

112TH CONGRESS
2D SESSION

H. R. 5283

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

APRIL 27, 2012

Mr. REED 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. ENHANCING CLINICAL TRIAL REGISTRY DATA**
4 **BANK REPORTING REQUIREMENTS AND EN-**
5 **FORCEMENT MEASURES.**

6 (a) CLARIFICATION THAT CLINICAL TRIAL REG-
7 ISTRY DATA BANK REQUIREMENTS APPLY REGARDLESS
8 OF TRIAL OUTCOMES.—Section 402(j)(1)(A)(i) of the
9 Public Health Service Act (42 U.S.C. 282(j)(1)(A)(i)) is
10 amended by inserting before the period at the end the fol-

1 lowing “, whether or not such a clinical trial results in
2 a positive or negative outcome”.

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

7 (c) ENHANCED ENFORCEMENT.—Section
8 402(j)(5)(A) of such Act (42 U.S.C. 282(j)(5)(A)) is
9 amended by adding at the end the following new clause:

10 “(v) ENHANCED ENFORCEMENT.—
11 After the 30-day period described in clause
12 (iii), if the head of an agency referred to
13 in clause (i), as applicable, verifies that a
14 grantee has not submitted clinical trial in-
15 formation as described in clause (ii), with
16 respect to an applicable clinical trial that is
17 funded in whole or in part by a grant from
18 the agency, such grantee—

19 “(I) shall not be eligible to re-
20 ceive any remaining funding for the
21 grant or funding for a future Federal
22 grant until such time as the grantee
23 comes into compliance with all appli-
24 cable reporting requirements under
25 this subsection; and

1 “(II) shall be liable to the United
2 States for repayment of any amount
3 provided under the grant for the clin-
4 ical trial for which the grantee failed
5 to comply with such reporting require-
6 ments.”.

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