

113TH CONGRESS
1ST SESSION

H. R. 2301

To amend the Public Health Service Act to enhance the clinical trial registry data bank reporting requirements and enforcement measures.

IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 2013

Mr. REED (for himself, Ms. SLAUGHTER, and Mr. COLLINS of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to enhance the clinical trial registry data bank reporting requirements and enforcement measures.

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 “Clinical Trial Cancer
5 Mission 2020 Act”.

1 **SEC. 2. ENHANCING CLINICAL TRIAL REGISTRY DATA BANK**
2 **REPORTING REQUIREMENTS AND ENFORCE-**
3 **MENT MEASURES.**

4 (a) CLARIFICATION THAT CLINICAL TRIAL REG-
5 ISTRY DATA BANK REQUIREMENTS APPLY REGARDLESS
6 OF TRIAL OUTCOMES.—Section 402(j)(1)(A)(i) of the
7 Public Health Service Act (42 U.S.C. 282(j)(1)(A)(i)) is
8 amended by inserting before the period at the end the fol-
9 lowing “, whether or not such a clinical trial results in
10 a positive or negative outcome”.

11 (b) APPLICATION TO GRANTS FROM DEPARTMENT
12 OF DEFENSE.—Section 402(j)(5)(A)(i) of such Act (42
13 U.S.C. 282(j)(5)(A)(i)) is amended by inserting “the De-
14 partment of Defense or” after “agency of”.

15 (c) ENHANCED ENFORCEMENT.—Section
16 402(j)(5)(A) of such Act (42 U.S.C. 282(j)(5)(A)) is
17 amended by adding at the end the following new clause:

18 “(v) ENHANCED ENFORCEMENT.—
19 After the 30-day period described in clause
20 (iii), if the head of an agency referred to
21 in clause (i), as applicable, verifies that a
22 grantee has not submitted clinical trial in-
23 formation as described in clause (ii), with
24 respect to an applicable clinical trial that is
25 funded in whole or in part by a grant from
26 the agency, such grantee—

1 “(I) shall not be eligible to re-
2 ceive any remaining funding for the
3 grant or funding for a future Federal
4 grant until such time as the grantee
5 comes into compliance with all appli-
6 cable reporting requirements under
7 this subsection; and

8 “(II) shall be liable to the United
9 States for repayment of any amount
10 provided under the grant for the clin-
11 ical trial for which the grantee failed
12 to comply with such reporting require-
13 ments.”.

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