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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.

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.

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 ''Trial and Experimental Studies Transparency Act of 2012'' or the ''TEST Act''.

SEC. 2. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(a) IN GENERAL.—Section 402(j) of the Public 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 conducted 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 defined 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—

"(aa) consent documents used to enroll subjects into the trial, as approved by the Institutional Review Board or equivalent committee prior to the start of the trial; and

"(bb) protocol documents, as approved by the Institutional Review Board or equivalent committee prior to the start of the trial;"; and

(iii) in subclause (IV), as so redesignated, in item (cc), by inserting "(or, in the case of a location outside of the United States, other appropriate location information)" after "zip code";

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

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

"(D) POSTING OF DATA.—The Director of NIH shall ensure that clinical trial information for an applicable clinical trial submitted in accordance with this paragraph is posted publically 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

(II) by redesignating subclause (IV) as subclause (III); and

(iii) by redesignating—

(I) clause (iii) as clause (ii); and

(II) clauses (v) through (vii) as clauses (iii) through (v), respectively;

(C) in subparagraph (E)—

(i) by striking clauses (i) through (v) and inserting the following:

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), the responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year after the primary completion date of such trial.

''(ii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that an applicable clinical trial involves a drug described in clause (iii) or a device described in 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

(4) in paragraph (4)(B)—

(A) in clause (i)(II), by striking ''(3)(E)(iii)'' and inserting ''(3)(E)(ii)''; and

(B) in clause (ii)(II)—

(i) by striking ''by both''; and

(ii) by striking ''and paragraph (3)(D)(ii)(II))''.

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

SEC. 3. REPORTING REQUIREMENT.

Not later than 2 years after the date of the enactment of this Act, and annually thereafter, the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration shall each submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that includes the following:

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

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

as trials that are likely to be subject to the reporting requirements of such section;

(B) of the trials identified under subparagraph (A), the estimated numbers and percentages of such trials—

(i) that have complete registration information; and

(ii) that have met the result reporting requirements of section 402(j) of the Public Health Service Act; and

(C) whether results of the trials have been submitted by the responsible party by the due dates outlined in section 402(j) of the Public Health Service Act and, if not, whether certifications for delayed submission of such results, or requests for extensions, have been submitted by the responsible party.

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

(2) A description of any actions taken to consult with other Federal agencies under 402(j)(5)(A)(iv) of the Public Health Service Act.

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

a description of any enforcement actions taken for violations of section 301(jj) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(jj)), including—

(A) warning letters or fines imposed related to reporting requirements; and

(B) any inquiries made to responsible parties to inform those parties of any potential enforcement action.

(4) In the case of a report submitted by the Director of the National Institutes of Health, a description of any actions taken to withhold grant funds from responsible parties that are not compliant with the requirements of this section as indicated in 402(j)(5)(A) of the Public Health Service Act.

SEC. 4. RULEMAKING RELATED TO FOREIGN CLINICAL STUDIES.

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

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

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

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

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