

114TH CONGRESS
1ST SESSION

H. R. 2455

To amend the Federal Food, Drug, and Cosmetic Act with respect to precision medicine.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. PITTS 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 with respect to precision medicine.

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. PRECISION MEDICINE GUIDANCE AND OTHER**
4 **PROGRAMS OF FOOD AND DRUG ADMINIS-**
5 **TRATION.**

6 Chapter V of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 351 et seq.) is amended by adding at the
8 end the following:

1 **“Subchapter J—Precision Medicine**

2 **“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION**
3 **MEDICINE.**

4 “(a) IN GENERAL.—The Secretary shall issue and
5 periodically update guidance to assist sponsors in the de-
6 velopment of a precision drug or biological product. Such
7 guidance shall—

8 “(1) define the term ‘precision drug or biologi-
9 cal product’; and

10 “(2) address the topics described in subsection
11 (b).

12 “(b) CERTAIN ISSUES.—The topics to be addressed
13 by guidance under subsection (a) are—

14 “(1) the evidence needed to support the use of
15 biomarkers (as defined in section 507(e)) that iden-
16 tify subsets of patients as likely responders to thera-
17 pies in order to streamline the conduct of clinical
18 trials;

19 “(2) recommendations for the design of studies
20 to demonstrate the validity of a biomarker as a pre-
21 dictor of drug or biological product response;

22 “(3) the manner and extent to which a benefit-
23 risk assessment may be affected when clinical trials
24 are limited to patient population subsets that are
25 identified using biomarkers;

1 “(4) the development of companion diagnostics
2 in the context of a drug development program; and

3 “(5) considerations for developing biomarkers
4 that aid prescribing decisions for a drug or biological
5 product, and when information regarding a bio-
6 marker may be included in the labeling for a drug
7 or biological product approved under section 505 of
8 this Act or section 351 of the Public Health Service
9 Act.

10 “(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The
11 Secretary shall issue guidance under subsection (a) not
12 later than 18 months after the date of the enactment of
13 the 21st Century Cures Act.

14 **“SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-**
15 **DRUG AND EXPEDITED-APPROVAL PRO-**
16 **GRAMS.**

17 “In the case of an application for a precision drug
18 or biological product under section 505(b)(1), or section
19 351(a) of the Public Health Service Act, that has been
20 designated under section 526 as a drug for a rare disease
21 for a serious condition, the Secretary may—

22 “(1) consistent with applicable standards for
23 approval, rely upon data or information previously
24 developed by the sponsor of the precision drug or bi-
25 ological product for a prior approved drug or indica-

1 tion (or that of another sponsor, provided the spon-
2 sor of the precision drug or biological product has
3 obtained a contractual right of reference to such
4 other sponsor's data and information) in order to ex-
5 pedite clinical development for a precision drug or
6 indication that is using the same or similar approach
7 as that of the prior approved drug or indication; and
8 “(2) as appropriate under section 506, consider
9 the application for approval of such precision drug
10 or biological product to be eligible for expedited re-
11 view, including under section 506(c) (relating to ac-
12 celerated approval).”.

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