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114TH CONGRESS
1ST SESSION

H. R. 2438

To amend the Federal Food, Drug, and Cosmetic Act with respect to broader application of Bayesian statistics and adaptive trial designs.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. COLLINS of New York 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 broader application of Bayesian statistics and adaptive trial designs.

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

SECTION 1. BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS.

(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating adaptive trial design and Bayesian methods into proposed clinical protocols and applications for new drugs under section 505 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF ADAPTIVE TRIAL DESIGNS AND BAYESIAN METHODS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (in this subsection referred to as the ''Secretary''), shall—

(A) update and finalize the draft guidance addressing the use of adaptive trial design for drugs and biological products; and

(B) issue draft guidance on the use of Bayesian methods in the development and regulatory review and approval or licensure of drugs and biological products.

(2) CONTENTS.—The guidances under paragraph (1) shall address—

(A) the use of adaptive trial designs and Bayesian methods in clinical trials, including clinical trials proposed or submitted to help satisfy the substantial evidence standard under

section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

(B) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to—

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

(3) PUBLIC MEETING.—Prior to updating or developing the guidances required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, and disease research foundations, through a public meeting to be held not later than 1 year after the date of enactment of this Act.

(4) SCHEDULE.—The Secretary shall publish—

(A) the final guidance required by paragraph (1)(A) not later than 18 months after the

date of the public meeting required by paragraph (3); and

(B) the guidance required by paragraph (1)(B) not later than 48 months after the date of the public meeting required by paragraph (3).

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