112TH CONGRESS
2D SESSION

S. 2236

To provide for the expedited development and evaluation of drugs designated as breakthrough drugs.

IN THE SENATE OF THE UNITED STATES

MARCH 26, 2012

Mr. BENNET (for himself, Mr. HATCH, and Mr. BURR) 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 provide for the expedited development and evaluation of drugs designated as breakthrough drugs.

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 ''Advancing Breakthrough Therapies for Patients Act of 2012''.

SEC. 2. BREAKTHROUGH THERAPIES AND FAST TRACK PRODUCTS.

(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) in the heading, by inserting ''**BREAKTHROUGH THERAPIES AND**'' before ''**FAST**'';

(2) by redesignating subsections (a) through (d) as subsections (b) through (e), respectively;

(3) by inserting before subsection (b), as so redesignated, the following:

''(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints (such as substantial treatment effects observed early in clinical development). (In this section, such a drug is referred to as a 'breakthrough therapy'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the 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.—

''(A) IN GENERAL.—Not later than 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 breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) shall include—

''(i) holding meetings with the sponsor and the review team throughout the development of the drug;

''(ii) providing timely advice to the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical

data necessary for approval is as efficient as practicable;

''(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iv) providing timely interactive communication with sponsors;

''(v) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

''(vi) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients enrolled in the trial and the duration of the trial and considering alternatives to the traditional multi-phase, sequential development approach, designed to abbreviate, consolidate, and condense clinical trials and studies.'';

(4) in subsection (e)(1), as so redesignated, by inserting ''breakthrough therapies and'' after ''applicable to''; and

(5) by adding at the end the following:

''(f) GUIDANCE; AMENDED REGULATIONS.—

''(1) IN GENERAL.—

''(A) GUIDANCE.—Not later than 18 months after the date of enactment of the Advancing Breakthrough Therapies for Patients Act of 2012, the Secretary shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, accelerated approval, and fast track products as set forth in subsections (a) through (e), as amended by the Advancing Breakthrough Therapies for Patients Act of 2012. After an opportunity for public comment and not later than 2 years after the date of enactment of the Advancing Breakthrough Therapies for Patients Act of 2012, the Secretary shall issue final guidance.

''(B) AMENDED REGULATIONS.—Not later than 2 years after the date of enactment of the Advancing Breakthrough Therapies for Patients Act of 2012, the Secretary shall amend the applicable regulations under title 21, Code of Fed-

eral Regulations, as may be necessary to implement the requirements under subsections (a) through (c), as amended by the Advancing Breakthrough Therapies for Patients Act of 2012.

''(2) REQUIREMENTS.—Guidance and regulations promulgated under this section shall—

''(A) distinguish between products that may qualify for—

''(i) treatment as a breakthrough therapy;

''(ii) treatment as a fast track product;

''(iii) accelerated approval; and

''(iv) a combination of all of the designations described in clauses (i) through (iii); and

''(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

''(g) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Sec-

retary shall, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality, efficiency, and predictability of biopharmaceutical development and regulatory review programs to evaluate the manner by which the Food and Drug Administration has applied the processes described in the section, as amended by the Advancing Breakthrough Therapies for Patients Act of 2012, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such evaluation shall be completed not later than 4 years after the date of enactment of the Advancing Breakthrough Therapies for Patients Act of 2012 and shall be made publicly available upon completion.

''(h) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, with respect to this section for the previous fiscal year—

''(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

''(2) the number of products designated as a breakthrough therapy; and

''(3) for each breakthrough therapy approved in the fiscal year—

''(A) the point in the drug development and review process at which such breakthrough designation occurred;

''(B) the total time from designation as a breakthrough therapy, including the total time to review and act on an application designated as a breakthrough therapy, to approval of the drug; and

''(C) the number of breakthrough therapies approved on the first review out of the total number of such therapies so approved.''.

(b) CONFORMING AMENDMENTS.—Section 506B(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b) is amended by striking ''section 506(b)(2)(A)'' each place such term appears and inserting ''section 506(c)(2)(A)''.

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