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112TH CONGRESS
1ST SESSION

H. R. 3209

To amend the Federal Food, Drug, and Cosmetic Act to provide predictability, consistency, and transparency to the premarket review process.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mr. SHIMKUS (for himself, Mr. GINGREY of Georgia, Mr. GUTHRIE, Mr. ALTMIRE, Mr. LANCE, Mrs. BLACKBURN, Mr. ROGERS of Michigan, Mr. BILBRAY, Mr. BURGESS, Mr. BARTON of Texas, Mr. PAULSEN, Mr. CASSIDY, and Mr. LATTA) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide predictability, consistency, and transparency to the premarket review process.

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 ''Premarket Predictability Act of 2011''.

SEC. 2. TRACKING AND REVIEW OF APPLICATIONS FOR INVESTIGATIONAL DEVICE EXEMPTIONS.

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

''(8)(A) Upon the submission of an application for an exemption for a device under this subsection, the submission of a request to classify a device under section 513, or the submission of a report for a device under section 510(k), whichever occurs first, the Secretary shall assign a tracking number to the device.

''(B) The Secretary shall use such tracking number to record the following interactions between the Secretary and applicant with respect to the device:

''(i) Submission or approval of an application for an exemption under this subsection.

''(ii) Submission or clearance of a report under section 510(k).

''(iii) Any meeting or meeting request, including in anticipation of the submission of such an application or report.

''(iv) Submission or approval of an application under section 515(c).

''(v) Any formal or informal request by the Secretary for additional information.

''(vi) Any deficiency letter.

''(vii) Any response by the applicant to a request described in clause (v) or a deficiency letter.

''(viii) Any written submission by the applicant to the Food and Drug Administration.

''(ix) Any other matter, as determined appropriate by the Secretary.

''(9) Upon the submission of an application for an exemption under this subsection for a device, the Secretary shall assign, to review the application, a reviewer with prior review experience with that type of device or technology or other relevant expertise.''.

SEC. 3. OTHER RULES RELATING TO INVESTIGATIONAL DEVICE EXEMPTIONS.

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

(1) in paragraph (2)(A), by adding at the end the following: ''Procedures and conditions pursuant to the preceding sentence shall require the Secretary, in determining whether to grant such an exemption, to evaluate whether the investigational study can be conducted ethically and with reasonable risk.'';

(2) in paragraph (2)(B)(ii), by striking ''evaluate the safety and effectiveness of the device'' and inserting ''evaluate whether the investigational study

is being conducted ethically and with reasonable risk'';

(3) in paragraph (4)(B), by adding at the end the following: ''The Secretary may not disapprove an application because the investigation does not or may not meet any requirement, including a data requirement, relating to the approval or clearance of a device because the Secretary believes that a different clinical testing design or plan could produce data more relevant to an approval or clearance decision.'';

(4) in paragraph (7)(A), by striking ''(7)(A) In the case'' and all that follows through the end paragraph (7)(A) and inserting the following:

''(7)(A)(i) In the case of a person intending to investigate the safety or effectiveness of a class II or a class III device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The

written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, information (if available) regarding the expected performance of the device, and a proposed plan (including a clinical protocol) for determining—

''(I) whether there is a reasonable assurance of safety and effectiveness; or

''(II) whether the device is substantially equivalent to or is at least as safe and effective as a legally marketed device that is not subject to approval requirements under section 515.

''(ii) In the case where the Secretary fails to meet the applicant not later than 30 days after receiving a request as described under clause (i), the proposed plan submitted in such request shall be deemed to be the agreement reached between the Secretary and the applicant under subparagraph (B) and such agreement shall not be subject to change except as provided in subparagraph (B).''; and

(5) in paragraph (7)(B)(ii), by inserting ''that has emerged since the date of the agreement and that is'' after ''substantial scientific issue''.

SEC. 4. CLARIFICATION OF LEAST BURDENSOME STANDARD.

(a) PREMARKET APPROVAL.—Section 513(a)(3)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) by redesignating clause (iii) as clause (iv); and

(2) by inserting after clause (ii) the following:

''(iii) In carrying out clause (ii), the Secretary—

''(I) shall not request information unrelated or irrelevant to a demonstration of reasonable assurance of device effectiveness;

''(II) shall consider alternative approaches to evaluating device effectiveness in order to reduce the time, effort, and cost of reaching proper resolution of the issue;

''(III) shall use all reasonable mechanisms to lessen review times and render regulatory decisions;

''(IV) shall consider whether pre-clinical data, such as well-designed bench and animal testing, can meet the statutory threshold for approval; and

''(V) if clinical data are needed, shall consider alternatives to randomized, controlled clinical trials and the use of surrogate endpoints.''.

(b) SUBSTANTIAL EQUIVALENCE DETERMINATION.—Section 513(i)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(i)(1)(D)) is amended—

(1) by striking ''(D) Whenever'' and inserting ''(D)(i) Whenever''; and

(2) by adding at the end the following:

''(ii) In carrying out clause (i), the Secretary—

''(I) shall focus on whether there is a reasonable assurance that the device is safe and effective for its intended use;

''(II) shall not request or accept information unrelated or irrelevant to the substantial equivalence evaluation;

''(III) shall review the labeling of the device to assess the intended use of the device, and shall not evaluate issues that do not present a major impact on the intended use as set forth in the labeling;

''(IV) shall consider alternative approaches to evaluating substantial equivalence in order to reduce the time, effort, and cost of reaching proper resolution of the issue; and

''(V) shall use all reasonable mechanisms to lessen review times and render regulatory decisions.''.

SEC. 5. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 517 (21 U.S.C. 360g) the following:

"SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.

"(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

"(1) IN GENERAL.—The Secretary shall completely document the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and their resolution.

"(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such complete documentation to the person who is seeking to submit, or who has submitted, such report or application.

"(b) APPEAL RIGHTS AND PROCEDURES.—

''(1) APPEAL TO CENTER DIRECTOR.—Any person may, within 30 days after a significant decision described in subsection (a)(1), appeal such decision to the Director of the Center for Devices and Radiological Health (in this subsection referred to as the 'Center Director').

''(2) PETITION; PROCEDURES.—The Center Director—

''(A) may require that an appeal under paragraph (1) be in writing and set forth the decision being appealed and the grounds for the appeal; and

''(B) subject to paragraph (6), may provide for such procedures as may be necessary with respect to such an appeal.

''(3) RESOLUTION BY CENTER DIRECTOR.—

''(A) MEETING.—The Center Director shall provide, upon the request of any person bringing an appeal under paragraph (1), for at least one meeting, to be held within 45 days after the filing of the appeal, to discuss the significant decision involved, the appeal of such decision, and possible resolutions of the appeal.

''(B) FINAL DECISION.—The Center Director shall issue a final written decision resolving

any appeal under paragraph (1), including the grounds for such decision, not later than 90 days after the filing of the appeal.

''(4) APPEAL TO COMMISSIONER.—

''(A) IN GENERAL.—Any person who files an appeal under paragraph (1)—

''(i) within 30 days after receiving any decision of the Center Director resolving the appeal, may appeal such decision to the Commissioner; or

''(ii) if the Center Director has not made a decision resolving the appeal under paragraph (1) within 90 days after the filing of such appeal, may file directly with the Commissioner an appeal of the significant decision subject to such appeal under paragraph (1).

''(B) FINAL DECISION.—The Commissioner shall issue a final written decision resolving any appeal under subparagraph (A), including the grounds for such decision, not later than 30 days after the filing of such appeal under subparagraph (A).

''(5) REPORT.—The Commissioner shall issue a public report on at least an annual basis that sets forth—

''(A) the number of appeals under paragraph (1) and the disposition of those appeals;

''(B) for each appeal under paragraph (1), the number of days taken to reach a final decision under paragraph (3)(B);

''(C) the number of appeals to the Commissioner under paragraph (4)(A), including the number of such appeals under paragraph (4)(A)(ii), and the disposition of those appeals; and

''(D) the number of appeals for which the Commissioner does not issue a final decision within 30 days as required by paragraph (4)(B).

''(6) AUTHORITY OF SECRETARY TO ESTABLISH APPEAL PROCEDURES AND TIMELINES.—

''(A) ESTABLISHMENT.—Subject to subparagraph (B), the Secretary may, by regulation or guidance, establish appeal procedures or timelines applicable to appeals under paragraph (1) or (4).

''(B) LIMITATION.—No procedure or timeline established under subparagraph (A) may alter any requirement or extend or delay any timeline specified in any of paragraphs (1) through (5).''.

SEC. 6. TRANSPARENCY IN CLEARANCE PROCESS.

(a) PUBLICATION OF DETAILED DECISION SUMMARIES.—Section 520(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(h)) is amended by adding at the end the following:

''(5) Subject to subsection (c) and section 301(j), the Secretary shall regularly publish detailed decision summaries for each clearance of a device under section 510(k).''.

(b) APPLICATION.—The requirement of section 520(h)(5) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to clearance of a device occurring after the date of the enactment of this Act.

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