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112TH CONGRESS
1ST SESSION

H. R. 3208

To reaffirm the Safe Medical Devices Act of 1990 by requiring that the Secretary of Health and Human Services establish a schedule and issue regulations as required under section 515(i) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mr. SHIMKUS (for himself, Mr. GINGREY of Georgia, Mr. GUTHRIE, Mr. LANCE, Mrs. BLACKBURN, Mr. ROGERS of Michigan, Mr. BILBRAY, Mr. BURGESS, Mr. BARTON of Texas, Mr. PAULSEN, Mr. CASSIDY, and Mr. LATTA) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To reaffirm the Safe Medical Devices Act of 1990 by requiring that the Secretary of Health and Human Services establish a schedule and issue regulations as required under section 515(i) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

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 ''Patients Come First Act of 2011''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Under the Safe Medical Devices Act of 1990 (Public Law 101–629), Congress amended section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) to require the Food and Drug Administration to reclassify preamendment class III devices to a lower class or to require them to go through the premarket approval process.

(2) The Food and Drug Administration still has not complied with the mandate of Congress under such Act, jeopardizing the health of the Nation's patients.

SEC. 3. ESTABLISHMENT OF SCHEDULE AND PROMULGATION OF REGULATION.

(a) ESTABLISHMENT OF SCHEDULE.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish the schedule referred to in section 515(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

(b) REGULATION.—Not later than one year after the date that the schedule is established under such section 515(i)(3) (as required by subsection (a)) the Secretary shall issue a final regulation under section 515(b) of such Act for each device that the Secretary requires to remain

in class III through a determination under section 515(i)(2) of such Act.

SEC. 4. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 518 (21 U.S.C. 360h) the following:

"SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

''(a) IN GENERAL.—The Secretary shall—

''(1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

''(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

''(3) develop detailed criteria for assessing whether a person performing a device recall has performed an effective correction or action plan for the recall; and

''(4) document the basis for each termination by the Food and Drug Administration of a device recall.

''(b) ASSESSMENT CONTENT.—The program established under subsection (a)(1) shall, at a minimum, identify—

''(1) trends in the number and types of device recalls;

''(2) devices that are most frequently the subject of a recall; and

''(3) underlying causes of device recalls.''.

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