

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. TRAINING AND OVERSIGHT IN LEAST BURDEN-**
4 **SOME APPROPRIATE MEANS CONCEPT.**

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

8 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-
9 SOME APPROPRIATE MEANS CONCEPT.—

1 “(1) TRAINING.—Each employee of the Food
2 and Drug Administration who is involved in the re-
3 view of premarket submissions under section 515 or
4 section 510(k), including supervisors, shall receive
5 training regarding the meaning and implementation
6 of the least burdensome appropriate means concept
7 in the context of the use of that term in subsections
8 (a)(3)(D) and (i)(1)(D) of this section and in section
9 515(c)(5).

10 “(2) GUIDANCE DOCUMENTS.—

11 “(A) DRAFT UPDATED GUIDANCE.—Not
12 later than 12 months after the date of enact-
13 ment of the 21st Century Cures Act, the Sec-
14 retary shall issue a draft guidance document
15 updating the October 4, 2002, guidance docu-
16 ment entitled ‘The Least Burdensome Provision
17 of the FDA Modernization Act of 1997: Con-
18 cept and Principles; Final Guidance for FDA
19 and Industry’.

20 “(B) MEETING OF STAKEHOLDERS.—In
21 developing such draft guidance document, the
22 Secretary shall convene a meeting of stake-
23 holders to ensure a full record to support the
24 publication of such document.

1 “(3) OMBUDSMAN AUDIT.—Not later than 18
2 months after the date of issuance of final version of
3 the draft guidance under paragraph (2), the om-
4 budsman for the organizational unit of the Food and
5 Drug Administration responsible for the premarket
6 review of devices shall—

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

9 “(B) include in such audit interviews with
10 a representative sample of persons from indus-
11 try regarding their experience in the device pre-
12 market review process.”.

13 (b) ADDITIONAL INFORMATION REGARDING PRE-
14 MARKET APPLICATIONS.—Subsection (c) of section 515 of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 360e) is amended by adding at the end the follows:

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

23 “(B) For purposes of subparagraph (A), the term
24 ‘necessary’ means the minimum required information that
25 would support a determination by the Secretary that an

1 application provides a reasonable assurance of the safety
2 and effectiveness of the device.

3 “(C) Nothing in this paragraph alters the standards
4 for premarket approval of a device.”.

○