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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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PRECISION MEDICINE GUIDANCE AND OTHER PROGRAMS OF FOOD AND DRUG ADMINISTRATION.

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

"Subchapter J—Precision Medicine

"SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

''(a) IN GENERAL.—The Secretary shall issue and periodically update guidance to assist sponsors in the development of a precision drug or biological product. Such guidance shall—

''(1) define the term 'precision drug or biological product'; and

''(2) address the topics described in subsection (b).

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

''(1) the evidence needed to support the use of biomarkers (as defined in section 507(e)) that identify subsets of patients as likely responders to therapies in order to streamline the conduct of clinical trials;

''(2) recommendations for the design of studies to demonstrate the validity of a biomarker as a predictor of drug or biological product response;

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

''(4) the development of companion diagnostics in the context of a drug development program; and

''(5) considerations for developing biomarkers that aid prescribing decisions for a drug or biological product, and when information regarding a biomarker may be included in the labeling for a drug or biological product approved under section 505 of this Act or section 351 of the Public Health Service Act.

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

''SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

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

''(1) consistent with applicable standards for approval, rely upon data or information previously developed by the sponsor of the precision drug or biological product for a prior approved drug or indica-

tion (or that of another sponsor, provided the sponsor of the precision drug or biological product has obtained a contractual right of reference to such other sponsor's data and information) in order to expedite clinical development for a precision drug or indication that is using the same or similar approach as that of the prior approved drug or indication; and

''(2) as appropriate under section 506, consider the application for approval of such precision drug or biological product to be eligible for expedited review, including under section 506(c) (relating to accelerated approval).''.

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