109TH CONGRESS
1ST SESSION

S. 470

To amend the Public Health Service Act to expand the clinical trials drug data bank.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2005

Mr. DODD (for himself, Mr. GRASSLEY, Mr. JOHNSON, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to expand the clinical trials drug data bank.

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 ''Fair Access to Clinical Trials Act of 2005'' or the ''FACT Act''.

SEC. 2. PURPOSE.

It is the purpose of this Act—

(1) to create a publicly accessible national data bank of clinical trial information comprised of a clin-

ical trial registry and a clinical trial results database;

(2) to foster transparency and accountability in health-related intervention research and development;

(3) to maintain a clinical trial registry accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions; and

(4) to establish a clinical trials results database of all publicly and privately funded clinical trial results regardless of outcome, that is accessible to the scientific community, health care practitioners, and members of the public.

SEC. 3. CLINICAL TRIALS 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), by striking ''for drugs for serious or life-threatening diseases and conditions'';

(2) in paragraph (2), by striking ''available to individuals with serious'' and all that follows through the period and inserting ''accessible to patients, other members of the public, health care

practitioners, researchers and the scientific community. In making information about clinical trials publicly available, the Secretary shall seek to be as timely and transparent as possible.'';

(3) by redesignating paragraphs (4) and (5), as paragraphs (8) and (9), respectively;

(4) by striking paragraph (3) and inserting the following:

''(3) The data bank shall include the following:

''(A)(i) A registry of clinical trials (in this subparagraph referred to as the 'registry') of health-related interventions (whether federally or privately funded).

''(ii) The registry shall include information for all clinical trials conducted to test the safety or effectiveness (including comparative effectiveness) of any drug, biological product, or device (including those drugs, biological products, or devices approved or cleared by the Secretary) intended to treat serious or life-threatening diseases and conditions, except those Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared med-

ical device. For purposes of this section, Phase I clinical trials are trials described in section 313.12(a) of title 21, Code of Federal Regulations (or any successor regulations).

''(iii) The registry may include information for—

''(I) Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device with the consent of the responsible person; and

''(II) clinical trials of other health-related interventions with the consent of the responsible person.

''(iv) The information to be included in the registry under this subparagraph shall include the following:

''(I) Descriptive information, including a brief title, trial description in lay terminology, trial phase, trial type, trial purpose, description of the primary and secondary clinical outcome measures to be examined in the trial, the time at which the outcome measures will be assessed,

and the dates and details of any revisions to such outcomes.

''(II) Recruitment information, including eligibility and exclusion criteria, a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children, a statement as to whether the trial is closed to enrollment of new patients, overall trial status, individual site status, and estimated completion date. For purposes of this section the term 'completion date' means the date of the last visit by subjects in the trial for the outcomes described in subclause (I).

''(III) Location and contact information, including the identity of the responsible person.

''(IV) Administrative data, including the study sponsor and the study funding source.

''(V) Information pertaining to experimental treatments for serious or life threatening diseases and conditions (whether federally or privately funded) that may be available—

"(aa) under a treatment investigational new drug application that has been submitted to the Secretary under section 360bbb(c) of title 21, Code of Federal Regulations; or

"(bb) as a Group C cancer drug (as defined by the National Cancer Institute).

"(B)(i) A clinical trials results database (in this subparagraph referred to as the 'database') of health-related interventions (whether federally or privately funded).

"(ii) The database shall include information for all clinical trials conducted to test the safety or effectiveness (including comparative effectiveness) of any drug, biological product, or device (including those drugs, biological products, or devices approved or cleared by the Secretary), except those Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device.

"(iii) The database may include information for—

''(I) Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device with the consent of the responsible person; and

''(II) clinical trials of other health-related interventions with the consent of the responsible person.

''(iv) The information to be included in the database under this subparagraph shall include the following:

''(I) Descriptive information, including—

''(aa) a brief title;

''(bb) the drug, biological product or device to be tested;

''(cc) a trial description in lay terminology;

''(dd) the trial phase;

''(ee) the trial type;

''(ff) the trial purpose;

''(gg) the estimated completion date for the trial; and

"(hh) the study sponsor and the study funding source.

"(II) A description of the primary and secondary clinical outcome measures to be examined in the trial, the time at which the outcome measures will be assessed, and the dates and details of any revisions to such outcomes.

"(III) The actual completion date of the trial and the reasons for any difference from such actual date and the estimated completion date submitted pursuant to subclause (I)(hh). If the trial is not completed, the termination date and reasons for such termination.

"(IV) A summary of the results of the trial in a standard, non-promotional summary format (such as ICHE3 template form), including the trial design and methodology, results of the primary and secondary outcome measures as described in subclause (II), summary data tables with respect to the primary and secondary outcome measures, including information on the statistical significance or lack thereof of such results.

"(V) Safety data concerning the trial (including a summary of all adverse events speci-

fying the number and type of such events, data on prespecified adverse events, data on serious adverse events, and data on overall deaths).

''(VI) Any publications in peer reviewed journals relating to the trial. If the trial results are published in a peer reviewed journal, the database shall include a citation to and, when available, a link to the journal article.

''(VII) A description of the process used to review the results of the trial, including a statement about whether the results have been peer reviewed by reviewers independent of the trial sponsor.

''(VIII) If the trial addresses the safety, effectiveness, or benefit of a use not described in the approved labeling for the drug, biological product, or device, a statement, as appropriate, displayed prominently at the beginning of the data in the registry with respect to the trial, that the Food and Drug Administration—

''(aa) is currently reviewing an application for approval of such use to determine whether the use is safe and effective;

''(bb) has disapproved an application for approval of such use;

"(cc) has reviewed an application for approval of such use but the application was withdrawn prior to approval or disapproval; or

"(dd) has not reviewed or approved such use as safe and effective.

"(IX) If data from the trial has not been submitted to the Food and Drug Administration, an explanation of why it has not been submitted.

"(X) A description of the protocol used in such trial to the extent necessary to evaluate the results of such trial.

"(4)(A) Not later than 90 days after the date of the completion of the review by the Food and Drug Administration of information submitted by a sponsor in support of a new drug application, or a supplemental new drug application, whether or not approved by the Food and Drug Administration, the Commissioner of Food and Drugs shall make available to the public the full reviews conducted by the Administration of such application.

"(B) Not later than 90 days after the date of the completion of a written consultation on a drug concerning the drug's safety conducted by the Office of Drug Safety, regardless of whether initiated by such Office or outside

of the Office, the Commissioner of Food and Drugs shall make available to the public a copy of such consultation in full.

''(C) Nothing in this paragraph shall be construed to alter or amend section 301(j) or section 1905 of title 18, United States Code.

''(D) This paragraph shall supersede section 552 of title 5, United States Code.

''(5) The information described in subparagraphs (A) and (B) of paragraph (3) shall be in a format that can be readily accessed and understood by members of the general public, including patients seeking to enroll as subjects in clinical trials.

''(6) The Secretary shall assign each clinical trial a unique identifier to be included in the registry and in the database described in subparagraphs (A) and (B) of paragraph (3). To the extent practicable, this identifier shall be consistent with other internationally recognized and used identifiers.

''(7) To the extent practicable, the Secretary shall ensure that where the same information is required for the registry and the database described in subparagraphs (A) and (B) of paragraph (3), a process exists to allow the responsible person to make only one submission.''; and

(5) by adding at the end the following:

''(10) In this section, the term 'clinical trial' with respect to the registry and the database described in subparagraphs (A) and (B) of paragraph (3) means a research study in human volunteers to answer specific health questions, including treatment trials, prevention trials, diagnostic trials, screening trials, and quality of life trials.''.

(b) ACTIONS OF SECRETARY REGARDING CLINICAL TRIALS.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (k) and (l) as subsections (q) and (r), respectively; and

(2) by inserting after subsection (j), the following:

''(k) FEDERALLY SUPPORTED TRIALS.—

''(1) ALL FEDERALLY SUPPORTED TRIALS.—With respect to any clinical trial described in subsection (j)(3)(B) that is supported solely by a grant, contract, or cooperative agreement awarded by the Secretary, the principal investigator of such trial shall, not later than the date specified in paragraph (2), submit to the Secretary—

''(A) the information described in subclauses (II) through (X) of subsection (j)(3)(B)(iv), and with respect to clinical trials in progress on the date of enactment of the

FACT Act, the information described in subclause (I) of subsection (j)(3)(B)(iv); or

''(B) a statement containing information sufficient to demonstrate to the Secretary that the information described in subparagraph (A) cannot reasonably be submitted, along with an estimated date of submission of the information described in such subparagraph.

''(2) DATE SPECIFIED.—The date specified in this paragraph shall be the date that is 1 year from the earlier of—

''(A) the estimated completion date of the trial, as submitted under subsection (j)(3)(B)(vi)(I)(hh); or

''(B) the actual date of the completion or termination of the trial.

''(3) CONDITION OF FEDERAL GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS.—

''(A) CERTIFICATION OF COMPLIANCE.—To be eligible to receive a grant, contract, or cooperative agreement from the Secretary for the conduct or support of a clinical trial described in subsection (j)(3)(B), the principal investigator involved shall certify to the Secretary that—

"(i) such investigator shall submit data to the Secretary in accordance with this subsection; and

"(ii) such investigator has complied with the requirements of this subsection with respect to other clinical trials conducted by such investigator after the date of enactment of the FACT Act.

"(B) FAILURE TO SUBMIT CERTIFICATION.—An investigator that fails to submit a certification as required under subparagraph (A) shall not be eligible to receive a grant, contract, or cooperative agreement from the Secretary for the conduct or support of a clinical trial described in subsection (j)(3)(B).

"(C) FAILURE TO COMPLY WITH CERTIFICATION.—If, by the date specified in paragraph (2), the Secretary has not received the information or statement described in paragraph (1), the Secretary shall—

"(i) transmit to the principal investigator involved a notice specifying the information or statement required to be submitted to the Secretary and stating that such investigator shall not be eligible to re-

ceive further funding from the Secretary if such information or statement is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

"(ii) include and prominently display, until such time as the Secretary receives the information or statement described in paragraph (1), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

"(D) FAILURE TO COMPLY WITH NOTICE.—If by the date that is 30 days after the date on which the notice described in subparagraph (C) is transmitted, the Secretary has not received from the principal investigator involved the information or statement required pursuant to such notice, the Secretary may not award a grant, contract, cooperative agreement, or any other award to such principal investigator until such principal investigator submits to the Secretary the information or statement required pursuant to such notice.

"(E) SUBMISSION OF STATEMENT BUT NOT INFORMATION.—

"(i) IN GENERAL.—If by the date specified in paragraph (2), the Secretary has received a statement described in paragraph (1)(B) but not the information described in paragraph (1)(A), the Secretary shall transmit to the principal investigator involved a notice stating that such investigator shall submit such information by the date determined by the Secretary in consultation with such investigator.

"(ii) FAILURE TO COMPLY WITH CERTIFICATION.—If, by the date specified by the Secretary in the notice under clause (i), the Secretary has not received the information described in paragraph (1)(B), the Secretary shall—

"(I) transmit to the principal investigator involved a notice specifying the information required to be submitted to the Secretary and stating that such investigator shall not be eligible to receive further funding from the Secretary if such information is

not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

"(II) include and prominently display, until such time as the Secretary receives the information described in paragraph (1)(B), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

"(F) FAILURE TO COMPLY WITH NOTICE.—If by the date that is 30 days after the date on which the notice described in subparagraph (E)(ii)(I) is transmitted, the Secretary has not received from the principal investigator involved the information required pursuant to such notice, the Secretary may not award a grant, contract, cooperative agreement, or any other award to such principal investigator until such principal investigator submits to the Secretary the information required pursuant to such notice.

''(G) RULE OF CONSTRUCTION.—For purposes of this paragraph, limitations on the awarding of grants, contracts, cooperative agreements, or any other awards to principal investigators for violations of this paragraph shall not be construed to include any funding that supports the clinical trial involved.

''(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prevent an investigator other than the investigator described in paragraph (3)(F) from receiving an ongoing award, contract, or cooperative agreement.

''(5) INCLUSION IN REGISTRY.—

''(A) GENERAL RULE.—The Secretary shall, pursuant to subsection (j)(5), include—

''(i) the data described in subsection (j)(3)(A) and submitted under the amendments made by section 4(a) of the FACT Act in the registry described in subsection (j) as soon as practicable after receiving such data; and

''(ii) the data described in clause (I) of subsection (j)(3)(B)(iv) and submitted under this subsection or the amendments made by section 4(a) of the FACT Act in

the database described in subsection (j) as soon as practicable after receiving such data.

''(B) OTHER DATA.—

''(i) IN GENERAL.—The Secretary shall, pursuant to subsection (j)(5), include the data described in subclauses (II) through (X) of subsection (j)(3)(B)(iv) and submitted under this section in the database described in subsection (j)—

''(I) as soon as practicable after receiving such data; or

''(II) in the case of data to which clause (ii) applies, by the date described in clause (iii).

''(ii) DATA DESCRIBED.—This clause applies to data described in clause (i) if—

''(I) the principal investigator involved requests a delay in the inclusion in the database of such data in order to have such data published in a peer reviewed journal; and

''(II) the Secretary determines that an attempt will be made to seek such publication.

"(iii) DATE FOR INCLUSION IN REGISTRY.—Subject to clause (iv), the date described in this clause is the earlier of—

"(I) the date on which the data involved is published as provided for in clause (ii); or

"(II) the date that is 18 months after the date on which such data is submitted to the Secretary.

"(iv) EXTENSION OF DATE.—The Secretary may extend the 18-month period described in clause (iii)(II) for an additional 6 months if the principal investigator demonstrates to the Secretary, prior to the expiration of such 18-month period, that the data involved has been accepted for publication by a journal described in clause (ii)(I).

"(v) MODIFICATION OF DATA.—Prior to including data in the database under clause (ii) or (iv), the Secretary shall permit the principal investigator to modify the data involved.

"(6) MEMORANDUM OF UNDERSTANDING.—Not later than 6 months after the date of enactment of

the FACT Act, the Secretary shall seek a memorandum of understanding with the heads of all other Federal agencies that conduct clinical trials to include in the registry and the database clinical trials sponsored by such agencies that meet the requirements of this subsection.

''(7) APPLICATION TO CERTAIN PERSONS.—The provisions of this subsection shall apply to a responsible person described in subsections (p)(1)(A)(ii)(II) or (p)(1)(B)(i)(II).

''(l) TRIALS WITH NON-FEDERAL SUPPORT.—

''(1) IN GENERAL.—The responsible person for a clinical trial described in subsection (j)(3)(B) shall, not later than the date specified in paragraph (3), submit to the Secretary—

''(A) the information described in subclauses (II) through (X) of subsection (j)(3)(B)(iv), and with respect to clinical trials in progress on the date of enactment of the FACT Act, the information described in subclause (I) of subsection (j)(3)(B)(iv); or

''(B) a statement containing information sufficient to demonstrate to the Secretary that the information described in subparagraph (A) cannot reasonably be submitted, along with an

estimated date of submission of the information described in such subparagraph.

''(2) SANCTION IN CASE OF NONCOMPLIANCE.—

''(A) INITIAL NONCOMPLIANCE.—If by the date specified in paragraph (3), the Secretary has not received the information or statement required to be submitted to the Secretary under paragraph (1), the Secretary shall—

''(i) transmit to the responsible person for such trial a notice stating that such responsible person shall be liable for the civil monetary penalties described in subparagraph (B) if the required information or statement is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

''(ii) include and prominently display, until such time as the Secretary receives the information described in paragraph (1), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

"(B) CIVIL MONETARY PENALTIES FOR NONCOMPLIANCE.—

"(i) IN GENERAL.—If by the date that is 30 days after the date on which a notice described in subparagraph (A) is transmitted, the Secretary has not received from the responsible person involved the information or statement required pursuant to such notice, the Secretary shall, after providing the opportunity for a hearing, order such responsible person to pay a civil penalty of $10,000 for each day after such date that the information or statement is not submitted.

"(ii) WAIVERS.—In any case in which a responsible person described in clause (i) is a nonprofit entity, the Secretary may waive or reduce the penalties applicable under such clause to such person.

"(C) SUBMISSION OF STATEMENT BUT NOT INFORMATION.—

"(i) IN GENERAL.—If by the date specified in paragraph (3), the Secretary has received a statement described in paragraph (1)(B) but not the information de-

scribed in paragraph (1)(A) the Secretary shall transmit to the responsible person involved a notice stating that such responsible person shall submit such information by the date determined by the Secretary in consultation with such responsible person.

''(ii) FAILURE TO COMPLY.—If, by the date specified by the Secretary in the notice under clause (i), the Secretary has not received the information described in paragraph (1)(A), the Secretary shall—

''(I) transmit to the responsible person involved a notice specifying the information required to be submitted to the Secretary and stating that such responsible person shall be liable for the civil monetary penalties described in subparagraph (D) if such information is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

''(II) include and prominently display, until such time as the Secretary receives the information described in paragraph (1)(A), as part

of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

''(D) NONCOMPLIANCE.—

''(i) IN GENERAL.—If by the date that is 30 days after the date on which a notice described in subparagraph (C)(ii)(I) is transmitted, the Secretary has not received from the responsible person involved the information required pursuant to such notice, the Secretary, after providing the opportunity for a hearing, order such responsible person to pay a civil penalty of $10,000 for each day after such date that the information is not submitted.

''(ii) WAIVERS.—In any case in which a responsible person described in clause (i) is a nonprofit entity, the Secretary may waive or reduce the penalties applicable under such clause to such person.

''(E) NOTICE OF PUBLICATION OF DATA.—If the responsible person is the manufacturer or distributor of the drug, biological product, or

device involved, the notice under subparagraphs (A)(i) and (C)(ii)(I) shall include a notice that the Secretary shall publish the data described in subsection (j)(3)(B) in the database if the responsible person has not submitted the information specified in the notice transmitted by the date that is 6 months after the date of such notice.

''(F) PUBLICATION OF DATA.—Notwithstanding section 301(j) of the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, or any other provision of law, if the responsible person is the manufacturer or distributor of the drug, biological product, or device involved, and if the responsible person has not submitted to the Secretary the information specified in a notice transmitted pursuant to subparagraph (A)(i) or (C)(ii)(I) by the date that is 6 months after the date of such notice, the Secretary shall publish in the registry information that—

''(i) is described in subsection (j)(3)(B); and

''(ii) the responsible person has submitted to the Secretary in any application,

including a supplemental application, for the drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351.

''(3) DATE SPECIFIED.—The date specified in this paragraph shall be the date that is 1 year from the earlier of—

''(A) the estimated completion date of the trial, submitted under subsection (j)(3)(B)(vi)(I)(hh); or

''(B) the actual date of completion or termination of the trial.

''(4) USE OF FUNDS.—

''(A) IN GENERAL.—The Secretary shall deposit the funds collected under paragraph (2) into an account and use such funds, in consultation with the Director of the Agency for Healthcare Research and Quality, to fund studies that compare the clinical effectiveness of 2 or more treatments for a disease or condition.

''(B) FUNDING DECISIONS.—The Secretary shall award funding under subparagraph (A) based on a priority list established not later than 6 months after the date of enactment of

the FACT Act by the Director of the Agency for Healthcare Research and Quality and periodically updated as determined appropriate by the Director.

''(5) INCLUSION IN REGISTRY.—

''(A) GENERAL RULE.—The Secretary shall, pursuant to subsection (j)(5), include—

''(i) the data described in subsection (j)(3)(A) and submitted under the amendments made by section 4(a) of the FACT Act in the registry described in subsection (j) as soon as practicable after receiving such data; and

''(ii) the data described in clause (I) of subsection (j)(3)(B)(iv) and submitted under this subsection in the database described in subsection (j) as soon as practicable after receiving such data.

''(B) OTHER DATA.—

''(i) IN GENERAL.—The Secretary shall, pursuant to subsection (j)(5), include the data described in subclauses (II) through (X) of subsection (j)(3)(B)(iv) and submitted under this section in the database described in subsection (j)—

''(I) as soon as practicable after receiving such data; or

''(II) in the case of data to which clause (ii) applies, by the date described in clause (iii).

''(ii) DATA DESCRIBED.—This clause applies to data described in clause (i) if—

''(I) the responsible person involved requests a delay in the inclusion in the database of such data in order to have such data published in a peer reviewed journal; and

''(II) the Secretary determines that an attempt will be made to seek such publication.

''(iii) DATE FOR INCLUSION IN REGISTRY.—Subject to clause (iv), the date described in this clause is the earlier of—

''(I) the date on which the data involved is published as provided for in clause (ii); or

''(II) the date that is 18 months after the date on which such data is submitted to the Secretary.

"(iv) EXTENSION OF DATE.—The Secretary may extend the 18-month period described in clause (iii)(II) for an additional 6 months if the responsible person demonstrates to the Secretary, prior to the expiration of such 18-month period, that the data involved has been accepted for publication by a journal described in clause (ii)(I).

"(v) MODIFICATION OF DATA.—Prior to including data in the database under clause (ii) or (iv), the Secretary shall permit the responsible person to modify the data involved.

"(6) EFFECT.—The information with respect to a clinical trial submitted to the Secretary under this subsection, including data published by the Secretary pursuant to paragraph (2)(F), may not be submitted by a person other than the responsible person as part of, or referred to in, an application for approval of a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or of a biological product under section 351, unless the information is available from a

source other than the registry or database described in subsection (j).

''(m) PROCEDURES AND WAIVERS.—

''(1) SUBMISSION PRIOR TO NOTICE.—Nothing in subsections (k) through (l) shall be construed to prevent a principal investigator or a responsible person from submitting any information required under this subsection to the Secretary prior to receiving any notice described in such subsections.

''(2) ONGOING TRIALS.—A factually accurate statement that a clinical trial is ongoing shall be deemed to be information sufficient to demonstrate to the Secretary that the information described in subsections (k)(1)(A) and (l)(1)(A) cannot reasonably be submitted.

''(3) INFORMATION PREVIOUSLY SUBMITTED.—Nothing in subsections (k) through (l) shall be construed to require the Secretary to send a notice to any principal investigator or responsible person requiring the submission to the Secretary of information that has already been submitted.

''(4) SUBMISSION FORMAT AND TECHNICAL STANDARDS.—

''(A) IN GENERAL.—The Secretary shall, to the extent practicable, accept submissions re-

quired under this subsection in an electronic format and shall establish interoperable technical standards for such submissions.

''(B) CONSISTENCY OF STANDARDS.—To the extent practicable, the standards established under subparagraph (A) shall be consistent with standards adopted by the Consolidated Health Informatics Initiative (or a successor organization to such Initiative) to the extent such Initiative (or successor) is in operation.

''(5) TRIALS COMPLETED PRIOR TO ENACTMENT.—The Secretary shall establish procedures and mechanisms to allow for the voluntary submission to the database of the information described in subsection (j)(3)(B) with respect to clinical trials completed prior to the date of enactment of the FACT Act. In cases in which it is in the interest of public health, the Secretary may require that information from such trials be submitted to the database. Failure to comply with such a requirement shall be deemed to be a failure to submit information as required under this section, and the appropriate remedies and sanctions under this section shall apply.

''(6) TRIALS NOT INVOLVING DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.—The Secretary shall establish procedures and mechanisms to allow for the voluntary submission to the database of the information described in subsection (j)(3)(B) with respect to clinical trials that do not involve drugs, biological products, or devices. In cases in which it is in the interest of public health, the Secretary may require that information from such trials be submitted to the database. Failure to comply with such a requirement shall be deemed to be a failure to submit information as required under this section, and the appropriate remedies and sanctions under this section shall apply.

''(7) SUBMISSION OF INACCURATE INFORMATION.—

''(A) IN GENERAL.—If the Secretary determines that information submitted by a principal investigator or a responsible person under this section is factually and substantively inaccurate, the Secretary shall submit a notice to the investigator or responsible person concerning such inaccuracy that includes—

''(i) a summary of the inaccuracies involved; and

"(ii) a request for corrected information within 30 days.

"(B) AUDIT OF INFORMATION.—

"(i) IN GENERAL.—The Secretary may conduct audits of any information submitted under subsection (j).

"(ii) REQUIREMENT.—Any principal investigator or responsible person that has submitted information under subsection (j) shall permit the Secretary to conduct the audit described in clause (i).

"(C) CHANGES TO INFORMATION.—Any change in the information submitted by a principal investigator or a responsible person under this section shall be reported to the Secretary within 30 days of the date on which such investigator or person became aware of the change for purposes of updating the registry or the database.

"(D) FAILURE TO CORRECT.—If a principal investigator or a responsible person fails to permit an audit under subparagraph (B), provide corrected information pursuant to a notice under subparagraph (A), or provide changed information under subparagraph (C),

the investigator or responsible person involved shall be deemed to have failed to submit information as required under this section and the appropriate remedies and sanction under this section shall apply.

''(E) CORRECTIONS.—

''(i) IN GENERAL.—The Secretary may correct, through any means deemed appropriate by the Secretary to protect public health, any information included in the registry or the database described in subsection (j) (including information described or contained in a publication referred to under subclause (VI) of subsection (j)(3)(B)(iv)) that is—

''(I) submitted to the Secretary for inclusion in the registry or the database; and

''(II) factually and substantively inaccurate or false or misleading.

''(ii) RELIANCE ON INFORMATION.—The Secretary may rely on any information from a clinical trial or a report of an adverse event acquired or produced under the authority of section 351 of this Act or of

the Federal Food, Drug, and Cosmetic Act in determining whether to make corrections as provided for in clause (i).

''(iii) DETERMINATIONS RELATING TO MISLEADING INFORMATION.—For purposes of clause (i)(II), in determining whether information is misleading, the Secretary shall use the standard described in section 201(n) of the Federal Food, Drug, and Cosmetic Act that is used to determine whether labeling or advertising is misleading.

''(iv) RULE OF CONSTRUCTION.—This subparagraph shall not be construed to authorize the disclosure of information if—

''(I) such disclosure would constitute an invasion of personal privacy;

''(II) such information concerns a method or process which as a trade secret is entitled to protection within the meaning of section 301(j) of the Federal Food, Drug, and Cosmetic Act;

"(III) such disclosure would disclose confidential commercial information or a trade secret, other than a trade secret described in subclause (II), unless such disclosure is necessary—

"(aa) to make a correction as provided for under clause (i); and

"(bb) protect the public health; or

"(IV) if such disclosure relates to a biological product for which no license is in effect under section 351, a drug for which no approved application is in effect under section 505(c) of the Federal Food, Drug, and Cosmetic Act, or a device that is not cleared under section 510(k) of such Act or for which no application is in effect under section 515 of such Act.

"(v) NOTICE.—In the case of a disclosure under clause (iv)(III), the Secretary shall notify the manufacturer or distributor

of the drug, biological product, or device involved—

"(I) at least 30 days prior to such disclosure; or

"(II) if immediate disclosure is necessary to protect the public health, concurrently with such disclosure.

"(8) WAIVERS REGARDING CLINICAL TRIAL RESULTS.—The Secretary may waive the requirements of subsections (k)(1) and (l)(1) that the results of clinical trials be submitted to the Secretary, upon a written request from the responsible person if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest or consistent with the protection of public health.

"(n) TRIALS CONDUCTED OUTSIDE OF THE UNITED STATES.—

"(1) IN GENERAL.—With respect to clinical trials described in paragraph (2), the responsible person shall submit to the Secretary the information required under subclauses (II) through (X) of subsection (j)(3)(B)(iv). Failure to comply with this paragraph shall be deemed to be a failure to submit information as required under this section, and the

appropriate remedies and sanctions under this section shall apply.

''(2) CLINICAL TRIAL DESCRIBED.—A clinical trial is described in this paragraph if—

''(A) such trial is conducted outside of the United States; and

''(B) the data from such trial is—

''(i) submitted to the Secretary as part of an application, including a supplemental application, for a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351; or

''(ii) used in advertising or labeling to make a claim about the drug, device, or biological product involved.

''(o) DEFINITIONS; INDIVIDUAL LIABILITY.—

''(1) RESPONSIBLE PERSON.—

''(A) IN GENERAL.—In this section, the term 'responsible person' with respect to a clinical trial, means—

''(i) if such clinical trial is the subject of an investigational new drug application or an application for an investigational de-

vice exemption, the sponsor of such investigational new drug application or such application for an investigational device exemption; or

"(ii) except as provided in subparagraph (B), if such clinical trial is not the subject of an investigational new drug application or an application for an investigational device exemption—

"(I) the person that provides the largest share of the monetary support (such term does not include in-kind support) for the conduct of such trial; or

"(II) in the case in which the person described in subclause (I) is a Federal or State agency, the principal investigator of such trial.

"(B) NONPROFIT ENTITIES AND REQUESTING PERSONS.—

"(i) NONPROFIT ENTITIES.—For purposes of subparagraph (A)(ii)(I), if the person that provides the largest share of the monetary support for the conduct of the clinical trial involved is a nonprofit en-

tity, the responsible person for purposes of this section shall be—

"(I) the nonprofit entity; or

"(II) if the nonprofit entity and the principal investigator of such trial jointly certify to the Secretary that the principal investigator will be responsible for submitting the information described in subsection (j)(3)(B) for such trial, the principal investigator.

"(ii) REQUESTING PERSONS.—For purposes of subparagraph (A)(ii)(I), if a person—

"(I) has submitted a request to the Secretary that the Secretary recognize the person as the responsible person for purposes of this section; and

"(II) the Secretary determines that such person—

"(aa) provides monetary support for the conduct of such trial;

"(bb) is responsible for the conduct of such trial; and

"(cc) will be responsible for submitting the information described in subsection (j)(3)(B) for such trial;

such person shall be the responsible person for purposes of this section.

"(2) DRUG, DEVICE, BIOLOGICAL PRODUCT.—In this section—

"(A) the terms 'drug' and 'device' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act; and

"(B) the term 'biological product' has the meaning given such term in section 351 of this Act.

"(3) INDIVIDUAL LIABILITY.—

"(A) LIMITATION ON LIABILITY OF INDIVIDUALS.—No individual shall be liable for any civil monetary penalty under this section.

"(B) INDIVIDUALS WHO ARE RESPONSIBLE PERSONS.—If a responsible person under subparagraph (A) or (B) of paragraph (1) is an individual, such individual shall be subject to

the procedures and conditions described in subsection (k).''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Section 402 of the Public Health Service Act (42 U.S.C. 282), as amended by this section, is further amended by adding at the end the following:

''(s) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as may be necessary to carry out this section.''.

SEC. 4. REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH.

(a) AMENDMENTS.—Section 492A(a) of the Public Health Service Act (42 U.S.C. 289a–1(a)) is amended—

(1) in paragraph (1)(A), by striking ''unless'' and all that follows through the period and inserting the following: ''unless—

''(i) the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting the review;

''(ii) such Board has submitted to the Secretary a notification of such approval; and

''(iii) with respect to an application involving a clinical trial to which section 402(j) applies, the principal investigator who has submitted such application has submitted to the Secretary for inclusion in the registry and the database described in section 402(j) the information described in paragraph (3)(A) and subclause (I) of paragraph (3)(B)(iv) of such section.''; and

(2) by adding at the end the following:

''(3) COST RECOVERY.—Nonprofit entities may recover the full costs associated with compliance with the requirements of paragraph (1) from the Secretary as a direct cost of research.''.

(b) REGULATIONS.—The Secretary of Health and Human Services shall modify the regulations promulgated at part 46 of title 45, Code of Federal Regulations, part 50 of title 21, Code of Federal Regulations, and part 56 of title 21, Code of Federal Regulations, to reflect the amendments made by subsection (a).

SEC. 5. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The entering into of a contract or other agreement by a responsible person or a manufacturer of a drug, biological product, or device with an individual who is not an employee of such responsible person or manufacturer, or the performance of any other act by such a responsible person or manufacturer, that prohibits, limits, or imposes unreasonable delays on the ability of such individual to—

''(A) discuss the results of a clinical trial at a scientific meeting or any other public or private forum; or

''(B) publish the results of a clinical trial or a description or discussion of the results of a clinical trial in a scientific journal or any other publication.

''(2) The entering into a contract or other agreement by a responsible person or a manufacturer of a drug, biological product, or device with an academic institution or a health care facility, or the performance of any other act by such a responsible person or manufacturer, that prohibits, limits, or imposes unreasonable delays on the ability of an individual who is not an employee of such responsible person or manufacturer to—

''(A) discuss the results of a clinical trial at a scientific meeting or any other public or private forum; or

''(B) publish the results of a clinical trial or a description or discussion of the results of a clinical trial in a scientific journal or any other publication.''.

SEC. 6. REPORTS.

(a) IMPLEMENTATION REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report on the status of the implementation of the requirements of the amendments made by section 3 that includes a description of the number and types of clinical trials for which information has been submitted under such amendments.

(b) DATA COLLECTION.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for the conduct of a study concerning the extent to which data submitted to the registry under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) has impacted the public health.

(2) REPORT.—Not later than 6 months after the date on which a contract is entered into under paragraph (1), the Institute of Medicine shall submit to the Secretary of Health and Human Services a

report on the results of the study conducted under such paragraph. Such report shall include recommendations for changes to the registry, the database, and the data submission requirements that would benefit the public health.

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