Calendar No. 413

114TH CONGRESS
2D 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, Mr. BENNET, Mr. DONNELLY, Mr. COTTON, and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 5, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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 development 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 Com-

missioner of Food and Drugs, shall publish guidance that—

(1) specifies how the Food and Drug Administration views collaboration between patients or patient 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.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patient-Focused Impact Assessment Act of 2016".

SEC. 2. PATIENT EXPERIENCE DATA.

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c) is amended—

(1) in subsection (a)—

(A) in the subsection heading, by striking "IN GENERAL" and inserting "PATIENT ENGAGEMENT IN DRUGS AND DEVICES";

(B) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly; and

(C) by striking "The Secretary" and inserting the following:

"(1) IN GENERAL.—The Secretary";

(2) by redesignating subsections (b) through (e) as paragraphs (2) through (5), respectively, and adjusting the margins accordingly; and

(3) by adding at the end the following:

"(b) STATEMENT OF PATIENT EXPERIENCE.—

"(1) IN GENERAL.—Following the approval of an application that was submitted under section 505(b)

of this Act or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) at least 6 months after the date of enactment of the Patient-Focused Impact Assessment Act of 2016, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application. The Secretary shall include in the statement information on whether the data and information described in paragraph (2) were submitted and reviewed as part of such application.

"(2) DATA AND INFORMATION.—The data and information referred to in paragraph (1) are—

"(A) patient experience data;

"(B) information on patient-focused drug development tools; and

"(C) other relevant information, as determined by the Secretary.

"(c) PATIENT EXPERIENCE DATA.—For purposes of this section, the term 'patient experience data' includes data that—

"(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

"(2) are intended to provide information about patients' experiences with a disease or condition, including—

"(A) the impact of such disease or condition, or a related therapy, on patients' lives; and

"(B) patient preferences with respect to treatment of such disease or condition.".

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

(a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than 18 months after that date of enactment, the Secretary shall issue a draft version of at least one such guidance document. Not later than 1 year after the public comment period on the draft document ends, the Secretary shall issue a final version of that document.

(b) PATIENT EXPERIENCE DATA.—For purposes of this section, the term "patient experience data" includes data that—

(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

(2) are intended to provide information about patients' experiences with a disease or condition, including—

(A) the impact of such disease or condition, or a related therapy, on patients' lives; and

(B) patient preferences with respect to treatment of such disease or condition.

(c) CONTENTS.—The guidance documents described in subsection (a) shall address—

(1) how a person seeking to collect patient experience data for submission to and proposed use by the Food and Drug Administration in regulatory decisionmaking may—

(A) submit initial concepts about how such person plans to gather patient experience data;

(B) develop and collect patient experience data using methodologies that—

(i) ensure data are accurate;

(ii) ensure data are representative of the intended population; and

(iii) are relevant and objective; and

(C) submit patient experience data, analysis, or other applicable related information, including through a regulatory application, a public docket, or other means;

(2) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Food and Drug Administration may submit such proposed draft guidance to the Food and Drug Administration;

(3) the format and content required for submissions under this section to the Food and Drug Administration, including with respect to the information described in paragraph (1);

(4) how the Secretary intends to respond to submissions under paragraph (1), if appropriate given the manner in which a submission is made, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

(5) how, when the Commissioner of Food and Drugs determines appropriate, such Commissioner

anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)).

SEC. 4. PATIENT INPUT EXEMPT FROM PAPERWORK REDUCTION ACT.

Chapter 35 of title 44, United States Code, shall not apply to collections of information to which a response is voluntary, that are initiated by the Secretary under section 3 of the Patient-Focused Impact Assessment Act of 2016.

SEC. 5. REPORT TO CONGRESS ON PATIENT EXPERIENCE DRUG DEVELOPMENT.

Not later than June 1 of 2021, 2026, and 2031, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall prepare and publish on the website of the Food and Drug Administration a report assessing the trends of the Food and Drug Administration with respect to the review of patient experience data and information on patient-focused drug development tools as part of approved applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

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