

109TH CONGRESS  
1ST SESSION

# S. 470

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

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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.

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 2005” 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.—Section 402(j) of the Public  
18 Health Service Act (42 U.S.C. 282(j)) is amended—

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

22 (2) in paragraph (2), by striking “available to  
23 individuals with serious” and all that follows  
24 through the period and inserting “accessible to pa-  
25 tients, other members of the public, health care

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

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

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

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

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

14 “(ii) The registry 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) intended to treat serious  
20 or life-threatening diseases and conditions, except  
21 those Phase I clinical trials conducted to test solely  
22 the safety of an unapproved drug or unlicensed bio-  
23 logical product, or pilot or feasibility studies con-  
24 ducted to confirm the design and operating speci-  
25 fications of an unapproved or not yet cleared med-

1 ical device. For purposes of this section, Phase I  
2 clinical trials are trials described in section  
3 313.12(a) of title 21, Code of Federal Regulations  
4 (or any successor regulations).

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

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

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

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

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

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

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

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

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

22 “(V) Information pertaining to experi-  
23 mental treatments for serious or life threat-  
24 ening diseases and conditions (whether federally  
25 or privately funded) that may be available—

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

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

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

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

23          “(iii) The database may include information  
24          for—

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

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

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

14                 “(I) Descriptive information, including—

15                         “(aa) a brief title;

16                         “(bb) the drug, biological product or  
17                         device to be tested;

18                         “(cc) a trial description in lay termi-  
19                         nology;

20                         “(dd) the trial phase;

21                         “(ee) the trial type;

22                         “(ff) the trial purpose;

23                         “(gg) the estimated completion date  
24                         for the trial; and

1                   “(hh) the study sponsor and the study  
2                   funding source.

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

8                   “(III) The actual completion date of the  
9                   trial and the reasons for any difference from  
10                  such actual date and the estimated completion  
11                  date submitted pursuant to subclause (I)(hh).  
12                  If the trial is not completed, the termination  
13                  date and reasons for such termination.

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

24                  “(V) Safety data concerning the trial (in-  
25                  cluding a summary of all adverse events speci-

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

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

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

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

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

24                  “(bb) has disapproved an application  
25                  for approval of such use;

1                   “(cc) has reviewed an application for  
2 approval of such use but the application  
3 was withdrawn prior to approval or dis-  
4 approval; or

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

7                   “(IX) If data from the trial has not been  
8 submitted to the Food and Drug Administra-  
9 tion, an explanation of why it has not been sub-  
10 mitted.

11                   “(X) A description of the protocol used in  
12 such trial to the extent necessary to evaluate  
13 the results of such trial.

14                   “(4)(A) Not later than 90 days after the date of the  
15 completion of the review by the Food and Drug Adminis-  
16 tration of information submitted by a sponsor in support  
17 of a new drug application, or a supplemental new drug  
18 application, whether or not approved by the Food and  
19 Drug Administration, the Commissioner of Food and  
20 Drugs shall make available to the public the full reviews  
21 conducted by the Administration of such application.

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

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

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

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

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

14 “(6) The Secretary shall assign each clinical trial a  
15 unique identifier to be included in the registry and in the  
16 database described in subparagraphs (A) and (B) of para-  
17 graph (3). To the extent practicable, this identifier shall  
18 be consistent with other internationally recognized and  
19 used identifiers.

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

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

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

7       (b) ACTIONS OF SECRETARY REGARDING CLINICAL  
8 TRIALS.—Section 402 of the Public Health Service Act  
9 (42 U.S.C. 282) is amended—

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

12           (2) by inserting after subsection (j), the fol-  
13 lowing:

14       “(k) FEDERALLY SUPPORTED TRIALS.—

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

22           “(A) the information described in sub-  
23 clauses (II) through (X) of subsection  
24 (j)(3)(B)(iv), and with respect to clinical trials  
25 in progress on the date of enactment of the

1           FACT Act, the information described in sub-  
2           clause (I) of subsection (j)(3)(B)(iv); or

3           “(B) a statement containing information  
4           sufficient to demonstrate to the Secretary that  
5           the information described in subparagraph (A)  
6           cannot reasonably be submitted, along with an  
7           estimated date of submission of the information  
8           described in such subparagraph.

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

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

15           “(B) the actual date of the completion or  
16           termination of the trial.

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

19           “(A) CERTIFICATION OF COMPLIANCE.—  
20           To be eligible to receive a grant, contract, or  
21           cooperative agreement from the Secretary for  
22           the conduct or support of a clinical trial de-  
23           scribed in subsection (j)(3)(B), the principal in-  
24           vestigator involved shall certify to the Secretary  
25           that—

1           “(i) such investigator shall submit  
2           data to the Secretary in accordance with  
3           this subsection; and

4           “(ii) such investigator has complied  
5           with the requirements of this subsection  
6           with respect to other clinical trials con-  
7           ducted by such investigator after the date  
8           of enactment of the FACT Act.

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

16          “(C) FAILURE TO COMPLY WITH CERTIFI-  
17          CATION.—If, by the date specified in paragraph  
18          (2), the Secretary has not received the informa-  
19          tion or statement described in paragraph (1),  
20          the Secretary shall—

21                 “(i) transmit to the principal investi-  
22                 gator involved a notice specifying the infor-  
23                 mation or statement required to be sub-  
24                 mitted to the Secretary and stating that  
25                 such investigator shall not be eligible to re-

1           ceive further funding from the Secretary if  
2           such information or statement is not sub-  
3           mitted to the Secretary within 30 days of  
4           the date on which such notice is trans-  
5           mitted; and

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

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

1                   “(E) SUBMISSION OF STATEMENT BUT  
2 NOT INFORMATION.—

3                   “(i) IN GENERAL.—If by the date  
4 specified in paragraph (2), the Secretary  
5 has received a statement described in para-  
6 graph (1)(B) but not the information de-  
7 scribed in paragraph (1)(A), the Secretary  
8 shall transmit to the principal investigator  
9 involved a notice stating that such investi-  
10 gator shall submit such information by the  
11 date determined by the Secretary in con-  
12 sultation with such investigator.

13                   “(ii) FAILURE TO COMPLY WITH CER-  
14 TIFICATION.—If, by the date specified by  
15 the Secretary in the notice under clause  
16 (i), the Secretary has not received the in-  
17 formation described in paragraph (1)(B),  
18 the Secretary shall—

19                   “(I) transmit to the principal in-  
20 vestigator involved a notice specifying  
21 the information required to be sub-  
22 mitted to the Secretary and stating  
23 that such investigator shall not be eli-  
24 gible to receive further funding from  
25 the Secretary if such information is

1 not submitted to the Secretary within  
2 30 days of the date on which such no-  
3 tice is transmitted; and

4 “(II) include and prominently  
5 display, until such time as the Sec-  
6 retary receives the information de-  
7 scribed in paragraph (1)(B), as part  
8 of the record of such trial in the data-  
9 base described in subsection (j), a no-  
10 tice stating that the results of such  
11 trials have not been reported as re-  
12 quired by law.

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

1           “(G) RULE OF CONSTRUCTION.—For pur-  
2           poses of this paragraph, limitations on the  
3           awarding of grants, contracts, cooperative  
4           agreements, or any other awards to principal  
5           investigators for violations of this paragraph  
6           shall not be construed to include any funding  
7           that supports the clinical trial involved.

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

13          “(5) INCLUSION IN REGISTRY.—

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

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

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

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

4 “(B) OTHER DATA.—

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

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

13 “(II) in the case of data to which  
14 clause (ii) applies, by the date de-  
15 scribed in clause (iii).

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

18 “(I) the principal investigator in-  
19 volved requests a delay in the inclu-  
20 sion in the database of such data in  
21 order to have such data published in  
22 a peer reviewed journal; and

23 “(II) the Secretary determines  
24 that an attempt will be made to seek  
25 such publication.

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

4                   “(I) the date on which the data  
5                   involved is published as provided for  
6                   in clause (ii); or

7                   “(II) the date that is 18 months  
8                   after the date on which such data is  
9                   submitted to the Secretary.

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

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

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

1 the FACT Act, the Secretary shall seek a memo-  
2 randum of understanding with the heads of all other  
3 Federal agencies that conduct clinical trials to in-  
4 clude in the registry and the database clinical trials  
5 sponsored by such agencies that meet the require-  
6 ments of this subsection.

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

11 “(1) TRIALS WITH NON-FEDERAL SUPPORT.—

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

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

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

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

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

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

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

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

1           “(B) CIVIL MONETARY PENALTIES FOR  
2 NONCOMPLIANCE.—

3           “(i) IN GENERAL.—If by the date that  
4 is 30 days after the date on which a notice  
5 described in subparagraph (A) is trans-  
6 mitted, the Secretary has not received from  
7 the responsible person involved the infor-  
8 mation or statement required pursuant to  
9 such notice, the Secretary shall, after pro-  
10 viding the opportunity for a hearing, order  
11 such responsible person to pay a civil pen-  
12 alty of \$10,000 for each day after such  
13 date that the information or statement is  
14 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           “(C) SUBMISSION OF STATEMENT BUT  
21 NOT INFORMATION.—

22           “(i) IN GENERAL.—If by the date  
23 specified in paragraph (3), the Secretary  
24 has received a statement described in para-  
25 graph (1)(B) but not the information de-

1 scribed in paragraph (1)(A) the Secretary  
2 shall transmit to the responsible person in-  
3 volved a notice stating that such respon-  
4 sible person shall submit such information  
5 by the date determined by the Secretary in  
6 consultation with such responsible person.

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

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

22 “(II) include and prominently  
23 display, until such time as the Sec-  
24 retary receives the information de-  
25 scribed in paragraph (1)(A), as part

1 of the record of such trial in the data-  
2 base described in subsection (j), a no-  
3 tice stating that the results of such  
4 trials have not been reported as re-  
5 quired by law.

6 “(D) NONCOMPLIANCE.—

7 “(i) IN GENERAL.—If by the date that  
8 is 30 days after the date on which a notice  
9 described in subparagraph (C)(ii)(I) is  
10 transmitted, the Secretary has not received  
11 from the responsible person involved the  
12 information required pursuant to such no-  
13 tice, the Secretary, after providing the op-  
14 portunity for a hearing, order such respon-  
15 sible person to pay a civil penalty of  
16 \$10,000 for each day after such date that  
17 the information is not submitted.

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

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

24 If the responsible person is the manufacturer or  
25 distributor of the drug, biological product, or

1 device involved, the notice under subparagraphs  
2 (A)(i) and (C)(ii)(I) shall include a notice that  
3 the Secretary shall publish the data described  
4 in subsection (j)(3)(B) in the database if the re-  
5 sponsible person has not submitted the informa-  
6 tion specified in the notice transmitted by the  
7 date that is 6 months after the date of such no-  
8 tice.

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

22 “(i) is described in subsection  
23 (j)(3)(B); and

24 “(ii) the responsible person has sub-  
25 mitted to the Secretary in any application,

1 including a supplemental application, for  
2 the drug or device under section 505, 510,  
3 515, or 520 of the Federal Food, Drug,  
4 and Cosmetic Act or for the biological  
5 product under section 351.

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

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

12 “(B) the actual date of completion or ter-  
13 mination of the trial.

14 “(4) USE OF FUNDS.—

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

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

1 the FACT Act by the Director of the Agency  
2 for Healthcare Research and Quality and peri-  
3 odically updated as determined appropriate by  
4 the Director.

5 “(5) INCLUSION IN REGISTRY.—

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

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

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

19 “(B) OTHER DATA.—

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

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

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

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

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

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

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

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

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

1                   “(iv) EXTENSION OF DATE.—The  
2                   Secretary may extend the 18-month period  
3                   described in clause (iii)(II) for an addi-  
4                   tional 6 months if the responsible person  
5                   demonstrates to the Secretary, prior to the  
6                   expiration of such 18-month period, that  
7                   the data involved has been accepted for  
8                   publication by a journal described in clause  
9                   (ii)(I).

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

15                   “(6) EFFECT.—The information with respect to  
16                   a clinical trial submitted to the Secretary under this  
17                   subsection, including data published by the Sec-  
18                   retary pursuant to paragraph (2)(F), may not be  
19                   submitted by a person other than the responsible  
20                   person as part of, or referred to in, an application  
21                   for approval of a drug or device under section 505,  
22                   510, 515, or 520 of the Federal Food, Drug, and  
23                   Cosmetic Act or of a biological product under section  
24                   351, unless the information is available from a

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

3 “(m) PROCEDURES AND WAIVERS.—

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

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

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

22 “(4) SUBMISSION FORMAT AND TECHNICAL  
23 STANDARDS.—

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

1           required under this subsection in an electronic  
2           format and shall establish interoperable tech-  
3           nical standards for such submissions.

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

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

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

15           “(7) SUBMISSION OF INACCURATE INFORMA-  
16          TION.—

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

24                   “(i) a summary of the inaccuracies in-  
25                   volved; and

1           “(ii) a request for corrected informa-  
2           tion within 30 days.

3           “(B) AUDIT OF INFORMATION.—

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

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

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

20          “(D) FAILURE TO CORRECT.—If a prin-  
21          cipal investigator or a responsible person fails  
22          to permit an audit under subparagraph (B),  
23          provide corrected information pursuant to a no-  
24          tice under subparagraph (A), or provide  
25          changed information under subparagraph (C),

1 the investigator or responsible person involved  
2 shall be deemed to have failed to submit infor-  
3 mation as required under this section and the  
4 appropriate remedies and sanction under this  
5 section shall apply.

6 “(E) CORRECTIONS.—

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

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

19 “(II) factually and substantively  
20 inaccurate or false or misleading.

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

1 the Federal Food, Drug, and Cosmetic Act  
2 in determining whether to make correc-  
3 tions as provided for in clause (i).

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

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

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

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

1           “(III) such disclosure would dis-  
2           close confidential commercial informa-  
3           tion or a trade secret, other than a  
4           trade secret described in subclause  
5           (II), unless such disclosure is nec-  
6           essary—

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

10                   “(bb) protect the public  
11                   health; or

12           “(IV) if such disclosure relates to  
13           a biological product for which no li-  
14           cense is in effect under section 351, a  
15           drug for which no approved applica-  
16           tion is in effect under section 505(c)  
17           of the Federal Food, Drug, and Cos-  
18           metic Act, or a device that is not  
19           cleared under section 510(k) of such  
20           Act or for which no application is in  
21           effect under section 515 of such Act.

22           “(v) NOTICE.—In the case of a disclo-  
23           sure under clause (iv)(III), the Secretary  
24           shall notify the manufacturer or distributor

1 of the drug, biological product, or device  
2 involved—

3 “(I) at least 30 days prior to  
4 such disclosure; or

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

8 “(8) WAIVERS REGARDING CLINICAL TRIAL RE-  
9 SULTS.—The Secretary may waive the requirements  
10 of subsections (k)(1) and (l)(1) that the results of  
11 clinical trials be submitted to the Secretary, upon a  
12 written request from the responsible person if the  
13 Secretary determines that extraordinary cir-  
14 cumstances justify the waiver and that providing the  
15 waiver is in the public interest or consistent with the  
16 protection of public health.

17 “(n) TRIALS CONDUCTED OUTSIDE OF THE UNITED  
18 STATES.—

19 “(1) IN GENERAL.—With respect to clinical  
20 trials described in paragraph (2), the responsible  
21 person shall submit to the Secretary the information  
22 required under subclauses (II) through (X) of sub-  
23 section (j)(3)(B)(iv). Failure to comply with this  
24 paragraph shall be deemed to be a failure to submit  
25 information as required under this section, and the

1 appropriate remedies and sanctions under this sec-  
2 tion shall apply.

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

5 “(A) such trial is conducted outside of the  
6 United States; and

7 “(B) the data from such trial is—

8 “(i) submitted to the Secretary as  
9 part of an application, including a supple-  
10 mental application, for a drug or device  
11 under section 505, 510, 515, or 520 of the  
12 Federal Food, Drug, and Cosmetic Act or  
13 for the biological product under section  
14 351; or

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

18 “(o) DEFINITIONS; INDIVIDUAL LIABILITY.—

19 “(1) RESPONSIBLE PERSON.—

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

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

1 vice exemption, the sponsor of such inves-  
2 tigational new drug application or such ap-  
3 plication for an investigational device ex-  
4 emption; or

5 “(ii) except as provided in subpara-  
6 graph (B), if such clinical trial is not the  
7 subject of an investigational new drug ap-  
8 plication or an application for an investiga-  
9 tional device exemption—

10 “(I) the person that provides the  
11 largest share of the monetary support  
12 (such term does not include in-kind  
13 support) for the conduct of such trial;  
14 or

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

19 “(B) NONPROFIT ENTITIES AND REQUEST-  
20 ING PERSONS.—

21 “(i) NONPROFIT ENTITIES.—For pur-  
22 poses of subparagraph (A)(ii)(I), if the  
23 person that provides the largest share of  
24 the monetary support for the conduct of  
25 the clinical trial involved is a nonprofit en-

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

3 “(I) the nonprofit entity; or

4 “(II) if the nonprofit entity and  
5 the principal investigator of such trial  
6 jointly certify to the Secretary that  
7 the principal investigator will be re-  
8 sponsible for submitting the informa-  
9 tion described in subsection (j)(3)(B)  
10 for such trial, the principal investi-  
11 gator.

12 “(ii) REQUESTING PERSONS.—For  
13 purposes of subparagraph (A)(ii)(I), if a  
14 person—

15 “(I) has submitted a request to  
16 the Secretary that the Secretary rec-  
17 ognize the person as the responsible  
18 person for purposes of this section;  
19 and

20 “(II) the Secretary determines  
21 that such person—

22 “(aa) provides monetary  
23 support for the conduct of such  
24 trial;

1                   “(bb) is responsible for the  
2                   conduct of such trial; and

3                   “(cc) will be responsible for  
4                   submitting the information de-  
5                   scribed in subsection (j)(3)(B)  
6                   for such trial;

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

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

10                  In this section—

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

14                   “(B) the term ‘biological product’ has the  
15                   meaning given such term in section 351 of this  
16                   Act.

17                   “(3) INDIVIDUAL LIABILITY.—

18                   “(A) LIMITATION ON LIABILITY OF INDI-  
19                   VIDUALS.—No individual shall be liable for any  
20                   civil monetary penalty under this section.

21                   “(B) INDIVIDUALS WHO ARE RESPONSIBLE  
22                   PERSONS.—If a responsible person under sub-  
23                   paragraph (A) or (B) of paragraph (1) is an  
24                   individual, such individual shall be subject to

1           the procedures and conditions described in sub-  
2           section (k).”.

3           (c) AUTHORIZATION OF APPROPRIATIONS.—Section  
4 402 of the Public Health Service Act (42 U.S.C. 282),  
5 as amended by this section, is further amended by adding  
6 at the end the following:

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

10 **SEC. 4. REVIEW AND APPROVAL OF PROPOSALS FOR RE-**  
11 **SEARCH.**

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

14           (1) in paragraph (1)(A), by striking “unless”  
15           and all that follows through the period and inserting  
16           the following: “unless—

17                           “(i) the application has undergone re-  
18                           view in accordance with such section and  
19                           has been recommended for approval by a  
20                           majority of the members of the Board con-  
21                           ducting the review;

22                           “(ii) such Board has submitted to the  
23                           Secretary a notification of such approval;  
24                           and

1           “(iii) with respect to an application  
2           involving a clinical trial to which section  
3           402(j) applies, the principal investigator  
4           who has submitted such application has  
5           submitted to the Secretary for inclusion in  
6           the registry and the database described in  
7           section 402(j) the information described in  
8           paragraph (3)(A) and subclause (I) of  
9           paragraph (3)(B)(iv) of such section.”; and  
10          (2) by adding at the end the following:

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

15          (b) REGULATIONS.—The Secretary of Health and  
16          Human Services shall modify the regulations promulgated  
17          at part 46 of title 45, Code of Federal Regulations, part  
18          50 of title 21, Code of Federal Regulations, and part 56  
19          of title 21, Code of Federal Regulations, to reflect the  
20          amendments made by subsection (a).

21          **SEC. 5. PROHIBITED ACTS.**

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

1       “(hh)(1) The entering into of a contract or other  
2 agreement by a responsible person or a manufacturer of  
3 a drug, biological product, or device with an individual  
4 who is not an employee of such responsible person or man-  
5 ufacturer, or the performance of any other act by such  
6 a responsible person or manufacturer, that prohibits, lim-  
7 its, or imposes unreasonable delays on the ability of such  
8 individual to—

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

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

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

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

1           “(B) publish the results of a clinical trial or a  
2           description or discussion of the results of a clinical  
3           trial in a scientific journal or any other publica-  
4           tion.”.

5 **SEC. 6. REPORTS.**

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

14          (b) DATA COLLECTION.—

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

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

1 report on the results of the study conducted under  
2 such paragraph. Such report shall include rec-  
3 ommendations for changes to the registry, the data-  
4 base, and the data submission requirements that  
5 would benefit the public health.

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