

110TH CONGRESS
2D SESSION

H. R. 6381

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

JUNE 26, 2008

Mr. PALLONE (for himself, Mr. WAXMAN, Mrs. CAPPS, Mr. WEINER, Mr. HINCHEY, Ms. SCHAKOWSKY, Mr. BRALEY of Iowa, Mr. DOYLE, Mr. TOWNS, Mr. STUPAK, Ms. SOLIS, Mr. GENE GREEN of Texas, Ms. SLAUGHTER, Mr. WELCH of Vermont, Ms. CASTOR, Mr. JOHNSON of Georgia, Mr. SCHIFF, Mr. MARKEY, Mr. ALLEN, Ms. ZOE LOFGREN of California, Mr. ROSS, Ms. BALDWIN, Ms. DELAURO, Mr. WEXLER, Mr. BOSWELL, Mr. DELAHUNT, Ms. ROYBAL-ALLARD, Mr. RUSH, Ms. WASSERMAN SCHULTZ, Ms. SUTTON, Mr. MCNERNEY, Mr. HASTINGS of Florida, Mr. EMANUEL, Mr. LIPINSKI, Mr. ROTHMAN, Mr. BACA, Mr. BERMAN, Ms. JACKSON-LEE of Texas, Ms. DEGETTE, Mr. DAVIS of Illinois, Mr. STARK, Mr. JOHNSON of Illinois, Mr. COBLE, Mr. LYNCH, Mr. TERRY, Ms. HIRONO, Mr. CONYERS, Mr. HIGGINS, Mrs. MCCARTHY of New York, Mr. SARBANES, Mr. FILNER, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. SCOTT of Virginia, Mr. BLUMENAUER, Mr. MEEKS of New York, Mr. HINOJOSA, Mr. WU, Mr. MELANCON, Ms. HOOLEY, Mr. GRIJALVA, Ms. NORTON, Mr. MCGOVERN, and Mr. DINGELL) 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medical Device Safety
3 Act of 2008”.

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

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

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

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

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

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

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