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114TH CONGRESS
1ST SESSION

H. R. 2424

To amend the Federal Food, Drug, and Cosmetic Act with respect to training and oversight in least burdensome appropriate means concept.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. SHIMKUS 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 with respect to training and oversight in least burdensome appropriate means concept.

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

SECTION 1. TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by inserting after subsection (i) the following:

"(j) TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.—

''(1) TRAINING.—Each employee of the Food and Drug Administration who is involved in the review of premarket submissions under section 515 or section 510(k), including supervisors, shall receive training regarding the meaning and implementation of the least burdensome appropriate means concept in the context of the use of that term in subsections (a)(3)(D) and (i)(1)(D) of this section and in section 515(c)(5).

''(2) GUIDANCE DOCUMENTS.—

''(A) DRAFT UPDATED GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue a draft guidance document updating the October 4, 2002, guidance document entitled 'The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry'.

''(B) MEETING OF STAKEHOLDERS.—In developing such draft guidance document, the Secretary shall convene a meeting of stakeholders to ensure a full record to support the publication of such document.

''(3) OMBUDSMAN AUDIT.—Not later than 18 months after the date of issuance of final version of the draft guidance under paragraph (2), the ombudsman for the organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

''(A) conduct, or have conducted, an audit of the training described in paragraph (1); and

''(B) include in such audit interviews with a representative sample of persons from industry regarding their experience in the device premarket review process.''.

(b) ADDITIONAL INFORMATION REGARDING PREMARKET APPLICATIONS.—Subsection (c) of section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended by adding at the end the follows:

''(5)(A) Whenever the Secretary requests additional information from an applicant regarding an application under paragraph (1), the Secretary shall consider the least burdensome appropriate means necessary to demonstrate device safety and effectiveness, and request information accordingly.

''(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.''.

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