II

114TH CONGRESS
1ST SESSION

S. 1597

To enhance patient engagement in the medical product development process, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 17, 2015

Mr. WICKER (for himself, Ms. KLOBUCHAR, Ms. COLLINS, Mr. FRANKEN, Mr. ISAKSON, and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To enhance patient engagement in the medical product development process, 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 ''Patient-Focused Impact Assessment Act of 2015''.

SEC. 2. PUBLIC DISCLOSURE OF SAFETY AND EFFECTIVENESS DATA IN ACTION PACKAGE.

Paragraph (2) of section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended—

(1) in subparagraph (C), by adding at the end the following:

''(vii) Documentation of the patient engagement assessment efforts made as part of the review, including identification of the patient-focused drug development tools and data reviewed in informing the decision to approve the application, and including an explanation of whether the following were reviewed or examined:

''(I) Patient population benefit and risk data.

''(II) Draft or final guidances issued by the Food and Drug Administration.

''(III) Patient-reported or caregiver-reported outcomes data.

''(IV) Patient preference data.

''(V) Perspectives of patients serving on advisory committees or participating in medical product development proceedings.

''(VI) Perspectives of medical and scientific professionals with relevant expertise.

''(VII) Other measures to assess the impact of patient-focused drug develop-

ment tools, as determined by the Secretary.''; and

(2) by adding at the end the following:

''(F) ANNUAL REPORTS.—The Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report summarizing the data collected from the action packages under subparagraph (C)(vii). Such report shall include an assessment by the Food and Drug Administration of the trends of such agency with respect to the use of patient-focused drug development tools in reviewing applications under subsection (b) and section 351 of the Public Health Service Act.''.

SEC. 3. GUIDANCE TO PATIENTS AND INDUSTRY ON PATIENT-FOCUSED DRUG DEVELOPMENT.

(a) PUBLICATION OF GUIDANCE; CONTENTS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall publish guidance that—

(1) specifies how the Food and Drug Administration views collaboration between patients or pa-

tient advocacy organizations and industry sponsors for the purposes of—

(A) developing patient-focused drug development tools; and

(B) obtaining patient perspectives on medical products under development;

(2) specifies the position of the Food and Drug Administration with respect to advocacy and industry collaborations that would be permitted to develop such tools and obtain such perspectives; and

(3) specifies the position of the Food and Drug Administration with respect to activities that would not be permitted for such purposes.

(b) TIMING.—The Secretary shall—

(1) not later than 6 months after the date of enactment of this Act, publish proposed guidance under this section; and

(2) not later than 6 months after the date of publication of such proposed guidance, and after providing an opportunity for the public to comment on such proposed guidance, publish final guidance under this section.

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