

110TH CONGRESS
1ST SESSION

S. 467

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

IN THE SENATE OF THE UNITED STATES

JANUARY 31, 2007

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

A BILL

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

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 “Fair Access to Clinical
5 Trials Act of 2007” or the “FACT Act”.

6 **SEC. 2. PURPOSE.**

7 It is the purpose of this Act—

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

1 ical trial registry and a clinical trial results data-
2 base;

3 (2) to foster transparency and accountability in
4 health-related intervention research and develop-
5 ment;

6 (3) to maintain a clinical trial registry acces-
7 sible to patients and health care practitioners seek-
8 ing information related to ongoing clinical trials for
9 serious or life-threatening diseases and conditions;
10 and

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

16 **SEC. 3. CLINICAL TRIALS DATA BANK.**

17 (a) IN GENERAL.—Subsection (i) of section 402 of
18 the Public Health Service Act (42 U.S.C. 282), as amend-
19 ed by Public Law 109–482, is amended—

20 (1) in paragraph (1)(A), by striking “for drugs
21 for serious or life-threatening diseases and condi-
22 tions”;

23 (2) in paragraph (2), by striking “available to
24 individuals with serious” and all that follows
25 through the period and inserting “accessible to pa-

1 tients, other members of the public, health care
 2 practitioners, researchers and the scientific commu-
 3 nity. In making information about clinical trials pub-
 4 licly available, the Secretary shall seek to be as time-
 5 ly and transparent as possible.”;

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

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

10 “(3) The data bank shall include the following:

11 “(A)(i) A registry of clinical trials (in this sub-
 12 paragraph referred to as the ‘registry’) of health-re-
 13 lated interventions (whether federally or privately
 14 funded).

15 “(ii) The registry shall include information for
 16 all clinical trials conducted to test the safety or ef-
 17 fectiveness (including comparative effectiveness) of
 18 any drug, biological product, or device (including
 19 those drugs, biological products, or devices approved
 20 or cleared by the Secretary) intended to treat serious
 21 or life-threatening diseases and conditions, except
 22 those Phase I clinical trials conducted to test solely
 23 the safety of an unapproved drug or unlicensed bio-
 24 logical product, or pilot or feasibility studies con-
 25 ducted to confirm the design and operating speci-

1 fications of an unapproved or not yet cleared med-
2 ical device. For purposes of this section, Phase I
3 clinical trials are trials described in section
4 313.12(a) of title 21, Code of Federal Regulations
5 (or any successor regulations).

6 “(iii) The registry may include information
7 for—

8 “(I) Phase I clinical trials conducted to
9 test solely the safety of an unapproved drug or
10 unlicensed biological product, or pilot or feasi-
11 bility studies conducted to confirm the design
12 and operating specifications of an unapproved
13 or not yet cleared medical device with the con-
14 sent of the responsible person; and

15 “(II) clinical trials of other health-related
16 interventions with the consent of the responsible
17 person.

18 “(iv) The information to be included in the reg-
19 istry under this subparagraph shall include the fol-
20 lowing:

21 “(I) Descriptive information, including a
22 brief title, trial description in lay terminology,
23 trial phase, trial type, trial purpose, description
24 of the primary and secondary clinical outcome
25 measures to be examined in the trial, the time

1 at which the outcome measures will be assessed,
2 and the dates and details of any revisions to
3 such outcomes.

4 “(II) Recruitment information, including
5 eligibility and exclusion criteria, a description of
6 whether, and through what procedure, the man-
7 ufacturer or sponsor of the investigation of a
8 new drug will respond to requests for protocol
9 exception, with appropriate safeguards, for sin-
10 gle-patient and expanded protocol use of the
11 new drug, particularly in children, a statement
12 as to whether the trial is closed to enrollment
13 of new patients, overall trial status, individual
14 site status, and estimated completion date. For
15 purposes of this section the term ‘completion
16 date’ means the date of the last visit by sub-
17 jects in the trial for the outcomes described in
18 subclause (I).

19 “(III) Location and contact information,
20 including the identity of the responsible person.

21 “(IV) Administrative data, including the
22 study sponsor and the study funding source.

23 “(V) Information pertaining to experi-
24 mental treatments for serious or life-threat-

1 ening diseases and conditions (whether federally
2 or privately funded) that may be available—

3 “(aa) under a treatment investiga-
4 tional new drug application that has been
5 submitted to the Secretary under section
6 360bbb(c) of title 21, Code of Federal
7 Regulations; or

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

10 “(B)(i) A clinical trial results database (in this
11 subparagraph referred to as the ‘database’) of
12 health-related interventions (whether federally or
13 privately funded).

14 “(ii) The database shall include information for
15 all clinical trials conducted to test the safety or ef-
16 fectiveness (including comparative effectiveness) of
17 any drug, biological product, or device (including
18 those drugs, biological products, or devices approved
19 or cleared by the Secretary), except those Phase I
20 clinical trials conducted to test solely the safety of
21 an unapproved drug or unlicensed biological product,
22 or pilot or feasibility studies conducted to confirm
23 the design and operating specifications of an unap-
24 proved or not yet cleared medical device.

1 “(iii) The database may include information
2 for—

3 “(I) Phase I clinical trials conducted to
4 test solely the safety of an unapproved drug or
5 unlicensed biological product, or pilot or feasi-
6 bility studies conducted to confirm the design
7 and operating specifications of an unapproved
8 or not yet cleared medical device with the con-
9 sent of the responsible person; and

10 “(II) clinical trials of other health-related
11 interventions with the consent of the responsible
12 person.

13 “(iv) The information to be included in the
14 database under this subparagraph shall include the
15 following:

16 “(I) Descriptive information, including—

17 “(aa) a brief title;

18 “(bb) the drug, biological product or
19 device to be tested;

20 “(cc) a trial description in lay termi-
21 nology;

22 “(dd) the trial phase;

23 “(ee) the trial type;

24 “(ff) the trial purpose;

1 “(gg) demographic data such as age,
2 gender, or ethnicity of trial participants;

3 “(hh) the estimated completion date
4 for the trial; and

5 “(ii) the study sponsor and the study
6 funding source.

7 “(II) A description of the primary and sec-
8 ondary clinical outcome measures to be exam-
9 ined in the trial, the time at which the outcome
10 measures will be assessed, and the dates and
11 details of any revisions to such outcomes.

12 “(III) The actual completion date of the
13 trial and the reasons for any difference from
14 such actual date and the estimated completion
15 date submitted pursuant to subclause (I)(ii). If
16 the trial is not completed, the termination date
17 and reasons for such termination.

18 “(IV) A summary of the results of the trial
19 in a standard, non-promotional summary for-
20 mat (such as ICHE3 template form), including
21 the trial design and methodology, results of the
22 primary and secondary outcome measures as
23 described in subclause (II), summary data ta-
24 bles with respect to the primary and secondary
25 outcome measures, including information on the

1 statistical significance or lack thereof of such
2 results.

3 “(V) Safety data concerning the trial (in-
4 cluding a summary of all adverse events speci-
5 fying the number and type of such events, data
6 on prespecified adverse events, data on serious
7 adverse events, and data on overall deaths).

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

13 “(VII) A description of the process used to
14 review the results of the trial, including a state-
15 ment about whether the results have been peer
16 reviewed by reviewers independent of the trial
17 sponsor.

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

1 “(aa) is currently reviewing an appli-
2 cation for approval of such use to deter-
3 mine whether the use is safe and effective;

4 “(bb) has disapproved an application
5 for approval of such use;

6 “(cc) has reviewed an application for
7 approval of such use but the application
8 was withdrawn prior to approval or dis-
9 approval; or

10 “(dd) has not reviewed or approved
11 such use as safe and effective.

12 “(IX) If data from the trial has not been
13 submitted to the Food and Drug Administra-
14 tion, an explanation of why it has not been sub-
15 mitted.

16 “(X) A description of the protocol used in
17 such trial to the extent necessary to evaluate
18 the results of such trial.

19 “(4)(A)(i) Not later than 90 days after the date of
20 the completion of the review by the Food and Drug Ad-
21 ministration of information submitted by a sponsor in sup-
22 port of a new drug application, or a supplemental new
23 drug application, whether or not approved by the Food
24 and Drug Administration, the Commissioner of Food and
25 Drugs shall make available to the public the full reviews

1 conducted by the Administration of such application, in-
2 cluding documentation of significant differences of opinion
3 and the resolution of those differences.

4 “(ii) When submitting information in support of a
5 new drug application or a supplemental new drug applica-
6 tion, the sponsor shall certify, in writing, that the informa-
7 tion submitted to the Food and Drug Administration com-
8 plies with the requirements of the Federal Food, Drug,
9 and Cosmetic Act and that such information presented is
10 accurate.

11 “(iii) If the sponsor fails to provide certification as
12 specified under clause (ii), the Secretary shall transmit to
13 the sponsor a notice stating that such sponsor shall submit
14 the certification by the date determined by the Secretary.
15 If, by the date specified by the Secretary in the notice
16 under this clause, the Secretary has not received the cer-
17 tification, the Secretary, after providing the opportunity
18 for a hearing, shall order such sponsor to pay a civil mone-
19 tary penalty of \$10,000 for each day after such date that
20 the certification is not submitted.

21 “(iv) If the Secretary determines, after notice and op-
22 portunity for a hearing, that the sponsor knew or should
23 have known that the information submitted in support of
24 a new drug application or a supplemental new drug appli-
25 cation was inaccurate, the Secretary shall order such spon-

1 sor to pay a civil monetary penalty of not less than
2 \$100,000 but not to exceed \$2,000,000 for any 30-day
3 period.

4 “(B)(i) The Secretary shall deposit the funds col-
5 lected under subparagraph (A) into an account and use
6 such funds, in consultation with the Director of the Agen-
7 cy for Healthcare Research and Quality, to fund studies
8 that compare the clinical effectiveness of 2 or more treat-
9 ments for similar diseases or conditions.

10 “(ii) The Secretary shall award funding under clause
11 (i) based on a priority list established not later than 6
12 months after the date of enactment of the FACT Act by
13 the Director of the Agency for Healthcare Research and
14 Quality and periodically updated as determined appro-
15 priate by the Director.

16 “(C) Not later than 90 days after the date of the
17 completion of a written consultation on a drug concerning
18 the drug’s safety conducted by the Office of Surveillance
19 and Epidemiology, regardless of whether initiated by such
20 Office or outside of the Office, the Commissioner of Food
21 and Drugs shall make available to the public a copy of
22 such consultation in full.

23 “(D) Nothing in this paragraph shall be construed
24 to alter or amend section 301(j) or section 1905 of title
25 18, United States Code.

1 “(E) This paragraph shall supersede section 552 of
2 title 5, United States Code.

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

8 “(6) The Secretary shall assign each clinical trial a
9 unique identifier to be included in the registry and in the
10 database described in subparagraphs (A) and (B) of para-
11 graph (3). To the extent practicable, this identifier shall
12 be consistent with other internationally recognized and
13 used identifiers.

14 “(7) To the extent practicable, the Secretary shall en-
15 sure that where the same information is required for the
16 registry and the database described in subparagraphs (A)
17 and (B) of paragraph (3), a process exists to allow the
18 responsible person to make only one submission.”; and

19 (5) by adding at the end the following:

20 “(10) In this section, the term ‘clinical trial’ with re-
21 spect to the registry and the database described in sub-
22 paragraphs (A) and (B) of paragraph (3) means a re-
23 search study in human volunteers to answer specific health
24 questions, including treatment trials, prevention trials, di-
25 agnostic trials, screening trials, and quality of life trials.”.

1 (b) ACTIONS OF SECRETARY REGARDING CLINICAL
 2 TRIALS.—Section 402 of the Public Health Service Act
 3 (42 U.S.C. 282), as amended by Public Law 109–482, is
 4 amended—

5 (1) by redesignating subsections (j) and (k) as
 6 subsections (o) and (p), respectively; and

7 (2) by inserting after subsection (i), the fol-
 8 lowing:

9 “(j) FEDERALLY SUPPORTED TRIALS.—

10 “(1) ALL FEDERALLY SUPPORTED TRIALS.—
 11 With respect to any clinical trial described in sub-
 12 section (i)(3)(B) that is supported solely by a grant,
 13 contract, or cooperative agreement awarded by the
 14 Secretary, the principal investigator of such trial
 15 shall, not later than the date specified in paragraph
 16 (2), submit to the Secretary—

17 “(A) the information described in sub-
 18 clauses (II) through (X) of subsection
 19 (i)(3)(B)(iv), and with respect to clinical trials
 20 in progress on the date of enactment of the
 21 FACT Act, the information described in sub-
 22 clause (I) of subsection (i)(3)(B)(iv); or

23 “(B) a statement containing information
 24 sufficient to demonstrate to the Secretary that
 25 the information described in subparagraph (A)

1 cannot reasonably be submitted, along with an
2 estimated date of submission of the information
3 described in such subparagraph.

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

7 “(A) the estimated completion date of the
8 trial, as submitted under subsection
9 (i)(3)(B)(vi)(I)(ii); or

10 “(B) the actual date of the completion or
11 termination of the trial.

12 “(3) CONDITION OF FEDERAL GRANTS, CON-
13 TRACTS, AND COOPERATIVE AGREEMENTS.—

14 “(A) CERTIFICATION OF COMPLIANCE.—
15 To be eligible to receive a grant, contract, or
16 cooperative agreement from the Secretary for
17 the conduct or support of a clinical trial de-
18 scribed in subsection (i)(3)(B), the principal in-
19 vestigator involved shall certify to the Secretary
20 that—

21 “(i) such investigator shall submit
22 data to the Secretary in accordance with
23 this subsection; and

24 “(ii) such investigator has complied
25 with the requirements of this subsection

1 with respect to other clinical trials con-
2 ducted by such investigator after the date
3 of enactment of the FACT Act.

4 “(B) FAILURE TO SUBMIT CERTIFI-
5 CATION.—An investigator that fails to submit a
6 certification as required under subparagraph
7 (A) shall not be eligible to receive a grant, con-
8 tract, or cooperative agreement from the Sec-
9 retary for the conduct or support of a clinical
10 trial described in subsection (i)(3)(B).

11 “(C) FAILURE TO COMPLY WITH CERTIFI-
12 CATION.—If, by the date specified in paragraph
13 (2), the Secretary has not received the informa-
14 tion or statement described in paragraph (1),
15 the Secretary shall—

16 “(i) transmit to the principal investi-
17 gator involved a notice specifying the infor-
18 mation or statement required to be sub-
19 mitted to the Secretary and stating that
20 such investigator shall not be eligible to re-
21 ceive further funding from the Secretary if
22 such information or statement is not sub-
23 mitted to the Secretary within 30 days of
24 the date on which such notice is trans-
25 mitted; and

1 “(ii) include and prominently display,
2 until such time as the Secretary receives
3 the information or statement described in
4 paragraph (1), as part of the record of
5 such trial in the database described in sub-
6 section (i), a notice stating that the results
7 of such trials have not been reported as re-
8 quired by law.

9 “(D) FAILURE TO COMPLY WITH NO-
10 TICE.—If by the date that is 30 days after the
11 date on which the notice described in subpara-
12 graph (C) is transmitted, the Secretary has not
13 received from the principal investigator involved
14 the information or statement required pursuant
15 to such notice, the Secretary may not award a
16 grant, contract, cooperative agreement, or any
17 other award to such principal investigator until
18 such principal investigator submits to the Sec-
19 retary the information or statement required
20 pursuant to such notice.

21 “(E) SUBMISSION OF STATEMENT BUT
22 NOT INFORMATION.—

23 “(i) IN GENERAL.—If by the date
24 specified in paragraph (2), the Secretary
25 has received a statement described in para-

graph (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 Sec-

1 retary receives the information de-
2 scribed in paragraph (1)(B), as part
3 of the record of such trial in the data-
4 base described in subsection (i), a no-
5 tice stating that the results of such
6 trials have not been reported as re-
7 quired by law.

8 “(F) FAILURE TO COMPLY WITH NO-
9 TICE.—If by the date that is 30 days after the
10 date on which the notice described in subpara-
11 graph (E)(ii)(I) is transmitted, the Secretary
12 has not received from the principal investigator
13 involved the information required pursuant to
14 such notice, the Secretary may not award a
15 grant, contract, cooperative agreement, or any
16 other award to such principal investigator until
17 such principal investigator submits to the Sec-
18 retary the information required pursuant to
19 such notice.

20 “(G) RULE OF CONSTRUCTION.—For pur-
21 poses of this paragraph, limitations on the
22 awarding of grants, contracts, cooperative
23 agreements, or any other awards to principal
24 investigators for violations of this paragraph

1 shall not be construed to include any funding
2 that supports the clinical trial involved.

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

8 “(5) INCLUSION IN REGISTRY.—

9 “(A) GENERAL RULE.—The Secretary
10 shall, pursuant to subsection (i)(5), include—

11 “(i) the data described in subsection
12 (i)(3)(A) and submitted under the amend-
13 ments made by section 4(a) of the FACT
14 Act in the registry described in subsection
15 (i) as soon as practicable after receiving
16 such data; and

17 “(ii) the data described in clause (I)
18 of subsection (i)(3)(B)(iv) and submitted
19 under this subsection or the amendments
20 made by section 4(a) of the FACT Act in
21 the database described in subsection (i) as
22 soon as practicable after receiving such
23 data.

24 “(B) OTHER DATA.—

1 “(i) IN GENERAL.—The Secretary
 2 shall, pursuant to subsection (i)(5), include
 3 the data described in subclauses (II)
 4 through (X) of subsection (i)(3)(B)(iv) and
 5 submitted under this section in the data-
 6 base described in subsection (i)—

7 “(I) as soon as practicable after
 8 receiving such data; or

9 “(II) in the case of data to which
 10 clause (ii) applies, by the date de-
 11 scribed in clause (iii).

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

14 “(I) the principal investigator in-
 15 volved requests a delay in the inclu-
 16 sion in the database of such data in
 17 order to have such data published in
 18 a peer reviewed journal; and

19 “(II) the Secretary determines
 20 that an attempt will be made to seek
 21 such publication.

22 “(iii) DATE FOR INCLUSION IN REG-
 23 ISTRY.—Subject to clause (iv), the date de-
 24 scribed in this clause is the earlier of—

1 “(I) the date on which the data
2 involved is published as provided for
3 in clause (ii); or

4 “(II) the date that is 18 months
5 after the date on which such data is
6 submitted to the Secretary.

7 “(iv) EXTENSION OF DATE.—The
8 Secretary may extend the 18-month period
9 described in clause (iii)(II) for an addi-
10 tional 6 months if the principal investi-
11 gator demonstrates to the Secretary, prior
12 to the expiration of such 18-month period,
13 that the data involved has been accepted
14 for publication by a journal described in
15 clause (ii)(I).

16 “(v) MODIFICATION OF DATA.—Prior
17 to including data in the database under
18 clause (ii) or (iv), the Secretary shall per-
19 mit the principal investigator to modify the
20 data involved.

21 “(6) MEMORANDUM OF UNDERSTANDING.—Not
22 later than 6 months after the date of enactment of
23 the FACT Act, the Secretary shall seek a memo-
24 randum of understanding with the heads of all other
25 Federal agencies that conduct clinical trials to in-

1 clude in the registry and the database clinical trials
 2 sponsored by such agencies that meet the require-
 3 ments of this subsection.

4 “(7) APPLICATION TO CERTAIN PERSONS.—The
 5 provisions of this subsection shall apply to a respon-
 6 sible person described in subsections (n)(1)(A)(ii)(II)
 7 or (n)(1)(B)(i)(II).

8 “(k) TRIALS WITH NON-FEDERAL SUPPORT.—

9 “(1) IN GENERAL.—The responsible person for
 10 a clinical trial described in subsection (i)(3)(B) shall,
 11 not later than the date specified in paragraph (3),
 12 submit to the Secretary—

13 “(A) the information described in sub-
 14 clauses (II) through (X) of subsection
 15 (i)(3)(B)(iv), and with respect to clinical trials
 16 in progress on the date of enactment of the
 17 FACT Act, the information described in sub-
 18 clause (I) of subsection (i)(3)(B)(iv); or

19 “(B) a statement containing information
 20 sufficient to demonstrate to the Secretary that
 21 the information described in subparagraph (A)
 22 cannot reasonably be submitted, along with an
 23 estimated date of submission of the information
 24 described in such subparagraph.

25 “(2) SANCTION IN CASE OF NONCOMPLIANCE.—

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

6 “(i) transmit to the responsible person
 7 for such trial a notice stating that such re-
 8 sponsible person shall be liable for the civil
 9 monetary penalties described in subpara-
 10 graph (B) if the required information or
 11 statement is not submitted to the Sec-
 12 retary within 30 days of the date on which
 13 such notice is transmitted; and

14 “(ii) include and prominently display,
 15 until such time as the Secretary receives
 16 the information described in paragraph
 17 (1), as part of the record of such trial in
 18 the database described in subsection (i), a
 19 notice stating that the results of such
 20 trials have not been reported as required
 21 by law.

22 “(B) CIVIL MONETARY PENALTIES FOR
 23 NONCOMPLIANCE.—

24 “(i) IN GENERAL.—If by the date that
 25 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 described in paragraph (1)(A) the Secretary shall transmit to the responsible person involved a notice stating that such responsible person shall submit such information

1 by the date determined by the Secretary in
2 consultation with such responsible person.

3 “(ii) FAILURE TO COMPLY.—If, by the
4 date specified by the Secretary in the no-
5 tice under clause (i), the Secretary has not
6 received the information described in para-
7 graph (1)(A), the Secretary shall—

8 “(I) transmit to the responsible
9 person involved a notice specifying the
10 information required to be submitted
11 to the Secretary and stating that such
12 responsible person shall be liable for
13 the civil monetary penalties described
14 in subparagraph (D) if such informa-
15 tion is not submitted to the Secretary
16 within 30 days of the date on which
17 such notice is transmitted; and

18 “(II) include and prominently
19 display, until such time as the Sec-
20 retary receives the information de-
21 scribed in paragraph (1)(A), as part
22 of the record of such trial in the data-
23 base described in subsection (i), a no-
24 tice stating that the results of such

1 trials have not been reported as re-
2 quired by law.

3 “(D) NONCOMPLIANCE.—

4 “(i) IN GENERAL.—If by the date that
5 is 30 days after the date on which a notice
6 described in subparagraph (C)(ii)(I) is
7 transmitted, the Secretary has not received
8 from the responsible person involved the
9 information required pursuant to such no-
10 tice, the Secretary, after providing the op-
11 portunity for a hearing, shall order such
12 responsible person to pay a civil penalty of
13 \$10,000 for each day after such date that
14 the information is not submitted.

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

20 “(E) NOTICE OF PUBLICATION OF DATA.—

21 If the responsible person is the manufacturer or
22 distributor of the drug, biological product, or
23 device involved, the notice under subparagraphs
24 (A)(i) and (C)(ii)(I) shall include a notice that
25 the Secretary shall publish the data described

1 in subsection (i)(3)(B) in the database if the re-
 2 sponsible person has not submitted the informa-
 3 tion specified in the notice transmitted by the
 4 date that is 6 months after the date of such no-
 5 tice.

6 “(F) PUBLICATION OF DATA.—Notwith-
 7 standing section 301(j) of the Federal Food,
 8 Drug, and Cosmetic Act, section 1905 of title
 9 18, United States Code, or any other provision
 10 of law, if the responsible person is the manufac-
 11 turer or distributor of the drug, biological prod-
 12 uct, or device involved, and if the responsible
 13 person has not submitted to the Secretary the
 14 information specified in a notice transmitted
 15 pursuant to subparagraph (A)(i) or (C)(ii)(I) by
 16 the date that is 6 months after the date of such
 17 notice, the Secretary shall publish in the reg-
 18 istry information that—

19 “(i) is described in subsection
 20 (i)(3)(B); and

21 “(ii) the responsible person has sub-
 22 mitted to the Secretary in any application,
 23 including a supplemental application, for
 24 the drug or device under section 505, 510,
 25 515, or 520 of the Federal Food, Drug,

1 and Cosmetic Act or for the biological
2 product under section 351.

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

6 “(A) the estimated completion date of the
7 trial, submitted under subsection
8 (i)(3)(B)(vi)(I)(ii); or

9 “(B) the actual date of completion or ter-
10 mination of the trial.

11 “(4) USE OF FUNDS.—

12 “(A) IN GENERAL.—The Secretary shall
13 deposit the funds collected under paragraph (2)
14 into an account and use such funds, in con-
15 sultation with the Director of the Agency for
16 Healthcare Research and Quality, to fund stud-
17 ies that compare the clinical effectiveness of 2
18 or more treatments for similar diseases or con-
19 ditions.

20 “(B) FUNDING DECISIONS.—The Secretary
21 shall award funding under subparagraph (A)
22 based on a priority list established not later
23 than 6 months after the date of enactment of
24 the FACT Act by the Director of the Agency
25 for Healthcare Research and Quality and peri-

odically updated as determined appropriate by
the Director.

“(5) INCLUSION IN REGISTRY.—

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

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

“(ii) the data described in clause (I)
of subsection (i)(3)(B)(iv) and submitted
under this subsection in the database de-
scribed in subsection (i) as soon as prac-
ticable after receiving such data.

“(B) OTHER DATA.—

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

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

1 “(II) in the case of data to which
 2 clause (ii) applies, by the date de-
 3 scribed in clause (iii).

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

6 “(I) the responsible person in-
 7 volved requests a delay in the inclu-
 8 sion in the database of such data in
 9 order to have such data published in
 10 a peer reviewed journal; and

11 “(II) the Secretary determines
 12 that an attempt will be made to seek
 13 such publication.

14 “(iii) DATE FOR INCLUSION IN REG-
 15 ISTRY.—Subject to clause (iv), the date de-
 16 scribed in this clause is the earlier of—

17 “(I) the date on which the data
 18 involved is published as provided for
 19 in clause (ii); or

20 “(II) the date that is 18 months
 21 after the date on which such data is
 22 submitted to the Secretary.

23 “(iv) EXTENSION OF DATE.—The
 24 Secretary may extend the 18-month period
 25 described in clause (iii)(II) for an addi-

1 tional 6 months if the responsible person
2 demonstrates to the Secretary, prior to the
3 expiration of such 18-month period, that
4 the data involved has been accepted for
5 publication by a journal described in clause
6 (ii)(I).

7 “(v) MODIFICATION OF DATA.—Prior
8 to including data in the database under
9 clause (ii) or (iv), the Secretary shall per-
10 mit the responsible person to modify the
11 data involved.

12 “(6) EFFECT.—The information with respect to
13 a clinical trial submitted to the Secretary under this
14 subsection, including data published by the Sec-
15 retary pursuant to paragraph (2)(F), may not be
16 submitted by a person other than the responsible
17 person as part of, or referred to in, an application
18 for approval of a drug or device under section 505,
19 510, 515, or 520 of the Federal Food, Drug, and
20 Cosmetic Act or of a biological product under section
21 351, unless the information is available from a
22 source other than the registry or database described
23 in subsection (i).

24 “(l) PROCEDURES AND WAIVERS.—

1 “(1) SUBMISSION PRIOR TO NOTICE.—Nothing
 2 in subsections (j) through (k) shall be construed to
 3 prevent a principal investigator or a responsible per-
 4 son from submitting any information required under
 5 this subsection to the Secretary prior to receiving
 6 any notice described in such subsections.

7 “(2) ONGOING TRIALS.—A factually accurate
 8 statement that a clinical trial is ongoing shall be
 9 deemed to be information sufficient to demonstrate
 10 to the Secretary that the information described in
 11 subsections (j)(1)(A) and (k)(1)(A) cannot reason-
 12 ably be submitted.

13 “(3) INFORMATION PREVIOUSLY SUBMITTED.—
 14 Nothing in subsections (j) through (k) shall be con-
 15 strued to require the Secretary to send a notice to
 16 any principal investigator or responsible person re-
 17 quiring the submission to the Secretary of informa-
 18 tion that has already been submitted.

19 “(4) SUBMISSION FORMAT AND TECHNICAL
 20 STANDARDS.—

21 “(A) IN GENERAL.—The Secretary shall,
 22 to the extent practicable, accept submissions re-
 23 quired under this subsection in an electronic
 24 format and shall establish interoperable tech-
 25 nical standards for such submissions.

1 “(B) CONSISTENCY OF STANDARDS.—To
2 the extent practicable, the standards established
3 under subparagraph (A) shall be consistent
4 with standards adopted by the Consolidated
5 Health Informatics Initiative (or a successor or-
6 ganization to such Initiative) to the extent such
7 Initiative (or successor) is in operation.

8 “(5) TRIALS COMPLETED PRIOR TO ENACT-
9 MENT.—The Secretary shall establish procedures
10 and mechanisms to allow for the voluntary submis-
11 sion to the database of the information described in
12 subsection (i)(3)(B) with respect to clinical trials
13 completed prior to the date of enactment of the
14 FACT Act. In cases in which it is in the interest of
15 public health, the Secretary may require that infor-
16 mation from such trials be submitted to the data-
17 base. To the extent practicable, submissions to the
18 database shall comply with paragraph (4). Failure to
19 comply with a requirement to submit information to
20 the database under this paragraph shall be deemed
21 to be a failure to submit information as required
22 under this section, and the appropriate remedies and
23 sanctions under this section shall apply.

24 “(6) TRIALS NOT INVOLVING DRUGS, BIOLOGI-
25 CAL PRODUCTS, OR DEVICES.—The Secretary shall

1 establish procedures and mechanisms to allow for
2 the voluntary submission to the database of the in-
3 formation described in subsection (i)(3)(B) with re-
4 spect to clinical trials that do not involve drugs, bio-
5 logical products, or devices. In cases in which it is
6 in the interest of public health, the Secretary may
7 require that information from such trials be sub-
8 mitted to the database. Failure to comply with such
9 a requirement shall be deemed to be a failure to sub-
10 mit information as required under this section, and
11 the appropriate remedies and sanctions under this
12 section shall apply.

13 “(7) SUBMISSION OF INACCURATE INFORMA-
14 TION.—

15 “(A) IN GENERAL.—If the Secretary deter-
16 mines that information submitted by a principal
17 investigator or a responsible person under this
18 section is factually and substantively inaccurate,
19 the Secretary shall submit a notice to the inves-
20 tigator or responsible person concerning such
21 inaccuracy that includes—

22 “(i) a summary of the inaccuracies in-
23 volved; and

24 “(ii) a request for corrected informa-
25 tion within 30 days.

1 “(B) AUDIT OF INFORMATION.—

2 “(i) IN GENERAL.—The Secretary
3 may conduct audits of any information
4 submitted under subsection (i).

5 “(ii) REQUIREMENT.—Any principal
6 investigator or responsible person that has
7 submitted information under subsection (i)
8 shall permit the Secretary to conduct the
9 audit described in clause (i).

10 “(C) CHANGES TO INFORMATION.—Any
11 change in the information submitted by a prin-
12 cipal investigator or a responsible person under
13 this section shall be reported to the Secretary
14 within 30 days of the date on which such inves-
15 tigator or person became aware of the change
16 for purposes of updating the registry or the
17 database.

18 “(D) FAILURE TO CORRECT.—If a prin-
19 cipal investigator or a responsible person fails
20 to permit an audit under subparagraph (B),
21 provide corrected information pursuant to a no-
22 tice under subparagraph (A), or provide
23 changed information under subparagraph (C),
24 the investigator or responsible person involved
25 shall be deemed to have failed to submit infor-

1 mation as required under this section and the
 2 appropriate remedies and sanction under this
 3 section shall apply.

4 “(E) CORRECTIONS.—

5 “(i) IN GENERAL.—The Secretary
 6 may correct, through any means deemed
 7 appropriate by the Secretary to protect
 8 public health, any information included in
 9 the registry or the database described in
 10 subsection (i) (including information de-
 11 scribed or contained in a publication re-
 12 ferred to under subclause (VI) of sub-
 13 section (i)(3)(B)(iv)) that is—

14 “(I) submitted to the Secretary
 15 for inclusion in the registry or the
 16 database; and

17 “(II) factually and substantively
 18 inaccurate or false or misleading.

19 “(ii) RELIANCE ON INFORMATION.—
 20 The Secretary may rely on any information
 21 from a clinical trial or a report of an ad-
 22 verse event acquired or produced under the
 23 authority of section 351 of this Act or of
 24 the Federal Food, Drug, and Cosmetic Act

1 in determining whether to make correc-
2 tions as provided for in clause (i).

3 “(iii) DETERMINATIONS RELATING TO
4 MISLEADING INFORMATION.—For purposes
5 of clause (i)(II), in determining whether
6 information is misleading, the Secretary
7 shall use the standard described in section
8 201(n) of the Federal Food, Drug, and
9 Cosmetic Act that is used to determine
10 whether labeling or advertising is mis-
11 leading.

12 “(iv) RULE OF CONSTRUCTION.—This
13 subparagraph shall not be construed to au-
14 thorize the disclosure of information if—

15 “(I) such disclosure would con-
16 stitute an invasion of personal pri-
17 vacy;

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

24 “(III) such disclosure would dis-
25 close confidential commercial informa-

tion or a trade secret, other than a
trade secret described in subclause
(II), unless such disclosure is nec-
essary—

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

“(bb) protect the public
health; or

“(IV) 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 disclo-
sure under clause (iv)(III), the Secretary
shall notify the manufacturer or distributor
of the drug, biological product, or device
involved—

1 “(I) at least 30 days prior to
2 such disclosure; or

3 “(II) if immediate disclosure is
4 necessary to protect the public health,
5 concurrently with such disclosure.

6 “(8) WAIVERS REGARDING CLINICAL TRIAL RE-
7 SULTS.—The Secretary may waive the requirements
8 of subsections (j)(1) and (k)(1) that the results of
9 clinical trials be submitted to the Secretary, upon a
10 written request from the responsible person if the
11 Secretary determines that extraordinary cir-
12 cumstances justify the waiver and that providing the
13 waiver is in the public interest, consistent with the
14 protection of public health, or in the interest of na-
15 tional security. Not later than 30 days after any
16 part of a waiver is granted, the Secretary shall no-
17 tify, in writing, the appropriate committees of Con-
18 gress of the waiver and provide an explanation for
19 why the waiver was granted.

20 “(m) TRIALS CONDUCTED OUTSIDE OF THE UNITED
21 STATES.—

22 “(1) IN GENERAL.—With respect to clinical
23 trials described in paragraph (2), the responsible
24 person shall submit to the Secretary the information
25 required under subclauses (II) through (X) of sub-

1 section (i)(3)(B)(iv). The Secretary shall ensure that
2 the information described in the preceding sentence
3 is made available in the database under subsection
4 (i) in a timely manner. Submissions to the database
5 shall comply with subsection (l)(4) to the extent
6 practicable. The Secretary shall include the informa-
7 tion described in the preceding sentence in the data-
8 base under subsection (i) as soon as practicable after
9 receiving such information. Failure to comply with
10 this paragraph shall be deemed to be a failure to
11 submit information as required under this section,
12 and the appropriate remedies and sanctions under
13 this section shall apply.

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

16 “(A) such trial is conducted outside of the
17 United States; and

18 “(B) the data from such trial is—

19 “(i) submitted to the Secretary as
20 part of an application, including a supple-
21 mental application, for a drug or device
22 under section 505, 510, 515, or 520 of the
23 Federal Food, Drug, and Cosmetic Act or
24 for the biological product under section
25 351; or

1 “(ii) used in advertising or labeling to
 2 make a claim about the drug, device, or bi-
 3 ological product involved.

4 “(n) DEFINITIONS; INDIVIDUAL LIABILITY.—

5 “(1) RESPONSIBLE PERSON.—

6 “(A) IN GENERAL.—In this section, the
 7 term ‘responsible person’ with respect to a clin-
 8 ical trial, means—

9 “(i) if such clinical trial is the subject
 10 of an investigational new drug application
 11 or an application for an investigational de-
 12 vice exemption, the sponsor of such inves-
 13 tigational new drug application or such ap-
 14 plication for an investigational device ex-
 15 emption; or

16 “(ii) except as provided in subpara-
 17 graph (B), if such clinical trial is not the
 18 subject of an investigational new drug ap-
 19 plication or an application for an investiga-
 20 tional device exemption—

21 “(I) the person that provides the
 22 largest share of the monetary support
 23 (such term does not include in-kind
 24 support) for the conduct of such trial;
 25 or

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

5 “(B) NONPROFIT ENTITIES AND REQUEST-
 6 ING PERSONS.—

7 “(i) NONPROFIT ENTITIES.—For pur-
 8 poses of subparagraph (A)(ii)(I), if the
 9 person that provides the largest share of
 10 the monetary support for the conduct of
 11 the clinical trial involved is a nonprofit en-
 12 tity, the responsible person for purposes of
 13 this section shall be—

14 “(I) the nonprofit entity; or

15 “(II) if the nonprofit entity and
 16 the principal investigator of such trial
 17 jointly certify to the Secretary that
 18 the principal investigator will be re-
 19 sponsible for submitting the informa-
 20 tion described in subsection (i)(3)(B)
 21 for such trial, the principal investi-
 22 gator.

23 “(ii) REQUESTING PERSONS.—For
 24 purposes of subparagraph (A)(ii)(I), if a
 25 person—

1 “(I) has submitted a request to
2 the Secretary that the Secretary rec-
3 ognize the person as the responsible
4 person for purposes of this section;
5 and

6 “(II) the Secretary determines
7 that such person—

8 “(aa) provides monetary
9 support for the conduct of such
10 trial;

11 “(bb) is responsible for the
12 conduct of such trial; and

13 “(cc) will be responsible for
14 submitting the information de-
15 scribed in subsection (i)(3)(B)
16 for such trial;

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

19 “(2) DRUG, DEVICE, BIOLOGICAL PRODUCT.—

20 In this section—

21 “(A) the terms ‘drug’ and ‘device’ have the
22 meanings given such terms in section 201 of
23 the Federal Food, Drug, and Cosmetic Act; and

1 “(B) the term ‘biological product’ has the
2 meaning given such term in section 351 of this
3 Act.

4 “(3) INDIVIDUAL LIABILITY.—

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

8 “(B) INDIVIDUALS WHO ARE RESPONSIBLE
9 PERSONS.—If a responsible person under sub-
10 paragraph (A) or (B) of paragraph (1) is an in-
11 dividual, such individual shall be subject to the
12 procedures and conditions described in sub-
13 section (j).”.

14 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
15 402 of the Public Health Service Act (42 U.S.C. 282),
16 as amended by this section, is further amended by adding
17 at the end the following:

18 “(q) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated such sums as may be
20 necessary to carry out this section.”.

21 (d) CONFORMING AMENDMENT.—Section
22 402(c)(1)(D) of the Public Health Service Act (42 U.S.C.
23 282(c)(1)(D)), as amended by Public Law 109–482, is
24 amended by striking “402(k)” and inserting “402(p)”.

1 **SEC. 4. REVIEW AND APPROVAL OF PROPOSALS FOR RE-**
2 **SEARCH.**

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

5 (1) in paragraph (1)(A), by striking “unless”
6 and all that follows through the period and inserting
7 the following: “unless—

8 “(i) the application has undergone re-
9 view in accordance with such section and
10 has been recommended for approval by a
11 majority of the members of the Board con-
12 ducting the review;

13 “(ii) such Board has submitted to the
14 Secretary a notification of such approval;
15 and

16 “(iii) with respect to an application
17 involving a clinical trial to which section
18 402(i) applies, the principal investigator
19 who has submitted such application has
20 submitted to the Secretary for inclusion in
21 the registry and the database described in
22 section 402(i) the information described in
23 paragraph (3)(A) and subclause (I) of
24 paragraph (3)(B)(iv) of such section.”; and

25 (2) by adding at the end the following:

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

5 (b) REGULATIONS.—The Secretary of Health and
6 Human Services shall modify the regulations promulgated
7 at part 46 of title 45, Code of Federal Regulations, part
8 50 of title 21, Code of Federal Regulations, and part 56
9 of title 21, Code of Federal Regulations, to reflect the
10 amendments made by subsection (a).

11 (c) CONFORMING AMENDMENT.—Section 492A(a)(2)
12 of the Public Health Service Act (42 U.S.C. 289a–
13 1(a)(2)), as amended by Public Law 109–482, is amended
14 by striking “402(k)” and inserting “402(p)”.

15 **SEC. 5. PROHIBITED ACTS.**

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

19 “(ii)(1) The entering into of a contract or other
20 agreement by a responsible person or a manufacturer of
21 a drug, biological product, or device with an individual
22 who is not an employee of such responsible person or man-
23 ufacturer, or the performance of any other act by such
24 a responsible person or manufacturer, that prohibits, lim-

1 its, or imposes unreasonable delays on the ability of such
2 individual to—

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

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

9 “(2) The entering into a contract or other agreement
10 by a responsible person or a manufacturer of a drug, bio-
11 logical product, or device with an academic institution or
12 a health care facility, or the performance of any other act
13 by such a responsible person or manufacturer, that pro-
14 hibits, limits, or imposes unreasonable delays on the abil-
15 ity of an individual who is not an employee of such respon-
16 sible person or manufacturer to—

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

20 “(B) publish the results of a clinical trial or a
21 description or discussion of the results of a clinical
22 trial in a scientific journal or any other publica-
23 tion.”.

1 **SEC. 6. REPORTS.**

2 (a) IMPLEMENTATION REPORT.—Not later than 1
 3 year after the date of enactment of this Act, the Secretary
 4 of Health and Human Services shall submit to the appro-
 5 priate committees of Congress a report on the status of
 6 the implementation of the requirements of the amend-
 7 ments made by section 3 that includes a description of
 8 the number and types of clinical trials for which informa-
 9 tion has been submitted under such amendments.

10 (b) DATA COLLECTION.—

11 (1) IN GENERAL.—The Secretary of Health and
 12 Human Services shall enter into a contract with the
 13 Institute of Medicine for the conduct of a study con-
 14 cerning the extent to which data submitted to the
 15 registry under section 402(i) of the Public Health
 16 Service Act (42 U.S.C. 282(i)) has impacted the
 17 public health.

18 (2) REPORT.—Not later than 6 months after
 19 the date on which a contract is entered into under
 20 paragraph (1), the Institute of Medicine shall submit
 21 to the Secretary of Health and Human Services a
 22 report on the results of the study conducted under
 23 such paragraph. Such report shall include rec-
 24 ommendations for changes to the registry, the data-

- 1 base, and the data submission requirements that
- 2 would benefit the public health.

