"(B) unless specifically stated, have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.".

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF PRIOR 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of 2007 (42 U.S.C. 247d–5a), relating to identification of clinically susceptible concentrations of antimicrobials, is repealed.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) ADDITION TO CATEGORIES OF MISBRANDED DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).".

(3) RECOGNITION OF INTERPRETIVE CRITERIA STANDARD AS DEVICE STANDARD.—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 a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section)".

(c) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the progress made in implementing section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as added by subsection (a).

(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 updating the lists established under section 511A(b) of the Federal Food, Drug, and Cosmetic Act and posted on the Interpretive Criteria Website established under section 511A(c) of such Act. 21 USC 360a–2 note.

Subtitle F—Medical Device Innovations

SEC. 3051. BREAKTHROUGH DEVICES.

(a) IN GENERAL.—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 added by section 3034(b), the following:

"SEC. 515C. BREAKTHROUGH DEVICES. 21 USC 360e–3.

"(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

"(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

"(2)(A) that represent breakthrough technologies;

"(B) for which no approved or cleared alternatives exist;

"(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to 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

"(D) the availability of which is in the best interest of patients.

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

"(d) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

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

"(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

"(A) was designated under this section; or

"(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

"(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d) 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 (c);

"(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 (c) for the device;

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

"(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

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

"(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

"(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

"(H) assign staff to be available within a reasonable time to address questions by 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 (d), 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 and flexible as practicable, when scientifically appropriate;

"(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

"(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

"(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

"(f) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (d);

"(B) provide a template for requests under subsection (c);

"(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

"(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

"(1) 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 and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

"(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

"(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

"(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.".

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by inserting "a request for designation under section 515C," after "application under section 515,".

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking "515(d)(6)" and inserting "515(d)(5)".

(d) REPORT.—On January 1, 2019, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in paragraph (1) by striking "fewer than 4,000" and inserting "not more than 8,000";

(2) in paragraph (2)(A) by striking "fewer than 4,000" and inserting "not more than 8,000"; and

(3) in paragraph (6)(A)(ii), by striking "4,000" and inserting "8,000".

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 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 draft guidance 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)(C)). 21 USC 360j note.

SEC. 3053. RECOGNITION OF STANDARDS.

(a) IN GENERAL.—Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

"(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

"(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

"(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

"(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

"(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

"(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

"(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition."; and

(2) by adding at the end the following:

"(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.".

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the 21 USC 360d note.

device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking "A report under subsection (k)" and inserting "(1) A report under subsection (k)"; and

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

"(2) Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

"(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking "(m)(1)" and all that follows through "by the Secretary." and inserting the following:

"(m)(1) The Secretary shall—

"(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

"(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

"(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

"(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).";

(2) in paragraph (2)—

(A) by striking "1 day after the date of publication of a list under this subsection," and inserting "1 calendar day after the date of publication of the final list under paragraph (1)(B),"; and

(B) by striking "30-day period" and inserting "60-calendar-day period"; and

(C) by adding at the end the following new paragraph:

"(3) Upon the publication of the final list under paragraph (1)(B)—

"(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

SEC. 3055. CLASSIFICATION PANELS.

(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) When a device is specifically the subject of review by a classification panel, the Secretary shall—

"(i) ensure that adequate expertise is represented on the classification panel to assess—

"(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device; and

"(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

"(C) For purposes of subparagraph (B)(i), the term 'adequate expertise' means that the membership of the classification panel includes—

"(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

"(ii) at least one voting member who is knowledgeable about the technology of the device.

"(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.".

(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, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided"; 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—

"(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

"(II) encourage free and open participation by all interested persons.

"(ii) Following the initial presentations described in clause (i), the panel may—

"(I) pose questions to a designated representative described in subparagraph (A)(iii); and

"(II) consider the responses to such questions in the panel's review of the device.".

SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in subsection (g)(3)—

(A) in subparagraph (A)(i)—

(i) by striking "local"; and

(ii) by striking "which has been"; and

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(2) in subsection (m)(4)—

(A) by striking subparagraph (A) and inserting the following:

"(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and";

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(C) in the matter following subparagraph (B), by striking "local".

42 USC 263a note.

SEC. 3057. CLIA WAIVER IMPROVEMENTS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

(1) revises "Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy" of the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" and dated January 30, 2008; and

(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.

SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

"(1) The Secretary shall—

"(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

"(B) periodically assess the implementation of the least burdensome requirements, including the employee training

under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

"(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

"(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

"(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

"(D) summarize the findings of such audit in a final audit report; and

"(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

"(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

"(ii) on the Internet website of the Food and Drug Administration.".

(b) PREMARKET APPLICATIONS.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

"(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

"(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

"(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

"(D) Nothing in this paragraph alters the standards for premarket approval of a device.".

(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by adding at the end the following:

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.".

SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION DATA REQUIREMENT.

(a) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

"(q) REUSABLE MEDICAL DEVICES.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

"(A) instructions for use, which have been validated in a manner specified by the Secretary; and

"(B) validation data, the types of which shall be specified by the Secretary;

regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

"(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

"(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.".

21 USC 360 note.

(b) DEVICE MODIFICATIONS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device. Such final guidance shall be issued not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.

SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

"(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

"(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

"(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

"(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats,

or display the equivalent of a paper medical chart, so long as—

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

"(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

"(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

"(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

"(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

"(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

"(2) In the case of a product with multiple functions that contains—

"(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

"(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

"(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1)

shall not be excluded from the definition of device under section 201(h) if—

"(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

"(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

"(B) Subparagraph (A) shall apply only if the Secretary—

"(i) publishes a notification and proposed order in the Federal Register;

"(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

"(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

"(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

"(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

"(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

"(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

"(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

"(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

"(A) exercise enforcement discretion as to any device subject to regulation under this Act;

"(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

"(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).".

21 USC 360j note.

(b) REPORTS.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act and every 2 years thereafter, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and

(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.

(c) CLASSIFICATION OF ACCESSORIES.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding at the end the following:

"(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.".

(d) CONFORMING AMENDMENT.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: "The term 'device' does not include software functions excluded pursuant to section 520(o).".

Subtitle G—Improving Scientific Expertise and Outreach at FDA

SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH AND BIOMEDICAL PRODUCT ASSESSMENT SERVICE.

(a) HIRING AND RETENTION AUTHORITY.—Section 228 of the Public Health Service Act (42 U.S.C. 237) is amended—

(1) in the section heading, by inserting "**AND BIOMEDICAL PRODUCT ASSESSMENT**" after "**RESEARCH**";

(2) in subsection (a)—

(A) in paragraph (1), by striking "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members" and inserting "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment";

(B) by amending paragraph (2) to read as follows:

"(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service."; and

(C) by adding at the end the following:

"(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "or clinical research evaluation" and inserting ", clinical research evaluation, or biomedical product assessment"; and