110TH CONGRESS
2D SESSION

S. 3046

To amend the Federal Food, Drug, and Cosmetic Act to create a new conditional approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 21, 2008

Mr. BROWNBACK (for himself, Mr. CASEY, Mr. COLEMAN, Mr. SPECTER, and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to create a new conditional approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Access, Compassion, Care, and Ethics for Seriously Ill Patients Act" or the "ACCESS Act".

SEC. 2. FINDINGS.

Congress finds the following:

(1) As of 2008, the standards of the Food and Drug Administration for approval of drugs, biological products, and devices may deny the benefits of medical progress to seriously ill patients who face morbidity or death from their disease.

(2) Seriously ill patients have a right to take actions to preserve their life by accessing available investigational drugs, biological products, and devices.

(3) The emphasis on statistical analysis of clinical information needs to be balanced by a reliance on clinical evaluation and patient-reported outcomes and considered with an understanding of the risks to patients from their disease, with the goal of providing additional treatment options for patients and their physicians to consider.

(4) Food and Drug Administration advisory committees should have greater representation of medical clinicians and patient advocates who represent the interests of seriously ill patients in early access to promising investigational therapies.

(5) The use of available investigational products for treatment is the responsibility of the physician and the seriously ill patient.

(6) The use of combinations of available investigational and approved products for treatment is the responsibility of the physician and the seriously ill patient.

(7) The Food and Drug Administration should have the expertise and flexibility to address the growing needs of seriously ill patients for individualized or personalized therapies.

SEC. 3. COMPASSIONATE INVESTIGATIONAL ACCESS APPROVAL SYSTEM FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

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

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

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

''(d) COMPASSIONATE INVESTIGATIONAL ACCESS.—

''(1) PURPOSE.—The purpose of this subsection is to facilitate the availability of promising new drugs to seriously ill patients as early in the drug development process as possible, before general marketing begins.

''(2) ACCESS.—Notwithstanding any other provision of law, upon submission by a sponsor of an application intended to provide widespread access to an investigational drug, biological product, or device for eligible patients (referred to in this subsection as 'Compassionate Investigational Access'), the Secretary shall permit such investigational drug, biological product, or device, to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that the requirements of this section are met with respect to Compassionate Investigational Access.

''(3) COMPASSIONATE INVESTIGATIONAL ACCESS.—Notwithstanding any other provision of law, an investigational drug, biological product, or device that receives approval for Compassionate Investigational Access under this subsection shall be subject to the provisions of section 505(i) or 520(g), as applicable, and regulations promulgated by the Secretary pursuant to this Act. The Secretary and the sponsor may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investiga-

tional device under Compassionate Investigational Access as approved under this subsection. The information submitted by the Secretary, in accordance with the preceding sentence, shall be the same type of information that is required by section 402(i)(3) of the Public Health Service Act.

''(4) SUBMISSION OF APPLICATION.—

''(A) APPLICATION CONTENT.—A sponsor of an investigational drug, biological product, or device applying for Compassionate Investigational Access approval of the product shall submit to the Secretary a notice of claimed exemption under section 505(i) or 520(g), as applicable, (referred to in this subsection as an 'application for Compassionate Investigational Access'), which shall contain—

''(i) data and information from completed Phase I clinical investigations and any other nonclinical or clinical investigations;

''(ii) preliminary evidence that the product may be effective in humans against a serious or life-threatening condition or disease, which evidence may be based on uncontrolled data such as case

histories, information about the pharmacological mechanism of action, data from animal and computer models, comparison with historical data, or other preliminary information, and may be based on a small number of patients or a subset of the patient population;

''(iii) evidence that the product is safe at the dose and duration proposed, considering whether the potential risk to a patient of the condition or disease outweighs the potential risk to a patient of the proposed dose and duration of treatment with the product, consistent with the level of information needed to initiate a Phase II clinical trial; and

''(iv) a statement that the sponsor is actively pursuing marketing approval with due diligence.

''(B) LIMITATION.—Compassionate Investigational Access approval shall be based upon multiple considerations that shall include clinical evaluation and unmet patient needs.

''(5) DETERMINATION BY SECRETARY.—

''(A) IN GENERAL.—Not later than 30 days after the receipt of an application for Compassionate Investigational Access approval, the Secretary shall either—

''(i) provide Compassionate Investigational Access approval of the application; or

''(ii) refer the application to the Accelerated Approval Advisory Committee.

''(B) RECOMMENDATION.—Not later than 90 days after receipt of an application for Compassionate Investigational Access approval, the Accelerated Approval Advisory Committee shall issue a recommendation to the Secretary on whether the Secretary shall provide Compassionate Investigational Access approval of the application.

''(C) FINAL DECISION.—Not later than 30 days after receipt of the recommendation from the Accelerated Approval Advisory Committee, the Secretary shall either provide Compassionate Investigational Access approval of the application or shall issue an order setting forth a detailed explanation of the reasons why the application was not so approved and the specific

data that the sponsor must provide so that the application may be so approved.

''(6) APPEAL.—If the Secretary does not provide Compassionate Investigational Access approval of an application, the sponsor of the application shall have the right to appeal the decision to the Secretary. The Secretary shall provide the sponsor with a hearing not later than 30 days following the nonapproval under this subsection of the application and shall issue an order not later than 30 days following the hearing either concurring in the nonapproval or so approving the application. The Secretary shall not delegate the responsibility described in this paragraph to any other person.

''(7) CRITERIA.—In making a determination under paragraph (5), the Secretary shall consider whether the totality of the information available to the Secretary regarding the safety and effectiveness of an investigational drug, biological product, or device, as compared to the risk of morbidity or death from a condition or disease, indicates that a patient (who may be representative of a small patient subpopulation) may obtain more benefit than risk if treated with the drug, biological product, or device. If the potential risk to a patient of the condition or

disease outweighs the potential risk of the product, and the product may possibly provide benefit to the patient, the Secretary shall provide Compassionate Investigational Access approval of the application.

''(8) PATIENT ELIGIBILITY FOR COMPASSIONATE ACCESS.—In order for a patient to access a product available through Compassionate Investigational Access, the physician must document in writing that the patient—

''(A) is seriously ill;

''(B) has exhausted all treatment options approved by the Secretary for the condition or disease for which the patient is a reasonable candidate; and

''(C) has unsuccessfully sought treatment or obtained treatment that was not effective, with an investigational drug, biological product, or device for which such individual is a reasonable candidate, which shall include consideration of a patient's ineligibility for participation in clinical trials, the lack of source of supply and geographic factors.

''(9) PRODUCT LABELING.—To receive Compassionate Investigational Access approval under this subsection, the sponsor of the product shall provide

labeling approved by the Secretary for the drug, biological product, or device that—

"(A) states that the product is intended for use by a patient whose physician has documented in writing that the patient has—

"(i) exhausted all treatment options approved by Secretary for the condition or disease for which the patient is a reasonable candidate; and

"(ii) unsuccessfully sought treatment, or obtained treatment that was not effective with an investigational drug, biological product, or device for which such individual is a reasonable candidate, which shall include a patient's ineligibility for participation in clinical trials, the lack of source of supply and geographic factors; and

"(B) states that every patient to whom the product is administered shall, as a mandatory condition of receiving the product, provide—

"(i) written informed consent, as described under part 50 of title 21, Code of Federal Regulations (or any successor regulations); and

"(ii) consent for the manufacturer of the product to obtain data and information about the patient and the patient's use of the product that may be used to support an application for Accelerated Approval or final approval.

"(10) CHARGING FOR COMPASSIONATE INVESTIGATIONAL ACCESS.—A sponsor or investigator may charge for a Compassionate Investigational Access drug without notifying the Secretary or seeking or obtaining prior approval of the amount charged, provided the sponsor of the drug is actively pursuing marketing approval with due diligence.

"(11) COMMENCEMENT OF REVIEW.—If the Secretary determines, after preliminary evaluation of the data and information submitted by the sponsor, that the product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application under this subsection before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant provides a schedule for submission of information necessary to make the application complete.

"(12) IMMUNITY.—

"(A) IN GENERAL.—A manufacturer, distributor, administrator, sponsor, or physician who manufactures, supplies, distributes or prescribes a product approved under an application for Compassionate Investigational Access shall be immune from suit or liability caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, efficacy, or use of a drug, biological product, or device subject to an approved Compassionate Investigational Access application.

"(B) CLAIMS.—No claim or cause of action against a manufacturer, distributor, administrator, sponsor, or physician who manufactures, supplies, distributes or prescribes a product subject to an approved Compassionate Investigational Access application shall exist in any Federal or State court for claims of property, personal injury, or death caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administra-

tion, efficacy, or use of a drug, biological product, or device subject to an approved Compassionate Investigational Access application. Any such claim or cause of action that is filed in Federal or State court shall be immediately dismissed.

''(13) FINAL APPROVAL.—For purposes of this Act, the term 'final approval' means—

''(A) with respect to a new drug or new biological product, approval of such drug or product under section 505(b)(1) or 505(b)(2) or section 351 of the Public Health Service Act, as the case may be; and

''(B) with respect to a new device, clearance of such device under section 510(k) or approval of such device under section 515(c)(1).''.

(b) ACCELERATED APPROVAL.—Chapter V of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 561 the following:

''SEC. 561A. ACCELERATED APPROVAL.

''(a) IN GENERAL.—

''(1) IN GENERAL.—As soon as practicable after the date of enactment of the Access, Compassion, Care, and Ethics for Seriously Ill Patients Act,

the Secretary shall promulgate regulations to provide for the treatment of an investigational drug, biological product, or device that receives Accelerated Approval under this section. This section shall be carried out in accordance with such regulations (and any successor regulations).

''(2) APPLICATION.—A sponsor of an investigational drug, biological product, or device applying for Accelerated Approval shall submit to the Secretary an application as described under section 505(b)(1) or 505(b)(2), or section 510(k) or 515(c)(1) of this Act, or section 351(a) of the Public Health Service Act, as applicable, which shall contain—

''(A) data and information that the drug, biological product, or device has an effect on a clinical endpoint or on a surrogate endpoint or biomarker that is reasonably likely to predict clinical benefit to a patient (who may be representative of a small patient subpopulation) suffering from a serious or life-threatening condition or disease; and

''(B) a statement that the sponsor is actively pursuing marketing approval with due diligence.

''(3) DETERMINATION BY SECRETARY.—

"(A) IN GENERAL.—Not later than 120 days after the receipt of an application for Accelerated Approval, the Secretary shall either—

"(i) provide Accelerated Approval of the application; or

"(ii) refer the application to the Accelerated Approval Advisory Committee.

"(B) RECOMMENDATION.—Not later than 90 days after receipt of an application for Accelerated Approval, the Accelerated Approval Advisory Committee shall issue a recommendation to the Secretary on whether the Secretary should provide Accelerated Approval of the application.

"(C) LIMITATION.—The Accelerated Approval Advisory Committee shall not consider off-label uses of drugs, biological products, and devices as existing or available therapies, to the extent that the Accelerated Approval Advisory Committee weighs existing or available therapies in determination of whether an investigational drug provides an improvement over treatments that are already available.

"(D) FINAL DECISION.—Not later than 30 days after receipt of the recommendation from

the Accelerated Approval Advisory Committee, the Secretary shall either provide Accelerated Approval of the application or issue an order setting forth a detailed explanation of the reasons why the application was not so approved and the specific data that the sponsor must provide so that the application may be so approved.

''(4) APPEAL.—If the Secretary does not provide Accelerated Approval of an application, the sponsor of the application shall have the right to appeal the decision to the Secretary. The Secretary shall provide the sponsor with a hearing not later than 30 days following the nonapproval under this subsection of the application and shall issue an order not later than 30 days following the hearing either concurring in such nonapproval or so approving the application. The Secretary shall not delegate the responsibility described in this paragraph to any other person.

''(A) with respect to a new drug or new biological product, approval of such drug or product under section 505(b)(1) or 505(b)(2) or section 351 of the Public Health Service Act, as the case may be; and

"(B) with respect to a new device, clearance of such device under section 510(k) or approval of such device under section 515(c)(1).

"(b) ACCELERATED APPROVAL ADVISORY COMMITTEE.—

"(1) IN GENERAL.—In order to facilitate the development and expedite the review of drugs, biological products, and devices intended to treat serious or life threatening conditions, the Secretary shall establish the Accelerated Approval Advisory Committee (referred to in this subsection as the 'Committee').

"(2) DELEGATION.—The Secretary may delegate decisionmaking authority for the Accelerated Approval Advisory Committee to the Office of the Commissioner of Food and Drugs. Such authority shall not be further delegated.

"(3) COMPOSITION.—

"(A) IN GENERAL.—The Committee shall be composed of 11 voting members, including 1 chairperson and 5 permanent members each of whom shall serve a term of 3 years and may be reappointed for a second 3-year term, and 5 nonpermanent members who shall be appointed to the Committee for a specific meeting, or part

of a meeting, in order to provide adequate expertise in the subject being reviewed. The Committee shall include as voting members no less than 2 representatives of patient interests, of which 1 shall be a permanent member of the Committee. The Committee shall include as nonvoting members a representative of interests of the drug, biological product, and device industry.

''(B) APPOINTMENTS.—The Secretary shall appoint to the Committee persons who are qualified by training and experience to evaluate the safety and effectiveness of the types of products to be referred to the Committee and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such products. The Secretary shall make appointments to the Committee so that the Committee shall consist of members with adequately diversified expertise and practical experience in such fields as clinical medicine, biological and physical sciences, and other related professions. Scientific, industry, and consumer organizations and members of the public shall be afforded an opportunity to

nominate individuals for appointment to the Committee. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a member of the Committee.

''(4) COMPENSATION.—Committee members, while attending meetings or conferences of the Committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime, and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for persons in the Government service employed intermittently.

''(5) ASSISTANCE.—The Secretary shall furnish the Committee with adequate clerical and other necessary assistance.

''(6) ANNUAL TRAINING.—The Secretary shall employ nongovernmental experts to provide annual training to the Committee on the statutory and regulatory standards for product approval.

''(7) TIMELINE.—The Committee shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

''(8) MEETINGS.—

''(A) OPPORTUNITIES FOR INTERESTED PERSONS.—Any person whose product is specifically the subject of review by the Committee shall have—

''(i) the same access to data and information submitted to the Committee as the Secretary;

''(ii) the opportunity to submit, for review by the Committee, data or information, which shall be submitted to the Secretary for prompt transmittal to the Committee;

''(iii) the same opportunity as the Secretary to participate in meetings of the Committee; and

''(iv) consent for the manufacturer of the product to obtain data about adverse events relating to the patient's use of the product.

''(B) ADEQUATE TIME; FREE AND OPEN PARTICIPATION.—Any meetings of the Committee shall provide adequate time for initial presentations and for response to any differing views by persons whose products are specifically the subject of the Committee review.

''(C) SUMMARIES.—At all meetings of the Committee, the Secretary shall provide a summary to the Committee of all applications submitted under this subsection and section 561(d) that the Committee did not consider that were approved by the Secretary since the last meeting of the Committee.

''(c) FINAL APPROVAL.—For purposes of this Act, the term 'final approval' means—

''(1) with respect to a new drug or new biological product, approval of such drug or product under section 505(b)(1) or 505(b)(2) or section 351 of the Public Health Service Act, as the case may be; and

''(2) with respect to a new device, clearance of such device under section 510(k) or approval of such device under section 515(c)(1).''.

(c) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations that define the terms ''seriously ill'' and ''serious or life-threatening''

for purposes of the amendments made by this Act, considering either—

(1) the medical prognosis for an individual's life expectancy from a disease or condition; or

(2) the prospect of irreversible disability from a disease or condition.

SEC. 4. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS AND DEVICES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 561A, as added by section 3, the following:

"SEC. 561B. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS AND DEVICES.

''(a) EXPANDED ACCESS PROGRAM.—The Secretary shall establish a new program to expand access to investigational treatments for individuals with serious or life threatening conditions and diseases. In carrying out this expanded access program, the Secretary shall publish and broadly disseminate written guidance that—

''(1) describes such expanded access programs for investigational drugs, biological products, and devices intended to treat serious or life-threatening conditions or diseases;

''(2) encourages and facilitates submission of applications and approvals under section 561(d) and 561A; and

''(3) facilitates the provision of investigational drugs, biological products, and devices to seriously ill individuals without unreasonable delay by recognizing that the use of available investigational products for treatment is the responsibility of the physician and the patient, and also by recognizing the goal of providing additional treatment options for patients and their physicians to consider.

''(b) IMPLEMENTATION OF EXPANDED ACCESS PROGRAMS.—

''(1) TRAINING OF PERSONNEL.—Not later than 90 days after the date of enactment of this section, the Secretary shall implement training programs at the Food and Drug Administration with respect to the expanded access programs established under this section.

''(2) POLICIES, REGULATIONS, AND GUIDANCE.—The Secretary shall establish policies, regulations, and guidance designed to most directly benefit seriously ill patients.

''(c) DEVELOPMENT OF SURROGATE ENDPOINTS AND BIOMARKERS.—

''(1) IN GENERAL.—The Secretary shall—

''(A) establish a program or expand upon an existing program to encourage the development of surrogate endpoints and biomarkers that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet patient needs;

''(B) request the Institute of Medicine to undertake a study to identify validated surrogate endpoints and biomarkers, and recommend research to validate surrogate endpoints and biomarkers, that may support approvals for products intended for the treatment of serious or life-threatening conditions or diseases; and

''(C) make widely available to the public a list of drugs, biological products, and devices that are being investigated for serious or life-threatening conditions or diseases and that have not yet received approval under section 561(d) or 561A for marketing.

''(2) STUDY CONTENT.—The study under paragraph (1)(B) shall include endpoints and biomarkers that address the unmet medical needs of subpopulations of patients and that facilitate the development

of individualized treatment approaches for patients with serious or life-threatening conditions or diseases.''.

SEC. 5. DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a demonstration project under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) under which payment is made for drugs, biological products, and devices approved for Compassionate Investigational Access under section 561(d) of the Federal Food, Drug, and Cosmetic Act in the case where the drug, biological product, or device is not otherwise covered under the Medicare program or by any other organization or entity (including a public assistance program or the sponsor of the application for such drug, biological product, or device).

(b) DURATION.—The demonstration project under this section shall be conducted for a 5-year period.

(c) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Hospital Insurance

Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t), in such proportion as the Secretary determines to be appropriate, of such sums as are necessary for the costs of carrying out the demonstration project under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under this section was not implemented.

(d) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration project under this section.

(e) REPORT.—Not later than 90 days after the last day of the 5-year period of the demonstration project under this section, the Secretary shall submit to Congress a report describing the rates of utilization by Medicare beneficiaries of drugs, biological products, and devices ap-

proved for Compassionate Investigational Access and the total cost of payments made under the Medicare program resulting from the demonstration project. The report shall describe recommendations for legislation or administrative action as the Secretary deems appropriate.

(f) TERMINATION.—The Secretary shall terminate payments under this section on the day after the last day of the 5-year period of the demonstration project under this section.

SEC. 6. USE OF PART B DEFINITION OF MEDICALLY ACCEPTED INDICATION FOR PART D DRUGS.

(a) IN GENERAL.—Section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)) is amended—

(1) in paragraph (1), in the matter following subparagraph (B), by striking ''(as defined in section 1927(k)(6))'' and inserting ''(as defined in paragraph (4))''; and

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

''(4) MEDICALLY ACCEPTED INDICATION DEFINED.—

''(A) IN GENERAL.—Subject to subparagraph (B), for purposes of paragraph (1), the term 'medically accepted indication' has the meaning given that term—

"(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1861(t)(2)(B), except that in applying such section, 'PDP sponsor or MA–PD sponsor' shall be substituted for 'carrier' each place it appears and the compendia identified in section 1927(g)(1)(B)(i)(III) shall be deemed to be included in the compendia described in section 1861(t)(2)(B)(ii)(I); and

"(ii) in the case of any other covered part D drug, in section 1927(k)(6).

"(B) CONSIDERATION OF OTHER CRITERIA ON A CASE-BY-CASE BASIS.—Nothing in this subsection shall preclude a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan from, after a request by an individual enrolled in the plan for a coverage determination under section 1860D–4(g)(1), providing coverage of a covered part D drug for the individual in the case where the sponsor or organization determines, based on guidance provided by the Secretary for determining whether the use of a covered part D

drug is for a medically accepted indication and supportive clinical evidence in peer reviewed medical literature, that the use of the covered part D drug is for a medically accepted indication.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to plan years beginning on or after January 1, 2010.

SEC. 7. MODERNIZATION OF THE FOOD AND DRUG ADMINISTRATION.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. POLICIES RELATED TO STUDY EVALUATION INFORMATION.

''(a) IN GENERAL.—

''(1) NONSTATISTICAL MEASURES.—The Secretary shall give consideration to clinical judgment and risks to the patient from the disease or condition involved in the evaluation of the safety and effectiveness of drugs, biological products, and devices that treat serious or life-threatening diseases or conditions. This policy shall apply—

''(A) in evaluating clinical study designs and endpoints; and

''(B) in making decisions with respect to product applications for approval under section 561(d) or 561A.

''(2) TYPES OF NONSTATISTICAL MEASURES.—The policy established under paragraph (1), for the purposes described in such paragraph—

''(A) shall include such nonstatistical information as—

''(i) clinical evaluation information, such as case history reports;

''(ii) scientific and clinical studies designed to measure or define mechanisms of action or molecular targeting;

''(iii) data from animal and computer models; and

''(iv) comparison with historical data; and

''(B) shall incorporate the use of—

''(i) evaluations of the adverse effect of delaying the availability of an investigational drug to even a small subpopulation of seriously ill patients; and

''(ii) scientific, observational, or clinical studies designed and conducted to collect well-documented information.

''(b) MEETINGS.—A meeting to address any pending scientific, medical, regulatory, or other issue relating to the development, investigation, review, or other aspect of a drug, biological product, or device shall ordinarily be held not later than 15 days of the receipt of a written request for the meeting by the sponsor of the product, which may be extended to 30 days for good cause. Such meetings shall ordinarily be conducted in person, but may be conducted by telephone or other form of communication if both parties agree. In order to reduce the burden of meetings, only those Food and Drug Administration employees who are intended to actively participate in the discussion shall attend a meeting. Minutes of a meeting shall be promptly prepared and exchanged by both parties immediately following the meeting and shall accurately summarize what occurred at the meeting.

''(c) RULE OF CONSTRUCTION.—The provisions of this chapter and section 351 of the Public Health Service Act shall be construed to incorporate the policy established in this section.''.

SEC. 8. MEMBERSHIP OF ONCOLOGY DRUGS ADVISORY COMMITTEE AND THE CELLULAR, TISSUE, AND GENE THERAPY ADVISORY COMMITTEE.

Notwithstanding any other provision of law, membership of the Oncology Drugs Advisory Committee, the Cel-

lular, Tissue, and Gene Therapy Advisory Committee of the Food and Drug Administration, and any other committee created by such Administration to evaluate or advise with respect to applications submitted under section 561(d) or 561A of the Federal Food, Drug, and Cosmetic Act (as added by this Act), shall consist of no less than 2 patient representatives who are voting members of the committee.

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