

112TH CONGRESS
2D SESSION

H. R. 6272

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

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2012

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

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) in paragraph (1)(A)—

(A) in clause (ii)—

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

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

(ii) in subclause (II)—

(I) by striking “pediatric”; and

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

(B) by amending clause (iii) to read as follows:

“(iii) APPLICABLE DRUG CLINICAL TRIAL.—The term ‘applicable drug clinical trial’ means an interventional study of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, including any interventional study of a drug conducted outside of the United States the results of which are submitted to the Secretary in support of—

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

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

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

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

(D) after clause (iii), by inserting the following new clause:

“(iv) INTERVENTIONAL STUDY.—For purposes of clauses (ii) and (iii), the term ‘interventional study’ means a study in human beings in which individuals are assigned by an investigator, based on a protocol, to receive specific interventions to evaluate their effects on biomedical or health-related outcomes.”; and

(E) in clause (vi), as redesignated by subparagraph (C)—

(i) in the heading, by inserting “; PRIMARY COMPLETION DATE” after “DATE”; and

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

(2) in paragraph (2)—

(A) in subparagraph (A)(ii)—

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

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

“(II) supporting documents, including—

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
13 redesignated, in item (cc), by inserting
14 “(or, in the case of a location outside of
15 the United States, other appropriate loca-
16 tion information)” 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

30 days after such submission is determined to meet the quality criteria established by the Director of NIH.”;

(3) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking “Not later than 1 year” and all that follows through the colon and inserting “Subject to subparagraph (2)(C), the Secretary shall include in the registry and results data bank the following elements for an applicable clinical trial:”; and

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

“(v) SUPPORTING DOCUMENTS.—
Final consent and protocol documents, including all dated amendments to the initial version of such documents, as approved by the Institutional Review Board or equivalent committee.”;

(B) in subparagraph (D)—

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

(ii) in clause (iii)—

(I) by striking subclause (III);

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-

mit to the Director of NIH, for inclusion in the registry and results data bank, the clinical trial information described in subparagraphs (C) and (D) not later than the earliest of the following:

“(I) The later of—

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

“(bb) 1 year after the primary completion date of the applicable clinical trial.

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

“(iii) DRUG DESCRIBED.—A drug described in this clause is a drug that contains an active ingredient, including any ester or salt, that has not been an ingredient in a drug approved in any other application under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed for any use under section 351 of this Act.

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

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

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

(iii) by adding at the end the following:

“(vi) PUBLIC POSTINGS RELATED TO DELAYS AND EXTENSIONS.—Information submitted by the responsible party as part of a certification for delayed submission of results submitted under clause (ii) or a request for extension submitted under clause (v) shall be posted publically in the registry data bank.”;

(D) by striking subparagraph (F);

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

(F) in subparagraph (F), as so redesignated, by inserting before the period at the end the following: “is determined to meet the quality criteria established by the Director of NIH”; 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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