

111TH CONGRESS
1ST SESSION

H. R. 1346

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

MARCH 5, 2009

Mr. PALLONE (for himself, Mr. WAXMAN, Mrs. CAPPS, Mr. STUPAK, Mr. BISHOP of Georgia, Mr. GRIJALVA, Mr. HINCHEY, Mr. DOYLE, Mr. HIGGINS, Mr. OLVER, Ms. SCHAKOWSKY, Mr. BRALEY of Iowa, Mr. DINGELL, Mr. WEINER, Mr. SARBANES, Ms. SUTTON, Mr. WEXLER, Mr. NADLER of New York, Mr. BACA, Mr. HINOJOSA, Mr. GENE GREEN of Texas, Mr. TERRY, Mr. KUCINICH, Mr. MARKEY of Massachusetts, Ms. ZOE LOFGREN of California, Mr. LIPINSKI, Mr. WU, Ms. DEGETTE, Ms. HIRONO, Mr. DELAHUNT, Mr. SCOTT of Virginia, Ms. WASSERMAN SCHULTZ, Mr. BLUMENAUER, Mr. LINCOLN DIAZ-BALART of Florida, Mr. BRADY of Pennsylvania, Mr. CONNOLLY of Virginia, Mr. MEEKS of New York, Mr. CONYERS, Mr. JOHNSON of Illinois, Mr. ROTHMAN of New Jersey, Ms. CASTOR of Florida, Ms. NORTON, Mr. LYNCH, Mr. BERMAN, Mr. BOSWELL, Mr. SCHIFF, Ms. DELAURO, Mr. LOEBSACK, Mr. STARK, Mr. FILNER, Mr. RUSH, Mrs. MCCARTHY of New York, Mrs. CHRISTENSEN, Mr. MCNERNEY, Ms. BALDWIN, Mr. BUTTERFIELD, Ms. SLAUGHTER, Ms. MATSUI, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. JACKSON-LEE of Texas, Mr. HASTINGS of Florida, Mr. AL GREEN of Texas, Mr. WELCH, Mr. DAVIS of Alabama, Mr. JOHNSON of Georgia, and Mr. HODES) 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 of 2009”.

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

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

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

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

17 (1) take effect as if included in the enactment
18 of the Medical Device Amendments of 1976 (Public
19 Law 94–295); and

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

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