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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R.

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

Mr. SHIMKUS (for himself, Mr. GINGREY of Georgia, and Mr. GUTHRIE) introduced the following bill; which was referred to the Committee on

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.

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 “Patients Come First
5 Act of 2011”.

1 **SEC. 2. FINDINGS.**

2 Congress find as follows:

3 (1) Under the Safe Medical Devices Act of
4 1990 (Public Law 101–629), Congress amended sec-
5 tion 515 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 360e) to require the Food and Drug
7 Administration to reclassify preamendment class III
8 devices to a lower class or to require them to go
9 through the premarket approval process.

10 (2) The Food and Drug Administration still has
11 not complied with the mandate of Congress under
12 such Act, jeopardizing the health of the Nation’s pa-
13 tients.

14 **SEC. 3. ESTABLISHMENT OF SCHEDULE AND PROMULGA-**
15 **TION OF REGULATION.**

16 (a) ESTABLISHMENT OF SCHEDULE.—Not later than
17 90 days after the date of enactment of this Act, the Sec-
18 retary of Health and Human Services shall establish the
19 schedule referred to in section 515(i)(3) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

21 (b) REGULATION.—Not later than one year after the
22 date that the schedule is established under such section
23 515(i)(3) (as required by subsection (a)) the Secretary
24 shall issue a final regulation under section 515(b) of such
25 Act for each device that the Secretary requires to remain

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

3 **SEC. 4. PROGRAM TO IMPROVE THE DEVICE RECALL SYS-**
4 **TEM.**

5 Chapter V of the Federal Food, Drug, and Cosmetic
6 Act is amended by inserting after section 518 (21 U.S.C.
7 360h) the following:

8 **“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**
9 **SYSTEM.**

10 “(a) IN GENERAL.—The Secretary shall—

11 “(1) establish a program to routinely and sys-
12 tematically assess information relating to device re-
13 calls and use such information to proactively identify
14 strategies for mitigating health risks presented by
15 defective or unsafe devices;

16 “(2) clarify procedures for conducting device re-
17 call audit checks to improve the ability of investiga-
18 tors to perform those checks in a consistent manner;

19 “(3) develop detailed criteria for assessing
20 whether a person performing a device recall has per-
21 formed an effective correction or action plan for the
22 recall; and

23 “(4) document the basis for each termination
24 by the Food and Drug Administration of a device re-
25 call.

1 “(b) ASSESSMENT CONTENT.—The program estab-
2 lished under subsection (a)(1) shall, at a minimum, iden-
3 tify—

4 “(1) trends in the number and types of device
5 recalls;

6 “(2) devices that are most frequently the sub-
7 ject of a recall; and

8 “(3) underlying causes of device recalls.”.