

113TH CONGRESS  
1ST SESSION

# H. R. 2031

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

MAY 16, 2013

Mr. MARKEY (for himself, Mr. WAXMAN, Ms. DELAURO, and Ms. SCHAKOWSKY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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”.

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

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

1 (1) in paragraph (1)(A)—

2 (A) in clause (ii)—

3 (i) by amending subclause (I) to read  
4 as follows:

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

21 (ii) in subclause (II)—

22 (I) by striking “pediatric”; and

23 (II) by inserting “that involves  
24 data collection from human subjects”  
25 before the period at the end;

1 (B) by amending clause (iii) to read as fol-  
2 lows:

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

13 “(I) an IND (as such term is de-  
14 fined in section 312.3 of title 21,  
15 Code of Federal Regulations);

16 “(II) an application filed under  
17 subsection (b) or (j) of such section  
18 505 of the Federal Food, Drug, and  
19 Cosmetic Act; or

20 “(III) an application for a license  
21 under section 351.”;

22 (C) by redesignating clauses (iv) through  
23 (ix) as clauses (v) through (x), respectively;

24 (D) after clause (iii), by inserting the fol-  
25 lowing new clause:

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

9                   (E) in clause (vi), as redesignated by sub-  
10                  paragraph (C)—

11                  (i) in the heading, by inserting “; PRI-  
12                  MARY COMPLETION DATE” after “DATE”;  
13                  and

14                  (ii) by inserting “, also referred to as  
15                  ‘primary completion date,’” before  
16                  “means”;

17                  (2) in paragraph (2)—

18                  (A) in subparagraph (A)(ii)—

19                   (i) by redesignating subclauses (II),  
20                   (III), and (IV) as subclauses (III), (IV),  
21                   and (V), respectively;

22                   (ii) by inserting after subclause (I)  
23                   the following:

24                                 “(II) supporting documents, in-  
25                                 cluding—

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

7                   “(bb) protocol documents, as  
8                   approved by the Institutional Re-  
9                   view Board or equivalent com-  
10                  mittee prior to the start of the  
11                  trial;”; and

12                  (iii) in subclause (IV), as so redesign-  
13                  ated, in item (cc), by inserting “(or, in  
14                  the case of a location outside of the United  
15                  States, other appropriate location informa-  
16                  tion)” after “zip code”;

17                  (B) in subparagraph (C)(ii) by striking  
18                  “21 days after” and inserting “before”; and

19                  (C) by amending subparagraph (D) to read  
20                  as follows:

21                  “(D) POSTING OF DATA.—The Director of  
22                  NIH shall ensure that clinical trial information  
23                  for an applicable clinical trial submitted in ac-  
24                  cordance with this paragraph is posted pub-  
25                  lically in the registry data bank not later than

1 30 days after such submission is determined to  
2 meet the quality criteria established by the Di-  
3 rector of NIH.”;

4 (3) in paragraph (3)—

5 (A) in subparagraph (C)—

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

13 (ii) by adding at the end the following  
14 new clause:

15 “(v) SUPPORTING DOCUMENTS.—  
16 Final consent and protocol documents, in-  
17 cluding all dated amendments to the initial  
18 version of such documents, as approved by  
19 the Institutional Review Board or equiva-  
20 lent committee.”;

21 (B) in subparagraph (D)—

22 (i) by striking clauses (ii) and (iv);

23 (ii) in clause (iii)—

24 (I) by striking subclause (III);

25 and

1 (II) by redesignating subclause  
2 (IV) as subclause (III); and  
3 (iii) by redesignating—  
4 (I) clause (iii) as clause (ii); and  
5 (II) clauses (v) through (vii) as  
6 clauses (iii) through (v), respectively;  
7 (C) in subparagraph (E)—  
8 (i) by striking clauses (i) through (v)  
9 and inserting the following:

10 “(i) IN GENERAL.—Except as pro-  
11 vided in clauses (ii) and (iii), the respon-  
12 sible party for an applicable clinical trial  
13 shall submit to the Director of NIH for in-  
14 clusion in the registry and results data  
15 bank the clinical trial information de-  
16 scribed in subparagraph (C) not later than  
17 1 year after the primary completion date  
18 of such trial.

19 “(ii) DELAYED SUBMISSION OF RE-  
20 SULTS WITH CERTIFICATION.—If the re-  
21 sponsible party for an applicable clinical  
22 trial submits a certification that an appli-  
23 cable clinical trial involves a drug described  
24 in clause (iii) or a device described in  
25 clause (iv), the responsible party shall sub-

1 mit to the Director of NIH, for inclusion  
2 in the registry and results data bank, the  
3 clinical trial information described in sub-  
4 paragraphs (C) and (D) not later than the  
5 earliest of the following:

6 “(I) The later of—

7 “(aa) 30 days after the drug  
8 or device is approved, licensed, or  
9 cleared, as applicable; or

10 “(bb) 1 year after the pri-  
11 mary completion date of the ap-  
12 plicable clinical trial.

13 “(II) The date that is 2 years  
14 after the primary completion date of  
15 the applicable clinical trial.

16 “(iii) DRUG DESCRIBED.—A drug de-  
17 scribed in this clause is a drug that con-  
18 tains an active ingredient, including any  
19 ester or salt, that has not been an ingre-  
20 dient in a drug approved in any other ap-  
21 plication under section 505 of the Federal  
22 Food, Drug, and Cosmetic Act or licensed  
23 for any use under section 351 of this Act.

24 “(iv) DEVICE DESCRIBED.—A device  
25 described in this clause is a device that has

1 not been approved or cleared for any use  
2 under section 510(k) or under section 515  
3 or 520(m) of the Federal Food, Drug, and  
4 Cosmetic Act.”;

5 (ii) by redesignating clause (vi) as  
6 clause (v); and

7 (iii) by adding at the end the fol-  
8 lowing:

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

17 (D) by striking subparagraph (F);

18 (E) by redesignating subparagraphs (G)  
19 through (I) as subparagraphs (F) through (H),  
20 respectively; and

21 (F) in subparagraph (F), as so redesi-  
22 gnated, by inserting before the period at the end  
23 the following: “is determined to meet the qual-  
24 ity criteria established by the Director of NIH”;  
25 and

1 (4) in paragraph (4)(B)—

2 (A) in clause (i)(II), by striking

3 “(3)(E)(iii)” and inserting “(3)(E)(ii)”; and

4 (B) in clause (ii)(II)—

5 (i) by striking “by both”; and

6 (ii) by striking “and paragraph

7 (3)(D)(ii)(II)”.

8 (b) IMPLEMENTATION.—The Secretary of Health and  
9 Human Services shall implement the amendments made  
10 by subsection (a) not later than 6 months after the date  
11 of enactment of this Act.

12 **SEC. 3. REPORTING REQUIREMENT.**

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

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

24 (A) the number of trials that the Director  
25 or Commissioner, as applicable, has identified

1 as trials that are likely to be subject to the re-  
2 porting requirements of such section;

3 (B) of the trials identified under subpara-  
4 graph (A), the estimated numbers and percent-  
5 ages of such trials—

6 (i) that have complete registration in-  
7 formation; and

8 (ii) that have met the result reporting  
9 requirements of section 402(j) of the Pub-  
10 lic Health Service Act; and

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

18 For purposes of this paragraph, the Secretary may  
19 use an algorithm or other technique for efficiently  
20 reviewing large amounts of data.

21 (2) A description of any actions taken to con-  
22 sult with other Federal agencies under  
23 402(j)(5)(A)(iv) of the Public Health Service Act.

24 (3) In the case of a report submitted by the  
25 Commissioner of the Food and Drug Administration,

1 a description of any enforcement actions taken for  
2 violations of section 301(jj) of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 331(jj)), includ-  
4 ing—

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

7 (B) any inquiries made to responsible par-  
8 ties to inform those parties of any potential en-  
9 forcement action.

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

17 **SEC. 4. RULEMAKING RELATED TO FOREIGN CLINICAL**  
18 **STUDIES.**

19 (a) DRUGS.—Not later than 1 year after the date of  
20 enactment of this Act, the Secretary of Health and  
21 Human Services shall issue final regulations to amend sec-  
22 tion 312.120 of title 21, Code of Federal Regulations (re-  
23 lating to foreign clinical studies not conducted under an  
24 IND) to require that clinical trial information for such a  
25 foreign clinical study be submitted for inclusion in the reg-

1 istry and results data bank in accordance with section  
2 402(j) of the Public Health Service Act (42 U.S.C.  
3 282(j)), as amended by this Act, as a condition for the  
4 acceptance of such study as support for an IND (as such  
5 term is defined in section 312.3 of title 21, Code of Fed-  
6 eral Regulations) or application for marketing approval  
7 (an application under section 505 of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 355) or section 351  
9 of the Public Health Service Act (42 U.S.C. 262)).

10 (b) DEVICES.—Not later than 1 year after the date  
11 of enactment of this Act, the Secretary of Health and  
12 Human Services shall issue final regulations (including  
13 regulations amending section 814.15 of title 21, Code of  
14 Federal Regulations (relating to research conducted out-  
15 side the United States)) to require that clinical trial infor-  
16 mation for studies conducted outside the United States be  
17 submitted for inclusion in the registry and results data  
18 bank in accordance with section 402(j) of the Public  
19 Health Service Act (42 U.S.C. 282(j)), as amended by this  
20 Act, as a condition for the acceptance of such studies to  
21 support a PMA (as such term is defined in section  
22 814.3(e) of title 21, Code of Federal Regulations), a pre-  
23 market notification required under section 510(k) of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.

- 1 360(k)), or HDE (as such term is defined in section
- 2 814.3(m) of title 21, Code of Federal Regulations).

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