

114TH CONGRESS
1ST SESSION

H. R. 2416

To amend the Federal Food, Drug, and Cosmetic Act to evaluate the potential use of evidence from clinical experience to help support the approval of new indications for approved drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. BURGESS introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to evaluate the potential use of evidence from clinical experience to help support the approval of new indications for approved drugs, 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. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
4 **ENCE.**

5 Chapter V of the Federal Food, Drug, and Cosmetic
6 Act is amended by inserting after section 505E of such
7 Act (21 U.S.C. 355f) the following:

1 **“SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
2 **ENCE.**

3 “(a) IN GENERAL.—The Secretary shall establish a
4 program to evaluate the potential use of evidence from
5 clinical experience—

6 “(1) to help support the approval of a new indi-
7 cation for a drug approved under section 505(b);
8 and

9 “(2) to help support or satisfy post-approval
10 study requirements.

11 “(b) EVIDENCE FROM CLINICAL EXPERIENCE DE-
12 FINED.—In this section, the term ‘evidence from clinical
13 experience’ means data regarding the usage, or potential
14 benefits or risks, of a drug derived from sources other
15 than randomized clinical trials, including from observa-
16 tional studies, registries, and therapeutic use.

17 “(c) PROGRAM FRAMEWORK.—

18 “(1) IN GENERAL.—Not later than 18 months
19 after the date of enactment of this section, the Sec-
20 retary shall establish a draft framework for imple-
21 mentation of the program under this section.

22 “(2) CONTENTS OF FRAMEWORK.—The frame-
23 work shall include information describing—

24 “(A) the current sources of data developed
25 through clinical experience, including ongoing

1 safety surveillance, registry, claims, and pa-
2 tient-centered outcomes research activities;

3 “(B) the gaps in current data collection ac-
4 tivities;

5 “(C) the current standards and methodolo-
6 gies for collection and analysis of data gen-
7 erated through clinical experience; and

8 “(D) the priority areas, remaining chal-
9 lenges, and potential pilot opportunities that
10 the program established under this section will
11 address.

12 “(3) CONSULTATION.—

13 “(A) IN GENERAL.—In developing the pro-
14 gram framework under this subsection, the Sec-
15 retary shall consult with regulated industry,
16 academia, medical professional organizations,
17 representatives of patient advocacy organiza-
18 tions, disease research foundations, and other
19 interested parties.

20 “(B) PROCESS.—The consultation under
21 subparagraph (A) may be carried out through
22 approaches such as—

23 “(i) a public-private partnership with
24 the entities described in such subpara-

1 graph, in which the Secretary may partici-
2 pate; or

3 “(ii) a contract, grant, or other ar-
4 rangement, as determined appropriate by
5 the Secretary with such a partnership or
6 an independent research organization.

7 “(d) PROGRAM IMPLEMENTATION.—The Secretary
8 shall, not later than 24 months after the date of enact-
9 ment of this section and in accordance with the framework
10 established under subsection (c), implement the program
11 to evaluate the potential use of evidence from clinical expe-
12 rience.

13 “(e) GUIDANCE FOR INDUSTRY.—The Secretary
14 shall—

15 “(1) utilize the program established in sub-
16 section (d), its activities, and any subsequent pilots
17 or written reports, to inform a guidance for industry
18 on—

19 “(A) the circumstances under which spon-
20 sors of drugs and the Secretary may rely on
21 evidence from clinical experience for the pur-
22 poses described in subsections (a)(1) or (a)(2);
23 and

24 “(B) the appropriate standards and meth-
25 odologies for collection and analysis of evidence

1 from clinical experience submitted for such pur-
2 poses;

3 “(2) not later than 36 months after the date of
4 enactment of this section, issue draft guidance for
5 industry as described in paragraph (1); and

6 “(3) not later than 48 months after the date of
7 enactment of this section, after providing an oppor-
8 tunity for public comment on the draft guidance,
9 issue final guidance.

10 “(f) RULE OF CONSTRUCTION.—

11 “(1) Subject to paragraph (2), nothing in this
12 section prohibits the Secretary from using evidence
13 from clinical experience for purposes not specified in
14 this section, provided the Secretary determines that
15 sufficient basis exists for any such non-specified use.

16 “(2) This section shall not be construed to
17 alter—

18 “(A) the standards of evidence under—

19 “(i) subsection (c) or (d) of section
20 505, including the substantial evidence
21 standard in such subsection (d); or

22 “(ii) section 351(a) of the Public
23 Health Service Act; or

24 “(B) the Secretary’s authority to require
25 post-approval studies or clinical trials, or the

- 1 standards of evidence under which studies or
- 2 trials are evaluated.”.

