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115TH CONGRESS
1ST SESSION

H. R. 2244

To direct the Secretary of Health and Human Services to carry out a pilot project under which no more than 3 sponsors agree to evaluate the psychological and social distress experienced by patients participating in a clinical trial, conducted by the respective sponsor, of a drug or biological product that is intended to treat a serious or life-threatening disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2017

Mr. LANCE (for himself and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To direct the Secretary of Health and Human Services to carry out a pilot project under which no more than 3 sponsors agree to evaluate the psychological and social distress experienced by patients participating in a clinical trial, conducted by the respective sponsor, of a drug or biological product that is intended to treat a serious or life-threatening disease or condition, 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 ''Patient Experience in Research Act of 2017''.

SEC. 2. PILOT PROJECT FOR EVALUATION OF PSYCHOLOGICAL AND SOCIAL DISTRESS EXPERIENCED BY PATIENTS IN CERTAIN CLINICAL TRIALS.

(a) IN GENERAL.—The Secretary shall carry out a pilot project under which—

(1) no more than 3 sponsors each agree to evaluate—

(A) the psychological and social distress experienced by patients participating in a qualified clinical trial, conducted by the respective sponsor, of a drug or biological product that is intended to treat a serious or life-threatening disease or condition; and

(B) the effects of providing psychological and social support to any such patients showing signs of distress on the primary outcome measures in the clinical trial; and

(2) the Secretary waives the fee that would otherwise apply under section 736(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)) to the submission by the respective sponsor of one human drug application for such

drug or biological product that includes the data resulting from such evaluation.

(b) SELECTION.—The Secretary shall select the sponsors referred to in subsection (a) on a competitive basis not later than the date that is 2 years after the date of enactment of this Act.

(c) MEETING.—The Secretary shall grant at least one meeting to each sponsor selected under subsection (b) for the specific purpose of discussing the activities to be carried out by the sponsor pursuant to this Act.

(d) DEFINITIONS.—In this Act:

(1) The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The term ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) The term ''human drug application'' has the meaning given to such term in section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g).

(4) The term ''qualified clinical trial'' means a clinical trial in which all participating patients will be enrolled not later than the date that is 5 years after the date of the enactment of this Act.

(5) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

(6) The term ''sponsor'' means the sponsor of a drug or biological product.

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