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115TH CONGRESS
1ST SESSION

H. R. 2474

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative standard for substantial equivalence determinations for devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2017

Mrs. MIMI WALTERS of California (for herself and Mr. BERA) 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 an alternative standard for substantial equivalence determinations for devices, and for other purposes.

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 ''Medical Product Review Harmonization Act of 2017''.

SEC. 2. ALTERNATIVE SUBSTANTIAL EQUIVALENCE SHOWING.

Subsection 513(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(i)(1)) is amended—

(1) by redesignating subparagraphs (B) through (F) as subparagraphs (C) through (G), respectively;

(2) by inserting after subparagraph (A) the following:

''(B)(i) As an alternative to clause (ii) of subparagraph (A), and for the purpose of determining substantial equivalence under subsection (f) and section 520(l), a person may submit information to the Secretary that demonstrates that a device conforms with national or international standards, standards established or recognized under section 514, or guidance documents developed by the Secretary to demonstrate that a device is as safe and effective as a legally marketed device, notwithstanding technological differences.

''(ii) Any person may propose to the Secretary, for purposes of clause (i), a national or international standard, a standard established or recognized under section 514, or a guidance document developed by the Secretary. Not later than 60 days after receipt of any such proposal, the Secretary shall provide to the person submitting the proposal a written determination—

''(I) accepting all, part, or none of the proposal for purposes of demonstrating substantial equivalence under this paragraph; and

''(II) stating the full rationale (including the scientific, technical, and regulatory basis) for the Secretary's determination.

''(iii) The Secretary shall—

''(I) except as provided in subclause (II), comply with the requirements for public participation described in section 701(h)(1)(C) before first using a standard or guidance document for purposes of this subparagraph; and

''(II) in the case of establishing or recognizing a standard, comply with the requirements described in section 514 for establishing or recognizing, as applicable, a performance standard.

''(iv) A person submitting a notification under section 510(k) may rely on a standard or guidance document identified, established, or recognized by the Secretary in accordance with clause (iii) to resolve some or all of the differences that exist between a new device and its legally marketed predicate device to demonstrate substantial equivalence.''; and

(3) in subparagraph (F) (as redesignated by paragraph (1)), by adding at the end the following:

''(iv) The reliance on standards or guidance documents to demonstrate substantial equivalence as described in subparagraph (B) shall be optional and have no effect

on the establishment of substantial equivalence pursuant to subparagraph (A) where such option is not exercised.''.

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