AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

II

112TH CONGRESS
2D SESSION

S. 2113

To empower the Food and Drug Administration to ensure a clear and effective pathway that will encourage innovative products to benefit patients and improve public health.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2012

Mrs. HAGAN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To empower the Food and Drug Administration to ensure a clear and effective pathway that will encourage innovative products to benefit patients and improve public health.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS; REFERENCES IN ACT.

(a) SHORT TITLE.—This Act may be cited as the "Transforming the Regulatory Environment to Accelerate Access to Treatments" or "TREAT Act".

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

(c) 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.).

TITLE I—ELEVATING FDA AND EMPOWERING OPERATIONAL EXCELLENCE

SEC. 101. MISSION STATEMENT.

Section 1003(b) (21 U.S.C. 393(b)) is amended—

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

(2) by inserting after paragraph (2), the following:

"(3) advance medical innovation, and strive to make novel products available to those who need them, by incorporating modern scientific tools, standards, methodologies, and approaches to ensure the timely and effective review, and the expeditious clearance, licensure, or approval, as appropriate, of innovative drugs, devices, and other regulated products;"; and

(3) in paragraph (5), as so redesignated, by striking "(1) through (3)" and inserting "(1) through (4)".

SEC. 102. MANAGEMENT REVIEW BOARD.

Chapter VII (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following:

"SEC. 714. MANAGEMENT REVIEW BOARD.

"(a) IN GENERAL.—Not later than 60 days after the date of enactment of the TREAT Act, the Secretary shall establish an advisory council within the Food and Drug Administration to be known as the Management Review Board (referred to in this section as the 'Board').

"(b) DUTIES.—

"(1) IN GENERAL.—The Board shall provide advice to the Secretary regarding the management and organization of the Food and Drug Administration.

"(2) REPORTS.—The Board shall—

"(A) periodically review the organization and responsibilities of individual offices, centers, and divisions within the Food and Drug Administration (referred to in this section as the 'Administration') in order to determine the optimal allocation of responsibilities and to improve the efficiency and effectiveness of each office, center, and division in achieving individual and overall missions of the Administration;

"(B) issue proposed and final reports on whether and to what extent changes should be made to the management and organization of the Administration to further the Administration's mission as set forth in section 1003(b); and

"(C) for any proposal for organizational changes to which the Board gives significant consideration as a recommendation, consider—

"(i) the budgetary and operational consequences of the proposed change; and

"(ii) an estimation of the level of resources that would be needed to implement the proposed change.

"(3) CONSULTATION.—In carrying out paragraph (2), the Board shall consult with—

"(A) the heads of centers and divisions within the Administration who are not members of the Board;

"(B) other scientific leaders who are officers or employees of the Administration and are not members of the Board; and

"(C) organizations representing regulated industries, venture capital, patients, and disease research, and that are not otherwise represented on the Board.

"(4) TOPICS FOR REVIEW.—

"(A) REQUEST OF SECRETARY.—The Secretary may, at any time, submit requests about management or organizational issues to the Board for assessment.

"(B) PUBLIC INPUT.—The Board shall seek input from the public on management and organizational issues that should be assessed by the Board, at such times as determined appropriate by the Board.

"(5) POWERS.—The Board may secure directly from the Administration such information as is necessary or appropriate for the Board to review issues under consideration.

"(6) CONFLICT OF INTEREST EXEMPTION.—Notwithstanding any other provision of law, the Board shall not be subject to section 712.

"(c) COMPOSITION OF BOARD.—

"(1) IN GENERAL.—The Board shall consist of—

"(A) the Secretary, who shall be a permanent nonvoting member on an ex officio basis; and

"(B) 21 additional members, all of whom shall be voting members, in accordance with paragraph (2).

"(2) VOTING MEMBERS.—The membership of the Board shall consist of the following:

"(A) OFFICERS AND EMPLOYEES OF THE FOOD AND DRUG ADMINISTRATION.—The Secretary shall designate not less than 9 individuals who are directors of centers within the Administration, directors of divisions within such Administration, or other similarly senior officials within such Administration.

"(B) OTHER MEMBERS.—The Secretary shall designate other individuals from among individuals who are not officers or employees of the United States. Such members shall include—

"(i) individuals representing the interests of public or private academic medical centers, physicians, and patient advocacy and disease research organizations;

"(ii) individuals representing the interests of industries regulated by the Administration, which shall include at least 1 representative from each of the pharmaceutical, biotechnology, medical device, and food industries; and

"(iii) individuals with broad expertise regarding how the Administration functions and with experience in successfully managing or consulting for large scientific research or other organizations (other than public or private entities described under clause (i)).

"(3) TERM; VACANCIES.—

"(A) TERMS.—The members appointed under paragraph (2)(B) shall be appointed for a term of 3 years, which may be renewed once.

"(B) VACANCIES.—A vacancy on the Board—

"(i) shall not affect the powers of the Board; and

"(ii) shall be filled in the same manner as the original appointment was made.

"(d) CHAIR.—The Chair of the Board shall be selected by the Secretary from among the members of the Board appointed under subsection (c)(1). The term of office of the Chair shall be 3 years.

"(e) MEETINGS.—

"(1) IN GENERAL.—The Board shall meet at the call of the Chair or upon the request of the Secretary, but not fewer than 6 times with respect to issuing any particular report under subsection (b)(2). The location of the meetings of the Board is subject to the approval of the Secretary.

"(2) PARTICULAR MEETINGS TO RECEIVE PUBLIC INPUT.—Of the meetings held under paragraph (1) with respect to proposals for management or organizational changes being considered under subsection (b)(2)—

"(A) 1 or more shall be directed towards receiving input from the pharmaceutical, medical device, and biotechnology industries, clinical researchers, and the physician and medical research communities to address regulatory and scientific needs and opportunities related to such proposals;

"(B) 1 or more shall be directed towards receiving input from patient advocacy, disease research organizations, and consumer groups to address patient and consumer needs and opportunities related to such proposals; and

"(C) 1 or more shall be directed towards receiving input from food, cosmetic, and dietary supplement industries to address regulatory and scientific needs and opportunities related to such proposals.

"(3) AVAILABILITY OF INFORMATION.—For each meeting held under this subsection, the Secretary shall post on the Internet Web site of the Administration a summary of the proceedings.

"(f) COMPENSATION.—Without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Secretary may—

"(1) establish the Board; and

"(2) appoint and fix the compensation of the members of the Board, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

"(g) REPORTS.—

"(1) PUBLIC COMMENT.—

"(A) PROPOSED REPORTS.—Each proposed report issued under subsection (b)(2) shall be posted on the Internet Web site of the Administration and made available for public comment for not less than 60 days prior to being made final and being submitted under paragraph (2).

"(B) FINAL REPORTS.—Not later than 90 days after receiving comments from the public on a proposed report under subparagraph (A), the Board shall post a final report on such Internet Web site incorporating an overview of comments accepted or rejected.

"(2) CONGRESSIONAL AND SECRETARY REVIEW.—Each final report issued under subsection (b)(2) shall be submitted to the—

"(A) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate;

"(B) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives; and

"(C) the Secretary.

"(3) TIMING AND FREQUENCY OF REPORTS.—Not later than January 31, 2015, the Board shall issue the first report under subsection (b)(2) and shall issue subsequent reports not less than once every 5 years thereafter.

"(h) PROCESS FOR REVIEW OF RECOMMENDED ORGANIZATIONAL OR MANAGEMENT CHANGES.—With respect to recommendations for organizational or management changes made in a report issued under subsection (b)(2), the Secretary shall, except as provided in subsection (i)(2), implement the recommendations in accordance with the following process:

"(1) Not later than 100 days after the report is submitted to the Secretary under subsection (g)(2), the Secretary shall initiate the applicable processes under subsection (i).

"(2) The recommendations shall be fully implemented not later than the expiration of the 3-year period beginning on the date on which such process is initiated.

"(i) ACTION BY THE SECRETARY.—

"(1) IN GENERAL.—Not less than 60 days prior to implementing any major organizational or management change recommended under subsection (b)(2), the Secretary shall provide notice to the congressional committees specified in subsection (g)(2) of the Secretary's agreement with the recommendation and the timeline for implementation.

"(2) OBJECTION.—Subsection (h) shall not apply to a recommendation for an organizational or management change made in a report issued under subsection (b)(2) if, not later than 90 days after the report is submitted to the Secretary under subsection (g)(2), the Secretary submits to the committees specified in such subsection a notice indicating that the Secretary objects to the recommended change, and setting forth the reasons for such objection. For purposes of this paragraph, an objection by the Secretary may be made to the entirety of the recommended organizational changes contained in a report issued under subsection (b)(2), or to 1 or more aspects of any proposed change or changes.

"(3) IMPLEMENTATION.—Any aspect of a proposed change not objected to by the Secretary in a notice under paragraph (2) shall be implemented in accordance with subsection (h), except as the Secretary may be directed otherwise by law.".

TITLE II—ADVANCING REGULATORY SCIENCE AND INNOVATION

SEC. 201. CHIEF INNOVATION OFFICER.

Chapter X is amended—

(1) by redesignating the second section 1011 (21 U.S.C. 399c) (as added by section 209(a) of Public Law 111–353) as section 1011A; and

(2) by adding at the end the following:

"SEC. 1013. OFFICE OF THE CHIEF INNOVATION OFFICER.

"(a) ESTABLISHMENT; APPOINTMENT.—The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Innovation Officer. The Secretary shall appoint a Chief Innovation Officer to lead such Office.

"(b) DUTIES.—The Chief Innovation Officer shall—

"(1) identify promising new scientific and regulatory approaches to ensure the rapid development, testing, and review of new drugs and devices, which may include the validation and qualification of biomarkers, the adoption of novel models or methodologies to enhance clinical trial design, clinical data evaluation, or predictive toxicology, and the coordination and optimization of efficient review processes for drugs, and devices;

"(2) ensure that such approaches are integrated into operations at all applicable levels of the Food and Drug Administration, and harmonized with the approaches of other applicable agencies;

"(3)(A) consider the recommendations of internal and external bodies involved in advancing innovation in regulatory science activities, such as those described in paragraph (1); and

"(B) make such recommendations available on the Internet Web site of the Food and Drug Administration;

"(4) develop pilot programs to implement and incorporate the recommendations considered under paragraph (3) into the regulatory review and approval processes of such Administration; and

"(5) in consultation with the heads of the centers and offices within such Administration, implement other pilot programs as the Chief Innovation Officer determines appropriate, and ensure participation by cross-disciplinary teams in such implementation, as applicable.

"(c) REPORTS AND IMPLEMENTATION PLANS.—

"(1) REPORTS.—The Chief Innovation Officer shall publish a report summarizing the consideration of applicable recommendations evaluated under subsection (b)(3) at least once every 2 years. Such reports shall—

"(A) provide an explanation as to whether, how, and why such recommendations will be implemented by the Food and Drug Administration;

"(B) provide a description of pilot programs being implemented and the progress of such Administration with respect to the integration of new scientific and regulatory approaches into its operations in order to accelerate the rapid development, review, approval, and patient access to new drugs and devices;

"(C) be made available for public comment for not less than 60 days prior to being made final;

"(D) following public comment, be finalized by the Chief Innovation Officer to include an overview of public comments accepted or rejected; and

"(E) once finalized, be made available on the Internet Web site of such Administration and submitted to—

"(i) the Committee on Health, Education, Labor and Pensions of the Senate; and

"(ii) the Committee on Energy and Commerce of the House of Representatives.

"(2) PUBLIC COMMENT REGARDING IMPLEMENTATION OF PILOT PROGRAMS.—The Chief Innovation Officer shall make each plan to implement a pilot program under subsection (b)(4) available for public comment for not less than 60 days before the implementation of the pilot program.

"(d) MAINTENANCE OF AUTHORITY OF CENTERS.—Nothing in this section limits the authority or ability of the individual Centers of the Food and Drug Administration to carry out any of the actions described in this section.".

SEC. 202. ENHANCING ACCESS TO EXTERNAL SCIENTIFIC AND MEDICAL EXPERTISE.

(a) ADVISORY COMMITTEES.—

(1) CONFLICTS OF INTEREST.—Section 712(c)(2) (21 U.S.C. 379d–1(c)(2)) is amended—

(A) in subparagraph (A), by striking "financial interest that could be affected by the advice given to the Secretary with respect to such matter" and inserting "financial interest in the outcome of such matter that is direct and predictable";

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

"(B) WAIVER.—

"(i) IN GENERAL.—If the Secretary makes a determination described in clause (ii), the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to—

"(I) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

"(II) participate as a voting member with respect to a particular matter considered in a committee meeting.

"(ii) DETERMINATION.—A determination described under this clause may be based on 1 or both of the following determinations:

"(I) The need for the services of the individual on the committee outweighs the potential for a conflict of interest created by the financial interest involved.

"(II) The financial interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual."; and

(C) by striking subparagraph (C).

(2) PATIENT GROUP REPRESENTATIVES.—Section 505(n)(3) (21 U.S.C. 355(n)(3)) is amended—

(A) in subparagraph (C), by striking "; and" and inserting a semicolon;

(B) in subparagraph (D), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(E) 2 or more members who are medical or scientific experts selected from a pool of nominations provided by patient advocacy or disease research organizations whose interests are in the specific disease or diseases proposed to be treated by the drug under consideration.''.

(3) REVISED REGULATIONS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall revise and update the regulations of the Food and Drug Administration relating to the application of the Federal Advisory Committee Act (5 U.S.C. App.) to reflect updated understanding of the scope of such Act, as embodied in regulations of the General Services Administration (as in effect on the date of enactment of this Act) and case law.

(B) CONTENT.—The revised and updated regulations under subparagraph (A) shall explicitly encourage officials of the Food and Drug Administration to utilize, to the maximum extent possible, the flexibility and exceptions provided by the Federal Advisory Committee Act to interact with stakeholder groups outside the confines of the advisory committees of such Act, including patient advocacy organizations, disease specialty societies, and others.

(b) CHIEF MEDICAL POLICY OFFICERS.—Chapter X (21 U.S.C. 391 et seq.), as amended by section 201, is further amended by adding at the end the following:

"SEC. 1014. CHIEF MEDICAL POLICY OFFICERS.

"(a) ESTABLISHMENT.—The Secretary shall establish an Office of the Chief Medical Policy Officer within each of the following Offices of the Food and Drug Administration:

"(1) The Office of the Director of the Center for Drug Evaluation and Research.

"(2) The Office of the Director of the Center for Biologics Evaluation and Research.

"(3) The Office of the Director of the Center for Devices and Radiological Health.

"(b) SELECTION.—Each Chief Medical Policy Officer shall be selected from the Senior Executive Service by the Secretary.

"(c) DUTIES.—Each Chief Medical Policy Officer shall—

"(1) in coordination with the Chief Innovation Officer, center Directors, and other Chief Medical Policy Officers, develop proactive and consistent approaches for the centers within the Food and Drug Administration and the divisions within such Administration that review applications for drug or device approval to address emerging medical and scientific policy issues bearing on new product review processes, including by—

"(A) advising on and regularly reviewing the implementation of such approaches by such centers and divisions; and

"(B) implementing peer learning programs to ensure the effective and consistent review and approval of new drugs and devices, including the incorporation of new scientific and regulatory approaches recommended by the Chief Innovation Officer under section 1013(b);

"(2) in coordination with the center Directors, sponsors, and relevant patient advocacy and disease research organizations, promote earlier and improved utilization of advisory committees throughout the drug and device development and review processes, including at the investigational testing phase, and recommend as appropriate the utilization of authorities by the Secretary under section 1007 in cases where the ability to obtain sufficient external experts for such advisory committees is limited;

"(3) in coordination with the Office of Special Medical Programs and appropriate Center medical and scientific officers, improve reviewer access to external experts outside of the advisory committee process, including utilization of authorities in section 1004;

"(4) periodically solicit input from industry, academia, and patient advocacy and disease research organizations on emerging scientific and medical policy issues bearing on new product review processes, including clinical trial methodologies; and

"(5) coordinate with the Chief Innovation Officer in the implementation of pilot programs under section 1013(b).

"(d) EXTERNAL EXPERTS.—When serving as officers or employees of the United States, the experts described under subsection (c)(3) shall be considered special government employees as defined in section 202(a) of title 18, United States Code.".

TITLE III—ENABLING MODERNIZED PATIENT-CENTRIC CLINICAL DEVELOPMENT

SEC. 301. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress makes the following findings:

(A) The Food and Drug Administration (referred to in this section as the ''FDA'') serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to the greatest extent possible to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining appropriate safety and effectiveness standards for such treatments.

(b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended to read as follows:

"SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

"(a) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

"(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

"(b) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—

"(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint, including an 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, taking into account the severity or rarity of the condition and the availability of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval'.

"(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic or other evidence developed using biomarkers, for example, or other scientific methods or tools.

"(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

"(A) That the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

"(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

"(A) the sponsor fails to conduct any required post-approval study of the drug with due diligence;

"(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

"(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

"(A) provides a schedule for submission of information necessary to make the application complete; and

"(B) pays any fee that may be required under section 736.

"(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) AWARENESS EFFORTS.—The Secretary shall—

"(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

"(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.''.

(c) GUIDANCE; AMENDED REGULATIONS.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb).

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.

(3) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to

the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.

(4) NO EFFECT OF INACTION ON REQUESTS.—If the Secretary fails to issue final guidance or amended regulations as required by this subsection, such failure shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).

(d) INDEPENDENT REVIEW.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Any such evaluation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

(e) CONSTRUCTION.—The amendments made by this section to section 506(b) of the Federal Food, Drug, and Cosmetic Act are intended to encourage the Secretary to utilize innovative approaches to the assessment of products under accelerated approval while maintaining appropriate safety and effectiveness standards for such products.

SEC. 302. ELECTRONIC HEALTH RECORDS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.), as amended by section 103, is further amended by adding at the end the following:

"SEC. 715. CLINICAL INFORMATICS COORDINATOR.

"(a) IN GENERAL.—The Secretary shall appoint, within the Office of the Commissioner, a Clinical Informatics Coordinator.

"(b) DUTIES.—The Clinical Informatics Coordinator shall—

"(1) develop a process to validate the use of health information technology in clinical research and encourage the use of new health information technologies in clinical research protocols; and

"(2) establish pilot programs to explore and evaluate the methods of incorporating emerging health information technology to make the clinical research process more efficient.

"(c) GUIDANCE.—Not later than 1 year after the conclusion of the pilot programs described in subsection (b)(2), the Secretary shall issue guidance for the conduct of clinical trials incorporating health information technology. The guidance shall explain how the Food and Drug Administration will evaluate such information when reviewing new drug and device applications.".

SEC. 303. DISCLOSURE TO DRUG SPONSORS OF REASONS FOR NON-APPROVAL OF A NEW DRUG APPLICATION.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

"(w) NOTICE OF REASONS FOR DENIAL OF A NEW DRUG APPLICATION.—If the Secretary denies approval of a new drug application under this section or of an application with respect to a biological product under section 351 of the Public Health Service Act, the Secretary shall provide to the sponsor of such drug or biological product—

"(1) a written explanation of the reasons for denying such application, including an explanation of the specific reasons the Secretary determines that—

"(A) the data submitted in the application are inadequate to support approval of the drug or biological product; and

"(B) labeling, risk evaluation and mitigation strategies under section 505–1, or post-approval studies or trials are inadequate to support a determination that the benefits of approval outweigh the risks; and

"(2) to the extent practicable, an explanation of what data will be required and what endpoints will need to be met in order to obtain approval.".

○