I

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.

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 ''Humanitarian Device Reform Act of 2011''.

SEC. 2. FINDINGS.

Congress finds as follows:

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

Drug Administration (FDA), is intended to accelerate the availability of innovative medical technologies to treat rare diseases or conditions, by allowing sponsors of such devices to demonstrate the safety and probable benefit to patients of medical devices to treat or diagnose a disease or condition that affects fewer than 4,000 patients in the United States per year.

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

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

(4) In 2010, the FDA conceded the scope of the remaining unmet medical needs for American patients, testifying to Congress that ''there are still an estimated 20 million Americans suffering from rare diseases for which there are no approved therapies available''.

(5) In 2010, the former Director of the FDA's Center for Devices and Radiological Health (CDRH) concluded, ''[t]he potential for HDEs to foster innovation has not been reached because of the regulatory burdens of the program''.

(6) In 2007, the American Academy of Pediatrics testified to Congress, ''The profit restriction on HDE-approved devices limits the effectiveness of the provision by forcing device manufacturers to only recover their research and development costs''.

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

SEC. 3. REPEAL OF PROFIT PROHIBITION.

Section 520(m) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

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

(2) in paragraph (5), by striking '', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,''.

SEC. 4. CLARIFICATION OF REFERENCES TO RARE DISEASES OR CONDITIONS.

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

360j(m)) are amended by inserting ''per year'' after ''4,000 individuals in the United States''.

○