

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Improving Access to
5 Clinical Trials Act of 2009”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) Advances in medicine depend on clinical
4 trial research conducted at public and private re-
5 search institutions across the United States.

6 (2) The challenges associated with enrolling
7 participants in clinical research studies are especially
8 severe for studies evaluating treatments for rare dis-
9 eases and conditions—those diseases and conditions
10 defined by the Orphan Drug Act of 1983 as affect-
11 ing fewer than 200,000 Americans—where the avail-
12 able number of willing and able research partici-
13 pants may be very small.

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

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

1 (5) The small numbers of potential trial partici-
2 pants and the possible loss of Supplemental Security
3 Income and Medicaid benefits make clinical trial re-
4 search for rare diseases and conditions exceptionally
5 difficult and may hinder research on new treatments
6 and potential cures for these rare diseases and con-
7 ditions.

8 (6) Individuals with rare diseases and condi-
9 tions may suffer a severe negative effect if trials on
10 new therapies are delayed or abandoned because of
11 the inability to enroll sufficient numbers of trial par-
12 ticipants.

13 (7) A change in the Supplemental Security In-
14 come program rules affecting payments for trial par-
15 ticipation would help ensure that clinical studies on
16 rare diseases and conditions proceed without delay.

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

21 (a) INCOME DISREGARD.—Section 1612(b) of the So-
22 cial Security Act (42 U.S.C. 1382a(b)) is amended—

23 (1) by striking “and” at the end of paragraph
24 (24);

1 (2) by striking the period at the end of para-
2 graph (25) and inserting “; and”; and

3 (3) by adding at the end the following:

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

10 “(A) has been reviewed and approved by
11 an institutional review board that—

12 “(i) is established to protect the rights
13 and welfare of human subjects partici-
14 pating in research; and

15 “(ii) meet the standards for such bod-
16 ies set forth in part 46 of title 45, Code of
17 Federal Regulations; and

18 “(B) meets the standards for protection of
19 human subjects for clinical research (as set
20 forth in such part).”.

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

23 (1) by striking “and” at the end of paragraph
24 (15);

1 (2) by striking the period at the end of para-
2 graph (16) and inserting “; and”; and

3 (3) by inserting after paragraph (16) the fol-
4 lowing:

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

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

11 (1) the date the Commissioner of Social Secu-
12 rity promulgates regulations to carry out the amend-
13 ments; or

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

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