112TH CONGRESS
1ST SESSION

S. _____

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

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

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. FIXED TERM OF OFFICE FOR THE COMMISSIONER.

Section 1003(d) (21 U.S.C. 393(d)(1)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following:

''(2) TERM OF OFFICE.—The Commissioner shall be appointed for a term of 6 years and shall be removed by the President only for good cause. The Commissioner may be reappointed without limitation.''.

SEC. 103. 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 the Board considers necessary to carry out this section.

''(6) MATTERS REVIEWED.—Notwithstanding any other provision of law, in no case shall any matter under review by the Board be considered a 'particular matter' under section 712 of this Act or section 208 of title 18, United States Code.

''(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 more 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 pharma-

ceutical, 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, devices, and companion diagnostics;

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

''(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 and how 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.''.

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'' and inserting ''direct and predictable financial interest in the outcome of'';

(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 means any 1 or more of the following determinations:

''(I) A waiver is necessary to afford the advisory committee essential expertise, such as for rare diseases or emerging technologies.

''(II) 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.

''(III) 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) and inserting the following:

''(C) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall be construed as limiting the applicability of section 208 of title 18, United States Code to the actions of the Sec-

retary with respect to consideration of prohibitions or waivers on participation on advisory committees.''.

(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.''.

(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; APPOINTMENT.—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) APPOINTMENT.—The Secretary shall appoint each Chief Medical Policy Officer.

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

''(1) in coordination with the Chief Innovation Officer and center Directors, 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 regu-

latory 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 (b)(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. ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS THROUGH PROGRESSIVE AND EXCEPTIONAL APPROVAL.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

''SEC. 506D. PROGRESSIVE AND EXCEPTIONAL APPROVAL TO ACCELERATE PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

''(a) IN GENERAL.—As set forth in this section, the Secretary shall establish processes to facilitate the development and expedite the review and approval of drugs that are intended to provide a meaningful advancement in the treatment of diseases or conditions that are serious or life

threatening or that present a significant risk to the public health, which shall include any drug intended to—

''(1) be the first approved treatment for such disease or condition or for a specific and identifiable subpopulation with such disease or condition;

''(2) treat patients unresponsive to, or intolerant of, treatments approved by the Secretary and commercially marketed at the time of the application for approval of the drug (referred to in this section as 'available approved treatments');

''(3) treat a rare disease or condition, as defined in section 526(a)(2), where such disease is serious or life threatening or presents a significant risk to the public health;

''(4) treat a subpopulation with such disease, through the use of pharmacogenomic or pharmacogenetic testing;

''(5) offer a significant improvement in outcomes for patients, compared to available approved treatments, either alone or in combination with such treatments, due to improved safety, improved efficacy, or otherwise; or

''(6) otherwise satisfy an unmet medical need, including by giving patients earlier access to a drug that has valid marketing authorization by the appro-

priate health authority in a country described in section 802(b)(1)(A).

''(b) DESIGNATION.—

''(1) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a drug that meets the criteria described in subsection (a). 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) of this Act or section 351(a)(3) of the Public Health Service Act. The failure of a sponsor to request designation under this subsection shall not preclude the submission of an application for approval as described in subsection (c).

''(2) DESIGNATION.—

''(A) DETERMINATION BY SECRETARY.—Not later than 60 days after the receipt of a request under paragraph (1), the Secretary shall communicate to the sponsor a determination whether the drug that is the subject of the request meets the criteria described in subsection (a). Such communication shall include a written explanation of the rationale for the decision.

"(B) EFFECT OF DESIGNATION.—If the Secretary finds that the drug meets the criteria described in subsection (a), the Secretary shall designate the drug as a drug described in subsection (a) and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

"(C) SUBSEQUENT DETERMINATIONS.—A determination by the Secretary that a drug is not eligible for designation under this subsection shall include an explanation of the showing that would be necessary to obtain designation in such case, and shall not preclude a subsequent determination, based upon new information, that the drug is eligible for such designation.

"(c) PROGRESSIVE APPROVAL.—

"(1) IN GENERAL.—The Secretary may approve an application for approval of a drug designated under subsection (b), or any other drug that meets the criteria described under subsection (a), under section 505(c) of this Act or section 351(a) of the Public Health Service Act, pursuant to an application described in section 505(b)(7) of this Act or

section 351(a)(4) of the Public Health Service Act. Such an application shall be entitled to priority review, and at the request of the sponsor, fast track product status. Approval described under this paragraph (referred to in this section as 'progressive approval') may be granted if the Secretary determines, based on relevant science, the strength and quality of the available data, and consideration of the benefits and risks of progressive approval with respect to the product under review for the intended population (or subpopulation) and use, that the evidence submitted in the application is reasonably likely to predict clinical benefit for such population and use.

''(2) DETERMINATION BY THE SECRETARY.—A determination by the Secretary that a drug will not be granted progressive approval shall include an explanation showing what would be necessary to satisfy the standard to obtain such approval and shall not preclude subsequent approval of the drug (based upon new information)—

''(A) as described under paragraph (1); or

''(B) otherwise under section 505(c) of this Act or section 351(a) of the Public Health Service Act (applied without regard to this subsection).

''(3) CONDITIONS.—

''(A) IN GENERAL.—Progressive approval of a drug shall be subject to the following conditions:

''(i) The execution of a written agreement between the Secretary and the sponsor requiring the sponsor to submit the data necessary to confirm the clinical benefit for the intended population and use.

''(ii) Until the date that the obligations of the sponsor under the agreement described in clause (i) are satisfied, that the sponsor submit copies of all promotional materials related to the drug at least 30 days prior to dissemination of the materials.

''(B) OTHER RESTRICTIONS.—If the standard described in paragraph (1) could be satisfied upon the imposition of a risk evaluation and mitigation strategy authorized under section 505–1 or any other risk management authorities available to the Secretary or voluntarily accepted by the applicant, the Secretary shall grant approval as described under paragraph (1) subject to such restrictions.

''(d) EXCEPTIONAL APPROVAL.—Based on an application described in section 505(b)(7), if the Secretary finds, with respect to a drug that meets the criteria described in subsection (a), that the data necessary to satisfy the standard for approval under section 505(c) of this Act or section 351(a)(2)(C) of the Public Health Service Act (applied without regard to subsection (c)) cannot ethically, feasibly, or practicably be generated with respect to such drug, the Secretary may, on the basis of an alternative showing within the discretion of the Secretary, deem such drug approved under such section 505(c) or section 351(a)(2)(C) (referred to in this section as 'exceptional approval').

''(e) APPEAL PROCESS.—

''(1) DESIGNATION.—In the event of an adverse determination by the Secretary with respect to a request for designation under subsection (b), the sponsor may appeal using dispute resolution procedures established by the Secretary in regulations and guidance. Notwithstanding any other provision of law, this determination shall not be subject to a hearing.

''(2) PROGRESSIVE APPROVAL.—If the Secretary issues a written determination pursuant to subsection (c)(2) that a drug cannot be approved as described under subsection (c)(1), the Secretary

shall provide to such applicant the written determination and an opportunity for an informal hearing before the Secretary denies the application. Such hearing shall include, at the request of the applicant, testimony by external scientific experts, patient and consumer groups, and healthcare professionals.

''(3) EXCEPTIONAL APPROVAL.—In the event of a determination by the Secretary not to grant exceptional approval under subsection (d), the sponsor may appeal using dispute resolution procedures established by the Secretary in regulations and guidance. Notwithstanding any other provision of law, this determination shall not be subject to a hearing.

''(f) REPORTING AND REVIEW.—

''(1) REPORTING BY SPONSOR.—Until the date that the obligations of the sponsor under the agreement described in subsection (c)(3)(A)(i) are satisfied or until the date that approval of a drug is withdrawn under subsection (g)(1) or suspended under subsection (g)(5), the sponsor of the drug shall, on a biennial basis, submit a report to the Secretary containing the information required under this subsection. This paragraph shall not be construed to limit the authority of the Secretary to impose postmarket reporting obligations on such spon-

sors pursuant to other applicable provisions of this Act.

''(2) REPORTS REGARDING PROGRESSIVE APPROVAL.—A report submitted under paragraph (1) by the sponsor of a drug approved as described under subsection (c)(1) shall include a description of the progress of the sponsor in implementing the written agreement between the sponsor and the Secretary required under subsection (c)(3)(A)(i), and a detailed summary of new information and evidence since approval or the prior report that might affect the safety, efficacy, or labeling of the drug in the approved indication and patient population.

''(3) REPORTS ON EXCEPTIONAL APPROVAL.—A report submitted under paragraph (1) by the sponsor of a drug granted exceptional approval shall include a detailed summary of new information and evidence since approval or the prior report that might affect the safety, efficacy, or labeling of the drug in the approved indication and patient population.

''(g) WITHDRAWAL OF APPROVAL.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary may withdraw the progressive approval of a drug or exceptional approval of a drug

at any time the Secretary determines, after full consideration of all authorized risk mitigation measures available to the Secretary, all reports submitted by the sponsor under subsection (f)(1), and the recommendations of any advisory committee convened under paragraph (3), that—

''(A) the applicable requirements for approval described under subsection (c)(1) or (d) is no longer met;

''(B) the sponsor is not in compliance with the agreement between the sponsor and the Secretary described under subsection (c)(3)(A); or

''(C) the sponsor has disseminated false or misleading promotional materials with respect to the drug.

''(2) NOTICE.—If the Secretary determines that progressive approval or exceptional approval of a drug under paragraph (1) should be withdrawn, the Secretary shall provide the sponsor with notice, a written explanation of the rationale for withdrawal, and an opportunity for a hearing under paragraph (3) prior to withdrawal being made effective. The determination of the Secretary shall be made publicly available 45 days after notice to the sponsor, or

in the case of a hearing under paragraph (3), 30 days after the hearing process concludes in the event of an adverse determination.

''(3) HEARING.—

''(A) IN GENERAL.—The sponsor of a drug that receives a notice of withdrawal under paragraph (1) shall have 15 days to file a request for a hearing on the Secretary's determination and shall have not less than 45 days to submit the data and information upon which it intends to rely at such hearing. If no request is filed, the Secretary's withdrawal shall become effective upon the expiration of the 15-day period, subject to paragraph (4).

''(B) ADVISORY COMMITTEE AND STAKEHOLDER INPUT.—At the option of the sponsor, the hearing shall include a standing advisory committee that shall be asked to provide its recommendation to the Secretary on whether the drug continues to meet the applicable standard of approval and shall include the testimony of external scientific experts, patient and consumer groups, and healthcare professionals.

''(C) TIMEFRAME.—A final decision under this subsection shall be issued no later than 180

days after the date on which the sponsor files a notice of appeal.

''(4) CONTINUING PATIENT ACCESS.—Subject to paragraph (5), in the event that progressive approval of a drug or exceptional approval of a drug is withdrawn under this subsection, the Secretary shall permit the sponsor, at the discretion of the sponsor and upon the request of a treating physician, to continue making the drug commercially available to patients to conclude courses of treatment ongoing at the time of such withdrawal. Withdrawal of approval of a drug under this subsection shall not be construed to require withdrawal of any investigational new drug application in effect, and the Secretary shall, at the request of the sponsor, consider permitting expanded access pursuant to section 561.

''(5) IMMINENT HAZARD.—If the Secretary finds that there is an imminent hazard to the public health, the Secretary may suspend the progressive approval of a drug or exceptional approval of a drug effective immediately upon notice under paragraph (2), and shall provide the applicant with an opportunity for an expedited hearing under this subsection.

''(h) STATUS AS A LISTED DRUG OR REFERENCE PRODUCT.—A drug granted approval as described under subsection (c)(1) may not be considered a listed drug for purposes of section 505(j) of this Act or a reference product for purposes of section 351(k) of the Public Health Service Act until the date that the obligations of the sponsor under the agreement described in subsection (c)(3)(A)(i) are satisfied.''.

(b) CONFORMING AMENDMENTS.—

(1) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(7) Any person may submit an application under paragraph (1) for progressive approval of a drug as described in section 506D(c)(1) or exceptional approval of a drug as described in section 506D(d). Notwithstanding subsections (c) and (d), such an application shall be subject to the processes, standards, and other requirements described under section 506D.''.

(2) PUBLIC HEALTH SERVICE ACT.—Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) is amended by adding at the end the following:

''(4) Any person may submit an application under this paragraph for progressive approval of a biological

product as described in subsection (c)(1) of section 506D of the Federal Food, Drug, and Cosmetic Act or exceptional approval of a biological product as described in subsection (d) of such section 506D. Such an application shall be subject to the processes, standards, and other requirements described under such section 506D.''.

(c) TREATMENT UNDER MEDICARE, MEDICAID, AND CHIP.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128J the following new section:

''TREATMENT OF DRUGS APPROVED UNDER PROGRESSIVE AND EXCEPTIONAL APPROVAL PROCESSES

''SEC. 1128K. (a) IN GENERAL.—For purposes of determining whether coverage or payment is available for an applicable drug under title XVIII, a State plan under title XIX (or a waiver of such plan), or a State child health plan under title XXI (or a waiver of such plan), the applicable drug shall be treated in the same manner as any other drug approved under a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, a biologic product licensed under section 351 of the Public Health Service Act.

''(b) DEFINITION OF APPLICABLE DRUG.—In this section, the term 'applicable drug' means a drug granted progressive approval as described under subsection (c)(1)

of section 506D of the Federal Food, Drug, and Cosmetic Act or granted exceptional approval as described under subsection (d) of such section 506D.''.

SEC. 302. WEIGHT-OF-EVIDENCE APPROACH.

Section 505(d) (21 U.S.C. 355(d)) is amended by striking the last sentence and inserting ''If the Secretary determines, based on relevant science, that data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation), or that the overall weight of the evidence (including all relevant scientific data and information not otherwise prohibited from reliance or reference by the agency), is sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence.''

SEC. 303. 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. 304. 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.''.