

108TH CONGRESS
2D SESSION

S. 2933

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 7, 2004

Mr. DODD (for himself, Mr. KENNEDY, Mr. JOHNSON, and Mr. WYDEN) 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 2004” or the “FACT Act”.

6 **SEC. 2. PURPOSE.**

7 It is the purpose of this Act—

8 (1) to create a centralized and comprehensive
9 national registry of all publicly and privately funded

1 clinical trials involving drugs, biological products, or
2 devices regardless of the outcome of the trial; and

3 (2) to make the information contained in the
4 registry available to researchers, health care pro-
5 viders, patients seeking to enroll as subjects in clin-
6 ical trials, and the general public in a timely fashion.

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

8 (a) IN GENERAL.—Section 402(j) of the Public
9 Health Service Act (42 U.S.C. 282(j)) is amended—

10 (1) in paragraph (1)(A), by striking “clinical
11 trial for drugs for serious or life-threatening diseases
12 and conditions” and inserting “clinical trials (includ-
13 ing pre-market and post-approval trials) for drugs,
14 biological products, and devices”;

15 (2) in paragraph (2), by striking “individuals
16 with serious or life-threatening diseases and condi-
17 tions, to other”; and

18 (3) by striking paragraph (3) and inserting the
19 following:

20 “(3) The data bank shall include a registry of clinical
21 trials (whether federally or privately funded) in accordance
22 with the following:

23 “(A) The registry shall include the information
24 required under subparagraph (B) for all clinical
25 trials conducted to test the safety or effectiveness

1 (including comparative effectiveness) of any drug, bi-
2 ological product, or device (including those drugs, bi-
3 ological products, or devices approved or cleared by
4 the Secretary), except those Phase I clinical trials
5 conducted to test solely the safety of an unapproved
6 drug or unlicensed biological product. The registry
7 may include Phase I clinical trials conducted to test
8 solely the safety of an unapproved drug or unli-
9 censed biological product with the consent of the re-
10 sponsible person. For purposes of this subparagraph,
11 Phase I clinical trials are trials described in section
12 313.12(a) of title 21, Code of Federal Regulations
13 (or any successor regulations).

14 “(B) The information required under this sub-
15 paragraph with respect to the clinical trial involved
16 includes the following:

17 “(i) A description of the purpose of the
18 clinical trial, including the drug, biological prod-
19 uct, or device to be tested.

20 “(ii) The eligibility criteria for participa-
21 tion in the clinical trial.

22 “(iii) A description of the location of trial
23 sites and the start date of the trial.

1 “(iv) A point of contact for those wanting
2 to enroll in the trial, including the identity of
3 the responsible person.

4 “(v) The funding source or sources of the
5 trial.

6 “(vi) The estimated completion date for
7 the trial. For purposes of this section, the term
8 ‘completion date’ means the date of the final
9 collection of data from subjects in the trial for
10 the outcomes described in clause (vii).

11 “(vii) A description of the primary and
12 secondary clinical outcomes to be examined in
13 the trial, the time at which the primary and
14 secondary outcomes will be assessed, and the
15 dates and details of any revisions to such out-
16 comes.

17 “(viii) The actual completion date of the
18 trial and the reasons for any difference from
19 such actual date and the estimated completion
20 date submitted pursuant to clause (vi). If the
21 trial is not completed, the termination date and
22 reasons for such termination.

23 “(ix) A summary of the results of the trial,
24 including summary data tables, with respect to
25 its primary and secondary outcomes as de-

scribed in clause (vii), including information on the statistical significance or lack thereof of such results.

“(x) Safety data concerning the trial (including a summary of adverse events specifying the number and type of such events).

“(xi) Any publications in peer reviewed journals relating to the trial.

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

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

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

“(II) has disapproved an application for approval of such use;

1 “(III) 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 “(IV) has not reviewed or approved
6 such use as safe and effective.

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

14 “(C) The information described in clauses (i)
15 through (xiv) of subparagraph (B) shall be in a for-
16 mat that can be readily accessed and understood by
17 members of the general public, including patients
18 seeking to enroll as subjects in clinical trials.

19 “(D) The Secretary shall assign each clinical
20 trial a unique identifier to be included in the reg-
21 istry.”.

22 (b) ACTIONS OF SECRETARY REGARDING CLINICAL
23 TRIALS.—Section 402 of the Public Health Service Act
24 (42 U.S.C. 282) is amended—

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

3 (2) by inserting after subsection (j), the fol-
 4 lowing:

5 “(k) FEDERALLY SUPPORTED TRIALS.—

6 “(1) ALL FEDERALLY SUPPORTED TRIALS.—

7 With respect to any clinical trial described in sub-
 8 section (j)(3)(A) that is supported solely by a grant,
 9 contract, or cooperative agreement awarded by the
 10 Secretary, the principal investigator of such trial
 11 shall, not later than the date specified in paragraph
 12 (2), submit to the Secretary—

13 “(A) the information described in clauses
 14 (viii) through (xv) of subsection (j)(3)(B), and
 15 with respect to clinical trials in progress on the
 16 date of enactment of the FACT Act, the infor-
 17 mation described in clauses (i) through (vii) of
 18 subsection (j)(3)(B); 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.

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

4 “(A) the estimated completion date of the
5 trial, as submitted under subsection
6 (j)(3)(B)(vi); or

7 “(B) the actual date of the completion or
8 termination of the trial.

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

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

18 “(i) such investigator shall submit
19 data to the registry in accordance with this
20 subsection; and

21 “(ii) such investigator has complied
22 with the requirements of this subsection
23 with respect to other clinical trials con-
24 ducted by such investigator.

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

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

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

23 “(ii) include and prominently display,
24 until such time as the Secretary receives
25 the information or statement described in

1 paragraph (1), as part of the record of
2 such trial in the registry described in sub-
3 section (j), a notice stating that the results
4 of such trials have not been reported as re-
5 quired by law.

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

18 “(E) SUBMISSION OF STATEMENT BUT
19 NOT INFORMATION.—

20 “(i) IN GENERAL.—If by the date
21 specified in paragraph (2), the Secretary
22 has received a statement described in para-
23 graph (1)(B) but not the information de-
24 scribed in paragraph (1)(A), the Secretary
25 shall transmit to the principal investigator

1 involved a notice stating that such investi-
2 gator shall submit such information by the
3 date determined by the Secretary in con-
4 sultation with such investigator.

5 “(ii) FAILURE TO COMPLY WITH CER-
6 TIFICATION.—If, by the date specified by
7 the Secretary in the notice under clause
8 (i), the Secretary has not received the in-
9 formation described in paragraph (1)(B),
10 the Secretary shall—

11 “(I) transmit to the principal in-
12 vestigator involved a notice specifying
13 the information required to be sub-
14 mitted to the Secretary and stating
15 that such investigator shall not be eli-
16 gible to receive further funding from
17 the Secretary if such information is
18 not submitted to the Secretary within
19 30 days of the date on which such no-
20 tice is transmitted; and

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

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

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

17 “(G) RULE OF CONSTRUCTION.—For pur-
18 poses of this paragraph, limitations on the
19 awarding of grants, contracts, cooperative
20 agreements, or any other awards to principal
21 investigators for violations of this paragraph
22 shall not be construed to include any funding
23 that supports the clinical trial involved.

24 “(4) RULE OF CONSTRUCTION.—Nothing in
25 this subsection shall be construed to prevent an in-

1 investigator other than the investigator described in
 2 paragraph (3)(F) from receiving an ongoing award,
 3 contract, or cooperative agreement.

4 “(5) INCLUSION IN REGISTRY.—

5 “(A) GENERAL RULE.—The Secretary
 6 shall, pursuant to subsection (j)(3)(C), include
 7 the data described in clauses (i) through (vi) of
 8 subsection (j)(3)(B) and submitted under this
 9 subsection in the registry described in sub-
 10 section (j) as soon as practicable after receiving
 11 such data.

12 “(B) OTHER DATA.—

13 “(i) IN GENERAL.—The Secretary
 14 shall, pursuant to subsection (j)(3)(C), in-
 15 clude the data described in clauses (vii)
 16 through (xv) of subsection (j)(3)(B) and
 17 submitted under this section in the registry
 18 described in subsection (j)—

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

21 “(II) in the case of data to which
 22 clause (ii) applies, by the date de-
 23 scribed in clause (iii).

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

1 “(I) the principal investigator in-
2 volved requests a delay in the inclu-
3 sion in the registry of such data in
4 order to have such data published in
5 a peer reviewed journal; and

6 “(II) the Secretary determines
7 that an attempt will be made to seek
8 such publication.

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

12 “(I) the date on which the data
13 involved is published as provided for
14 in clause (ii); or

15 “(II) the date that is 18 months
16 after the date on which such data is
17 submitted to the Secretary.

18 “(iv) EXTENSION OF DATE.—The
19 Secretary may extend the 18-month period
20 described in clause (iii)(II) for an addi-
21 tional 6 months if the principal investi-
22 gator demonstrates to the Secretary, prior
23 to the expiration of such 18-month period,
24 that the data involved has been accepted

1 for publication by a journal described in
2 clause (ii)(I).

3 “(v) MODIFICATION OF DATA.—Prior
4 to including data in the registry under
5 clause (ii) or (iv), the Secretary shall per-
6 mit the principal investigator to modify the
7 data involved.

8 “(6) MEMORANDUM OF UNDERSTANDING.—Not
9 later than 6 months after the date of enactment of
10 the FACT Act, the Secretary shall seek a memo-
11 randum of understanding with the heads of all other
12 Federal agencies that conduct clinical trials to in-
13 clude in the registry clinical trials sponsored by such
14 agencies that meet the requirements of this sub-
15 section.

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

20 “(l) TRIALS WITH NON-FEDERAL SUPPORT.—

21 “(1) IN GENERAL.—The responsible person for
22 a clinical trial described in subsection (j)(3)(A) shall,
23 not later than the date specified in paragraph (3),
24 submit to the Secretary—

“(A) the information described in clauses (viii) through (xv) of subsection (j)(3)(B), and with respect to clinical trials in progress on the date of enactment of the FACT Act, the information described in clauses (i) through (vii) of subsection (j)(3)(B); or

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

“(2) SANCTION IN CASE OF NONCOMPLIANCE.—

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

“(i) transmit to the responsible person for such trial a notice stating that such responsible person shall be liable for the civil monetary penalties described in subparagraph (B) if the required information or statement is not submitted to the Secretary

1 within 30 days of the date on which such
2 notice is transmitted; and

3 “(ii) include and prominently display,
4 until such time as the Secretary receives
5 the information described in paragraph
6 (1), as part of the record of such trial in
7 the registry described in subsection (j), a
8 notice stating that the results of such
9 trials have not been reported as required
10 by law.

11 “(B) CIVIL MONETARY PENALTIES FOR
12 NONCOMPLIANCE.—

13 “(i) IN GENERAL.—If by the date that
14 is 30 days after the date on which a notice
15 described in subparagraph (A) is trans-
16 mitted, the Secretary has not received from
17 the responsible person involved the infor-
18 mation or statement required pursuant to
19 such notice, the Secretary shall, after pro-
20 viding the opportunity for a hearing, order
21 such responsible person to pay a civil pen-
22 alty of \$10,000 for each day after such
23 date that the information or statement is
24 not submitted.

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

6 “(C) SUBMISSION OF STATEMENT BUT
 7 NOT INFORMATION.—

8 “(i) IN GENERAL.—If by the date
 9 specified in paragraph (3), the Secretary
 10 has received a statement described in para-
 11 graph (1)(B) but not the information de-
 12 scribed in paragraph (1)(A) the Secretary
 13 shall transmit to the responsible person in-
 14 volved a notice stating that such respon-
 15 sible person shall submit such information
 16 by the date determined by the Secretary in
 17 consultation with such responsible person.

18 “(ii) FAILURE TO COMPLY.—If, by the
 19 date specified by the Secretary in the no-
 20 tice under clause (i), the Secretary has not
 21 received the information described in para-
 22 graph (1)(A), the Secretary shall—

23 “(I) transmit to the responsible
 24 person involved a notice specifying the
 25 information required to be submitted

1 to the Secretary and stating that such
 2 responsible person shall be liable for
 3 the civil monetary penalties described
 4 in subparagraph (D) if such informa-
 5 tion is not submitted to the Secretary
 6 within 30 days of the date on which
 7 such notice is transmitted; and

8 “(II) include and prominently
 9 display, until such time as the Sec-
 10 retary receives the information de-
 11 scribed in paragraph (1)(A), as part
 12 of the record of such trial in the reg-
 13 istry described in subsection (j), a no-
 14 tice stating that the results of such
 15 trials have not been reported as re-
 16 quired by law.

17 “(D) NONCOMPLIANCE.—

18 “(i) In general.—If by the date that is
 19 30 days after the date on which a notice
 20 described in subparagraph (C)(ii)(I) is
 21 transmitted, the Secretary has not received
 22 from the responsible person involved the
 23 information required pursuant to such no-
 24 tice, the Secretary, after providing the op-
 25 portunity for a hearing, order such respon-

1 sible person to pay a civil penalty of
2 \$10,000 for each day after such date that
3 the information is not submitted.

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

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

10 If the responsible person is the manufacturer or
11 distributor of the drug, biological product, or
12 device involved, the notice under subparagraphs
13 (A)(i) and (C)(ii)(I) shall include a notice that
14 the Secretary shall publish the data described
15 in subsection (j)(3)(B) in the registry if the re-
16 sponsible person has not submitted the informa-
17 tion specified in the notice transmitted by the
18 date that is 6 months after the date of such no-
19 tice.

20 “(F) PUBLICATION OF DATA.—Notwith-
21 standing section 301(j) of the Federal Food,
22 Drug, and Cosmetic Act, section 1905 of title
23 18, United States Code, or any other provision
24 of law, if the responsible person is the manufac-
25 turer or distributor of the drug, biological prod-

uct, or device involved, and if the responsible person has not submitted the Secretary the information specified in a notice transmitted pursuant to subparagraph (A)(i) or (C)(ii)(I) by the date that is 6 months after the date of such notice, the Secretary shall publish in the registry information that—

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

“(ii) the responsible person has submitted to the Secretary in any application, including a supplemental application, for the drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351.

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

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

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

“(4) USE OF FUNDS.—

1 “(A) IN GENERAL.—The Secretary shall
2 deposit the funds collected under paragraph (2)
3 into an account and use such funds, in con-
4 sultation with the Director of the Agency for
5 Healthcare Research and Quality, to fund stud-
6 ies that compare the clinical effectiveness of 2
7 or more treatments for a disease or condition.

8 “(B) FUNDING DECISIONS.—The Secretary
9 shall award funding under subparagraph (A)
10 based on a priority list established not later
11 than 6 months after the date of enactment of
12 the FACT Act by the Director of the Agency
13 for Healthcare Research and Quality and peri-
14 odically updated as determined appropriate by
15 the Director.

16 “(5) INCLUSION IN REGISTRY.—

17 “(A) GENERAL RULE.—The Secretary
18 shall, pursuant to subsection (j)(3)(C), include
19 the data described in clauses (i) through (vi) of
20 subsection (j)(3)(B) and submitted under this
21 subsection in the registry described in sub-
22 section (j) as soon as practicable after receiving
23 such data.

24 “(B) OTHER DATA.—

1 “(i) IN GENERAL.—The Secretary
 2 shall, pursuant to subsection (j)(3)(C), in-
 3 clude the data described in clauses (vii)
 4 through (xv) of subsection (j)(3)(B) and
 5 submitted under this section in the registry
 6 described in subsection (j)—

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 responsible person in-
 15 volved requests a delay in the inclu-
 16 sion in the registry 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 responsible person
11 demonstrates to the Secretary, prior to the
12 expiration of such 18-month period, that
13 the data involved has been accepted for
14 publication by a journal described in clause
15 (ii)(I).

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

21 “(6) EFFECT.—The information with respect to
22 a clinical trial submitted to the Secretary under this
23 subsection, including data published by the Sec-
24 retary pursuant to paragraph (2)(F), may not be
25 submitted by a person other than the responsible

1 person as part of, or referred to in, an application
2 for approval of a drug or device under section 505,
3 510, 515, or 520 of the Federal Food, Drug, and
4 Cosmetic Act or of a biological product under section
5 351, unless the information is available from a source
6 other than the registry described in subsection (j).

7 “(m) PROCEDURES AND WAIVERS.—

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

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

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

1 “(4) SUBMISSION FORMAT AND TECHNICAL
2 STANDARDS.—

3 “(A) IN GENERAL.—The Secretary shall,
4 to the extent practicable, accept submissions re-
5 quired under this subsection in an electronic
6 format and shall establish interoperable tech-
7 nical standards for such submissions.

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

15 “(5) TRIALS COMPLETED PRIOR TO ENACT-
16 MENT.—The Secretary shall establish procedures
17 and mechanisms to allow for the voluntary submis-
18 sion to the registry of the information described in
19 clauses (viii) through (xv) of subsection (j)(3)(B)
20 with respect to clinical trials completed prior to the
21 date of enactment of the FACT Act. In cases in
22 which it is in the interest of public health, the Sec-
23 retary may require that information from such trials
24 be submitted to the registry. Failure to comply with
25 such a requirement shall be deemed to be a failure

1 to submit information as required under this section,
2 and the appropriate remedies and sanctions under
3 this section shall apply.

4 “(6) TRIALS NOT INVOLVING DRUGS, BIOLOGI-
5 CAL PRODUCTS, OR DEVICES.—The Secretary shall
6 establish procedures and mechanisms to allow for
7 the voluntary submission of the information de-
8 scribed in clauses (viii) through (xv) of subsection
9 (j)(3)(B) with respect to clinical trials that do not
10 involve drugs, biological products, or devices. In
11 cases in which it is in the interest of public health,
12 the Secretary may require that information from
13 such trials be submitted to the registry. Failure to
14 comply with such a requirement shall be deemed to
15 be a failure to submit information as required under
16 this section, and the appropriate remedies and sanc-
17 tions under this section shall apply.

18 “(7) SUBMISSION OF INACCURATE INFORMA-
19 TION.—

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

1 tigator or responsible person concerning such
2 inaccuracy that includes—

3 “(i) a summary of the inaccuracies in-
4 volved; and

5 “(ii) a request for corrected informa-
6 tion within 30 days.

7 “(B) AUDIT OF INFORMATION.—

8 “(i) IN GENERAL.—The Secretary
9 may conduct audits of any information
10 submitted under subsection (j).

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

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

23 “(D) FAILURE TO CORRECT.—If a prin-
24 cipal investigator or a responsible person fails
25 to permit an audit under subparagraph (B), pro-

1 vide corrected information pursuant to a notice
2 under subparagraph (A), or provide changed in-
3 formation under subparagraph (C), the investi-
4 gator or responsible person involved shall be
5 deemed to have failed to submit information as
6 required under this section and the appropriate
7 remedies and sanction under this section shall
8 apply.

9 “(E) CORRECTIONS.—

10 “(i) IN GENERAL.—The Secretary
11 may correct, through any means deemed
12 appropriate by the Secretary to protect
13 public health, any information included in
14 the registry described in subsection (j) (in-
15 cluding information described or contained
16 in a publication referred to under clause
17 (xi) of subsection (j)(3)(B)) that is—

18 “(I) submitted to the Secretary
19 for inclusion in the registry by a prin-
20 cipal investigator under subsection (k)
21 or by a responsible person under sub-
22 section (l); and

23 “(II) factually and substantively
24 inaccurate or false or misleading.

1 “(ii) RELIANCE ON INFORMATION.—

2 The Secretary may rely on any information
3 from a clinical trial or a report of an ad-
4 verse event acquired or produced under the
5 authority of section 351 of this Act or of
6 the Federal Food, Drug, and Cosmetic Act
7 in determining whether to make correc-
8 tions as provided for in clause (i).

9 “(iii) DETERMINATIONS RELATING TO
10 MISLEADING INFORMATION.—For purposes
11 of clause (i)(II), in determining whether
12 information is misleading, the Secretary
13 shall use the standard described in section
14 201(n) of the Federal Food, Drug, and
15 Cosmetic Act that is used to determine
16 whether labeling or advertising is mis-
17 leading.

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

21 “(I) such disclosure would con-
22 stitute a clearly unwarranted invasion
23 of personal privacy;

24 “(II) such information concerns a
25 method or process which as a trade

1 secret is entitled to protection within
2 the meaning of section 301(j) of the
3 Federal Food, Drug, and Cosmetic
4 Act;

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

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

14 “(bb) protect the public
15 health; or

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

1 “(v) NOTICE.—In the case of a disclo-
 2 sure under clause (iv)(III), the Secretary
 3 shall notify the manufacturer or distributor
 4 of the drug, biological product, or device
 5 involved—

6 “(I) at least 30 days prior to
 7 such disclosure; or

8 “(II) if immediate disclosure is
 9 necessary to protect the public health,
 10 concurrently with such disclosure.

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

20 “(n) 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 clauses (viii) through (xv) of sub-

1 section (j)(3)(B). Failure to comply with this para-
 2 graph shall be deemed to be a failure to submit infor-
 3 mation as required under this section, and the appro-
 4 priate remedies and sanctions under this section shall
 5 apply.

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

8 “(A) such trial is conducted outside of the
 9 United States; and

10 “(B) the data from such trial is—

11 “(i) submitted to the Secretary as
 12 part of an application, including a supple-
 13 mental application, for a drug or device
 14 under section 505, 510, 515, or 520 of the
 15 Federal Food, Drug, and Cosmetic Act or
 16 for the biological product under section
 17 351; or

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

21 “(o) DEFINITIONS; INDIVIDUAL LIABILITY.—

22 “(1) RESPONSIBLE PERSON.—

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

1 “(i) if such clinical trial is the subject
 2 of an investigational new drug application
 3 or an application for an investigational de-
 4 vice exemption, the sponsor of such inves-
 5 tigational new drug application or such ap-
 6 plication for an investigational device ex-
 7 emption; or

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

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

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

22 “(B) NONPROFIT ENTITIES AND REQUEST-
 23 ING PERSONS.—

24 “(i) NONPROFIT ENTITIES.—For pur-
 25 poses of subparagraph (A)(ii)(I), if the

1 person that provides the largest share of
2 the monetary support for the conduct of
3 the clinical trial involved is a nonprofit en-
4 tity, the responsible person for purposes of
5 this section shall be—

6 “(I) the nonprofit entity; or

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

15 “(ii) REQUESTING PERSONS.—For
16 purposes of subparagraph (A)(ii)(I), if a
17 person—

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

23 “(II) the Secretary determines
24 that such person—

1 “(aa) provides monetary
2 support for the conduct of such
3 trial;

4 “(bb) is responsible for the
5 conduct of such trial; and

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

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

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

13 In this section—

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

17 “(B) the term ‘biological product’ has the
18 meaning given such term in section 351 of this
19 Act.

20 “(3) INDIVIDUAL LIABILITY.—

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

24 “(B) INDIVIDUALS WHO ARE RESPONSIBLE
25 PERSONS.—If a responsible person under sub-

1 paragraph (A) or (B) of paragraph (1) is an in-
 2 dividual, such individual shall be subject to the
 3 procedures and conditions described in sub-
 4 section (k).”.

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

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

12 **SEC. 4. REVIEW AND APPROVAL OF PROPOSALS FOR RE-**
 13 **SEARCH.**

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

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

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

1 “(ii) such Board has submitted to the
 2 Secretary a notification of such approval;
 3 and

4 “(iii) with respect to an application
 5 involving a clinical trial to which section
 6 402(j) applies, the principal investigator
 7 who has submitted such application has
 8 submitted to the Secretary for inclusion in
 9 the registry described in section 402(j) the
 10 information described in clauses (i)
 11 through (vii) of paragraph (3)(B) of such
 12 section.”; and

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

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

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

1 **SEC. 5. PROHIBITED ACTS.**

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

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

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

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

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

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

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

8 **SEC. 6. REPORTS.**

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

17 (b) DATA COLLECTION.—

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

1 (2) REPORT.—Not later than 6 months after
2 the date on which a contract is entered into under
3 paragraph (1), the Institute of Medicine shall submit
4 to the Secretary of Health and Human Services a
5 report on the results of the study conducted under
6 such paragraph. Such report shall include rec-
7 ommendations for changes to the registry or the
8 data submission requirements that would benefit the
9 public health.

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