusions of the Commission, together with its recommendations for legislation the Commission considers appropriate.

(f) DEFINITION.—In this section, the term ''clinical data registry'' means [*How should ''clinical data registry'' be defined?*]

(g) TERMINATION.—The Commission shall terminate on the date the report is submitted under subsection (e).

SEC. 2092. RECOMMENDATIONS FOR DEVELOPMENT AND USE OF CLINICAL DATA REGISTRIES.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall make recommendations for the development and use, when appropriate, of clinical data registries that are integrated with clinical practice guidelines and best practices or standards of care, including registries designed to minimize duplication and burden on those operating or reporting to such registries, for the improvement of patient care. The Secretary shall make such recommendations available to the public by posting them on a public website of the Department of Health and Human Services.

(b) SPECIFIC RECOMMENDATIONS.—Such recommendations, with respect to such registries, shall include the following:

(1) Recommendations for a set of standards that, if adopted by such registries, would allow for the bidirectional, interoperable exchange of information between the electronic health records of the reporting clinicians and such registries.

(2) Recommendations on how clinical registries, including outcomes-based registries, may be developed and then used to evaluate various care models and methods, including improved clinical care coordination, and the impact of such models and methods on the management of diseases as measured by appropriate care parameters based on clinical practice guidelines and best practices (such as A1C, blood pressure, and cholesterol levels in the case of diabetes).

(3) Recommendations on how such registries should be structured to facilitate the recording and reporting of postmarket data for the purposes of monitoring safety and efficacy of FDA-approved devices and drugs, reporting relevant clinical data to satisfy attestation requirements for coverage of prescribed devices and drugs, and better defining appro-

priate clinical use in support of evidence development for the Medicare program (such as improving patient access to safe and effective glucose monitoring systems and future glucose monitoring technologies).

(4) Recommendations on how data from such registries may be used to inform physicians and other health care professionals regarding clinical practices for the prevention of diseases (such as diabetes and the precursor conditions of diabetes) and appropriate methods for the dissemination of clinical practice support tools and other educational resources that may be derived from registry data.

(5) Recommendations for how registries can be used to promote preventive health benefits such as screenings and the Medicare annual wellness visits that may reduce the risk of chronic diseases (such as obesity, osteoporosis, cardiovascular disease, cancer, diabetes, and their complications).

(c) CONSULTATION WITH CLINICAL EXPERTS.—The Secretary shall consult with national medical specialty societies and with manufacturers of drugs and medical devices in the development of such recommendations as they relate to the diseases that they (or their manufactured drugs or devices) manage and treat (such as with

endocrinologists with respect to recommendations relating to diabetes and prediabetes conditions). *[Note on this subtitle: Are there other ideas for supporting the use of data to support new cures and increase the quality of patient care?]*

Subtitle G—Utilizing Real-World Evidence

SEC. 2101. UTILIZING REAL-WORLD EVIDENCE.

Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 1261, is further amended by inserting after section 505G of such Act the following:

"SEC. 505H. UTILIZING REAL-WORLD EVIDENCE.

''(a) IN GENERAL.—The Secretary shall establish a program under which a sponsor may submit real-world evidence for purposes including—

''(1) to support the approval of the use of a drug for a new indication; and

''(2) to support or satisfy post-approval study requirements.

''(b) REAL-WORLD EVIDENCE DEFINED.—In this section, the term 'real-world evidence' means data about the usage, benefits, or risks of a drug derived from sources other than randomized clinical trials, including from observational studies and registries, used to establish safety or effectiveness under section 505(d).

''(c) GUIDANCE.—

''(1) IN GENERAL.—The Secretary shall—

''(A) not later than 12 months after the date of enactment of this section, issue draft guidance for implementation of the program under this section; and

''(B) not later 18 months after the date of enactment of this section, after providing an opportunity for public comment on the draft guidance, issue final guidance for implementation of the program under this section.

''(2) CONTENTS OF GUIDANCE.—The guidance under paragraph (1) shall include guidance describing—

''(A) the appropriate standards and methodologies for the collection and analysis of real-world evidence submitted for the purposes described in paragraphs (1) and (2) of subsection (a); and

''(B) the circumstances under which sponsors of drugs and the Secretary may rely on real-world evidence for such purposes.

''(3) CONSULTATION.—In developing guidance under paragraph (1), the Secretary shall consult with the regulated industry, academia, organized

medicine, representatives of patient advocacy organizations and disease research foundations, and other interested parties through a public process.

''(d) REPORTS.—Not later than 2 years after the date of enactment of this section, and not later than 4 years after such date of enactment, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and make publicly available, a report on the implementation of the real-world evidence program under this section. The reports required by this subsection shall address the following:

''(1) How the program under this section has been utilized by sponsors of drugs.

''(2) How the program under this section has impacted regulatory decisionmaking, including 'substantial evidence' determinations under section 505(d).

''(3) How the program under this section could be expanded for the use of real-world evidence for additional purposes.

''(e) RULE OF CONSTRUCTION.—Nothing in this section prohibits the Secretary from using real-world evidence for purposes not specified in this section.''.

Subtitle H—Coverage With Evidence Development

SEC. 2121. AUTHORITY FOR COVERAGE WITH EVIDENCE DEVELOPMENT FOR MEDICAL DEVICES UNDER THE MEDICARE PROGRAM.

(a) EXCEPTION TO REASONABLE AND NECESSARY REQUIREMENT.—Section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1395y(a)(1)(A)) is amended by inserting ''or a CED item or service (as described in section 1861(iii))'' after ''(as described in section 1861(ddd)(1))''.

(b) DEFINITION OF CED ITEM OR SERVICE.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(iii) CED ITEM OR SERVICE.—

''(1) IN GENERAL.—The term 'CED item or service' means an item or service that is for coverage with evidence development (as described in paragraph (2)).

''(2) COVERAGE WITH EVIDENCE DEVELOPMENT.—For purposes of paragraph (1), an item or service is for coverage with evidence development if—

''(A) the item or service is furnished to individuals as part of a clinical study performed

to determine whether the furnishing of such item or service improves the health outcomes of such individuals, as determined under paragraph (3); and

''(B) the furnishing of the item or service to the individual is determined by the Secretary to be reasonable and necessary to the carrying out of such clinical study.

''(3) DETERMINATION OF IMPROVED HEALTH OUTCOMES.—For purposes of paragraph (2)(A), a determination of whether the furnishing to individuals of items or services improves the health outcomes of such individuals shall be determined by assessing whether the furnishing of such items or services improves the—

''(A) diagnosis or treatment of illnesses or injuries of such individuals (as compared to the diagnosis or treatment of illnesses or injuries of comparable individuals who are not so furnished such items or services); or

''(B) functioning of malformed body members of such individuals (as compared to the functioning of malformed body members of comparable individuals who are not so furnished such items or services).''.

(c) LOCAL COVERAGE DETERMINATIONS.—Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)) is amended by adding at the end the following new sentence: ''For purposes of the preceding sentence, a determination of whether a particular item or service is subject to the exception for CED items and services described in section 1862(a)(1)(A) shall be considered to be a determination respecting whether such item or service is so covered in accordance with such section.''

Subtitle I—Combination Products

SEC. 2141. REGULATION OF COMBINATION PRODUCTS BY THE FOOD AND DRUG ADMINISTRATION.

Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) in paragraph (4)(C), by adding at the end the following:

''(iii) The Office shall ensure that the agency center with primary jurisdiction for the premarket review of a combination product shall be the sole point of contact for the sponsor of the product. The Office shall also coordinate communications to and from any consulting agency center involved in such premarket review. Agency communications and commitments from the center with primary jurisdiction shall be binding on all other centers involved in the review.

''(iv) The Office shall, with respect to the premarket review of a combination product—

''(I) ensure that any meeting between the Food and Drug Administration and the sponsor of the product is attended by each agency center involved in the review;

''(II) require that each consulting agency center has completed its premarket review and provided the results of such review to the agency center with primary jurisdiction within timeframes that allow the agency center with primary jurisdiction to meet the review goals established pursuant to the most recent authorization or reauthorization of parts 2, 3, 7, and 8, as applicable, of subchapter C of title VII; and

''(III) ensure that each consulting agency center complies with the guidance described in clause (vi) and other relevant regulations, guidances, and policies.

''(v) Not later than 10 days after the receipt by an agency center of an application under section 505, 510(k), or 520 of this Act, or under section 351 of the Public Health Service Act, for a combination product or an application for investigational use of a combination product under section 505(i) or 520(g), the agency center shall inform the Office of such receipt.

''(vi) Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue final guidance that describes the responsibilities of each agency center regarding its review of combination products, including each center's role in evaluating labeling, product usability assessments, and human factors testing. The Office shall, after soliciting public comment, review and update the guidance at least biannually and specify in such updated guidance the reasons for updates.

''(vii) Before finalizing any guidance developed by an agency center or centers under this subparagraph the Office shall review the guidance to determine its applicability to combination products. If applicable, the Office shall ensure that such guidance is consistent with the requirements of subparagraph (F).'';

(2) in paragraph (4)(G)—

(A) in clause (ii), by striking ''and'' at the end;

(B) in clause (iii), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor; and

''(v) identifying the percentage of meetings between the Food and Drug Administration and the sponsor of a combination product at which all of the centers participating in the review of the combination product were in attendance, as required by subparagraph (C)(iv)(I).''; and

(3) in paragraph (5), by adding at the end the following:

''(D) The terms 'premarket review' and 'reviews' include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application or notification submitted under section 505, 510(k), 515, or 520 of this Act or under section 351 of the Public Health Service Act, including with respect to investigational use of the product.''.

SEC. 2142. GAO REPORT ON FDA REGULATION OF COMBINATION PRODUCTS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Congress a report on the regulation by the Food and Drug Administration (in this section referred to as the ''FDA'') of combination products.

(b) ISSUES TO BE ADDRESSED.—The report under subsection (a) shall provide information on the following:

(1) The number of letters of request (as defined in section 3.2(j) of title 21, Code of Federal Regulations) the Food and Drug Administration received each year during the period beginning with 2003 and ending with 2013 (in this subsection referred to as the ''applicable 11-year period'') that were sent to the Office of Combination Products.

(2) How do the designations made by the Food and Drug Administration, pursuant to such letters, compare to the sponsor's requested designation (including both formal and informal requests)?

(3) How many combination product applications (including new drug applications, biological products license applications, and premarket clearance notifications) have been received annually by the FDA during the applicable 11-year period?

(4) For informal requests for designation, as described in paragraph (1), how often did sponsors submit in accordance with the advice received (with respect to the lead center)? How many times annually in the applicable 11-year period did a sponsor submit an application to one center and have it reassigned to another center?

(5) Is there a formal internal process that documents the inter-center consultation and review and ensures the feedback from both centers is sent to the sponsor? If so, what is the process and how often is it followed (or was it followed during the applicable 11-year period)? How do sponsors have access to those inter-center consulting reviews? How many times during the applicable 11-year period did a sponsor request consulting center participation and not have it occur? How far into the review process does one center bring the other centers for consulting reviews, including whether other centers are included during presubmission consulting reviews?

(6) Is there a well-established process across the centers determining when simulated use (such as human factor studies and labeling comprehension studies)(HF) versus use in clinical trials are required for instructions for use (IFU)? Is there a consistent unit that reviews HF studies, independent of the lead center? If not, is there a process for determining who reviews HF studies?

(7) How many products types are regulated as combination products that were previously regulated by a single center (such as drug-coated devices and drug-delivery devices? How many products annually

during the applicable 11-year period were impacted by these changes in categorizations? What types of products (such as integral, co-labeled, kitted products) constitute the increase in the number of combination products during the applicable 11-year period? How did the FDA make the decision to change the regulation of these products?

(8) Does the Office of the Commissioner of Food and Drugs have a process to collect metrics regarding the management of the combination product review process, including the following:

(A) Are there dedicated project managers or team leaders assigned with accountability for oversight of—

(i) the metrics for review meetings with required joint center review teams and transparent review reports and meetings; and

(ii) decision timelines, authorities, and milestones built into the application and review process?

(B) Does the Office ensure the Office's involvement in any guidance of the Food and Drug Administration that addresses combination products, such as in the development of the

draft Guidance for Industry on Rheumatoid Arthritis: Developing Drug Products for Treatment?

(C) Does the Office play a role in establishing cross-center expert committees or centers of excellence to uniformly review scientific aspects that span the centers (such as single Human Factor review committee)?

(9) What training does FDA staff receive on combination product review and regulation? Has the FDA developed training on methodologies and inspection approaches, such as quality by design, critical or risk-based inspection and review practices, patient-focused reviews, human factor testing, biocompatibility testing, bridging study designs, and endpoints for device design or drug/biological product formulation changes before and after marketing?

(10) What are the experience and expertise of the staff of the Office of Combination Products (established under section 503(g)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(4)(A))?

(c) RECOMMENDATIONS.—The report under subsection (a) shall include such recommendations as the Comptroller General may have to improve the process for

the timely and efficient development and review of combination products.

(d) COMBINATION PRODUCT DEFINED.—In this section, the term ''combination product'' means a combination product as such term is used in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

Subtitle J—Modernizing Regulation of Diagnostics

SEC. 2161. [TO BE SUPPLIED].

Subtitle K—Interoperability

SEC. 2181. [TO BE SUPPLIED].

Subtitle L—NIH–Federal Data Sharing

SEC. 2201. SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end the following:

''SEC. 498E. SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.

''(a) AUTHORITY.—As a condition on the award of a grant or the provision of other financial support for research, irrespective of whether the research is fully or only partially funded through such grant or other support, the

Director of NIH may require the recipient of such grant or other support to agree to share with the public data generated through such research.

''(b) LIMITATION.—Subsection (a) does not authorize the Director of NIH to require the sharing of—

''(1) any individually identifiable information with respect to a human subject participating in the research; or

''(2) any trade secret or commercial or financial information that is privileged or confidential.''.

Subtitle M—Accessing, Sharing, and Using Health Data for Research Purposes

SEC. 2221. ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES.

(a) IN GENERAL.—The HITECH Act (title XIII of division A of Public Law 111–5), as amended by section 2087, is further amended by adding at the end of subtitle D of such Act (42 U.S.C. 17921 et seq.) the following:

''PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

''SEC. 13441. DEFINING HEALTH DATA RESEARCH AS PART OF HEALTH CARE OPERATIONS.

''(a) IN GENERAL.—Subject to subsection (b), the Secretary shall allow the use and disclosure of protected

health information by a covered entity for research purposes, including studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for health care operations described in subparagraph (1) of the definition of health care operations in section 164.501 of title 45, Code of Federal Regulations (or any successor regulations).

''(b) MODIFICATIONS TO RULES FOR DISCLOSURES FOR HEALTH CARE OPERATIONS.—In applying section 164.506, of title 45, Code of Federal Regulations (or any successor regulation), to the disclosure of protected health information described in subsection (a)—

''(1) the Secretary shall require that the disclosure be made by the covered entity to—

''(A) another covered entity for health care operations (as defined in such section 164.501 of such title);

''(B) a business associate that has entered into a contract with the disclosing covered entity to perform health care operations; or

''(C) a business associate for the purpose of data aggregation (as defined in such section 164.501); and

''(2) the disclosure shall not be subject to the limitation described in section 164.506(c)(4) of such title (or any successor regulation).

"SEC. 13442. TREATING DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH SIMILARLY TO DISCLOSURES OF SUCH INFORMATION FOR PUBLIC HEALTH PURPOSES.

''(a) REMUNERATION.—The Secretary shall authorize the disclosure of protected health information for research purposes pursuant to section 164.502(a)(5)(ii)(B)(2)(ii) of title 45, Code of Federal Regulations (or any successor regulation), without applying the limitation on remuneration described in such section.

''(b) PERMITTED USES AND DISCLOSURES.—The public health activities and purposes for which a covered entity may disclose protected health information to a person subject to the jurisdiction of the Food and Drug Administration with respect to a product or activity regulated by such Administration for which that person has responsibility, as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation), shall include research activities, including comparative effectiveness research activities.

"SEC. 13443. PERMITTING REMOTE ACCESS TO PROTECTED HEALTH INFORMATION BY RESEARCHERS.

"Subparagraph (B) of section 164.512(i)(1)(ii) of title 45, Code of Federal Regulations (prohibiting the removal of protected health information by a researcher) (or any successor regulation) shall not prohibit remote access to health information by a researcher from a portal or other access point outside of the covered entity so long as—

"(1) appropriate security and privacy safeguards are maintained by the covered entity; and

"(2) the protected health information is not copied or otherwise retained by the researcher.

"SEC. 13444. ALLOWING ONE-TIME AUTHORIZATION OF USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES.

"(a) IN GENERAL.—In applying section 164.508(c) of title 45, Code of Federal Regulations, with respect to the use or disclosure of protected health information of an individual for research purposes, the individual may submit a one-time valid authorization for the use or disclosure of protected health information of the individual with respect to all future research purposes, including the use and disclosure of protected health information of the individual that is collected after the date of such authorization, and such one-time authorization shall satisfy the re-

quirement under paragraph (1)(iv) of such section with respect to such future research if such authorization—

"(1) sufficiently explains that the information will be used and disclosed for future research;

"(2) states that the authorization will remain valid unless and until it is withdrawn by the individual; and

"(3) permits the individual, and provides instruction to the individual on how to opt-out of, or otherwise withdraw, such authorization at any time.

"(b) WITHDRAWAL OF AUTHORIZATION.—A withdrawal pursuant to subsection (a) of a valid authorization with respect to the use or disclosure of protected health information of an individual for research purposes shall terminate such authorization for any use or disclosure after the date of such withdrawal, provided that a reasonable period of time for implementation of such termination of authorization shall be specified by the Secretary, not to exceed 60 days. Such withdrawal shall not affect research using the protected health information of the individual that has been undertaken before such implementation date in reliance on the valid authorization.

"SEC. 13445. STRENGTHENING PRIVACY AND SECURITY PROTECTION OF HEALTH DATA USED FOR RESEARCH.

"(a) IN GENERAL.—In applying paragraph (e)(1) of section 164.514 of title 45, Code of Federal Regulations, a covered entity may use or disclose a limited data set for research purposes, without a data use agreement as required by paragraph (e)(4) of such section 164.514 only if the requirements described in subsection (b) are satisfied.

"(b) REQUIREMENTS.—For purposes of subsection (a), the requirements described in this subsection, with respect to the use or disclosure of a limited data set for research purposes, are the following:

"(1) The specific use of such limited data set has been reviewed and approved by an institutional review board that is registered with the Department of Health and Human Services.

"(2) The recipient of such limited data set protects the limited data set with safeguards that conform to the required and addressable standards and implementation specifications set forth in sections 164.308, 164.310, 164.312, and 164.316 of title 45, Code of Federal Regulations.

"(c) NO RE-IDENTIFICATION OF HEALTH INFORMATION USED OR DISCLOSED FOR RESEARCH.—

''(1) IN GENERAL.—Subject to paragraph (2), no person who has received or been granted access to a limited data set or health information that has been de-identified, in accordance with paragraphs (a) through (c) of section 164.514 of title 45, Code of Federal Regulations, may:

''(A) knowingly identify or contact, or attempt to identify or contact, individuals whose data are included in the limited data set or de-identified health information; or

''(B) knowingly permit or authorize a third party to knowingly identify or contact, or attempt to identify or contact, individuals whose data are included in the limited data set or de-identified health information.

''(2) EXCEPTION.—The prohibition under paragraph (1) shall not apply to a person who has received or been granted access to a limited data set or health information that has been de-identified if the person performs the functions of identifying or contacting individuals whose data are included in the limited data set or de-identified health information on behalf of a covered entity pursuant to a business associate agreement in compliance with the require-

ments under section 164.504(e) of title 45, Code of Federal Regulations.

''(3) PENALTY.—The provisions of subsections (a) and (b) of section 1176 of the Social Security Act (42 U.S.C. 1320d–5) shall apply to a violation of paragraph (1) in the same manner as such provisions apply to a violation of a provision of part C of title XI of such Act. Any person or entity receiving a limited data set or de-identified health information pursuant to this section who is in violation of paragraph (1) shall be criminally punishable under subsections (a) and (b) of section 1176 of the Social Security Act (42 U.S.C. 1320d–5) or other relevant Federal criminal statutes.

''(d) LIMITED DATA SET DEFINED.—For purposes of this section, the term 'limited data set' means a limited data set described in section 164.514(e)(2) of title 45, Code of Federal Regulations.''.

(b) REVISION OF REGULATIONS.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise the provisions of title 45, Code of Federal Regulations, for consistency with part 4 of subtitle D of the HITECH Act, as added by subsection (a).

Subtitle N—21st Century Chronic Disease Initiative Act

SEC. 2241. PLAN FOR LONGITUDINAL STUDY ON OUTCOMES OF PATIENTS WITH A CHRONIC DISEASE.

(a) DEVELOPMENT AND SUBMISSION.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Director of the National Institutes of Health, shall develop and submit to the appropriate committees of the Congress a plan to carry out a longitudinal study designed to improve the outcomes of patients with a chronic disease through better understanding of risk, transition from wellness to disease, disease progression, diagnosis, and other factors related to chronic disease, including by identifying potential targets for preventive or therapeutic intervention.

(b) CONTENTS.—The plan developed under subsection (a) shall—

(1) ensure that the longitudinal study's design and execution can support the goal of improving the outcomes of patients with a chronic disease;

(2) address the roles of the following types of people in developing the plan and implementing the longitudinal study: scientific and medical researchers, patient representatives, experts in the design

and implementation of longitudinal studies related to chronic disease, health care providers with expertise in chronic disease, ethicists, academic researchers, government researchers, representatives of clinical research organizations, and scientific or medical staff from biopharmaceutical manufacturers and developers;

(3) identify existing and ongoing studies that are relevant to informing and developing the longitudinal study;

(4) include in the plan a description of how patient cohorts will be utilized, coordinated, and expanded in support of the longitudinal study to ensure sufficient enrollment; and

(5) include a description of how the efforts of researchers and investigators participating in the longitudinal study will interact and be coordinated with other chronic disease research efforts, including research under the National Alzheimer's Project Act.

Subtitle O—Helping Young Emerging Scientists

SEC. 2261. FUNDING RESEARCH BY EMERGING SCIENTISTS THROUGH COMMON FUND.

(a) USE OF FUNDS.—Section 402(b)(7)(B) of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) in clause (i), by striking ''and'' at the end;

(2) by redesignating clause (ii) as clause (iii); and

(3) by inserting after clause (i) the following:

''(ii) shall, with respect to funds reserved under section 402A(c)(1)(C) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A) and is carried out by one or more emerging scientists (as defined in section 402A(c)(1)(C)(iv)); and''.

(b) RESERVATION OF FUNDS.—Section 402A(c)(1) of the Public Health Service Act (42 U.S.C. 282a(c)(1)) is amended—

(1) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively; and

(2) by inserting after subparagraph (B) the following:

''(C) ADDITIONAL RESERVATION FOR RESEARCH BY EMERGING SCIENTISTS.—

''(i) INAPPLICABILITY OF TAP FOR EVALUATION ACTIVITIES.—Beginning with fiscal year 2015, funds appropriated to the

National Institutes of Health shall not be subject to section 241.

"(ii) RESERVATION.—In addition to the amounts reserved for the Common Fund under subparagraph (B) and amounts appropriated to the Common Fund under subsection (a)(2), the Director of NIH shall reserve an amount for the Common Fund for fiscal year 2015 and each subsequent fiscal year that is equal to the amount that, but for clause (i), would be made available under section 241 for evaluation activities for such fiscal year.

"(iii) PURPOSE OF RESERVATION.—Amounts reserved under clause (ii) shall be used for the purpose of carrying out section 402(b)(7)(B)(ii) (relating to the conduct and support of research that is identified under section 402A(b)(7)(A) and is carried out by one or more emerging scientists).

"(iv) DEFINITION.—In this subparagraph, the term 'emerging scientist' means an investigator who—

"(I) will be the principal investigator or the program director of the proposed research;

"(II) has never been awarded, or has been awarded only once, a substantial, competing grant by the National Institutes of Health for independent research; and

"(III) is within 15 years of having completed—

"(aa) the investigator's terminal degree; or

"(bb) a medical residency (or the equivalent).".

(c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER.—Funds reserved pursuant to section 402A(c)(1)(C) of the Public Health Service Act, as added by subsection (b)—

(1) shall be used to supplement, not supplant, the funds otherwise allocated by the National Institutes of Health for young investigators; and

(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than allocating funds as described in

section 402(b)(7)(B)(ii) of the Public Health Service Act, as added by subsection (a).

(d) CONFORMING AMENDMENTS.—

(1) Section 241(a) of the Public Health Service Act (42 U.S.C. 238j(a)) is amended by striking ''Such portion'' and inserting ''Subject to section 402A(c)(1)(C)(i), such portion''.

(2) Section 402A(a)(2) of the Public Health Service Act is amended—

(A) by striking ''402(b)(7)(B)(ii)'' and inserting ''402(b)(7)(B)(iii)''; and

(B) by striking ''reserved under subsection (c)(1)(B)(i)'' and inserting ''reserved under subparagraph (B)(i) or (C)(ii) of subsection (c)(1)''.

(3) Section 3(c)(2) of the Gabriella Miller Kids First Research Act (Public Law 113–94) is amended by striking ''402(b)(7)(B)(ii) of the Public Health Service Act, as added by subsection (a)'' and inserting ''402(b)(7)(B)(iii) of the Public Health Service Act, as added by subsection (a) and redesignated by section 2(a) of the YES to Cures Act of 2014''.

(e) RULE OF CONSTRUCTION.—Nothing in this Act (and the amendments made by this Act) is intended to

affect the amount of funds authorized to be appropriated to the Agency for Healthcare Research and Quality.

SEC. 2262. REPORT ON TRENDS IN AGE OF RECIPIENTS OF NIH-FUNDED MAJOR RESEARCH GRANTS.

Not later than six months after the date of enactment of this Act, the Director of the National Institutes of Health shall submit a report to the Congress—

(1) explaining why, over the 30-year period preceding the enactment of this Act—

(A) there has been a substantial increase in the age of investigators receiving their first major research grant from the National Institutes of Health;

(B) there has been a substantial increase in the average age of all recipients of major research grants from the National Institutes of Health; and

(C) there has been a dramatic drop in the number of investigators under 40 years of age receiving major research grants from the National Institutes of Health; and

(2) describing—

(A) the steps taken by the National Institutes of Health in recent years to address the trends identified in paragraph (1); and

(B) the impact of taking such steps.

Subtitle P—Fostering High-Risk, High-Reward Science

SEC. 2281. HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM.

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

"SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM.

''The director of each national research institute, in collaboration with other scientists, shall—

''(1) establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs; and

''(2) set aside a specific percentage of funding, to be determined by the Director of NIH for each national research institute, for such projects.''.

Subtitle Q—Precision Medicine

SEC. 2301. [TO BE SUPPLIED].

TITLE III—MODERNIZING CLINICAL TRIALS

Subtitle A—Clinical Research Modernization

SEC. 3001. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 491 the following section:

"SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

''(a) PROTECTION OF HUMAN SUBJECTS.—

''(1) IN GENERAL.—All human subject research described in paragraph (2)(A) shall be conducted in accordance with the HHS Human Subject Regulations, and as applicable to the human subjects involved in such research, with the vulnerable-populations rules.

''(2) APPLICABILITY.—

''(A) IN GENERAL.—This section applies to human subject research that is—

''(i) conducted or supported by the Department of Health and Human Services; or

''(ii) otherwise subject to regulation by the Department under a provision of Federal law (other than this section).

''(B) OTHER FEDERAL DEPARTMENTS AND AGENCIES.—The Secretary shall make available assistance to any Federal department or agency seeking—

''(i) to improve the regulation or oversight of human subject research; or

''(ii) to apply the HHS Human Subject Regulations or the vulnerable-populations rules to human subject research that is conducted, supported, or regulated by such department or agency.

''(b) HHS HUMAN SUBJECT REGULATIONS; OTHER DEFINITIONS.—

''(1) HHS HUMAN SUBJECT REGULATIONS; VULNERABLE-POPULATIONS RULES.—For purposes of this section:

''(A) The term 'HHS Human Subject Regulations'—

"(i) subject to clause (ii), means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations); and

"(ii) in the case of human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

"(B) The term 'vulnerable-populations rules'—

"(i) subject to clause (ii), means the provisions of subparts B through D of such part 46 (or any successor regulations); and

"(ii) as applicable to the human subjects involved in research described in subparagraph (A), means the provisions applicable to vulnerable populations under part 56 of such title 21 (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

''(2) HUMAN SUBJECT RESEARCH.—For purposes of this section:

''(A) Except as provided in subparagraph (B), the term 'human subject research' means research, as defined in subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations), that involves a human subject, as defined in such subpart A (or any successor regulations).

''(B) In the case of an investigation that is subject to the provisions of part 50 of title 21, Code of Federal Regulations (or any successor regulations), the term 'human subject' has the meaning given such term in such part 50, and the term 'human subject research' means a clinical investigation as defined in such part 50.

''(3) OTHER DEFINITIONS.—For purposes of this section:

''(A) The term 'institutional review board' has the meaning that applies to the term 'institutional review board' under the HHS Human Subject Regulations.

''(B) The term 'lead institutional review board' means an institutional review board that otherwise meets the requirements of the HHS

Human Subject Regulations and enters into a written agreement with an institution, another institutional review board, a sponsor, or a principal investigator to approve and oversee human subject research that is conducted at multiple locations. References to an institutional review board include an institutional review board that serves a single institution as well as a lead institutional review board.

''(c) SCOPE OF AUTHORITY OF SECRETARY.—

''(1) IN GENERAL.—The HHS Human Subject Regulations (including provisions regarding exemptions) and the vulnerable-populations rules, as in effect on the day before the date of the enactment of the 21st Century Cures Act, continue to be in effect on and after such date, subject to paragraph (2).

''(2) MODIFICATIONS.—

''(A) COMPLIANCE WITH LAW.—Promptly after the date of the enactment of the Act referred to in paragraph (1), the Secretary shall promulgate regulations to make such modifications to the provisions of the HHS Human Subject Regulations as may be necessary to ensure that such provisions implement, and do not conflict with, this section.

''(B) OTHER MODIFICATIONS.—This section may not be construed as affecting the authority of the Secretary to modify the provisions of the HHS Human Subject Regulations or the vulnerable-populations rules, except to the extent that any such modification is in conflict with this section. Any such modification shall be made by regulation or guidance, as applicable.

''(d) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—

''(1) IN GENERAL.—The Secretary shall—

''(A) make such modifications to the provisions of the HHS Human Subject Regulations and the vulnerable-populations rules as may be necessary—

''(i) to reduce regulatory duplication and unnecessary delays;

''(ii) to modernize such provisions in the context of multisite and cooperative research projects; and

''(iii) to incorporate local considerations, community values, and mechanisms to protect vulnerable populations;

"(B) ensure that human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, and is therefore subject to parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations), is not subject to subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations); and

"(C) ensure that human subject research that is described in subparagraph (B), and is cooperative research as such term is defined in section 46.114 of title 45, Code of Federal Regulations (or any successor regulations), may—

"(i) use joint or shared review;

"(ii) rely upon the review of—

"(I) an independent institutional review board; or

"(II) an institutional review board of an entity other than the sponsor of the research; or

"(iii) use similar arrangements to avoid duplication of effort.

"(2) REGULATIONS AND GUIDANCE.—Not later than 12 months after the date of enactment of the

21st Century Cures Act, the Secretary, acting through the relevant agencies and offices of the Department of Health and Human Services, including the Office for Human Research Protections and relevant agencies and offices of the Food and Drug Administration, shall issue such regulations and guidance and take such other actions as may be necessary to implement this subsection. Such regulations and guidance shall include clarification of requirements and policies relating to the following:

"(A) Arrangements to avoid duplication described in paragraph (1)(C), including—

"(i) delineating the roles of institutional review boards in multisite or cooperative, multisite studies where one or more local institutional review boards are relied upon, or similar arrangements are used;

"(ii) the risks and benefits to human subjects;

"(iii) standardization of informed consent and other processes and legal documents; and

"(iv) incorporating community values through the use of local institutional re-

view boards while continuing to use central or lead institutional review boards.

''(B) Concerns about regulatory and legal liability contributing to decisions by the sponsors of research to rely on local institutional review boards for multisite research.

''(3) CONSULTATION.—In issuing regulations or guidance pursuant to paragraph (2), the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology and medical device developers, clinical research organizations, patient groups, and others).''.

SEC. 3002. USE OF INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is amended by striking ''local'' each place it appears in subparagraphs (A)(i) and (B).

(b) REGULATIONS.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise or issue such regulations or guidance as may be necessary to carry out the amendments made by subsection (a).

Subtitle B—Broader Application of Bayesian Statistics and Adaptive Trial Designs

SEC. 3021. CLINICAL TRIAL MODERNIZATION.

(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 507A of such Act, as added by section 1022 of this Act, the following new section:

"SEC. 507B. CLINICAL TRIAL MODERNIZATION.

''To promote the efficiency of the development and regulatory review and approval, licensure, or clearance of drugs, biological products, and devices and the timely availability of innovative treatments, the Secretary shall, after providing notice and an opportunity for public comment, establish and implement a framework through which sponsors of drugs, biological products, or devices may submit to the Secretary a proposal for the incorporation of adaptive trial designs, Bayesian methods, or other alternative statistical methods into proposed clinical protocols and marketing applications for drugs, biological products, or devices.''.

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

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (in this subsection referred to as the ''Secretary''), shall—

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

(B) issue draft guidance on the use of Bayesian methods in the development and regulatory review and approval, licensure, or clearance of drugs, biological products, and devices.

(2) CONTENTS.—The guidances under paragraph (1) shall—

(A) establish or clarify standards for using adaptive trial designs and Bayesian methods in clinical trials, including clinical trials that form the primary basis for approval, clearance, or licensure of the products involved (such as trials that provide substantial evidence for the approval of drugs);

(B) establish a mechanism for sponsors to obtain feedback from the Secretary under section 507B, as added by subsection (a), on technical issues related to modeling and simulations prior to—

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) specify the types of quantitative and qualitative information required for review; and

(D) specify the recommended analysis methodology.

(3) PUBLIC MEETING.—Prior to updating or developing the guidances required by paragraph (1), the Secretary shall consult, through a public meeting to be held no later than 1 year after the date of enactment of this Act, with stakeholders including representatives of regulated industry, academia, patient advocacy organizations, and disease research foundations.

(4) SCHEDULE.—The Secretary shall, after providing notice and opportunity for public comment, publish—

(A) the final guidance required by paragraph (1)(A) not later than 6 months after the date of the public meeting required by paragraph (3); and

(B) the guidance required by paragraph (1)(B) not later than 12 months after the date

of the public meeting required by paragraph (3).

(5) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—Not later than 48 months after the date of enactment of this Act, the Secretary shall review and, as appropriate, revise the guidance documents required by subparagraphs (A) and (B) of paragraph (1) to reflect developments in statistical methods that could be appropriate for use in clinical trials, including clinical trials that—

(A) form the primary basis for approval, clearance, or licensure of drugs, biological products or devices; or

(B) provide substantial evidence for the approval of drugs.

Subtitle C—Postapproval Studies and Clinical Trials

SEC. 3031. EVALUATIONS OF REQUIRED POSTAPPROVAL STUDIES AND CLINICAL TRIALS.

(a) IN GENERAL.—Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is amended by adding at the end the following new subparagraph:

"(G) EVALUATIONS OF REQUIRED POSTAPPROVAL STUDIES AND CLINICAL TRIALS.—

"(i) IN GENERAL.—The Secretary shall establish a process under which the Secretary, on the initiative of the Secretary or at the request of a responsible person, shall periodically evaluate a postapproval study or clinical trial required to be conducted under this paragraph to determine whether—

"(I) the trial or study is no longer scientifically warranted; or

"(II) the design, or the timelines applicable to the completion of, the study or trial should be renegotiated because of changes in medical practice or the standard of care.

"(ii) NOT SCIENTIFICALLY WARRANTED.—In the case of a determination under clause (i)(I) that a postapproval study or clinical trial required to be conducted under this paragraph is no longer scientifically warranted, the Secretary shall no longer require the responsible person to conduct the study or trial.

"(iii) RENEGOTIATION.—In the case of a determination under clause (i)(II) that

the design, or the timelines applicable to the completion of, a postapproval study or clinical trial required to be conducted under this paragraph should be renegotiated, the Secretary shall enter into negotiations with the responsible person to make such changes as may be necessary to such design or timelines as the Secretary determines are necessary.''.

(b) GUIDANCE.—Not later than one year after the date of the enactment of this Act, the Secretary shall issue draft guidance on the implementation of subparagraph (G) of section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3), as added by subsection (a). Not later than two years after such date of enactment, the Secretary shall issue final guidance on such implementation.

Subtitle D—Pediatric Research Network Improvement

SEC. 3041. NATIONAL PEDIATRIC RESEARCH NETWORK.

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

(1) in paragraph (1)—

(A) by striking ''in consultation with the Director of the Eunice Kennedy Shriver Na-

tional Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research'' and inserting ''in collaboration with the national research institutes and national centers that carry out activities involving pediatric research'';

(B) by striking subparagraph (B);

(C) by striking ''may be comprised of, as appropriate'' and all that follows through ''the pediatric research consortia'' and inserting ''may be comprised of, as appropriate, the pediatric research consortia''; and

(D) by striking ''; or'' at the end and inserting a period; and

(2) in paragraph (1), paragraph (2)(A), the first sentence of paragraph (2)(E), and paragraph (4), by striking ''may'' each place it appears and inserting ''shall''.

Subtitle E—Global Pediatric Clinical Trial

SEC. 3061. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the National Institutes of Health should support a global pediatric clinical trial network through the allocation of grants to supplement the salaries of young researchers who participate in the global pediatric clinical trial network;

(2) National Institutes of Health grants should be awarded, solely for the purpose of supplementing the salaries of young researchers, to entities that participate in the global pediatric clinical trial network;

(3) the Food and Drug Administration should engage the European Medicines Agency and other foreign regulatory entities during the formation of the global pediatric clinical trials network to encourage their participation; and

(4) once a global pediatric clinical trial network is established and becomes operational, the Food and Drug Administration should continue to engage the European Medicines Agency and other foreign regulatory entities to encourage and facilitate their participation in the network with the goal of enhancing the global reach of the network.

TITLE IV—ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

Subtitle A—National Institutes of Health

SEC. 4001. NIH RESEARCH STRATEGIC INVESTMENT PLAN.

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

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

''(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, including through development, use, and updating of the research strategic investment plan under subsection (m);''; and

(2) by adding at the end the following:

''(m) RESEARCH STRATEGIC INVESTMENT PLAN.—

''(1) IN GENERAL.—For fiscal year 2016 and each subsequent fiscal year, the Director of NIH, in consultation with the directors of the national research institutes and national centers, researchers,

patient advocacy groups, and industry leaders, shall develop and maintain a 5-year biomedical research strategic investment plan (in this subsection referred to as the 'strategic investment plan') that—

"(A) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

"(B) identifies areas, to be known as strategic focus areas, in which the resources of the National Institutes of Health can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research; and

"(C) includes measurable objectives for each such strategic focus area.

"(2) USE OF PLAN.—The Director of NIH and the directors of the national research institutes and national centers shall use the strategic investment plan—

"(A) to make resource allocation decisions; and

"(B) to develop individual strategic investment plans for the research activities of each of

the national research institutes and national centers that—

"(i) have a common format; and

"(ii) identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal described in paragraph (1)(B).

"(3) CONTENTS OF PLANS.—

"(A) FUNDING PRIORITY FOR NIH OVERALL.—In developing and maintaining a strategic investment plan under this subsection, the Director of NIH shall ensure that at least 55 percent of the funds that are used by the National Institutes of Health to support extramural research for any fiscal year are used to support basic biomedical extramural research.

"(B) STRATEGIC FOCUS AREAS.—The strategic focus areas identified pursuant to paragraphs (1)(B) and (2)(B) shall—

"(i) be identified in a manner that—

"(I) maximizes the return on investment to the United States public through the investments of the Na-

tional Institutes of Health in biomedical research; and

"(II) contributes to expanding knowledge to improve the United States public's health through biomedical research; and

"(ii) include up to 10 strategic focus areas, to be known as Mission Priority Focus Areas, which best serve the goals of preventing or eliminating the burden of a disease or condition and scientifically merit an enhanced and focused research engagement campaign over the next 5 years.

"(C) RARE AND PEDIATRIC DISEASES AND CONDITIONS.—In developing and maintaining a strategic investment plan under this subsection, the Director of NIH shall ensure that rare and pediatric diseases and conditions remain a priority.

"(4) INITIAL PLAN.—Not later than 270 days after the date of enactment of this subsection, the Director of NIH and the directors of the national research institutes and national centers shall—

"(A) complete the initial strategic investment plans required by paragraphs (1) and (2); and

"(B) make such initial strategic investment plans publicly available on the website of the National Institutes of Health.

"(5) REVIEW; UPDATES.—

"(A) METRICS REVIEWS.—Not less than biannually, the Director of the NIH, in consultation with the directors of the national research institutes and national centers, shall conduct metrics reviews for each strategic focus area identified under paragraph (1)(B).

"(B) UPDATES.—Not later than the end of the 5-year period covered by the initial strategic investment plan under this subsection, and every 5 years thereafter, the Director of NIH, in consultation with the directors of the national research institutes and national centers, stakeholders in the scientific field, advocates, and the public at large, shall—

"(i) conduct a review of the plan, including each strategic focus area identified under paragraph (1)(B); and

''(ii) update such plan in accordance with this section.''.

SEC. 4002. BIOMEDICAL RESEARCH WORKING GROUP TO REDUCE ADMINISTRATIVE BURDEN ON RESEARCHERS.

(a) ESTABLISHMENT.—There is established a working group, to be known as the ''Biomedical Research Working Group''. The Director of the National Institutes of Health shall serve as the Chairperson of such working group.

(b) DUTIES.—The Biomedical Research Working Group shall—

(1) review literature and reports on—

(A) administrative burdens of researchers funded by the National Institutes of Health; and

(B) improving replicability of research funded by the National Institutes of Health;

(2) provide recommendations to the Director of the National Institutes of Health to—

(A) reduce such administrative burdens, including with respect to the extent to which (and how) the grant proposal submission and progress report requirements of the National

Institutes of Health should be restructured, streamlined, and simplified; and

(B) improve replicability of research funded by the National Institutes of Health;

(3) evaluate and provide recommendations on the extent to which it is required for Congress to provide any statutory authority to implement any recommendation proposed pursuant to paragraph (2); and

(4) prepare a plan, including timeframes, for implementing recommendations proposed pursuant to paragraph (2) [for which congressional action is not required].

(c) MEMBERSHIP.—The Biomedical Research Working Group shall be composed of the following members:

(1) FEDERAL MEMBERS.—

(A) The Director of the National Institutes of Health.

(B) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health.

(C) The Director of Extramural Programs of the National Institutes of Health.

(D) The Director of Intramural Programs of the National Institutes of Health.

(2) NON-FEDERAL MEMBERS.—Seven non-Federal members representing physicians, health practitioners, academics, scientists, and entrepreneurs whose work, research specialization, or professional expertise includes a significant focus on basic and clinical research that is funded by the National Institutes of Health—

(A) three of whom shall be appointed by the Secretary of Health and Human Services, in consultation with the Director of the National Institutes of Health;

(B) one of whom shall be appointed by the Speaker of the House of Representatives;

(C) one of whom shall be appointed by the minority leader of the House of Representatives;

(D) one of whom shall be appointed by the majority leader of the Senate; and

(E) one of whom shall be appointed by the minority leader of the Senate.

(d) IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health, taking into account the rec-

ommendations, evaluations, and plan described in subsection (b), shall implement measures to—

(1) reduce the administrative burdens of researchers funded by the National Institutes of Health; and

(2) improve replicability of research funded by the National Institutes of Health.

(e) REPORTS.—

(1) REPORT BY WORKING GROUP ON RECOMMENDATIONS AND PLAN.—Not later than one year after the date of the enactment of this Act, the Biomedical Research Working Group shall submit to Congress a report including the recommendations, evaluations, and plan described in subsection (b).

(2) PERIODIC REPORTS BY DIRECTOR OF NIH ON IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—Not later than six months after the date of the submission of the report under paragraph (1) and every six months thereafter, the Director of the National Institutes of Health shall submit to Congress a report on the extent to which the Director has implemented measures pursuant to subsection (d).

(f) TERMINATION.—The Biomedical Research Working Group shall terminate 30 days after the date of the submission of the report under subsection (e)(1).

[SEC. 4003. NIH TRAVEL.

[TO BE SUPPLIED]]

SEC. 4004. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

(a) APPOINTMENT AND TERMS OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—Subsection (a) of section 405 of the Public Health Service Act (42 U.S.C. 284) is amended to read as follows:

''(a) APPOINTMENT; TERMS.—

''(1) APPOINTMENT.—The Director of the National Cancer Institute shall be appointed by the President and the directors of the other national research institutes and national centers shall be appointed by the Director of NIH. The directors of the national research institutes and national centers shall report directly to the Director of NIH.

''(2) TERMS.—

''(A) IN GENERAL.—The term of office of a director of a national research institute or national center shall be 4 years.

''(B) REMOVAL.—The director of a national research institute or national center may

be removed from office by the Director of NIH prior to the expiration of such director's 4-year term.

"(C) REAPPOINTMENT.—At the end of the term of a director of a national research institute or national center, the director may be reappointed. There is no limit on the number of terms a director may serve.

"(D) VACANCIES.—If the office of a director of a national research institute or national center becomes vacant before the end of such director's term, the director appointed to fill the vacancy shall be appointed for a 4-year term starting on the date of such appointment.

"(E) TRANSITIONAL PROVISION.—Each director of a national research institute or national center serving on the date of enactment of the _____Act of 2014 is deemed to be appointed for a 4-year term under this subsection starting on such date of enactment.".

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

''(3) Before an award is made by a national research institute or national center for a grant for a research program or project (commonly referred to as an 'R-series grant'), other than an award constituting a renewal of such a grant, the director of such national research institute or national center—

''(A) shall personally review and approve the award; and

''(B) shall take into consideration—

''(i) whether the goals of the research program or project are a national priority and have public support;

''(ii) whether other agencies are funding programs or projects to accomplish the same goal; and

''(iii) whether the monetary investment is worth the potential scientific discovery.''.

(c) GAO STUDY ON DUPLICATION IN FEDERAL BIOMEDICAL RESEARCH.—Not later than 270 days after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) complete a study on the extent to which biomedical research conducted or supported by Federal agencies is duplicative; and

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

(d) GAO STUDY ON WASTE, FRAUD, AND LACK OF CONSISTENCY WITH THE NIH MISSION.—Not later than 270 days after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) complete a study on the extent to which there is waste, fraud, and lack of consistency with the mission of the National Institutes of Health in the conduct and support of research by the National Institutes of Health; and

(2) submit a report to the Congress on the results of such study.

SEC. 4005. GAO REPORT ON COMMON FUND.

(a) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the Common Fund established under section 402A(c) of the Public Health Service Act (42 U.S.C. 282a(c)).

(b) CONTENTS.—The report under subsection (a) shall include an analysis of how amounts reserved under such section have been used and the impact of that funding on the each of the areas that received funding.

SEC. 4006. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

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

(1) in subparagraph (C), by striking ''; or'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting ''; or''; and

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

''(E) during the conduct of research by the National Institutes of Health.''.

SEC. 4007. ADDITIONAL FUNDING FOR NIH COMMON FUND.

Section 402A(a) of the Public Health Service Act (42 U.S.C. 282a(a)) is amended by adding at the end the following:

''(3) ADDITIONAL AMOUNT FOR COMMON FUND.—For the purpose of carrying out section 402(b)(7)(B), there is authorized to be appropriated to the Common Fund [$_____] for each of fiscal years 2016 through 2020. Amounts made available pursuant to the preceding sentence shall be in addition to amounts otherwise made available under paragraph (1), (2), or (4) of this subsection and in

addition to amounts reserved under subsection (c)(1)(B).''.

SEC. 4008. ADDITIONAL FUNDING FOR NIH BRAIN RESEARCH.

Section 402A(a) of the Public Health Service Act (42 U.S.C. 282a(a)), as amended by section 1, is further amended by adding at the end the following:

''(4) ADDITIONAL FUNDING FOR BRAIN RESEARCH.—For the purpose of conducting or supporting brain research under this title, including through the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative, there is authorized to be appropriated [$_____] for each of fiscal years 2016 through 2020. Amounts made available pursuant to the preceding sentence shall be in addition to amounts otherwise made available under paragraph (1), (2), or (3) and shall not be subject to reservation under subsection (c)(1)(B).''.

SEC. 4009. NCATS PHASE IIB RESTRICTION.

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

(1) prior to making the amendments under paragraph (2), by striking ''IIB'' each place it appears and inserting ''III''; and

(2) by striking ''IIA'' each place it appears and inserting ''IIB''.

Subtitle B—Advancing Research for Neurological Diseases

SEC. 4021. NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE SYSTEM.

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

''SEC. 399V–6 SURVEILLANCE OF NEUROLOGICAL DISEASES.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

''(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson's disease; and

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

''(b) RESEARCH.—The Secretary shall ensure that the National Neurological Diseases Surveillance System is

designed in a manner that facilitates further research on neurological diseases.

''(c) CONTENT.—In carrying out subsection (a), the Secretary—

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

''(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, such as information concerning—

''(A) demographics and other information associated or possibly associated with neurological diseases, such as age, race, ethnicity, sex, geographic location, and family history;

''(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

''(C) diagnosis and progression markers;

''(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

''(A) the epidemiology of the diseases;

''(B) the natural history of the diseases;

''(C) the prevention of the diseases;

''(D) the detection, management, and treatment approaches for the diseases; and

''(E) the development of outcomes measures; and

''(4) may address issues identified during the consultation process under subsection (d).

''(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

''(1) epidemiologists with experience in disease surveillance or registries;

''(2) representatives of national voluntary health associations that—

''(A) focus on neurological diseases, including multiple sclerosis and Parkinson's disease; and

''(B) have demonstrated experience in research, care, or patient services;

''(3) health information technology experts or other information management specialists;

''(4) clinicians with expertise in neurological diseases; and

''(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

''(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

''(f) COORDINATION WITH OTHER FEDERAL AGENCIES.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to Federal departments and agencies, such as the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and the Department of Defense.

''(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.

''(h) PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).

''(i) REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall sub-

mit a report to the Congress concerning the implementation of this section. Such report shall include information on—

"(1) the development and maintenance of the National Neurological Diseases Surveillance System;

"(2) the type of information collected and stored in the System;

"(3) the use and availability of such information, including guidelines for such use; and

"(4) the use and coordination of databases that collect or maintain information on neurological diseases.

"(j) DEFINITION.—In this section, the term 'national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

"(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated [$_____] for each of fiscal years 2015 through 2019.".

Subtitle C—Vaccine Access, Certainty, and Innovation

PART 1—DEVELOPMENT, LICENSURE, AND RECOMMENDATIONS

SEC. 4041. PROMPT REVIEW OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

Section 2102(a) of the Public Health Service Act (42 U.S.C. 300aa–2(a)) is amended by adding at the end the following:

''(10) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—

''(A) STANDARD PERIODS OF TIME FOR MAKING RECOMMENDATIONS.—The Director of the Program shall establish standard timelines during which the Advisory Committee on Immunization Practices should consider and make recommendations with respect to the route of administration, dosage, and frequency of administration of vaccines for specified populations.

''(B) EXPEDITED REVIEW PURSUANT TO REQUEST BY SPONSOR OR MANUFACTURER.—If the Advisory Committee does not make the recommendations described in subparagraph (A)

for a vaccine by the date that is 120 calendar days after the licensure of the vaccine under section 351, the Advisory Committee, at the request of the sponsor of the vaccine, shall make such recommendations within 60 calendar days of the Advisory Committee's receipt of the request.

''(C) EXPEDITED REVIEW FOR BREAKTHROUGH THERAPIES AND FOR USE DURING PUBLIC HEALTH EMERGENCIES.—If a vaccine is designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act, the Advisory Committee shall make the recommendations described in subparagraph (A) on an expedited basis.

''(D) DEFINITION.—In this paragraph, the terms 'Advisory Committee on Immunization Practices' and 'Advisory Committee' mean the advisory committee on immunization practices established by the Secretary pursuant to section 222, acting through the Director of the Centers for Disease Control and Prevention.''.

SEC. 4042. REVIEW OF TRANSPARENCY AND CONSISTENCY OF ACIP RECOMMENDATION PROCESS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the transparency and consistency of the process used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines.

(b) CONSIDERATIONS.—The review under subsection (a) shall include assessment of—

(1) the criteria used to evaluate new and existing vaccines;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the working groups of the Advisory Committee on Immunization Practices are transparent and consistent.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 1 year after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress and make publicly available a report on the results of the review under subsection (a), including recommendations on improving the transparency and consistency of the process described in such subsection.

(e) DEFINITION.—In this section, the term ''Advisory Committee on Immunization Practices'' means the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 4043. GUIDANCE ON VACCINE DEVELOPMENT.

(a) ISSUANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance to facilitate the use of accelerated and expedited pathways for the development and licensure of vaccines to prevent—

(1) emerging, re-emerging, or rare infectious diseases with respect to which the low prevalence or nature of the disease may render the existence or

collection of clinical outcome data unlikely or impractical; and

(2) infectious diseases with respect to which currently available vaccines are not addressing the full scope of public health needs.

(b) CONSIDERATIONS.—In developing the guidance required by this section, the Secretary of Health and Human Services shall consider issues relating to clinical development strategies for diseases described in subsection (a), including the development and acceptability of novel clinical and surrogate endpoints, the use of novel or accelerated study designs, the use of observational real-world data, the use of novel adjuvants, the use of new technologies or approaches to collecting and monitoring patient-level data, and the demonstration of efficacy through studies in healthy volunteers for the purpose of licensure.

SEC. 4044. MEETINGS BETWEEN CDC AND VACCINE DEVELOPERS.

Section 310 of the Public Health Service Act (42 U.S.C. 242o) is amended by adding at the end the following:

''(c)(1) In this subsection, the term 'vaccine developer' means a nongovernmental entity engaged in—

''(A) the development or production of a vaccine; and

''(B) vaccine research.

''(2)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts in immunization programs, epidemiology, and other relevant areas, including such experts from the Food and Drug Administration and the National Vaccine Program, at which the Director (or the Director's designee), for the purpose of informing the vaccine developer's understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—

''(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer's potential vaccine profile; and

''(ii) potential implications of such perspectives for the vaccine developer's vaccine research and development planning.

''(B) The Director of the Centers for Disease Control and Prevention (or the Director's designee) shall convene a meeting requested under subparagraph (A) not later than 90 calendar days after receipt of the request for the meeting.

''(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based disease epidemiological analyses or data that—

''(i) are specified in the request;

''(ii) have been published;

''(iii) have been performed by or are in the possession of the Centers; and

''(iv) are not a trade secret or otherwise confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 90 calendar days after receipt of the request for the analyses.

''(4) The Secretary shall promptly notify a vaccine developer if—

''(A) the Secretary becomes aware of any change to information that was—

''(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or

''(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and

''(B) the change may have implications for the vaccine developer's vaccine research and development.''.

SEC. 4045. MODIFICATIONS TO PRIORITY REVIEW VOUCHER PROGRAM FOR TROPICAL DISEASES.

Section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S. Code 360n) is amended—

(1) in subsection (a)—

(A) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking ''This term'' and inserting ''In this section, this term'';

(ii) in subparagraph (R), by striking ''designated by order of the Secretary'' and inserting ''designated by the Secretary pursuant to paragraph (4)'';

(B) by redesignating paragraph (4) as paragraph (5); and

(C) by inserting after paragraph (3) the following:

''(4) DESIGNATION OF OTHER INFECTIOUS DISEASES AS TROPICAL DISEASES.—

''(A) IN GENERAL.—The Secretary shall establish a process under which the Secretary—

''(i) using a methodology that is made available to the public on the Website of the Food and Drug Administration, designates infectious diseases other than the diseases specified in subparagraphs (A) through (Q) of paragraph (3) to be tropical diseases for purposes of this section; and

''(ii) publishes on such Website a complete, updated list of the diseases that are tropical diseases for purposes of this section.

''(B) CONSIDERATIONS.—In designating an infectious disease as a tropical disease under subparagraph (A), the Secretary shall—

''(i) consider the potential impact of the disease on the public health due to—

''(I) the potential rate of spread of the disease; and

''(II) the potential severity of the disease in terms of human morbidity and mortality; and

''(ii) consult with experts in tropical infectious diseases, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, the clinical research community, and the World Health Organization.

''(C) REVIEW.—Every 5 years, or more frequently as determined necessary by the Secretary, the Secretary shall review, provide modifications to, and republish the list published under subparagraph (A) and any revisions made to the methodology for designation of diseases under such subparagraph.'';

(2) in subsection (b)—

(A) in paragraph (2), by striking ''The sponsor of a tropical disease'' and inserting:

''(A) IN GENERAL.—The sponsor of a tropical disease'';

(B) by inserting after such paragraph (2)(A) the following:

''(B) NOTIFICATION OF TRANSFER.—Each person to whom a priority review voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 calendar days after such transfer.'';

(C) in paragraph (4), by striking ''The sponsor of a human drug application'' and inserting:

''(A) IN GENERAL.—The sponsor of a human drug application''; and

(D) by inserting after paragraph (4)(A), as designated by subparagraph (D), the following:

''(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of intent under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification. Upon such a transfer, notwithstanding subparagraph (A), such sponsor shall not remain legally committed to pay a user fee because of the sponsor's notification of intent under such subparagraph.''; and

(3) in subsection (c), by amending paragraph (2) to read as follows:

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary based on the difference between—

''(A) the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year; and

''(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.''.

SEC. 4046. GUIDANCE ON CHANGES TO AN APPROVED APPLICATION FOR BIOLOGICAL PRODUCTS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance that—

(1) addresses changes in a licensed biological product or the labeling, production process, quality controls, equipment, facilities, or responsible personnel for such a product established in the application for the product that was approved under section 351 of the Public Health Service Act (42 U.S.C. 262);

(2) does not address such changes for specified biotechnology or specified synthetic biological products listed in section 601.2(c) of title 21 of the Code of Federal Regulation; and

(3) updates and supersedes the guidance entitled ''Changes to an Approved Application: Biological Products,'' that was issued by the Food and Drug Administration in July 1997.

SEC. 4047. EXPEDITING THE PROCESS FOR EXPORT CERTIFICATIONS FOR VACCINES.

Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) in the matter following clause (ii) in subparagraph (A), by striking ''within 20 days of the receipt of a request for such certification'' and inserting ''within [20 calendar days] of the receipt of a request for such certification, except that in the case of a vaccine the Secretary shall issue such certification within [10 business days] of the receipt of a request for such certification''; and

(2) in subparagraph (B), by striking ''within the 20 days prescribed by subparagraph (A)'' and inserting ''within the period prescribed by subparagraph (A)''.

SEC. 4048. NIH VACCINE RESEARCH.

(a) IN GENERAL.—Subpart 6 of part C of title IV of the Public Health Service Act (42 U.S.C. 285f et seq.) is amended by adding at the end the following:

"SEC. 447D. ADVANCEMENT OF VACCINE DEVELOPMENT.

''In carrying out the general purpose described in section 446, the Director of the Institute shall conduct or support translational science, research, and research training to advance the development of vaccines for the prevention of diseases, including the advancement of vaccine development programs into clinical trials.''.

(b) REVIEW OF NIH VACCINE RESEARCH.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Director of the National Institutes of Health shall—

(A) conduct a review on vaccine research being conducted or supported by the Institutes; and

(B) publish a report on the results of such review.

(2) CONTENTS.—At a minimum, the report under paragraph (1)(B) shall—

(A) describe intramural and extramural vaccine research and development programs that are being conducted or supported by the National Institutes of Health, including those that are translational or clinical phase studies;

(B) provide a summary of funding allocations made to conduct or support the matters described in section 447D of the Public Health

Service Act, as added by subsection (a), and identify projected funding needs with regard to future research or support with regard to these matters; and

(C) identify funding and collaborations with the private sector through—

(i) the Small Business Innovation Research and Small Business Technology Transfer programs; and

(ii) cooperative research and development agreements.

PART 2—MEDICARE, MEDICAID, AND OTHER PROVISIONS

SEC. 4061. REQUIRING PROMPT UPDATES TO MEDICARE PROGRAM UPON ISSUANCE OF ACIP RECOMMENDATIONS.

In the case that the Advisory Committee on Immunization Practices (as defined in paragraph (10)(D) of section 2102(a) of the Public Health Service Act (42 U.S.C. 300aa–2(a))) issues a recommendation for a vaccine or an update to a recommendation for a vaccine that the Secretary of Health and Human Services is using under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to coverage of vaccines or immunizations under such title, the Secretary shall determine whether or

not to update policies under such title with respect to such coverage on a date that is not later than 60 calendar days after the date on which such Advisory Committee issues such recommendation or update.

SEC. 4062. ENCOURAGING HEALTH PLANS TO ESTABLISH PROGRAMS TO INCREASE ADULT IMMUNIZATION.

(a) PRIVATE HEALTH PLANS.—Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18) is amended by adding at the end the following new subsection:

''(f) PROGRAMS TO INCREASE ADULT IMMUNIZATION.—

''(1) IN GENERAL.—For purposes of this section, for plan years beginning on or after the date of enactment of the Vaccine Access, Certainty, and Innovation Act of 2015, activities that improve health care quality described in subsection (a)(2) shall include programs to increase adult immunization.

''(2) ADMINISTRATION.—Not later than December 31, 2016, the Secretary shall establish standardized methodologies, including definitions, for which activities, and in what regard such activities, constitute programs to increase adult immunization in

accordance with this subsection. The Secretary shall consult with relevant stakeholders in establishing such methodologies.''.

(b) MEDICARE ADVANTAGE AND PART D PLANS.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

''(5) INCLUSION OF EXPENDITURES ON PROGRAMS TO INCREASE ADULT IMMUNIZATION IN MINIMUM MEDICAL LOSS RATIO CALCULATION.—For purposes of calculating the minimum medical loss ratio under paragraph (4), for plan years beginning at least 12 months after the date of enactment of this Act, the numerator shall include any expenditures on programs to increase adult immunization.''.

Subtitle D—Reagan-Udall Improvements Bill

SEC. 4081. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

''(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.''; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking ''The ex officio members shall ensure'' and inserting ''The ex

officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure''.

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: ''For purposes of this section, the term 'employee of the Federal Government' does not include a 'special Government employee', as that term is defined in section 202(a) of title 18, United States Code.''.

(3) STAGGERED TERMS.—Subparagraph (A) of section 770(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended to read as follows:

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

''(i) the terms of offices for the members of the Board initially appointed under

paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

''(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.''.

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking ''but shall not be greater than the compensation of the Commissioner''.

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking ''are held in separate accounts from funds received from entities under subsection (i)'' and inserting ''are managed as individual programmatic funds under subsection (i), according to best accounting practices''.

Subtitle E—FDA Hiring, Travel, and Training

[SEC. 4101. [TO BE SUPPLIED].

Subtitle F—FDA Succession Planning

SEC. 4121. PROFESSIONAL DEVELOPMENT OF FDA STAFF.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 746 of such Act (21 U.S.C. 749l) the following:

"SEC. 746A. PROFESSIONAL DEVELOPMENT OF FDA STAFF.

''(a) ENHANCED TRAINING AND EDUCATION.—The Secretary, acting through the Commissioner of Food and Drugs, shall enhance the professional development of technical and scientific staff of the Administration on a continuous basis. Such actions shall include facilitating the attendance of such staff at technical and scientific conferences, meetings, and working groups that provide training and education on emerging technology and science relevant to the development and regulation of products under the jurisdiction of the Administration.

''(b) EFFICIENT ADMINISTRATION.—The Commissioner of Food and Drugs shall ensure that—

''(1) procedures for review and approval of attendance of such staff at such conferences, meetings, and groups are as efficient as practicable to achieve

the goal of enhancing professional development, as described in subsection (a); and

''(2) responsibility for such procedures is delegated to the relevant supervising officials and employees of the Food and Drug Administration.''.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit to the Congress a report on the actions taken to carry out section 746A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

SEC. 4122. FDA MANAGEMENT SUCCESSION PLANNING.

(a) IN GENERAL.—Section 1003 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) is amended by adding at the end the following:

''(j) MANAGEMENT SUCCESSION PLANNING.—The Secretary shall—

''(1) develop and implement a formal succession plan for management positions within the Food and Drug Administration at or higher than the level of a director of a center; and

''(2) include in such plan staffing contingency planning, internal and external recruitment strategies, training and professional development for management candidates, and considerations regarding

any need for special or direct hiring or compensation flexibility.''.

(b) INITIAL PLAN.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall complete the development of the initial succession plan required by section 1003(j) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

Subtitle G—Disposable Medical Technologies

SEC. 4141. COVERAGE OF CERTAIN DISPOSABLE MEDICAL TECHNOLOGIES UNDER THE MEDICARE PROGRAM.

(a) COVERAGE.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 2121, is further amended, by adding at the end the following new subsection:

''Substitute Disposable Medical Technology

''(jjj) The term 'substitute disposable medical technology' means medical equipment that—

''(1) is primarily and customarily used to serve a medical purpose;

''(2) would otherwise be covered as durable medical equipment under this title but for the fact that such equipment is not durable (as defined by

the Secretary for purposes of coverage of durable medical equipment under this title); and

''(3) the Secretary determines substitutes for durable medical equipment.''.

(b) PAYMENT PROVISIONS.—Section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) is amended by adding at the end the following new paragraph:

''(23) SPECIAL PAYMENT RULE FOR SUBSTITUTE DISPOSABLE MEDICAL TECHNOLOGIES.—Notwithstanding the preceding provisions of this subsection, the Secretary shall determine the payment amount under this subsection for a substitute disposable medical technology (as defined in section 1861(jjj)), and for any services and supplies used in conjunction with such technology, in accordance with the following:

''(A) SINGLE PAYMENT AMOUNT.—The Secretary shall determine a single payment amount that shall be paid for a substitute disposable medical technology and for any services and supplies used in conjunction with such technology. A payment for such a technology and for any such services and supplies that is made in the amount of such single payment amount shall constitute full payment under this

title for such technology and such services and supplies.

"(B) CALCULATION OF PAYMENT AMOUNT.—The single payment amount described in subparagraph (A) for a substitute disposable medical technology and for any services and supplies used in conjunction with such technology shall be calculated by—

"(i) calculating the sum of the amounts of payment that otherwise would be made under this section for—

"(I) the item of durable medical equipment for which the Secretary determines, pursuant to section 1861(jjj)(3), that such substitute disposable medical technology substitutes; and

"(II) all services and supplies used in conjunction with such item of durable medical equipment;

"(ii) calculating the amount that is 95 percent of the sum calculated under clause (i); and

"(iii) calculating the single payment amount for the substitute disposable med-

ical technology and for any services and supplies used in conjunction with such technology such that the sum of the payments under this subsection for—

"(I) all substitute disposable medical technologies that the Secretary determines, pursuant to section 1861(jjj)(3), will be necessary to provide a substitute for the item of durable medical equipment described in clause (i)(I); and

"(II) any services and supplies used in conjunction with such technologies;

is equal to the amount calculated under clause (ii).

"(C) LUMP-SUM PAYMENT.—The single payment amount described in subparagraph (A) for a substitute disposable medical technology and for any services and supplies used in conjunction with such technology shall be made in a lump-sum amount.".

(c) NONAPPLICATION OF COMPETITIVE ACQUISITION.—Section 1847(a)(7)(B) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)(B)) is amended—

(1) in clause (i), by striking ''and'' at the end;

(2) in clause (ii), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new clause:

''(iii) that are substitute disposable medical technologies (as defined in section 1861(n)(2)(B)).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to items and services furnished on or after the date that is one year after the date of the enactment of this section.

Subtitle H—Local and National Coverage Decision Reforms

SEC. 4161. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE 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?*]

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following subparagraph:

''(D) REQUIREMENTS FOR LOCAL COVERAGE DETERMINATION PROCESS FOR MEDICARE ADMINISTRATIVE CONTRACTORS.—

''(i) IN GENERAL.—The Secretary shall require each medicare administrative contractor to establish a timely process for development of local coverage determinations that provides for opportunities for public comment and for disclosure of information to the public regarding such determinations.

''(ii) PROCESS.—Before releasing a new or significantly revised local coverage determination, a medicare administrative contractor shall—

''(I) issue a proposed local coverage determination and provide a period for public comment of at least 45 days (or 60 days in the case described in clause (iii));

''(II) upon request of individuals (including providers or representatives of Medicare beneficiaries) within the jurisdiction of the contractor, convene an open, public meeting to review the proposed local coverage determination and to receive comments from attendees; and

''(III) meet upon request with individuals (including providers or representatives of Medicare beneficiaries) within such jurisdiction and manufacturers or sponsors of items affected by the proposed local coverage determination.

''(iii) PROCESS FOR LIMITATIONS.—If a medicare administrative contractor proposes a local coverage determination that would limit or preclude coverage of an item or service, the contractor shall convene a meeting of its Carrier Advisory Committee as required under chapter 13 of the Medicare Program Integrity Manual to secure its advice on the proposed determination and shall provide a period for public comment on the proposed determination of at least 60 days.

''(iv) RESPONDING TO COMMENTS.—A medicare administrative contractor shall include with any public release of a final local coverage determination—

''(I) the contractor's response to comments on the proposed local coverage determination; and

''(II) a description of the evidence the contractor considered in making the determination and the rationale for the policy adopted.

''(v) ADOPTING DETERMINATIONS IN OTHER JURISDICTIONS.—A medicare administrative contractor may adopt for its jurisdiction a local coverage determination proposed or adopted for another jurisdiction only if it undertakes the process as described in this subparagraph in its jurisdiction with respect to such determination, including providing an opportunity for comment and meetings in its jurisdiction on such determination.

''(vi) TREATMENT OF REVISIONS.—A medicare administrative contractor may issue a revised local coverage determination without regard to clauses (ii), (iii), and (iv) if the determination is—

''(I) a clarification that does not restrict coverage;

"(II) a change for a compelling clinical, safety, or technical reason, such as prevention of harm to individuals (subject to the approval of the Secretary);

"(III) a change for coding, coverage, or payment updates over which the medicare administrative contractor does not have discretion;

"(IV) a discretionary coding update that does not restrict coverage;

"(V) a change to effectuate a decision of an administrative law judge on a challenge under section 1869(f); or

"(VI) another type of change that the Secretary may specify in regulations.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall be effective with respect to local coverage determinations proposed or revised on or after the date that is 90 days after the date of the enactment of this Act.

Subtitle I—Telemedicine

SEC. 4181. ADVANCING TELEHEALTH OPPORTUNITIES IN MEDICARE.

(a) PAYMENT FOR SELECTED TELEHEALTH SERVICES.—

(1) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

"SEC. 1899C. PAYMENT FOR SELECTED TELEHEALTH SERVICES.

''(a) IN GENERAL.—Subject to subsections (b)(1) and (d)(2), beginning not later than 4 years after the date of the enactment of this section, the Secretary shall implement a methodology to provide for coverage and payment for a telehealth service (or episodes of such services) included on the list published under subsection (c) and furnished via a telecommunications system to an individual entitled to benefits under part A or enrolled under part B to the same extent and in the same amount as would be provided under this part if the supplier furnishing such service were at the same location as the individual. In developing the methodology under the previous sentence, the provisions of section 1834(m) shall apply, except the Secretary may, subject to subsections (b)(1) and (d)(2), waive any provision of such section that applies a limitation on

what qualifies as an originating site, any geographic limitation, or any limitation on the type of health care provider who may furnish such services.

''(b) LIMITATION AND CONSIDERATIONS.—

''(1) LIMITATION.—In no case may the application of the methodology under subsection (a) result in expenditures under this title for a year being greater than projected expenditures under this title without application of such methodology for such year.

''(2) CONSIDERATIONS.—In developing the methodology under subsection (a), the Secretary shall take into account, with respect to telehealth services (or episodes of such services) proposed to be included on the list under subsection (c), the following:

''(A) The extent to which, and how, fully capitated rates and bundled payments under this title, with respect to such services or episodes, may achieve reduced expenditures under this title.

''(B) The extent to which, and how, defined episodes, with respect to such services, may help facilitate such reduced expenditures.

"(C) How the methodology might be used to utilize cost-effective sites of service, with respect to such services or episodes, that may result in savings to individuals entitled to benefits under part A or enrolled under part B and reduced expenditures under this title.

"(D) Proposals for reforms to the original Medicare fee-for-service program under parts A and B, including safe harbors from any limitations under section 1834(m), that would be needed to enable the methodology with respect to such services or episodes to result in such savings and reduced expenditures.

"(c) SELECTION OF SERVICES.—

"(1) INITIAL LIST.—

"(A) PROPOSED LIST.—Not later than **[**____**]**, the Secretary shall, through notice of proposed rulemaking, select telehealth services and episodes of such services, if any, to be included on a proposed initial list of such services and episodes for which payment may be made under the methodology under subsection (a).

"(B) PUBLISHED LIST.—If the Chief Actuary of the Centers for Medicare & Medicaid Services certifies under subsection (d)(2) that

the methodology under subsection (a), with respect to the telehealth services and episodes included in the proposed list under subparagraph (A), would reduce (or would not result in any increase in) net program spending under this title, the Secretary shall, through rulemaking, publish such list in the Federal Register.

''(2) MODIFICATIONS.—The Secretary may periodically, subject to subsection (b)(1) and through rulemaking, make modifications to the list under paragraph (1).

''(3) CONSIDERATIONS.—The Secretary shall consider for inclusion on the list published under paragraph (1), as may be modified under paragraph (2), the following:

''(A) Telehealth services that meet unmet service needs, as defined by the Secretary.

''(B) Telehealth services that are substitutions for an in-person visit.

''(C) Telehealth services that are proven to reduce readmissions (or other costly services), as defined by the Secretary.

''(D) Telehealth services that, without the provision of such a service, would not allow a

patient to be moved to a lower level of care (including home health care).

''(d) CONTINGENT IMPLEMENTATION.—

''(1) CERTIFICATION.—Not later than **[____]**, the Chief Actuary of the Centers for Medicare & Medicaid Services shall certify whether or not the methodology under subsection (a), with respect to the telehealth services (and episodes of such services) proposed to be included in the initial list published under subsection (c), would reduce (or would not result in any increase in) net program spending under this title.

''(2) IMPLEMENTATION.—The Secretary shall, through rulemaking, implement the methodology under subsection (a), with respect to the initial list of services and episodes to be published under subsection (c), if the Chief Actuary of the Centers for Medicare & Medicaid Services certifies under paragraph (1) that such methodology, with respect to such initial list, would reduce (or would not result in any increase in) net program spending under this title.

''(3) REPORT.—If the Chief Actuary of the Centers for Medicare & Medicaid Services does not certify under paragraph (1) that the methodology

under subsection (a) would reduce (or would not result in any increase in) net program spending under this title, then the Secretary—

"(A) shall not publish the initial list under subsection (c) and shall not implement such methodology; and

"(B) not later than **[**____**]**, shall submit to Congress a report containing the proposed methodology under subsection (a), the proposed initial list of telehealth services (and episodes of services) under subsection (c), and the analysis of the Chief Actuary of the Centers for Medicare & Medicaid Services from which the certification under paragraph (1) was made.

"(e) TELEHEALTH SERVICES DEFINED.—For purposes of this section, the term 'telehealth services' has the meaning given such term under section 1834(m)(4)(F).".

(2) CONFORMING AMENDMENTS.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended in the subsection heading, by striking "SERVICES.—" and inserting "SERVICES.—Subject to subsection (r), the following shall apply:".

(b) ENCOURAGING GREATER ACCESS TO TELEHEALTH SERVICES IN BUNDLED PAYMENT MODELS.—

(1) WAIVER OF CERTAIN MEDICARE TELEHEALTH LIMITATIONS FOR PURPOSES OF DEMONSTRATIONS AND MODELS.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall permit any demonstration project or model that is carried out with respect to the Medicare program under title XVIII of the Social Security Act, under section 1115A of the such Act (42 U.S.C. 1315a) or otherwise, to include under such project or model, with respect to individuals entitled to benefits under part A of such title or enrolled under part B of such title participating in such project or model, telehealth services (as defined in paragraph (4)(F) of section 1834(m) of such Act (42 U.S.C. 1395m(m)) furnished to such individuals and for which payment may otherwise be made under such title without application of any provision under such section 1834(m) that applies a limitation on what qualifies as an originating site, any geographic limitation, or any limitation on the type of health care provider who may furnish such services. In no case shall the application of the previous sentence, with respect to individuals entitled to benefits under part A of such title or enrolled under part B of such title who are participating in such

project or model, result in expenditures under the respective demonstration project or model, with respect to a period, that are greater than the amount of expenditures that would have resulted under such project or model during such period without application of such sentence.

(2) TELEHEALTH SERVICES DEFINITION.—Section 1834(m)(4)(F) of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)) is amended by adding at the end the following new clause:

''(iii) STORE-AND-FORWARD TECHNOLOGY.—*[How should 'store-and-forward' be defined?]* The term 'telehealth service' shall include, for purposes of application with respect to any demonstration project or model conducted with respect to the program under this title, store-and-forward technologies. For purposes of the previous sentence, the term 'store-and-forward technology' means technologies that allow for the electronic transmission of medical information, such as digital images, documents, and prerecorded videos through secure email transmission.''.

(c) SENSE OF CONGRESS REGARDING STATE MEDICAL BOARD COMPACTS.—It is the sense of Congress that States should collaborate, through the use of State medical board compacts, to create common licensure requirements for providing telehealth services in order to facilitate multistate practices and allow for health care providers to provide such services across State lines.

(d) CONSTRUCTION.—Nothing in this section shall be construed to change the application of the HIPAA privacy regulations (as defined in section 1180(b)(3) of the Social Security Act (42 U.S.C. 1320d–9(b)(3))) with respect to a health care professional's provision of telehealth services (as defined in section 1834(m)(4)(F) of the Social Security Act (42 U.S.C. 1395m(m)(4)(F))).

Subtitle J—Revise IPPS New Technology Add-On Payment (NTAP) Reimbursement Amounts

SEC. 4201. CODING AND REIMBURSEMENT REFORMS.

(a) PERMITTING APPEALS OF NTAP DETERMINATIONS UNDER PART A.—Section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) is amended—

(1) in paragraph (5)(K), by adding at the end the following new clause:

"(x) Administrative review of an application for additional payment under this

subparagraph with respect to a discharge occurring on or after the date of the enactment of the 21st Century Cures Act shall be conducted in an expedited manner and shall be completed not later than 90 days after the date on which the appeal is filed with the Secretary.''; and

(2) in paragraph (7)(B), by inserting ''but not including a denial by the Secretary of an application for additional payment under paragraph (5)(K) with respect to a discharge occurring on or after the date of the date of the enactment of the 21st Century Cures Act'' after ''paragraph (4)(D)''.

(b) REPLACING HCPCS CODES WITH NDC CODES FOR PURPOSES OF PART B CODING.—

(1) IN GENERAL.—Section 1847A(b) of the Social Security Act (42 U.S.C. 1395w–3a(b)) is amended by adding at the end the following new paragraph:

''(9) USE OF NDC CODES.—Not later than two years after the date of the enactment of this paragraph, the Secretary shall—

''(A) eliminate the use of HCPCS Level II codes for drugs and biologicals for purposes of

coverage, coding, and reimbursement under this part; and

''(B) replace such codes with National Drug Codes for such drugs and biologicals.''.

(2) CONFORMING AMENDMENTS.—Section 1847A(b) of such Act (42 U.S.C. 1395w–3a(b)), as amended by paragraph (1), is further amended—

(A) in paragraph (3), by inserting '', subject to paragraph (10),'' after ''products included'';

(B) in paragraph (6)—

(i) in subparagraph (A), by inserting '', subject to paragraph (10),'' after ''products included''; and

(ii) in subparagraph (B), by inserting '', subject to paragraph (10),'' after ''associated''; and

(C) by adding at the end the following new paragraph:

''(10) APPLICATION OF BILLING AND PAYMENT CODE REFERENCES.—

''(A) IN GENERAL.—In applying—

''(i) paragraph (3) and subparagraphs (A), (A)(i)(I), and (A)(ii)(II) of paragraph (6) on a date that is after the date de-

scribed in subparagraph (B), the Secretary shall treat each reference to all drug products included within the same multiple source drug billing and payment code (including each reference to 'the billing and payment code' in such subparagraphs (A)(i)(I) and (A)(ii)(II)) as a reference to all drug products that are within National Drug Codes qualified as therapeutically equivalent by the Food and Drug Administration in the Approved Drug Products with Therapeutic Equivalence Evaluations list; and

''(ii) paragraph (6)(B) on a date that is after the date described in subparagraph (B), the Secretary shall treat the reference to a billing and payment code as a reference to National Drug Codes so qualified as therapeutically equivalent.

''(B) DATE DESCRIBED.—The date described in this paragraph is the date on which the Secretary, pursuant to paragraph (9), eliminates the use of HCPCS Level II codes for drugs and biologicals for purposes described in such paragraph and replaces such codes with

National Drug Codes for such drugs and biologicals.''.

(3) NOTICE IN FEDERAL REGISTER.—The Secretary of Health and Human Services shall, on a date that is not later than 90 days before the date on which the Secretary, pursuant to paragraph (9) of section 1847A(b) of the Social Security Act (42 U.S.C. 1395w–3a(b)), eliminates the use of HCPCS Level II codes for drugs and biologicals for purposes described in such paragraph and replaces such codes with National Drug Codes for such drugs and biologicals, publish in the Federal Register a notification of the HCPCS Level II codes that will be so eliminated and replaced, and of the National Drug Codes that will provide such replacement.

(c) SENSE OF CONGRESS.—It is the sense of the Congress that novel emerging therapies will offer a major step forward in the treatment and curing of diseases, as many of these new and emerging therapies, such as regenerative medicines, novel gene therapies, and new stem cell therapies, will be used across multiple sites of care. The Centers for Medicare & Medicaid Services are urged to begin the development of appropriate billing and payment coding regimes to anticipate the use of these and other new technologies for the treatment and curing of disease.

Subtitle K—Lowering Medicare Patients OOP Costs

SEC. 4221. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

(a) IN GENERAL.—Beginning not later than **[**____**]**, the Director of the National Institute for Standards and Technology, in consultation with the Secretary of Health and Human Services, shall establish and periodically update a searchable public website to disclose to individuals entitled to benefits under part A of title XVIII of the Social Security Act and enrolled for benefits under part B of such title the information described in subsection (b). Such information shall be provided for each payment area involved and shall be accessible by any zip code included in such area, by item or service specified pursuant to subsection (b)(1), and by applicable type of Medicare Advantage plan offered under part C of such title.

(b) INFORMATION.—For purposes of subsection (a), the information described in this subsection, with respect to a payment area, zip code included in such area, and, as applicable, Medicare Advantage plan, is the following:

(1) A list of at **[**least ____**]** the items and services specified by the Secretary, which may be furnished at different types of sites of service and for

which payment may be made under such title at each of such types of sites.

(2) With respect to each item and service so listed—

(A) each type of site of service described in paragraph (1) at which such item or service may be furnished;

(B) a list of providers (and contact information for such providers) within such area and, as applicable, participating in the network of such plan, that furnishes such item and service; and

(C) for each type of site of service specified pursuant to subparagraph (A)—

(i) any criteria required to be satisfied for payment to be made under such title if such item or service were furnished at such a site;

(ii) the maximum out-of-pocket cost, including deductible and cost sharing, responsibility applicable to such an individual if such item or service were furnished at such a site; and

(iii) the rate of payment for such item or service applicable to such a site under

such title, without regard to any deductible or cost sharing.

(c) ASSISTANCE.—The Secretary of Health and Human Services shall provide to the Director of the National Institute for Standards and Technology such assistance as may be necessary for the Director to carry out subsection (a).

(d) CONTRACT AUTHORITY.—The Director may enter into an agreement with an appropriate entity to carry out subsection (a).

(e) CLAIMS DATA.—The Director of the National Institute for Standards and Technology, in collaboration with the Secretary of Health and Human Services, shall determine the extent to which it is feasible for the Director to have access to the claims database of the Centers for Medicare & Medicaid Services to assess individualized (and in real time) the extent to which (and amount by which) an individual described in subsection (a) is subject to a deductible or out-of-pocket cost limitation with respect to items and services specified pursuant to subsection (b)(1) and types of sites of services described in subsection (b)(2)(A) for purposes of enabling such individual to access such information through the database established under subsection (a).

Subtitle L—Global Surgery Services Rule

SEC. 4241. TREATMENT OF GLOBAL SURGERY SERVICES RULE.

Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not implement or enforce any provision of the final rule published on November 13, 2014 (79 Federal Register 67582 through 67591), relating to transitioning and revaluing 10-day and 90-day global surgery services with 0-day global periods.

Subtitle M—Providers Consolidation and Medicare Payments Examined Through Evaluation

SEC. 4261. RULEMAKING THAT IMPLEMENTS CERTAIN MEDICARE PAYMENT CHANGES TO CONSIDER EFFECTS ON PROVIDER CONSOLIDATION.

(a) IN GENERAL.—Beginning for 2016, as part of any annual notice and comment rulemaking process to implement changes to payment systems under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for items and services under title XVIII of the Social Security Act (including those for inpatient and outpatient hospital services, physicians' services, and services furnished by other providers of services and suppliers), the Secretary of Health and Human Services shall seek public comment on

and evaluate the extent to which, and how, such a change is projected to affect provider consolidation.

(b) COORDINATION AND CONSULTATION.—

(1) INTERNAL COORDINATION.—For purposes of conducting the evaluations under subsection (a), the Secretary of Health and Human Services shall ensure appropriate coordination within the Centers for Medicare & Medicaid Services such that experts with respect to the applicable payment system under title XVIII of the Social Security Act work collaboratively for purposes of such evaluations.

(2) CONSULTATION.—For purposes of conducting the evaluations under subsection (a), the Secretary of Health and Human Services may consult with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6), the Federal Trade Commission, other governmental agencies, and private sector entities.

(c) PROVIDER CONSOLIDATION DEFINED.—For purposes of this section, the term ''provider consolidation'' includes the vertical integration among providers of services and suppliers, including professional practices, health care settings, and ancillary services by any entity (such as a health system, group practice, or health insurer).

Subtitle N—Medicare Part D Patient Safety and Drug Abuse Prevention

SEC. 4281. ESTABLISHING PDP SAFETY PROGRAM TO PREVENT FRAUD AND ABUSE IN MEDICARE PRESCRIPTION DRUG PLANS.

(a) PDP SAFETY PROGRAM.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) in paragraph (1)(D)—

(A) by inserting ", designed to" after "program"; and

(B) by inserting ", that includes the procedures described in paragraph (4)" after "waste"; and

(2) by adding at the end the following:

"(4) SAFE PHARMACY ACCESS PROGRAM.—

"(A) PDP SPONSOR PROCEDURES.—A PDP sponsor (or an MA organization offering an MA–PD plan) shall have in place procedures designed—

"(i) to identify an individual who has obtained coverage for a covered part D drug that is a frequently abused schedule II, III, IV, or V controlled substance, as

determined in accordance with utilization guidelines established by the Secretary and the sponsor (or MA organization), and to notify such individuals that they have been so identified;

''(ii) to contract with pharmacies authorized to dispense such controlled substances to create a safe pharmacy network that meets the criteria specified in subparagraph (C);

''(iii) taking into account the location of the individual's residence (or residences), work site, mobility, and other relevant factors, to limit coverage to schedule II, III, IV, or V controlled substances for some or all classes of covered part D drugs for an individual identified under clause (i) (or under subparagraph (B)) to drugs dispensed by one or more pharmacies contracted with under clause (ii);

''(iv) to provide to the Secretary the name, and other information that the Secretary may require, of individuals so identified and of the fact of such individual's disenrollment (if any) from the plan of the

sponsor (or the MA–PD plan offered by the MA organization);

"(v) to provide for an appeals process whereby an individual so identified may appeal such identification on the basis that the identification was not appropriate;

"(vi) to provide for a process whereby an individual so identified may petition for the termination of such identification on the basis that the limitation on coverage is no longer necessary to prevent fraud and abuse by the individual; and

"(vii) to provide that coverage shall be provided for a schedule II, III, IV, or V controlled substance only if it is prescribed in accordance with an electronic prescribing program under subsection (e), except in such exceptional circumstances as the Secretary may permit.

"(B) SHARING INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall share information, with respect to the identity of an individual identified under subparagraph (A)(i) who disenrolls from a plan under subparagraph (A)(iv), with a PDP spon-

sor (or MA organization) that subsequently enrolls such individual under another plan in order that the provisions of subparagraph (A)(iii) would apply under such subsequent enrollment.

''(C) SAFE PHARMACY NETWORK CRITERIA.—The criteria specified in this subparagraph for a safe pharmacy network are the following:

''(i) The pharmacies in the network are able to properly monitor the usage of schedule II, III, IV, and V controlled substances.

''(ii) Such pharmacies and network meet such other drug safety criteria as the Secretary or the PDP sponsor (or MA organization) determines to be appropriate, such as use of a State prescription drug monitoring program, if such a program is available in the State.''.

(b) DUAL ELIGIBLES.—Section 1860D–1(b)(3)(D) of the Social Security Act (42 U.S.C. 1395w–101(b)(3)(D)) is amended by inserting '', subject to such limits as the Secretary may establish for individuals identified pursuant to section 1860D–4(c)(4)(A)(i)'' after ''the Secretary''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning after the date that is 8 months after the date of the enactment of this Act.

SEC. 4282. PART D SUSPENSION OF CLAIMS PAYMENT.

Section 1860D–12(b)(4) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)) is amended by adding at the end the following new subparagraph:

"(H) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—

"(i) IN GENERAL.—A PDP sponsor may suspend payments and clean claim notifications to a pharmacy pending an investigation of a credible allegation of fraud (as defined in clause (ii)) against the pharmacy, unless the Secretary determines there is a good cause not to suspend payments.

"(ii) CREDIBLE ALLEGATION OF FRAUD DEFINED.—In this subparagraph, the term 'credible allegation of fraud' includes—

"(I) a complaint made on the Medicare fraud hotline;

''(II) detection of potential fraud through the analysis of claims data;

''(III) detection of potential fraud through identification of inappropriate dispensing through audits, civil false claims cases, and law enforcement investigations; and

''(IV) claims referred to Medicare drug integrity contractors (MEDICs).

''(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as limited the authority of a PDP sponsor to conduct postclaim payment review.''.

SEC. 4283. IMPROVING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).

(a) IN GENERAL.—Section 1893 of the Social Security Act (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

''(j) IMPROVING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

''(1) IN GENERAL.—Under contracts entered into under this section (each in this subsection referred to as a 'MEDIC contract') with Medicare drug integrity contractors (each in this subsection

referred to as a 'MEDIC'), the Secretary shall authorize MEDICs to directly obtain prescription and medical records from entities such as pharmacies, PDP and physicians.

''(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor refers information to a MEDIC for investigation, under the MEDIC contract the MEDIC must acknowledge receipt of the referral and must report back to the sponsor the result of the MEDIC's investigation within 45 days of the date of the referral and share such results with appropriate agencies, such as law enforcement officials and State licensing authority.

''(3) UNIFORM ANNUAL REPORT CRITERIA.—In order to assess the performance of MEDICs, the Secretary shall develop a uniform reporting criteria for the annual reporting of the results of investigations by MEDICs to the Secretary and to Congress. Each such annual report shall include information on the number of referrals for investigation made to a MEDIC, the average time required for investigation, the results of the investigation, and the number of results that were referred to the Inspector General of the Department of Health and Human Serv-

ices and to State licensing officials for further investigations.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply as quickly as possible to MEDIC contracts, including MEDIC contracts entered into before such date of enactment.

SEC. 4284. REQUIRING E-PRESCRIBING FOR COVERAGE OF COVERED PART D CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e)) is amended by adding at the end the following:

''(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—Except in such emergent circumstances as the Secretary may specify, coverage shall not be provided for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance unless the prescription for the drug has been transmitted electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2015.

Subtitle O—Accelerating Innovation in Medicine

SEC. 4301. ESTABLISHMENT OF MANUFACTURER OPT-OUT PROGRAM FOR MEDICAL DEVICES.

(a) IN GENERAL.—Section 1862 of the Social Security Act (42 U.S.C. 1395y) is amended by adding at the end the following new subsection:

''(p) ESTABLISHMENT OF ACCELERATING INNOVATION IN MEDICINE (AIM) LIST OF MEDICAL DEVICES VOLUNTARILY EXCLUDED FROM COVERAGE.—

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this subsection, the Secretary shall develop and maintain a listing (in this section referred to as the 'AIM list') of medical devices for which, because of their inclusion in such listing, no insurance benefit and no payment may be made for such a device under this title either directly or on a capitated basis such that no claim for payment may be submitted under this title for such a device and an individual who consents to receive such a device is responsible for payment for

the device and services related to furnishing the device.

''(2) PROCEDURES FOR INCLUSION IN AIM LIST.—

''(A) REQUIREMENT FOR WRITTEN CONSENT OF MANUFACTURER.—No medical device may be included in the AIM list without the written consent of the manufacturer of the device.

''(B) SUBMISSION PROCESS.—A manufacturer seeking to have a medical device included in the AIM list shall submit to the Secretary a request for inclusion of the device in the AIM list. In the case of such a device for which—

''(i) there is a request for approval or clearance for marketing and sale of the device by the Food and Drug Administration pursuant to authority granted by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including pursuant to section 510(k) or 515(c) of such Act (21 U.S.C. 360(k), 360e(c)), the request for inclusion of the device in the AIM list may not be submitted earlier than the date of the request for such approval or clearance

and no later than the first business day of the month beginning at least 30 days after the date of such approval or clearance; or

''(ii) the device is exempt from such approval and clearance requirements, the request may be submitted at a time that is not later than the first business day of the month beginning at least 30 days after the date of the first sale of the device by its manufacturer.

''(3) LISTING PERIODS; REMOVAL FROM LIST.—

''(A) 3-YEAR LISTING PERIODS.—A medical device included in the AIM list shall be initially listed for a period of 3 years and shall remain so listed for subsequent 3-year periods subject to subparagraphs (B) and (C).

''(B) REMOVAL AT REQUEST OF MANUFACTURER.—At any time a device of a manufacturer included in the AIM list shall be removed from the AIM list upon the written request of the manufacturer. Subject to subparagraph (C), such a device of a manufacturer may not be removed from the AIM list except upon the written request of the manufacturer.

"(C) PROVISION OF DATA ON CLINICAL STUDIES AS A CONDITION FOR CONTINUED LISTING.—As a condition for the continued inclusion of the device of a manufacturer in the AIM list for a subsequent 3-year listing period under subparagraph (A), the manufacturer shall provide the Secretary with published or publicly available data on clinical studies completed for the device at the end of the previous 3-year listing period. If the Secretary determines that a manufacturer of a device has materially failed to provide such data for the device, the Secretary may remove the device from the AIM list or not renew the listing for the device or both.

"(4) MEDICAL DEVICE DEFINED.—In this subsection, the term 'medical device' has the meaning given the term 'device' in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

"(5) POSTING OF LISTED DEVICES ON WEBSITE.—The Secretary shall post on a public website of the Department of Health and Human Services or other publicly accessible manner a list of the medical devices included in the AIM list and

shall provide for updating the website on a real-time basis (but no less frequently than monthly) to reflect changes in the medical devices in the AIM list.

''(6) REGULATIONS NOT REQUIRED.—Nothing in this subsection shall be construed as requiring the Secretary to promulgate regulations to carry out this subsection.

''(7) REQUIREMENT FOR INFORMED CONSENT IN ORDER FOR PROVIDER TO CHARGE FOR DEVICE.—If a physician or other entity furnishes a medical device included in the AIM list to an individual under this title and failed to obtain, before furnishing the device, an appropriate informed consent under which the individual is informed of and accepts liability under paragraph (1) for payment for the device (and related services), the physician or other entity is deemed to have agreed not to impose any charge under this title for such device (and for services related to furnishing the device).''.

(b) CONFORMING AMENDMENT.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (24), by striking ''or'' at the end;

(2) in paragraph (25), by striking the period at the end and inserting ''; or''; and

(3) by inserting after paragraph (25) the following new paragraph:

''(26) where such expenses are for a medical device included in the AIM list under section 1862(p) or for items and services related to furnishing such device.''.

Subtitle P—Medicare Pharmaceutical and Technology Ombudsman

SEC. 4321. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808(c) of the Social Security Act (42 U.S.C. 1395b–9(c)) is amended by adding at the end the following new paragraph:

''(4) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—Not later than 12 months after the date of the enactment of this paragraph, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

''(A) are from entities that manufacture pharmaceutical, biotechnology, medical device,

or diagnostic products that are covered or for which coverage is being sought under this title; and

"(B) regard coverage, coding, or payment under this title for such products.

The ombudsman shall submit to Congress an annual report on the activities carried out under this paragraph".

Subtitle Q—Ensuring Local Medicare Administrative Contractors Evaluate Data Related to Category III Codes

SEC. 4341. ENSURING LOCAL MEDICARE ADMINISTRATIVE CONTRACTORS EVALUATE DATA RELATED TO CATEGORY III CODES.

Section 1874A of the Social Security Act (42 U.S.C. 1395kk–1) is amended—

(1) in subsection (a)(4), by inserting ", subject to subsection (b)(3)(D)," after "(including"; and

(2) in subsection (b)(3), by adding at the end the following new subparagraph:

"(D) DATA EVALUATION REQUIREMENT FOR LOCAL COVERAGE DETERMINATIONS.—The Secretary shall include, as one of the requirements developed under subparagraph (A), a re-

quirement that a medicare administrative contractor performing the function of developing local coverage determinations (as described in subsection (a)(4)) with respect to an item or service included as a Current Procedural Terminology Code that is a Category III Code shall, prior to developing such a determination with respect to such an item or service, evaluate all data related to such code.''.

Subtitle R—Advancing Care for Exceptional Kids

SEC. 4361. FINDINGS.

Congress finds the following:

(1) Approximately 3,000,000 children in the United States suffer from medically complex conditions and approximately 2,000,000 of such children are enrolled in State plans under the Medicaid program under title XIX of the Social Security Act.

(2) Such children account for an estimated 6 percent of Medicaid enrollees and approximately 40 percent of children's Medicaid spending is due to the severity of the illnesses of such children.

(3) The creation of nationally designated children's hospital networks focused upon better coordination and integration of care for such pediatric

population will result in improved health outcomes and savings under the Medicaid program and the Children's Health Insurance Program under title XXI of the Social Security Act.

SEC. 4362. ESTABLISHMENT OF MEDICAID AND CHIP CARE COORDINATION PROGRAM FOR CHILDREN WITH MEDICALLY COMPLEX CONDITIONS AS MEDICAID STATE OPTION.

(a) MEDICAID.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(1) in section 1905(a) (42 U.S.C. 1396d(a))—

(A) by striking ''and'' at the end of paragraph (27);

(B) by redesignating paragraph (29) as paragraph (30); and

(C) by inserting after paragraph (28) the following new paragraph:

''(29) items and services furnished under an MCCC program under section 1947 to eligible children enrolled in an MCCC program under such section.''; and

(2) by adding at the end the following new section:

"SEC. 1947. MEDICAID CHILDREN'S CARE COORDINATION PROGRAMS FOR CHILDREN WITH COMPLEX MEDICAL CONDITIONS.

"(a) IN GENERAL.—Beginning January 1, 2015, a State, at its option as a State plan amendment, may elect to provide medical assistance for items and services furnished to eligible children enrolled in an MCCC program that meets the requirements of this section. As a condition on an eligible child's receipt of medical assistance under this title, the State shall require, under such an amendment, that the eligible child be enrolled in an MCCC program that meets the requirements of this section.

"(b) MCCC PROGRAM REQUIREMENTS.—An MCCC program meets the requirements of this section if the MCCC program—

"(1) coordinates, integrates, and provides for the furnishing of the full range of MCCC program services to eligible children enrolled in the program;

"(2) enrolls eligible children in accordance with subsection (c);

"(3) is operating under a program agreement that meets the requirements of subsection (d); and

"(4) meets the pediatric network adequacy standards developed under subsection (e).

"(c) ELIGIBILITY DETERMINATIONS; ASSIGNMENT.—

''(1) ENROLLMENT.—Subject to the assignment requirements of paragraph (2), the enrollment and disenrollment of eligible children in an MCCC program shall be carried out in accordance with regulations issued by the Secretary and the applicable program agreement.

''(2) NETWORK ASSIGNMENT.—

''(A) IN GENERAL.—Eligible children shall be prospectively enrolled in an MCCC program by initially assigning such eligible children to a nationally designated children's hospital network for a period of not less than 90 days beginning on the date on which the child is initially assigned to such hospital network.

''(B) BASIS FOR INITIAL ASSIGNMENT.—Such an assignment shall be based upon any of the following factors (or a combination thereof):

''(i) The prevalence of visits by the child to a pediatrician or other specialist who is participating in the nationally designated children's hospital network.

''(ii) The selection of the child's family.

''(iii) The location of the primary residence of the child.

''(iv) The proximity of the child to regional referral networks established by the nationally designated children's hospital network.

''(C) LIMITATION ON CERTAIN ASSIGNMENTS.—An assignment of a child under clause (iii) or (iv) of subparagraph (B) may only be made in the case of a nationally designated children's hospital network that offers medical home access within 30 miles of the primary residence of the child.

''(D) REASSIGNMENT.—Following the 90-day period referred to in subparagraph (A), the child may elect—

''(i) to be assigned to the nationally designated children's hospital network of their choice that has an MCCC program agreement in effect with respect to an MCCC program in which the child is eligible to enroll; or

''(ii) to not participate in any MCCC program and receive care through enrollment in the State plan under this title or the State child health plan under title XXI.

''(d) PROGRAM AGREEMENTS.—

''(1) IN GENERAL.—The Secretary, in close cooperation with the State administering agencies electing to provide the medical assistance described in subsection (a), shall establish procedures for entering into, extending, and terminating program agreements under this section.

''(2) TERMS.—

''(A) IN GENERAL.—A program agreement entered into under this section by the Secretary, a State administering agency, and a nationally designated children's hospital network shall provide for each of the following terms:

''(i) The agreement shall designate the service area of the MCCC program that is the subject of the agreement.

''(ii) The agreement shall be effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate, and is subject to termination by the Secretary and the State administering agency at any time for cause (as provided under the agreement).

''(iii) The agreement shall require that the nationally designated children's hospital network submit care management network and coverage plans to the Secretary that are centered around medical home models and that describe the governance of the network.

''(iv) The agreement shall require the hospital network to meet all applicable requirements imposed by State and local laws.

''(v) The agreement shall require such State, in the case of eligible children who are residents of the State, to make payments to the hospital network, regardless of whether MCCC program services are furnished to such eligible children in another State.

''(vi) The agreement shall require that the standards and measures developed under subsection (e) be applied to the hospital network, including measures requiring, with respect to network adequacy standards, that the hospital network establish such provider networks for primary,

secondary, and tertiary care as are necessary to ensure the adequate furnishing of MCCC program services to eligible children enrolled in the MCCC program that is the subject of the agreement.

''(vii) The agreement shall require the hospital network to comply with the data collection and recordkeeping requirements of subparagraph (C).

''(viii) The agreement shall require the hospital network to accept as payment any payment made using the risk-based methodology developed under subsection (g).

''(ix) The agreement shall contain such additional terms and conditions as the parties may agree to, so long as such terms and conditions are consistent with this section.

''(B) SERVICE AREA OVERLAP.—In designating a service area under subparagraph (A)(i), the Secretary (in consultation with the relevant State administering agency) shall consider the impacts of designating an area that is already covered under another program agree-

ment, for purposes of avoiding the unnecessary duplication of services and the impairment of the financial and service viability of another MCCC program.

''(C) DATA AND RECORDKEEPING REQUIREMENTS.—The data collection and recordkeeping requirements under this subparagraph, with respect to a nationally designated children's hospital network, are as follows:

''(i) The hospital network shall collect claims data on claims submitted with respect to eligible children who are furnished MCCC program services under an MCCC program. Such data shall be reported in a standardized format and made available to the public for purposes of establishing a national database on such claims.

''(ii) The hospital network shall maintain, and provide the Secretary and the State administering agency access to, the records relating to the MCCC program operated by the hospital network, including pertinent financial, medical, and personnel records.

"(iii) The hospital network shall submit to the Secretary and the State administering agency such reports as the Secretary finds (in consultation with the State administering agency) necessary to monitor the operation, cost, and effectiveness of the MCCC program operated by the hospital network.

"(3) TERMINATION OF AGREEMENTS.—The Secretary shall issue regulations establishing the circumstances under which—

"(A) the Secretary or a State administering agency may terminate an MCCC program agreement for cause; and

"(B) a nationally designated children's hospital network may terminate such an agreement after appropriate notice to the Secretary, the State administering agency, and enrollees.

"(e) QUALITY ASSURANCE.—

"(1) DEVELOPMENT OF STANDARDS AND MEASURES.—The Secretary shall, in consultation with nationally designated children's hospital networks and national pediatric policy organizations (such as the Children's Hospital Association and the American Academy of Pediatrics)—

"(A) establish a national set of quality assurance and improvement protocols and procedures to apply under MCCC programs;

"(B) develop pediatric quality measures;

"(C) develop pediatric network adequacy standards for access by eligible children to MCCC program services; and

"(D) develop criteria for national pediatric-focused care coordination for eligible children.

"(2) USE OF PQMP MEASURES.—In carrying out subparagraph (A), the Secretary shall apply, to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under this title, title XXI, and section 1139A and take into account HEDIS quality measures as required under section 1852(e)(3) and other quality measures.

"(f) STANDARD MEDICAID DATA SET.—

"(1) IN GENERAL.—The Secretary, the States, and the nationally designated children's hospital networks shall collaborate to obtain consistent and verifiable Medicaid Analytic Extract data or a comparable data set and shall establish data-sharing agreements to further support collaborative planning

and care coordination for medically complex children.

"(2) CLAIMS ANALYSIS.—The Secretary shall—

"(A) perform claims analysis on the data set developed under paragraph (1) to determine the utilization of items and services furnished under an MCCC program to eligible children; and

"(B) submit to Congress and make publicly available on the Website of the Centers for Medicare & Medicaid services, a report on such claims in a standardized format for purposes of building a national database.

"(3) PAYMENT FOR REPORTING INCENTIVES.—The Secretary may provide for pay-for-reporting incentives during the first two years of any MCCC program agreement entered into under this section to ensure participation and analysis of consistent data under this paragraph to enable the development of an appropriate risk-based payment methodology under subsection (g).

"(g) PAYMENTS TO NATIONALLY DESIGNATED CHILDREN'S HOSPITAL NETWORKS.—

"(1) IN GENERAL.—The State plan shall provide for payment to nationally designated children's

hospital networks pursuant to the terms of an MCCC program agreement using a risk-based payment methodology (or methodologies) established by the Secretary in accordance with this subsection.

''(2) TRANSITION FROM FEE-FOR-SERVICE TO RISK-BASED PAYMENT MODEL.—

''(A) IN GENERAL.—Payment to nationally designated children's hospital networks under this subsection shall be based initially on a fee-for-service payment model and shall gradually transition, over a 5-year period, to an equitable, risk-based payment model using a methodology developed under paragraph (3). For the first two years of such period, a nationally designated children's hospital network may receive, in addition to any fee-for-service payments made to such hospital network, per capita care coordination payments with respect to expenditures for items and services furnished to eligible children enrolled in the MCCC program operated by the hospital network through medical home programs and other care coordination activities for which an all-inclusive payment model is more suitable than fee-for-service reimbursement.

"(B) DATA ANALYSIS DURING INITIAL PERIOD.—During the first two years of the implementation of an MCCC program, the Secretary shall analyze data collected under subsection (f) for purposes of developing a risk-based payment methodology that would be implemented beginning with the third year of implementation of the MCCC program.

"(3) DEVELOPMENT OF RISK-BASED PAYMENT METHODOLOGY.—The Secretary shall develop payment methodologies under this subsection in coordination with the Medicaid and CHIP Payment and Access Commission and the pediatric health care provider community that—

"(A) take into account the data analyzed under paragraph (2)(B);

"(B) are actuarially sound, as determined by the Secretary and the relevant State administering agency, in coordination with National Association of Insurance Commissioners, using an actuarial methodology that is adopted using historic pediatric claims data;

"(C) include—

"(i) a risk adjustment method, re-insurance system, and risk-corridor proce-

dure to account for variations in acuity of the eligible children enrolled in MCCC programs; and

''(ii) a shared-savings component; and

''(D) may provide for a model for making payments other than payments made on a per-member, per-month basis.

''(h) WAIVERS OF REQUIREMENTS.—With respect to carrying out an MCCC program under this section, the following provisions of law shall not apply:

''(1) Section 1902(a)(1), relating to statewideness.

''(2) Section 1902(a)(10), insofar as such section relates to comparability of services among different population groups.

''(3) Sections 1902(a)(23) and 1915(b)(4), relating to freedom of choice of providers.

''(4) Section 1903(m)(2)(A), insofar as such section would prohibit a nationally designated children's hospital network from receiving certain payments.

''(5) Such other provisions of this title, title XVIII, sections 1128A and 1128B, and any provisions of the Federal antitrust laws as the Secretary determines are inapplicable or the waiver of which

are necessary for purposes of carrying out an MCCC program under this section.

''(i) PREEMPTION OF STATE LAW.—A State may not impose any requirement on the nationally qualified children's hospital network's operation of an MCCC program under a program agreement that meets the requirements of this section that is inconsistent with or would otherwise impede the satisfaction by such hospital network of the requirements of this section (including the requirements of such program agreement).

''(j) DEFINITIONS.—In this section:

''(1) ELIGIBLE CHILD.—The term 'eligible child' means, with respect to an MCCC program, an individual who is under the age of 18 and who—

''(A) is eligible for medical assistance under the State plan under this title or child health assistance under the State child health plan under title XXI; and

''(B) has, or is at a heightened risk of developing, a chronic, physical, developmental, behavioral, or emotional condition that—

''(i) affects two or more body systems;

''(ii) requires intensive care coordination to avoid excessive hospitalizations or emergency department visits; or

"(iii) meets the criteria for medical complexity using risk adjustment methodologies (such as Clinical Risk Groups) agreed upon by the Secretary in coordination with a national panel of pediatric experts.

"(2) MCCC PROGRAM.—The term 'MCCC program' means a Medicaid coordinated care program that provides eligible children with MCCC program services through a nationally designated children's hospital network in accordance with a program agreement that meets the requirements of subsection (d).

"(3) MCCC PROGRAM SERVICES.—The term 'MCCC program services' means the full range of items and services for which medical assistance is available under a State plan for children, including pediatric care management services and pediatric-focused care coordination and health promotion, as specified in the program agreement.

"(4) QUALIFIED CHILDREN'S HOSPITAL.—The term 'qualified children's hospital' means a children's hospital that—

"(A) qualifies to receive payment under section 340E of the Public Health Service Act

(relating to children's hospitals that operate graduate medical education programs); or

"(B) meets 3 or more of the following criteria:

"(i) MINIMUM PEDIATRIC DISCHARGES.—The hospital has at least 5,000 annual pediatric discharges (including neonates, but excluding obstetrics and normal newborns) for the most recent cost reporting period for which data are available.

"(ii) MINIMUM NUMBER OF BEDS.—The hospital has 100 licensed pediatric beds, not including beds in neonatal intensive care units but including beds in pediatric intensive care units and other acute care beds.

"(iii) ACCESS TO PEDIATRIC EMERGENCY SERVICES.—The hospital has access (through ownership or otherwise) to pediatric emergency services.

"(iv) MEDICAID RELIANT.—At least 30 percent of the pediatric discharges or inpatient days (excluding observation days) in the hospital for the most recent cost reporting period for which data are available

were children eligible for medical assistance under this title or for children's health assistance under title XXI.

''(v) AFFILIATION WITH ACCREDITED PEDIATRIC RESIDENCY TRAINING PROGRAM.—The hospital sponsors or is affiliated with a pediatric residency program that is accredited by the Accreditation Council for Graduate Medical Education.

''(vi) PEDIATRIC MEDICAL HOME PROGRAMS.—The hospital has established and implemented demonstrable pediatric medical home programs dedicated to medically complex children.

''(5) NATIONALLY DESIGNATED CHILDREN'S HOSPITAL NETWORK.—The term 'nationally designated children's hospital network' means a network of hospitals and health care providers—

''(A) anchored by a qualified children's hospital or hospitals with principal governance responsibility over the hospital network;

''(B) in which the full complement of health care providers needed to provide the best care for children in the network participate; and

''(C) that represents the interests of physicians, other health care providers, parents of medically complex children, and other relatives of such children.

''(6) PROGRAM AGREEMENT.—The term 'program agreement' means, with respect to a nationally designated children's hospital network, an agreement, between the hospital network, the Secretary, and a State administering agency for the operation of an MCCC program by the hospital network in the State that meets the requirements of this section.

''(7) STATE ADMINISTERING AGENCY.—The term 'State administering agency' means, with respect to the operation of an MCCC program in a State, the agency of that State (which may be the single agency responsible for administration of the State plan under this title in the State) responsible for administering program agreements under this section.''.

(b) APPLICATION UNDER CHIP.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended by adding at the end the following new subparagraph:

"(P) Section 1947 (relating to Medicaid children's care coordination programs for children with complex medical conditions).".

(c) REGULATIONS.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall make rules on the record, after opportunity for an agency hearing to carry out the amendments made by this section in accordance with sections 556 and 557 of title 5, United States Code.

Subtitle S—Continuing Medical Education Sunshine Exemption

SEC. 4381. EXEMPTING FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES.

(a) IN GENERAL.—Section 1128G(e)(10)(B) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is amended—

(1) in clause (iii), by inserting ", including peer-reviewed journals, journal reprints, journal supplements, and medical textbooks" after "patient use"; and

(2) by adding at the end the following new clause:

"(xiii) A transfer of anything of value to a covered recipient who is a physician if

the thing of value is intended solely for purposes of providing continuing medical education to the physician.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to transfers of value made on or after the date of the enactment of this Act.

Subtitle T—Medical Testing Availability

SEC. 4401. CLARIFICATION REGARDING RESEARCH USE ONLY PRODUCTS.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following subsection:

''(o) PRODUCTS WITH RESEARCH USE ONLY LABELING.—

''(1) IN GENERAL.—A product whose labeling bears the statement described in section 809.10(c)(2)(i) of title 21, Code of Federal Regulations, as in effect on the date of the enactment of this subsection, may not be deemed to be adulterated or misbranded under this Act on the basis that the manufacturer or distributor of the product—

''(A) sells the product to an end user who uses the product in a manner inconsistent with such statement; or

''(B) engages in business communications regarding the product with an end user of the product.

''(2) BUSINESS COMMUNICATIONS DEFINED.—In this subsection, the term 'business communications', with respect to a product with labeling described in paragraph (1)—

''(A) means oral, written, or electronic contact between a manufacturer or distributor of such product and an end user regarding the functioning of such product; and

''(B) includes any such contact consisting of technical support, customer service, assistance with the installation of such product, communication relating to ensuring the performance of the product, and other similar contacts.

''(3) SUNSET.—This subsection shall cease to be effective on the last day of the five-year period beginning on the date of enactment of this section.''.

TITLE V—MODERNIZING MEDICAL PRODUCT REGULATION

Subtitle A—Manufacturing Incentives

SEC. 5001. EXTENSION OF EXCLUSIVITY PERIOD FOR AMERICAN-MANUFACTURED GENERIC DRUGS AND BIOSIMILARS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 2101, is further amended by inserting after section 505H of such Act (21 U.S.C. 355f) the following:

"SEC. 505I. EXTENSION OF EXCLUSIVITY PERIOD FOR AMERICAN-MANUFACTURED GENERIC DRUGS AND BIOSIMILARS.

"(a) DESIGNATION.—The Secretary shall designate a drug (including a biological product) as an American-manufactured drug for purposes of granting the extensions under subsection (b) if—

"(1) an application is submitted for approval or licensure of such drug under section 505(j) of this Act or section 351(k) of the Public Health Service Act;

"(2) the manufacturer or the sponsor of the drug includes in such application a request for designation of the drug as an American-manufactured

drug [*What additional or different requirements (relative to those set forth in paragraph (3)) should a manufacturer have to meet in order to receive the designation as an American-manufactured drug?*]; and

"(3) the request demonstrates to the Secretary's satisfaction that all quantities of the drug intended to be marketed in the United States will be manufactured, prepared, propagated, compounded, and processed, as applicable, in the United States.

"(b) EXTENSION.—If the Secretary designates a drug as an American-manufactured drug, as described in subsection (a)—

"(1) the 180-day period described in clause (iv) of section 505(j)(5)(B) shall be extended by [_____]; or

"(2) the period of 1 year, 18 months, or 42 months, as applicable, described in section 351(k) of the Public Health Service Act shall be extended by [_____].

"(c) LIMITATIONS.—Subsection (b) does not apply to the approval of—

"(1) a supplement to an application under section 505(j) of this Act for a drug or under section 351(k) of the Public Health Service Act for a bio-

logical product for which an extension described in subsection (b) is in effect or has expired; or

''(2) a subsequent application filed with respect to a drug approved under section 505(j) or a biological product licensed under section 351(k) for a change that results in a new route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength.''.

(b) APPLICATION.—Section 505I of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved or licensed under section 505(j) of such Act (21 U.S.C. 355(j)) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) on or after the date of the enactment of this Act.

Subtitle B—21st Century Manufacturing

SEC. 5021. UPDATING REGULATIONS AND GUIDANCE ON CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, and taking into consideration modern manufacturing techniques, shall issue final regulations and guidance, as appli-

cable, updating the regulations and guidance for ensuring that drugs are manufactured, processed, packed, and held in conformity with current good manufacturing practice requirements, including the requirements under section 501(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(1)).

Subtitle C—Controlled Substance Manufacturing and Exports

SEC. 5041. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.

Section 1003(f) of the Controlled Substances Import and Export Act (21 U.S.C. 953(f)) is amended—

(1) in paragraph (5)—

(A) by striking ''(5)'' and inserting ''(5)(A)'';

(B) by inserting '', except that the controlled substance may be exported from the second country to another country that is a member of the European Economic Area'' before the period at the end; and

(C) by adding at the end the following:

''(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that

is a member of the European Economic Area to any other such country, provided that—

''(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substances is exported pursuant to this paragraph; and

''(ii) the conditions applicable with respect to the second country under such paragraphs are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph.''; and

(2) by adding at the end the following:

''(g) LIMITATION.—The Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation among European Economic Area countries (as provided in subsection (f)(5)), including by promulgating or enforcing any requirement that—

''(1) re-exportation from the first country to the second country or re-exportation from the second country to another country (as such terms are used in subsection (f)) occur within a specified period of time; or

''(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States.''.

Subtitle D—Medical Device Reforms

SEC. 5061. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A of such Act (21 U.S.C. 360n–1) the following:

''SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

''(a) ACCREDITATION AND ASSESSMENT.—

''(1) RELIANCE ON ACCREDITED PERSONS.— [*need more specificity. what types of changes: technology, manufacturing, modifications that do not alter a device's fundamental technology, and labeling – are appropriate for this type of certification, if any? What types of changes are not appropriate, if any?*]The Secretary shall rely on persons accredited under section 523 or under this section to assess and certify a facility's capability to evaluate and implement—

''(A) technology changes to devices that were found to be substantially equivalent to a

predicate device for purposes of classification under section 513(f);

"(B) changes in the manufacturing of a device;

"(C) changes that do not alter a device's fundamental technology; and

"(D) labeling changes described in section 814.39(d) of title 21, Code of Federal Regulations (or any successor regulations).

"(2) ASSESSMENTS.—An assessment pursuant to paragraph (1) shall assess the facility in which a device is manufactured or designed and determine whether the facility's quality system, including the facility's design controls, is capable of evaluating, on a continuing basis, the types of changes listed in paragraph (1) so as to provide a reasonable assurance of safety and effectiveness.

"(3) ACCREDITATION PROCESS.—

"(A) IN GENERAL.—Except as inconsistent with this section, the process and qualifications for accreditation of persons, and renewal of such accreditation, under section 523 shall apply with respect to accreditation of persons, and renewal of such accreditation, under this section.

''(B) EXCEPTIONS.—The provisions of subsections (a)(2), (a)(3), and (c) of section 523 shall not apply for purposes of this section.

''(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

''(A) INITIATION OF SERVICES.—Use of one or more accredited persons to assess changes listed in paragraph (1), with respect to a device, shall be at the initiation of the person who registers and lists the device under section 510.

''(B) COMPENSATION.—Compensation for such accredited persons shall—

''(i) be determined by agreement between the accredited person and the person who engages the services of the accredited person; and

''(ii) be paid by the person who engages such services.

''(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a facility's quality system, as described in paragraphs (1) and (2), shall select the accredited person from a list of such per-

sons published by the Secretary in the Federal register for purposes of this section.

''(b) EFFECT OF THIRD-PARTY ASSESSMENT.—

''(1) DETERMINATION EFFECT.—If a facility is determined by an accredited person to have a quality system, as described in subsection (a)(2), then the facility need not submit a premarket notification under section 510(k) nor a supplement under section 515(d)(6) with respect to any change listed in subsection (a)(1), so long as the accredited person determines, in writing, that the change is in compliance with the requirements of this Act and the regulations thereunder, including part 820 of title 21, Code of Federal Regulations (or any successor regulations).

''(2) DURATION.—A determination under paragraph (1)—

''(A) shall remain in effect for a period of two years from the date of such determination, and may be renewed through the process described in this section; and

''(B) shall continue to apply with respect to changes made during such two-year period, irrespective of whether such determination is renewed after such two-year period.''.

SEC. 5062. VALID SCIENTIFIC EVIDENCE.

Section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

(1) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(2) by striking ''(B) If the Secretary'' and inserting ''(B)(i) If the Secretary''; and

(3) by adding at the end the following:

''(ii)(I) Valid scientific evidence for purposes of clause (i) means evidence described in well-documented case histories, including registry data, that are collected and monitored under an acceptable protocol, and studies published in peer-reviewed journals that are internationally recognized as authoritative sources of information.

''(II) The data from studies published in a journal described in subclause (I) shall be presumed valid based on the peer-review process that supports publication of the studies, and the Secretary may not require submission of the data for the Secretary's review.

''(III) Valid scientific evidence may include data collected in countries other than the United States so long as such data otherwise meets the criteria specified in subclause (I).''.

SEC. 5063. TRAINING AND OVERSIGHT IN LEAST BURDENSOME MEANS CONCEPT.

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by inserting after subsection (i) the following:

''(j) TRAINING AND OVERSIGHT IN LEAST BURDENSOME MEANS CONCEPT.—

''(1) TRAINING.—Each employee of the Food and Drug Administration who is involved in the review of premarket submissions under section 515 or section 510(k), including supervisors, shall receive training regarding the meaning and implementation of the least burdensome means concept in the context of the use of that term in subsections (a)(3)(D) and (i)(1)(D). Such training shall include consideration of when advisory panels are appropriate and necessary to review premarket submissions under section 515 or section 510(k). The Secretary shall require that each such employee receive re-training on an annual basis to reinforce the initial training received by such employee under this paragraph regarding the meaning and implementation of such concept.

''(2) GUIDANCE DOCUMENTS.—

''(A) IN GENERAL.—The Secretary shall ensure that adequate guidance documents de-

scribing the least burdensome means concept set forth in subsections (a)(3)(D) and (i)(1)(D) and its implementation are available to the persons involved in the review of premarket submissions under section 515 or 510(k). Such guidance documents shall include tools that such persons may use to ensure adherence to the least burdensome means concept, such as an evidentiary matrix based on a device type's benefits and risks.

''(B) PUBLICATION.—The Secretary shall publish updated guidance documents, as required by subparagraph (A), not later than 12 months after the date of enactment of this subsection. In developing such guidance documents, the Secretary shall convene a meeting of stakeholders to ensure a full record to support the publication of such guidance.

''(3) OMBUDSMAN AUDIT.—The ombudsman for the organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall conduct, or have conducted, an audit of such organizational unit to determine the unit's performance in implementing the least burdensome means concept set forth in subsections (a)(3)(D) and

(i)(1)(D). Such ombudsman shall include in such audit interviews with a representative sample of persons from industry regarding their experience in the device premarket review process.''.

SEC. 5064. RECOGNITION OF STANDARDS.

Section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d) is amended—

(1) in subsection (c)(1)—

(A) in subparagraph (A)—

(i) by striking ''shall'' and inserting ''may''; and

(ii) by striking ''all or part of an appropriate standard'' and inserting ''any standard applicable to devices that is''; and

(B) by striking subparagraph (B) and inserting the following new subparagraph:

''(B) The publication under subparagraph (A) with respect to the Secretary's recognition of a standard described in such subparagraph shall be made not later than 60 days after the date on which the applicable standard development organization makes such standard available. If the Secretary chooses not to recognize a standard described in such subparagraph, the Secretary shall publish in

the Federal Register the basis for refusing to recognize the standard.''; and

(2) by adding at the end the following:

''(d) TRAINING ON USE OF STANDARDS.—The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices training on the concept and use of recognized standards to facilitate the premarket review of devices and to provide reasonable assurance of safety and effectiveness, including standards relevant to an employee's area of device review. Such training shall be provided—

''(1) to all new employees of the Food and Drug Administration who are involved in such review, not later than 30 days of the commencement of their employment; and

''(2) to other employees of the Administration involved in such review, on an annual basis.''.

SEC. 5065. NOTIFICATION OF MARKETING OF CERTAIN CLASS I DEVICES.

Subsection (l) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following: ''For a class I device described in the preceding sentence, the requirement for a report under subsection (k) may be satisfied by the submission to the Secretary of a notification that contains a

written determination by a person accredited under section 523 that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device conforms with the requirements of section 520(f) and that is received by the Secretary not less than 5 business days before the class I device is introduced, or delivered for introduction, into interstate commerce.''.

SEC. 5066. GENERAL AND SPECIFIC USES.

Subparagraph (E) of section 513(i)(1) is amended by adding at the end the following:

''(iv) In the context of a report for a device under section 510(k), the Secretary may not—

''(I) refuse to accept an indication for use statement for a device to the extent the predicate for such device has the same indication statement; or

''(II) require from the person submitting the report information or data related to an indication other than the proposed indication in the report.''.

SEC. 5067. HUMANITARIAN DEVICE EXEMPTION APPLICATION TO IN VITRO DIAGNOSTICS.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (1)—

(A) by striking ''it is the purpose of this subsection to encourage'' and inserting the following: ''it is the purpose of this subsection—

''(A) to encourage'';

(B) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(B) to benefit patients in the treatment and diagnosis of diseases or conditions that affect greater than 4,000 individuals in the United States annually, when the applicant demonstrates that the severity of the disease or condition is such that—

''(i) the public health requires a greater availability of the device to treat or diagnose such patients; and

''(ii) no satisfactory alternative is available for such treatment or diagnosis.''; and

(2) in paragraph (2)—

(A) in subparagraph (A), by inserting ''or the device is designed to treat a disease or condition that affects greater than 4,000 individuals in the United States annually upon a showing that the criteria identified in paragraph (1)(B) are met'' after ''in the United States''; and

(B) in the continuation text following paragraph (3), by adding at the end the following: ''An order granting a request for an exemption under this subsection shall not in any way limit the number of devices that are subject to the exemption if such devices are determined by the Secretary to be medically necessary to treat, diagnose, or monitor individuals with diseases or conditions described in subparagraph (A) or (B) of paragraph (1).''.

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a guidance document that defines the criteria for establishing ''probable benefit'' as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)).

SEC. 5068. ADVISORY COMMITTEE PROCESS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking ''(5)'' and inserting ''(5)(A)''; and

(2) by adding at the end the following:

''(B) The Secretary shall convene such a meeting not later than 60 days after the matters to be considered by the panel during such meeting are ready, as determined by the Secretary, for panel review.

''(C) Not later than 30 calendar days before the date on which such a meeting is to be convened, the Secretary shall make available to the panel and the person whose device is subject to review by the panel during such meeting any material on the matters to be considered during such meeting. Not later than 14 calendar days before the date on which such a meeting is to be convened, the Secretary shall make any material that is made available to the members of the panel under the preceding sentence available to the public in a format that provides for appropriate redactions of any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(D) For review by a classification panel of a submission for a device, the Secretary shall—

''(i) consult with the person whose submission is subject to panel review regarding the person's recommendations on the expertise needed among the voting members of the panel;

''(ii) give due consideration to such recommendations and ensure that adequate expertise is represented on advisory panels to assess—

''(I) the disease or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

''(II) the technology of the device.

''(E) For purposes of subparagraph (D)(ii), the term 'adequate expertise' means that the membership of the classification panel includes—

''(i) two or more voting members who are specialists or have other expertise in the disease or condition for which the device is under review; and

''(ii) an equal number of voting members who are knowledgeable about the technology of the device.''.

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end '', including by being seated at a location that is the same distance from the panel chairperson as the Secretary is from the chairperson''; and

(2) by striking subparagraph (B) and inserting the following new subparagraph:

''(B)(i) Any meeting of a classification panel with respect to the review of a device shall provide adequate time for initial presentations by the person whose device is specifically the subject of such review, the Secretary, or any other interested party, and for a response to any differing views by such person, and shall encourage free and open participation by all interested persons. Any initial presentation made by the person whose device is specifically the subject of such review shall be made before the Secretary's initial presentation. Such a meeting shall provide such person with adequate time to respond to the Secretary's initial presentation.

''(ii) Following the initial presentations and responses described in clause (i), the panel shall have a period of time the panel considers appropriate to pose to the person whose device is the subject of the review questions that—

''(I) have been provided by the Secretary to the panel for purposes of the panel's review of the device; and

''(II) have been agreed upon by the Secretary and such person for such purposes.

''(iii) The panel shall consider the responses to such questions in the panel's review of the device.''.

Subtitle E—Supply Chain Security for Devices

SEC. 5081. SHORT TITLE.

This subtitle may be cited as the ''Device Distribution Licensing Act of 2015''.

SEC. 5082. DEVICE DISTRIBUTION SUPPLY CHAIN.

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

''Subchapter I—Device Supply Chain Licensing

''SEC. 586. DEFINITIONS.

''In this subchapter:

''(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has the power to control, both of the business entities.

''(2) AUTHORIZED.—The term 'authorized' means—

''(A) in the case of a manufacturer, having a valid registration in accordance with section 510, as applicable;

''(B) in the case of a wholesale distributor, having a valid license under State law or section 586B;

''(C) in the case of a third-party logistics provider, having a valid license under State law or section 586C; and

''(D) in the case of a dispenser, having a valid license under State law, as applicable.

''(3) DEVICE.—The term 'device' means a device as defined in section 201(h).

''(4) DISPENSER.—The term 'dispenser' means any person who makes final delivery or sale of a prescription device to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling, including—

''(A) a retail pharmacy, hospital pharmacy, or group of chain pharmacies under common ownership and control that do not act as a wholesale distributor;

''(B) a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility; and

''(C) a physician or other health care provider authorized by applicable law to prescribe and administer prescription devices.

''(5) IMPORTER.—The term 'importer' means any person who imports a prescription device into the United States and who furthers the marketing of the prescription device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the prescription device or prescription device package.

''(6) MANUFACTURER.—The term 'manufacturer' means the person who manufactures, prepares, propagates, compounds, assembles, or processes a prescription device by chemical, physical, biological, or other procedure. The term includes any person who—

''(A) repackages or otherwise changes the container, wrapper, or labeling of a prescription device in furtherance of the distribution of the prescription device from the original place of manufacture;

''(B) initiates specifications for prescription devices that are manufactured by a second

party for subsequent distribution by the person initiating the specifications;

"(C) manufactures components or accessories that are prescription devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient;

"(D) reprocesses a single-use prescription device that has previously been used on a patient;

"(E) is an importer; or

"(F) is the United States agent of a foreign manufacturer.

["(7) PRESCRIPTION DEVICE.—The term 'prescription device' means a restricted device, as defined in section 520(e)(1)—**]**

["(A) that is intended for use by humans;**]**

["(B) which, because of any potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practi-

tioner licensed by law to direct the use of such device;]

[''(C) for which the Secretary has determined adequate directions for use cannot be prepared; and]

[''(D) that is required to carry on its label 'Rx', 'Rx only', a designation for physician-use or dentist-use only, or a statement that Federal law restricts the device to sale by or on the order of a licensed health care practitioner.]

''(8) SINGLE-USE PRESCRIPTION DEVICE.—The term 'single-use prescription device' means a prescription device that is a single-use device.

''(9) SPECIFIC PATIENT NEED.—The term 'specific patient need'—

''(A) refers to the transfer of a prescription device from one dispenser to another to fill a prescription or order for an identified patient; and

''(B) does not include the transfer of a prescription device from one dispenser to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

''(10) THIRD-PARTY LOGISTICS PROVIDER.—The term 'third-party logistics provider' means an

entity that provides or coordinates warehousing of, or other logistics services with respect to, a prescription device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a prescription device, but does not take ownership of the prescription device, nor have responsibility to direct the sale or disposition of the prescription device.

''(11) TRADING PARTNER.—The term 'trading partner' means—

''(A) a manufacturer, wholesale distributor, or dispenser from whom a manufacturer, wholesale distributor, or dispenser accepts direct ownership of a prescription device or to whom a manufacturer, wholesale distributor, or dispenser transfers direct ownership of a prescription device; or

''(B) a third-party logistics provider from whom a manufacturer, wholesale distributor, or dispenser accepts direct possession of a prescription device or to whom a manufacturer, wholesale distributor, or dispenser transfers direct possession of a prescription device.

''(12) WHOLESALE DISTRIBUTION.—The term 'wholesale distribution'—

''(A) means—

''(i) the distribution or sale of a prescription device to a person other than a consumer or patient, including warehousers, repackagers, own-label distributors, and retail pharmacy warehousers; or

''(ii) receipt of a prescription device by a person other than the consumer or patient; and

''(B) does not include—

''(i) intracompany distribution of any prescription device within a manufacturer or between a manufacturer and an affiliate of such manufacturer;

''(ii) the dispensing of a prescription device pursuant to a prescription or order;

''(iii) the purchase or other acquisition by a dispenser of a prescription device for use by such dispenser;

''(iv) the distribution of a prescription device by the manufacturer of such prescription device;

''(v) the receipt or transfer of a prescription device by an authorized third-party logistics provider, provided that such

third-party logistics provider does not take ownership of the prescription device;

''(vi) the receipt or transfer of a prescription device by a common carrier that transports such prescription device, provided that the common carrier does not take ownership of the prescription device;

''(vii) the distribution of a prescription device, or an offer to distribute a prescription device among hospitals or other health care entities which are under common control;

''(viii) the distribution of a prescription device or an offer to distribute a prescription device for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

''(ix) the receipt of a single-use prescription device by, or the transfer of a single-use prescription device to, a reprocessor of such single-use prescription device;

''(x) salable return of a prescription device when conducted by a dispenser; or

''(xi) facilitating the distribution of a prescription device by providing solely administrative services, including processing of orders and payments.

''(13) WHOLESALE DISTRIBUTOR.—The term 'wholesale distributor' means a person engaged in wholesale distribution.''.

SEC. 5083. AUTHORIZED TRADING PARTNERS.

Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 5082, is further amended by adding at the end the following:

''SEC. 586A. AUTHORIZED TRADING PARTNER REQUIREMENTS.

''(a) MANUFACTURER.—Beginning not later than January 1, 2016, the trading partners of a manufacturer may only be authorized trading partners.

''(b) WHOLESALE DISTRIBUTOR.—Beginning not later than January 1, 2016, the trading partners of a wholesale distributor may only be authorized trading partners.

''(c) THIRD-PARTY LOGISTICS PROVIDER.—Beginning not later than January 1, 2016, the trading partners of a third-party logistics provider may only be authorized trading partners.

''(d) DISPENSER.—Beginning not later than January 1, 2016, the trading partners of a dispenser may only be authorized trading partners.''.

SEC. 5084. NATIONAL LICENSING STANDARDS FOR WHOLESALE DEVICE DISTRIBUTORS.

Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended, is further amended by adding at the end the following:

''SEC. 586B. NATIONAL LICENSING STANDARDS FOR WHOLESALE DEVICE DISTRIBUTORS.

''(a) REQUIREMENT.—No person may engage in wholesale distribution of a prescription device in any State unless such person has a valid license under section 583 or, if not required to be licensed under section 583—

''(1)(A) is licensed by the State from which the prescription device is distributed; or

''(B) if the State from which the prescription device is distributed has not established a licensure requirement, is licensed by the Secretary; and

''(2) if the prescription device is distributed interstate, is licensed by the State into which the prescription device is distributed if the State into which the prescription device is distributed requires the licensure of a person that distributes prescription devices into the State.

''(b) COSTS.—

''(1) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a prescription device, the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount as may be necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amounts provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) STATE LICENSING FEES.—Nothing in this Act shall prohibit States from collecting fees from

wholesale distributors in connection with State licensing of such distributors.

''(c) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding subsections (a) and (b), each entity that meets the definition of a third-party logistics provider under section 586—

''(1) shall obtain a license as a third-party logistics provider as described in section 586C(a); and

''(2) is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the prescription device it handles.

''(d) REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of the Device Distribution Licensing Act of 2015, establish by regulation standards for the licensing of persons under subsection (a), including the revocation, reissuance, and renewal of such license.

''(2) CONTENT.—For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under paragraph (1) shall apply without variation to all State and Federal licenses described under subsection (a) and shall include standards for the following:

"(A) The receipt, storage, and handling of prescription devices, including facility requirements.

"(B) Notification to the relevant State licensing authority or the Food and Drug Administration of any known contraband, counterfeit, or misbranded nonconforming device in its possession or control.

"(C) The furnishing of a bond or other equivalent means of security, as follows:

"(i)(I) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

"(II) For purposes of subclause (I), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

"(ii) If a wholesale distributor can provide evidence that it possesses the re-

quired bond in a State, the requirement for a bond in another State shall be waived.

"(D) Mandatory background checks and fingerprinting of facility managers or designated representatives.

"(E) The establishment and implementation of qualifications for key personnel.

"(F) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable timeframe from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with paragraph (3).

"(G) In accordance with paragraph (4), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

"(3) INSPECTIONS.—To satisfy the inspection requirement under paragraph (2)(F), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

''(4) PROHIBITED PERSONS.—The standards established under paragraph (1) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

''(A) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i), (k), or (r) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

''(B) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

''(5) REQUIREMENTS.—The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5, United States Code—

''(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

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

''(C) provide that the final regulation take effect on the date that is 1 year after the date such final regulation is published.''.

SEC. 5085. NATIONAL LICENSING STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended, is further amended by adding at the end the following:

''SEC. 586C. NATIONAL LICENSING STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

''(a) REQUIREMENTS.—No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider has a valid license under section 584 or, if not required to be licensed under section 584—

''(1)(A) is licensed by the State from which the prescription device is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (c); or

''(B) if the State from which the prescription device distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (c); and

''(2) if the prescription device is distributed interstate, is licensed by the State into which the prescription device is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute prescription devices into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

''(b) COSTS.—

''(1) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics providers located in such State and may collect a reasonable fee in such amount as may be necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such

sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) STATE LICENSING FEES.—

''(A) STATE ESTABLISHED PROGRAM.—Nothing in this Act shall prohibit a State that has established a program to license a third-party logistics provider from collecting fees from a third-party logistics provider for such a license.

''(B) NO STATE ESTABLISHED PROGRAM.—A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohibited from collecting a State licensing fee from a third-party logistics provider.

''(c) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Device Distribution Licensing Act of 2015, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and

reissuance of such a license, to third-party logistics providers under this section.

''(2) CONTENT.—For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under paragraph (1) shall apply without variation to all State and Federal licenses described under subsection (a) and shall include standards for the following:

''(A) Establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section.

''(B) Establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program.

''(C) Require that the third-party logistics provider complies with storage practices, as de-

termined by the Secretary for such facility, including—

"(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine prescription devices unfit, or believed to be unfit, for distribution;

"(ii) maintaining adequate security; and

"(iii) having written policies and procedures to—

"(I) address receipt, security, storage, inventory, shipment, and distribution of a prescription device;

"(II) identify, record, and report confirmed losses or thefts in the United States;

"(III) correct errors and inaccuracies in inventories;

"(IV) provide support for manufacturer recalls;

"(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or op-

eration at the facility, such as a strike, fire, or flood;

''(VI) ensure that any outdated prescription device is segregated from other prescription devices and returned to the manufacturer or destroyed;

''(VII) notify the relevant State licensing authority or the Secretary of any known contraband, counterfeit, or misbranded nonconforming device in its possession or control; and

''(VIII) quarantine or destroy a prescription device unfit for distribution if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

''(D) Provide for periodic inspection by the licensing authority, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section.

''(E) Prohibit a facility from having as a manager or designated representative anyone who has been convicted of any felony violation

of subsection (i), (k), or (r) of section 301, or any violation of section 1365 of title 18, United States Code relating to product tampering.

"(F) Provide for mandatory background checks of a facility manager or a designated representative of such manager.

"(G) Require a third-party logistics provider to provide the applicable licensing authority, upon a request by such authority, a list of all prescription device manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.

"(H) Include procedures under which any third-party logistics provider license—

"(i) expires on the date that is 3 years after issuance of the license; and

"(ii) may be renewed for additional 3-year periods.

"(3) PROCEDURE.—In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5, United States Code—

"(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

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

''(C) provide that the final regulation takes effect upon the expiration of 1 year after the date that such final regulation is issued.

''(d) VALIDITY.—A license issued under this section shall remain valid as long as the third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider.''.

SEC. 5086. WAIVERS AND EXEMPTIONS.

Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended, is further amended by adding at the end the following:

''SEC. 586D. WAIVERS AND EXEMPTIONS.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Device Distribution Licensing Act of 2015, the Secretary shall, by guidance—

''(1) establish a process—

''(A) by which a wholesale distributor or third-party logistics provider may request a

waiver from any of the requirements set forth in section 586B or 586C; and

"(B) under which the Secretary may grant the waiver—

"(i) if the Secretary determines that such requirements would result in an undue economic hardship; or

"(ii) for emergency medical reasons, including a public health emergency declared pursuant to section 319 of the Public Health Service Act; and

"(2) establish a process by which the Secretary may determine certain types or categories of wholesale distributors, third-party logistics providers, or prescription devices to be exempt from the requirements of section 586B or 586C.

"(3) CONTENT.—The guidance issued under subsection (a)(1) shall include a process for the biennial review and renewal of any waiver.".

SEC. 5087. UNIFORM NATIONAL POLICY.

Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended, is further amended by adding at the end the following:

"SEC. 586E. UNIFORM NATIONAL POLICY.

"(a) IN GENERAL.—Beginning on the date of enactment of the Device Distribution Licensing Act of 2015, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to device distribution or third-party logistics provider licensure that are inconsistent with, different than, or in addition to the standards and requirements applicable under section 586B, in the case of device distribution, or section 586C, in the case of a third-party logistics provider.

"(b) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third-party logistics providers as wholesale distributors.

"(c) STATE REGULATION OF OTHER ACTIVITY.—No State shall require licensure as a wholesale device distributor or third-party logistics provider by any person or for any activity related to the manufacture, distribution, delivery, or dispensing of a device for which licensure is not required under section 586B or 586C, including the distribution of a device which is not a prescription device.

"(d) WHOLESALE DISTRIBUTOR LICENSING PRIOR TO EFFECTIVE DATE OF STANDARDS.—Until the effective date of the wholesale distributor licensing regulations under section 586B, a State may continue in force a State requirement for wholesale distributor licensing provided

such requirement is limited solely to wholesale distribution of prescription devices.

''(e) THIRD-PARTY LOGISTICS PROVIDER LICENSING PRIOR TO EFFECTIVE DATE OF STANDARDS.—Until the effective date of the third-party logistics provider licensing regulations under section 586C, a State may continue in force a State requirement for third-party logistics provider licensing provided such requirement is limited solely to third-party logistics provider activities related to prescription devices.

''(f) ADMINISTRATION FEES.—Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale prescription device distributor and third-party logistics provider licensure requirements under sections 586B and 586C.

''(g) ENFORCEMENT, SUSPENSION, AND REVOCATION.—Notwithstanding paragraph (1), a State—

''(1) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 586B or 586C;

''(2) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State; and

''(3) upon conviction of violations of Federal, State, or local device laws or regulations, may provide for fines, imprisonment, or civil penalties.''.

SEC. 5088. PENALTIES.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), is amended by adding at the end the following:

''(ddd) Failure to comply with any requirement under section 586A, 586B, or 586C.''.