114TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to require patient medication information to be provided with certain prescription drugs.

IN THE SENATE OF THE UNITED STATES

Mrs. GILLIBRAND (for herself, Ms. WARREN, Ms. STABENOW, Mr. BROWN, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require patient medication information to be provided with certain prescription drugs.

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 ''Cody Miller Patient Medication Information Act''.

SEC. 2. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505E the following:

"SEC. 505F. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

''(a) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final regulations regarding the authorship, content, format, and dissemination requirements for patient medication information for drugs subject to section 503(b)(1).

''(b) CONTENT.—The regulations promulgated under subsection (a) shall require that the patient medication information with respect to a drug—

''(1) be scientifically accurate, include relevant patient safety information, and be based on the professional labeling approved by the Secretary; and

''(2) include standard, nontechnical, understandable, plain language that is not promotional in tone or content, and contain at least—

''(A) the established name of the drug or the proper name of the biological product, as applicable;

''(B) drug uses;

''(C) general directions for proper use;

"(D) contraindications, the most frequently occurring adverse reactions, and adverse reactions that are important for other reasons (such as because they are serious), especially with respect to certain groups such as children, pregnant women, and the elderly;

"(E) measures patients may be able to take, if any, to reduce the side effects and risks of the drug;

"(F) when a patient should contact his or her health care professional;

"(G) instructions not to share medications, and, if any exist, key storage requirements, and recommendations relating to proper disposal of any unused portion of the drug;

"(H) known clinically important interactions with other drugs and substances; and

"(I) a statement of whether sufficient data are available concerning the use of the drug in specified subpopulations, such as women, pregnant women, lactating women, women and men of reproductive age, pediatric, geriatric, racial and ethnic minority groups, and other subpopulations.

''(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—The regulations promulgated under subsection (a) shall include standards relating to how the Secretary—

''(1) shall perform timely reviews and updates of patient medication information as new drugs and new information become available;

''(2) may perform, when appropriate, updates to help communicate information that is shared by similar drug products or drugs within classes of medications in order to avoid patient confusion and harm; and

''(3) shall develop a process, including consumer testing, to assess the quality and effectiveness of patient medication information in ensuring that patient medication information developed in accordance with this section promotes patient understanding and safe and effective medication use.

''(d) ELECTRONIC REPOSITORY.—The regulations promulgated under subsection (a) shall provide for the development of a publicly accessible electronic repository for all patient medication information documents and content to facilitate the availability of patient medication information.''.

SEC. 3. ENFORCEMENT AND DISSEMINATION.

(a) ENFORCEMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(dd) If it is a drug subject to section 503(b)(1) and patient medical information described in section 505F is not provided, as required under section 503(b)(1).''.

(b) DISSEMINATION.—Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) is amended by inserting ''Under the circumstances determined by the Secretary through regulation or guidance, a drug dispensed in accordance with this paragraph shall be accompanied by the patient medication information for such drug developed in accordance with section 505F'' after ''by the pharmacist.''.