I

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.

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 Trial Cancer Mission 2020 Act''.

SEC. 2. ENHANCING CLINICAL TRIAL REGISTRY DATA BANK REPORTING REQUIREMENTS AND ENFORCEMENT MEASURES.

(a) CLARIFICATION THAT CLINICAL TRIAL REGISTRY DATA BANK REQUIREMENTS APPLY REGARDLESS OF TRIAL OUTCOMES.—Section 402(j)(1)(A)(i) of the Public Health Service Act (42 U.S.C. 282(j)(1)(A)(i)) is amended by inserting before the period at the end the following ‘‘, whether or not such a clinical trial results in a positive or negative outcome’’.

(b) APPLICATION TO GRANTS FROM DEPARTMENT OF DEFENSE.—Section 402(j)(5)(A)(i) of such Act (42 U.S.C. 282(j)(5)(A)(i)) is amended by inserting ‘‘the Department of Defense or’’ after ‘‘agency of’’.

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

‘‘(v) ENHANCED ENFORCEMENT.—After the 30-day period described in clause (iii), if the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), with respect to an applicable clinical trial that is funded in whole or in part by a grant from the agency, such grantee—

"(I) shall not be eligible to receive any remaining funding for the grant or funding for a future Federal grant until such time as the grantee comes into compliance with all applicable reporting requirements under this subsection; and

"(II) shall be liable to the United States for repayment of any amount provided under the grant for the clinical trial for which the grantee failed to comply with such reporting requirements.".

○