

112TH CONGRESS
1ST SESSION

H. R. 3211

To amend the Federal Food, Drug, and Cosmetic Act to improve humanitarian device regulation.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mr. BASS of New Hampshire (for himself, Mr. ROGERS of Michigan, Mr. LANCE, Mrs. BLACKBURN, Mr. GUTHRIE, Mr. PAULSEN, Mr. LATTA, and 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 to improve humanitarian device regulation.

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 “Humanitarian Device
5 Reform Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) The humanitarian device exemption (HDE)
9 approval pathway, administered by the Food and

1 Drug Administration (FDA), is intended to accel-
2 erate the availability of innovative medical tech-
3 nologies to treat rare diseases or conditions, by al-
4 lowing sponsors of such devices to demonstrate the
5 safety and probable benefit to patients of medical
6 devices to treat or diagnose a disease or condition
7 that affects fewer than 4,000 patients in the United
8 States per year.

9 (2) Since the inception of the humanitarian de-
10 vice exemption, only 53 medical devices have been
11 granted an HDE in the United States. From 2005
12 through 2009, only 20 HDE applications were filed,
13 and a mere 11 were approved by the FDA.

14 (3) In sharp contrast, under the Orphan Drug
15 Act (Public Law 97–414) more than 2,150 drugs
16 have been designated by the Secretary of Health and
17 Human Services as being for rare diseases or condi-
18 tions and 358 such drugs have been approved for
19 use in the United States.

20 (4) In 2010, the FDA conceded the scope of the
21 remaining unmet medical needs for American pa-
22 tients, testifying to Congress that “there are still an
23 estimated 20 million Americans suffering from rare
24 diseases for which there are no approved therapies
25 available”.

1 (5) In 2010, the former Director of the FDA’s
2 Center for Devices and Radiological Health (CDRH)
3 concluded, “[t]he potential for HDEs to foster inno-
4 vation has not been reached because of the regu-
5 latory burdens of the program”.

6 (6) In 2007, the American Academy of Pediat-
7 rics testified to Congress, “The profit restriction on
8 HDE-approved devices limits the effectiveness of the
9 provision by forcing device manufacturers to only re-
10 cover their research and development costs”.

11 (7) Targeted reforms are consequently needed
12 to strengthen and enhance the HUD/HDE pathway.

13 **SEC. 3. REPEAL OF PROFIT PROHIBITION.**

14 Section 520(m) of the Federal Food, Drug and Cos-
15 metic Act (21 U.S.C. 360j(m)) is amended—

16 (1) by striking paragraphs (3), (6), (7), and
17 (8); and

18 (2) in paragraph (5), by striking “, if the Sec-
19 retary has reason to believe that the requirements of
20 paragraph (6) are no longer met,”.

21 **SEC. 4. CLARIFICATION OF REFERENCES TO RARE DIS-**
22 **EASES OR CONDITIONS.**

23 Paragraphs (1) and (2)(A) of section 520(m) of the
24 Federal Food, Drug and Cosmetic Act (21 U.S.C.

- 1 360j(m)) are amended by inserting “per year” after
- 2 “4,000 individuals in the United States”.

○