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111TH CONGRESS
1ST SESSION

H. R. 2866

To provide for a disregard under the Supplemental Security Income program of compensation for participation in clinical trials for rare diseases or conditions.

IN THE HOUSE OF REPRESENTATIVES

JUNE 15, 2009

Mr. MARKEY of Massachusetts (for himself, Mr. STEARNS, Mr. BERRY, Mr. BOUSTANY, Ms. GINNY BROWN-WAITE of Florida, Mr. COHEN, Mr. CONAWAY, Ms. DEGETTE, Ms. DELAURO, Mr. DICKS, Mr. DOYLE, Mr. GORDON of Tennessee, Mr. GENE GREEN of Texas, Ms. JENKINS, Mr. KING of New York, Mr. LEWIS of Georgia, Mr. MCGOVERN, Mr. MEEK of Florida, Mr. MORAN of Virginia, Mr. MURPHY of Connecticut, Mr. OLVER, Mr. PAUL, Mr. ROGERS of Alabama, Mr. ROSS, Ms. SCHAKOWSKY, Ms. SCHWARTZ, Mr. STARK, Mr. WAXMAN, Mr. WEXLER, and Mr. WHITFIELD) introduced the following bill; which was referred to the Committee on Ways and Means

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A BILL

To provide for a disregard under the Supplemental Security Income program of compensation for participation in clinical trials for rare diseases or conditions.

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 ''Improving Access to Clinical Trials Act of 2009''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Advances in medicine depend on clinical trial research conducted at public and private research institutions across the United States.

(2) The challenges associated with enrolling participants in clinical research studies are especially severe for studies evaluating treatments for rare diseases and conditions—those diseases and conditions defined by the Orphan Drug Act of 1983 as affecting fewer than 200,000 Americans—where the available number of willing and able research participants may be very small.

(3) In accordance with ethical standards of the National Institutes of Health, sponsors of clinical trial research may provide payments to trial participants for the out-of-pocket costs associated with trial enrollment and for the time and commitment demanded by enrolling in a study. Such financial incentives aid the recruitment of trial participants.

(4) The offer of payment for trial participation may also pose a barrier to trial enrollment since such payments threaten the eligibility of clinical trial participants for Supplemental Security Income and Medicaid benefits.

(5) The small numbers of potential trial participants and the possible loss of Supplemental Security Income and Medicaid benefits make clinical trial research for rare diseases and conditions exceptionally difficult and may hinder research on new treatments and potential cures for these rare diseases and conditions.

(6) Individuals with rare diseases and conditions may suffer a severe negative effect if trials on new therapies are delayed or abandoned because of the inability to enroll sufficient numbers of trial participants.

(7) A change in the Supplemental Security Income program rules affecting payments for trial participation would help ensure that clinical studies on rare diseases and conditions proceed without delay.

SEC. 3. DISREGARD UNDER THE SUPPLEMENTAL SECURITY INCOME PROGRAM OF COMPENSATION FOR PARTICIPATION IN CLINICAL TRIALS FOR RARE DISEASES OR CONDITIONS.

(a) INCOME DISREGARD.—Section 1612(b) of the Social Security Act (42 U.S.C. 1382a(b)) is amended—

(1) by striking ''and'' at the end of paragraph (24);

(2) by striking the period at the end of paragraph (25) and inserting ''; and''; and

(3) by adding at the end the following:

''(26) the first $2,000 per year received by such individual (or such spouse) for participation in a clinical trial to test a treatment for a rare disease or condition (within the meaning of section 5(b)(2) of the Orphan Drug Act (Public Law 97–414)), that—

''(A) has been reviewed and approved by an institutional review board that—

''(i) is established to protect the rights and welfare of human subjects participating in research; and

''(ii) meet the standards for such bodies set forth in part 46 of title 45, Code of Federal Regulations; and

''(B) meets the standards for protection of human subjects for clinical research (as set forth in such part).''.

(b) RESOURCE DISREGARD.—Section 1613(a) of such Act (42 U.S.C. 1382b(a)) is amended—

(1) by striking ''and'' at the end of paragraph (15);

(2) by striking the period at the end of paragraph (16) and inserting ''; and''; and

(3) by inserting after paragraph (16) the following:

''(17) the first $2,000 per year received by such individual (or such spouse) for participation in a clinical trial, as described in section 1612(b)(26).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to benefits payable for calendar months beginning after the earlier of—

(1) the date the Commissioner of Social Security promulgates regulations to carry out the amendments; or

(2) the 180-day period that begins with the date of the enactment of this Act.

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