

115TH CONGRESS
1ST SESSION

H. R. 2164

To amend the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices.

IN THE HOUSE OF REPRESENTATIVES

APRIL 26, 2017

Mr. FITZPATRICK (for himself, Ms. SLAUGHTER, and Ms. DELAURO) 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 liability under State and local requirements respecting devices.

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. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Safety
5 Act”.

1 **SEC. 2. LIABILITY UNDER STATE AND LOCAL REQUIRE-**
2 **MENTS RESPECTING DEVICES.**

3 (a) AMENDMENT.—Section 521 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by
5 adding at the end the following:

6 “(c) NO EFFECT ON LIABILITY UNDER STATE
7 LAW.—Nothing in this section shall be construed to mod-
8 ify or otherwise affect any action for damages or the liabil-
9 ity of any person under the law of any State.”.

10 (b) EFFECTIVE DATE; APPLICABILITY.—The amend-
11 ment made by subsection (a) shall—

12 (1) take effect as if included in the enactment
13 of the Medical Device Amendments of 1976 (Public
14 Law 94–295); and

15 (2) apply to any civil action pending or filed on
16 or after the date of enactment of this Act.

○