

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.

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 “~~Patient-Focused Im-~~
5 ~~pact Assessment Act of 2015~~”.

1 **SEC. 2. PUBLIC DISCLOSURE OF SAFETY AND EFFECTIVE-**
2 **NESS DATA IN ACTION PACKAGE.**

3 Paragraph (2) of section 505(l) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended—
5 (1) in subparagraph (C), by adding at the end
6 the following:

7 “(vii) Documentation of the patient en-
8 gagement assessment efforts made as part of
9 the review, including identification of the pa-
10 tient-focused drug development tools and data
11 reviewed in informing the decision to approve
12 the application, and including an explanation of
13 whether the following were reviewed or exam-
14 ined:

15 “(I) Patient population benefit and
16 risk data.

17 “(II) Draft or final guidances issued
18 by the Food and Drug Administration.

19 “(III) Patient-reported or caregiver-
20 reported outcomes data.

21 “(IV) Patient preference data.

22 “(V) Perspectives of patients serving
23 on advisory committees or participating in
24 medical product development proceedings.

1 “(VI) Perspectives of medical and sci-
 2 entific professionals with relevant exper-
 3 tise.

4 “(VII) Other measures to assess the
 5 impact of patient-focused drug develop-
 6 ment tools, as determined by the Sec-
 7 retary.”; and

8 (2) by adding at the end the following:

9 “(F) ANNUAL REPORTS.—The Secretary shall
 10 prepare and submit to the Committee on Health,
 11 Education, Labor, and Pensions of the Senate and
 12 the Committee on Energy and Commerce of the
 13 House of Representatives an annual report summa-
 14 rizing the data collected from the action packages
 15 under subparagraph (C)(vii). Such report shall in-
 16 clude an assessment by the Food and Drug Adminis-
 17 tration of the trends of such agency with respect to
 18 the use of patient-focused drug development tools in
 19 reviewing applications under subsection (b) and sec-
 20 tion 351 of the Public Health Service Act.”.

21 **SEC. 3. GUIDANCE TO PATIENTS AND INDUSTRY ON PA-**
 22 **TIENT-FOCUSED DRUG DEVELOPMENT.**

23 (a) PUBLICATION OF GUIDANCE; CONTENTS.—The
 24 Secretary of Health and Human Services (referred to in
 25 this section as the “Secretary”), acting through the Com-

1 missioner of Food and Drugs, shall publish guidance
2 that—

3 ~~(1)~~ specifies how the Food and Drug Adminis-
4 tration views collaboration between patients or pa-
5 tient advocacy organizations and industry sponsors
6 for the purposes of—

7 ~~(A)~~ developing patient-focused drug devel-
8 opment tools; and

9 ~~(B)~~ obtaining patient perspectives on med-
10 ical products under development;

11 ~~(2)~~ specifies the position of the Food and Drug
12 Administration with respect to advocacy and indus-
13 try collaborations that would be permitted to develop
14 such tools and obtain such perspectives; and

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

18 ~~(b) TIMING.~~—The Secretary shall—

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

22 ~~(2)~~ not later than 6 months after the date of
23 publication of such proposed guidance, and after
24 providing an opportunity for the public to comment

1 on such proposed guidance, publish final guidance
2 under this section.

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Patient-Focused Impact*
5 *Assessment Act of 2016”.*

6 **SEC. 2. PATIENT EXPERIENCE DATA.**

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

9 *(1) in subsection (a)—*

10 *(A) in the subsection heading, by striking*
11 *“IN GENERAL” and inserting “PATIENT EN-*
12 *GAGEMENT IN DRUGS AND DEVICES”;*

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

16 *(C) by striking “The Secretary” and insert-*
17 *ing the following:*

18 *“(1) IN GENERAL.—The Secretary”;*

19 *(2) by redesignating subsections (b) through (e)*
20 *as paragraphs (2) through (5), respectively, and ad-*
21 *justing the margins accordingly; and*

22 *(3) by adding at the end the following:*

23 *“(b) STATEMENT OF PATIENT EXPERIENCE.—*

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

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

12 “(2) *DATA AND INFORMATION.*—*The data and*
 13 *information referred to in paragraph (1) are—*

14 “(A) *patient experience data;*

15 “(B) *information on patient-focused drug*
 16 *development tools; and*

17 “(C) *other relevant information, as deter-*
 18 *mined by the Secretary.*

19 “(c) *PATIENT EXPERIENCE DATA.*—*For purposes of*
 20 *this section, the term ‘patient experience data’ includes data*
 21 *that—*

22 “(1) *are collected by any persons (including pa-*
 23 *tients, family members and caregivers of patients, pa-*
 24 *tient advocacy organizations, disease research founda-*
 25 *tions, researchers, and drug manufacturers); and*

1 “(2) are intended to provide information about
2 patients’ experiences with a disease or condition, in-
3 cluding—

4 “(A) the impact of such disease or condi-
5 tion, or a related therapy, on patients’ lives; and

6 “(B) patient preferences with respect to
7 treatment of such disease or condition.”.

8 **SEC. 3. GUIDANCE TO PATIENTS AND INDUSTRY ON PA-**
9 **TIENT-FOCUSED DRUG DEVELOPMENT.**

10 (a) *PUBLICATION OF GUIDANCE DOCUMENTS.*—Not
11 later than 6 months after the date of enactment of this Act,
12 the Secretary of Health and Human Services (referred to
13 in this section as the “Secretary”), acting through the Com-
14 missioner of Food and Drugs, shall develop a plan to issue
15 draft and final versions of one or more guidance documents,
16 over a period of 5 years, regarding the collection of patient
17 experience data, and the use of such data and related infor-
18 mation in drug development. Not later than 18 months after
19 that date of enactment, the Secretary shall issue a draft
20 version of at least one such guidance document. Not later
21 than 1 year after the public comment period on the draft
22 document ends, the Secretary shall issue a final version of
23 that document.

1 (b) *PATIENT EXPERIENCE DATA.*—For purposes of
 2 this section, the term “patient experience data” includes
 3 data that—

4 (1) are collected by any persons (including pa-
 5 tients, family members and caregivers of patients, pa-
 6 tient advocacy organizations, disease research founda-
 7 tions, researchers, and drug manufacturers); and

8 (2) are intended to provide information about
 9 patients’ experiences with a disease or condition, in-
 10 cluding—

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

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

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

17 (1) how a person seeking to collect patient expe-
 18 rience data for submission to and proposed use by the
 19 Food and Drug Administration in regulatory deci-
 20 sionmaking may—

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

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

25 (i) ensure data are accurate;

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

3 (iii) are relevant and objective; and

4 (C) submit patient experience data, anal-
5 ysis, or other applicable related information, in-
6 cluding through a regulatory application, a pub-
7 lic docket, or other means;

8 (2) how a person seeking to develop and submit
9 proposed draft guidance relating to patient experience
10 data for consideration by the Food and Drug Admin-
11 istration may submit such proposed draft guidance to
12 the Food and Drug Administration;

13 (3) the format and content required for submis-
14 sions under this section to the Food and Drug Admin-
15 istration, including with respect to the information
16 described in paragraph (1);

17 (4) how the Secretary intends to respond to sub-
18 missions under paragraph (1), if appropriate given
19 the manner in which a submission is made, including
20 any timeframe for response when such submission is
21 not part of a regulatory application or other submis-
22 sion that has an associated timeframe for response;
23 and

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

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.

14 *Not later than June 1 of 2021, 2026, and 2031, the*
15 *Secretary of Health and Human Services, acting through*
16 *the Commissioner of Food and Drugs, shall prepare and*
17 *publish on the website of the Food and Drug Administra-*
18 *tion a report assessing the trends of the Food and Drug*
19 *Administration with respect to the review of patient experi-*
20 *ence data and information on patient-focused drug develop-*
21 *ment tools as part of approved applications submitted*
22 *under section 505(b) of the Federal Food, Drug, and Cos-*
23 *metic Act (21 U.S.C. 355(b)) and section 351(a) of the Pub-*
24 *lic Health Service Act (42 U.S.C. 262(a)).*

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