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(Original Signature of Member)

112TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To amend title IV of the Public Health Service Act to expand the clinical trial registry data bank, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. MARKEY introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend title IV of the Public Health Service Act to expand the clinical trial registry data bank, and for other purposes.

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 “Trial and Experi-  
5       mental Studies Transparency Act of 2012” or the “TEST  
6       Act”.

1 **SEC. 2. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.**

2 (a) IN GENERAL.—Section 402(j) of the Public  
3 Health Service Act (42 U.S.C. 282(j)) is amended—

4 (1) in paragraph (1)(A)—

5 (A) in clause (ii)—

6 (i) by amending subclause (I) to read  
7 as follows:

8 “(I) an interventional study of a  
9 device subject to section 510(k), 515,  
10 or 520(m) of the Federal Food, Drug,  
11 and Cosmetic Act, including any  
12 interventional study of a device con-  
13 ducted outside of the United States  
14 the results of which are submitted to  
15 the Secretary in support of a PMA  
16 (as such term is defined in section  
17 814.3(e) of title 21, Code of Federal  
18 Regulations); a premarket notification  
19 required under section 510(k) of the  
20 Federal Food, Drug, and Cosmetic  
21 Act; or a HDE (as such term is de-  
22 fined in section 814.3(m) of title 21,  
23 Code of Federal Regulations).”; and

24 (ii) in subclause (II)—

25 (I) by striking “pediatric”; and

1 (II) by inserting “that involves  
2 data collection from human subjects”  
3 before the period at the end;

4 (B) by amending clause (iii) to read as fol-  
5 lows:

6 “(iii) APPLICABLE DRUG CLINICAL  
7 TRIAL.—The term ‘applicable drug clinical  
8 trial’ means an interventional study of a  
9 drug subject to section 505 of the Federal  
10 Food, Drug, and Cosmetic Act or to sec-  
11 tion 351 of this Act, including any inter-  
12 ventional study of a drug conducted out-  
13 side of the United States the results of  
14 which are submitted to the Secretary in  
15 support of—

16 “(I) an IND ( as such term is  
17 defined in section 312.3 of title 21,  
18 Code of Federal Regulations);

19 “(II) an application filed under  
20 subsection (b) or (j) of such section  
21 505 of the Federal Food, Drug, and  
22 Cosmetic Act; or

23 “(III) an application for a license  
24 under section 351.”;

1 (C) by redesignating clauses (iv) through  
2 (ix) as clauses (v) through (x), respectively;

3 (D) after clause (iii), by inserting the fol-  
4 lowing new clause:

5 “(iv) INTERVENTIONAL STUDY.—For  
6 purposes of clauses (ii) and (iii), the term  
7 ‘interventional study’ means a study in  
8 human beings in which individuals are as-  
9 signed by an investigator, based on a pro-  
10 tocol, to receive specific interventions to  
11 evaluate their effects on biomedical or  
12 health-related outcomes.”; and

13 (E) in clause (vi), as redesignated by sub-  
14 paragraph (C)—

15 (i) in the heading, by inserting “; PRI-  
16 MARY COMPLETION DATE” after “DATE”;  
17 and

18 (ii) by inserting “, also referred to as  
19 ‘primary completion date’,” before  
20 “means”;

21 (2) in paragraph (2)—

22 (A) in subparagraph (A)(ii)—

23 (i) by redesignating subclauses (II),  
24 (III), and (IV) as subclauses (III), (IV),  
25 and (V), respectively;

1 (ii) by inserting after subclause (I)  
2 the following:

3 “(II) supporting documents, in-  
4 cluding—

5 “(aa) consent documents  
6 used to enroll subjects into the  
7 trial, as approved by the Institu-  
8 tional Review Board or equiva-  
9 lent committee prior to the start  
10 of the trial; and

11 “(bb) protocol documents, as  
12 approved by the Institutional Re-  
13 view Board or equivalent com-  
14 mittee prior to the start of the  
15 trial;”; and

16 (iii) in subclause (IV), as so  
17 redesignated, in item (cc), by inserting  
18 “(or, in the case of a location outside of  
19 the United States, other appropriate loca-  
20 tion information)” after “zip code”;

21 (B) in subparagraph (C)(ii) by striking  
22 “21 days after” and inserting “before”; and

23 (C) by amending subparagraph (D) to read  
24 as follows:

1           “(D) POSTING OF DATA.—The Director of  
2           NIH shall ensure that clinical trial information  
3           for an applicable clinical trial submitted in ac-  
4           cordance with this paragraph is posted pub-  
5           lically in the registry data bank not later than  
6           30 days after such submission is determined to  
7           meet the quality criteria established by the Di-  
8           rector of NIH.”;

9           (3) in paragraph (3)—

10           (A) in subparagraph (C)—

11           (i) by striking “Not later than 1  
12           year” and all that follows through the  
13           colon and inserting “Subject to subpara-  
14           graph (2)(C), the Secretary shall include in  
15           the registry and results data bank the fol-  
16           lowing elements for an applicable clinical  
17           trial.”; and

18           (ii) by adding at the end the following  
19           new clause:

20           “(v) SUPPORTING DOCUMENTS.—  
21           Final consent and protocol documents, in-  
22           cluding all dated amendments to the initial  
23           version of such documents, as approved by  
24           the Institutional Review Board or equiva-  
25           lent committee.”.

- 1 (B) in subparagraph (D)—
- 2 (i) by striking clauses (ii) and (iv);
- 3 (ii) in clause (iii)—
- 4 (I) by striking subclause (III);
- 5 and
- 6 (II) by redesignating subclause
- 7 (IV) as subclause (III);
- 8 (iii) by redesignating—
- 9 (I) clause (iii) as clause (ii); and
- 10 (II) clauses (v) through (vii) as
- 11 clauses (iii) through (v), respectively;
- 12 (C) in subparagraph (E)—
- 13 (i) by striking clauses (i) through (v)
- 14 and inserting the following:
- 15 “(i) IN GENERAL.—Except as pro-
- 16 vided in clauses (ii) and (iii), the respon-
- 17 sible party for an applicable clinical trial
- 18 shall submit to the Director of NIH for in-
- 19 clusion in the registry and results data
- 20 bank the clinical trial information de-
- 21 scribed in subparagraph (C) not later than
- 22 1 year after the primary completion date
- 23 of such trial.
- 24 “(ii) DELAYED SUBMISSION OF RE-
- 25 SULTS WITH CERTIFICATION.—If the re-

1           sponsible party for an applicable clinical  
2           trial submits a certification that an appli-  
3           cable clinical trial involves a drug described  
4           in clause (iii) or a device described in  
5           clause (iv), the responsible party shall sub-  
6           mit to the Director of NIH, for inclusion  
7           in the registry and results data bank, the  
8           clinical trial information described in sub-  
9           paragraphs (C) and (D) not later than the  
10          earliest of the following:

11                           “(I) The later of—

12   “(aa) 30 days after the drug  
13   or device is approved, licensed, or  
14   cleared, as applicable; or

15   “(bb) 1 year after the pri-  
16   mary completion date of the ap-  
17   plicable clinical trial.

18                           “(II) The date that is 2 years  
19                           after the primary completion date of  
20                           the applicable clinical trial.

21                           “(iii) DRUG DESCRIBED.—A drug de-  
22                           scribed in this clause is a drug that con-  
23                           tains an active ingredient, including any  
24                           ester or salt, that has not been an ingre-  
25                           dient in a drug approved in any other ap-

1                   plication under section 505 of the Federal  
2                   Food, Drug, and Cosmetic Act or licensed  
3                   for any use under section 351 of this Act.

4                   “(iv) DEVICE DESCRIBED.—A device  
5                   described in this clause is a device that has  
6                   not been approved or cleared for any use  
7                   under section 510(k) or under section 515  
8                   or 520(m) of the Federal Food, Drug, and  
9                   Cosmetic Act.”;

10                   (ii) by redesignating clause (vi) as  
11                   clause (v); and

12                   (iii) by adding at the end the fol-  
13                   lowing:

14                   “(vi) PUBLIC POSTINGS RELATED TO  
15                   DELAYS AND EXTENSIONS.—Information  
16                   submitted by the responsible party as part  
17                   of a certification for delayed submission of  
18                   results submitted under clause (ii) or a re-  
19                   quest for extension submitted under clause  
20                   (v) shall be posted publically in the reg-  
21                   istry data bank.”;

22                   (D) by striking subparagraph (F);

23                   (E) by redesignating subparagraphs (G)  
24                   through (I) as subparagraphs (F) through (H),  
25                   respectively; and

1 (F) in subparagraph (F), as so redesignated,  
2 nated, by inserting before the period at the end  
3 the following: “is determined to meet the qual-  
4 ity criteria established by the Director of NIH”;  
5 and

6 (4) in paragraph (4)(B)—

7 (A) in clause (i)(II), by striking  
8 “(3)(E)(iii)” and inserting “(3)(E)(ii)”; and

9 (B) in clause (ii)(II)—

10 (i) by striking “by both”; and

11 (ii) by striking “and paragraph  
12 (3)(D)(ii)(II)”.

13 (b) IMPLEMENTATION.—The Secretary of Health and  
14 Human Services shall implement the amendments made  
15 by subsection (a) not later than 6 months after the date  
16 of enactment of this Act.

17 **SEC. 3. REPORTING REQUIREMENT.**

18 Not later than 2 years after the date of the enact-  
19 ment of this Act, and annually thereafter, the Director  
20 of the National Institutes of Health and the Commissioner  
21 of the Food and Drug Administration shall each submit  
22 to the Committee on Energy and Commerce of the House  
23 of Representatives and the Committee on Health, Edu-  
24 cation, Labor and Pensions of the Senate a report that  
25 includes the following:

1           (1) Based on information that is readily avail-  
2           able in the data bank described in section 402(j) of  
3           the Public Health Service Act (42 U.S.C. 282(j))—

4                   (A) the number of trials that the Director  
5                   or Commissioner, as applicable, has identified  
6                   as trials that are likely to be subject to the re-  
7                   porting requirements of such section;

8                   (B) of the trials identified under subpara-  
9                   graph (A), the estimated numbers and percent-  
10                  ages of such trials—

11                           (i) that have complete registration in-  
12                           formation; and

13                           (ii) that have met the result reporting  
14                           requirements of section 402(j) of the Pub-  
15                           lic Health Service Act; and

16                   (C) whether results of the trials have been  
17                   submitted by the responsible party by the due  
18                   dates outlined in section 402(j) of the Public  
19                   Health Service Act and, if not, whether certifi-  
20                   cations for delayed submission of such results,  
21                   or requests for extensions, have been submitted  
22                   by the responsible party.

23           For purposes of this paragraph, the Secretary may  
24           use an algorithm or other technique for efficiently  
25           reviewing large amounts of data.

1           (2) A description of any actions taken to con-  
2           sult with other federal agencies under  
3           402(j)(5)(A)(iv) of the Public Health Service Act.

4           (3) In the case of a report submitted by the  
5           Commissioner of the Food and Drug Administration,  
6           a description of any enforcement actions taken for  
7           violations of section 301(jj) of the Federal Food,  
8           Drug, and Cosmetic Act (21 U.S.C.  
9           331(jj)), including—

10                   (A) warning letters or fines imposed re-  
11                   lated to reporting requirements; and

12                   (B) any inquiries made to responsible par-  
13                   ties to inform those parties of any potential en-  
14                   forcement action.

15           (4) In the case of a report submitted by the Di-  
16           rector of the National Institutes of Health, a de-  
17           scription of any actions taken to withhold grant  
18           funds from responsible parties that are not compli-  
19           ant with the requirements of this section as indi-  
20           cated in 402(j)(5)(A) of the Public Health Service  
21           Act.

22 **SEC. 4. RULEMAKING RELATED TO FOREIGN CLINICAL**  
23 **STUDIES.**

24           (a) DRUGS.—Not later than 1 year after the date of  
25           enactment of this Act, the Secretary of Health and

1 Human Services shall issue final regulations to amend sec-  
2 tion 312.120 of title 21, Code of Federal Regulations (re-  
3 lating to foreign clinical studies not conducted under an  
4 IND) to require that clinical trial information for such a  
5 foreign clinical study be submitted for inclusion in the reg-  
6 istry and results data bank in accordance with section  
7 402(j) of the Public Health Service Act (42 U.S.C.  
8 282(j)), as amended by this Act, as a condition for the  
9 acceptance of such study as support for an IND ( as such  
10 term is defined in section 312.3 of title 21, Code of Fed-  
11 eral Regulations) or application for marketing approval  
12 (an application under section 505 of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 355) or section 351  
14 of the Public Health Service Act (42 U.S.C. 262)).

15 (b) DEVICES.—Not later than 1 year after the date  
16 of enactment of this Act, the Secretary of Health and  
17 Human Services shall issue final regulations (including  
18 regulations amending section 814.15 of title 21, Code of  
19 Federal Regulations (relating to research conducted out-  
20 side the United States)) to require that clinical trial infor-  
21 mation for studies conducted outside the United States be  
22 submitted for inclusion in the registry and results data  
23 bank in accordance with section 402(j) of the Public  
24 Health Service Act (42 U.S.C. 282(j)), as amended by this  
25 Act, as a condition for the acceptance of such studies to

1 support a PMA (as such term is defined in section  
2 814.3(e) of title 21, Code of Federal Regulations), a pre-  
3 market notification required under section 510(k) of the  
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 360(k)), or HDE (as such term is defined in section  
6 814.3(m) of title 21, Code of Federal Regulations).