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114TH CONGRESS
1ST SESSION

H. R. 1066

To amend the Federal Food, Drug, and Cosmetic Act to promote the use of adaptive trial designs, Bayesian methods, and other innovative statistical methods in clinical protocols for drugs, biological products, and devices, and with respect to the requirement to conduct postapproval studies and clinical trials, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2015

Mr. COLLINS of New York (for himself and Mr. POMPEO) 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 to promote the use of adaptive trial designs, Bayesian methods, and other innovative statistical methods in clinical protocols for drugs, biological products, and devices, and with respect to the requirement to conduct postapproval studies and clinical trials, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Clinical Trials Modernization Act of 2015''.

SEC. 2. CLINICAL TRIAL MODERNIZATION.

(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506F (21 U.S.C. 356f) the following new section:

"SEC. 507. CLINICAL TRIAL MODERNIZATION.

"(a) IN GENERAL.—To promote the efficiency of the development and regulatory review and approval, licensure, or clearance of drugs, biological products, and devices and the timely availability of innovative treatments, the Secretary shall, after providing notice and an opportunity for public comment, establish and implement a framework through which—

"(1) sponsors of drugs, biological products, or devices may submit to the Secretary a proposal for the incorporation of adaptive trial designs, Bayesian methods, or other alternative statistical methods into proposed clinical protocols and marketing applications for drugs, biological products, or devices; and

"(2) the Secretary will commit to timelines for reviewing and providing feedback on proposals so submitted.".

(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, licensure, or clearance of drugs, biological products, and devices.

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

(A) establish or clarify standards for using adaptive trial designs and Bayesian methods in clinical trials, including clinical trials that form the primary basis for approval, clearance, or licensure of the products involved (such as trials that provide substantial evidence for the approval of drugs);

(B) establish a mechanism for sponsors to obtain feedback from the Secretary under section 507, as added by subsection (a), 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) specify the types of quantitative and qualitative information required for review; and

(D) specify the recommended analysis methodology.

(3) PUBLIC MEETING.—Prior to updating or developing the guidances required by paragraph (1), the Secretary shall consult, through a public meeting to be held no later than 1 year after the date of enactment of this Act, with stakeholders including representatives of regulated industry, academia, patient advocacy organizations, and disease research foundations.

(4) SCHEDULE.—The Secretary shall, after providing notice and opportunity for public comment, publish—

(A) the final guidance required by paragraph (1)(A) not later than 6 months after the date of the public meeting required by paragraph (3); and

(B) the guidance required by paragraph (1)(B) not later than 12 months after the date

of the public meeting required by paragraph (3).

(5) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—Not later than 48 months after the date of enactment of this Act, the Secretary shall review and, as appropriate, revise the guidance documents required by subparagraphs (A) and (B) of paragraph (1) to reflect developments in statistical methods that could be appropriate for use in clinical trials, including clinical trials that—

(A) form the primary basis for approval, clearance, or licensure of drugs, biological products or devices; or

(B) provide substantial evidence for the approval of drugs.

SEC. 3. EVALUATIONS OF REQUIRED POSTAPPROVAL STUDIES AND CLINICAL TRIALS.

(a) IN GENERAL.—Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is amended by adding at the end the following new subparagraph:

"(G) EVALUATIONS OF REQUIRED POSTAPPROVAL STUDIES AND CLINICAL TRIALS.—

"(i) IN GENERAL.—The Secretary shall establish a process under which the

Secretary, on the initiative of the Secretary or at the request of a responsible person, shall periodically evaluate a postapproval study or clinical trial required to be conducted under this paragraph to determine whether—

"(I) the trial or study is no longer scientifically warranted; or

"(II) the design, or the timelines applicable to the completion of, the study or trial should be renegotiated because of changes in medical practice or the standard of care.

"(ii) NOT SCIENTIFICALLY WARRANTED.—In the case of a determination under clause (i)(I) that a postapproval study or clinical trial required to be conducted under this paragraph is no longer scientifically warranted, the Secretary shall no longer require the responsible person to conduct the study or trial.

"(iii) RENEGOTIATION.—In the case of a determination under clause (i)(II) that the design, or the timelines applicable to the completion of, a postapproval study or

clinical trial required to be conducted under this paragraph should be renegotiated, the Secretary shall enter into negotiations with the responsible person to make such changes as may be necessary to such design or timelines as the Secretary determines are necessary.''.

(b) GUIDANCE.—Not later than one year after the date of the enactment of this Act, the Secretary shall issue draft guidance on the implementation of subparagraph (G) of section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)), as added by subsection (a). Not later than two years after such date of enactment, the Secretary shall issue final guidance on such implementation.

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