~~Title: To amend the Federal Food, Drug, and Cosmetic Act with respect to the regulation of medical devices, and for other purposes.~~

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

~~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 "_____ Act of ____".~~

~~SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.~~

~~(a) Table of Contents.—The table of contents for this Act is as follows:~~

~~Sec.15.Humanitarian use device exemptions.~~

~~Sec.16.Reauthorization of third-party review.~~

~~Sec.17.Advisory committee conflicts of interest.~~

~~(b) References in Act.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).~~

~~SEC. 3~~ **SEC. 601**. RECLASSIFICATION PROCEDURES.

(a) Classification Changes.—

(1) IN GENERAL.—Section 513(e)(1) (21 U.S.C. 360c(e)(1)) is amended to read as follows:

"(e)(1)**(A)** Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of Chapter 5 of ~~Title~~ **title** 5 of the United States Code. An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such ~~device.".~~

device.

"(B) Authority to issue such administrative order shall not be delegated below the Commissioner. The Commissioner shall issue such an order as proposed by the Director of the Center for Devices and Radiological Health unless the Commissioner, in consultation with the Office of the Secretary of Health and Human Services, concludes that the order exceeds the legal authority of the Food and Drug Administration or that the order would be lawful, but unlikely to advance the public health.".

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(e)(2) (21 U.S.C. 360c(e)(2)) is amended by striking "regulation promulgated" and inserting "an order issued".

(B) Section 514(a)**(1)** (21 U.S.C. 360d(a)~~)~~**(1))** is amended **in paragraph (1),** by striking "under a regulation under section 513(e) but such regulation" and inserting "under an administrative order under section 513(e) ~~but such order".~~**(or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation)";**

(C) Section 517(a)(1) (21 U.S.C. 360g(a)) is amended by striking "or changing the

classification of a device to class I" and inserting ", an administrative order changing the classification of a device to class I,".

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this subsection shall have no effect on a regulation promulgated with respect to the classification of a device under section 513(e) of the Federal Food, Drug, and Cosmetic Act prior to the date of enactment of this Act.

(B) APPLICABILITY OF OTHER PROVISIONS.—In the case of a device reclassified under section 513(e) of the Federal Food, Drug, and Cosmetic Act by regulation prior to the date of enactment of this Act, section 517(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 517(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(b) Devices Marketed Before May 28, 1976.—

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ~~"a regulation promulgated"~~**"regulation promulgated under subsection (b)"** and inserting "an order ~~issued";~~ **issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)";**

(B) in subsection (b)—

(i) in paragraph ~~(1), in the matter following subparagraph (B),~~**(1)—**

(I) in the heading, by striking "Regulation" and inserting "Order"; and

(II) in the matter following subparagraph (B)—

(aa) by striking "by regulation, promulgated in accordance with this subsection" and inserting "by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code,"; **and**

(bb) by adding at the end the following:

"Authority to issue such administrative order shall not be delegated below the Commissioner. Before publishing such administrative order, the Commissioner shall consult with the Office of the Secretary of Health and Human Services. The Commissioner shall issue such an order as proposed by the Director of the Center for Devices and Radiological Health unless the Commissioner, in consultation with the Office of the Secretary of Health and Human Services, concludes that the order exceeds the legal authority of the Food and Drug Administration or that the order would be lawful, but

unlikely to advance the public health.";

(ii) in paragraph (2)—

(I) by striking subparagraph (B); and

(II) in subparagraph (A)—

(aa) by striking "(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—" and inserting "(2) A proposed order required under paragraph (1) shall contain—";

(bb) by redesignating clauses (i) through (iv) as subparagraphs (A) through (D), respectively;

(cc) in subparagraph (A), as so redesignated, by striking "regulation" and inserting "order"; and

(dd) in subparagraph (C), as so redesignated, by striking "regulation" and inserting "order"; and

(iii) in paragraph (3)—

(I) by striking "proposed regulation" each place such term appears and inserting "proposed order";

(II) **by striking "paragraph (2) and after" and inserting "paragraph (2),";**

(III) by inserting "and a meeting of a device classification panel described in section 513(b)," after "such proposed regulation and findings,";

(IV) by striking "(A) promulgate such regulation" and inserting "(A) issue an administrative order under paragraph (1)";

~~(III)~~**(V)** by striking "paragraph (2)(A)(ii)" and inserting "paragraph (2)(B)"; and

~~(IV)~~**(VI)** by striking "promulgation of the regulation" and inserting "issuance of the administrative order"; and

(iv) by striking paragraph (4); and

(C) in subsection (i)—

(i) in paragraph (2)—

(I) in the matter preceding subparagraph (A)—

(aa) by striking "December 1, 1995" and inserting "the date that is 2 years after the date of enactment of the ~~[short title]"~~ **Food and Drug Administration Safety and Innovation Act"**; and

(bb) by striking "publish a regulation in the Federal Register" and inserting "issue an administrative order following publication of a

proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code,";

(II) in subparagraph (B)~~,~~ by striking "final regulation has been ~~promulgated"~~ **promulgated under section 515(b)"** and inserting "administrative order has been ~~issued";~~ **issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)";**

(III) in the matter following subparagraph (B), by striking "regulation requires" and inserting "administrative order issued under this paragraph requires"; and

(IV) by striking the third and fourth sentences; and

(ii) in paragraph (3)—

(I) by striking "regulation requiring" each place such term appears and inserting "order requiring"; and

(II) by striking "promulgation of a section 515(b) regulation" and inserting "issuance of an administrative order under subsection (b)".

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Section 501(f) (21 U.S.C. 351) is amended—

(A) in subparagraph (1)(A)—

(i) in subclause (i), by striking "a regulation promulgated" and inserting "an order issued"; and

(ii) in subclause (ii), by striking "promulgation of such regulation" and inserting "issuance of such order";~~ and~~

(B) in subparagraph (2)(B)—

(i) by striking "a regulation promulgated" and inserting "an order issued"; and

(ii) by striking "promulgation of such regulation" and inserting "issuance of such order"**; and**~~.~~

~~SEC. 4~~**(C) by adding at the end the following:**

"(3) In the case of a device with respect to which a regulation was promulgated under section 515(b) prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act, a reference in this subsection to an order issued under section 515(b) shall be deemed to include such regulation.".

(3) APPROVAL BY REGULATION PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—The amendments made by this subsection shall have no effect on a regulation that was

promulgated prior to the date of enactment of this Act requiring that a device have an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for premarket approval.

(c) Reporting.—The Secretary of Health and Human Services shall annually post on the Internet web site of the Food and Drug Administration—

(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1));

(2) the number and type of class II and class III devices reclassified as class I or class II in the previous calendar year under such section 513(e)(1); and

(3) the number and type of devices reclassified in the previous calendar year under section 515.

SEC. 602. CONDITION OF APPROVAL STUDIES.

Section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)) is amended—

(1) by striking "(ii)" and inserting "(ii)(I)"; and

(2) by adding at the end the following:

"(II) An order approving an application for a device may require as a condition to such approval that the applicant conduct a postmarket study regarding the device.".

SEC. ~~5~~ **603**. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360l) is amended—

(1) in subsection (a)(1)(A), in the matter preceding clause (i), by inserting ", at the time of approval or clearance of a device or at any time thereafter," after "by order"; and

(2) in subsection (b)(1), by inserting "The manufacturer shall commence surveillance under this section not later than ~~the day that is 1 year~~ **15 months** after the day ~~of such determination."~~ **on which the Secretary issues an order under this section."** after the second sentence.

SEC. ~~6. SENTINEL.~~ **604. SENTINEL.**

~~(a) Inclusion of Devices in Postmarket Risk Identification and Analysis System.—~~ **Section** 519 (21 U.S.C. 360i) is amended by adding at the end the following:

"(h) Inclusion of Devices in the Postmarket Risk Identification and Analysis System.—

"(1) IN ~~GENERAL.—THE~~ **GENERAL.—**

"(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

"(B) EXCEPTION.—Clause (i)(II) of section 505(k)(3)(C) shall not apply to devices.

"(C) CLARIFICATION.—With respect to devices, the private sector health-related electronic data provided under section 505(k)(3)(C)(i)(III)(bb) may include medical device utilization data, health insurance claims data, and procedure and device registries.

"(2) DATA.—In expanding the system as described ~~under~~ **in** subsection (a), the Secretary shall use **relevant** data with respect to devices cleared under section 510(k) or approved under section 515, including claims data, patient survey data, ~~standardized analytic files that allow for the pooling and analysis of data from disparate data environments,~~ and any other data deemed appropriate by the Secretary.

"(3) **STAKEHOLDER INPUT.—To help ensure effective implementation of the system described in subsection (a), the Secretary shall engage outside stakeholders in development of the system through a public hearing, advisory committee meeting, public docket, or other like measures, as appropriate.**

"(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification for devices.".

~~(b) Amendments to Postmarket Risk Identification and Analysis System.—Section 505(k)(3)(C)(i) (21 U.S.C. 355(k)(3)(C)(i)) is amended—~~

~~(1) by striking subclause (II);~~

~~(2) by redesignating subclauses (III) through (VI) as subclauses (II) through (V), respectively; and~~

~~(3) in item (bb) of subclause (II), as so redesignated, by striking "pharmaceutical purchase data and health insurance claims data" and inserting "medical device purchase data, health insurance claims data, and procedure and device registries".~~

~~SEC. 7~~ **SEC. 605**. RECALLS.

(a) Assessment of Device Recall Information.—

(1) IN GENERAL.—

(A) ASSESSMENT PROGRAM.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall enhance the Food and Drug Administration's recall program to routinely and systematically assess—

(i) information submitted to the Secretary pursuant to a device recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)); and

(ii) information required to be reported to the Secretary regarding a correction or removal of a device under section 519(g) of such Act (21 U.S.C. 360i(g)).

(B) USE.—The Secretary shall use the assessment of information described under subparagraph (A) to proactively identify strategies for mitigating health risks presented by defective or unsafe devices.

(2) DESIGN.—The program under paragraph (1) shall, at a minimum, identify—

(A) trends in the numbers and types of device recalls;

(B) the types of devices in each device class that are most frequently recalled;

(C) the causes of device recalls; and

(D) any other information as the Secretary determines appropriate.

(b) Audit Check Procedures.—The Secretary shall clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.

(c) Assessment Criteria.—The Secretary shall develop explicit criteria for assessing whether a person subject to a recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to a requirement under section 519(g) of such Act (21 U.S.C. 360i(g)) has performed an effective correction or removal action under such section 519(g).

(d) Termination of Recalls.—The Secretary shall document the basis for the termination by the Food and Drug Administration of—

(1) an individual device recall ordered under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)); and

(2) ~~the requirement on a manufacturer or importer of a device to report~~ any correction or removal action for which a report is required to be submitted to the Secretary under section 519(g) of such Act (21 U.S.C. 360i(g)).

SEC. ~~8~~ **606**. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

"(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

"(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

"(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

"(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

"(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.".

SEC. ~~9~~ **607**. UNIQUE DEVICE IDENTIFIER.

Section 519(f) (21 U.S.C. 360i(f)) is ~~amended~~ **amended—**

(1) by striking "The Secretary shall promulgate" and inserting "Not later than December 31, 2012, the Secretary shall issue final"; and

(2) by adding at the end the following:

"The Secretary shall implement the unique device identification system under this subsection as soon as practicable.".

SEC. ~~10~~ **608**. CLARIFICATION OF LEAST BURDENSOME STANDARD.

(a) Premarket Approval.—Section 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) by redesignating clause (iii) as clause (v); and

(2) by inserting after clause (ii) the following:

"(iii) For purposes of clause (ii) , the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

"(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.".

(b) Premarket Notification Under Section 510(k).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is amended—

(1) by striking "(D) Whenever" and inserting "(D)(i) Whenever"; and

(2) by adding at the end the following:

"(ii) For purposes of clause (i), the term 'necessary' means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

"(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.".

SEC. ~~11~~ **609**. AGENCY DOCUMENTATION AND REVIEW OF CERTAIN DECISIONS REGARDING DEVICES.

Chapter V ~~of the Federal Food, Drug, and Cosmetic Act~~**(21 U.S.C. 351 et seq.)** is amended by inserting after section 517 ~~(21 U.S.C. 360g)~~ the following:

"SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF CERTAIN DECISIONS REGARDING DEVICES.

"(a) Documentation of Rationale for Denial.—If the Secretary renders a final decision to deny clearance of a premarket notification under section 510(k) or approval of a premarket application under section 515, or when the Secretary disapproves an application for an investigational exemption under 520(g), the written correspondence to the applicant communicating that decision shall provide a ~~thorough~~ **substantive** summary of the scientific and regulatory rationale for the decision.

"(b) Review of Denial.—

"(1) IN GENERAL.—A person who has submitted a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g) and for whom clearance of the report or approval of the application is denied may request a supervisory review of the decision to deny such clearance or approval. Such review shall be conducted by an individual at the organizational level above the organization level at which the decision to deny the clearance of the report or approval of the application is made.

"(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such denial and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

"(3) TIMEFRAME.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

"(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that ~~are referred to~~ **involve consultation with** experts outside of the Food and Drug ~~Administration.".~~ **Administration, or in cases in which the sponsor seeks to introduce evidence not already in the administrative record at the time the denial decision was made.".**

~~SEC. 12~~ SEC. 610. GOOD GUIDANCE PRACTICES RELATING TO DEVICES.

Subparagraph ~~(C)~~ **C** of section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended—

(1) by striking "(C) For guidance documents" and inserting "(C)(i) For guidance documents"; and

(2) by adding at the end the following:

"(ii) ~~Upon issuance of any guidance document described in clause (i) that relates to devices, the Secretary shall—~~

~~"(I) designate the draft as proposed or final; and~~

~~"(II) not later than 18 months after the date of the close of the comment period, issue a final draft.~~

~~"(iii) Except as provided in clause (iv), if the Secretary issues a proposed draft under clause (ii) and fails to finalize the draft by the deadline determined under clause (ii)(II), the Secretary shall, beginning on the date of such deadline, treat the proposed draft as null and void.~~

~~"(iv) If the Secretary convenes a Food and Drug Administration advisory committee or conducts a hearing under part 15 of title 21, Code of Federal Regulations (or any successor regulations) regarding a proposed draft guidance document described under clause (ii) before the deadline determined under clause (ii)(II) but fails to finalize the draft by the date that is 24 months after the date of the close of the comment period, the Secretary shall, beginning on such date, treat the proposed draft as null and void.~~

~~[~~"(v) The Secretary shall, as appropriate—~~]~~

~~[~~"(I) conduct an analysis of guidance documents issued by the Center for Devices and Radiological Health (referred to in this clause as the 'Center') to ensure such documents reflect the current thinking of the Center;~~]~~

~~[~~"(II) based on such analysis, update the guidance documents to reflect the current thinking of the Center; and~~]~~

~~[~~"(III) train reviewers on such updated guidance. [Pending review of MDUFA language.]~~]~~

~~"(vi)~~ With respect to devices, **if** a notice to industry guidance letter, a notice to industry advisory letter, ~~and~~ **or** any similar notice ~~that~~ sets forth initial interpretations of a ~~statute or~~ regulation **or policy** or sets forth changes in interpretation or policy**, such notice** shall be treated as a guidance document for purposes of this ~~subparagraph. Any document relating to internal procedures of the Food and Drug Administration, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms shall not be treated as a guidance document for purposes of this subparagraph.".~~ **subparagraph.".**

~~SEC. 13. PERFORMANCE STANDARD.~~

~~(a) In General.—Section 514(c)(1)(A) (21 U.S.C. 360d(c)(1)(A)) is amended by striking "or other" and inserting ", for purposes of establishing substantial equivalence under section 513(f), or to meet another".~~

~~(b) Section 513(f)(1)(A)(ii) (21 U.S.C. 360c(f)(1)(A)(ii)) is amended by inserting "or to a performance standard recognized by the Secretary under section 514(c)(1)(A)" after "type".~~

~~SEC. 14~~ **SEC. 611**. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) In General.—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended—

(1) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively;

(2) by amending subparagraph (A) to read as follows:

"(A) In the case of a type of device that has not previously been classified under this Act, a person may do one of the following:

"(i) Submit a report under section 510(k), and, if the device is classified into class III under paragraph (1), such person may request, not later than 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

"(ii) Submit a request for initial classification of the device under this subparagraph, if the person declares that there is no legally marketed device upon which to base a substantial equivalence determination as that term is defined in subsection (i). Subject to subparagraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such ~~assurance.";~~ **assurance. Requests under this clause shall be subject to the electronic copy requirements of section 745A(b).";**

(3) by inserting after subparagraph (A) the following:

"(B) The Secretary may decline to undertake a classification request submitted under clause (2)(A)(ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low-moderate risk."; and

(4) in subparagraph (C), as so redesignated—

(A) in clause (i), by striking "Not later than 60 days after the date of the submission of the request under subparagraph (A)," and inserting "Not later than ~~90~~ **120** days after the date of the submission of the request under subparagraph (A)(i) or ~~120~~ **150** days after the date of the submission of the request under subparagraph (A)(ii),"; and

(B) in clause (ii), by inserting "or is classified in" after "remains in".

(b) GAO Report.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall complete a study and submit to Congress a report on the effectiveness of the review pathway under section 513(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

(c) Conforming Amendment.—Section 513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by inserting "a request under paragraph (2) or" after "response to".

SEC. ~~15~~ **612**. HUMANITARIAN USE DEVICE EXEMPTIONS.

(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 (6)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking "subparagraph (D)" and inserting "subparagraph (C)";

(ii) by striking clause (i) and inserting the following:

"(i) The device with respect to which the exemption is granted—

"(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

"(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.";

(iii) by striking clause (ii) and inserting the following:

"(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the number of such devices needed to treat, diagnose, or cure a population of 4,000 individuals in the United States (referred to in this paragraph as the 'annual distribution number').."; and

(iv) in clause (iv), by striking "2012" and inserting "2017";

(B) by striking subparagraph (C);

(C) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively; and

(D) in subparagraph (C), as so redesignated, by striking "and modified under subparagraph (C), if applicable,";

(2) in paragraph (7), by striking "regarding a device" and inserting "regarding a device described in paragraph (6)(A)(i)(I)"; and

(3) in paragraph (8), by striking "of all devices described in paragraph (6)" and inserting "of all devices described in paragraph (6)(A)(i)(I)".

(b) Applicability to Existing Devices.—A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the date of enactment of this Act may seek a determination under

subclause (I) or (II) of section 520(m)(6)(A)(i) (as amended by subsection (a)). If the Secretary determines that such subclause (I) or (II) applies with respect to a device, clauses (ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), and (D) of paragraph (6) of such section 520(m) shall apply to such device.

(c) Report.—Not later than January 1, 2017, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a) in stimulating innovation with respect to medical devices, including any favorable or adverse impact on pediatric device development;

(2) the impact of such amendments on pediatric device approvals for devices that received a humanitarian use designation under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) prior to the date of enactment of this Act;

(3) the status of public and private insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m) (as amended by subsection (a)) and costs to patients of such devices;

(4) the impact that paragraph (4) of such section 520(m) has had on access to and insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m); and

(5) the effect of the amendments made by subsection (a) on patients described in such section 520(m).

SEC. ~~16~~ **613**. REAUTHORIZATION OF THIRD-PARTY REVIEW **AND INSPECTIONS.**

(a) Third Party Review.—Section ~~.~~

~~Section~~ 523(c) (21 U.S.C. 360m(c)) is amended by striking "2012" and inserting "2017".

(b) Third Party Inspections.—Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking "2012" and inserting "2017".

SEC. 614 ~~SEC. 17~~. ADVISORY COMMITTEE CONFLICTS OF INTEREST.

Section 712 ~~of the Federal Food, Drug, and Cosmetic Act~~(21 U.S.C. 379d–1) is amended—

(1) in subsection (b)—

(A) by striking paragraph (2); and

(B) in paragraph (1)—

(i) by redesignating subparagraph (B) as paragraph (2);

(ii) in subparagraph (A), by redesignating clauses (i) through (iii) as subparagraphs (A) through (C), respectively;

(iii) by striking "(1) RECRUITMENT" and inserting "(1) RECRUITMENT IN GENERAL—The Secretary shall—";

(iv) by striking "(A) IN GENERAL—The Secretary shall—";

(v) by redesignating clauses (i) through (iii) of paragraph (2) (as so redesignated) as subparagraphs (A) through (C), respectively; and

(vi) in paragraph (2) (as so redesignated), in the matter before subparagraph (A) (as so redesignated), by striking "subparagraph (A)" and inserting "paragraph (1)";

(2) by amending subsection (c)(2)(C) to read as follows:

"(C) CONSIDERATION BY SECRETARY.—The Secretary shall ensure that each determination made under subparagraph (B) considers the type, nature, and magnitude of the financial interests at issue and the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.";

(3) in subsection (e), by inserting ", and shall make publicly available," after "House of Representatives"; and

(4) by adding at the end the following:

"(g) Guidance on Reported Financial Interest or Involvement.—The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are reported under subsection (c)(1) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18, United States Code for the purposes of participating in a particular matter.".