Calendar No. 426

114TH CONGRESS
2D SESSION

S. 1622

To amend the Federal Food, Drug, and Cosmetic Act with respect to devices.

IN THE SENATE OF THE UNITED STATES

JUNE 18, 2015

Mr. BURR (for himself, Mr. FRANKEN, Mr. KIRK, Mr. ENZI, and Mr. ALEXANDER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 18, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to devices.

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 "FDA Device Accountability Act of 2015".~~

SEC. 2. ENSURING LEAST BURDENSOME MEANS OF EVALUATING DEVICES.

(a) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

"(1) TRAINING AND ASSESSMENT.—The Secretary shall—

"(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) and section 515(c)(5); and

"(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A) to ensure that the least burdensome requirements are fully and consistently applied.

"(2) OMBUDSMAN AUDIT.—Not later than 180 calendar days after the date of enactment of the FDA Device Accountability Act of 2015, the om-

budsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct an audit of the training described in paragraph (1)(A);

"(B) include in such audit interviews of persons who are representatives of the device industry regarding their experience in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and the application of postmarket requirements to facilitate premarket decisionmaking;

"(C) include in such audit an assessment of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including the effectiveness of such tools and the effectiveness of the implementation of the least burdensome requirements; and

"(D) within 30 calendar days of completion of the audit, make such audit available—

"(i) 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

"(ii) on the Internet website of the Food and Drug Administration.".

(b) PREMARKET APPLICATIONS.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

"(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

"(B) For purposes of subparagraph (A) the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

"(C) Nothing in this paragraph alters the standards for premarket approval of a device.

"(D) For purposes of this paragraph, the Secretary shall consider whether the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness would be achieved through reliance on postmarket information.".

(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by adding at the end the following:

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include an explanation of how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D) and section 513(a)(3)(D) and section 515(c)(5), as applicable.".

SEC. 3. PERMITTING NON-LOCAL INSTITUTIONAL REVIEW BOARDS.

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

(1) in subsection (g)(3)—

(A) by striking "local" each place it appears; and

(B) in subparagraph (A)(i), by striking "which has been"; and

(2) in subsection (m)(4)—

(A) by striking "local" each place it appears; and

(B) by amending subparagraph (A) to read as follows:

''(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and''.

(b) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise or issue such regulations or guidance as may be necessary to carry out the amendments made by subsection (a).

SEC. 4. CLARIFYING CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish a draft guidance that—

(1) revises section ''V. Demonstrating Insignificant Risk of an Erroneous Result'' – ''Accuracy'' of the guidance entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' and dated January 30, 2008; and

(2) includes guidance on the appropriate use of comparable performance between a waived user and

~~a moderately complex laboratory user to demonstrate accuracy.~~

~~(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "FDA Device Accountability Act of 2016".

SEC. 2. USE OF NONLOCAL INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS AND HUMAN DEVICE EXEMPTIONS.

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

(1) in subsection (g)(3)—

(A) in subparagraph (A)(i)—

(i) by striking "local"; and

(ii) by striking "which has been"; and

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(2) in subsection (m)(4)—

(A) by striking subparagraph (A) and inserting the following new subparagraph:

"(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary, and";

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(C) in the matter following subparagraph (B), by striking "local".

SEC. 3. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

(1) revises section "V. Demonstrating Insignificant Risk of an Erroneous Result" – "Accuracy" of the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" and dated January 30, 2008; and

(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.

SEC. 4. ENSURING LEAST BURDENSOME MEANS OF EVALUATING DEVICES.

(a) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

"(1) TRAINING AND ASSESSMENT.—The Secretary shall—

"(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) and section 515(c)(5); and

"(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A) to ensure that the least burdensome requirements are fully and consistently applied.

"(2) OMBUDSMAN AUDIT.—Not later than 18 months after the date of enactment of the FDA Device Accountability Act of 2016, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

"(B) include in such audit interviews of persons who are representatives of the device industry regarding their experience in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

"(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including those referenced in para-

graph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

"(D) summarize the findings of such audit in a final audit report; and

"(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

"(i) 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

"(ii) on the Internet website of the Food and Drug Administration.".

(b) PREMARKET APPLICATIONS.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

"(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

"(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required

information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

"(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

"(D) Nothing in this paragraph may alter the standards for premarket approval of a device.".

(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by adding at the end the following:

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.".

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